PRACTICAL APPLICATION OF REACH

Regional Activity Centre for Cleaner Production

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REACH COORDINATOR

First, identify the human resources within the company that will be in charge of REACH and ensure that they receive information regularly, for example, subscribing to the distribution list of an association.

It may be useful also designate a **Coordinator** to handle the administrative tasks. REACH implementation will begin by establishing a phased plan and scheduling deadlines and the person responsible for each task.

INVENTORY OF SUBSTANCES

An important step is to inventory all substances and preparations, specifying their composition, if they are imported, distributed, exported or handled within the company. The important fields that must be known for each substance are:

a) Their correct identification: IUPAC name, CAS number, EINECS or ELINCS.
b) Define the role of company in the supply chain, if you act as manufacture, importer, distributor or as downstream user.
c) The quantity manufactured and exported to the EU in the last three years.
d) The profit margin resulting from their sale.
e) It is also important to collect basic information of the substances (analysis, test ...)

SUBSTANCE TONNAGE BAND

It is necessary to confirm the total amount of each substance, identifying the tonnage band to which they belong, that is, if exported to the European Union in quantities of 1-10, 10-100, 100-1000 or more than 1000 tons annually.

With these first three steps your company may:

- Establish the possible scenarios of situations that may occur.
- Identify the requirements of all the substances that the company use.
- Identify and justify possible exemptions from the substance.

SUBSTANCES OF VERY HIGH CONCERN

Identify substances of very high concern, with particular attention to the CMR category 1 and 2 in accordance with Directive 67/548/CEE, PBT, mPmB and endocrine disrupters.

These are substances that may require an authorization process and will require special attention within the regulation.

SAFETY DATA SHEETS

Launch a review process of the safety data sheets (SDS) information and quality.

Until 2010 the short version with minor changes of the Safety Data Sheet (SDS) could be used, and from 2010 an extended version of the SDS will be necessary with all the uses of the substance and more information e.g. the chemical safety report for substance imported in more that 10 tons/year.

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COMMUNICATION WITH THE CLIENTS

It is necessary to contact with the customers and identify the uses that are given to the substances throughout its life cycle. This can suppose problems related to the level of confidentiality to which the provider intends to reach if there are manufacture secrets to protect.

Need o decide within systems of information technology, the tools that are used to treat the flow of information up and down the supply chain.

Definition of the information requirements

Define the data requirements for each substance based on their tonnage or risk.

Collecting all data available in the company records relating to the intrinsic properties of the substances to be registered. It is recommended to locate the documents supporting the costs of testing and evaluate the quality of the data, for example if they are GLP.

Testing requirements

After selecting all the available information, specify the missing data to complete the analysis requirements. In the identification of these gaps will be distinguish between those tests requested in Annexes VII and VIII of the Regulation, to be developed for the registration dossier, and those in Annexes IX and X, for which you should submit testing proposals.

It will be analyze which data must be shared, for example those involving vertebrate animals

Cost Estimate

To get an idea of the impact that REACH will have on the business, it will be done a preliminary assessment of future needs. If it is necessary to obtain further information on properties, it will be necessary to estimate the costs of laboratory tests.

In addition to the estimate of the testing costs, we must take into account the indirect costs, that are, the administrative costs for the preparation of the dossiers, for the constitution of a consortium, for the chemical safety assessment and the payment of fees.

Working groups-Pre-consortiums

Once the pre-registration has been done, the company will be part of a SIEF, a database containing the names of the different manufacturers of the same substance.

However, it can be develop a preliminary assessment to see if other companies are interested in the same substance, how much of that substance they currently manufacture and commercialize and what data is currently available. Define the substances to be pre-registered and will establish contacts with other companies to share data.

New system of Classification and Labeling GHS (Globally Harmonized System)

Another significant change in the legislation, the GHS, has been adopted in the European Union in the same period of REACH entry into force. In this regard, it should be convenient to review the classification and labeling, assessing the changes introduced by the new system.

MAIN MARKET ACCESS CONDITIONS IN THE EU UNDER REACH FOR NON-EU COMPANIES.

- *REACH is a European regulation: Only registered substances under REACH could be marketed in the EU (if they are not exempted)*

- *REACH* is in force, and affects directly all chemical manufacturers and importers within the EU and indirectly to downstream users.

- Manufacturers of substances or substances in mixtures outside the EU also have to follow *REACH* if they want to market their products in the EU, this means that the substance has to be registered.

Manufacturers from outside the EU have three possibilities of having their substances registered with the European Chemicals Agency (ECHA):

- by their own agent established in the EU,
- by importers
- by an Only Representative

First possibility:

Registration by the non-EU company own agent established in the EU

Not all the non-EU companies have a subsidiary or an agent in the EU !!!

Second possibility: Registration by an importer

A customer develops the registration and imports the substance into the EU market. The customer becomes an importer and he is responsible to comply with REACH for the substance that enters the EU market.

Disadvantages for the non EU company:

- If a company sells to many clients or many substances in Europe **several importers** are needed: the coordination and communication with all of this importers could be difficult to manage.
- **All EU customers who purchase to the manufacturer outside the EU will have to become importers** (with the consequent efforts and expenses) or all customers would have to buy only from that importer (which would become a single distributor of the substance that is purchased from outside the EU. If the importer stops the relation to the company from outside the EU, the non-EU company couldn't sell in the EU. The importer may buy the substance of any other manufacturer outside the EU.
- **Market confidential data** is passed on within the manufacturer‘s own supply chain without control.
- This possibility is interesting when very few substances are sold in the EU and only few customers

Third possibility:

The REACH offers manufacturers outside the EU the possibility of appointing an Only Representative

It is the best business possibility because the non EU company can sell freely to all European customers!

Only Representative (OR)

- *"A natural or legal person 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 fulfil, as his only representative, the obligations on importers ".*

- *"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, 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."*

- *"If an Only Representative is appointed , the non-Community manufacturer shall inform the importer(s) within the same supply chain of the appointment. These importers shall be regarded as downstream users for the purposes of this Regulation."*

The advantages for the non-EU manufacturer of appointing an Only Representative (OR) :

- The manufacturer does not need to have its own company in the EU.
- None of the costumers are obliged to register: facilitating the purchase.
- Confidential data are communicated exclusively to a neutral partner.
- The manufacturer has direct control over the registration process of its substances.

Customers of the company outside the EU (the importers) will also benefit if the company register through an OR:

- They buy registered substances without incurring in the costs of having to register themselves.
- Customers will also save the costs of time and training required to develop a registration.
- As "downstream users", customers assume less obligations than if they were registrants.

What does the OR do

- Comply with the obligations of REACH on behalf of the company outside the EU
- Keep Client informed of REACH developments in EU.
- Understand Client's products manufacture outside the EU, client's customers and supply-chain .

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- Keep available and up-to-date information regarding the substance registered.
- Keep informed the supply chain of the updates on the safety data sheet.
- Meet the requirements of REACH as a manufacturer of chemicals:
  - Meet the Reach requirements for the registration of the substance (send the registration and pre-registration dossier)
  - Fulfill the obligation of share data for registration, request of authorization (if required) and notification of classification and labeling.
  - Ensures that risks from the use of the substance are identified, controlled and documented (safety data sheets)

Conclusion:

Non EU Companies needs always an importer or an European Only Representative to sell in the EU:

A company outside the EU who want to sells substances in Europe and wants to continue with business, from 01 June del 2008 requires someone who is:

- A subsidiary of the same company (which act as OR)
- A European player of the same company (which act as OR)
- A European customer (acting as importer)
- A European OR hired by the company outside the EU

- Just in the case of a.), b) and d) the company outside the EU will be the owner of substance's registration and may sell in Europe.

- In the case of c.), the owner of registration will be the importer and the Non-EU company may only sell to them. This importer can buy the registered substance to any company outside the EU.

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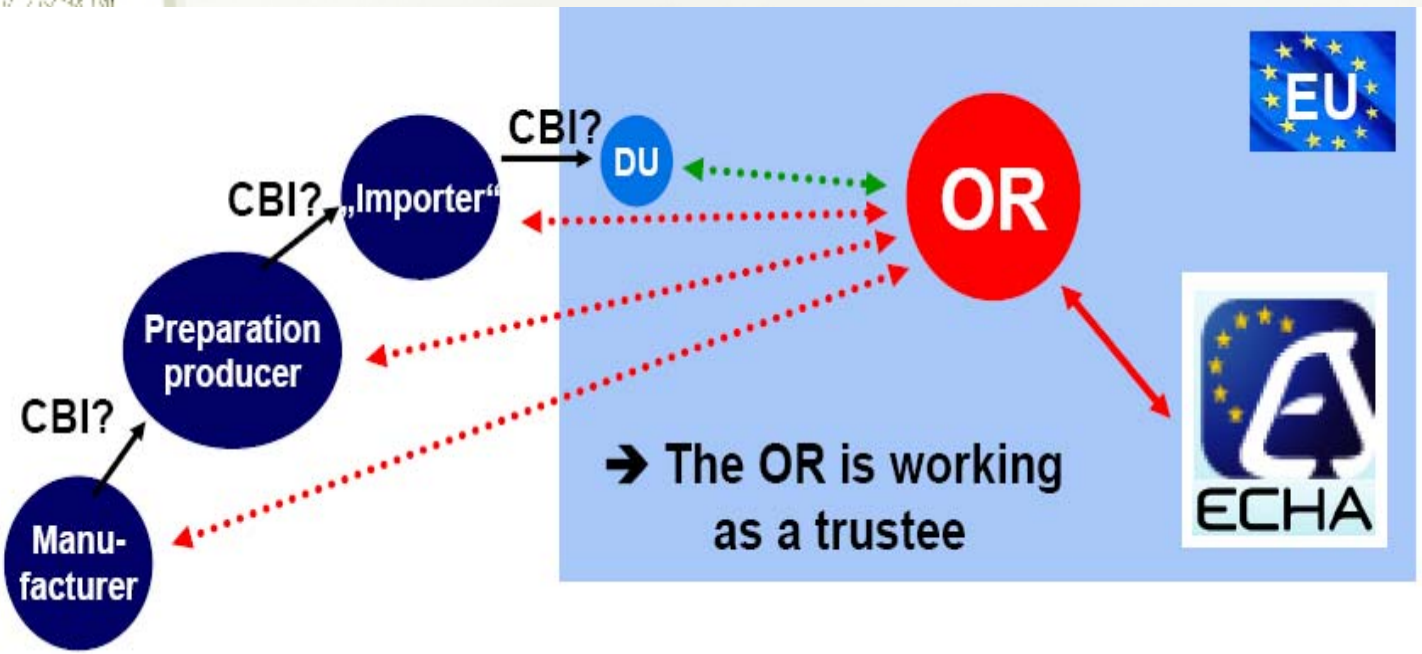
CBI?
DU
CBI?
„Importer"
OR
EU
Preparation producer
CBI?
Manu-facturer
➔ The OR is working as a trustee
ECHA
Fees, Information
Material, Information
Certificate
Information, Cost, Secrecy agreement
OR: Only Representative
DU: Downstream User
CBI: Confidential Business Information

Thank you

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