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# Informing you about REACH

The new European  
Legislation on Chemicals

  
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# What is REACH?

**REACH** is the new European Legislation on Chemicals. REACH is the acronym for **R**egistration – **E**valuation and **A**uthorisation of **C**hemicals.

The new regulation came into force on 1 June 2007. It **applies fully in each member state** and does not need to be transposed into national law.

## The Legislative Process and Important Milestones

When?	Who?	What?
2003– 2006	Commission, Council, Parliament, Stakeholder Groups	Legislative Process: Co-Decision Procedure, Internet Consultation, Studies on Workability
30 Dec 2006	Council and Parliament	Publication in Official Journal of the EU Reg.(EC)1907/2006
1 June 2007		REACH Entry into Force
1 June– 30 Nov 2008		Pre-Registration Process
2010	Industry and Chemicals Agency in Helsinki together with National Competent Authorities	Registration of > 1000 t/a and CMR Substances > 1 t/a and R50/53 substances > 100 t/a
2013		Registration of >= 100 t/a substances
2018		Registration of >= 1 t/a chemicals

## What is new?

REACH applies to all chemical **substances** which are manufactured or imported in the European Union. It **covers the whole supply chain** of a product. Not only the manufacturer or importer has obligations under the new legislation, but also every member of the supply chain.

Manufacturers or Importers of formulations need to make sure that each individual substance in a formulation complies with REACH.

Information about the intended use needs to be passed up the supply chain so that the manufacturer or importer can register a substance for that use (**notified use**). A substance may **ONLY** be used for its registered (notified) use.

A new central **European Chemicals Agency** has been established in Helsinki. It handles the REACH process together with the national competent authorities.

For substances with annual volumes of 10 t and more, **Chemical Safety Reports** have to be created and relevant use and exposure information have to be included into an Annex of the Safety Data Sheet.

In order to avoid unnecessary animal testing, manufacturers and importers of the same substances need to form **SIEF** (**S**ubstance **I**nformation **E**xchange **F**ora) to share test data.

## What will change?

Under **REACH** all substances have to follow the same registration, evaluation and authorisation **procedure**. From 1 June 2008, all chemical substances which are manufactured or imported into Europe at volumes of 1 t or above need to be registered.

However, substances which are on EINECS (European Inventory of Existing Chemical Substances) have **phase-in status** and can be **pre-registered** between 1 June 2008 and 1 December 2008. Thus, manufacturers and importers can take advantage of extended registration deadlines.

Depending on the annual volume and the hazard properties of phase-in substances, manufacturers, importers and down-stream users need to register within 3.5 years (>1000 t/a), 6 years (>100 t/a) or 11 years (>1 t/a) respectively.

Substances of "very high concern", namely CMR (Carcinogen, Mutagen, Toxic to Reproduction) and R50/53 (very toxic to aquatic organisms, may cause long-term adverse effects in aquatic environment) substances need to be registered within 3.5 years if their annual volume exceeds 1 t or 100 t respectively.

If the evaluation by the Agency shows that there is a high risk associated with the use of a substance, the authorisation process is started, which may result in a restriction in use or a ban of the substance.

# How will my company be affected by REACH?

## If you are located in the European Union

As a **down-stream user**, you need to make sure that the **raw materials** you are purchasing will be **registered** under REACH.

But registration alone is not sufficient. You also need to ensure that your specific use will be registered (**notified use**). If not, you may either ask your supplier to notify your use or you have to register yourself.

As a **manufacturer or importer** you have to **register all substances you handle** at quantities at or above 1 t/a. For substances at or above 10 t/a you have to perform a Chemical Safety Assessment and create a Chemical Safety Report.

Due to the high costs related to registration and testing, low margin **products may disappear from market**. Also, **confidentiality and intellectual property issues** may arise due to the high amount of information required to be disclosed during the registration process.

## If you are located outside the European Union

Under REACH, only volumes of substances which have been manufactured in the EU or have been imported into the EU can be registered. It is not possible to proactively register a substance manufactured outside the EU just in case it might be imported further down the supply chain. This means, **each importer** of a substance – even if it comes from the same source – **has to register** the volume he imports if it reaches 1 t/a.

Although polymers are exempt from registration under REACH, for **imported polymers**, all monomers and other components which are present in the polymer at quantities of 2% and above, and where the total annual volume reaches 1 t, need to be registered by the importer.

For non-European manufacturers who sell product to European customers this means that they need to **be prepared to disclose the composition** of their preparations and polymers to the customers or importers.

In order to avoid the disclosure of composition, non-European companies may appoint an **“Only Representative”** to fulfil the registration requirements for all imports of substances

manufactured by this company. The “Only Representative” can be a European subsidiary or a third party located in the European Union.

These provisions do not apply for substances, polymers or polymer-components which are **re-imported** and have already been registered further up the supply chain.

RohMax Oil Additives will appoint an Only Representative to support our non-EU customers to comply with REACH.

## How can my company prepare for REACH?

Most of the processes under REACH apply to manufacturers and down-stream users inside the EU as well as to companies located outside the EU if their products are imported into the EU.

**Start preparing for REACH now.**

### **Raw Materials:**

- Make sure you have a **complete list of all raw materials and related suppliers**, so that you can contact them to check whether they will (pre-) register.
- CEFIC developed a standard questionnaire for the communication along the Supply Chain. RohMax recommends using this questionnaire (Download at: <http://www.cefic.org/files/Publications/REACHIndustryPreparationLetterNo5.pdf>).

### **Products:**

- Compile a **complete list of all substances** you currently manufacture or import so that you can make sure they have phase-in status and get pre-registered.
- Obtain use information from your customers. RohMax recommends using the CEFIC standard questionnaire for the communication with your customers.
- Screen all **available test data** on your substances and plan for additional tox testing if necessary.
- Prepare for a membership in **SIEF**.

# How does RohMax prepare for REACH?

RohMax Oil Additives supports the overall REACH goals of protecting human health and the environment. These goals are consistent with our corporate Environmental, Health, Safety and Quality Policy

We are well prepared for REACH.

RohMax VISCOPLEX® and VISCOBASE® products are based on **polymers which are exempt from registration and evaluation** under REACH. However, monomers need to be registered.

Our **REACH Implementation Team** already is well prepared for pre-registration. We are in the process of appointing an Only Representative who will help our customers to import our components into the European Union.

Monomers as well as Sulfolane products (manufactured by our sister company Evonik Degussa Stanlow Limited) will be pre-registered.

Our regulatory experts are thoroughly following all new developments on REACH and evaluate the impact on RohMax products. As part of the Evonik organisation we also benefit from their expertise and advocacy work.

Our goal is to work with our customers to make the transition to the new legislation for our customers as smooth as possible and to be able to supply you with our products as usual.

# If you have general questions about REACH:

REACH legal text

<http://eur-lex.europa.eu/JOHtml.do?uri=OJ:L:2007:136:SOM:EN:HTML>

European Chemicals Agency (ECHA)

<http://www.echa.europa.eu>

Directorate General Enterprise (Commission)

[http://ec.europa.eu/enterprise/reach/index\\_en.htm](http://ec.europa.eu/enterprise/reach/index_en.htm)

European Chemicals Bureau

<http://ecb.jrc.it/REACH/>

CEFIC (European Chemicals Council)

<http://www.cefic.be/>

CEFIC REACH Centrum

<http://www.reachcentrum.eu>

ATC (Additives Technical Committee)

<http://www.atc-europe.org>

ACC (American Chemistry Council)

<http://www.americanchemistry.com>

VCI (Verband der Chemischen Industrie)

<http://www.vci.de> (German, only downloads in English)

CIA (Chemical Industry Association) UK

<http://www.cia.org.uk/newsite/>

UIC (Union des Industries Chimiques) France

<http://www.uic.fr/fr/reach00.htm>

This information was compiled by RohMax Oil Additives as a service to our customers and suppliers and is based on our present knowledge and experience. However, it implies no liability or other legal responsibility on our part. For full and detailed information on REACH, please refer to the official text of the final version.

# If you have questions concerning RohMax products:

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