European Chemicals Agency and REACH

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Topics

• Overview on ECHA

• Key elements of REACH
  – Deadlines
  – Processes
  – Actors
  – Downstream Users
ECHA - Overview

Make REACH reachable
Mission of ECHA

- Manage and carry out technical, scientific and administrative aspects of REACH
- Ensure consistency at Community level in relation to these aspects
- Provide the Member States and the institutions of the Community with the best possible scientific and technical advice on questions relating to chemicals which fall under REACH
- Provide guidance and advice for stakeholders
- Support national helpdesk and run a helpdesk for registrants on REACH, IUCLID and REACH IT
- Make information on chemicals publicly accessible
Status of ECHA

- ECHA started in Helsinki on 1 June 2007
- Staff has been recruited over past 15 months (1 September 2008: more than 200 people)
- Providing informative website, Guidance and Helpdesk
- Organisation is set up, IT systems and work processes are operational from 1 June 2008

We work to ensure safe use of chemicals across the EU
What is ECHA?

- **ECHA comprises (Art. 76)**
  - The Management Board
    - 1 per MS, 2 by EP, 3 by COM, 3 by interested parties (IND, NGO, Trade Unions)
  - The Committees:
    - Risk Assessment (RAC) and Socio-economic Analysis Committees (SEAC)
    - The Member State Committee (MSC)
    - The Forum for Exchange of Information on Enforcement
  - The Secretariat under the Executive Director ED
  - The Board of Appeal (BOA, independent)

**Note: All these are integral parts of ECHA**
The Forum

• Coordinates a network of Member States' competent authorities responsible for enforcement

• Tasks include:
  – Promotion of best practices & tools
  – Development of electronic info exchange procedures
  – Identification of enforcement strategies
  – Coordination and evaluation of harmonised enforcement projects
  – Liaison with industry
REACH Help Net

- ECHA Helpdesk is the focal point of the network of national REACH helpdesks
- Objective of the network is to achieve consistent and harmonised advice to stakeholders within the whole EU by exchanging information
- Tools:
  - REACH Helpdesk Exchange Platform (RHEP)
  - REACH Helpdesk Correspondent’s Network (REHCORN)
REACH
key elements
REACH: Key elements

- Introduces a Single Coherent System for new (non phase-in) and existing (phase-in) substances
- Key elements:
  - Registration by industry of manufactured/imported chemical substances > 1 tonne/year (staggered dead-lines over 11 years)
  - Increased information and communication throughout the supply chain
  - Evaluation of some registered substances (Agency and Member States)
  - Authorisation only for use of substances of very high concern
  - Restrictions: “Safety net” (Community wide action)
  - of Chemicals - Agency to efficiently manage the system

Focus on priorities:
- High volumes (chemicals with greatest likely exposure register first)
- Greatest concern (CMR and R50/53 register first)
REACH: the main questions

• What?
• Who?
• Obligations?
• When?
What is subject to REACH?

• Phase-in substances:
  – Existing substances – listed on EINECS
  – A few other types: See REACH Article 3(19)

• Non phase-in substances:
  – If not a phase-in substances, i.e. equivalent to ‘new substances’ not yet placed on the market today

More information:
  – Article 3(20) of REACH
  – Guidance on registration (1.7 – Phase-in versus non-phase in)
Who are the actors of REACH?

The main actors in REACH are

- **Manufacturers** — means any natural or legal person established within the Community who manufactures a substance within the Community; **Article 3(9)**

- **Importers** - means any natural or legal person established within the Community who is responsible for import; **Article 3(11)**

- **Only representatives** — natural or legal person established within the EC to act on behalf of a non-EU company; **Article 8**
Who are the actors of REACH?

• **Downstream Users** - according to Article 3(13) of REACH:
is someone other than manufacturer or importer ‘who uses a substance, either on its own or in preparation, in the course of his industrial or professional activities’

• **It is crucial to identify your role correctly:**
  - Navigator: [http://reach.jrc.it/navigator_en.htm](http://reach.jrc.it/navigator_en.htm)
Obligations acc. to REACH?

The main processes of REACH are

- Pre-registration
- Registration
- Evaluation
- Authorisation and Restriction
- Information to recipients and customers on substances in articles (Art. 33)
Pre-registration

• **When:** 1 June – 1 December 2008
• **What:** Phase-in Substances (Art. 3(20))
• **Who:** EU Manufacturers or Importers & Only Representatives of non-EU manufactures
• **Why:** Allows extended registration deadlines – 2010, 2013 or 2018
Registration (1)

• **When:** 1 June 2008 onwards

• **What:** Non phase-in substances before placing on the market, phase-in substances – if pre-registered – according to extended registration deadlines (Art.23):
  – 30 November 2010 for CMR[1] ≥ 1 t/y, R 50-53[2] ≥ 100 t/y and other substances ≥ 1000 t/y; or
  – 31 May 2013 for other substances ≥ 100 t/y; or
  – 31 May 2018 for other substances ≥ 1 t/y;

• **Who:** EU Manufacturers or Importers & Only Representatives of non-EU manufactures

[1] Classified as carcinogenic, mutagenic or toxic to reproduction, categories 1 and 2, in accordance with Directive 67/548/EEC.
[2] Classified as very toxic to aquatic organisms and may cause long-term adverse effects in the aquatic environment (R50-53) in accordance with Directive 67/548/EEC.
Registration (2)

• **Why:** Manufacturers and importers obtain information on their substances and use this knowledge to ensure responsible and well-informed management of the risks these substances may present.

• **How:** By submitting a Registration Dossier = Documentation according to Annexes IV to IX of REACH in IUCLID format [http://ecbwbiu5.jrc.it/](http://ecbwbiu5.jrc.it/)
  ➔ Technical Dossier: starting at 1 tonnes per year
  ➔ Chemical Safety Report: starting at 10 tonnes per year

**More information:**
- [http://reach.jrc.it/registration_en.htm](http://reach.jrc.it/registration_en.htm)
- Guidance on registration
When?

Deadlines under REACH

Notification of SVHC in articles

- 1000+ tonnes
- CMRs 1+ tonne
- very toxic to aquatics (R50/53) 100+ tonnes

Agency start up

Pre-registration

100-1000 tonnes

1-100 tonnes

Non-phase-in substances

- 12 months
- 18 months
- 3.5 years
- 6 years
- 11 years

EIF June 2007
Industry obligations are

- **Authorisation:** industry is not allowed to place on the market or use a substance included in Annex XIV unless industry has an authorisation granted by the Commission

- **Restriction:** industry has to comply with the conditions of the restriction in Annex XVII for the substance
Substances subject to

- **Authorisation:** substances meeting the criteria of Article 57, identified according to Article 58 and are listed in Annex XIV
  - Article 57: CMR cat 1 and 2, PBT, vPvB and substances of equivalent concern (SVHC = substances of very high concern)

- **Restrictions:** any substance giving rise to unacceptable risks which needs to be addressed on a Community-wide basis
Communication on substances in articles (Art. 33 of REACH)

- Only if article contains SVHC on the candidate list (1st candidate list to be published in October 2008, will be regularly updated)

- No exemption
  - There is no exemption from this obligation merely via registration under Article 7(6) for the same use
  - There is no exemption from this obligation via Article 7(3) concerning the absence of exposure under reasonably foreseeable conditions of use

- No tonnage limit → also applies < 1 tonne/year
Downstream User

REACH obligations
When do downstream users have to comply with REACH?

Downstream users do not have registration obligations under REACH, but downstream users should not place on the market any substances which are not registered in accordance with REACH.

Communicate with your supplier as early as possible!

1 June 2007 - the obligations related to communication in the supply chain started to apply.
  e.g. the duty to provide safety data sheets when supplying dangerous substances and preparations.

1 June 2008 - obligations linked to the registration of substances started to apply.
  e.g. the obligation to comply with the exposure scenario developed by the supplier (or to be developed by them for uses not covered) applies twelve months after the downstream user received a safety data sheet with a registration number.
Obligations for Formulators

If your company produces preparations

- You have to provide safety data sheets under REACH
- You will have to include the relevant information contained in safety data sheet and exposure scenario you receive from your supplier.
- It is important that the information in the exposure scenarios is consistent with the safety data sheets (not only to combine information on the hazards of substances and preparations for safety data sheet, but also to combine and forward information to customers on exposures and conditions of use).
Downstream Users and Pre-registration

DU should not pre-register but it is advisable that you contact your suppliers before pre-registration ends to make sure they will pre-register the substances that you are using.

- DU can benefit from ECHA support for substances not listed in the Pre-registration list - by expressing interest in that substance
- DU can benefit from “1st time provision” if they start manufacturing or importing after 1 DEC 2008 (Article 28(6))

DU may submit info on availability of data to become a Data Holder with the interest of being part of a SIEF. This will be possible from January 2009 via REACH-IT, after ECHA published the list of pre-registered substances.
Consequences of registration process for downstream users

You are not required to register the substances that you use, but the registration of these substances by their manufacturers and importers will affect you in a number of ways:

- Substances which are **not registered will no longer be available** on the EU market.
- The **classification and labelling of some substances may change** and, if you are a formulator using such substances, you will need to review the classification of your products and their safety data sheets accordingly.
- **Safety data sheets** will also be **updated or extended** with information generated through the registration process. If you receive an exposure scenario attached to a safety data sheet, this will trigger additional obligations for you.
Common misunderstanding

• As a downstream user, you are not required by REACH to register substances but
• if you act as a manufacturer or importer of a substance (as such or in a preparation), or as a producer or importer of substances present in articles and intended to be released, in quantities of one tonne per year or more you become a potential registrant!
Questions
If needed
The Management Board

Composition

• 27 voting members from the Member States
• 2 voting members nominated by the European Parliament
• 3 voting members from the European Commission
• 3 non-voting members from industry, trade unions, NGO’s

• Chairperson – will be voted for on the September meeting as Mr. Juka Malm (FI) is now the Director of Dir. B in ECHA; Vice-Chair – Mr. A. Lapalorcia (IT)

Tasks

• Selection & appointment of the Executive Director
• Work programme & Multi-annual work programme
• Appointment of members to 2 Committees
• Approval of final budget
• Adoption of Agency’s rules & procedures
The Committees

• Agency’s work is supported by three scientific committees
  – Risk Assessment Committee (RAC)
    • Prepares Agency’s opinions
  – Socio-economic Assessment Committee (SEAC)
    • Prepares Agency’s opinions
  – Member State Committee (MSC)
    • Resolves differences of opinions on draft decisions
    • Make proposals for substances of very high concern
Evaluation
(by Agency and Member States)

Provide confidence that industry is meeting obligations
Prevent unnecessary testing

Dossier evaluation
Check test proposals
Compliance

Substance evaluation
Examine any information on a substance

Output:
• Further information decisions
• Info to other parts of REACH/other legislation
Authorisation and restrictions – objectives:

• Authorisation and restrictions: the available regulatory instruments for authorities under REACH for risk management

• Authorisation to ensure that
  – the risks from substances of very high concern are properly controlled and
  – that these substances are progressively substituted by alternative substances or technologies where these are economically and technically viable whilst
  – ensuring the good functioning of the internal market

• Restrictions: the safety net
Step 1 –
Inclusion of substances in the list of substances subject to authorisation (Annex XIV)

EU Member State or Agency prepares an Annex XV dossier

Comments
- Authorities
- Interested parties

Agreement / COM decision

Candidate list

Agency recommends priority substances

COM decision

Annex XIV

First list within two years

(June ’09)
Step 2-
Granting (or refusing) the authorisation

Applicant applies for authorisation for a substance on Annex XIV

Interested parties - Information on alternatives

Agency C’ttees’ draft opinions

Applicant’s comments

Agency C’ttees’ opinions

COMM decision

Review of authorisation

Applicant’s review report

Authorisation granted / not granted
Summary of the main aspects of REACH relevant to downstream users

1. If you use dangerous substances and preparations, you will still receive safety data sheets, which, under REACH, may have one or more exposure scenarios attached. If you receive an exposure scenario, you must check whether your current use is covered and whether you comply with the conditions described in that exposure scenario.

2. If you place dangerous preparations on the market (formulator) you will still have to provide safety data sheets to your customers. In some cases, this may require you to consolidate or develop exposure scenarios covering uses of substances in your preparations further down the supply chain and to attach them to the safety data sheet (article 31 of REACH).

3. Communication along the supply chain on the use of substances and preparations will significantly increase under REACH. You will need to communicate upstream and downstream, e.g. when pro-actively identifying your uses to a supplier, or collecting information on customers’ uses.

4. The use of some substances may be subject to an authorisation requirement. This will be indicated by your supplier, usually in the safety data sheet. You may use the substance provided that the use is in accordance with the conditions of an authorisation granted to an actor up your supply chain.

5. Some substances may be subject to restrictions on their use, placing on the market or to bans (article 67 of REACH). Restrictions that were in place under the Marketing & Use Directive (76/769/EEC) are carried over in REACH.

6. If you produce or import articles, you may have to register substances which are intended to be released from the articles. If the article contains above 0.1% (w/w) of certain substances of high concern, you may have to notify the Chemicals Agency and inform your customers on safe use of the article. Consumers of articles can also request information about these substances.