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B-3

# REACH

## Registration, Evaluation and Authorization of Chemicals

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# REACH – background information, implications for the coating and plastics industries, and how BYK is getting ready for it.

The Management Board of BYK fully agrees with the overall objectives of REACH and has already expressed its explicit commitment to achieving them. It has also expressed its firm commitment to sustain the entire sales products portfolio under the obligations of REACH, in an effort to continue to serve BYK's current and future customers.

## Introduction

REACH (**R**egistration, **E**valuation and **A**uthorization of **Ch**emicals) is the new EU (European Union) legislation for chemical substances and their use which came into force on June 1, 2007. This EU legislation regulates crucial aspects of the manufacture and trade of chemical substances, also affecting imports from countries outside the European Union. The regulations of the REACH legislation apply both to individual substances and to preparations (formulations) and products containing these substances.

The **main consequences** of REACH can be summed up as:

- replacement of most existing EU legislation on chemical substances, including the EINECS inventory
- a so-called 'paradigm change'; this means that the responsibility for the handling of chemical substances will in future be on the industry. The newly-created European Chemical Agency in Helsinki gathers and evaluates substance data
- communication of existing chemical risks throughout the entire supply chain – from manufacturer or importer through to downstream user
- all substances subject to REACH will have to be registered and evaluated on the basis of prescribed physical, chemical, toxicological and ecotoxicological data regarding their identified uses
- high-risk substances in particular will be subject to authorization, which can result in restrictions and bans for these identified uses where these risks cannot be adequately managed

## Which chemical substances are subject to REACH?

REACH applies directly to substances only, and indirectly to preparations (formulations) and products containing these substances.

**Substances in terms of REACH are chemical compounds that are obtained by any manufacturing process, including any component to preserve its stability and any impurity derived from the manufacturing process.**

The regulations in REACH apply only to substances that are marketed/imported in quantities exceeding 1 metric ton per annum. Isolated intermediates and transported intermediates are subject to reduced registration requirements.

**REACH does not apply to**

- non-isolated intermediates
- special categories of substances such as polymers (if monomers > 2 % are registered), biocides, medical products, food and feedstuffs, cosmetics

## Registration of substances affected by REACH

**Pre-registration** took place from June 1 to December 1, 2008. It comprisesd all chemical substances, which were on the market at that date and which were marketed or imported in quantities exceeding 1 metric ton per annum.
For these,

- the name of the manufacturer or importer,
- the identity of the substance, and
- the annual tonnage band (corresponding to the annual sales per manufacturer or importer)

have been registered. For example, the cost of registration for a substance with an annual tonnage band of above 1,000 tonnes per annum will be at least € 1,000,000.

The actual **registration** will then follow in three priority stages:

1. annual tonnage bands of above 1,000 tonnes and/or classified as belonging in a 'high-risk' category (CMR, PBT, and vPvB substances)
2. annual tonnage band above 100 tonnes
3. all other substances not covered by the above categories

Substances classified as belonging to a 'high-risk' category include all CMR, PBT, and vPvB substances.

**CMR substances = cancer-inducing (carcinogenic) and genetically harmful (mutagenic) substances, and substances impairing reproductive systems (reprotoxic).**

**PBT substances = substances which degrade slowly and which display high accumulation in cellular tissue (persistent and bio-accumulating substances) and which are also toxic.**

**vPvB substances = substances which degrade very slowly and which display very high accumulation in cellular tissue (persistent and bio accumulating substances).**

The basic data required for registration depend on the annual tonnage band. For substances in the tonnage band above 100 tonnes per annum (priority class 2), proposals for subsequent tests must be submitted. Prior to being conducted, these tests require to be authorized by the EU Chemical Agency in Helsinki which determines the final test program.

In the course of the process of registration, data must be submitted on **risk potential**, **uses and applications**, and **risk management** measures for chemical substances in all priority stages.

The **evaluation** of the submitted substance data will be conducted by the European Chemicals Agency. In cases where a higher risk to humans or the environment is believed to exist, the Agency can instigate further research tests.

### Authorization of substances subject to REACH

If the registration data for a chemical substance indicate with sufficient probability that the substance displays CMR, PBT, or vPvB properties, then authorization may be required. In such cases, an EU Member State may apply to the European Commission for the substance to be placed on the candidate list for authorization. The EU Commission is empowered to decide whether any substance can be officially put on the list of substances subject to authorization, reaching its decision based on a prioritization of the following criteria:

1. PBT or vPvB properties
2. nature of use or application
3. volume put into circulation

If authorization is required, the full body of data for the substance will be evaluated by the EU Chemicals Agency. If use-specific authorization and registration are agreed, the EU Commission will grant authorization for the substance, quite possibly with a time limit, under prescribed conditions, and subject to regular checks and controls.

## Sequence of steps required to comply with REACH

**Pre-registration**
of chemical substances > 1 tonne per annum

Depending on the volume, toxicological/ecotoxocological properties, and uses:

- supplying the missing data
- conducting a chemical safety assessment
- drawing up a chemical safety report, a technical dossier and an extended safety data sheet

**Registration**

**Authorization**
for toxicologically/ecotoxicologically questionable substances

## The terms 'use' and 'exposure' in relation to REACH

The registration, evaluation, and authorization (or restriction) of a substance are use-specific. Consequently, the assessment of a substance takes not only its hazardous properties, but also its interaction (exposure) into consideration.
With regard to the use of a chemical substance, differentiation is made between:

- industrial use
- professional use
- consumer use

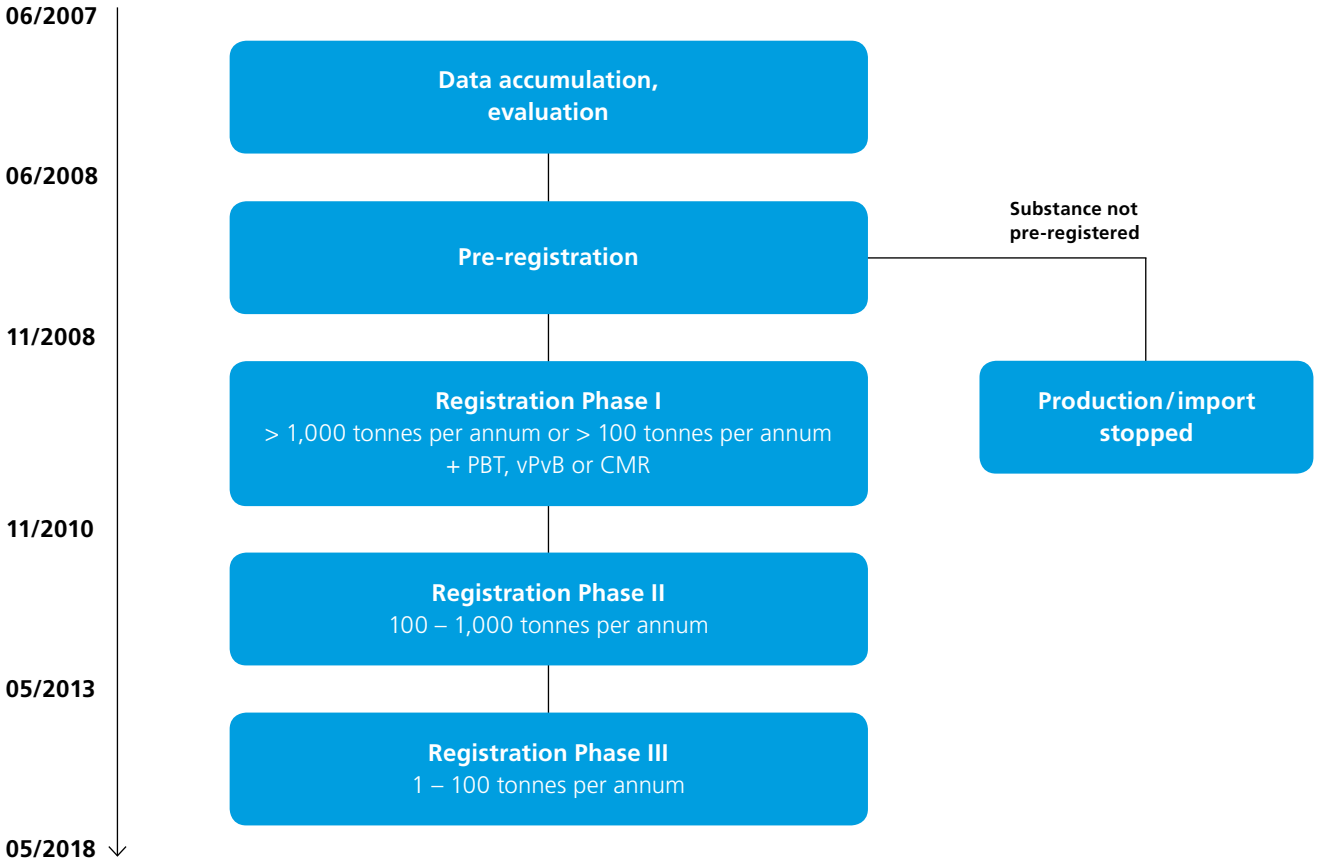
The means of exposure to a substance are subdivided into the categories:

- human exposure (oral, dermal and/or inhalatory)
- environmental exposure (water, air, solid waste and/or soil)
- pattern of exposure (accidental/infrequent, occasional and/or continuous/frequent)

## Communication along the supply chain

Communication among the manufacturer and/or importer, the formulator, and the downstream user occurs with the help of the extended safety datasheets. A prior exchange of information between manufacturers and downstream users on exposure and on the suitable uses is essential.

# Timetable for introducing REACH

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