IBMA WHITE PAPER

NEW EU REGULATORY FRAMEWORK FOR BIOPROTECTION AGENTS

IBMA Vision on how to improve regulation in the European Union

IBMA
INTERNATIONAL BIOCONTROL MANUFACTURERS ASSOCIATION

EXECUTIVE SUMMARY

Bioprotection technologies provide effective and innovative plant protection for modern agriculture. This makes them a vital tool in the EU's work to support farmers and effectively implement the Sustainable Use of Pesticides Directive (SUD, Directive 128/2009/EC).

However, the current lack of a specialist bioprotection regulatory body, legislation, procedure and data requirements means that the EU is not fully reaping the benefits of this rapidly growing, predominately SME-based, industry.

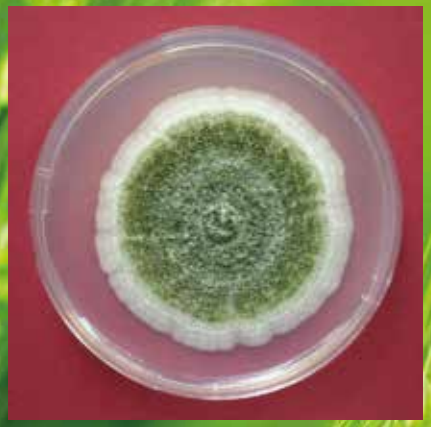
IBMA therefore propose that by the end of 2020 the EU establishes a bioprotection-specific body that has developed and implemented a short and precise timeline for the evaluation process, with evidence-based procedures and tailored data requirements. Risk-based evaluations should be conducted using high-level scientific expertise and in close communication with applicants. In parallel an interim arrangement in Reg. 1107/2009 to protect the viability of biological plant protection product producers until the new Regulation comes into force must be enacted.

This new approach would benefit human health, the environment, biodiversity and the bio-based circular economy and, therefore, society as a whole.

INTRODUCTION

The 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.
The EU Sustainable Use of Pesticides Directive (SUD, Dir. 128/2009/EC) reinforces an approach to agriculture that balances the need for good quality food for an increasing population whilst minimising harm to human health and the environment. This Directive aims to have a nature-inclusive agriculture that supports ecological biodiversity and ecosystem services across the landscape.

There is strong scientific evidence that effective plant protection best manages health and productivity by considering plant protection in an ecosystem context, fully understanding the multi-trophic influences on it. To support farmers and effectively implement the SUD whilst meeting societal needs the EU requires an extensive range of innovative plant protection measures: bioprotection technologies are such vital tools for modern agriculture.



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BIOPROTECTION

Bioprotection technologies are biological plant protection tools for management of pests weeds and diseases. They originate from nature or are nature-identical when synthesised and in general have a low impact on human health and the environment. Examples are micro-organisms, semiochemicals, plant extracts (botanicals) or natural substances. The term biopesticides is often used in the same way, but the suffix – "cidal" often does not describe the true mechanism(s) of these substances as they do not directly "kill" the target, but rather they protect the plant. IBMA propose the use of the words 'bioprotection' and 'bioprotectants' in future.

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Bioprotection technologies are:

- of natural origin
- produced from renewable resources
- supporting holistic agro-ecosystems-based approaches for growing food with negligible harm to the environment
- providing comprehensive solutions for robust and resilient IPM that fill gaps in the farmers toolbox with enduring solutions of particular usefulness for speciality uses and minor crops
- historically available tools used by generations of farmers with a long history of safe use

Current mechanisms for bioprotection technologies approvals have evolved from regulations for conventional chemical pesticides. At the latest count, 60% of submissions to the EU are bioprotection technologies but evidence indicates that, the existing approach is not working well in Europe, despite guidance produced for use in Reg. (EC) 1107/2009 for these types of technologies. The lack of importance given to bioprotection solutions and their specific regulatory issues is clearly demonstrated by this Regulation.

The EU COM initiated REFIT exercise devotes very little of their focus on this group of products when the reality is that submission of new active substance dossiers in the EU are now dominated by bioprotection technologies. This is backed up by the recent SAPEA report[1] where a claim for a separate legislative approach is identified despite only a single paragraph being devoted to these products whilst being even ignored in the SAM[2] proposal extracted from it. Existing regulations are significantly slowing down market entry, and often deter applicants. Consequently, there is a failure to support Europe's farming needs: the system hinders the throughput of innovative bioprotection technologies and hampers the competitiveness of EU agriculture.

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.

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WHAT ARE THE ADVANTAGES OF FINDING NEW REGULATORY SOLUTIONS?

The advantages of a new risk-based appropriate and proportional regulation for bioprotection technologies are:

- 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

There are significant societal benefits from the use of bioprotection technologies, they:

- answer societal calls for safe food without residues and with minimal impact of the environment in compliance with SUD Directive 128/2009/EC
- are technologies that support Member States implement their National Action Plans
- support the call for sustainable plant protections goals from the EU Council
- support renewable systems within the circular economy
- create a thriving bio-based economy with business and job opportunities
- can support the growth of SME industry to compete in the global market-place
- foster pan-European public-private partnerships for research and innovations in the bio-based green economy SMEs, and;
- support EU farmers to be competitive in the global marketplace

WHAT CAN WE LEARN FROM OTHER REGULATORY FRAMEWORKS AND MECHANISMS?

The USA EPA process for regulating biopesticides is the best example of a system which has been set up solely to regulate bioprotection products. It has a track record of delivering new product approvals through robust rigorous review within a year of submission since it was established in 1994. Importantly it follows a tiered approach and reviews are conducted by dedicated evaluators with relevant expertise. Currently, the USA has about four times more bioprotectants available compared to the EU, and the same for pending products in 2018. Similar regulatory approaches are being recommended by FAO and adopted by countries including Australia, Brazil, Canada and China and are being promoted by OECD.

The EU has a track record of particular specific measures used in other regulatory frameworks which could be of added value for a new appropriate, streamlined and faster regulatory procedure for bioprotection technologies.

The European Medicines Agency has implemented a centralised procedure under the direction of the agency with participation from Member State experts. Authorisations under this regulation are delivered in 210 days; an accelerated assessment procedure for innovative therapies even delivers evaluations within 150 days. Provision also exists through the agency for the granting of a conditional marketing authorisation to deliver immediate benefits to society. There are a number of provisions and procedures available for specific types of medicines. For example, for herbal medicinal products a number of provisions have been established taking into account their nature and history of safe use. Support activities are also made available through the Innovation Task Force (ITF) and the Micro, Small and Medium-sized Enterprises (SME) Office to assist applicants in delivering innovative solutions to the market in this field.

The REACH legislation involves a dedicated dossier being submitted to the centralised agency ECHA. The data requirements are designated by quantity (tonnage) bands which equate to exposure levels to the substance for both human and environment. This facilitates niche solutions being made available with reduced regulatory time and expense. As the procedure is based on the principal of notification, an applicant is required to produce and lodge a dossier but can commence marketing products without waiting for an approval. Similar pragmatism would particularly enable innovative bioprotection products produced by SMEs to enter niche markets without undue cost and delay.

Other centralised EU regulatory systems for feed additives, biocides and cosmetics have similar procedures with special procedures for biological products with appropriate data requirements, communication options with applicants, appeal procedures, and sometimes fast track processes. For an overview we refer to the Arche-IBMA Regulatory Framework Review Report, available on the IBMA website[3].

It should be obvious that such facilitating procedures are not only appropriate for those other regulated products within the EU. It would be disingenuous to claim that plant protection products are indeed special and have a need for higher protection standards than other regulatory frameworks assessing placing on the market of medicines, food, feed, biocides and cosmetics. To deliver the green goals anticipated for delivery in agriculture from UN agencies with Sustainable Development Goals, OECD Vision for Green Growth and regulatory harmonisation (Reg. 1007/2009) and the Sustainable Uses Directive in the EU, we urgently need a different regulatory approach for bioprotection products. We also need to re-evaluate how we interpret and apply the precautionary principle for bioprotection plant protection products.

In a global marketplace led by OECD and its devolved principles, an organisation which Europe is at the heart of, we need to enact their call for global regulatory harmonisation and mutual recognition of registrations.

WHAT WOULD A NEW SYSTEM LOOK LIKE?

Good implementation of streamlined and faster regulation can be achieved by a system designed with the following parameters:

A single EU body for regulating bioprotection technologies:

- To coordinate registration of active substance and products integrally (together)
- To ensure evaluations are provided by experts with the proper field of expertise and relevant scientific know-how
- A panel to decide whether a technology fits within the scope of this new regulation (borderline technology)
- Simple and timely mechanism for MS authorities to ratify EU authorisation

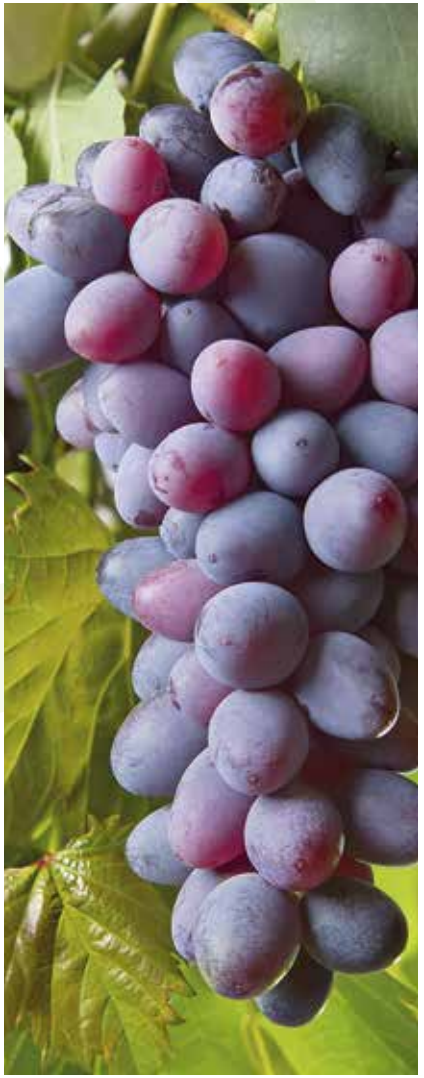
A new Regulation incorporating:

- Proportional data requirements for each of the bioprotection technologies
- Parallel evaluations and recognition of approvals under other regulatory frameworks and organisations (e.g. REACH, herbal medicines, QPS and ECHA, EPA, OECD)
- Transparency, including:
  - fixed timelines that are respected
  - clear justification of decisions
  - effective and timely appeal mechanism
- Clear and proportional fees
- Close liaison between applicants and authorities from early stage pre-submission to final decision, including hearing and defence options
- Authorisation extension possible for either target pest or crop
- Data protection recognition
- Time unlimited approval unless evidence of adverse effects
- Provision for fast-track authorisation

New data requirements including:

- Compliance with Uniform Principles that are adapted for the various bioprotection technologies
- A presumption of 'safe use'
  - A tiered assessment with reduced and differentiated data requirements justified by;
    - low tonnage
    - niche uses
    - minimal impact to humans and environment
    - existing experience and evidence, including QPS
    - active substance characterisation
    - microorganism group
- Presumption of MRL exemption unless there is strong evidence for a residue of concern

Of note is that the model proposed would be applicable for bioprotection agents as well as other categories of products for use and release in the environment (e.g. biocides, biostimulants, organic inputs).



PROPOSAL

IBMA proposes the EU develops a new appropriate legislative framework and streamlined provisions with a dedicated centralised regulatory body, presumption of safe use, tiered assessment and tailored data requirements.

IBMA foresees a centralised procedure under the direction of this regulatory body with the participation from Member States experts, and this should be operational by 2021. There is also a requirement to have in parallel an interim arrangement in Reg. 1107/2009 to protect the viability of plant protection product producers until the new Regulation comes into force.

As a result farmers will get more sustainable tools to grow healthy and productive crops within an Integrated Pest Management programme in which biocontrol and ecosystem services provide resilient food production with a minimum impact on the environment and human health.

This will enable the EU to meet its goal of a future-proof sustainable agriculture and achieve the sustainability goals that our society urgently demands for food safety and food security, human health and protection of the environment.

1: https://www.sapea.info/wp-content/uploads/SAPEA_PESTICIDES_forJune.pdf

2: https://ec.europa.eu/research/sam/pdf/sam_ppp_report.pdf

3: http://www.ibma-global.org/upload/documents/20180924archeibmaregulatoryframeworkreview.pdf

GREEN TOOLS 1st

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