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Fundamentals of EU Agrochemical Regulations

Live Online Academy

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MEET THE TRAINER

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Marianne is an independent regulatory consultant with a mastery of both EU regulations as well as Sub-Saharan African regulations for agrochemicals.Following 12 years of experience working as a Patent officer, QA specialist and Regulatory Specialist, Marianne set up her own regulatory consultancy. Through this she facilitates approvals for plant protection products globally and leading complexed regulatory projects.

Agenda

Module 1: Background/history

- Why the need to regulate plant protection products?
- Historical perspective of Regulation 1107/2009 and related regulations
- Ongoing REFIT evaluation
- Candidates for substitution and comparative risk assessment
- Low risk active substances
- Data protection and confidentiality
- Avoidance of duplicate testing on vertebrates
- Air programme

Module 2: Active substance approval

- Article 4 criteria for approval/renewal
- Cut-off criteria
- Brief overview of the approval process of the active substance
- Procedures for new a.s. and renewal
- Completeness check, evaluation by RMS and Peer Review by EFSA
- DAR/RAR/review report/conclusion report
- Confirmatory data

Agenda

Module 3: Structure and content of an active substance dossier – part 1

- Introduction to data requirements
- What is in an active substance dossier – structure overview
- Document A, B, C, E, F, G, H and I
- Document D - What is a GAP?
- Document J
- Document KCA
- Document LCA
- Document MCA
- Document O

Module 4: Structure and content of an active substance dossier – part 2

- Part 0: Introduction
- Document N1 section 1-3 (identity, phys/chem, further information)
- Document N1 Section 4 (analytical methods)
- Document N1 section 5 (toxicology)
- Document N1 section 6 (residue)
- Document N1 section 7 (environmental fate)
- Document N1 section 8 (ecotoxicology)
- Document N1 section 9 and 10 (literature data and classification and labelling)
- Document N2-5

Agenda

Module 5: Relevant information of active substance approval

- Classification
- Timelines
- Guidance documents on active substance for dossier preparation, procedures etc. to consider
- Technical equivalence
- Definition of endocrine disruptors criteria and its impact on the registration of active substances
- Legislation on safeners and synergists

Module 6: Product authorisation by the zonal system – part 1:

- What is a product authorisation?
- Introduction to the zonal system
- Inter- and intrazonal steering committees
- Mutual recognition – intra- and interzonal
- Articles 4 and 43 criteria for product authorisation and renewal
- Procedures for submission and review
- Overview of (some) of the guidance documents
- Timelines

Agenda

Module 7: Product authorisation by the zonal system – part 2

- Background information
- How to structure your PPP dossier
  - Administrative documents
  - dRR
  - Document K
  - GAP
  - Labels
  - SDS
  - Data active substance
- Classification and labeling
- Do you have other options than the zonal system?

Module 8: Risk envelope, uniform principle and other relevant subjects

- Risk envelope approach
- How, when and why?
- What is the Uniform principles?
- How to perform a risk assessment according to the uniform principle
- Guidance documents related to the uniform principle
- Integrated Pest Management (IPM)
- Fees

Agenda

Module 9: MRL’s

- What is EU MRLs and when are MRLs required?
- Historical perspective on MRL’s
- The principle on setting an MRL
- How to apply for an MRL
- Cumulative Risk Assessment
- How to comply with the fixed MRL’s
- MRL’s outside EU (CODEX, US)

Module 10: Project planning

- From idea to authorisation
- Costs and how long does it take?
- Brief on data gap analysis
- Test for research and development purposes
- Patents
- What can I do after an authorisation has been granted?
- What is an emergency authorisation (Art 53)?

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