

REACH – the safe use of products in terms of health and environment

- General information
- Registration
- Evaluation
- Approval
- Restriction of chemical substances

The majority of chemical substances available on the market have not been tested with regard to their use in specific applications in terms of their environmental impact or their impact on health. In order to guarantee safe production and application the member states of the European Union have agreed a uniform chemical legislation, REACH (Registration, Evaluation, Authorisation of Chemicals) with a focus on protection of human health and environment.



Consequences of the new European Chemical Legislation REACH

Important information for architects, consulting engineers and contractors



MC-Bauchemie Müller GmbH & Co. KG
Am Kruppwald 1-8 • 46238 Bottrop, Germany
Phone: +49 (0) 2041 101-10 • Fax: +49 (0) 2041 101-188
protection-technologies@mc-bauchemie.com • www.mc-bauchemie.com

akur 080651 GB



BASIC PRINCIPLES



Registration, Evaluation, Authorisation of Chemicals: What is REACH?

The high technical standard in today's society is based on using chemical components in many products to make our lives easier and more beautiful. Many products would be inconceivable without the contribution from the chemical industry. This development has led to approximately 30,000 chemicals being used in about 100,000 products available on the European market today.

To ensure the safe production and use of chemicals, the member states of the European Union have agreed a uniform chemical legislation, REACH, which has a strong focus on the protection of human health and the environment. The REACH-Regulation creates new standards for the whole of Europe in terms of registration, evaluation and approval of old and new chemical substances.

With REACH Europe's industry is facing the implementation of the most comprehensive legislation with regard to environmental policies that the EU has brought about in the last 20 years.

The new EU chemical legislation obligates both manufacturers and importers of chemical substances to evidence that their substances, compositions and products are harmless to the health of the applicator or user and do not harm the environment. With this producers now bear the responsibility for the safe production and handling of chemicals produced by them.

With REACH the formulators of preparations, amongst them also MC, now take a central position between manufacturers and users of chemicals. They ensure that risks are communicated consistently and without fail within the supply chain.

As a European company, MC stands for reliable compliance with REACH and supports its customers in its practical application.

REACH now in force – what's changing?

With the new chemical legislation which came into force on June 1st, 2007 a political process that ran for several years has finally been completed. As a result companies in the chemical industry have in future a variety of new and challenging tasks to tackle.

The REACH system makes both manufacturers and importers individually responsible for the safety of their chemical products (reversal of the burden of proof). In future only substances are permitted to be placed on the market for which a sufficient data set has been registered with the European Chemicals Agency in Helsinki ("no data – no market"). As a rule not just the substance properties are evaluated, but also their uses.

Registration

Substances that have not been registered must neither be manufactured nor sold. Substances that have been registered as new substances following the previous EU directive are classed as registered. For substances that are already being traded within the European movement of goods at the time of REACH coming into force, i.e. the so-called "phase-in goods", extended transition periods apply of either three and a half, six or eleven years – depending on production volume and potential danger level. These can however only be done if a pre-registration was made between June 1st 2008 and December 1st 2008. In this phase manufacturers and importers must submit the names of all existing substances to the European Chemicals Agency that they intend to register at a later date. For the registration obligation under REACH a time schedule expiring on 31st December 2018 is planned.

The registered data are published on the internet from January 1st 2009 by the European Chemicals Agency in Helsinki. The aim of the pre-registration is for manufacturers and importers to communicate in an information-exchange forum about identical substances. Downstream users are able to find out via this list, which raw materials will also be available in future and where to expect potential shortages.

Downstream users should in any case check whether or not the substances important to them have been pre-registered by their suppliers. As a safeguard, there is the possibility to pre-register key raw materials for themselves in order to avoid production downtimes.

CONSEQUENCES



Consequences

REACH not only obligates manufacturers and importers of chemical substances, but equally obliges so-called downstream users. In the sense of REACH this includes such companies that use substances and/or preparations to manufacture new preparations (formulators) – such as MC – and those that use substances and/or preparations in industrial plants or commercial activities (end user / applicator).

REACH coming into force also means the start of the obligation to pass on information in either direction of the supply chain. Both suppliers and customers must pass on new findings. This means downstream users, too, have additional tasks on their hands. As a user of chemicals in the EU it is usually sufficient to check whether the application is registered on the extended safety data list. On top of that, the risk minimisation measures mentioned in this list must be adhered to.

Should one of the conditions not be fulfilled or should uncertainties regarding risk minimisation arise, information is exchanged with the supplier, so that the supplier can evaluate the application and add it to the safety data sheet. An alternative would be to have the application evaluated independently of the supplier and to compile one's own data sheet.

Potential consequences for downstream users

- Own application is not covered
- Additional risk minimisation measures must be taken
- Additional → **exposure scenarios** must be developed

→ For explanations see page 7

Exposure Scenarios

No product must be added to the European movement of goods that has not been tested in accordance with REACH.

To this end REACH obligates manufacturers of substances to carry out a substance safety evaluation for all applications and application conditions within the product's life cycle with regard to its toxicological and ecotoxicological characteristics by way of practical application (so-called → **"exposure scenarios"**). Here the contact (exposition) of humans or environmental elements with chemicals are assessed in respect of their application conditions and are evaluated in accordance with the threshold values as stipulated under REACH.

In the event of a downstream user's application not being covered by the safety dossier as passed on by the manufacturer, they are also obligated to carry out their own → **exposure scenarios** and to submit a substance safety report.

In addition to the raw material producers MC also performs comprehensive testing of their preparations regarding health and environmental impact. By means of this established testing methods the uncritical threshold values are derived which allow an allocation to the different → **exposure scenarios** (REACH-assessment procedure).

Example workplace with epoxy resin (EP) coating.
Threshold values derived from REACH for exposition of substances from hardened coatings:
→ **"inhalation periodical"**



Example residential building with EP coating.
Threshold values derived from REACH for long-term exposure to substances from hardened coatings:
→ **"inhalation long-term"**



Example fair-faced concrete surface exposed to the weather.
Threshold values derived from REACH for short-term exposure of rainwater with substances from concrete:
→ **"water contact periodical"**



Example grouting (injection into soil).
Threshold values derived from REACH for long-term exposure of groundwater with substances from hardened injection materials:
→ **"water contact long-term"**



TASKS



MC: Fit for REACH

REACH means the comprehensive re-structuring of the European chemical policy, which is going to impact directly on the international movements of goods. As MC has been involved in the REACH development since the very early days, it is now well-prepared for this new chemical legislation.

As a reliable and competent partner MC can offer its customers help and support in all matters concerning REACH.

What's important for manufacturers and importers?

The new EU Chemical Legislation obligates manufacturers and importers of chemical substances to evidence that their substances, preparations and products do not harm the health of applicators or users and are harmless to the environment. By this producers take the responsibility of safe manufacture and handling of their products.

In the sense of REACH this also includes so-called downstream users. These are companies that use substances and/or preparations to produce new preparations (as does MC) and/or preparations within the scope of an industrial or commercial activity (end user/applicator).

- **Obligation to individual producer responsibility**
- **Shift of responsibility from authority to individual enterprise**

What kind of information must manufacturers provide?

In order to achieve the safe use of substances, preparations and products with regard to human health and environment manufacturers determine the potential application areas. Such information is recorded in the technical data sheets and the safety data sheets.

The basis for determining application areas are comprehensive tests, an evaluation and the compilation and submittal of a substance dossier at the European Chemicals Agency in Helsinki.

- **Relevant substance information**
- **Defined application areas**

What's important for downstream users?

As a downstream user of chemicals within the EU it is generally sufficient to check whether the application is covered in terms of the information provided in the technical and safety data sheets. On top of that the risk minimisation measured described therein must also be adhered to. Is the application not covered or should uncertainties arise, information must be sought from the supplier so that they can evaluate the application.

- **Adherence to application area**

What's important for planners and tendering offices?

Planners and tendering offices in the EU must make sure to specify only REACH-assessed products and systems that are suited to the intended application area. REACH documentations as submitted by the manufacturer form part of the building documents. Is the application not covered or should uncertainties arise, information must be sought from the supplier so that they can evaluate the application.

- **Tender specifications to contain only REACH-assessed products and systems**

What's important for everyone?

REACH coming into force also means the start of the obligation to pass on information in either direction of the supply chain. Both suppliers and customers must pass on new findings. This ensures the complete communication of risks within the supply chain across manufacturers, importers, formulators right down to the end user.

- **Risk management:**
Pooling of all available information

Key Terms

- **Exposure**
Substances contained in chemical products may potentially have a harmful effect on human health and the environment.
- **Exposure Threshold Values**
REACH defines certain models of standard scenarios of such an exposure. Based on established findings in toxicology and ecotoxicology threshold values for each substance with regard to exposure quantity and length of time are defined.
- **Substance Evaluation and Substance Dossier**
Within the framework of a substance safety assessment comprehensive material testing and examinations serve to determine a correlation to the given threshold values and serve to check that these are not being exceeded.
- **Exposure Scenario**
On the basis of the test results the application conditions and areas are defined in which the chemical products are safe to be used with regard to exposure to humans and environment. All polymer-based products from MC have been tested and assessed for the following exposure scenarios:
 - **Inhalation periodical**
Standard scenario for human inhalation exposure:
e.g. in the workplace
 - **Inhalation long-term**
Special scenario of inhalation exposure for humans in particular need of protection:
e.g. old or sick people, and children – also for use in private life
 - **Water contact periodical**
Standard scenario for a potential elution of substances from chemical products in the event of contact with water,
e.g. rain showers
 - **Water contact long-term**
Special scenario when using chemical products in connection with water:
e.g. groundwater coming in contact with injection materials
 - **Processing of fresh, unmixed or already mixed but not yet cured polymer products**
e.g. during application in interior areas and also during grouting
- **Documentation**
These positively assessed application areas are identified for each individual product in the corresponding technical and safety data sheets. MC thus complies with its information obligation according to REACH.