IBMA White Paper

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IBMA

a member of the BPG global federation of biocontrol associations

www.bioprotectionglobal.org
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We are at the start of a true green revolution in agriculture
A change is needed in regulatory science

As we embrace more biology and less chemistry IBMA Member solutions will be a major part of this.
Why: legitimate major concerns need to be addressed

In the environment

Loss of biodiversity

Climate Change
Legitimate major concerns need to be addressed

In human health

Workers
Consumers
Society at large
Legitimate major concerns need to be addressed

And changes have to be made in feeding a growing world population

diet more plant based

energy crops v food crops

waste in the food chain

uniformity of produce
This said we come from a place where:

• Concentration has been on yields
• Storage has been more important than taste
• Uniformity has been crucial
• Control has been practised not management

• We regulate all PPPs including biologicals as if they are chemicals
• We use data requirements designed for chemicals
• We use test methods designed for chemicals
• We have expert evaluators experienced in chemical evaluation
IBMA Document Trilogy:
White Paper, Arche-IBMA Report, IBMA-C & C Roadmap
The IBMA White Paper

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

IBMA
INTERNATIONAL BIOCONTROL MANUFACTURERS ASSOCIATION
## The key messages of the White Paper

<table>
<thead>
<tr>
<th>Other regulations in Europe cater for SMEs</th>
<th>Other regulations in Europe offer provisional regulation</th>
<th>Other regulations in Europe work on a notification basis</th>
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<tbody>
<tr>
<td>Regulated biological PPPs in other regions operate fast-track</td>
<td>Regulated biological PPPs in other regions are quicker</td>
<td>Regulated biological PPPs in other regions have delivered more registered products</td>
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In the White Paper - ideal regulation would deliver:

• A separate regulation specific for Biocontrol Plant Protection Products
• Specialist evaluators
• Specialist peer review
• Dedicated uniform principles
• Dedicated data requirements
• Provisional authorisations
• Labelling to acknowledge low-risk or similar
Coming from nature:

It is not per se safe but coming from a different starting point

- Confidence from known scientific observations
- Established pathways and mechanisms
- Concentrate on real areas of concern
- Ask appropriate questions for all types of solutions
- Smaller data package
- Evaluation by skilled experts in the field
A compromise is on offer as:

• DG Sante acknowledge the big shift towards biological PPPs
• DG Sante acknowledge a need for specialists in EU COM, EFSA and some MS
• DG Sante realise a need for quicker evaluation
• DG Sante acknowledge a change in data requirements and to have uniform principles appropriate for biologicals
• DG Sante acknowledge the need for labelling as low-risk

• DG Sante unlike the European Parliament do not see a need for a separate regulation
• DG Sante do not see a possibility for a provisional authorisation process
Result

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
Many thanks for listening

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