



Council of the European Union  
General Secretariat

**Brussels, 09 December 2022**

**WK 17337/2022 INIT**

**LIMITE**

**AGRI  
PESTICIDE  
SEMENCES  
AGRILEG  
ENV  
PHYTOSAN  
CODEC**

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## **MEETING DOCUMENT**

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**From:** General Secretariat of the Council  
**To:** Working Party on Food and Food Systems (Pesticide Residues)  
Working Party on Plants and Plant Health Questions (Pesticides/Plant Protection Products)

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**Subject:** Working Party on Plants and Plant Health Questions (Pesticides/Plant Protection Products) on 7 December 2022 - Agenda item 1: EC initiatives to bring biological alternatives to the market

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Following the Working Party on Plants and Plant Health Questions (Pesticides/Plant Protection Products) on 7 December 2022, delegations will find in annex the presentation given by the Commission services, on the above subject.



# EC initiatives to bring biological alternatives to the market

SANTE E4

5.1.2.e

*Council Working Party on Pesticides*

*7 December 2022*

# Farm to Fork and Sustainable use of pesticides

## From Farm to Fork:

Our food, our health, our planet, our future

The European Green Deal

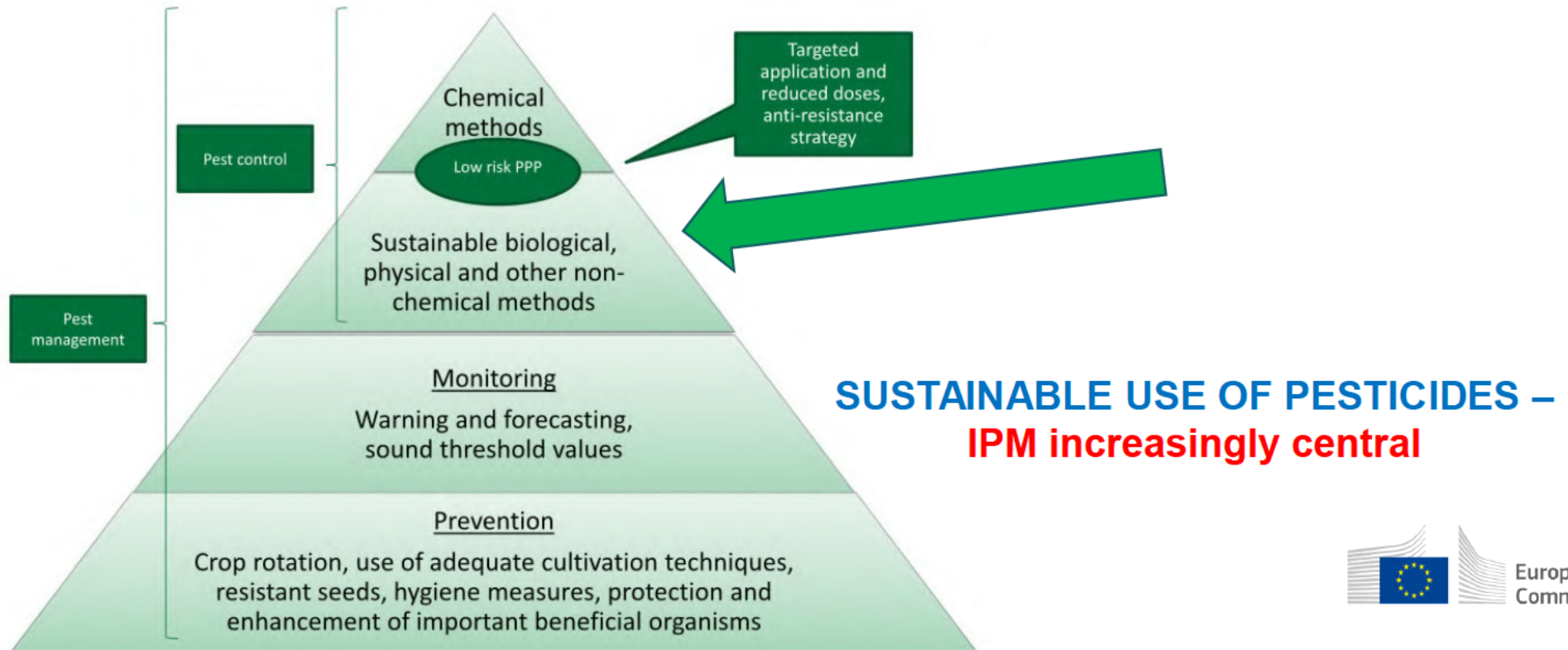


The use of pesticides in agriculture contributes to pollution of soil, water and air. The Commission will take actions to:

- ✓ reduce by 50% the use and risk of chemical pesticides by 2030.
- ✓ reduce by 50% the use of more hazardous pesticides by 2030.



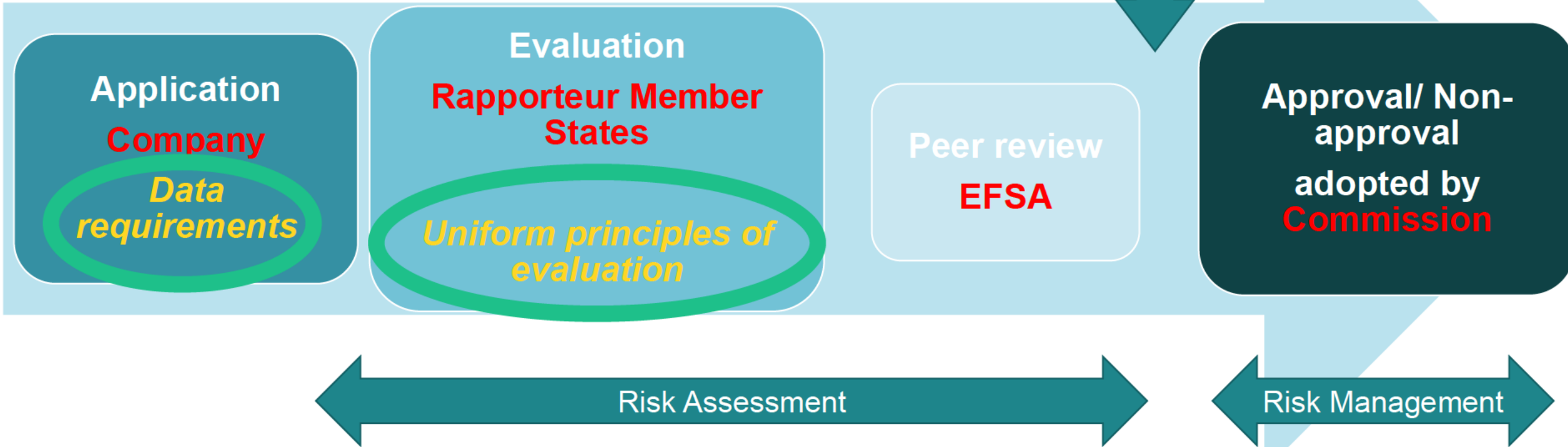
Organic farming is an environmentally-friendly practice that needs to be further developed. The Commission will boost the development of EU organic farming area with the aim to achieve **25% of total farmland under organic farming by 2030**.



# Regulation 1107/2009

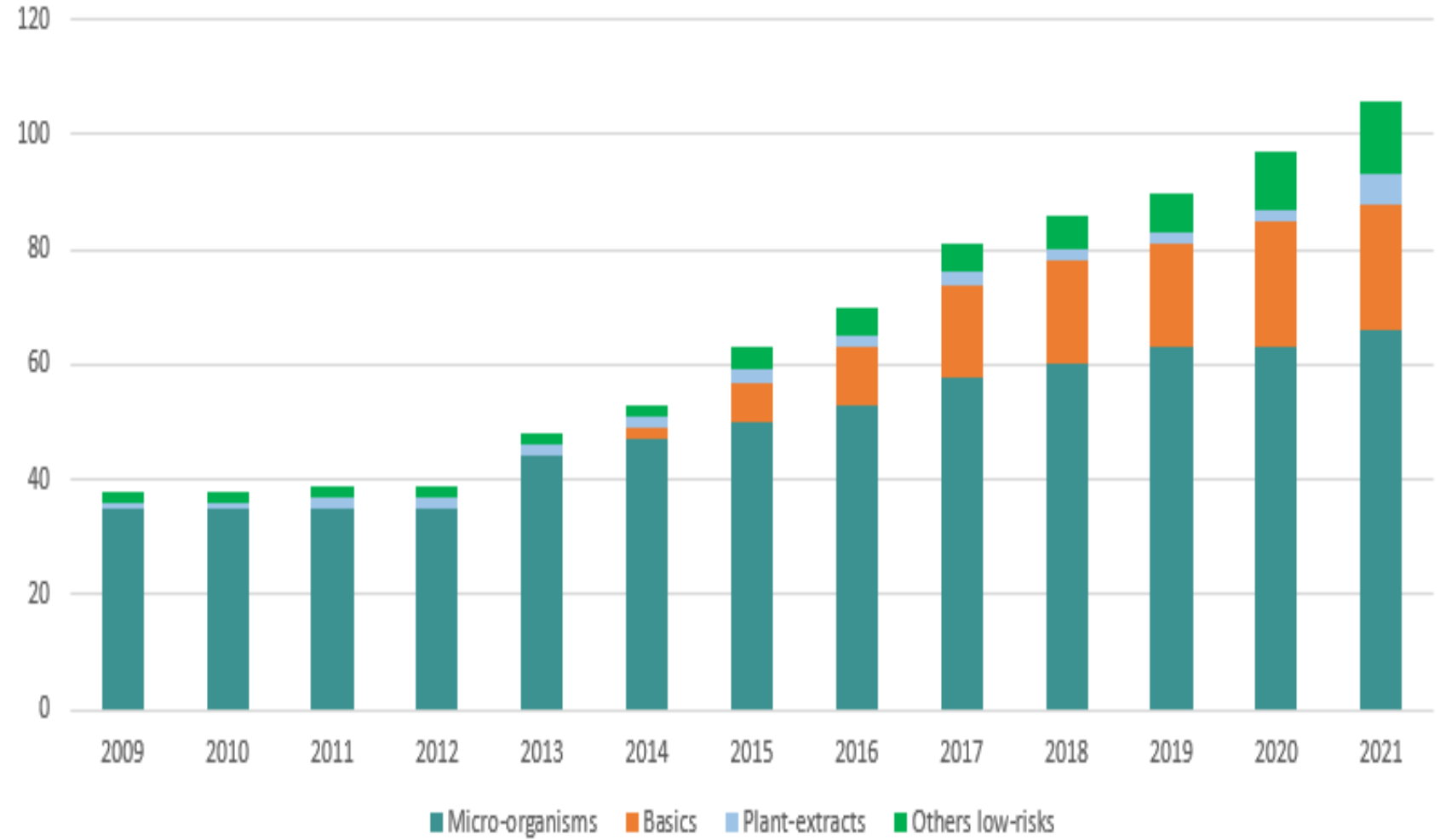
## Active substances (EU level)

- Standing Committee for Plants Animals Food and Feed (PAFF, 27 MS)
- Restrictions of use and/or risk mitigations could be set



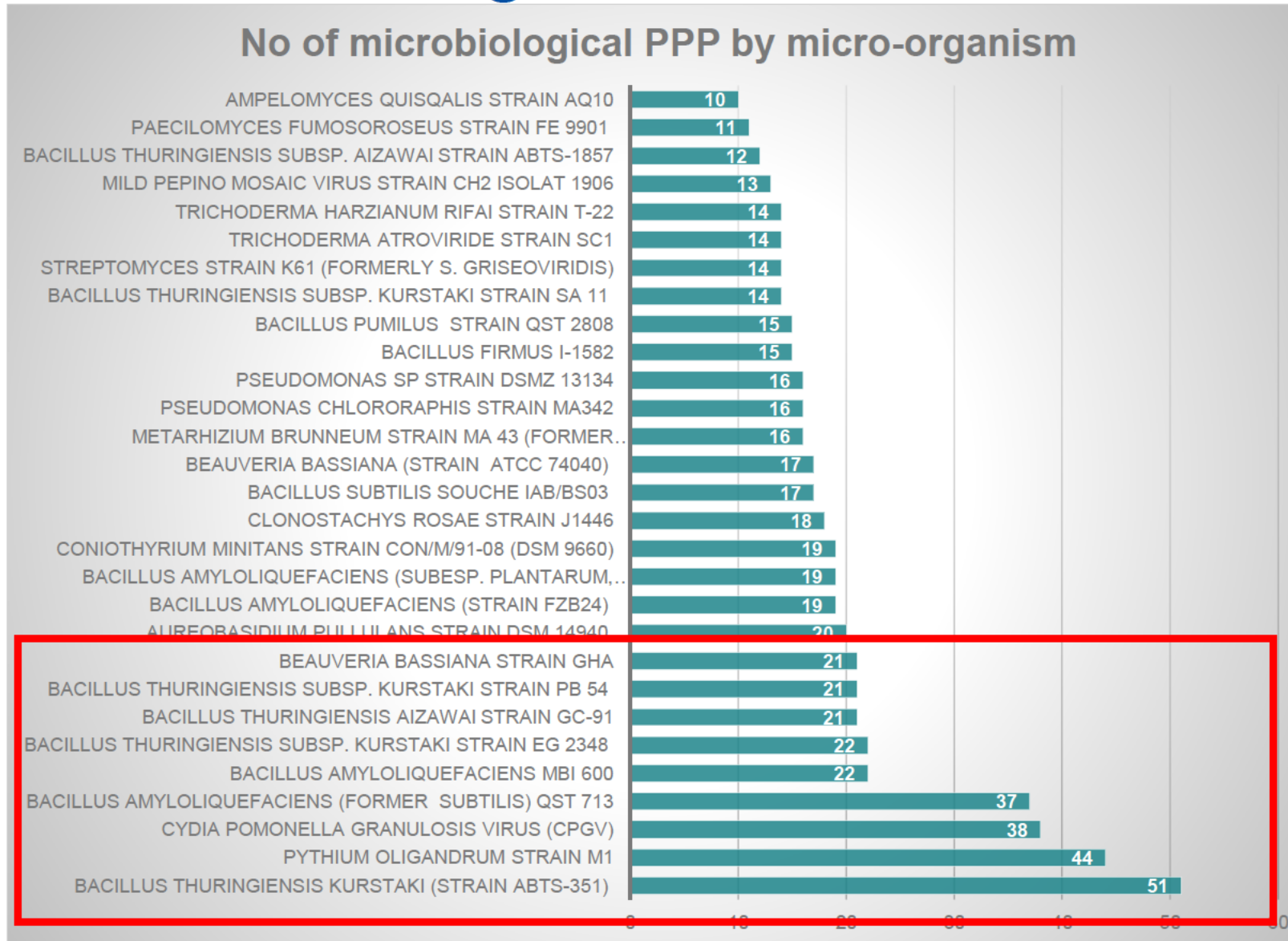
# Revision of EU framework: why focusing on micro-organisms?

Low hazard active substances approved in EU



“Low risk” substances?  
Organic farming?

# No of microbiological PPP authorised in EU?



# Uses in crops of some of the microbiological PPP?

*n.b. preliminary analysis based on microbiological-PPP authorised in BE, DE, FR, IT, NL*

<b>Top 5 microbial strains authorised in EU</b>	<b>Total Number of Crops authorised for use</b>	<b>Fruits</b>	<b>Vegetables</b>	<b>Arable crops</b>	<b>Cereals</b>
Bacillus thuringiensis kurstaki	78	7	67	4	0
Pythium oligandrum	22	1	15	3	3
Cydia pomonella granulovirus	6	6	0	0	0
Bacillus amyloliquefaciens	64	15	40	8	1
Beauveria bassiana	59	11	45	3	0

# Amendment of Regulations on micro-organisms:

- ❑ **Reg. 283/2013** (data requirements AS): «*which data are needed to an applicant to submit a dossier of an AS?*»
- ❑ **Reg. 284/2013** (data requirements PPP): «*which data are needed to an applicant to submit a dossier of a PPP?*»
- ❑ **Reg. 546/2011** (Uniform Principles) + **Annex II Reg 1107/2009**: «*evaluation of AS and PPP, decision making criteria, low-risk status?*»

**New Regulations applicable since 21 November 2022!!!**



# Principles of the revision

- ❑ New scientific approaches:
  - ✓ Stop mimicking chemical approach
  - ✓ Evolution of science and technology
  - ✓ Experience with current applications
  
- ❑ “Need-to-know” approach (i.e. which questions are relevant to answer?)
  
- ❑ Tiered-based approach (mandatory and conditional requirements)
  
- ❑ Increasing quality of dossiers and assesment

# Biological properties (Reg 283/2013)

- **Central role** in data requirements (e.g. production of “metabolites of concern”)

## Biological properties (WoE)



# Main comments from stakeholders consultation

Improvements from «old» Regulations:

- ✓ **increased clarity**
- ✓ **clear deviation from chemicals**
- ✓ **solid grounds on biology and ecology**
- ✓ **weight of evidence can replace many animal studies**

# Main comments from stakeholders consultation

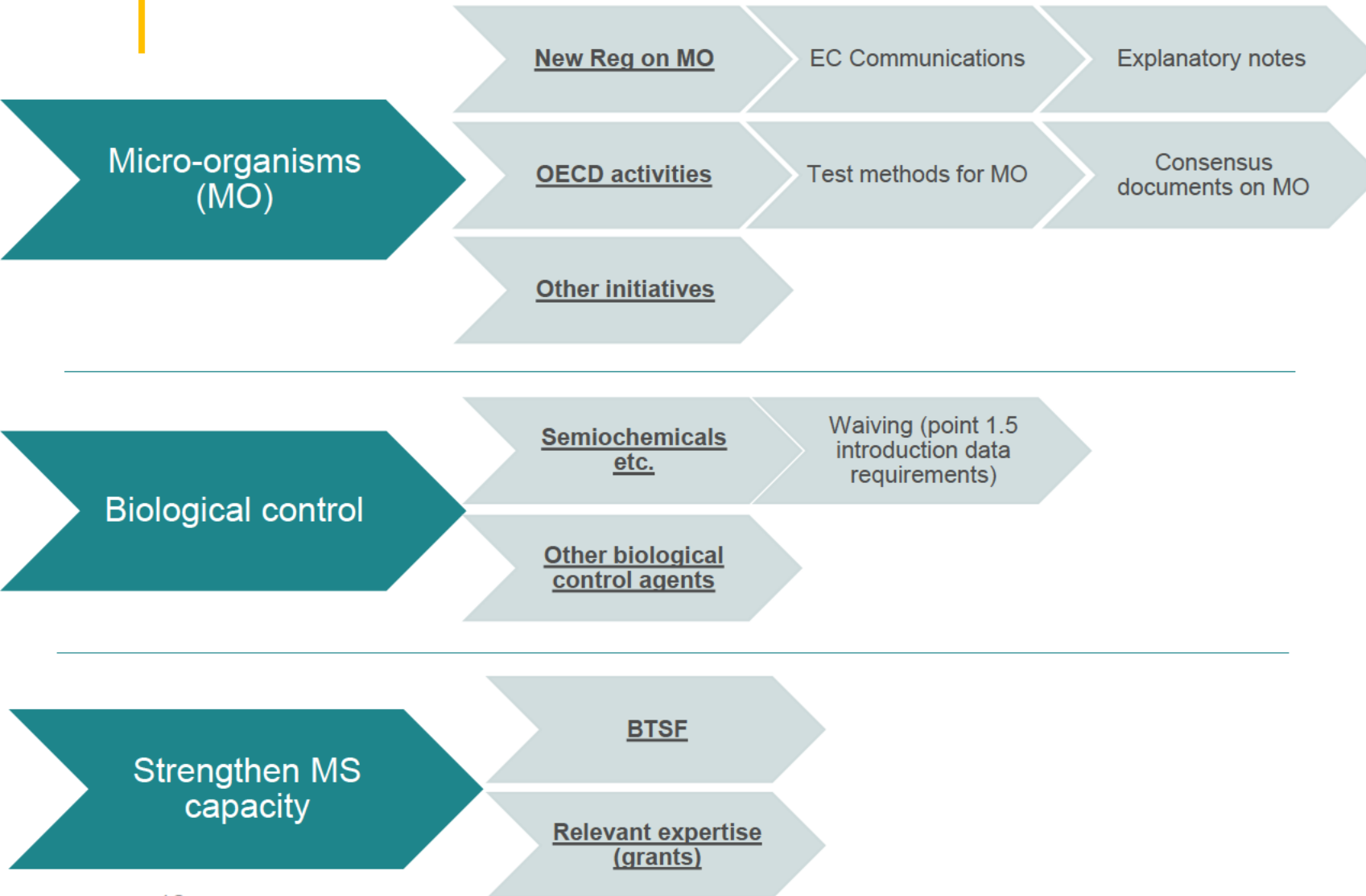
## Possible pitfalls:

- **interpretation issues: flexibility VS legal certainty**
- **harmonisation and expertise among risk assessors**
- **not solving the lack of capacity among competent authorities**



- ✓ **«explanatory notes» and other supporting documents**
- ✓ **Better Training for Safer Food**
- ✓ **Grants for MS**
- ✓ **Biopesticides WG (...and others)**

# Road to 2030!



2030



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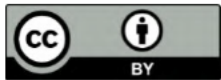


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