

DISCOVER  
OUR SEGMENT

# CHEMICALS/ REACH



SCC

WE CARE FOR YOUR SUCCESS





**Dr Thomas Roth**  
Head of Chemicals, Cosmetics,  
Consumer Products and  
Feed & Food Additives

## Our focus

**In SCC, you have found the perfect partner for your substance rollout – both within and beyond the EU. We have the necessary experience and knowledge, as well as excellent insight into future developments on the ever-changing chemicals market.**

Our REACH specialists help you to navigate the complex requirements of the EU regulatory framework for the registration of chemical substances. Our global registration services have an optimal cost-performance ratio, and our solutions are not only tailored to your specific challenges but to the markets, countries and authorities they are targeting. We are always well prepared for new developments, rules and regulations, helping you achieve the best possible results – no matter the size of your project.

# Our services

- Support for the **registration process** (EU, non-EU countries)
- **International registration strategies and services**
- Targeted **test strategies** and group approaches
- Online **database search** and literature services
- Assessment and **evaluation of data packages**
- **Portfolio analysis**, data review/evaluation (incl. commercial value) and data gap analysis
- **Project co-ordination**
- Scientific and regulatory **organisation and monitoring of studies**
- **Risk assessment** for potentially hazardous substances in accordance with national and international standardised procedures
- **Model calculations**: QSAR modelling for physico-chemical properties, toxicity and ecotoxicity, as well as the prediction of environmental behaviour
- **Exposure modelling** (e.g. EUSES, Risk of Derm, CONSEXPO, EASYTRA, CHESAR, ART and Stoffenmanager)
- **GHS/classification and labelling** support including **eSDS** (Annex), CLH dossier, GPS support
- Compilation of **IUCLID dossiers**
- Preparation of **chemical safety assessments** and **chemical safety reports**
- Submission and defence of **registration dossiers** at member state (CoRAP) and ECHA level
- **Fast track notification**: performance of all required studies (e.g. for REACH Annex VII) and notification to ECHA can be achieved within 4–6 months
- **Downstream user communication**
- **SIEF and Consortia Management** including LoA management
- **OR and Trustee services under REACH**

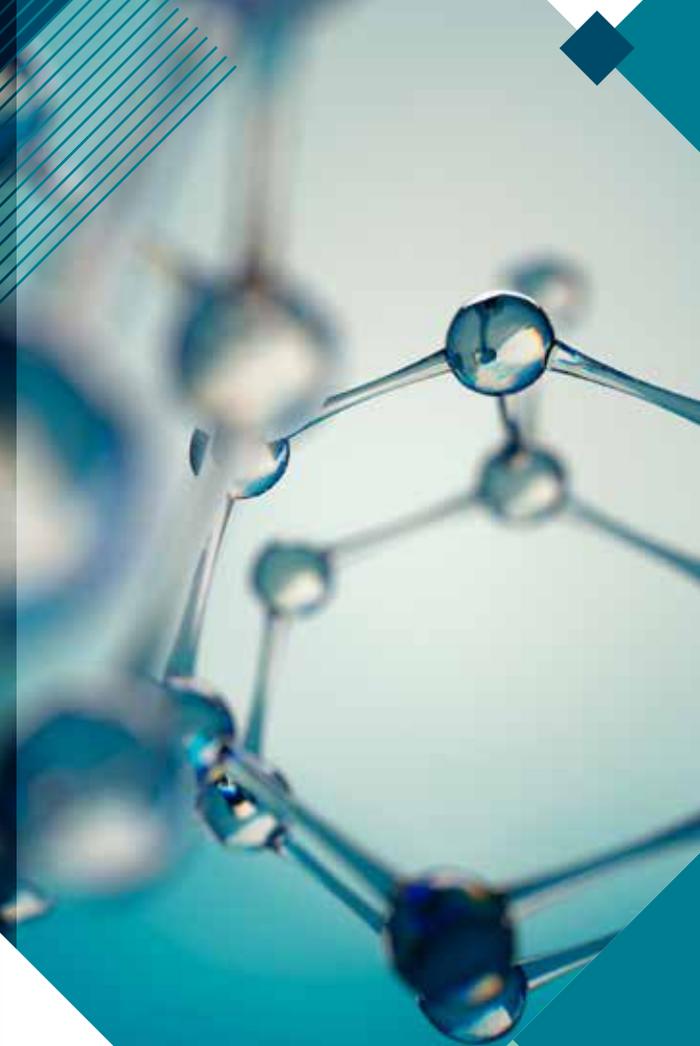


# Requirements for REACH

Under the REACH Regulation, all companies that manufacture or import a chemical substance in quantities of one tonne or more a year must prepare a technical dossier which has to be registered with the European Chemicals Agency (ECHA):

- For new substances, a base set of data has to be prepared before production or import
- For all new or existing chemicals produced or imported in quantities of 10 tonnes or more annually, a chemical safety report (CSR) must be submitted with the dossier
- The CSR has to evaluate potential health and environmental risks and must cover the entire life cycle of the substance

Downstream users whose specific use of chemicals is not covered by the manufacturer's or importer's CSR are required to prepare their own downstream user (DU) CSR. All CSRs have to include exposure assessments for the various fields the substance will be used in.

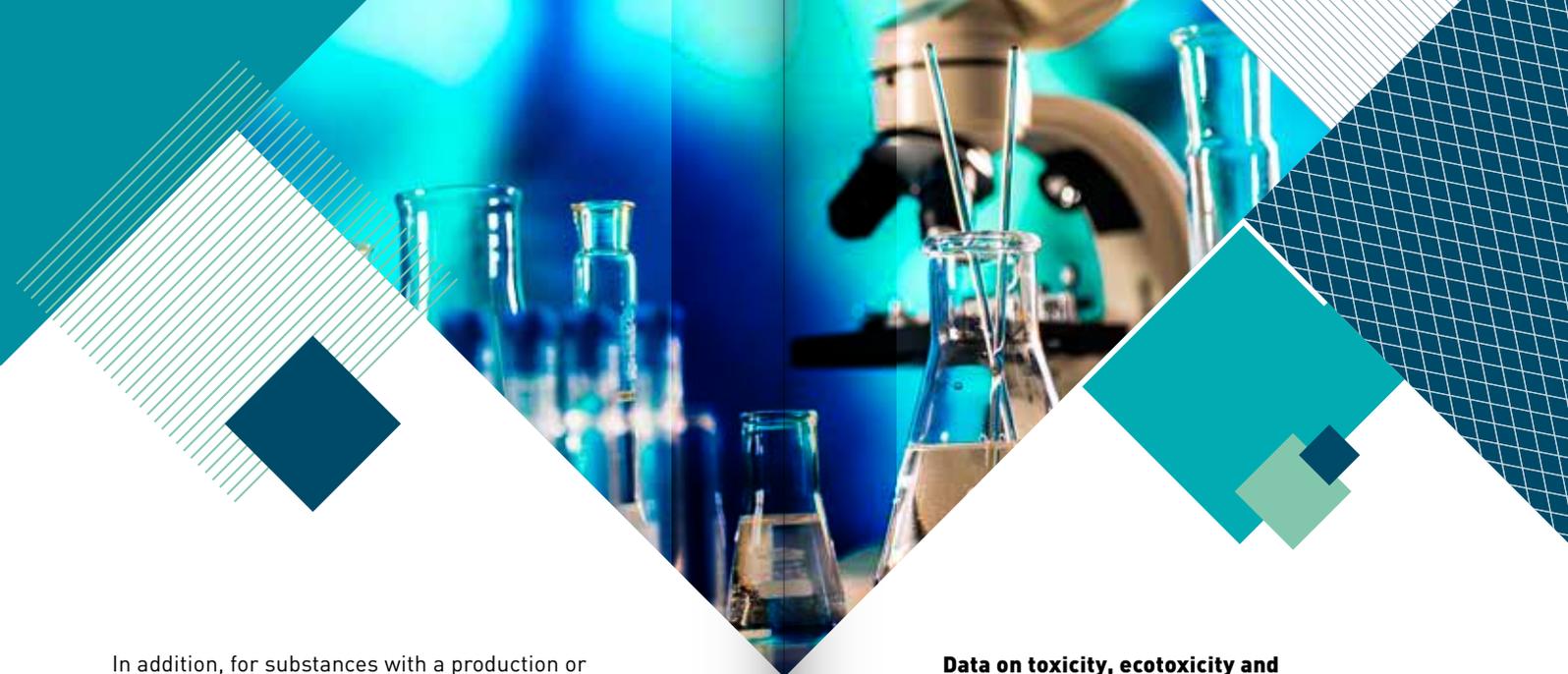


# Basic requirements for producers and importers

For all substances with a production or import quantity of more than one tonne per year, the following basic information must be submitted:

- Substance ID, including IUPAC name, CAS and EC number
- Substance characteristics (spectra, purity, etc.)
- Annual production/import volume
- Safety data
- Intended uses





In addition, for substances with a production or import quantity of 10 to 100 tonnes a year, the following endpoints from Annex VII and VIII have to be addressed:

**Physico-chemical data:**

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

**Data on toxicity, ecotoxicity and environmental behaviour:**

- Acute toxicity
- Skin and eye irritation
- Skin sensitisation
- Mutagenicity in vitro
- Subacute repeated dose toxicity
- Toxicity to reproduction (screening)
- Toxicokinetics
- Biodegradation
- Hydrolysis
- Adsorption/desorption
- Aquatic toxicity (fish, daphnia, algae)
- Toxicity to microorganisms

SCC prepares dossiers for tonnage bands from 100–1,000 t/a (Annex IX) and over 1,000 t/a (Annex X), including scientific waiving arguments and testing proposals/strategies, where required.

# Our expertise

Since REACH came into force in 2007, we have successfully filed more than 300 lead dossiers for phase-in and non-phase-in substances. We also have extensive experience in managing consortia and SIEFs, as well as in representing individual members of such data-sharing groups. We maintain excellent relationships with all relevant EU authorities and ECHA, while also being able to boast a first-rate record of approved notifications and registrations worldwide. When working with us, our clients profit from:

- Skilful development of comprehensive REACH and/or international registration concepts, including intelligent testing strategies
- In-depth knowledge of notification/registration processes and the associated data requirements
- Highly competitive prices for testing packages, including complex studies (e.g. for toxicity or teratogenicity), thanks to our collaboration with international GLP-certified labs (e.g. in Eastern Europe)
- Regular dealings with all aspects of chemical hazard, exposure and risk assessment, including analogue approaches, strategies for PBT substances, etc.

When using read-across strategies and QSAR-modelling to waive testing, we can rely on an extensive network of academic specialists for support. At the same time, we ourselves serve as an expert partner for many EU industry organisations, such as CEFIC or HERA (a subgroup of CEFIC). We have in-depth experience in analysing and helping to solve supply chain problems (OR, trustee function), and we also offer support for all issues related to classification and labelling.

# Who we are

SCC – Scientific Consulting Company – was founded in 1989 by Dr Friedbert Pistel. Since then, we have risen to become one of Europe's largest privately owned and independent scientific consulting companies, supporting global customers in the regulatory affairs business.

Our headquarters are located in Germany in the culturally rich Rhein-Nahe region, less than one hour's drive from Frankfurt Airport.

Our other offices in Berlin, established in 2014, and in Tokyo, opened in 2007, complement our headquarters in Bad Kreuznach and guarantee our international customers broader access to our services.

At SCC, you will find an open-minded, innovative entrepreneurial spirit backed by the expertise and commitment of a strong team. This winning combination has played a significant role in the rapid development of the company. It embodies values such as high quality, flexibility, reliability and versatility, coupled with vast knowledge and a wealth of experience. And that is what drives us forward.



**85%**

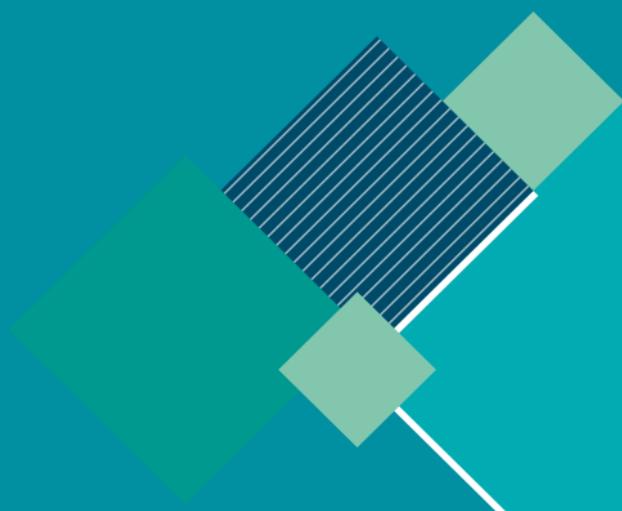
with a university degree

in  
**19**  
different disciplines

from  
**10**  
nations

**130**  
SCC employees





**SCC – SCIENTIFIC CONSULTING COMPANY**  
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