North America Regulatory Services

Award-Winning Consultancy Providing Innovative Solutions to Meet Regulatory and Environmental Challenges

CSI's experienced consultants design regulatory strategies for original and follow-on registration of FIFRA-regulated agrochemicals, biopesticides, home and garden pesticides, antimicrobial products, and pesticidal devices. We also have consultants that specialize in registration of non-FIFRA regulated products including fertilizers, soil and plant amendments, innoculants, and biostimulants. Our regulatory strategies cross jurisdictions and can include joint submissions to Canada, the EU and the USA. Once the registration strategy is determined, CSI will function as Agency liaison and will manage registration dossier preparation and submission.

EPA & PMRA Pesticide Registration

- Regulatory strategies for original and follow-on registration of agrochemicals, biopesticides, biologicals, home and garden pesticides, and antimicrobial products.
- Agency liaison and negotiation, EPA-FIFRA and PMRA registration dossier preparation and submission.
- Experience with coordination of joint submissions to Canada, EU, UK, and USA.

State Registration Management

In the US, federal registration must be followed by state registration prior to distribution of a product to a given state. CSI manages first-time registrations in all 50 states, the District of Columbia, and US territories. We also carry this forward with annual renewal of product licenses and registration according to individual State schedules and fees. Non-FIFRA regulated products begin at the state level, where CSI consultants manage first-time registrations and appropriate renewals and tonnage reporting, where applicable. State registration packages are assembled to include state-specific application forms, product labels, MSDSs, technical data, authorization letters, and product summaries.

Data Development, Study Placement & Monitoring

- Identification of required studies to support registration intent, and data gap analysis.
- Placement and monitoring of studies at contract research organizations (CROs).
- Review and interpretation of study results, assure compliance with Good Laboratory Practice (GLP) standards.

Risk Assessment

CSI's consultants lend extensive experience in all aspects of human health and ecological risk assessment, including endangered species analysis and strategy, spatial analysis and data systems, and applied economic impact analysis and cost benefit assessment. This expertise will be applied during the process of registration applications as well as during registration review and data call-ins that arise during the lifetime of the product registration. This work is used to conduct hazard identification, effects analysis, exposure assessment, and risk characterization.

Toxicology and Chemistry Consultation

CSI's multi-disciplinary team of scientists supports registration activities by providing expert guidance on toxicology, ecotoxicology, environmental fate, and product and residue chemistry aspects that will influence the product category, registration status, use restrictions, and tolerance considerations that must be evaluated prior to registration.

Regulatory and Scientific Insights

The regulatory environment is constantly changing, triggering emerging regulatory and scientific developments that may impact current and future registrations. Our consultants participate in numerous topical and trade associations as well as agency-led work groups to stay abreast of these developments. We draw on this insight to recommend approaches to bring products into compliance with new regulations, including prevention and response to specific state regulations like California Proposition 65 and the state's Safer Consumer Products / Green Chemistry initiative.

Litigation Support & Expert Witness Testimony

- Data compensation evaluation and expertise in supporting arbitration or settlement in lieu of litigation.
- Comprehensive due diligence support to companies and investors prior to mergers, acquisitions, joint ventures and other activities.
- In-depth expertise to support attorneys with case development.
- Qualified trial depositions and expert witness testimony including support for data valuation, crop damage assessment, pesticide use or misuse and regulatory compliance.
- Advice on emerging regulatory and scientific developments that may impact current and future litigation proceedings.

Global Regulatory and Environmental Strategies since 1988

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