

# Advancing Biocontrol in Europe: Policy Developments, Opportunities & Bottlenecks

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# Presentation of IBMA

- International Biocontrol Manufacturers Association, founded in 1995, **with over 200 members in 33 countries and 10 national associations.**
- IBMA is the **experienced voice of biocontrol** for a sustainable and resilient global agriculture for healthier food systems to benefit farmers, environment and consumers.
- Our goals :
  - proportionate (fit-for-purpose) authorisation of biocontrol (mostly at EU level)
  - demonstrating biocontrol so farmers can use it and policymakers know it works



# IBMA Technical & Regulatory Working groups

IBMA has 4 Professional Groups, each representing the different types of biocontrol.



**Macrobia**



**Microbial**



**Natural  
substances**



**Semiochemical**

**Working  
parties**



**Protein & Peptide**



**Microbial Based  
Fermented Mixtures**



**Formulation &  
Application**

+ more

# Providing solutions to farmers – why we need more biocontrol

## Farmers' challenges

- **Loss of key conventional active substances** (withdrawal, pesticide resistance)
- **Emergence of new pests, change in pest and disease distribution** due to climate change
- Farmers are keen to **manage resistance to conventional pesticides** and maintain longer efficacy of these PPPs
- **Residue management and market access** for farmers (some European retailers are requiring residues 30-80% below approved MRL)

## Biocontrol answer

**Biocontrol can fill the gap within a holistic approach, working alone and in IPM programmes with conventional pesticides**

### **Advantages of biocontrol for growers:**

- ✓ Pest-disease management
- ✓ Resistance management through the introduction of additional modes of action offered by biocontrol products
- ✓ Residue management – market access
- ✓ Soft on beneficial insects and other non-target organisms
- ✓ Maintains / enhance biodiversity

## EU slow approval process for biocontrols has 360° consequences






**European agriculture is falling behind:** the toolbox of European farmers to protect their crops will be less and less full compared to that of its global competitors between lack of biocontrol solutions and less chemical solutions available

**Europe is losing its potential to maintain a leadership position in the crop protection business, of which biocontrol is the segment rich in innovation and high growth.**

Increasingly, we see that innovative companies, even European ones, are turning primarily or even exclusively to other countries where approval times are much shorter and returns on investment more attractive.

**Europe is depriving itself of an important leverage to achieve the transition to more sustainable agriculture**

# Biocontrol innovation economics

-  **Lower ROI rate for biocontrol PPPs in EU: -30%** than global figure
-  **Important starting cost for SMEs (1.5 – 2.5 MEUR baseline for AS+PPP dossier submission)** but could be much more depending on extent of literature review for micro-organisms metabolites, additional studies
-  **Unpredictable timelines (5-10 years) affect the attractiveness for venture capital funds** which require predictable ROI timelines
-  **Delays – missed seasons = missed sales,** postponing the execution of the business plan
-  **Extra costs** – back and forth with Member States and EFSA, IUCLID updates (extra consultant costs), higher fees in some RMS (registration, MR)

- “Against this background, **it remains financially challenging to justify investments in biocontrol R&D** given the present cost structures and opportunity costs” (EY study)
- **Unpredictable timelines potentially make venture capital investment more difficult** as they often request generating revenue after 5 years.
- As a result, **biocontrol companies are increasingly seeking a first approval in US, Brazil or other regions to generate revenue** before entering the EU

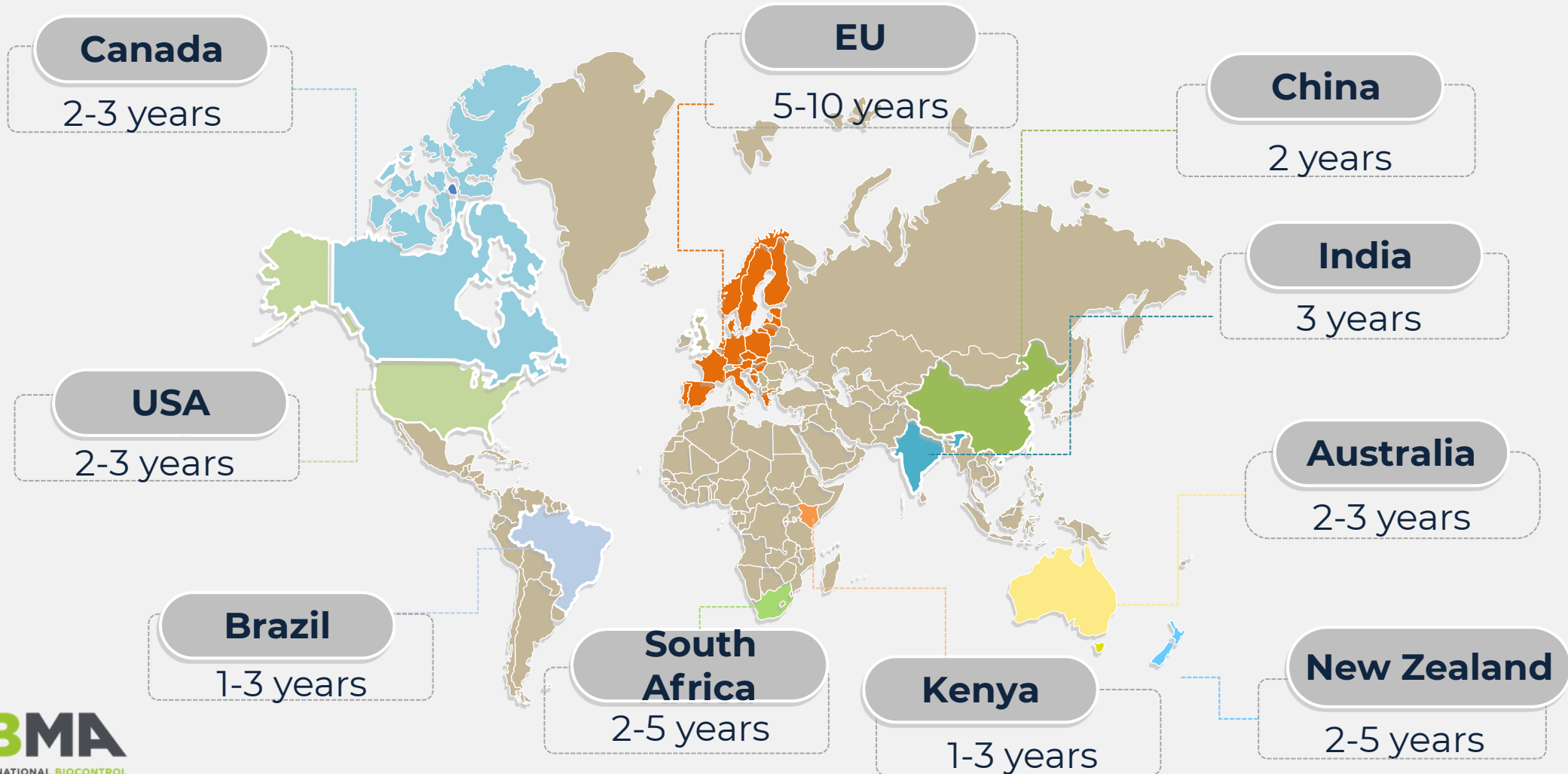


## Mutual Recognition Case Study – Biocontrol PPP for Use in Greenhouse

In all Member States, an authorization was ultimately granted, according to the submitted dossier and proposed use/application. Purely administrative procedure given a single regulatory zone without discussion on climatic zones (as for greenhouse use). No obvious reason for exceeding regulatory timelines (120 days)

Member State	Deviation from statutory 120 days	Reported Economic Impact
Lithuania	-56	Positive impact, the mutual recognition met the business plan timeline. The business department experienced no delays and could start marketing the product immediately. Growers were thus able to treat their crops on time.
Finland	-31	
Latvia	+15	No impact, the mutual recognition met the business plan timeline. Although the evaluation period was exceeded, the business department could start marketing the product before the season started. Growers were thus able to treat their crops on time.
Norway	+45	
Sweden	+21	
Croatia	+37	
Greece	+53	
Germany	+257	Direct financial impact nearing 400KEUR per season, even if these are not the largest markets for the company, the loss is significant. In addition to the direct financial impact, the delay also slowed down their overall development and positioning within these markets
Slovenia	+260	
Slovakia	+177	

# Biocontrol registration timelines in the World

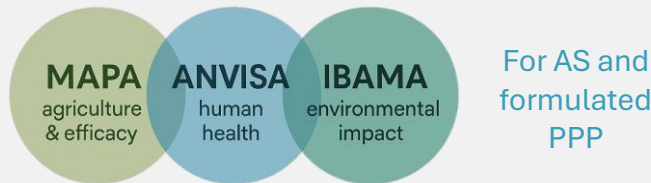


# Regulatory Fast-track in Brazil – A biocontrol Powerhouse



## ➤ 2014 – regulatory reforms

**Dedicated approval pathway for biocontrol with institutional support.**



**Brazilian authorities responded to farmer demand** for biocontrol by prioritizing it in the authorization process.

- **Prioritized evaluation - “Pest not crop” registration** - accelerates market entry.
- **1 PPP already registered by any company** - Same active & use → only 1 efficacy trial needed.

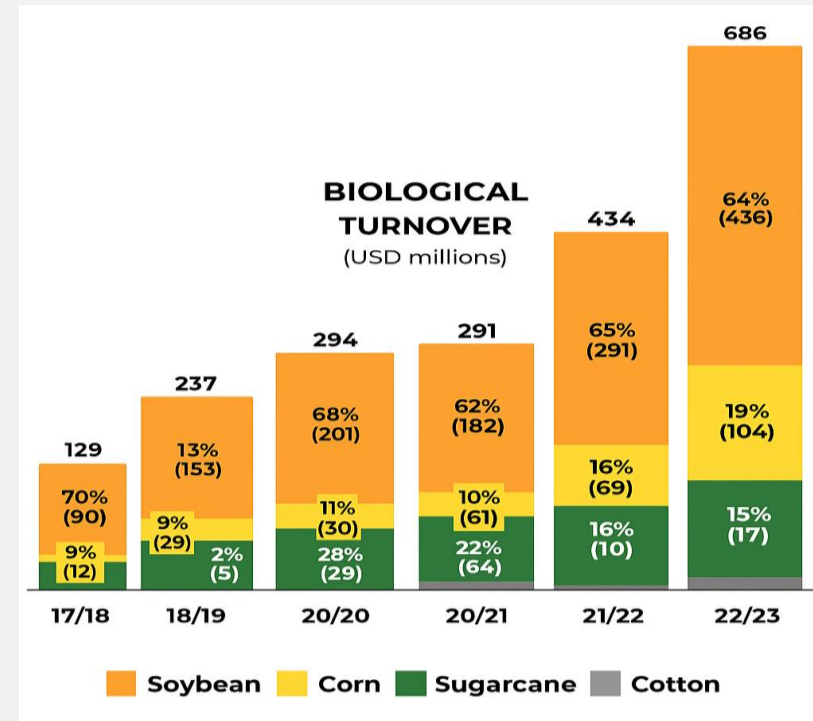
**Raise awareness of biocontrol.** In Brazil, 90% of farmers know about biocontrol whereas in the US, 86% of farmers don't know about it.

**Provide training on how to assess biocontrol.**

**Help farmers use biocontrol.** Make biocontrol available, invite farmers to demonstrations, show them how it works. Farmers will then make their own choices. In Brazil, this choice is for biocontrol.

**In the last 2 years, around an additional 100 biological products registered which continues to grow annually.**

- sales have grown exponentially since the regulatory fast-track
- **Used on 60%+ of farmland**

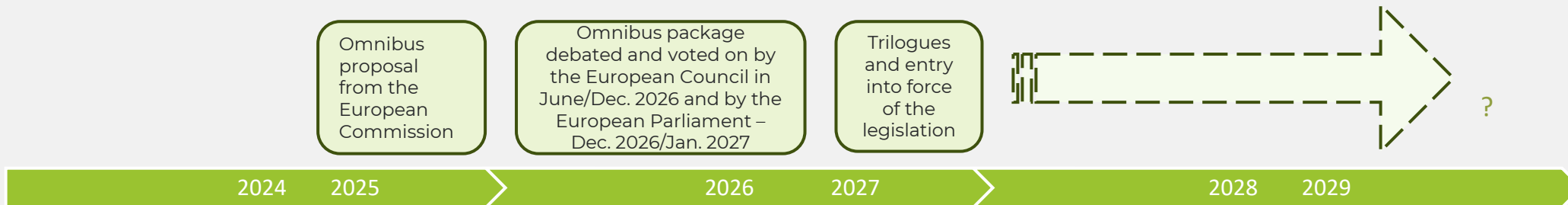


# Prioritising the approval of biocontrol is key – Time is the essence

## *How a priority lane for biocontrol could work*

- PPP authorisation currently involves **two stages**:
  - **EU level** : active substances evaluated by the Rapporteur Member State, peer-reviewed by EFSA, and approved by the European Commission.
  - **Member State level** : plant protection products evaluated and authorised nationally.
- A priority lane should apply at both stages of the process.
- Member States should create dedicated, well-resourced expert lanes for biocontrol dossiers, with priority over non-biological products.
- The objective should be to reduce approval timelines to less than 3 years from active substance submission to product authorisation to maintain global competitiveness.

# A New Momentum for Biocontrol: The EU Simplification package Proposal



- The Simplification Package deals with 10 different regulations related to food and feed safety requirements.

With regards to EC 1107/2009 the European Commission acknowledges that:

- *“... it is necessary to accelerate access to the market for new biocontrol substances and products containing them in order to increase their availability to European farmers with the objective **to support the shift towards more sustainable plant protection practices and reduce the use of more hazardous chemical plant protection products.**”*
- *“...**Biocontrol substances (such as micro-organisms, semiochemicals (pheromones), plant extracts) are more sustainable alternatives** to chemical active substances.”*
- *“... the capacity and expertise in Member States to conduct the necessary risk assessments is insufficient and that the time-to-market is too long.”*
- *“... address concerns about continued ability of farmers to produce crops to ensure food security”*

## How the Simplification Package addresses current challenges

To solve the issue of capacity and expertise the European Commission proposes:

1. to increase the resources at **EFSA**,
2. to enable Member States to ask for EFSA support in the preparation of the DAR
3. to implement measures to use more efficiently the existing resources at the level of the Members States by:
  - 1) reinforcing the **mutual recognition procedure** (tacit agreement after 120 days)
  - 2) introducing **unlimited approval for all active substances** (but keeping a 15-year authorisation period for plant protection products)
  - 3) reinstating **provisional authorisation** for biocontrol products
  - 4) adopting a **single zone for biocontrol** and low-risk products
  - 5) granting **priority for biocontrol and low-risk products**

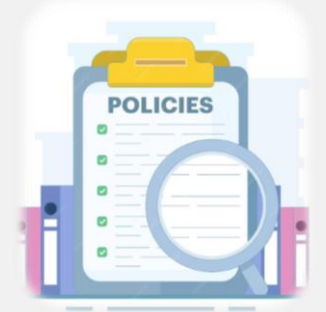


# Unlimited Approval Periods for Biocontrol - Removal of Automatic Renewal - A must have for Biocontrol solutions



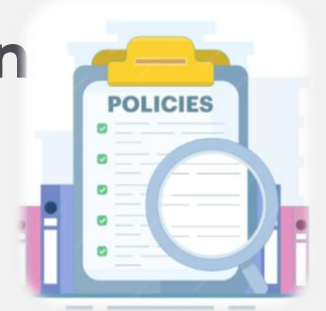
- **Facilitates faster access to innovative biocontrol solutions** for farmers by removing the need for automatic re-registration.
- **Renewal procedures consume significant regulatory resources** in Member States—often **50–90% of competent authorities’ time** reviewing existing substances.
- Eliminating automatic renewal would allow authorities to **focus resources on evaluating new biocontrol innovations**.
- Current re-registration cycles - **every 10 years**, taking **around 5–7 years including product renewal** - create **delays in access to new solutions**.
- For **biocontrol substances**, renewals rarely change the risk assessment endpoints, making automatic re-registration **inefficient and disproportionate**.
- **Safety safeguards remain in place**: under **Article 21 of Regulation (EC) 1107/2009**, authorities can **“call in” substances for review** if health or environmental concerns arise.
- Additional safeguards allow **Member States to request the European Commission to review an active substance** if needed.
- **Unlimited approval is a pragmatic and safe approach** that helps **accelerate biocontrol innovation**, improves **farmer access**, and supports the **transition to more sustainable agriculture in Europe**.

# One Zone for Biocontrol solutions – a more efficient set up



- **Climate change is accelerating the spread of pests and diseases across Europe.**
- When **Regulation (EC) 1107/2009** was adopted (~20 years ago), **clear differences existed between registration zones.**
- Today, **pests and diseases spread rapidly across Southern, Central, and Northern Europe**, reducing the relevance of the original climatic distinctions.
- The **current zonal system no longer reflects today's pest distribution reality.**
- **Bringing biocontrol into a single zone** would **reduce multiple submissions for the same innovation.**
- This would **improve efficiency and better use Member States' evaluation resources.**
- Ultimately, it would **accelerate access to biocontrol solutions for farmers across the EU.**

# Provisional authorisation is instrumental for biocontrol solution



## *Provisional Authorisation for Biocontrol - Key Points:*

- *Political objective:* accelerate the authorisation of biocontrol solutions.
- *Existing legal basis:* Article 30 of Regulation (EC) 1107/2009 already allows provisional authorisation.
- *Not deregulation:* provisional authorisation is granted only after a full safety evaluation and the Draft Assessment Report (DAR) from the Rapporteur Member State (RMS).
- *Enhanced process:* under the Simplification Procedure, EFSA could perform the RMS role.
- More efficient than emergency authorisations: emergency approvals require new submissions and evaluations each season, creating repeated work.
- Provisional authorisation lasts up to 5 years, reducing administrative burden for both authorities and industry.



## IBMA Position – 2026.03.16

# Other policy measures for biocontrol

<b>Articles supported by IBMA</b>	Articles 5, 14 and 18, for biocontrol	Approvals of (biocontrol) active substances
	Article 30	Provisional authorisation for biocontrol products
	Articles 37, 40 and 42	Mutual recognition of biocontrol products
	Articles 3 and 33	One regulatory zone for biocontrol
	Articles 11 and 37	Priority lane for biocontrol active substances and products
	Articles 7 and 11	Reinforce EFSA's resources and role with regards to biocontrol
<b>Articles where IBMA suggests Amendments</b>	Article 32	Approvals of (biocontrol) PPPs
	Article 59	Data protection
	Article 4 (7)	Derogation conditions
<b>New provisions recommended by IBMA</b>	New Article 82.a	Commitment to evaluate the appropriateness of the simplification measures for biocontrol and need for a new stand-alone regulation for biocontrol in the longer-term

[Link to our detailed position](#)

# An EU wide Definition Proposal

## ‘35. ‘biocontrol substance’ means:



- (a) micro-organisms,
- (b) inorganic substances as occurring in nature, with the exception of heavy metals and their salts or
- (c) substances of biological origin or produced synthetically that are functionally identical and structurally similar to them.

**IBMA Position – 2026.03.03**

## Biocontrol Definition - suggested amendments to EU Commission proposal

IBMA, established in 1995, represents the biocontrol industry with 137 biocontrol manufacturers proposes the following amendments to the EU Commission proposal:

### **'biocontrol substance', means**

**(a) micro-organisms** <sup>1</sup>

**(b) semiochemicals,**

**(c) inorganic substances as occurring in nature, ~~with the exception of heavy metals and their salts~~**

**(d) substances that are structurally similar and functionally identical to natural substances <sup>2</sup> of biological origin or produced synthetically <sup>3</sup>**



<sup>1</sup> Microorganisms both viable and non-viable are included.

<sup>2</sup> Natural substances consist of one or more components that originate from nature, including but not limited to: plant extracts, algae/microalgae, non-viable microorganisms, peptides, proteins (e.g. enzymes, antibodies), that are identical as occurring in nature

<sup>3</sup> Peptides and proteins containing sequence modifications of a peptide/protein sourced from nature are deemed nature identical provided all of the following conditions are met: (1) they contain only naturally occurring amino-acids; (2) such modifications do not change the 3-dimensional structure; (3) such modifications do not change the biological function and; (4) the biological breakdown occurs in a predicted way according to a natural pathway.



## IBMA Position – 2026.03.03

# Biocontrol Definition - suggested amendments to EU Commission proposal

**IBMA considers that biocontrol substances which are identical to those occurring in nature—whether directly from nature or synthesised—do not require additional interpretative guidance.**

### ***Guidance on structurally similar and functionally identical substances***

- The use of “structurally similar and functionally identical” as a basis for classifying biocontrol substances provides scope for new innovations to be defined as biocontrol substance.
- However, it also risks being too broad and opening biocontrol to conventional plant protection products based on natural products.

To avoid this confusion, some additional clarification is needed, which should include:

- Identical in behaviour to naturally occurring substances
- Degrade through a known and established biological pathway
- For proteins and peptides contain only naturally occurring amino acids
- Have no changes to the active site of the molecule

[Link to our detailed position](#)

# Conclusions: Time to Accelerate Biocontrol in Europe

- Biocontrol is essential for the transition to sustainable agriculture giving:
  - Farmers product choice
  - Food Security in times of climate change and pest resistance
  - Minimal impact on human health, biodiversity, and the environment
- Making Europe Competitive:
  - Authorisation +/- 10 years vs 2–3 years (USA, Brazil)
- Bringing biocontrol innovation back to Europe
  - Investment
  - Improved Return on Investment



**Fast implementation of the simplification package is needed to realize the benefits for farmers, the industry and European agriculture**

**Thank you**  
**&**  
**Questions ?**

