



## Biopesticide Regulatory Services

### Regulatory and Scientific Specialists

### Support for Product Registration and Risk Assessments



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### Leaders in Biopesticide Regulatory Support

Provide regulatory and environmental strategies for biological products used for pest control, including microbial products (bacteria, viruses and fungi), botanicals and plant extracts, biochemical products (including plant and insect growth regulators, hormones, plant defence activators), semiochemicals including pheromones, and plant-incorporated protectants (PIPs - pesticidal substances produced by plants containing added genetic material). Strategic guidance on emerging regulatory and scientific policies that may impact current and future biopesticide registrations.

### Skilled International Registration Management

Registration guidance and support for compliance with EU Plant Protection Product or Biocidal Product legislation, as well as U.S. FIFRA regulations for pesticidal products. Preparation and submission of active ingredient/substance and end-use product dossiers for pan-EU, zonal and Member State, as well as U.S. Federal and State registrations as applicable. U.S. State registration regulatory guidance and support, including initial registration approvals and annual renewals. Regulatory submission and maintenance of organic input certifications (NOP, OMRI, WSDA). Support for global regulatory and international joint submissions. Identification of required studies to support biopesticide registration requirements (Data Gap Analysis).

### Study Placement, Monitoring and Protocol Development

Placement and monitoring of studies at Contract Research Organizations (CROs), development and critique of study protocols, and review and interpretation of study results, to comply with technical guidelines and Good Laboratory Practice (GLP) standards.

### Expert Human Health and Environmental Risk Assessment

Active substance definition for risk assessment: identification and analysis of impurities, metabolites etc. Preliminary and refined risk assessments (human health and environmental exposure modeling / risk characterisation), and development of comprehensive qualitative and quantitative assessments. Types of assessments provided include Endocrine Disruptor (ED) assessment, Classification, Labelling and Packaging (CLP), and dietary exposure evaluation.

CSI is a Regulatory Consultant Member of the Biological Products Industry Alliance (BPIA) that promotes the responsible development of safe and effective biological products.

