Regulatory Affairs for Biopesticides

Dates: 10-11 October 2017
Location: Radisson Blu Edwardian Kenilworth, London

Price:

If booked by the 12th September 2017: £1495 + VAT (20%) = £1794 *save £100*
If booked after the 12th September 2017 : £1595 + VAT (20%) = £1914

Two Day Agenda: Both days will start at 09.00 and finish at 17.00

Day 1

Course introduction and overview of biopesticide product types

- Course overview and introduction to biopesticides
- What do we mean by a biopesticide?
- Clarifying international differences in the definition:
    - Living organisms
    - Pheromones
    - Natural extracts
    - Biostimulants
    - Genetically modified organisms
- What are the opportunities and the constraints for biopesticides?
- Specific product examples

Group activity

Discussion: Can biopesticides be registered and used globally? If not, do they create trade barriers for commodities?

Overview of the European regulatory environment for biopesticides

- The regulatory environment for biopesticides under 11/07 and 91/414
- Outlining key challenges:
    - Comparing the efficacy of biologicals with conventionals
    - Are approval timelines the same for biologicals and conventionals?
    - What are the regulatory incentives to develop and commercialise biologicals?
    - Do biologicals pose lower risks than conventionals?
    - Is it possible to save time in getting the product to market?
- Essential regulatory updates – ongoing discussions by the commission
- Success strategies for working with the authorities
- Quality parameters
- Standardised testing methodologies
- Bio efficacy standards
- Data validation and acceptance
- How up-to-speed are the various Member States in the EU to deal with biopesticides?

Group activity

Discussion: Strategic approach to the planning of efficacy studies for approval of a biopesticide Europe wide.

Regulatory risk assessments

- Uniform principles for biopesticides
- Defining risk scenarios
- Understanding how the Regulator's perform regulatory risk assessments
- Overcoming common pitfalls
    - Indigenous versus alien
    - Production methods
    - Quality control
    - Formulation
    - Residues: Active substance and formulants
    - Risk mitigation

Group activity

What does an assessor do? The day-to-day jobs of an assessor.

Day 2

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
- How to harmonise and collaborate
    - Identifying the players
    - Common interests or competition

Group activity

Identify potential co-operators for your product and understand common interests in regulatory approvals

Regulatory updates for other key global markets

- National, regional or global approvals?
- Understanding the importance of building knowledge about international registrations and the differences and similarities between the different areas in the world
- Approaching the Regulators
- Exploring the major differences:
    - Definitions
    - Processes
    - Data requirements
    - Working with the authorities
    - Risk assessments

Group activity

Developing the scenario for the global approval of a biopesticide

Market intelligence and maximising commercial opportunities

- Connecting the global market for food, feed and fibre crops to that of pest control products
- Understanding the market opportunities
- Avoiding non-tariff trade-barriers
- Building stakeholder collaborations in the development of national, regional and global dossiers
    - Identifying and contacting users, scientists, manufacturers and Regulators
    - Splitting the tasks among collaborators
    - Keeping the team together and moving it forward through approvals
    - Remaining in charge of your product and keeping it up-to-date

Group activity

Describing potential hurdles and ways to ov ercome them

Global developments: The drivers and next steps

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