REGULATORY AFFAIRS SERVICES

EFFICACY

INDEPENDENCE
INTEGRITY
TRUST
RELIABILITY
QUALITY

The biological efficacy of a product answers the question; "Does the product do what it is designed to do according to the label?" As part of the approvals process for plant protection products, sufficient "good" efficacy data must be provided to support all label claims, and to justify the use of the product. In addition to effective control of the target pest or disease; dose justification, a comparative risk assessment, and development of appropriate resistance management strategies are just three of the many aspects of efficacy that are of strategic importance.

At SGS our regulatory experts are experienced in the appraisal of existing data packages, the planning of national or international efficacy programs to fill any data gaps, and / or the conduct of new development product programs. The SGS regulatory team is head-quartered on the same site as the UK field trials team.This research facility comprises 25 ha (~ 60 acres) of sandy silt loam with a rotational cropping regime principally comprising winter and spring cereals, winter oil seed rape, beans, potatoes and sugar beet. On site nursery polytunnels are also available to the team for carrying out protected crop trials, screening and controlled work. The proximity of the teams allows for close monitoring of study programmes and immediate turnaround of data.

Further trial sites with different growing conditions are also accessible throughout the world. In addition, the regulatory team have a number of efficacy and residues experts who have experience working as Trials Agronomists.

The SGS regulatory team will conduct an evaluation of the efficacy data for a product; checking the dose response and identifying the minimum effective dose. SGS will assess that the trials are performed to a sufficiently high standard, with the correct number of trials per region and with appropriate statistical evaluation of the data obtained. A comprehensive Biological Assessment Dossier (BAD) containing summaries and evaluations of all individual trial results will be prepared based on understanding the product, how it is used, and with specific detailed knowledge of the requirements of individual countries. In Europe, with the implementation of zonal dRRs and the proposed "living document" concept, flexible and intelligent project management is essential for sustainable success. During all phases of a regulatory process a close interaction between the regulatory team and the client is key to presenting a quality submission to the authorities.

SGS is the world's leading inspection, verification, testing and certification company. SGS is recognised as the global benchmark for quality and integrity. With more than 70 000 employees, SGS operates a network of over 1 350 offices and laboratories around the world.

WHY SGS

- Collaboration with a global network of GEP field trial teams
- Data analysis and in-house data management
- Cost competitive solutions
- Holistic, cohesive approach
- Adjuvant and tank mix testing
- Biopesticide and biocide studies
- Bespoke rainfastness testing equipment
- Seed enhancement studies and quality testing

SGS CAPABILITIES

- Preliminary efficacy studies
- GEP experimental field trials
- Dose response
- Resistance
- Yield
- Selectivity
- Neighbouring crops
- Adjuvants
- Minimum effective dose
- Taint testing
- Following crop studies
- Rainfastness
- Nozzle effectiveness
- Cleaning application equipment
- Transformation processes
- Resistance analysis
- Tank mix compatibility

SGS SERVICES

- Data GAP analysis
- Detailed planning of trial programs globally
- Development of study protocols based on appropriate guidance documents
- Comprehensive study monitoring, according to relevant guidelines
- Data analysis using current and bespoke data management, analysis and statistical software
- Design and executing trials to satisfy all climatic and regulatory zonal requirements
- Dossier preparation
  - Summary dossier
  - Biological Assessment Dossier
  - Country specific addenda
  - Mutual recognition dossiers
  - Comparability / proof statements
- Integration into CADDY format
- Analysis of resistance and development of possible resistance management strategies
- Drafting and design of product labels

FURTHER INFORMATION:

ISO 9000 certified

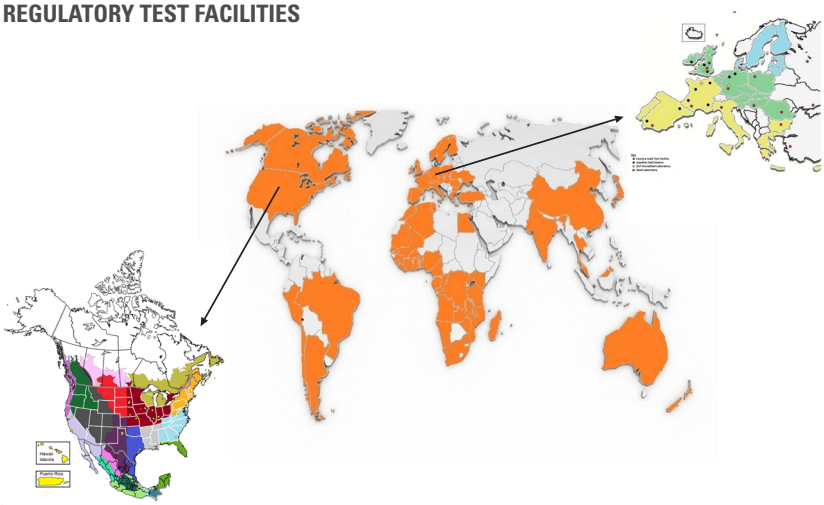
ISO 9001 certified

Study protocols are based on the appropriate guidance documents (EPPO, FAO, WHO, ISO, EPA, OECD, CEB)

SGS Global trials teams are accredited to the relevant GEP standards.

SGS UK trials teams are GEP ORETO certified.

REGULATORY TEST FACILITIES



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WHEN YOU NEED TO BE SURE

SGS