

Biocontrol faster access to the market: bottlenecks and opportunities

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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.



IBMA Vision and Mission

VISION



Biology first to meet the needs of a sustainable world

MISSION



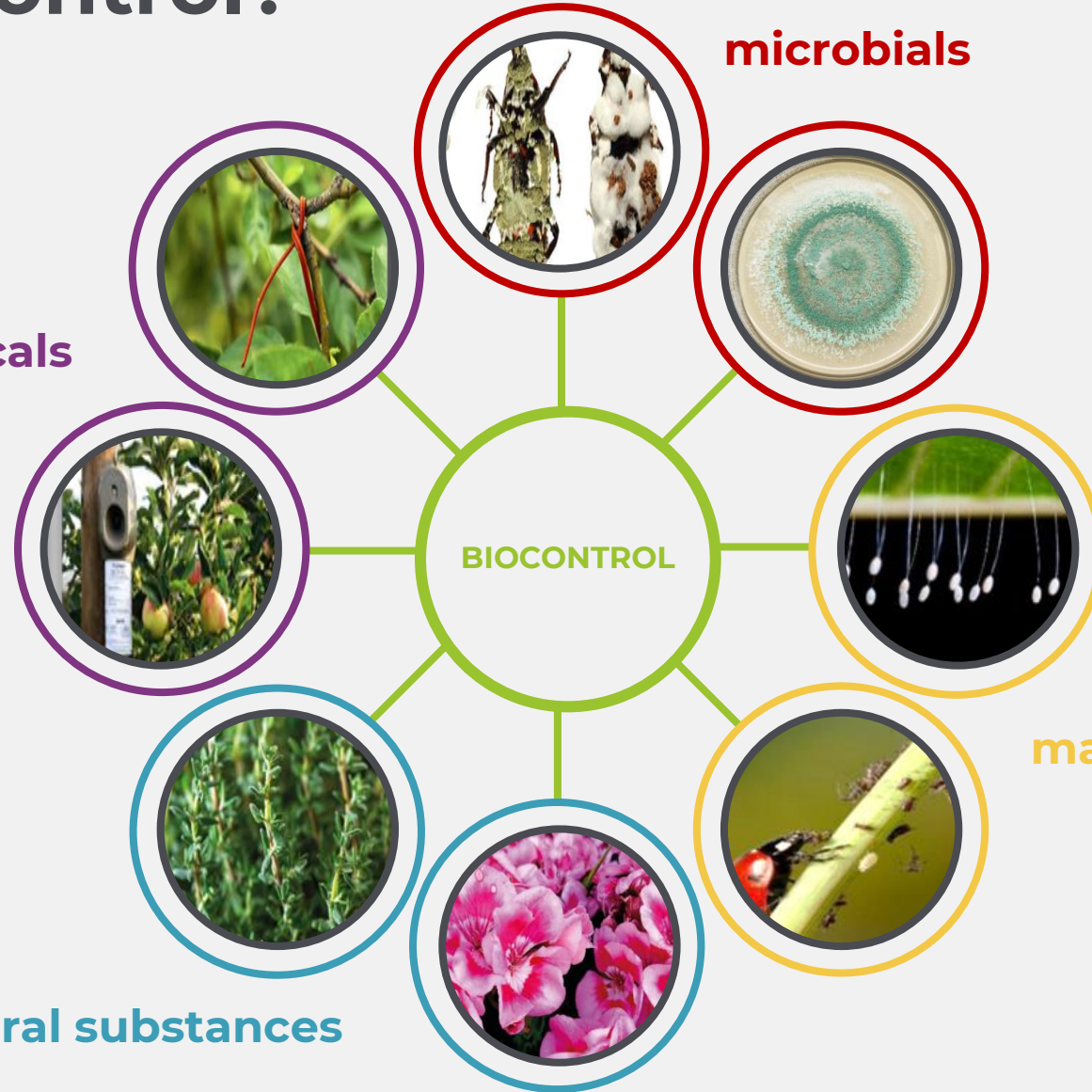
IBMA is the experienced **voice of biocontrol for a sustainable and resilient global agriculture** for healthier food systems to benefit farmers, environment and consumers.

Working with nature, our members are leading the way in innovative and **effective biocontrol for agriculture, forestry, amenity, and public health.**

What is biocontrol?

semiochemicals

microbials



BIOCONTROL

macrobiols

natural substances

EU slow approval process 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

Brazil and his leading position in Biocontrol

- The advancement of biocontrol in Brazil was not driven by a goal of reducing chemical pesticides.
- Brazilian farmers favoured biocontrol solutions because of their effectiveness and attractive cost.
- Without major changes to the legislation,
- Systematically prioritizing biocontrol products in the approval system, the required authorization time was significantly reduced.
- As a result, the number of authorizations increased significantly, and farmers enthusiastically adopted these solutions, as evidenced by their impressive growth rate.



Brazil – A biocontrol Powerhouse

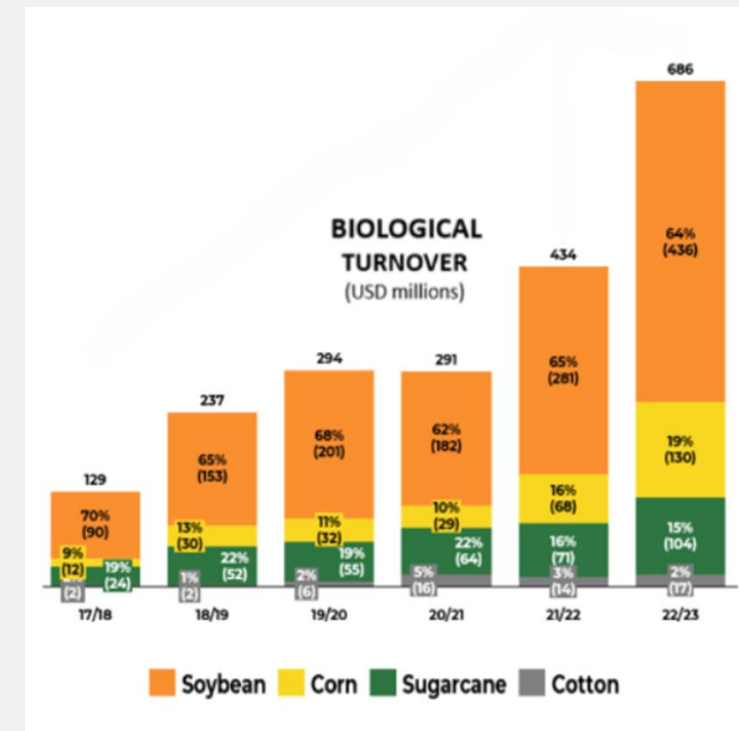
Brazil is a biocontrol powerhouse.

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

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

- **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.

Biocontrol sales have grown exponentially since the establishment of the regulatory fast-track



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

- The European Commission Vision for Agriculture and Food calls for a fast-track procedure for biocontrol approval.
- Prioritising biocontrol dossiers would allow farmers to access environmentally friendly and effective solutions more quickly.

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.

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**.

Mutual Recognition – Far from a straightforward process

Timelines

Substantial delays, often without clear justifications

Very different adherence to timelines across MSs of a same zone (even for an 'easy/straightforward' MR dossier such as a greenhouse use)

Often, very little communication on delays and expected completion date by MS

 **Major impact on applicants** 

National Specificities

National requirements, application systems, ways of communicating and submission forms

Some national requirements, can lead to rejection of the MR request in specific cases

Reassessment of the dossier or part of it by some MSs

Some uses, packaging sizes not always mutually recognised by MSs

Very specific label requirements in some MSs

In some MS the MR dossier is reviewed by different competent authorities, with only one contact point

Dossiers

National languages for communication and documents required the hiring of a local consultant

Variety of requirements of what to submit with the application. This varies from just a form to a complete dossier

Different crop lists in MSs, generating issues for MR (very specific national ways of expressing the uses)

Authorities ask for paper copies of certain documents, but only provide an PO box, issues when using parcel delivery

Regulatory Process

Regulatory zones are not equal to the efficacy zones. which complicates MR

Most times No MR possible due to frozen period until completion of art. 43 (Renewal) preventing MR applications for many years.

Some national requirements or request for additional studies can lead to the rejection of a MR request. In some cases, it leaves the applicant with no other choice than submitting the dossier for approval to the MS (the MS will be the zRMS and only cMS). More costs and time

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 solutions

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.

The European Commission Simplification Package focus for Biocontrol

- 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”*

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.

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**



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 ¹

(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 ² of biological origin or produced synthetically ³

¹ Microorganisms both viable and non-viable are included.

² 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

³ 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.

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:

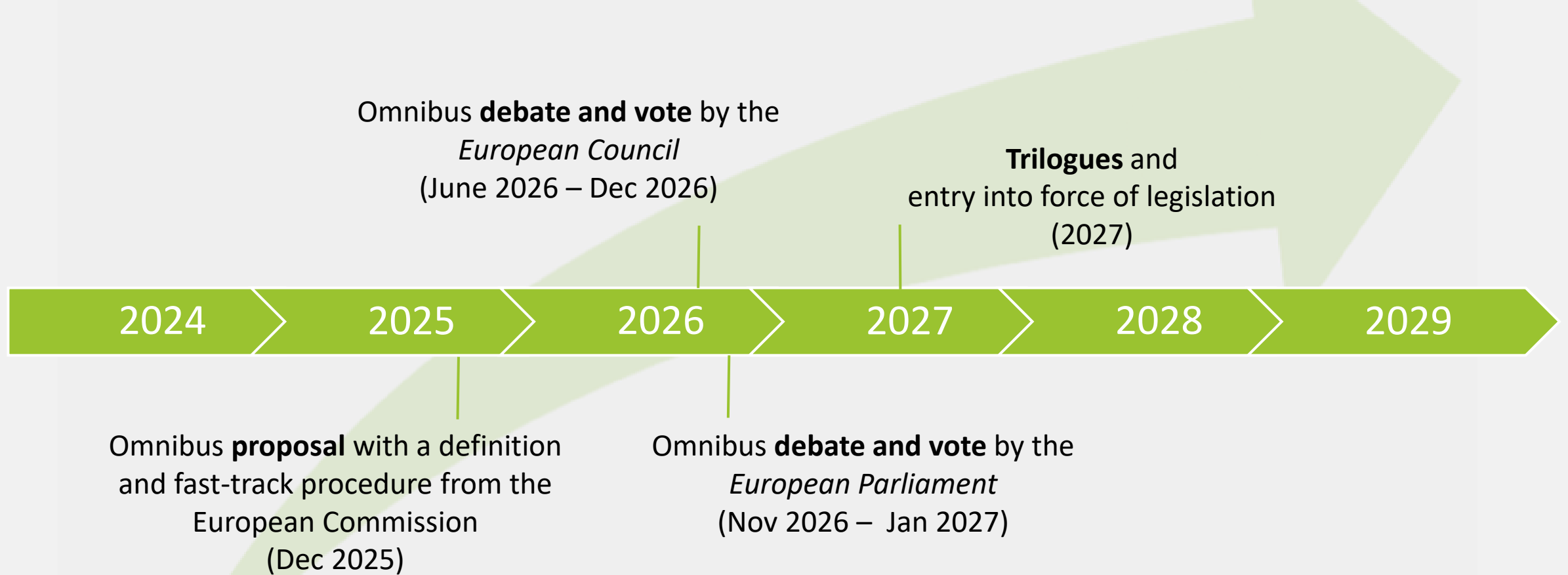
- Identical in behaviour to naturally occurring substances
- Degrade through a known and established biological pathway
- For proteins and peptides contain only naturally occurring amino acids
- Have no changes to the active site of the molecule

Other policy measures for biocontrol

Articles supported by IBMA	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
Articles where IBMA suggests Amendments	Article 32	Approvals of (biocontrol) PPPs
	Article 59	Data protection
	Article 4 (7)	Derogation conditions
New provisions recommended by IBMA	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



European Commission Simplification Package – Focus on Biocontrol



Cypriot Presidency of the European Council (1 Jan-30 June): measures on biocontrol in their work programme
Followed by the Irish Presidency (30 June-31 Dec)

This timeline is an IBMA estimate based on our experience and insights.

A Pivotal moment for biocontrol that provides



Farmers tools and product choice



Access to biocontrol innovation available in the rest of the world, making Europe Competitive with an authorisation process closer to 2 to 4 years, compared to 7 to 10 years right now



Continues building sustainable agriculture to provide food security in Europe, in times of climate change and pest resistance, while having minimal impact on human health, biodiversity, and the environment - with cross party and stakeholders' support -



Fast implementation is needed to realize the benefits for farmers, the industry and European agriculture

**Thank you
&
Questions ?**

