

Product authorisations in Europe

In Europe, there is a two-phase system for the registration of plant protection products. Active substances are first approved at the EU level, then products are authorised for use within each Member State.

Challenges for product authorisations in Europe

Despite efforts to harmonise requirements and procedures, product authorisations in Europe remain complex.

Member States continue to define and change their national requirements and procedures.

In addition, communication with some regulatory authorities can be challenging without knowledge of local language and culture.

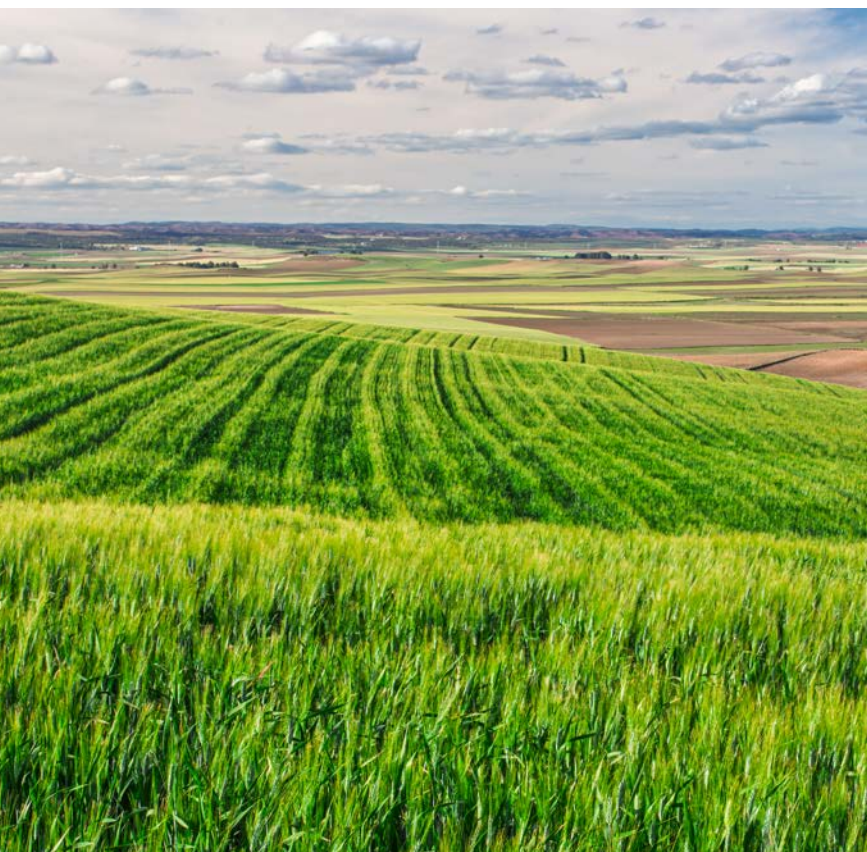
These challenges can cause delays and increase the cost to companies trying to develop markets for their products across Europe.

How Sagentia Regulatory can help

Well-established offices in Germany, Spain and the UK are core to Sagentia Regulatory's scientific and regulatory services to the plant protection industry.

Facilitating product authorisations work, our team of experienced consultants are well practiced with their requisite authorities. The team speaks over 30 languages and is on hand to translate items including product labels, letters from authorities and trial reports where necessary. Furthermore, Sagentia Regulatory's established network of reliable associates provides national expertise and long-standing relationships with authorities across Central & Eastern Europe.

Central management ensures a consistent approach to provide the highest standards of project management, ensuring responsiveness, good communication, efficiency and delivery. This is facilitated by each client being assigned a direct contact for their project, establishing a clear and efficient communication route for project requirements.



Plant protection services

Sagentia Regulatory provides a fully comprehensive, pan-European service for plant protection products covering all types of products, including herbicides, fungicides and biopesticides:

- Dossier preparation including all required sections, resistance risk analysis and comparative assessment
- Zonal applications
- National registrations
- Mutual recognition applications
- Renewal of active substance approvals
- Label extensions
- IUCLID and CADDY dossier preparation
- Preparation and review of product labels and MSDSs
- Poison Centre Notifications
- Data Gap Analysis including study monitoring services
- Literature searches
- Administrative applications (e.g. authorisation holder changes)
- Translation services
- Strategic advice and guidance
- Liaison with regulatory authorities – before, during and after submission



About Sagentia Regulatory

For over 35 years, Sagentia Regulatory (formerly TSG Consulting) has provided companies around the world with regulatory guidance and scientific expertise. Our experts are highly knowledgeable in the core sciences and the public policy decisions that are used to structure and implement environmental and chemical regulations. By combining this knowledge with our industry experience, we provide companies with comprehensive services from the early stages of product development to marketplace entry and ongoing compliance.

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