

DISCOVER  
OUR SEGMENT

# AGROCHEMICALS & BIORATIONALS





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Vice President, Head of  
Agrochemicals & Biopesticides

## Our focus

**We are familiar with all types of conventional agrochemicals and biorationals, such as biocontrol agents, biostimulants, plant strengtheners, soil conditioners, plant aids and fertilisers for professional and amateur use. We are the perfect partner for all your agrochemical, biopesticide, biostimulant and fertiliser registrations, whether you are a small or mid-sized enterprise or a large multinational.**

While Regulation 1107/2009 is in the REFIT process and creates new uncertainties, SCC remains a reliable partner at your side. Since the company's establishment in 1989, our expert teams have witnessed and actively dealt with the introduction of Directive 91/414/EEC, which proved to be a challenge within the European national regulatory framework with Lists 1 to 4 and a wide range of seemingly irrevocable deadlines. Again, in 2009, SCC steered numerous large and small customers around the pitfalls opened up by Regulation 1107/2009, mastering new challenges (e.g. hazard assessments, candidates for substitution, etc.) and seizing new opportunities – such as establishing our departments for Biopesticides and Low-risk Substances. With the same commitment that allowed us to successfully gain initial approval for their active substances, we now manage the Annex I renewal (AIR) process or approval procedures for new active substances on behalf of our customers.

# Our services in plant protection

Just like developing effective plant protection products, confidently guiding them through the complex regulatory environment requires a lot of skill and experience. Our experts have plenty of both and are deeply versed in every aspect of the registration process. Their competence and dedication is what keeps our customers' products successfully in the market and our clients coming back for more – for almost three mutually successful decades now.

- **Nearly 30 years of experience** in dossier writing for all kinds of products used in agriculture
- **Preparation of more than 500 dossiers** for the plant protection product industry in accordance with Directive 91/414/EEC and Regulation 1107/2009
- **Submission of applications** to all EU member states, as well as to other European and non-European countries
- **Involvement** in the evaluation and defence of more than 90 chemical and biological active substances for 1<sup>st</sup> Annex I inclusion in accordance with Directive 91/414/EEC and/or in the renewal of approval under Regulation 1107/2009
- **Detailed knowledge** of written and unwritten laws, regulations and procedures
- **Ongoing contact** with scientists in the industry and with national and international authorities

- **Consultancy** for non-governmental and governmental organisations
- **Daily experience** in preparing dossiers for active substances, plant protection products, agrochemicals and biorationals used in agriculture, including the preparation of state-of-the-art CADDY dossiers
- **Independence and neutrality** with no ties to contract research organisations
- **Data analysis** in line with Regulations 283/2013 and 284/2013, existing and upcoming national plant protection laws, EU and national fertiliser laws for conventional and organic production
- **Broad experience** in designing, monitoring and evaluating higher-tier studies (e.g. operator exposure studies (OPEX studies), micro-/mesocosm studies, birds/mammals (e.g. focal species and effect studies), as well as NTA/bee semi-field and field studies)
- **Strategy/concept development** for new active substances and products






# Our special services and expertise for integrated crop management and organic farming

**Modern farming methods focus on sustainability, integrated production methods and organic farming using environmentally friendly, low-toxicity biorational products. Developing these very diverse substances and products as well as qualifying them for approval requires a great deal of knowledge and attention to detail. SCC is a strong partner in all these tasks.**

We offer **high quality regulatory and scientific support** for biorationals, basic and low-risk active substances, biostimulants and fertiliser products, including R&D, steering research projects and academic cooperations.

# Our special services and expertise for integrated crop management and organic farming

- **Data analysis** in line with relevant European, national and international plant protection and fertiliser regulations and guidelines, including use of scientific approaches for dossier preparation by literature search and evaluation, identification of study waivers, scientific rationales and extrapolation strategies
  - **Design and monitoring of trial programmes** for Integrated Crop Production and Organic Farming
  - **Development of suitable registration strategies**, considering current and future Common Agricultural Policy (CAP) requirements, National Action Plans, Integrated Pest Management and the Sustainable Use Directive 2009/128
  - **Preparation, submission and defence of applications** for registration of biorational active substances and products, including biocontrol agents, biostimulants and fertilisers under European and national plant protection and fertiliser laws
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- **Handling of transition** from Fertiliser Regulation 2003/2003 to new requirements for EU CE-marked fertilisers, including survey of fertiliser and biostimulant product portfolios and development of appropriate registration strategies
  - **Preparation, submission and defence of dossiers** concerning the request to amend annexes of Regulation 889/2008 on **organic production**, including survey of product portfolios taking into account current and upcoming legislative frameworks
  - **Consultancy for GOs and NGOs, farmers and farmer associations** on scientific and regulatory issues related to Integrated Crop Management and Organic Farming

# Our special services and expertise for efficacy

New products developed to broaden the existing scope of plant protection products will only be accepted if their benefits can be shown to outweigh potential risks. Their approval depends on a realistic assessment of this balance and compelling proof of their efficacy and value. SCC has a substantial history of facilitating that proof by managing the associated studies and documents.

- **Planning of study programmes** across Europe and worldwide for new active substances, product re-registrations and label extensions
- **Study monitoring** of efficacy, crop safety and special studies
- **Data gap analysis** of existing data packages
- **Generation and development of study plans and ARM protocols** according to relevant standards
- **Data evaluation with ARM-ST**

- **Dossier generation** (dRR, zonal Biological Assessment Dossier, national addenda) in accordance with Regulation 1107/2009 for all types of conventional and biological plant protection products
- **Upgrading of out-dated or incomplete biological assessment dossiers and dRRs**
- **Intra- and interzonal mutual recognition applications**
- **Resistance analysis** and development of resistance management strategies
- **Comparative assessment strategies**
- **Product development and product support**



# Our special services and expertise for efficacy

- **Excellent knowledge of agricultural practices**
- **Nearly 30 years of planning and monitoring trial programmes and BAD-writing**
- **Intensive contacts with EPP0, national authorities and scientists** in the field of efficacy and agronomy
- **Training for efficacy experts**, e.g. workshops at regulatory conferences

## To date, our team has worked on

- **A broad range of substances:** e.g. herbicides, fungicides, insecticides/acaricides plant growth regulators, molluscicides, nematocides and soil disinfectants
- **Many classes and types of chemical and biologic products for all kinds of crops and uses**
- **Research trials** from climate chamber and glasshouse screening to large-scale field trial programmes
- **Professional and amateur applications**



# Task force/ consortium management

Task forces and consortia need a trusted partner and moderator to successfully work together. If managed efficiently, this joint method of seeking EU approval can lead to considerable savings in time and money. SCC has served as a reliable coordinator of approval-seeking task forces and consortia for almost 30 years now and is highly experienced in all related organisational activities.

- **Three decades of involvement in numerous task forces/consortia**, ranging from two to well over a dozen member companies
- **Up-to-date meeting rooms** 45 minutes away from Frankfurt International and Hahn Airport
- **Complete event management**, including travel arrangements and hotel accommodation
- **Moderation/chairmanship** with scientific, regulatory and administrative expertise
- **Reliable follow-up** of action points
- **Communication** between members, authorities and CROs
- **Organisation and tracking** of financial issues within the consortium/task force



- **Real-time budget overview** through our unique cost and project information database system (SCC-PRO)
- **Study value determinations and LOA management**
- **Central archiving and database functions** to keep track of all pertinent documentation using the electronic document and dossier management system (SCC-EDDMS)
- **Arrangements for meeting room facilities** and event management worldwide





## Electronic submission of dossiers

Electronic submission of data is not only a sustainable and cost-saving alternative to the traditional paper-based method. It has also become the only route of application many authorities will accept. SCC has been generating computer-aided dossiers for more than ten years now and is comfortably at home with all required forms and technicalities.

### **CADDY**

Saving resources: paper, copying materials, shipping and storage costs

Pre-requisite for agrochemical applications at the EU level and many national authorisations

Generation and submission of CADDY (Computer Aided Dossier and Data Supply) dossiers since 2004

SCC staff has a nonrecurring registration at the German BVL that enables placement of electronic applications/submissions using the portal and the Virtual Post Office. Electronic application is mandatory as of 1 February 2014.

# 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.

Bad Kreuznach  
Berlin

Tokyo

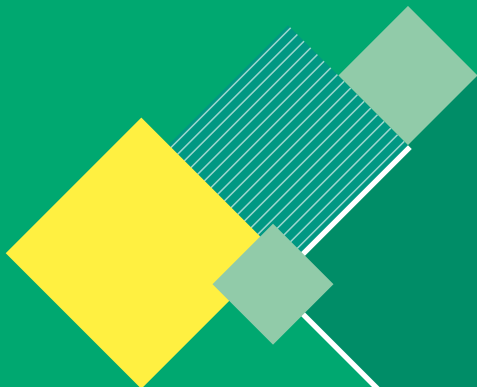
**85%**  
with a university  
degree

in  
**19**  
different  
disciplines

from  
**10**  
nations

**130**  
SCC employees





**SCC – SCIENTIFIC CONSULTING COMPANY**  
Chemisch-Wissenschaftliche Beratung GmbH

**HEADQUARTERS**  
**BAD KREUZNACH**

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