



# Authorization/ Renewal of microbial products

minor changes leading to major  
outcome

BPWG, Brussels, 10-11 June 2024



**IBMA**

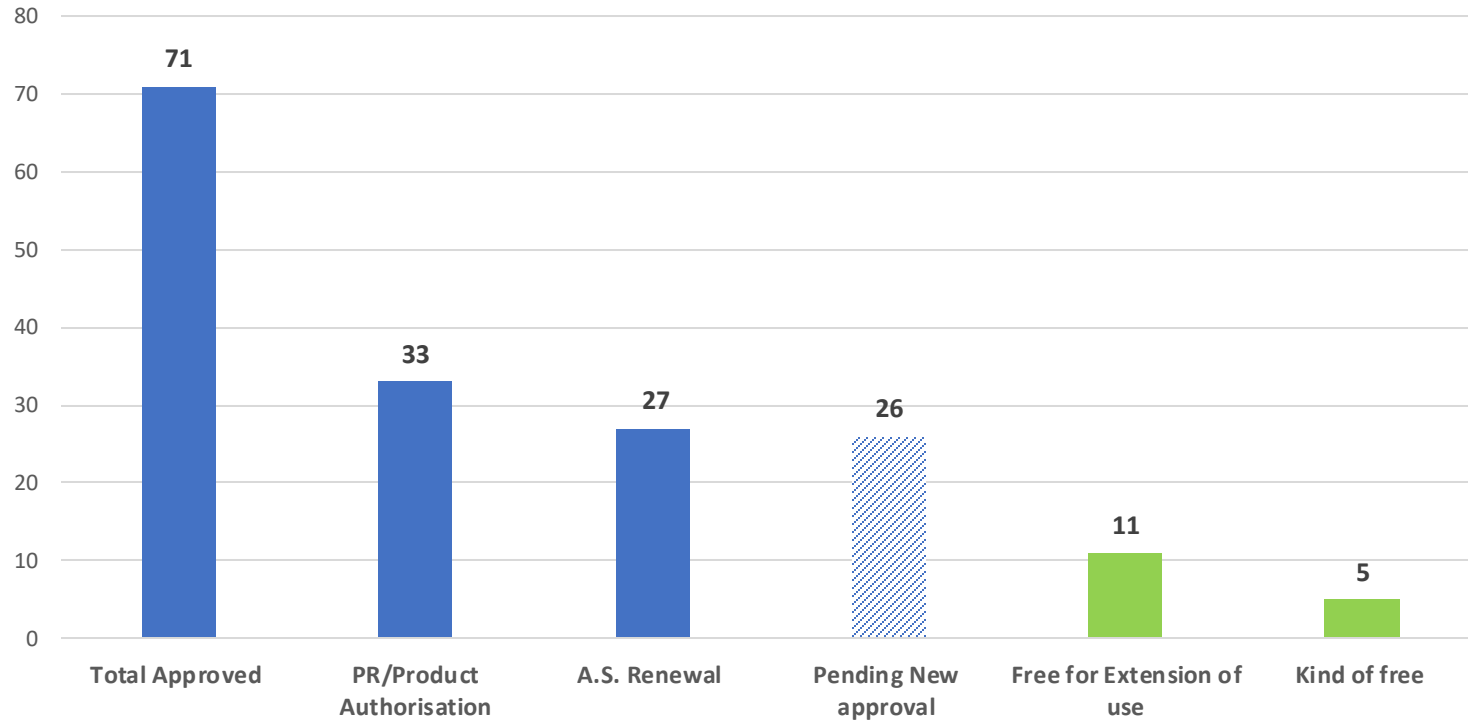
INTERNATIONAL **BIOCONTROL**  
MANUFACTURERS ASSOCIATION



- The EU has 71 microorganism strains approved and about 26 pending approval (June 2024)
- About 60 approved strains (85%) are “locked” in some Renewal process preventing Label Expansions, new formulations and Mutual Recognitions (in most MS). i.e **at least 60 products are already authorised** and could be expanded to other MS and their Labels extended.
- Pending MPCAs could lead to 26 new products but in the long term (>3-4 years): 20 of the new dossiers in 2 RMSs
  - IUCLID updates are a huge issue for RMS and applicants of MPCA!

**85% of MPCAs potential is locked by renewal processes.**

## MPCAs in the EU (June 2024)

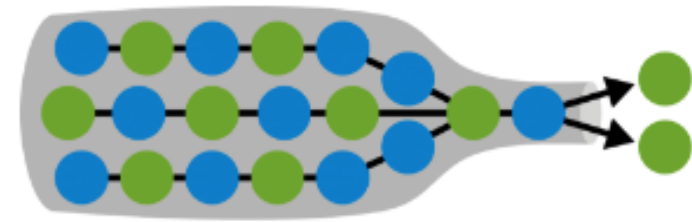


- Only 17 MPCAs are currently not “locked” by renewal processes;
- Slots for New product applications are extremely difficult to get (MSs busy with renewal processes)
- Extensions of use, new product authorisations and MR often blocked during MPCA and Product renewal processes

**85% of potential is locked by renewal processes**

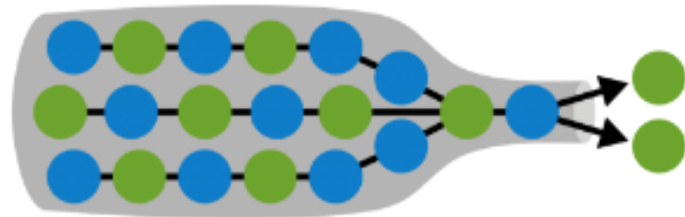
# MPCAs with “freedom to operate”

*Ampelomyces quisqualis* (1 strain)  
*Bacillus amyloliquefaciens* (1)  
*Bacillus subtilis* (1)  
*Beauveria bassiana* (2)  
*Clonostachys rosea* (ex. *Gliocladium catenulatum*)  
*Coniothyrium minitans* (1)  
*Isaria fumosorosea* (1)  
*Metschnikowia fructicola* (1)  
*Pasteuria nishizawae* (1)  
*Pepino mosaic virus* (3)  
*Saccharomyces cerevisiae* (1)  
*Trichoderma atroviride* (1)  
*Verticillium albo-atrum* (1)



Very limited number of MPCA that can be used for new product authorisations and label expansions

- **Label extensions, New products and Mutual Recognitions during renewal processes of MPCA** are crucial to make new products and new uses available to growers in the short term (< 4 years).
- The renewal processes take much longer than the timelines established by Reg. 1107/2009, blocking new application for years → unlikely to change in the short term
- What needs to be (re)assessed during a renewal process and what changes in terms of product safety?
- Consider the sense of Zonal Dossier for MPCA: this is blocking assessments, delaying authorisations/renewals and increasing the gap of products/uses available to growers across zones



- **Reduce number of Emergency Uses for MPCA** (of registered a.s.): 145 emergency uses in the past 4 years with MPCAs approved (note: if semi-chemicals and plant extracts/oils are looked at, the number of EM could be significantly reduced)
- **Allowing Label extensions, New formulations and MR** during renewal processes will make existing products available for new uses and new product development
- **Give a clear sign to business operators to invest in** product development under European agronomic conditions.
- **Provide farmers with biocontrol products to use in field programmes** and kick start to transition at field level with products with proven safety
- Prevent the collapse of EU biocontrol SMEs, most of which have been funded with public Innovation funds

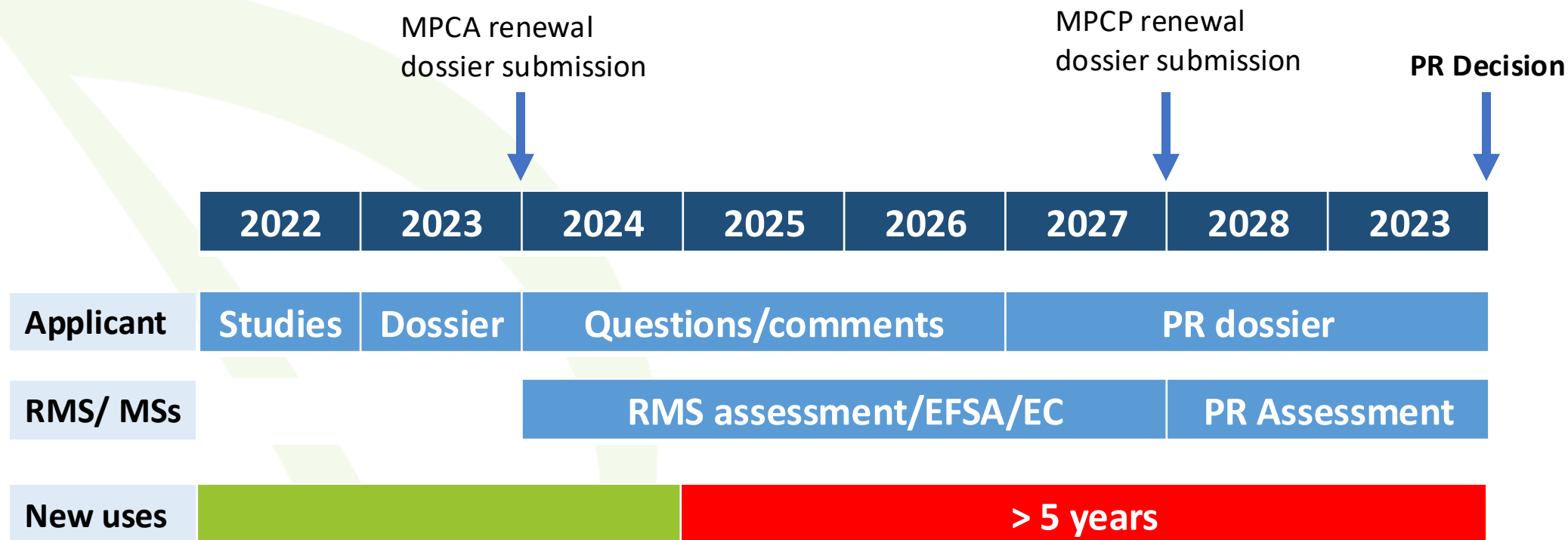
Current Status	2024	2025	2026	2027
<b>33 MPCA (PR/New authorisation)</b>	Red	Red	Yellow	Yellow
<b>27 MPCA (A.S. Renewal)</b>	Yellow	Yellow	Red	Red
<b>17 MPCA</b>	Green	Green	Green	Yellow

Possibility of Label Ext, New AT, MR	2024	2025	2026	2027
<b>33 MPCA (PR/New authorisation)</b>	Yellow	Yellow	Green	Green
<b>27 MPCA (A.S. Renewal)</b>	Green	Green	Yellow	Yellow
<b>17 MPCA</b>	Green	Green	Green	Yellow

Existing microbial PPPs could deliver >100 new uses to the market within 2 years, many of these targeted at arable crops where gaps in the farmers toolbox are significant

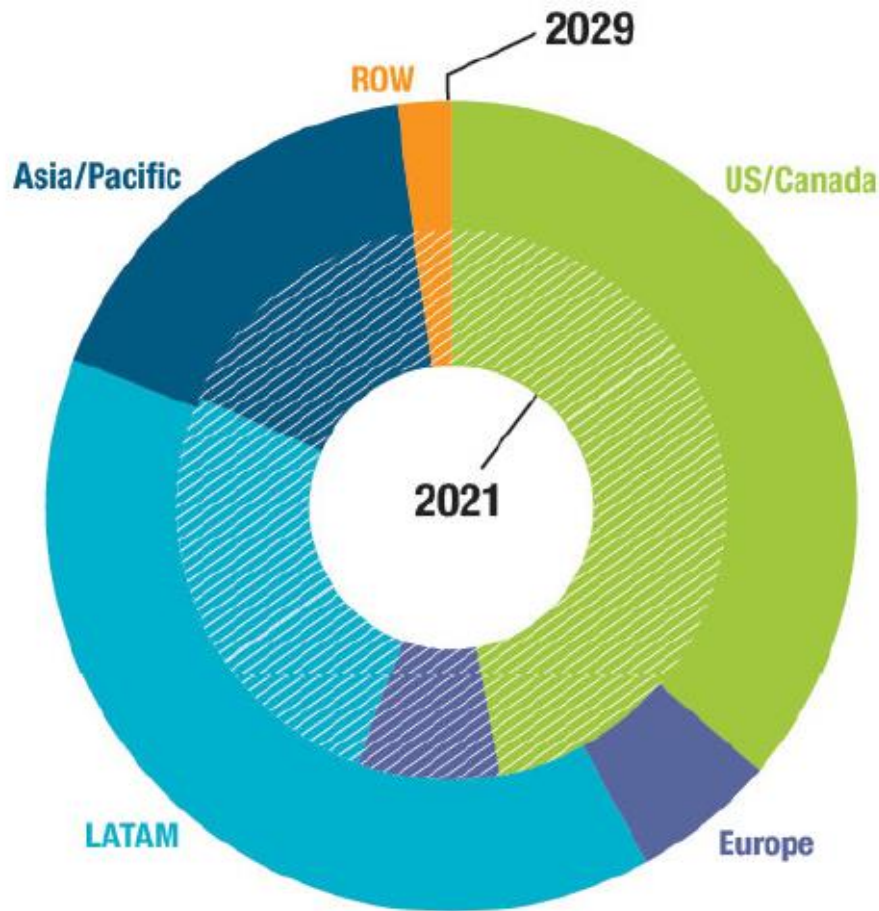


# Why are renewals blocking new uses & products



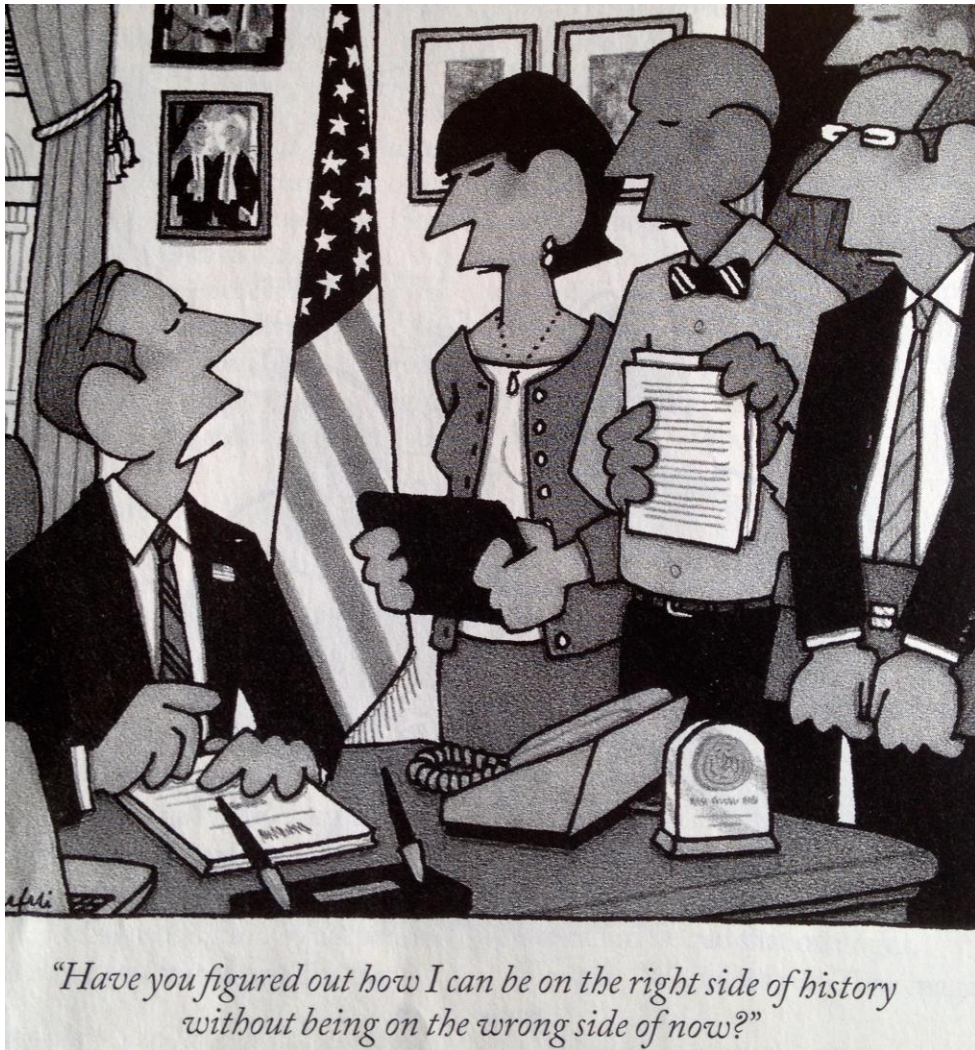
- At least 5-6 years are lost for new uses/ new products
- Assuming 0.5-1 M EUR investment for a MPCA renewal process (zero return for applicants): **at least 500-1000 demonstration field trials could be done**
- Resources capacity at MSs as well as Applicants are blocked for at least 5 years (no new uses/products)





- Europe has a small market share today (7%) and it is not expected to grow at the same pace (according to market projection) unless major major policy changes are implemented.
  - North America (about 50%) and South America (25%) represent the major markets for microbial products and are expected to grow, driven by Brazil and US.
- Smaller and fragmented markets, longer timelines, highest uncertainty on investment;
  - Development of biocontrol driven by agronomic conditions and challenges happening outside of Europe.

- **The renewal processes (a.s. and products) under Reg. 1107/2009 are blocking extensions of use and new products. 85% of Microorganisms potential is blocked** by the procedures and timelines → to continue for many years as the MPCA enters the next renewal cycle.
- **Immediate action is needed** if MSs want to deliver new uses and new product to the growers (due to the number of microorganisms locked under renewal processes)
- The renewals are driving the investment of business operators:
  - Investment is moving outside of Europe due to the status quo on 1107/2009 procedures
  - Consider the new questions being place, new data requests, the sense of zones for MPCA
  - **Investment should be moved to growers' field demonstrations and training programs to improve uptake of MPCP use and its integration in IPM programs for arable crops.**



Source: The New Yorker, 7<sup>th</sup> April 2014 (p. 54)

- The ZAPID workshop recognized that prioritization is needed at MS level.
- Farmers need tools urgently
- Microbial products exist with many label extension and mutual recognition opportunities
- Renewal process should not delay these opportunities reaching farmers (by using the existing approved endpoints)





Thank you

