Services

Carroll-Loye provides scientific testing, product development and registration services for insect repellents, organic, natural and low toxicity pesticides, fertilizers and soil amendments.

Since 1989 we have developed pioneering protocols for EPA, FDA and PRMA (Canada), including delivering GLP and human subject data for US EPA and PMRA pesticide registrations.

We perform gap analysis, quality assurance, product development planning and management, performance testing, regulatory compliance and product registration. We use cost-effective approaches to meet efficacy and safety guidelines mandated by the US EPA, FDA, PMRA EU and other regulatory authorities. We provide and coordinate chemistry, toxicology, and legal expertise to achieve your objectives. This range and depth of capacities helps us to meet your needs in full.

The Carroll-Loye Three-Step Process

Step 1: Product Safety & Efficacy Assessment

- Review product safety information
- Perform formulation assessment
- Evaluate efficacy
- Detail areas of compliance
- Identify opportunities for improvement

Step 2: Product Performance Enhancement

- Deliver a prioritized action plan
- Work with your staff to mitigate identified product risks
- Detail areas of opportunity for improved product development
- Implement cost effective measures to bring your product into compliance

Step 3: Performance Testing

- Perform efficacy testing as needed
- Present a written performance report
- Review documentation and labeling to ensure accuracy and compliance
- GLP compliance and auditing as needed

EPA guidelines and review

What you need to know about EPA's repellent guidelines

The Environmental Protection Agency of the United States has issued guidelines for the performance of personal insect repellents.

Currently under revision, the EPA “Product Performance Guidelines for Insect Repellents” describes the “Good Laboratory” and “Good Field” Practices that, when followed, ensure adequate testing while minimizing risks to participants.

The Practices have become the de facto minimum registration standards for product developers. As a registrant, it is valuable to understand these scientific guidelines to provide the data required for registration and marketing of any insect repellent. Carroll-Loye actively assists US EPA in formulating and refining the efficacy test guidelines.

Navigating the EPA Human Studies Review Board

Proposals to collect insect repellent efficacy data for registration purposes must first be reviewed by the US Environmental Protection Agency.

The purpose of this review is to ensure the rights and safety of human research subjects in repellent efficacy tests. Scientific merit and potential societal benefit are also evaluated, as balanced against risks. The agency is supported in the review by the Human Studies Review Board (HSRB), a Blue Ribbon Panel of academic Bioethicists and Biomedical Researchers. This 16 member Board convenes quarterly in the Washington DC area to review our protocols and study reports.

Since the advent of this augmented regulation in early 2006, Carroll-Loye has worked intensively with EPA staff to further refine our state-of-the-art protocols. The EPA has recommended our protocols and study reports to the HSRB, and the Board has reviewed them favorably. Under the EPA review system, Carroll-Loye is the only repellent science company to deliver successful results to sponsors for both field and laboratory efficacy studies.

More information about the HSRB may be found through the link below. For answers to specific questions, and additional insight into meeting EPA and HSRB requirements, please contact us.

Regulatory services

US EPA product registration

The requirements for federal and state pesticidal product registration in the United States are complex and can vary substantially in time and cost to complete. This variation depends largely on ingredient and product attributes, prescribed uses and label claims. While some pesticidal products require no federal registration (those with 25B compliance), federal product registration packages are extensive, and include product chemistry, toxicology, environmental fate, ecological impact, residual chemistry and human health and safety data. Federal pesticide labeling requirements are extensive, and a well developed, draft product label is essential to the early determination of the information needed for a complete EPA registration submission package. Certain states have their own pesticide registration processes, which typically follow federal regulatory approval. Some states have additional submission requirements beyond those of federal packages. Both state and federal product registration requirements must be met prior to pesticidal product sales in any state.

NOP organic product material review

OMRI, WSDA - We provide advice for United States NOP organic product or organic material review, product registration and certification for use in organic farming operations, including OMRI and WSDA product and material listings.

Products intended for use in organic agriculture in the United States must meet National Organic Program (NOP) requirements via certification from either the Washington State Department of Agriculture (WSDA), or the Organic Material Review Institute (OMRI). Some states require a secondary organic certification, following NOP compliance. State and federal registration requirements must be met prior to product sales for organic agricultural use within a given state. Non-domestic products can also establish NOP compliance, and subsequently use the “organic material” certification for product marketing purposes within or outside of the United States. Organic product categories include crop products such as fertilizers and pesticides, livestock products and production and handling aids.

Fertilizer registration advice for registering commercial and specialty fertilizers, amendments and bulk minerals in the United States

Researchers for fertilizer product registration in the United States. Services include state registration regulatory guidance for commercial fertilizers, specialty fertilizers, soil amendments, soil conditioners, agricultural minerals, gypsum and auxiliary substances for individual states that require dealer and product registration.

In the United States, there is no federal option for registering fertilizer products in all states simultaneously. Fertilizers are registered independently with each individual state, with ingredients that comply with federal TSCA regulations. Each state has its own regulatory body and requirements for fertilizer regulatory submissions. State applications for fertilizer registration typically include detailed product information, a state-compliant product label, and company information. Guaranteed content

values and heavy metal quantification analyses can be required. Fertilizers, soil conditioners, soil amendments, bulk and trace mineral products, soil inoculants and compost products often require state product registration, but this requirement can vary for some of these product categories, depending on product characteristics, label claims and individual state requirements. Product classifications for a single product can vary from state to state, and certain states require a U.S. agent for overseas product registration. Once a product is registered, quarterly tonnage reports and annual or semiannual regulatory fees are required for each state.