Our services for

Biorationals, fertilisers, IPM, precision/digital & organic farming

Independent expertise in R&D and registration

Paving the way forward – from innovation to effective products

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SCC
WE CARE FOR YOUR SUCCESS

YOUR OPPORTUNITY – YOUR SOLUTION

Biorationals, characterised by their low environmental impact, are a huge and very diverse group of substances or products such as biopesticides, biostimulants or plant aids. Typically, they are of biological origin or, if synthetic, structurally and functionally similar to their natural occurring analogue.Development of biorationals is driven by constant innovation and is an important pillar for the bioeconomy and Green Deal policies. It offers great opportunities to support the worldwide efforts in boosting the use of environmentally friendly and low-toxicity products as a basis for the production of residue-free food.

The European Green Deal, the Farm to Fork and Biodiversity Strategies, new transparency, and biostimulant and fertiliser requirements significantly influence the perception and use of plant protection products, fertilisers and biostimulants. This is especially true for the compatibility with Integrated Production (IP, including Integrated Pest Management (IPM)), Organic, Precision and Digital farming and the impact on product use, performance or risk assessments.

FROM FARM TO FORK – FROM R&D TO SALES

The first steps in any product development include determining Mode(s) of Action, product formulation, uses and conditions of use. At this stage, testing and strategy development play a crucial role.

Registration of biorationals includes aspects not applying to conventional chemicals and vice versa. For example, some biorationals are botanicals, having a complex mixture of several compounds, affected by biological variation. Others are based on micro-organisms, requiring the assessment of secondary metabolites or pathogenicity.

Expert knowledge of agricultural, regulatory, technical and scientific requirements and innovations is the key factor for success of your substances and products and one of SCC's field of expertise.

IPM AND ORGANIC FARMING

The balance between food safety and effective pest control and crop cultivation methods is one of the most challenging aspects of agriculture. Integrated Production (IP), including Integrated Pest Management (IPM), Organic Farming and Precision/Digital Farming, are key factors to achieve this balance.

SCC helps you review your product portfolios with IP, IPM, organic and precision farming potential and offers expert advice on all regulatory and scientific topics for sustainable, integrated crop management.

BIOPESTICIDES

Since entry into force of Regulation 1107/2009, special considerations were made for the very inhomogeneous group of biopesticides, for example regarding the data requirements for micro-organisms or botanicals. However, due to the diversity of 'biopesticide' active substances, such as fungi, bacteria, plant extracts and microbial metabolites, the registration of 'biopesticides' remains complex, requiring knowledge of the latest scientific research and regulatory procedures. This is especially true since, according to European legislation, 'biopesticides' are not a regulatory defined group of active substances and products. Instead, Europe distinguishes between conventional, basic and low risk active substances, for which different data requirements and regulations apply.

Please visit our website for more information:
https://www.scc-gmbh.de/crop-health-plant-nutrition-products-compliance
or contact one of our experts:
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BIOSTIMULANTS AND FERTILISERS

The new European Fertiliser Regulation 2019/1009 for CE-marked products, applicable from 16 July 2022, determines fertilising products* can only be placed on the market if they are sufficiently effective, which can be proved, for example, by providing scientific evidence of the product's agronomic efficiency. National registrations for products that are not conform to EU criteria remain possible and even gain importance since new EU and national regulations allow for an improved free movement of fertilising products in the EU.

*Products of the Product Function Categories (PFCs, i.a. organic, organo-mineral and inorganic fertilisers, liming materials, soil improvers, growing media, nitrification, denitrification and urease inhibitors, plant biostimulants, and fertilising blends.

ADJUVANTS

There are currently no harmonised regulatory frameworks for formulation or tank-mix partners, such as adjuvants. For example, for the use of plant protection products, adjuvants theoretically fall under the scope of the plant protection products regulation 1107/2009. However, no harmonised registration procedures or data requirements have been implemented so far. At the same time, technical and scientific developments, such as the development and use of efficient and environmentally friendly products, increase the importance of adjuvants. National requirements differ hugely, ranging from administrative notification procedures up to dossier submissions, including ecotox or efficacy studies.

OUR SERVICES

To offer our customers tailormade services, SCC has established an expert team specialised in the regulatory and scientific aspects of the registration of biorationals.

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

From innovation to effective product, from R&D to study programme

- Assessment of registration possibilities based on product-specific Modes of Action, global regulatory status or claims for "dual use" products considering all available legislative frameworks for food, feed, IPM, organic farming, pharmaceuticals, cosmetics, etc.
- Red flag or Data Gap Analysis of new or existing study packages
- Made-to-measure solutions for exceptional products where no or only insufficient regulatory guidance is available
- Analysis of data for usability on a global scale
- Literature search and evaluation for R&D and product (GAP) development or regulatory issues, applying scientific rationales for study waivers
- Specialty and R&D trials for elaboration of Mode(s) of Action, formulation development, resistance mechanisms, etc. in accordance with relevant EU and international guidelines
- Testing and incorporating Integrated Production (IP) and Integrated Pest Management (IPM) application schemes
- Incorporation of Precision and Digital Farming methods, forecast models and Decision Support Systems (DSS)
- Species and strain specific identification & characterisation through sequence analysis (incl. alignments, sequence comparisons to available DNA databases and phylogenetic analysis)

Dossier preparation for biopesticides, basic substances and low risk substances

- Risk assessments for human health and environment based on state-of-the-art exposure modelling or substance-specific scientific justifications/waivers
- Preparation, submission and defence of dossiers for new and existing substances and products in the EU, on national, zonal or international levels
- Re-registrations of substances (AIR programmes) and re-authorisations of products
- Preparation and submission of applications for residue exemptions such as inclusion in Annex IV of Regulation 396/2005
- Development of suitable efficacy testing programmes for all biorational products, considering specific characteristics, requirements, guidelines and extrapolation possibilities
- Usability check of data being non-compliant with current guidelines, e.g. data for 3-dimensional crops considering the leaf wall area concept, to give “old treasures” a second chance
- Evaluation of product portfolio and product application range for use extensions
- Extrapolations for use and GAP extensions to keep the number of trials at the lowest acceptable level

Regulatory strategies for biostimulants and fertilisers

- Review of products and product portfolios, reflecting current, new and future legislative frameworks for product registrations
- R&D, testing and registration issues for CE-marked fertilisers of all Product Function Categories (PFCs), including authorised representative obligations
- Handling the transition from current rules to new regulations/requirements or from national registrations to EU requirements
- National efficacy for registration and mutual recognition applications
- Handling of national registration procedures
- Support with obtaining Mutual Recognition between Member States and drafting Mutual Recognition Declarations

IPM and organic farming

- Product and portfolio reviews and full dossier support regarding the request to amend annexes of the organic production regulation
- Notification and registration of companies and products at organic farming certification bodies
- Developing effective registration strategies in view of current and future Common Agricultural Policy (CAP) requirements and integrating the complete spectrum of legislative frameworks
- Developing IPM strategies considering the use of simulation models, chemical, biological, physical and mechanical plant protection methods
- Testing and incorporating Integrated Production (IP) and Integrated Pest Management (IPM) application schemes to increase scope of applications and product use
- Designing registration strategies by considering current and future developments in Precision and Digital Farming methods, fore-cast models and Decision Support Systems (DSS)
- Providing scientific and regulatory advice to GOs and NGOs, farmers and farmer associations