

WE CARE FOR YOUR SUCCESS



Product performance and efficacy testing and assessment are far more than a regulatory requirement for plant protection products, fertilisers, biostimulants and adjuvants. It can guarantee the effectiveness, safety and economic benefits of a product. It is a quality mark, an asset in the product value chain.

Product performance and efficacy testing and assessment are key factors to developing your research and business strategies, bringing more value to your product.

## ... even if legal regulations change ...

The new European Fertiliser Regulation 2019/1009 entered into force on 5 June 2019 and applies from 16 July 2022 onwards. The EU regulation states that "EU fertilising products should be placed on the market only if they are sufficiently effective", meaning that for EU fertilising products "scientific evidence that they ensure agronomic efficiency" needs to be provided.

Scientific evidence will be required for claims such as the improvement of nutrient use efficiency, tolerance to abiotic stress, quality traits, or availability of confined nutrients in the soil or rhizosphere.

# ... or the politics are changing ...

The European Green Deal, including Farm to Fork and Biodiversity Strategy are significantly influencing the use and perception of plant protection products, fertilisers and biostimulants.

Detailed knowledge of agricultural requirements and innovations, such as compatibility with Integrated Production (IP) including Integrated Pest Management (IPM), organic farming or Precision and Digital farming and their impact on efficacy and product performance will become leading factors for efficient and successful product development, registration and sales under the new political framework.

# ... from Farm to Fork – from R&D to your customer ...

In the complex world of CROs, Academia and research institutes you need someone to provide you with **tailor made project strategies** to meet your targets and needs. Someone who relies on his **experience and independence** to provide you with recommendations **optimally suited** for your **individual purpose**.

As a privately owned, independent and neutral organisation, without any ties to contract research organisations and vast experience with efficacy and product performance, SCC can provide independent support and advice you need.

... SCCs efficacy experts are looking forward to accompany you and your products ...

Please visit our website for more information:

https://www.scc-gmbh.de/scientificregulatory-services/efficacy-evaluation

or contact one of our experts:

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## From R&D ... to study programme ...

Product formulation, uses and conditions of use are some of the first steps in the product development of plant protection products, fertilisers, biostimulants and adjuvants.

Product performance and efficacy data play a crucial role at this stage by:

- Assessment of registration possibilities based on product-specific Modes of Action, global regulatory status or claims for "dual use" products
- 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 (non-EU data for EU registration and vice versa)
- Literature search and evaluation for R&D and product (GAP) development or regulatory issues including e.g. resistance
- Speciality and R&D trials for elaboration of Mode(s) of Action, formulation development, resistance mechanisms, etc.
- Testing and incorporation of Integrated Production (IP) and Integrated Pest Management (IPM) application schemes
- Incorporation of Precision and Digital Farming methods, forecast models and Decision Support Systems (DSS)

#### ... to dossier preparation and registration ...

- Justification of uses and associated application rates, based on trial data as well as public literature and officially recognized or scientifically reasonable extrapolation possibilities
- Usability check of data being non-compliant with current guidelines e.g. for 3-dimensional crops with regard to the leaf wall area concept, to give "old treasures" a second chance
- National efficacy trials for fertilisers and biostimulants for registration and mutual recognition applications
- Assessment of the need for resistance monitoring data – strategy and study development, monitoring and assessment

#### ... and beyond ...

- Evaluation of product portfolio and product application range for use extensions
- Extrapolations for use and GAP extensions keeping the number of trials at the lowest acceptable level
- Assessment of available data sets in case of the need for reduction of the application rates to avoid new studies
- Preparation of a comparative assessment for products containing "Candidate for Substitution (CfS)" active substances.
- Statements for bridging in case of formulation changes e.g. due to new endpoints
- Efficacy evaluation for "Serious danger to plant health" – applications

