CONCEPT

Pesticide Registration and Agrochemical Regulation: Data Package, MRLs and Labels

4 – 8 October 2027
Barcelona - Eixample district four-star



Pesticide Registration and Agrochemical Regulation: Data Package, MRLs and Labels

Ref: 848_20576 **Date:** 4 – 8 October 2027 **Location:** Barcelona - Eixample district four-star **Fees:** 23500 SAR

Introduction:

Pesticide registration files are often delayed or rejected because data gaps surface late, residue trials do not match the proposed use pattern, labels contradict the risk assessment and generic equivalence claims lack a reference profile. Once approved, products still face re-evaluation, residue violations in export markets and pressure to phase out highly hazardous pesticides. This Core Concept course trains regulatory affairs and product stewardship staff to manage agrochemical regulation across the registration lifecycle, from data package to label and post-registration duties. Participants produce a Registration Dossier Plan and Label Review for a case product.

Course Objectives:

- Map a crop protection portfolio against the registration lifecycle and the roles set out in the International Code of Conduct on Pesticide Management
- Specify the registration data package for an active substance and formulated product, from identity and chemistry to efficacy
- Interpret toxicology, operator exposure, environmental fate and ecotoxicology endpoints within a structured risk assessment
- Plan supervised residue trials and derive maximum residue limit proposals, including import tolerance requests
- Review product labels and safety data sheets for consistency with GHS classification and the approved use pattern
- Prepare generic equivalence, renewal and post-registration stewardship submissions, including measures for highly hazardous pesticides

Target Audience:

- Regulatory affairs staff who prepare and submit crop protection registration dossiers
- Product stewardship leads who manage label changes, incident reports and container programmes
- Registration managers at distributors and generic manufacturers who source data and letters of access
- Evaluators and technical officers at regulatory agencies who assess pesticide applications
- Agribusiness technical managers who decide which products and uses to support in new markets

Course Outline:

Day 1: Agrochemical Regulation Foundations and the Registration Lifecycle

- International Code of Conduct on Pesticide Management: Duties of Regulators, Registrants and Distributors
- Crop Protection Product Types: Herbicides, Insecticides, Fungicides, Biopesticides and Plant Growth Regulators
- Formulation Types and Co-Formulants: EC, SC, WG, SL and Seed Treatment Products
- Registration Lifecycle Map: Pre-Submission, Evaluation, Approval, Renewal and Withdrawal
- Portfolio Regulatory Status Gap Assessment for Active Substances and End-Use Products

Day 2: The Registration Data Package and Risk Assessment Principles

- Active Substance Identity, Physical-Chemical Properties, Batch Analysis and Impurity Profile
- Mammalian Toxicology Endpoints and Reference Values: ADI and ARfD
- Operator, Worker, Bystander and Resident Exposure Estimation Models
- Environmental Fate and Ecotoxicology: Soil Degradation, Leaching, Aquatic Organisms and Pollinators
- Efficacy and Crop Safety Trial Packages Within the Four-Step Risk Assessment Sequence

Day 3: Residue Trials, Maximum Residue Limits and Label Content

- Supervised Residue Trial Design at Critical GAP and Pre-Harvest Interval Setting
- Maximum Residue Limit Derivation and Dietary Intake Checks Against Reference Values
- Codex MRLs, Import Tolerance Requests and Export Residue Screening Plans
- GHS Classification of Formulated Pesticides: Pictograms, Signal Words, Hazard and Precautionary Statements
- Directions for Use, Re-Entry Intervals and Pesticide Safety Data Sheet Alignment

Day 4: Generic Equivalence, Re-Evaluation, Stewardship and Highly Hazardous Pesticides

- Technical Equivalence of Generic Active Substances: Impurity and Toxicity Profile Comparison
- Data Protection, Letters of Access and Study Sharing Between Registrants
- Renewal and Re-Evaluation Dossiers: New Endpoints, Use Restrictions and Phase-Out Decisions
- Post-Registration Monitoring: Residue Violations, Poisoning Incident Reports and Resistance Management
- Highly Hazardous Pesticide Criteria, Empty Container Rinsing Schemes and Obsolete Stock Disposal

Day 5: Case Product Registration Dossier Plan and Label Review

- Case Product Brief: Active Substance, Formulation, Target Crops and Use Pattern
- Data Requirement Matrix and Study Gap Analysis for the Case Product
- Residue and Toxicology Study Programme Timeline with Cost Drivers
- Draft Label Review Against the Risk Assessment Conclusions and GHS Classification
- Registration Dossier Plan Defence Before a Mock Evaluation Panel

Skills You Will Gain:

- Registration Lifecycle Planning
- Regulatory Data Gap Analysis
- Pesticide Risk Assessment Interpretation
- Residue Trial Planning
- MRL and Import Tolerance Preparation
- Pesticide Label Review
- Generic Equivalence Assessment
- Product Stewardship Management

Why Attend This Course:

- Leave with a Registration Dossier Plan and Label Review for a case product that can be adapted to your own portfolio
- Spot data gaps, mismatched residue trials and label errors before an evaluator raises them
- Prepare for re-evaluation outcomes and highly hazardous pesticide phase-out with a clear stewardship response
- Compare registration practice with peers from research-based manufacturers, generic companies, distributors and regulatory agencies

Conclusion:

Agrochemical approval depends on a data package that answers the evaluator's questions, residue evidence that matches the use pattern and a label that reflects the risk assessment. The week moves from product types and the registration lifecycle, through toxicology, exposure, fate and efficacy data, to residue trials, maximum residue limits, GHS classification and labels, then to generic equivalence, renewal, stewardship and highly hazardous pesticides. The final day applies these methods to a case product and produces a Registration Dossier Plan and Label Review.