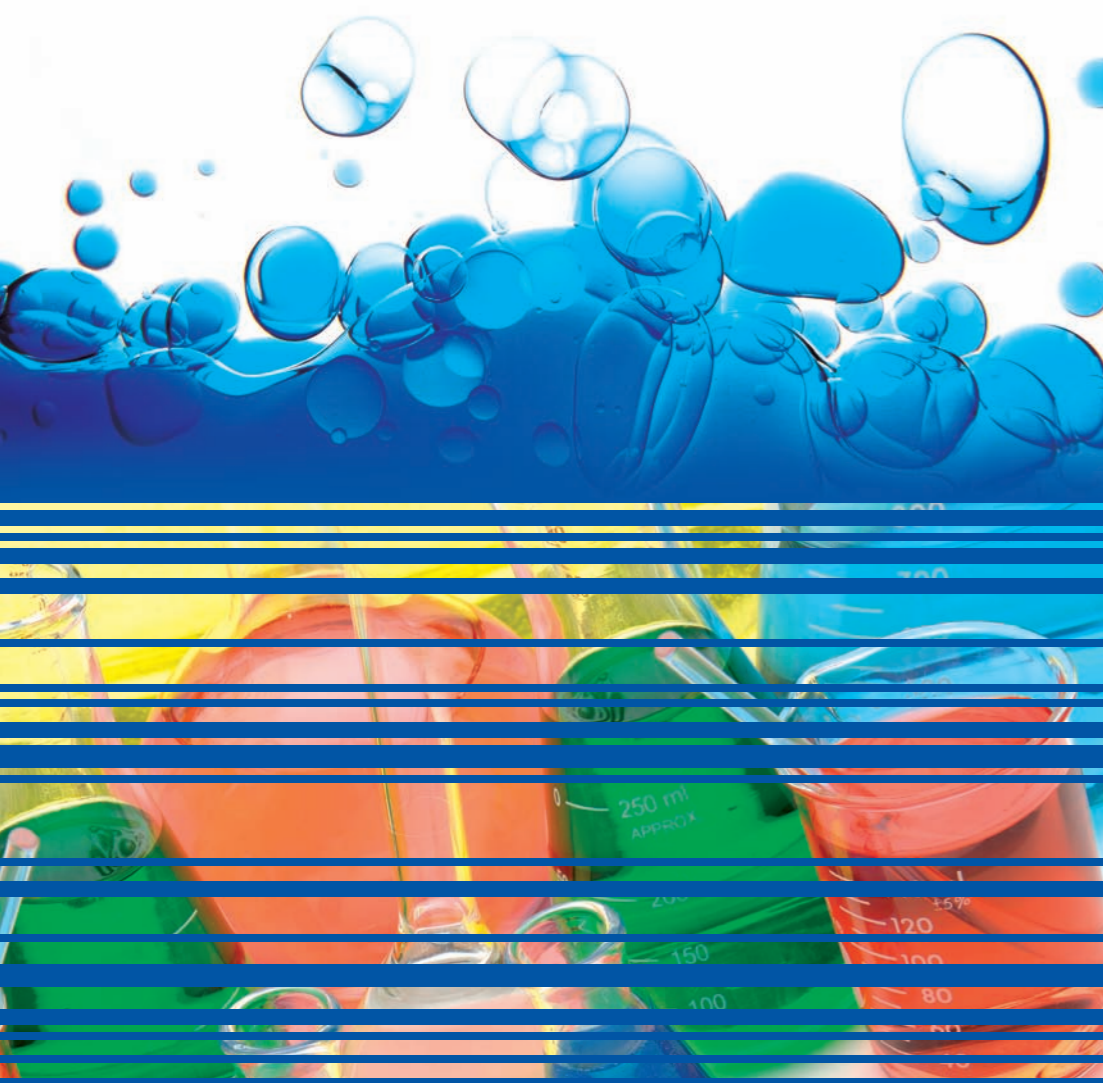



# Get within REACH



**EuroChemLink**

A Regulatory Services Company

A member of the BioChemAlliance  BioChemAlliance

## Let EuroChemLink help you succeed with REACH by:

- Preparing an inventory of substances coming under REACH;
- Organising pre-registration of existing substances;
- Organising and participating in consortia;
- Obtaining and preparing data for registration;
- Organising risk assessments for the Chemical Safety Report;
- Helping prepare Safety Data Sheets;
- Preparing the technical dossier;
- Submitting the technical dossier via IUCLID;
- Providing the answers to questions arising from the evaluation of the registration.

Take the last step – make contact now.

**EuroChemLink**

A Regulatory Services Company

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# Out of REACH



Now that REACH (Registration, Evaluation and Authorisation of CHemicals) is here, we at EuroChemLink, have the expertise in regulatory affairs, as well as the legal and technical knowledge, to help our clients understand how REACH will impact on their businesses and how to meet their obligations under this new legislation.

## But what is REACH

REACH is the European Commission's new EU regulatory system designed to regulate the manufacture, import, marketing and use of chemicals.

Under REACH, all manufacturers, importers and downstream users must demonstrate that substances they manufacture, market or use do not adversely affect human health or the environment.



# The REACH procedure

The REACH procedure involves several steps and EuroChemLink can help its clients every step of the way.

## STEP ONE

### Decide which substances come under REACH

An inventory of substances, preparations and finished articles will need to be prepared to evaluate which fall under REACH.

*EuroChemLink can help you identify which of your substances come under REACH and will need to be registered. We can also identify which substances will be exempt or do not come under the provisions of REACH.*

## STEP TWO

### Keep substances on the market

Substances already on the market, 'phase-in' substances, must be pre-registered between June 2008 and the end of November 2008 to stay on the market. Early pre-registration will help set up Substance Information Exchange Fora (SIEF) with other registrants of the same substances.

*EuroChemLink can help you by compiling and submitting the information and advising you on setting up a SIEF on a regulatory or technical basis.*

## STEP THREE

### Obtain registration data

The registration process will take place in phases and requirements will vary depending on tonnage and potential hazard.

Key deadlines are:

- **By 1 December 2010** – registration of substances in quantities over 1,000 tonnes per year and some hazardous substances over one tonne per year;
- **By 1 June 2013** – registration of substances in quantities of over 100 tonnes per year;
- **By 1 June 2018** – registration of substances in quantities over one tonne.

**The dossier** – the technical dossier for registration must include:

- Physico-chemical properties;
- Toxicology;
- Ecotoxicology;
- Environmental fate.

*EuroChemLink can help you by accessing data, working with consortia and organising studies if required. We can also develop arguments for waivers against some studies.*

## STEP FOUR

### Prepare a Chemical Safety Report

For all substances marketed in quantities over 10 tonnes, a Chemical Safety Report is required. This should include assessments of hazards to human health and the environment based on exposure scenarios over its life-cycle. There should also be a physico-chemical hazard assessment and an assessment of whether a substance is persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB).

*EuroChemLink has excellent links to experts in the complex area of risk assessment and we can help organise and prepare assessments to the required standard.*

## STEP FIVE

### Prepare a Safety Data Sheet

A Safety Data Sheet will be required for substances classified as dangerous under Directive 67/548/EEC or 1999/45/EC or classified as a PBT or vPvB.

*EuroChemLink can help prepare 'Safety Data Sheets' based on information supplied by companies of given substances.*

## STEP SIX

### Prepare a technical dossier

The technical dossier must include the identity and manufacturing route of the substance, its classification, labelling, guidance for safe use, study summaries and the Chemical Safety Report. Submission must be made electronically using International Uniform Chemical Information Database (IUCLID).

*EuroChemLink can help prepare study summaries, preparing arguments waiving studies and prepare the technical dossier. With experience of IUCLID we are well placed to prepare and submit dossiers for REACH.*

## STEP SEVEN

### Handle queries after submission

The final step in the REACH process is evaluation. At this stage queries might arise from information or study data contained in the submitted technical dossier or a proposal for authorisation or restriction of the substance.

*Whatever the question EuroChemLink has the expertise to help with the answers and proposing the best way forward for you.*

*Communication plays an important role and EuroChemLink has good relations with the European Chemicals Agency and other authorities in the Member States.*