

REACH

Registration,
Evaluation and
Authorisation of
Chemicals

LET SCC BE YOUR REACH SPECIALIST!

LET SCC'S PARTNERS HELP YOU WITH YOUR REACH TESTING REQUIREMENTS!

To achieve the aims set forth in **REACH**, it is necessary to have considerable experience of the notification/registration and the associated data requirements. **SCC** has the knowledge to help you with your REACH registration. Since 1989, **SCC** has prepared over 100 chemical notifications for new chemical substances, and successfully filed > 100 lead dossiers for the 2010 deadline under REACH. **SCC** has established a network to the Competent Authorities within the entire EU and is recognized as a reliable and competent partner by the authorities.

SCC is also recognized as a knowledgeable partner for EU industry organizations such as CEFIC or HERA (a subgroup of CEFIC) and has dealt with all aspects of hazard exposure and risk assessment of chemicals including analogous considerations, strategies for PBT substances, etc.

SCC can provide you with:

- "Only representative support"
- Support in the (pre-) registration process
- Support in prioritization/advice on required action in your company for the upcoming deadlines
- Data review and identification of data gaps
- Establishment of study requirements as well as organizing and monitoring of those studies
- Analysis of potential analogous / family approaches, and development of test strategies
- Comparison of "intended uses" and "identified uses"
- Exposure modelling (including EUSES, Risk of Derm, Consexpo, ...)
- Human and environmental risk assessments
- Preparation of the Chemical Safety Report
- Submission/defense of the dossier at authority level
- SIEF and Consortia Management including trust account
- C & L support (CLH dossier according to Annex XV, eSDS including Annex)
- (Q)SAR tools, e.g. to support group approaches

Due to the increasing demands for testing foreseeable under REACH, **SCC** has additionally established co-operations with laboratories in Eastern Europe and India to offer testing packages for labor-intensive studies, such as 90-day (toxicity and teratogenicity studies, etc.) at very competitive prices. Our partner laboratories are GLP certified and audited by **SCC**, and are capable of handling all required testing.

We have also established a network with university experts to support group approaches/analogous considerations or waiving arguments using QSAR-Modelling.

CONSORTIUM MANAGEMENT AT SCC

One Substance, One Registration. This REACH requirement means that consortia/task forces will have to be established to prepare and submit the dossiers. **SCC** has dealt with over 20 task forces since 1989, and is currently active in more than 10. Our experience is your advantage.

SCC

We take care!

Your contact person for REACH:

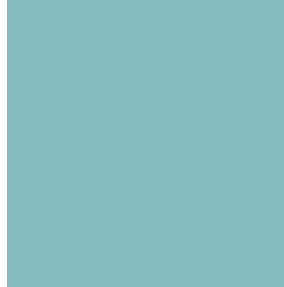
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THE NEW EU CHEMICALS POLICY: REACH

REACH, the **R**egistration, **E**valuation and **A**uthorization of **C**hemicals, is the new EU regulatory framework for the registration of chemical substances in effect since June 2007. This wide-ranging regulatory legislation affects all producers, importers and users of new or existing substances, as well as downstream users, formulators and producers of articles. The first deadline on 30 November 2011 showed the real challenges with REACH. However, the evaluation process by the authorities has just started.

REACH bundles the current regulations regarding the registration of existing and new chemicals, and combines them with broader regulations regarding the testing requirements, hazard identification and quantification, targeted exposure and risk assessment, management measures and the establishment of **new extended MSDSs (eSDS)**.

It abolishes the artificial division between new and existing chemicals by requiring each manufacturer or importer of more than 1 ton of a chemical substance per year to prepare a technical dossier which will be registered in a central database within a time period of more than 10 years, depending on annual volume and hazard characteristics. For new substances, a base set of data must be prepared before production or import.

For all chemicals, new or existing, produced or imported in quantities of 10 tons or more annually, the dossiers will also require a **Chemical Safety Report (CSR)**, which evaluates the potential risks to man and environment.

Importers and producers must prepare the report with regard to the intended uses of the substance, while the downstream user must prepare the CSA if their specific use is not covered in the CSA prepared by the manufacturer. Thus, not only producers, but also so-called "downstream users" are heavily affected by REACH. This has been realized by Industry based on dossiers filed in 2010 and the first eSDS now becoming available.

WHAT ARE THE REACH REQUIREMENTS FOR THE PRODUCER / IMPORTER?

For all substances with a production or import quantity of ≥ 1 tpa the following basic information is required:

- Substance ID including IUPAC name, CAS and EC No.
- Substance characteristics (spectra, purity, ...)
- Annual production / import volume
- Safety data
- Intended uses

In addition, for the substances with a production or import quantity of ≥ 10 tpa, the following endpoints according to Annex VI are to be addressed:

Phys-chem data:

- Density
- Melting / boiling points
- Water solubility
- Vapor pressure
- Partition coefficient
- Explosive properties
- Flash point
- Flammability
- Surface tension
- Oxidizing properties
- Granulometry
- Self-ignition temperature

Toxicological, eco-toxicological and environmental behavior data:

- Acute toxicity
- Skin & eye irritation
- Skin sensitization
- Toxicokinetics
- Mutagenicity in vitro
- Biodegradation
- Aquatic toxicity
- Adsorption/Desorption

Exposure assessments for the different fields of use are also required and have to be considered in the CSA.

WHAT ARE THE REACH REQUIREMENTS FOR USERS?

Users also have requirements to fulfill under **REACH**. These include:

- Estimate of amount to be used annually in the preparations.
- Specification of substances purchased.
- Listing of use categories.
- Is the planned use covered within the intended use in the safety data sheet?
- Safety measures must be examined with regard to the use in the facility.
- Can safety management requirements be met?

OTHER REQUIREMENTS (e.g. ≥ 100 tpa; Annexes VII / VIII) UNDER REACH...

... include data regarding:

- Mutagenicity / Genotoxicity
- Toxicokinetics
- Dermal penetration
- Chronic toxicity
- Reproduction toxicity
- Chronic ecotoxicity (fish, daphnia)
- Degradation in soil
- Toxicity for sediment dwelling organisms
- Bioaccumulation

Literature research will be required and "intended uses" have to be identified.

In all, a comprehensive data package needs to be prepared. The problem is, how to get it done?