



Challenge

A global chemical products manufacturer had conducted a preliminary data gap analysis (DGA) for a new fungicide active substance and established that it had a favorable hazard profile. Whilst the company had the resources to undertake this preliminary assessment in-house, it needed specialist guidance on higher tiered and definitive data development. The company engaged TSG Consulting to inform it of the overall data anticipated to secure United States Environmental Protection Agency (US EPA) acceptance of the substance's proposed food use, as well as active substance approval in the European Union (EU).

Approach

TSG compared current available data against data requirements applicable under EC Regulation No 1107/2009 as set out in Commission Regulations (EU) 283/2013.

Our regulatory and scientific specialists also compared completed or in-progress study data and planned data yet to be commissioned against US EPA's data requirements for pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and its implementing regulations in the Code of Federal Regulations, Title 40, Part 158.

Outcome

TSG presented the findings of the DGA in a written report, tabulating the active substance data requirements applicable for a new active substance approval and its intended use patterns. Our specialists commented on the suitability of the existing data, made proposals for possible data waivers and recommendations for additional data required. TSG also advised that certain non-GLP (Good Laboratory Practice) studies be recommissioned under GLP conditions to ensure acceptability of the study data by regulators.

The client is currently scheduling definitive testing and TSG is on hand to support them throughout the registration and approval process.

