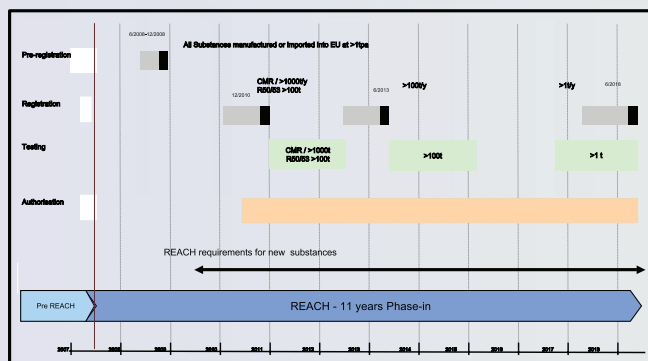


# REACH DO NOT MISS IT!

The REACH regulation is a new EU legislation, which foresees **R**egistration, **E**valuation, **A**uthorisation and restriction of **C**hemicals. The regulation was developed in order to “ensure a high level of protection of human health and the environment as well as the free movement of substances, on their own, in preparations and in articles, while enhancing competitiveness and innovation” (article 1). REACH was published in the Official Journal of the European Union on 30 December 2006 (Regulation (EC) 1907/2006) and will enter into force on 1 June 2007.

Under REACH about 30,000 existing chemicals used on the European market, so-called phase-in chemicals, must be registered within a period of 11 years. The registration deadlines within this 11 year period are based on tonnage and hazardous properties (see picture). For new chemicals the registration under REACH starts at 1 June 2008 after a transition period of one year during which the old notification regime is kept in place.

## REACH timeframe



On 1 June 2008, the pre-registration phase starts for the phase-in substances (deadline 1 December 2008). Pre-registration means in fact commitment to prepare a registration dossier and thus the intention to keep a substance on the market and available to downstream users. If a phase-in substance is not pre-registered, it will need immediate registration when produced or imported in the EU just like non-phase-in (new) substances. After pre-registration the phase-in substances can remain on the EU market until the phase-in deadlines (see picture above).

A pre-registration can only be done by a registrant (manufacturer or importer) within the EU. For non-EU companies it is therefore necessary to have a legal representative in the EU. This can either be the importer or an “only representative”. When applying the concept of the only representative, all importers of the same substance in the EU become downstream

users and the only representative fulfils the REACH related obligations of the importer(s). This can be a big advantage for a non-EU company, as it will be dealing with only one entity.

What is necessary for a pre-registration? Next to company name and address, the name of the contact person, the envisaged deadline for the registration and the tonnage band, the potential registrant should provide the identity and the name of the substance and possible structural analogues.

A substance has to be identified according to the criteria in RIP 3.10 including specific concentration ranges of the main constituents. This is likely to be rather simple for well defined substances, but much more difficult for Substances of Unknown or Variable composition (UVCB substances).

In addition, the inclusion in the pre-registration of one or more structural analogues (with data available) of the substance is in most cases not straight forward. The equivalence between the pre-registered substance and the analogue(s) has to be substantiated based on the results from physicochemical and (eco) toxicological testing. This process is called read across or grouping of chemicals. At present, there are no or limited tools available to find analogues and forming chemical categories is limited by the lack of formal methods. This means that expert judgement is very important in this aspect.

When REACH enters into force, the very first phase of the registration process starts with preparation for pre-registration. A successful pre-registration and concomitant registration means a lot of work during the first year:

1. company inventory of substances
2. roles of the company (related to its substances)
3. obligations related to substances – need to pre-register?
4. identification of legal entity
5. substance identification
6. investigations of possible analogues
7. identification of company owned and public available data – data gap analysis

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