

# REGULATORY AFFAIRS



Move into new international markets with confidence. Battelle offers a full range of regulatory services to help you get your agrochemical and biocide products to market quickly and efficiently.

## REGISTRATION AND RE-REGISTRATION SUPPORT

We integrate industry-leading scientific lab work and deep experience in international regulatory requirements to help you accelerate product registration and re-registration.

- Analysis of regulatory requirements
- Data gap analysis, and proposal of testing strategies
- Harmonization of Good Agricultural Practices (GAP)
- Study monitoring and project management
- Dossier preparation and follow-up

## RISK ASSESSMENT AND EVALUATION

We give you reliable and defensible data for both standard and higher-tier risk assessments so you can meet health and safety regulatory standards and minimize your exposures.

- Human health risk assessment (operator, worker, bystander and consumer)
- Development of rebuttals and waivers
- Environmental impact, fate and ecotoxicology
- Risk evaluation and mitigation strategies

## DOSSIER SUBMISSION AND DEFENSE

Let our experts help you move through product registration or re-registration confidently. We give you expert advice and consulting services so you can focus your resources on your core business.

- Pre-submission meetings with key regulatory agencies and their experts
- Negotiation of registration strategies with national agencies and EU Rapporteur (RMS)
- Follow-up through the entire evaluation process

## Open Market: Creating a Clearing for Commercialization

### CHALLENGE

The patent life of a crop protection active ingredient (AI) had expired, giving an international company access to a generic molecule manufactured in China. Among the challenges facing the organization, however, was the potential cost of re-approval of the active ingredient in Europe.

Could there be a profitable payoff in pursuing product registrations—before re-approval of the AI—in order to tap into new market opportunities?

More importantly, could the company, with its limited resources, lack of in-house regulatory expertise and narrow window of opportunity, navigate a myriad of mandatory compliance and regulatory requirements in time?

### SOLUTION

At the outset, it was a matter of risk versus reward when the company asked Battelle for help in obtaining registrations in order to commercialize their product.

The Battelle team decided that the best and swiftest course of action was to develop a minimum work program to gain access to a complete European regulatory data package.

To start, Battelle translated and summarized client-provided data into a Good Agricultural Practices table. Then, using a variety of background materials (including the draft assessment report from the Rapporteur Member State), Battelle conducted a detailed data gap analysis. The Battelle team also challenged data-protection studies, replacing them with equivalent studies and conducting risk assessments to ensure safe use results.

Then, with regulatory authority feedback in hand, Battelle amended the work plan accordingly. Finally, the Battelle team filled in data gaps, as well as provided needed waivers and robust risk assessments. This data, along with a letter of access to vertebrate studies, supported the new product registrations in the European marketplace.

### OUTCOME

- Quickly delivered a viable work plan to the European regulatory authority
- Amended required documentation for compliance
- Successfully submitted complete data packages on both the AI and affected products
- Cleared the way for product commercialization

Every day, the people of Battelle apply science and technology to solving what matters most. At major technology centers and national laboratories around the world, Battelle conducts research and development, designs and manufactures products, and delivers critical services for government and commercial customers. Headquartered in Columbus, Ohio since its founding in 1929, Battelle serves the national security, health and life sciences, and energy and environmental industries. For more information, visit [www.battelle.org](http://www.battelle.org).

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