Benefits of good regulation for plant biologicals

Roma Gwynn, W. Ravensberg, R-U Ehlers, D. Cary
International Biocontrol Manufacturers Association
roma.gwynn@ibma-global.org
(www.ibma-global.org)
UN Sustainable Development Goals

Aim to:
End poverty, protect the planet and ensure prosperity for all: a healthy and productive environment is needed to support this.

Agricultural intensification puts pressure on the environment and increases threats to human health.
Bioprotectants globally

Food security

30 – 40 % crops lost before harvest

>10 % after harvest

To meet the challenges

we need ‘Best Practice’ crop protection

Bioprotectants

increasingly the mainstay of sustainable crop protection
Bioprotectants

Macroorganisms

Microorganisms

Botanicals

Semio-chemicals
Natural forces control populations

One year
↓
one cabbage aphid
↓
250 million tonnes

Information and photo: courtesy of D. Chandler, Warwick Crop Centre and eplantswholesale.com.au respectively
Crop protection

Monitoring

Crop botany

Agro-ecosystem

IBMA

IPM

Botanicals

Biorationales

Semiochemicals

Synthetic Chemical pesticides

Micro-organisms

EPN

Insects

Predatory mites

Macro-organisms

Bacteria

Fungi

Virus
EU new plant protection products – pending*
Bioprotectant markets

Global market increased over 300% * 2008-2018

Global market 2019 value over $6 billion * Increase

* Dunham Trimmer, 2018
Society requires good regulation

Protection of:

- Consumer safety
- Operator and worker safety
- Environmental safety
- Crop safety
- Assure product quality
- Technology & innovation
Regulatory approaches for bioprotectants for PPP uses

**Out of scope for PPP**
- Natural enemies
- Entomopathogenic nematodes
- Root symbionts

**Registered EU PPP**
- Microorganism
- Semio-chemicals
- Natural substances

**PPP Basic substances**
- Not PPP but may be used for plant protection

**PPP Low Risk**
- Products where active substance is assessed as Low Risk
PFC : PLANT BIOSTIMULANT
1. A plant biostimulant shall be a CE marked fertilising product stimulating plant nutrition processes independently of the product’s nutrient content with the sole aim of improving one or more of the following characteristics of the plant: (a) nutrient use efficiency, (b) tolerance to abiotic stress, or (c) crop quality traits.

Further: PFC 6(A): Microbial plant biostimulant
1. A microbial plant biostimulant shall consist solely of a micro-organism or a consortium of micro-organisms referred to in Component Material Category 7 of Annex II.

And: CMC 7: MICRO-ORGANISMS
A CE marked fertilising product may contain micro-organisms, including dead or empty-cell micro-organisms and non-harmful residual elements of the media on which they were produced, which
• have undergone no other processing than drying or freeze-drying and
• are listed in this list:

Azotobacter spp.
Mycorrhizal fungi
Rhizobium spp.
Azospirillum spp.
EU registration timelines for PPP: 1107/2009

Regulatory system - same for all plant protection products

Year
0
1
2
3
4
5

Active substance

Submit dossier

Assess dossier - DAR

Peer review - EFSA

EU vote - Approval

Products - zonal

Submit dossier

Zonal assessment

Product approval

Products - Low risk

Submit dossier

Zonal assessment

Product approval
Regulation of bioprotectants

Are bioprotectants different from conventional chemical pesticides?

Guidance documents
- Microbials
- Semiochemicals
- Botanicals

Low Risk
- Products where active substance is assessed as Low Risk

YES
Plant colonising microorganisms

Plant colonising microbials are common – no plant is microbial free
Secondary compounds will be produced
Plant colonising microbials will affect plant physiology
Persistence
Interactions operate at multiple levels
Inevitably, studies of interactions are complex to perform
Difficult to attribute effects
Bioprotectant regulatory skills

soil ecology, plant ecology, landscape ecology, biology, microbiology, genetics, microbial ecology, population biology, plant physiology, population modelling, landscape modelling, population ecology, etc.

and maybe, sometimes, even chemistry
IBMA call for appropriate and proportional regulation

PROPOSAL FOR SOLUTIONS

To ensure implementation in the circular bio-economy in the agricultural sector, appropriate, streamlined and faster regulatory procedures that will deliver sustainable bioprotection solutions and provide innovative tools for farmers and other users of the natural environment need to be enacted.
What are the advantages of a new regulatory system for bioprotectants?

Eliminating disproportionate costs compared to the risks these technologies represent.

Efficiently assessing the risk specifically linked to bioprotection technologies, in consequence reducing the required resources whilst appropriately addressing potential risks.

Shorter evaluation periods resulting in more bioprotection products placed faster on the market, replacing products deemed to be of concern.
IBMA white paper: ‘New EU regulatory framework for bioprotection agents’
Thank you for your attention