EFFICACY – THE GOOD, THE BAD, AND THE DRR

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 (PPPs), sufficient "good" efficacy data must be provided to support all label claims. The inherent nature of a PPP carries potential risk; to humans, to the environment, and to non-target organisms; thus their use for the control of pests and diseases must be thoroughly justified.

SGS can meet all requirements for the registration of a PPP in terms of biological assessment. The Biological Assessment Dossier (BAD) contains all the efficacy and selectivity data and in Europe, is a required part of the draft Registration Report (dRR).

Our experts are skilled in the collation and appraisal of existing data packages, have the experience required to extrapolate data where feasible, or can design and commission trials programmes to achieve a complete data set. SGS' regulatory team is based on the same site as the UK field trials team. The proximity of the teams allows for close monitoring of study programmes and immediate turnaround of data. The team also benefits from having a number of efficacy experts who have experience working as Trials Agronomists.

The regulatory team will justify the application dose, conduct a comparative risk assessment, and develop resistance management strategies, alongside conducting an evaluation of the efficacy data for a product. 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 together with an overall assessment, data summary, and conclusion.

Our regulatory team works to ensure that all label claims are robust and that evidence is provided to prove effectiveness under the proposed

application regime. An understanding of the product, how it is to be used, and detailed knowledge of the requirements of individual countries ensure smooth progress through the registration process.

OUR SERVICES:

- Preliminary Data GAP analysis
- Design and execution of trials to satisfy climatic, country, and zonal regulatory requirements
- Comprehensive study monitoring, according to relevant guidelines
- Data analysis using current and bespoke data management, analysis and statistical software
- Guidance through the process of registration
- Drafting and design of product label
- Dossier preparation
  - Summary dossier
  - Biological Assessment Dossier
  - Country specific addenda
  - Mutual recognition dossiers
  - Comparability/proof statements
  - dRR format dossier
- Analysis of resistance and development of resistance management strategies
- Integration into CADDY format

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