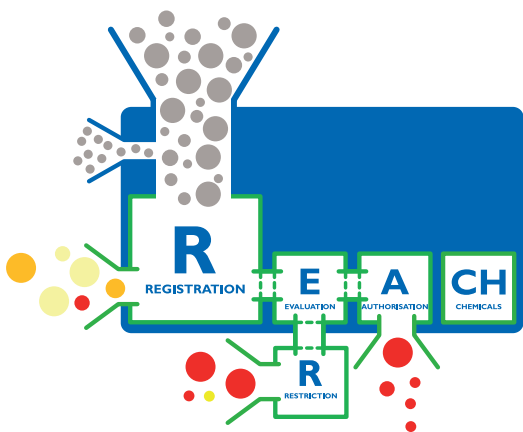


FACT SHEET

GENERAL INTRODUCTION TO REACH

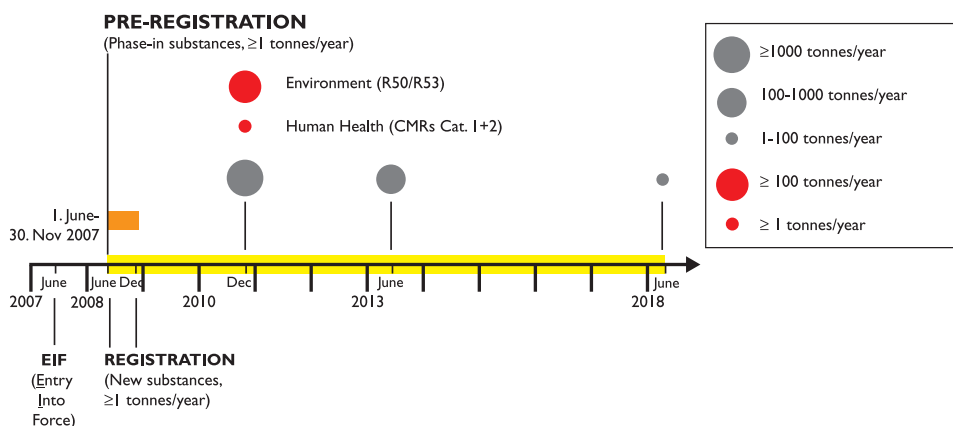


REACH is a new regulation applying to chemicals manufactured in, imported into and used in the EU.

Today, too little information is known on the chemical substances and their use, and the key goal for REACH is to ensure that the data documentation of the inherent properties of chemical substances and how they can be used safely is improved. Industry is required to hand in a **registration** dossier of this information to a new chemical agency at specific deadlines according to the nature of the chemicals and their tonnage. Registration is required for chemical substances manufactured or imported in tonnages above 1 tonnes per year per legal entity disregarding some exemptions.

The agency will **evaluate** by a random spot-check (5%) if the registration dossiers have an acceptable quality. It will also be evaluated if there is reason for special concern for chemical substances, which are inherently very dangerous either to humans or to environment. And with REACH, uses of these chemicals may be further **restricted** by the authorities. Also for some of the other very dangerous chemicals, industry will have to apply for **authorisation** in order to continue using them.

REACH TIME-LINE

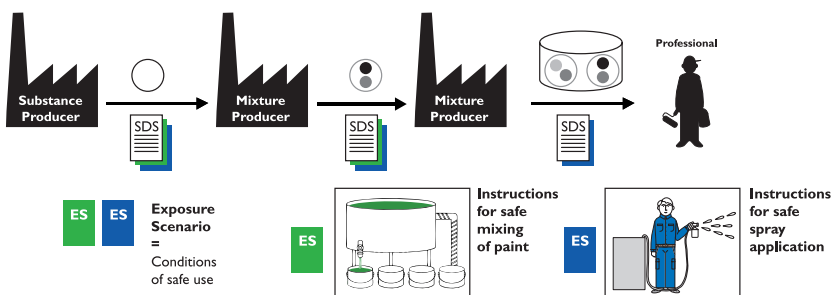


REACH entered into force on June 1, 2007. All chemical substances manufactured in or imported into EU in quantities above 1 tonnes per year have to be registered.

Registration formally starts already by June 2008, but registration of chemical substances already on the market – the so-called phase-in substances – may be postponed to an 11 year transitional period. They may however only benefit from the transitional period if they are pre-registered in a narrow time-window from June 1st – November 30th, 2008.

The registration deadlines relevant for the pre-registered chemical substances will mainly be according to their tonnage. Registration will start with chemical substances manufactured or imported in volumes above 1000 tonnes per year in 2010 and will end with the small tonnages in 2018. At the first deadline in 2010, some additional chemical substances will be required to be registered because they are considered to be very dangerous to humans or environment.

USE AND EXPOSURE SCENARIOS



An exposure scenario, ES, is a description of how a specific chemical substance can be used safely. The description of safe use includes the specific operational conditions of the use and the risk management measures, which should be implemented. The ES will be enclosed as an annex to the safety data sheet. An exposure scenario will only be required for chemical substances, which are dangerous or of high environmental concern (e.g. PBT or vPvB) and are manufactured or imported in volumes higher than 10 tonnes per year per legal company.

A chemical substance may have many different uses in its entire supply chain. One example could be the mixing of the chemical substance with other chemical products in an industrial plant. Another example is a spray application of the end product by a professional painter. An exposure scenario is required for all the uses supported by the manufacturer or importer of the chemical substance.

Communication of an exposure scenario will only be legally required *after* the chemical substance is registered. Therefore it may take quite some years before **all** the relevant Safety datasheets are annexed with an Exposure Scenario.

FACT SHEET

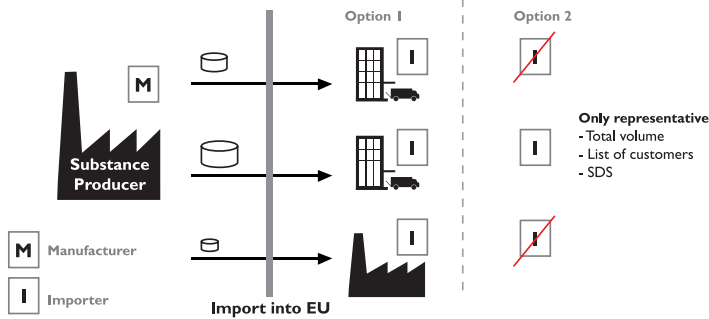
DATA REQUIREMENTS

The registration dossier contains general registration information and data on physico-chemical properties, toxicological data for the assessment of human health effects and eco-toxicological data for the assessment of environmental effects. The data requirements for the registration are specified in the Annexes VII-XI to the REACH regulation. The data requirements depend on the tonnage of the substance, the higher the tonnage – the higher the requirements!

Annex VII is relevant to all chemical substances to be registered while requirements listed in the subsequent annexes should be added annex by annex as the tonnage increases. Annex XI includes some important specifications as to which quality of data can be used and whether the registrant has a possibility to waive some of the requirements.

Substances causing very serious effects such as cancer may be required to be documented even further. Also, the documentation of safe use needed for the specific exposure scenario may in some cases result in a request for even further data.

ONLY REPRESENTATIVE (OR)



A manufacturer of a chemical substance placed outside of EU may sell his product to several customers inside EU. These may be trading companies distributing the chemical product further down the supply chain or they may be producing companies themselves. Regardless of their business activities, they will be regarded as importers having a REACH registration responsibility. Only companies legally established within the EU can register a chemical substance manufactured in or imported into the EU.

A non-EU manufacturer of a chemical substance has two options:

- Option 1:** He may agree with his customers within the EU that each of them carries out the registration using a data documentation, which may be supplied partly by him. In this case the chemical substance supplied from the non-EU manufacturer is required to be registered by each importing company importing 1 tonnes or more per year.
- Option 2:** He may appoint an only representative (OR) established within EU as the responsible for registration. In this case only one registration for the chemical substance will be required, and his remaining customers will no longer have any importer status, and do not have to make a REACH registration. The commercial business transactions may however still be carried out directly between the non-EU manufacturer and all of his customers. The OR is required to keep updated information on total quantities imported into EU, safety data sheet for the product imported, and a list of the non-EU manufacturer's direct customers. In this case, the chemical substance supplied from the non-EU manufacturer is required to be registered by the OR if the *accumulated* tonnage imported into EU is greater than 1 tonnes per year.

WHAT DOES REACH INCLUDE?

REACH is focused at the individual chemical substances, which can be included in various chemical products¹:

- in the pure form - an example is xylene.
- as part of a mixture supplied for an end use – an example is xylene included in a paint.

Under REACH all individual chemical substances should be registered if they are manufactured or imported into EU in quantities above 1 tonnes per year.

There are however some important exceptions to this general rule.

- Substances, which have been extensively documented according to existing regulations, are considered as already registered. Examples of these are:
 - active ingredients used in biocide and pesticide products.
 - new chemical substances introduced to the market after 1981.
- Substances covered by existing regulation with similar requirements. Examples of these are ingredients for food, feed-stuff and medicinal products. Substances only used in these areas are not covered by REACH, and ingredients for cosmetics have a lighter set of requirements.
- Polymers do not need to be registered, but the monomers used for the polymers will in most cases require registration.
- And finally REACH includes two set of annexes listing further exemptions, either excluded by their CAS-numbers (Annex IV) or due to some special situations and sources (Annex V).

¹. There are special rules for chemical substances included in articles, but a description of these are outside the scope of this leaflet.

REACH PROJECT

In order to prepare the Danish traders and distributors for REACH, a large project was started primo 2006. It is funded by the Danish EPA and will run until ultimo 2007. In this project, dedicated tools for the specific preparation of the trade to REACH are developed and tested by the participating companies. Examples of tools are:

- Material to be used by the management at internal kick-off meetings to start the implementation activities within their company.
- Guidance on how to make a mapping of the products with reference to (pre)registration.
- Discussion paper of when the company has importer responsibility.



The Danish Association for Trade and Distribution of Chemicals
www.chemicals.dk