

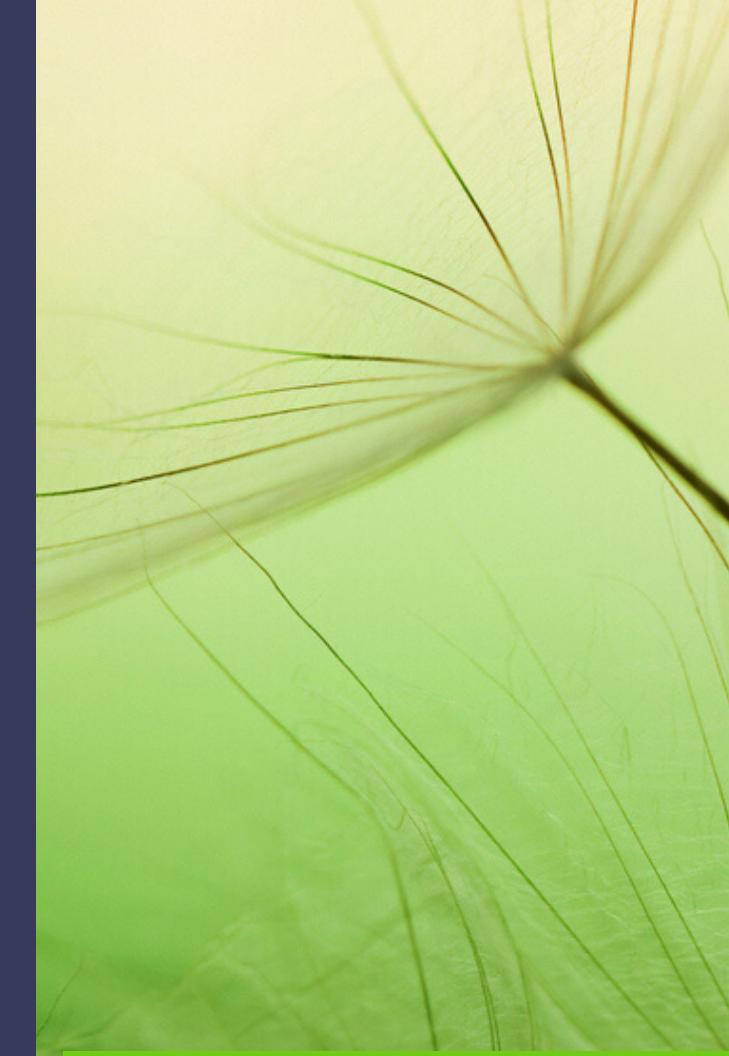


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# Fundamentals of EU Biopesticide Regulations

**5-week Online Academy**  
Starts 14 September 2020



# MEET THE TRAINER



## DR JOSÉ CARVALHO

Dr José Carvalho has 10 years of experience in the agrochemicals field with the main focus on regulatory issues and environmental risk assessment. Prior to joining the Knoell group, he led a GLP chromatography laboratory for agrochemicals monitoring in surface water and developed new methods for chemical analytical control for a German governmental agency (BAM). He authored 10 publications in international peer-reviewed journals in the field of chemistry/environmental and two book chapters on Food Chemistry published by the Royal Society of Chemical.

For the past 5 years, José has been coordinating agrochemical dossiers for active substances and formulated product for regulatory approval. He has led several trainings on regulatory aspects of formulated products, data protection and confidentiality claims.

# Agenda

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## **Module 1: Introduction to Biopesticides**

- What do we mean by a biopesticide?
- Clarifying differences in the definition:
  - Living organisms (Macrobiotics)
  - Pheromones
  - Natural extracts
  - Biostimulants
  - Genetically modified organisms
- What are the opportunities and the constraints for biopesticides?

## **Module 2: The European Regulatory Landscape**

- EU Regulation 1107/2009
- Key challenges
- Low-risk criteria applied to biological products
- Testing strategies and methodologies
- Bio efficacy standards
- Data acceptance
- Interplay between Regulation 1107/2009, the Sustainable Uses Directive, National Action Plan and Organic Listing

# Agenda

## **Module 3: Regulatory Risk Assessments**

- Uniform principles for biopesticides
- Defining risk scenarios
- How do the Regulator's perform regulatory risk assessments?
- Overcoming common pitfalls
  - Indigenous versus alien
  - Production methods, manufacturing and sourcing
  - Quality control
  - Formulation challenges
  - Residue definition

## **Module 4: Comparison to US/Canadian (NAFTA) regulatory environment for biopesticides**

- Understanding the regulatory environment for biopesticides under NAFTA
- On-going developments
- Exploring the major differences:
  - Definitions
  - Data requirements
  - Working with the authorities
  - Risk assessments

# Agenda

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## **Module 5: Regulatory updates for other key global markets**

- The Regulatory Framework
- Exploring the major differences:
  - Definitions
  - Processes
  - Data requirements
  - Working with the authorities
- Import Tolerances/MRLs settings for biologicals: differences between countries and regions



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please contact our Training Consultants**

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