

**REACH-ing Industry –
The New European Chemical Legislation
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REACH impact on third countries

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Contents

- REACH General overview
- REACH for non-EU companies
- Only representatives
- ECHA's involvement of third countries and communication

REACH – General overview (1/6)



Before REACH, 4 main EU legislative instruments for chemicals:

- Directive 67/548: notification of new chemicals, classification and labelling of dangerous chemicals and safety data sheets
- Directive 99/45: classification and labelling of dangerous preparations (mixtures)
- Regulation 793/93: evaluation and control of risks of existing substances
- Directive 76/769: Restrictions of marketing and use of certain dangerous substances and preparations

Main successes of former/existing legislation:

- Large data gathering and summarising process for HPVCs
- Agreement on RA principles (TGD/EUSES)
- Agreement on priority setting (HERO)
- EU harmonised risk assessments for many controversial substances, forming the solid basis for EU wide risk reduction measures

REACH – General overview (3/6)

Main problems:

- Data gaps: 86% of HPVCs had less than base set data
- The process took (far) too much time
- Burden of proof was on public authorities
- Generally Downstream Users stayed out of the picture, actual uses of chemicals remained unknown
- Safety Data Sheets were generally of a low quality and not well implemented
- The system was inefficient: a myriad of directives and regulations to be faced by Industry
- Administrative burden for new, mostly low volume, chemicals prevents innovation

Solution to the previous problems:
a new EU Chemicals Policy

Registration, **E**valuation and
Authorisation of **CH**emicals

Shift of the burden of proof on
(un)safety of chemicals from
authorities to industry

Objective = Sustainable Development

- Protection of human health and the environment
- Enhance innovation and competitiveness
- Maintain the Internal Market
- Increased transparency and consumer awareness
- Integration with international efforts
- Promotion of non-animal testing
- Conformity to WTO obligations

REACH – General overview (6/6)



- 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 11years)
 - 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)
 - 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)

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
within the scope of REACH**

**→ for imported substances/preparations/articles,
REACH obligations* must be fulfilled by the **EU-
importers or Only Representatives (OR)**
nominated by non-EU companies**

*e.g. registration of substances, notification of SVHC in articles if above 0,1%, info. for downstream users

Principle n°2:

EU-importers/OR rely on their suppliers in third countries **for hazard data** and safe use **information** that is required for registration purposes

→ in practice, non-EU companies have to provide data of sufficient quality (OECD GLP certified labs) and should allow their importers/OR to participate in data-sharing and SIEF's

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

- work with your EU-importer(s)

or

- use your own EU “legal entity”

or

- use your EU “Only Representative”

... and then initiate a trustful and fruitful cooperation to make good quality data available to EU-based partners

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.

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.”

If you decided to use an EU “only representative”, the EU OR should:

- comply with all obligations of an EU-importer
- have a sufficient background in handling substance
- keep available up to date on imported volumes and customers
- have and distribute the latest version of SDS

The non-Community manufacturer shall inform the importers within the same supply chain of the appointment.

These importers will be regarded as downstream users.

In practice, how to pre-register as an OR?

- Sign up in REACH-IT as a company, pre-register the substances by 1st December and confirm this to the exporter
 - + OR must be able to document who it is representing and provide with the documentary evidence to enforcement authorities on request. This legal document doesn't have to be attached in REACH-IT during pre-registration. However the OR is advised to attach it in IUCLID 5 section 1.7 when compiling the registration dossier

Focus on Only Representatives (4/5)



Only Representatives and (pre-)registration :

- The Only Representative can represent one or several “non-Community manufacturers”. If it acts on behalf of several “non-Community manufacturers” it must submit a separate pre-registration for each of them.
- The tonnage of the substance to be reported in each pre-registration is the total of the tonnages of the substance covered by the specific “non-Community manufacturer” represented by him. The information requirements for the registration dossier shall be determined according to this tonnage.
- By making separate submissions, the confidential business information of the “non-Community manufacturer” can be preserved and equal treatment with EU manufacturers can be ensured (EU manufacturers must submit separate registration dossiers for each legal entity).
- If OR is changed after registration, the new one can update the registration submitted by the earlier one, provided that the previous agrees to the modifications

Focus on Only Representatives (5/5)

As clarified and reported in the updated guidance on registration (released in November 2008):

1. It is neither necessary nor advisable for an OR to appoint a third party representative because as it is not obliged to disclose to the other participants the identity of the “non-Community manufacturer” he is representing
2. The OR’s registration should clearly specify which quantity of the imported substance it covers. If an importer is also importing quantities of the same substance, both should clearly document which imports are covered by whom
3. An OR appointed after 1 December 2008 can pre-register the substance in accordance with Article 28(6) until 12 months before the relevant registration deadline if the substance originating from the non-EU manufacturer was not placed on the market previously in a quantity at or above 1 tonne/year after 1 June 2008
4. Non-EU manufacturer is allowed to change OR after 01/12/08 and to continue to benefit from the phase-in DLs.

Involvement of third countries in ECHA's work



- EEA countries, Iceland, Liechtenstein and Norway have become members of the Agency without voting rights
- Management Board may invite other third countries to participate in the work of ECHA if they align their chemicals legislation with REACH, e.g. in advance of accession to EU; MB is currently discussing the approach
- Management Board may invite representatives of international organisations with interest in the field of chemicals regulation to participate in the work of ECHA
 - OECD secretariat invited by the Board and subsequently by the RAC and the MSC to participate in their meetings as an observer.

Communication with third countries



- ECHA is mainly interacting with industry associations, trade representatives and governments
- ECHA Helpdesk service assists many non-EU companies and organisations
- Cooperation and exchange of information with equivalent national and international agencies has started
- Speaking engagements and training packages around the globe (ECHA staff, COM delegations with ECHA support)
- In June 2008 European Commission third countries to support more widely

Reference



For more detailed and/or updated information, please consult the ECHA web site through the following link:

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

Thank you for your attention