# SYLLABUS

## FUNDAMENTALS OF EU AGROCHEMICAL REGULATIONS



### Course Information - Time and Agenda Overview

This is a 2 day online training course.

The time and course structure is as follows:

**Day 1 09:00-11:30 & 13:00-16:00 CET**

09:00- 11.30 CET: Module 1 (1 hour)

Q&A module 1 (15 minutes)

Module 2 (1 hour)

Q&A module 2 (15 minutes)

13:00-16:00 CET: Module 3 (1 hour)

Q&A module 3 (15 minutes)

Module 4 (1 hour and 25 minutes)

Q&A module 4 (15 minutes)

**Day 2: 09:00 - 11:30 & 13:00 -14:30**

9-11.30 CET: Module 5 (1 hour)

Q&A module 5 (15 minutes)

Module 6 (1 hour)

Q&A module 6 (15 minutes)

13:00 -14.30 CET: Module 7 (1 hour)

Q&A module 7 (15 minutes)

### Module 1: Background/history

- Why the need to regulate plant protection products?
- Historical perspective of Regulation 1107/2009 and related regulations
- Candidates for substitution and comparative risk assessment (Art 24 + 50)
- Low risk active substances (Art 22 + 47)
- Data protection and confidentiality (Art 59 + 63)
- Avoidance of duplicate testing on vertebrates (Art 61 + 62)
- Definition of endocrine disruptors criteria and its impact on the registration of active substances

### Module 2: Active substance approval

- Article 4 criteria for approval/renewal
- Cut-off criteria
- Technical equivalence
- 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

### 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 chapter 1-3 (identity, phys/chem, further information)
- Document N1 chapter 4 (analytical methods)
- Document N1 chapter 5 (toxicology)
- Document N1 chapter 6 (residue)
- Document N1 chapter 7 (environmental fate)
- Document N1 chapter 8 (ecotoxicology)
- Document N1 chapter 9 and 10 (literature data and classification & labelling)
- Document N2-5
- Guidance documents on active substance for dossier preparation, procedures etc. to consider

### Module 5: 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

### Module 6: 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 labelling

### Module 7: Risk envelope, uniform principle and other relevant subjects

- Risk envelope approach
- How, when and why?
- What are 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)