



Agrochemicals & Biorationals

Take advantage of our long-standing expertise and experience in the crop protection industry



Your guide in the complex regulatory environment

Effectively guiding agrochemical products through the complex European and international regulatory environment, requires skill and experience. Our in-house experts are deeply versed in every aspect of those regulatory processes.

Since our foundation in 1989, our experts have actively supported our customers in meeting the requirements of EU Directive 91/414/EEC and later on EU Regulation 1107/2009. They have been successfully mastering new challenges related to hazard assessments, candidates for substitution, etc., on the one hand, and seizing new opportunities, such as the establishment of SCC's dedicated expert team for biorationals and low-risk substances, on the other.

Relying on decades of accumulated know-how, we offer our customers regulatory and scientific support for all types of agrochemicals and biorationals, such as biocontrol agents, biostimulants, plant strengtheners, soil conditioners, plant aids and fertilisers for professional and consumer use in the EU and across the world.

OUR EXPERIENCE AND EXPERTISE

- More than 500 dossiers in accordance with EU Directive 91/414/EEC and EU Regulation 1107/2009
- Having submitted applications to all EU member states, as well as to multiple other European and non-European countries
- Active involvement in the evaluation and defence of more than 90 chemical and biological active substances

- Detailed knowledge of laws, regulations and procedures
- Active network of scientists in the industry and national and international authorities
- Support of several non-governmental and governmental organisations
- Broad experience in designing, monitoring and evaluating higher-tier studies, such as operator exposure studies (OPEX studies), micro-/mesocosm studies, birds/mammals, as well as NTA/bee semi-field and field studies.
- An extensive network of Contract Research Organisations (CRO), offering internationally accepted studies at competitive prices.

OUR INTERNATIONAL PRESENCE

Alongside our strong experience and expertise in the EU, we offer full-scale regulatory and registration support for countries outside the EU.

For years, we have been providing expert guidance and mastering regulatory challenges in the Asian-Pacific, Eurasian and North and South American markets. Via our extensive network of partners and associates in various corners of the world, we can guarantee our customers access to top-qualified and first-hand expertise in your target markets.

Please visit our website for more information:

<https://www.scc-gmbh.de/agrochemicals-compliance>

or contact one of our experts:

scc@scc-gmbh.de

OUR APPROACH

Our experts guide you confidently through the approval and authorisation processes for agrochemical and biorationals products. We provide you with step-by-step services, individually tailored to your specific regulatory needs.

1. Data Gap Analysis

The first step in any project, is to estimate the likely regulatory costs based on a data gap analysis. By identifying missing studies and finding waiving opportunities, our experts specify necessary studies, and plan, commission and monitor these studies.

Our experts independently monitor new studies to ensure they will be accepted all over the world, including the EU and the US.

2. Preparation of a Regulatory Strategy

We help you develop and design a cost-effective and efficient registration strategy and help you decide on the registration type and category best suited to your needs.

3. Submitting and defending dossier

We write the complete dossier, including carrying out risk assessments, and closely follow the submission process until the final registration has been granted.

This also includes preparing position papers, waiver documents and presenting clarifications to the responsible authorities.

OUR SERVICES

- Developing individual registration and compliance strategies to meet your needs
- Data gap analysis, including:
 - evaluating the adaptability of existing data packages to European and (inter)national guidelines
 - examining the possibilities for read-across of available registration data authorised in other regions
- Designing, contracting and monitoring all necessary studies at CROs best suited to your needs
- Environmental fate and modelling, human and ecotoxicological risk assessments
- Preparing and submitting registration dossiers to the European and (inter)national competent authorities
- Handling all kinds of import tolerance applications and MRL setting.

INDEPENDENT AND NEUTRAL PARTNER

As a privately owned, independent and neutral organisation, without any ties to contract research organisations, but with vast experience in R&D and registration of agrochemicals, biorationals and fertilisers, SCC provides you with independent support and advice regardless whether you are a small, medium-sized, or large multinational business.

Do not hesitate to contact our experts if you have questions or want to learn how we can help you ensure the regulatory compliance of your agrochemicals and biorational products on international markets.



WHO WE ARE

Privately owned, independent and neutral

SCC is a privately owned, independent and neutral consulting company with an extensive global network but no commercial ties to contract research organisations. Since 1989, we have been supporting our customers with tailored solutions for their scientific and regulatory needs within and outside the EU. Our expertise extends over a broad range of areas:

- Agrochemicals & biorationals, incl. fertilisers and biostimulants
- Biocides
- Chemicals
- Medical devices
- Cosmetics and consumer products
- Pharmaceuticals
- Food contact materials
- Feed additives
- International MRL setting
- Genetically modified/edited crop (Japan)
- Legal and consortia management (SCC Legal)
- Market Analysis
- GLP-Archiving

OUR OFFICES

- **SCC headquarters, Bad Kreuznach, Germany**
- **SCC Office Berlin**
- **SCC Japan**
- **SCC UK**

All our teams in different locations consist of highly educated and team-oriented experts, mostly academics and PhDs. More than 140 professionals are employed at the headquarters in Bad Kreuznach. Our offices with their expert teams complement the headquarters and guarantee our international customers broader access to our services.

Over three decades, we have been acting on the side of our customers providing them with expert guidance and helping them to master their regulatory challenges in the EU, Asian-Pacific, Eurasian and North and South American markets.

In this time, we have established an extensive network of partners and associates in various regions to guarantee our customers access to top-qualified and first-hand expertise in their target markets.

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 our company development. 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.

