

Case Study: Regulatory Compliance

Client: Major Agricultural Chemical Company

Challenge



The European Union (EU), under Directive 91/414/EEC, requires major manufacturers of agrichemicals to examine previously submitted regulatory studies for compliance with current registration standards. The older studies must be assessed for adherence to specific acceptance

criteria, and a comprehensive product review related to regulatory compliance must be submitted. Deadlines are non-negotiable, and failure to produce a revised registration package could result in cessation of product sales in the EU, with a concomitant loss of revenue for the company.

Contribution

IVI's professional staff worked closely with the client's scientists to define the scope and specific requirements of this project. Two fungicide and two herbicide products needed to undergo review, and more than 150 studies in animal metabolism, plant metabolism, field residue, mammalian toxicology, ecotoxicology, environmental fate, animal feeding and product chemistry had to be assessed. IVI scientists evaluated the data and wrote a quality assessment and summary of each study (Tier I and Tier II documents, respectively). Additional data were compiled and used to develop position papers that addressed specific data gaps. Finally, IVI composed documents that provided a broad overview of each agrichemical product's compliance with current standards (Tier III document).



Outcome

IVI's detailed and thorough work enabled the client to submit re-registration packages to the EU for four agricultural products in time to meet a preset administrative deadline. As a result, marketing of these four agricultural products throughout Europe remains uninterrupted. IVI's coordinated work with the client's scientists resulted in a timely, polished final product that was well received by the client and the EU.

