



SAFETY ASSESSMENT

Agrochemicals and Biocides Regulatory Support

We can prepare:

- Active substance approval and renewal dossiers
- Core dRR and national addenda for plant protection products
- IUCLID product dossiers for biocide products
- CADDY dossiers for agrochemicals products
- Occupational and environmental exposure modelling

Understanding the ever-evolving regulatory environment for agrochemical and biocide products is essential to success. Charles River offers a thorough understanding of the regulations, plus the scientific expertise needed for compliance, to avoid unnecessary delays in the approval of your products.

An Organized Approach

We take a stepwise approach to cover all aspects of active substance approval or renewal and product authorization. After a thorough inventory and gap analysis, including the evaluation of existing data against requirements, we will work with the client to finalize the right strategy for their active or product before completing the data requirements through statements, waivers and studies. A dossier that includes hazard, exposure and risk assessment is then prepared, which, once finalised, will be ready for submission. Our aftercare includes post-submission support and discussion with authorities. Throughout the process, a single point of contact makes communication easy.

Everything Our Clients Need

We have extensive experience with new and existing agrochemical and biocide compounds in Europe and have intimate knowledge of evaluation procedures within the region. Our in-house expertise covers all areas (physical chemistry, analysis, toxicology, residues, environmental fate, ecotoxicology, and related hazard, exposure and risk assessment).

In addition to the assessment of data requirements and preparation of relevant dossiers, we can also assist with the selection of Rapporteur Member State and provide support for pre-submission meetings and discussions with authorities. Our experts can advise on (Q)SAR analysis, read across and/or grouping strategies, import tolerance dossiers, conduct technical equivalence assessments, and assist with classification and labeling (CLP/GHS) and preparation of CLH reports.

EVERY STEP OF THE WAY