



REACH – The importance for chemicals companies from non-EU countries.

REACH – The registration by an authorised “third party” provides access to the markets of the EU economic area for non-EU companies.

The intention of the new draft European law REACH - *Registration, Evaluation, Authorisation and Restriction of Chemicals* - is that industrial companies should be directly

responsible for investigating their chemical substances for possible dangers to humans and the environment and have to register their purpose. In future, companies

whose manufacturing base is outside the EU, and have no representation or importer within the EU, will require the support of a third party to be able to participate in the European market.



chemical industry • drapery and leather industry • plastics processing
pharmaceutical products • coking plant • petroleum processing
printing industry • furniture • plant engineering and construction

Facts about REACH – In future, only those substances about which there is sufficient data may still be sold in Europe. This information complying first and foremost with the maxim “No Data, No Market” as per the respective production volume. Chemicals of which more than a tonne per year is produced or imported must be registered throughout the EU.

The higher the production volume, the more data must be supplied: “More Market, More Data”. These data include physical-chemical properties, toxicity and ecotoxicity information and the known purposes of the substances and preparations.

If the quantity exceeds 10 t/a, a Chemical Safety Report must also be drawn up which assesses the substances with regard to possible risks to humans and the environment. If a substance presents a particularly high risk – CMR, PBT or vPvB substance – it must be assessed and approved by the European Commission.

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Consequences for chemicals companies outside Europe –

Every year, chemicals to the value of € 67 billion are imported into the European economic area. This corresponds to about 10% of total sales of chemicals in Europe. For example, in 2004 North American companies exported chemicals to the value of approx. € 20 billion to the EU.

To comply with REACH, these companies require a branch in Europe or a partner for registration whose registered office is in the EU. This is a mandatory requirement in order to register products or participate in consortia.

In terms of registration, therefore, companies from non-EU countries are either reliant on the support of their importers or they need to appoint a “sole distributor” who is responsible for registration on their behalf and who participates in consortia.

Help within the EU – Possible solutions include having the registration carried out by importers, setting up a legal entity in Europe or authorising a third party to carry out the registration. With this in mind, TÜV BioTech GmbH is therefore offering to carry out the registration on behalf of non-European companies with all the rights and obligations involved.

This includes

- carrying out the pre-registration,
- determining and assessing the costs and potential for cost reduction,
- analysing gaps in the data,
- drawing up and submitting the necessary registration documents,
- representing the companies in consortia and to the European Chemicals Agency.

The TÜV Rheinland Group has operated for almost 140 years as a neutral and confidential partner to industry across the world. Corporate organisation and expertise are essential to avoid anti-trust difficulties and to protect the secret formulations of the preparations. Detailed knowledge of chemicals legislation in Europe guarantees a smooth registration process for chemicals.

TÜV BioTech GmbH offers a range of services to companies headquartered outside the EU. From advice on REACH to registering their substances, companies are supported so that they continue to be represented in the world’s biggest domestic market.