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First steps for Indian Enterprises exporting to the EU

**International Workshop on “Implications of the European Union’s Environmental Policies on automobile, Textile & Clothing and electrical & Electronics industry of India”,
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General Background

The Scope of REACH

REACH – Procedures

- **Pre-Registration**
- **Registration**
- **Authorisation**

First Steps for Exporters to the EU

A new EU approach to chemicals policy

- **Increasing transparency and safety in the use of chemicals, especially by the phase in of old substances**
- **Promotion of a non-toxic environment by substituting chemicals of very high concern**
- **Leveling the playing field between old chemicals and new chemicals**
- **Streamlining of current legislation**
- **Increased responsibility for producers, users, and importers**

Components

- Registration of **old substances** (phase-in substances) – data collection, testing, (self)-assessment of all chemicals
- Information for users
- Authorization for substances of highest concern
- Establishment of a new central administrative agency

Timescale

- **10 October 2006: second reading vote in Parliament environment committee**
- **11 December 2006: scheduled vote in Parliament plenary (second reading)**
- **Before end 2006: expected agreement in Council and possible final approval of REACH in second reading**
- **Entry into force (expected): April 2007**

Are you directly affected by REACH?

Reach does cover:

- substances on their own
- substances in preparations
- only in a few cases articles (substances in articles)

Reach requires a registration only for substances which are produced or imported at or above 1 t/a.

Relevant is the total quantity which the European importer does import!

Exemptions

General exemptions (e.g. radioactive substances, substances in transit under customs supervision, waste)

Specific exemptions (e.g. medical products, food or feedingstuffs, well known substances like water, nitrogen, natural oils, fatty acids or glucose, certain incidental chemical reaction products, natural and noble gases, minerals, ores, liquid petroleum etc.), polymers

Substances regarded as being registered biocides and pesticides and substances which are already notified in accordance with Directive 67/548/EEC (non-phase-in substances)

Articles

Reach does cover articles (substances in articles) in exceptional cases:

- **the substance is intended to be released (e.g. ink in a printer)**
or
 - **the substance is classified as**
 - a) carcinogenic, mutagenic or toxic for reproduction (CMR I & II) or**
 - b) is persistent, bioaccumulative and toxic (PBT) or**
 - c) is very persistent and very bioaccumulative (vPvB)**
- and is present in those articles above a concentration of 0,1 %.**

Steps to REACH

REACH does cover a large spectrum of substances and preparations and a small spectrum of goods.

Clarify, if your exported goods are subject to REACH or not.

Be aware that not exported quantities are decisive but imported quantities.

Pre-Registration (April 2008 to September 2008)

- **name of the substance including EINECS or CAS number**
- **name and address of the registrant (contact person)**
- **the envisage deadline for registration / tonnage band**
- **information which are relevant for the possible grouping of substances with similar structure**

No data – no market!

Without pre-registration a substance must undergo the procedures for non phase-in substances.

Pre-registration is the basis for building consortia for registration and for information exchange.

Steps to REACH

Pre-registration will be the first phase under REACH. Missing Pre-registration might cause many problems. Make sure, your substances will be pre-registered!

Registration of phase-in substances

- **At least 3 years after entry into force of REACH the following substances must be registered:**
 - substances in quantities reaching 1000 t/a and more
 - CMR-substances reaching 1 t/a and more
 - substances which are very toxic to aquatic organisms reaching 100 t/a or more
- **At least 6 years after entry into force of REACH substances in quantities reaching 100 t/a or more**
- **At least 11 years after entry into force of REACH substances in quantities reaching 1 t/a or more articles**

Registration requires a Technical Dossier:

- **identity of manufacturer/importer and substance**
- **information on manufacture and use of the substance**
- **the classification and labelling**
- **summaries of studies on the substance**
- **guidance on safe use**
- **robust study summaries if required**
- **1 to 10 t/a: exposure information for substances**
- **information about external assessment of the submitted information**

Furthermore:

- **Chemical Safety Report (CSR) for substances above 10 t/a**
- **Exposure scenarios containing likely exposures and protection measures for dangerous substances or PBT or vPvB above 10 t/a**
- **Proposals for testing above 100 t/a (if necessary)**

OSOR: one substance – one registration

Common dossier

- **the classification and labelling**
- **study summaries (Annexes VII to XI)**
- **robust study summaries if required under Annex I**
- **proposals for testing (Annexes IX and X)**
- **information about external assessment of the submitted information**

Individual dossier

- **identity of manufacturer/importer and substance**
- **information on manufacture and use (Annex VI section 3)**

Common or individual dossier

- **Guidance on safe use**
- **Chemicals safety report**

The only representative

The „Only Representative“

In order to avoid submitting sensitive data to the importer a non-Eu-exporter can name an only representative. The only representative

- has to be appointed by the non-EU exporter**
- must be established in the EU**
- has to carry out all tasks under the registration procedure**
- has to comply with all other obligations of importers under Reach**
- has to have the necessary technical expertise**

The exporter has to inform all importer(s) within the same supply chain of the appointment. The importers will become downstream users.

Steps to REACH

Registration involves submitting a large set of data. Your importer does need these data and will request them. If you do not want to submit them, consider in time to name an only representative.

Authorisation

- **Essentially a use restrictions process**
- **Applies to chemicals of very high concern – CMRs 1&2, PBTs, vPvB, and other high concern substances**
- **Requirement to request authorization for high concern chemicals**
- **Consideration of socio-economic benefits, alternatives, controls in place (safe use)**

Steps to REACH

Some substances will no longer be allowed at all, or they will no longer be allowed for a specific use or they simply will not be registered for a certain use.

Prepare for market changes which might result!

Exporters of substances:

- 1. Get some basic information on REACH.**
- 2. Clarify if you are directly affected by REACH (quantities and kind of substances/preparations/articles).**
- 3. If you are not sure, make a first inventory of your goods/clarify the situation with your EU-Importer.**
- 4. If you are subject to REACH make a proper inventory (substances, importers, data availability etc.).**
- 5. Make sure that your substances are pre-registered.**
- 6. Clarify in time, if you want the importer to handle the registration process of you want to use an „only representative“.**

Thank you for your attention.

