Progress Towards Proportionate Regulation for Biologicals

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IBMA International Biocontrol Manufacturers Association
a member of the BPG global federation of biocontrol associations
Technologies included in IBMA

Biological Control protecting crops using biological means is an increasing market global CAGR 13% since 2014 and CAGR 14% forecast to 2024 (source IHS Markit)
What has been the agricultural focus up to now?

- Focus on yields
- Operational efficiency
- Food security and supply
- Shelf life

- PPP regulation (1107/2009) is designed for chemicals
- Data requirements are inappropriate for biologicals
- We use test methods designed for chemicals
- EU evaluators experienced in chemical evaluation
IBMA White Paper: Proportionate Regulation: Dual Track

• 1107/2009 – Data Requirements
  • New data requirements MS
  • IBMA Member working groups to propose decision tree 4Q19
  • Review with EU COM Q12020

• Push for new biological regulation
  • Member endorsement
  • Engagement of MS (NL vision)
  • Review with other MS
The IBMA White Paper

- Looks at other Competent Authorities in other regions
- Looks at other regulated products in Europe
- Looks at regulation for products from SMEs
- Looks at speedy approvals and provisional authorisations
What can we learn from other Regulatory Authorities

Source Arche Consulting Report June 2018

- Specific legislation
- Case by case evaluation
- Recognise flexibility in data requirements

- Register within 1 year
- Lower data requirements
- Risk assessment conducted

www.certiseurope.com
What can we learn about Regulation of other Products
Source Arche Consulting Report June 2018

Medicinal Products Regulation

• Biosimilar Medicines
• Fast registration for biological medicines that are very similar to another approved biological medicine.

• The European Medicines Agency (EMA) had a consultation in 2015 which led to the implementation of several initiatives in guidance:
  • Accelerated assessment
  • Conditional marketing approval
  • Unmet medical needs
  • Positive benefit-risk balance
What can we learn about support for SME and quicker approvals in PPP regulation

- Proactive approach to improving dossier preparation and speed through the registration process
- Article 53 derogation for wireworm protection in potatoes based on Metarhizium
- Fast track evaluation and SCoPAFF for weak strain pepino to reinforce immunity to Pepino mosaic virus in tomatoes

Green Deal NL

- German Derogation for Attracap
- Proactive approach to improving dossier preparation and speed through the registration process
- Article 53 derogation for wireworm protection in potatoes based on Metarhizium
- Fast track evaluation and SCoPAFF for weak strain pepino to reinforce immunity to Pepino mosaic virus in tomatoes
| Other regulations in Europe support SMEs | Other regulations in Europe offer provisional regulation | Regulated biological PPPs in other regions operate fast-track and have delivered more products | Other regulations in Europe work on a notification basis |

The key messages of the White Paper
In the White Paper - ideal regulation would deliver:

• Dedicated uniform principles 😊
• Dedicated data requirements 😊
• Specialist evaluators 😊
• Specialist peer review 😊
• Labelling to acknowledge low-risk or similar 😞
• A separate regulation specific for Biological PPPs 😞
• Provisional authorisations 😞
Summary

A quicker review concentrating appropriately on the issues of concern gives confidence by all parties that the solutions are safe and effective for the intended uses.
Harmonised evolving regulatory processes

FAO
New guidance

OECD
Guidance
Seminars
Issues

EU
Guidance
Revision of:
Uniform Principles
Data requirements
Thank you

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