For more information about REACH in English, please visit
- European Chemicals Agency website
  www.echa.europa.eu
- E-learning
  www.ereach.dhigroup.com

For more information about REACH in Danish, please visit
- DI helpdesk
  www.reach-klarbesked.dk
- Danish EPA helpdesk
  www.mst.dk/Kemikalier/REACH+ Helpdesk

For more information the association's efforts in connection with REACH, please visit our website at www.fdlf.dk

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General principles concerning REACH

– The European Chemical Regulation

REACH entered into force on 1 June 2007.

REACH is a regulation laying down detailed rules applying immediately for all EU member states.

REACH STANDS FOR:

REGISTRATION – registration of the individual chemical substances

EVALUATION – evaluation of the substances based on their properties and effects

AUTHORISATION – authorisation of substances of very high concern

CHEMICALS – to be registered

SUSTAINABLE HANDLING OF CHEMICAL SUBSTANCES

REACH sets up a framework that ensures that each individual chemical substance can be used safely down and up the supply chain – both relating to health and environmental properties.

Industry shall be responsible for providing adequate documentation of the chemical substances.

THE SUPPLY CHAIN – FROM MANUFACTURER TO END USER OF SUBSTANCES

The general principles concerning REACH are best explained on the basis of a chemical substance's supply chain.

The chemical substance may be manufactured in or imported to the Community by a manufacturer/importer who delivers the substance to the raw material supplier who – after mixing it with other chemical substances – resells the raw material to the manufacturer of paints, printing inks or adhesives.

Again he will mix substances and raw materials into the finished chemical preparation and sell it to professional or private users.

The supply chain may of course be composed of other important links than the above-mentioned links, as distributors, agents, wholesalers etc. may also be included. Likewise a chemical substance may have several supply chains because it may have various uses.

The purpose of this leaflet is to describe the information flow both down and up the supply chain and to describe a few but important key areas in REACH.

- Pre-registration
- Registration
- Authorisation
- Import

REGISTRATION OF CHEMICAL SUBSTANCES

The registration of the chemical substances under the newly established European Chemicals Agency will become a central point for implementation of REACH. Central points for registration:

- All chemical substances placed on the market in the Community in quantities totalling over one tonne per year shall be registered.
- The manufacturer or importer shall submit a registration.
- A submission for registration shall be accompanied by a **Technical Dossier** (TD) including information about the substance, its uses, testing and documentation material on the properties of the substance as regards human health and environmental hazards etc.
- A chemical safety assessment shall be performed and a **Chemical Safety Report** (CSR) completed for all substances subject to registration in quantities of 10 tonnes or more.
- If these substances are classified, an **Exposure scenario** (ES) shall be generated and submitted down the supply chain accompanying the safety data sheet (SDS).

INFORMATION FLOW FROM SUPPLIER DOWN THE SUPPLY CHAIN

Today a safety data sheet accompanies the chemical substance down the supply chain.

They form the basis in preparation of the raw material's safety data sheet and further they form the basis of the finished preparation's safety data sheet which accompanies the goods to the professional user. This will not be changed with the implementation of REACH.

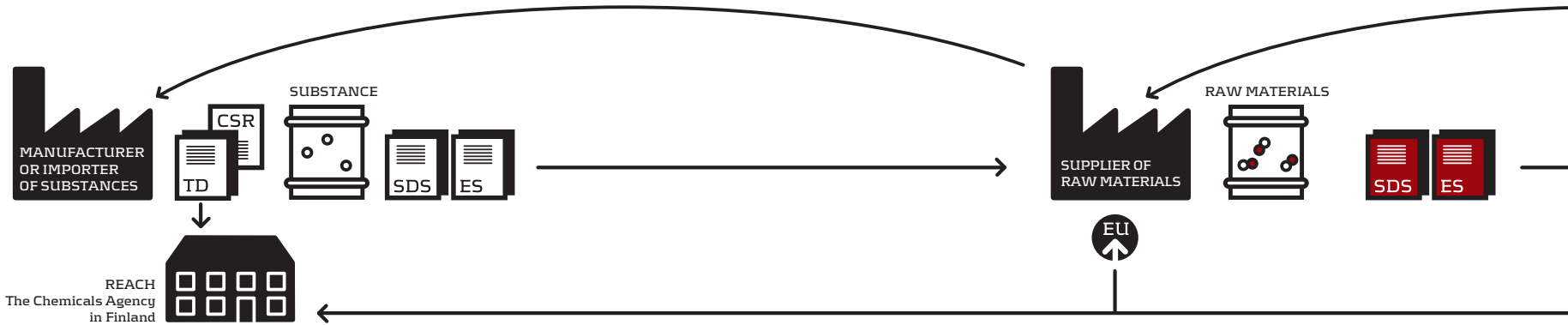
However, the contents of the safety data sheets have to be updated, especially as the substances are registered and new information is received.

Subject to REACH an exposure scenario for all substances classified and registered in quantities totalling over 10 tonnes per manufacturer or importer shall be placed in an annex to the safety data sheet covering all identified uses.

Supply chain:

TD: Technical Dossier
SDS: Safety Data Sheet
ES: Exposure Scenario
CSR: Chemical Safety Report

Import of substances in quantities totalling over one tonne outside the Community. A registration of these substances shall be submitted to the Chemicals Agency.



The exposure scenario shall, among other things, include a description of the conditions under which the substance can be safely used in relation to human health and the environment.

A raw material or a chemical preparation may contain various substances with an exposure scenario. Any relevant exposure scenario generated shall be considered when the exposure scenario of the raw material or preparation is prepared.

OBTAINING INFORMATION ABOUT IDENTIFIED USES UP THE SUPPLY CHAIN

In order that the supplier can prepare an exposure scenario for a substance, the uses of the substance need to be made known to the supplier.

The uses of a substance shall therefore be identified and information obtained from the end user and up the supply chain shall be sent back to the substance supplier.

This is expected to be carried out at industry level whenever possible.

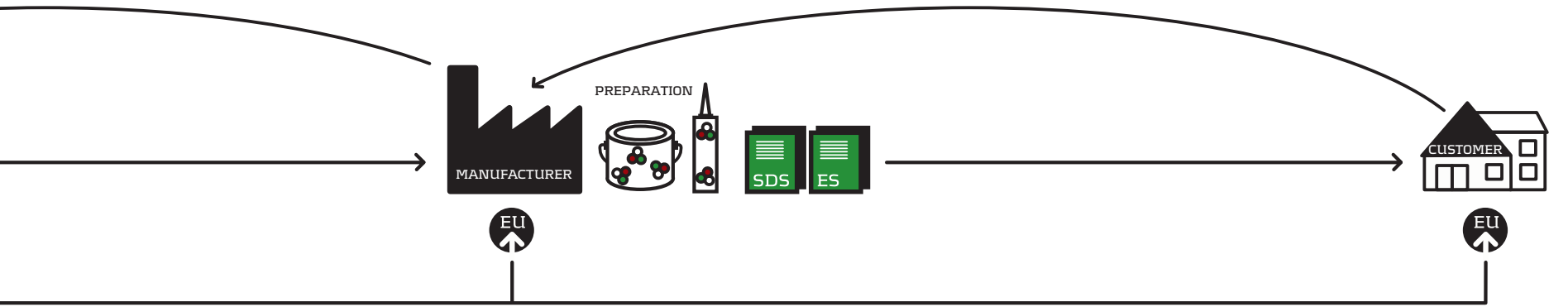
IMPORT OF CHEMICAL SUBSTANCES, RAW MATERIALS OR PRODUCTS

Basically, as mentioned above, the supplier shall submit a registration of a chemical substance.

But this responsibility may lie with everyone in the supply chain if they import a substance in quantities totalling over one tonne per year from a non-Community member state:

- as a pure substance,
- as a substance in an imported raw material or
- as a substance in an imported preparation.

On this background, what determines whether you are an importer and thus is responsible subject to REACH is whether you are responsible for customs supervision of the imported goods. It is therefore crucial that any actor in the supply chain is aware of the importer role. If you are an importer you shall firstly observe the procedures for **Pre-registration.**



PRE-REGISTRATION

The registration process shall be commenced by a pre-registration during the period

from 1 June 2008 to 1 December 2008

The responsibility of pre-registration lies with the actor placing the substance on the European market as is the case with registration.

Upon pre-registration the registrant shall submit the following information to the Chemical Agency:

- Identification of the substance, e.g. by CAS or EINECS No.
- Date of when the substance is expected to be registered and volumes produced or imported by the relevant supplier per year.
- The registrant's contact details.

After pre-registration the Agency will make the names of the pre-registered substances available to the general public and establish a system in order that all potential registrants of the same substance can identify each other and establish the so-called Substance Information Exchange Forums (SIEF) to help exchange of information.

Is it important to pre-register?

If you are under an obligation to register and you wish to use the **Registration deadlines**, subject to the transitional rules for existing substances (the phase-in substances), it is important to pre-register. If you do not pre-register, the rules for new substances shall be complied with. This means that a substance shall be registered before it can be placed on the market.

REGISTRATION DEADLINES

Registration of substances already placed on the market (phase-in substances) will be carried out at three stages over 11 years (cf. timeline) where substances with the highest tonnage shall be registered first.

Not later than 1 December 2010 the following registrations will be made:

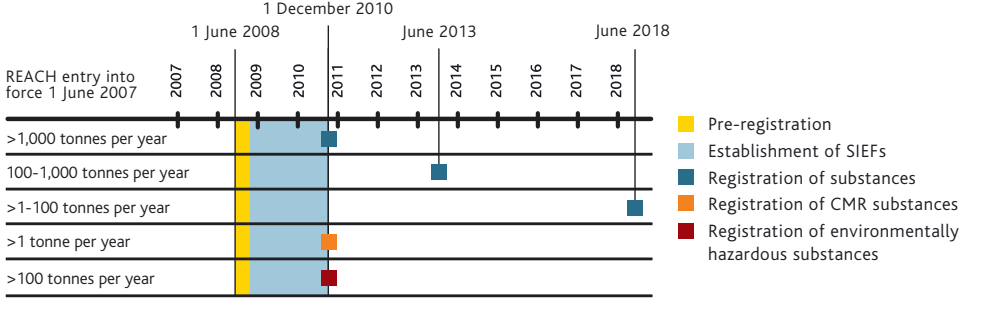
- CMR substances category 1 and 2 placed on the market in quantities totalling over one tonne per manufacturer or importer per year.
- PBT and vPvB substances placed on the market in quantities totalling over 100 tonnes per manufacturer or importer per year.
- Other substances placed on the market in quantities totalling over 1,000 tonnes per manufacturer or importer per year.

Not later than 1 June 2013 the following registrations will be made:

- Substances placed on the market in quantities totalling 100-1,000 tonnes per manufacturer or importer per year.

Not later than 1 June 2018 the following registrations will be made:

- Substances placed on the market in quantities totalling 1-100 tonnes per manufacturer or importer per year.



AUTHORISATION OF SUBSTANCES OF VERY HIGH CONCERN

Substances of very high concern will be required to be authorised.

All substances of very high concern will be included in a candidate list. Each year a number of substances will be identified as meeting the criteria for authorisation.

In order to be authorised to continue using such substances, application for authorisation shall be submitted to the European Chemicals Agency and authorisation to use the substances will then only be granted for the areas specifically authorised.

A total ban on some substances will be imposed if suitable alternative substances are available or if the overall hazardous properties of the substances exceed their efficacy.

Substances of very high concern:

CMR substances:
- are substances that are classified as carcinogenic, mutagenic or toxic for reproduction.

PBT substances:
- are persistent, bioaccumulative and toxic substances.

vPvB-substances:
- are very persistent and very bioaccumulative substances.

Substances that have similar properties
- e.g. substances causing hormonal imbalance.

A SUBSTANCE means a chemical element and its compounds in the natural state or obtained by any manufacturing process for which CAS, EINECS or ELINCS numbers have been defined.

EXISTING SUBSTANCES/PHASE-IN SUBSTANCES means substances already placed on the market for which an EINECS number has been defined. See REGISTRATION DEADLINES.

NOTIFIED SUBSTANCES means substances for which a notification has already been submitted and an ELINCS number has been allocated. Registration is deemed to be complete.

NEW SUBSTANCES means substances, which are not manufactured or imported to the Community before the entry into force of REACH, for which EINECS or ELINCS numbers have not been allocated, must not be marketed until the registration is deemed to be complete.

Approx. 40,000 substances shall be registered.