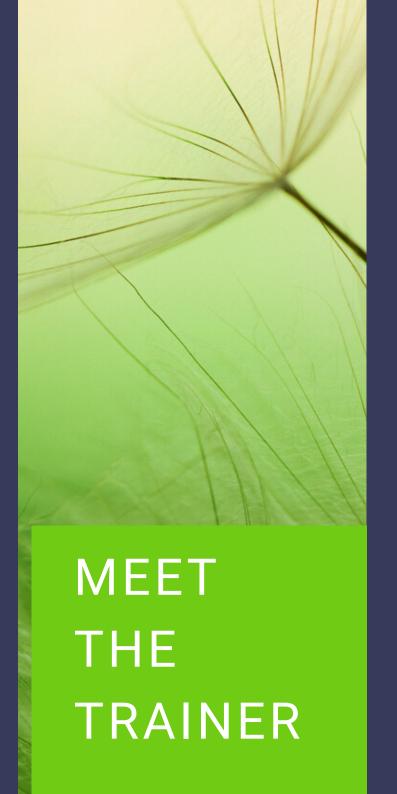


## ATI



## Fundamentals of EU Agrochemical Regulations

Live Online Academy 20-22 April 2021





# MARIANNE THUEN JAKOBSEN

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.

#### 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

#### 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

#### 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

#### 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

#### 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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