

DISCOVER  
OUR SEGMENT

# CHEMICALS/ REACH



SCC

WE CARE FOR YOUR SUCCESS





## 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 and 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 challenge 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 **(PRE-)REGISTRATION PROCESS**  
(EU, non-EU countries)

## **GLOBAL 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 prediction of environmental behaviour

**EXPOSURE MODELLING** (e.g. EUSES, Risk of Derm, CONSEXPO, EASYTRA, CHESAR, and ART)

**GHS/CLASSIFICATION AND LABELLING** support including **eSDS** (Annex), CLH dossier, GPS support

Compilation of **IUCLID DOSSIERS**

Preparation of the **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 and bank account management

**OR** and **TRUSTEE SERVICES UNDER REACH**

# REQUIREMENTS FOR REACH

**EACH MANUFACTURER OR IMPORTER**  
of more than one ton of a chemical substance per 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 must be prepared  
before production or import

**FOR ALL CHEMICALS**, new or exist-  
ing, 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 the environment

**DOWNSTREAM USERS**  
must prepare their own Downstream User  
(DU) CSR if their specific use is not covered  
by the CSR prepared by the manufacturer


**EXPOSURE ASSESSMENTS**  
for the various fields of use are also required  
and have to be considered in the CSR

**IMPORTERS AND  
PRODUCERS** must  
prepare the Chemical Safety  
Report and cover the entire  
lifecycle of the substance

## BASIC REQUIREMENTS FOR PRODUCERS AND IMPORTERS

**FOR ALL SUBSTANCES WITH A PRODUCTION OR IMPORT QUANTITY OF MORE THAN ONE TON PER ANNUM, 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 SUBSTANCES WITH A PRODUCTION OR IMPORT QUANTITY OF TEN TO ONE HUNDRED TONS PER ANNUM, THE FOLLOWING ENDPOINTS ACCORDING TO ANNEX VII AND VIII ARE TO BE ADDRESSED:**

**→ Phys-chem data:**

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

SCC prepares dossiers for tonnage band >100 t/a (ANNEX IX) and >1000 t/a (ANNEX X), including scientific waiving arguments and testing proposals/strategies, where required.

**→ Toxicological, eco-toxicological and environmental behaviour data:**

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

## OUR EXPERTISE

**DEVELOPMENT** of comprehensive REACH and/or global registration strategy including intelligent testing strategies

**PREPARATION** of hundreds of chemical notifications for new chemical substances and successful filing of more than 100 dossiers each for the 2010 and 2013 deadline under REACH

**EXCELLENT COLLABORATION** with the competent authorities within the entire EU and to ECHA

**SUCCESSFUL NOTIFICATION/REGISTRATION** of chemicals in almost all regions of the world

**OUTSTANDING EXPERIENCE** of notification/ process and the associated data requirements

**VERY COMPETITIVE PRICES** for testing packages, including labour-intensive studies (e.g. toxicity and teratogenicity) thanks to cooperations with GLP-certified laboratories, for example in Eastern Europe and India

**NETWORK OF UNIVERSITY EXPERTS** to support group approaches/analogous considerations or waiving arguments using QSAR-Modelling

**CONSORTIA MANAGEMENT:** more than 20 consortia/task forces managed since 1989

**RECOGNITION AS AN EXPERT PARTNER** for EU industry organisations, such as CEFIC or HERA (a subgroup of CEFIC)

**REGULAR DEALINGS** with all aspects of hazard exposure and risk assessment of chemicals, including analogous considerations, strategies for PBT substances, etc.

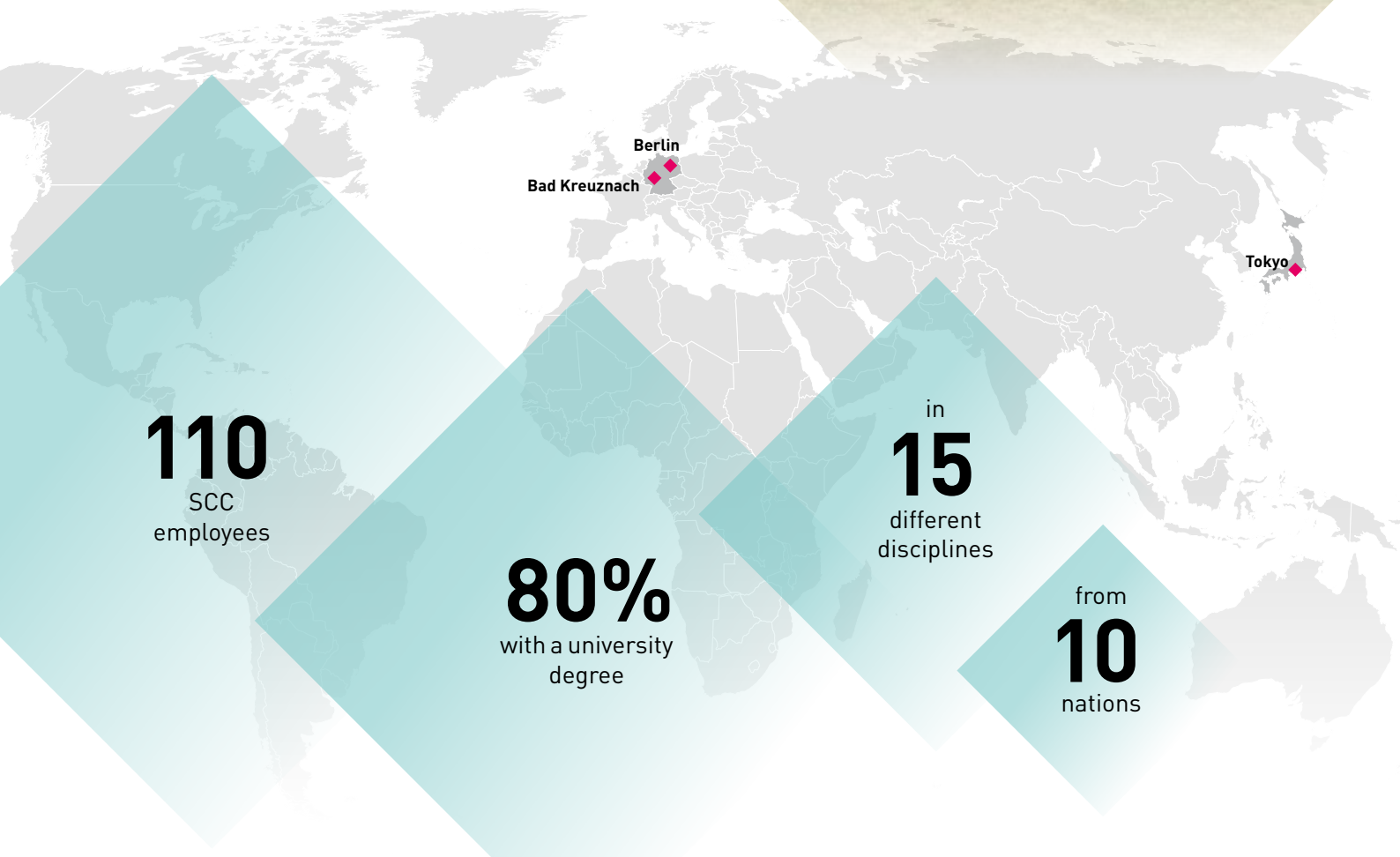
**IN-DEPTH KNOWLEDGE** of supply chain problems (OR, trustee function)

**SUPPORT FOR ALL ISSUES** related to classification and labelling

## OUR TEAM

SCC – Scientific Consulting Company – was founded in 1989 by Dr Friedbert Pistel. During our 25-year history we have become one of Europe's largest privately owned and independent consulting companies, supporting global customers in the regulatory affairs business.

SCC is headquartered in Germany in the culturally attractive Rhein-Nahe region and located in a modern building complex. The Global Office Japan was established in 2007 and the Global Office Berlin in 2014.



**110**  
SCC  
employees

**80%**  
with a university  
degree

in  
**15**  
different  
disciplines

from  
**10**  
nations

## **SCC – SCIENTIFIC CONSULTING COMPANY**

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