# REGULATORY AFFAIRS SERVICES

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SGS

# INDEPENDENCE
# INTEGRITY
# TRUST
# RELIABILITY
# QUALITY

Prior to any Plant Protection Product (PPP) can be used, sold, supplied, advertised, or stored it must be approved for use. The SGS regulatory team has many years experience in all aspects of the registration process and consists of expert scientists representing each of the regulatory disciplines.

In general, approvals are required for the following:

- Any new active substance or PPP
- Any changes to the use of an existing product
- Any change to the formulation of an existing product
- Parallel importation
- To test an unapproved product in a situation where release into the environment will occur
- To test an approved product in an unapproved situation

SGS regulatory experts have the expertise and knowledge to efficiently identify gaps in a data set and the management skills to effectively place and monitor required regulatory studies. As part of the multidisciplinary network within SGS, the regulatory team have access to a global network of test site facilities, field teams, and laboratories with expert capabilities and state-of-the-art equipment.

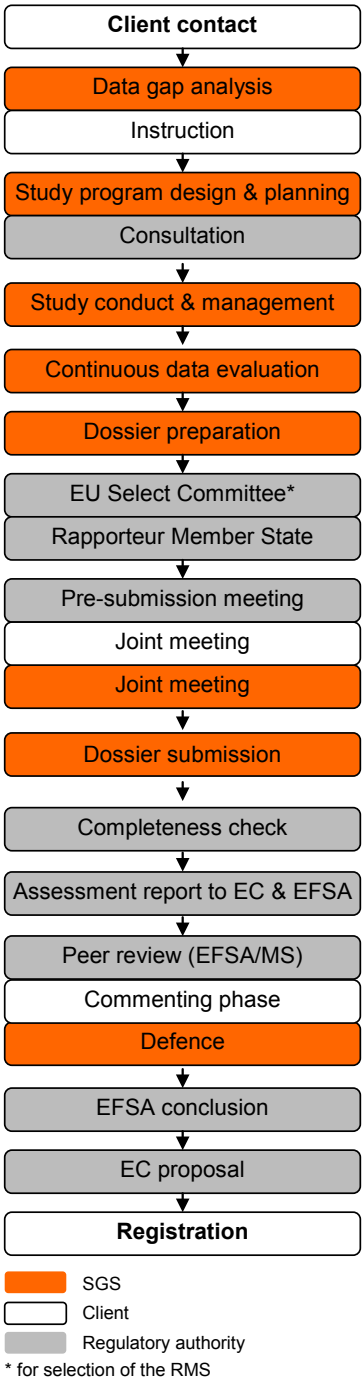
SGS is the world's leading inspection, verification, testing and certification company. SGS is recognised as the global benchmark for quality and integrity. With more than 70 000 employees, SGS operates a network of over 1 350 offices and laboratories around the world.

Gathered and generated data is thoroughly evaluated for suitability, and analyses are carefully checked for accuracy by SGS regulatory experts. The compilation of the various dossiers is approached using a structured methodology to ensure compliance with the regulatory authorities.

SGS regulatory team can facilitate the registration of PPPs throughout the World using an internal network of country experts, associations with country specific consultants, and connections with various regulatory authorities. The SGS regulatory experts have a thorough understanding of EU and global regulatory processes, monitoring developments and implementing changes as required; and possess many years of experience in dealing with a range of regulatory applications.

In Europe, with the implementation of zonal draft registration reports (dRRs) and the proposed "living document" concept, flexible and intelligent project management is essential for sustainable success. Within SGS Regulatory Affairs Services the European registration process may be explained by the representation to the right (similar processes may be followed for global registrations; from the production of the basic regulatory data to the approval and sales of the plant protection product):

During all phases of a regulatory process a close interaction between the regulatory team and the client is essential in presenting a homogenous submission to the authorities.



## WHY SGS

- Global network of capabilities
- Discipline specific expert scientists
- Cost competitive approach
- Accredited facilities following OECD principles
- Integrated solutions for quality, experience, and accuracy
- Specialist and progressive industry knowledge

## SGS CAPABILITIES

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|---|---|
| **PHYSICAL CHEMISTRY** | Physical and chemical properties of an active substance or formulation<br>• Commissioning, conducting and monitoring of studies |
| **METHODS OF ANALYSIS** | Accurate, fully validated methods to establish a technical specification and residue levels<br>• SGS have a global network of GLP accredited laboratories<br>• Technical advice on method refinement and development |
| **TOXICOLOGY** | Adverse effects to human health following Plant Protection Product exposure<br>• Design, placement, and scientific monitoring of studies<br>• Human health risk assessments |
| **RESIDUES** | Potential risk by human consumption of Plant Protection Product residues in food and food products<br>• Comprehensive summaries of metabolism studies<br>• Management of residue studies, feeding and processing studies<br>• Expert knowledge in crop extrapolation, comparability, MRL calculation |
| **ENVIRONMENTAL FATE** | Movement and degradation of Plant Protection Products in water, soil, and air<br>• SGS specialist teams for soil dissipation, lysimeter, & monitoring studies<br>• Experienced in use of predictive models: FOCUS / HardSPEC |
| **ECOTOXICOLOGY** | Potential risk to non-target species posed by Plant Protection Products<br>• Management of aquatic / terrestrial study program<br>• Calculation of PECs and TERs |
| **EFFICACY** | Does the product do what it is designed to do according to the label?<br>• Collaboration with a global network of GEP field trial teams<br>• Data analysis and bespoke data management |

## SGS SERVICES

- Maintain excellent client contact at all stages of the process, to advise and to inform
- Consult with the relevant governmental regulatory authorities before and during development processes
- Complete a Data Gap Analysis for any existing regulatory data
- Design a study program to be appropriate, efficient, and cost-effective
- Commission and monitor the co nduct of all required regulatory studies
- Check the quality and suitability of all study reports
- Complete all necessary risk assessments
- Supply template summary dossiers for each dossier section
- Prepare Tier 1 (as appropriate), Tier 2 and Tier 3 summaries for each dossier sub-section
- Submit the dossier, to defend the data and to follow the registration process through to approval
- JMPR dossier preparation and submission

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WHEN YOU NEED TO BE SURE

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