



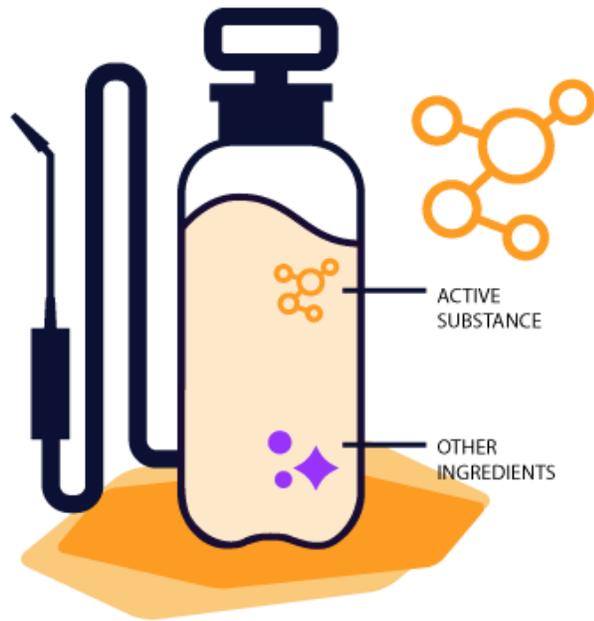
# Micro-organismi in biopesticidi: Regolamenti UE nel contesto Farm to Fork e loro modifiche

European Commission, SANTE E4 – Pesticides and Biocides

Domenico Deserio

*Webinar sulla strategia europea Farm to Fork, 26 Luglio 2022*

# Active substance and Plant Protection Product (PPP)



- **Active substances**: components of PPP that actually prevent, destroys or control harmful organisms (the so-called pests, such as insects, fungi and weeds) or plant diseases.

→ Approved at **EU level**

- **Plant protection products**: mixtures containing one or several active substance(s) and other ingredients (so-called co-formulants).

→ Authorised at **Member State (or zonal) level**

# The regulatory lifecycle for PPP

Regulation 1107/2009  
(placing on the market)

Directive 2009/128/EC  
(sustainable use of  
pesticide)\*

Regulation 396/2005  
(Maximum Residue  
Levels)

*To sell PPP to users*



*To use PPP properly*



*To sell PPP treated food  
products*

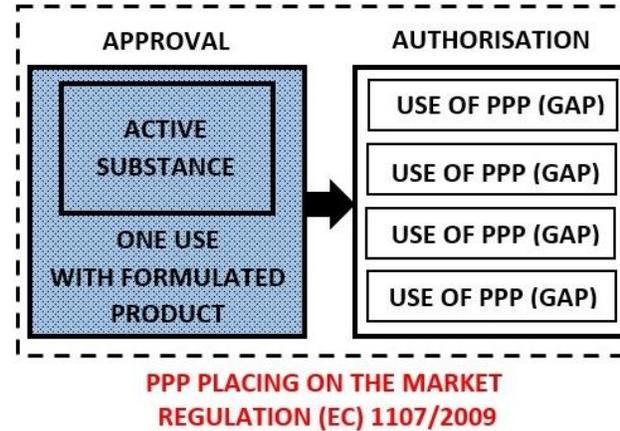


# Regulation 1107/2009 (placing on the market)



## Active substances

AS may be used in PPP (1 safe scenario)



## Plant protection products

PPP may be used under certain conditions (dose, frequency, conditions and restrictions)

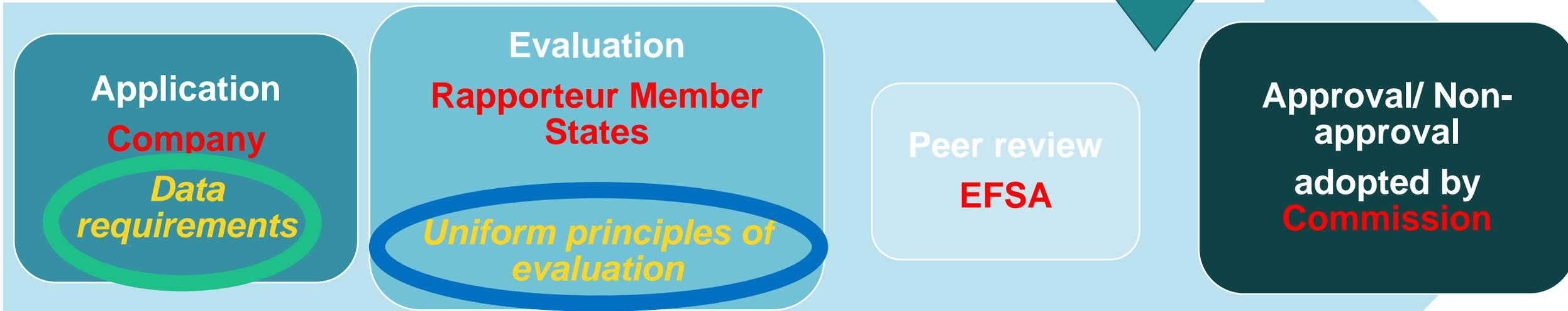


# Regulation 1107/2009

Active substances (EU level)

Process:

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



• **Reg. 283/2013** active substances

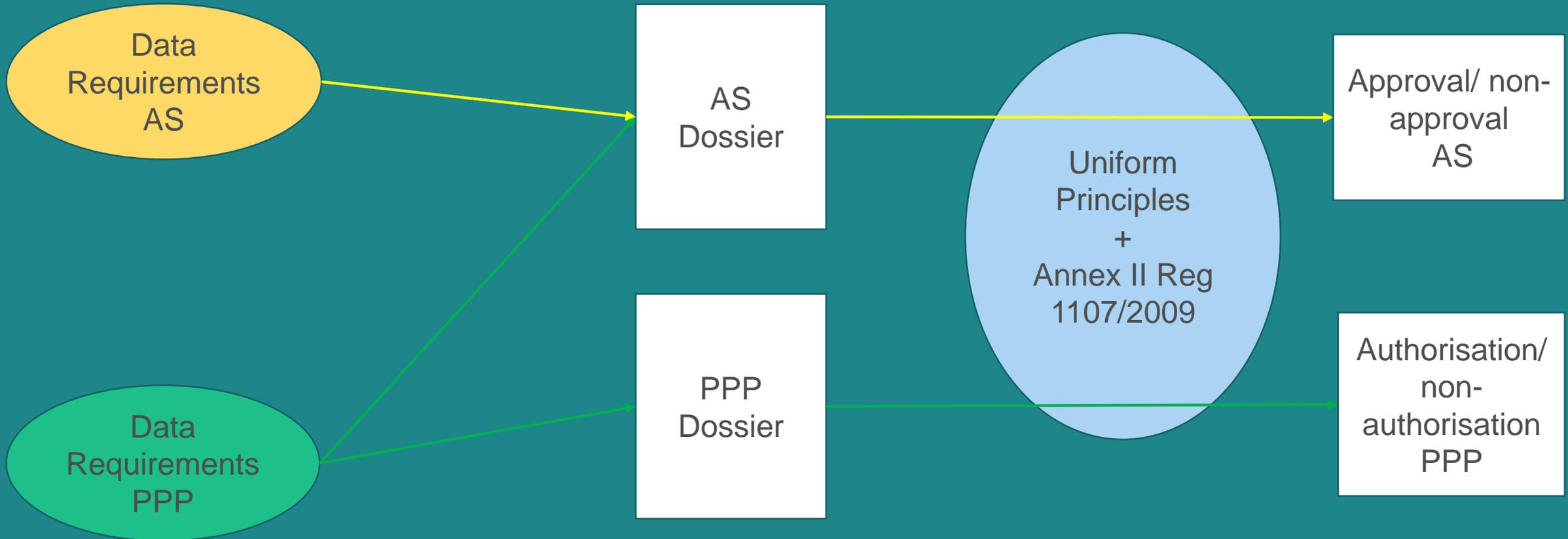
• **Reg. 284/2013** plant protection products

• **Reg. 546/2011** Uniform Principles + Annex II Reg 1107/2009



# How the Regulations interact

Reg 1107/2009



# Farm to Fork and Sustainable use of pesticides

## From Farm to Fork:

Our food, our health, our planet, our future

The European Green Deal



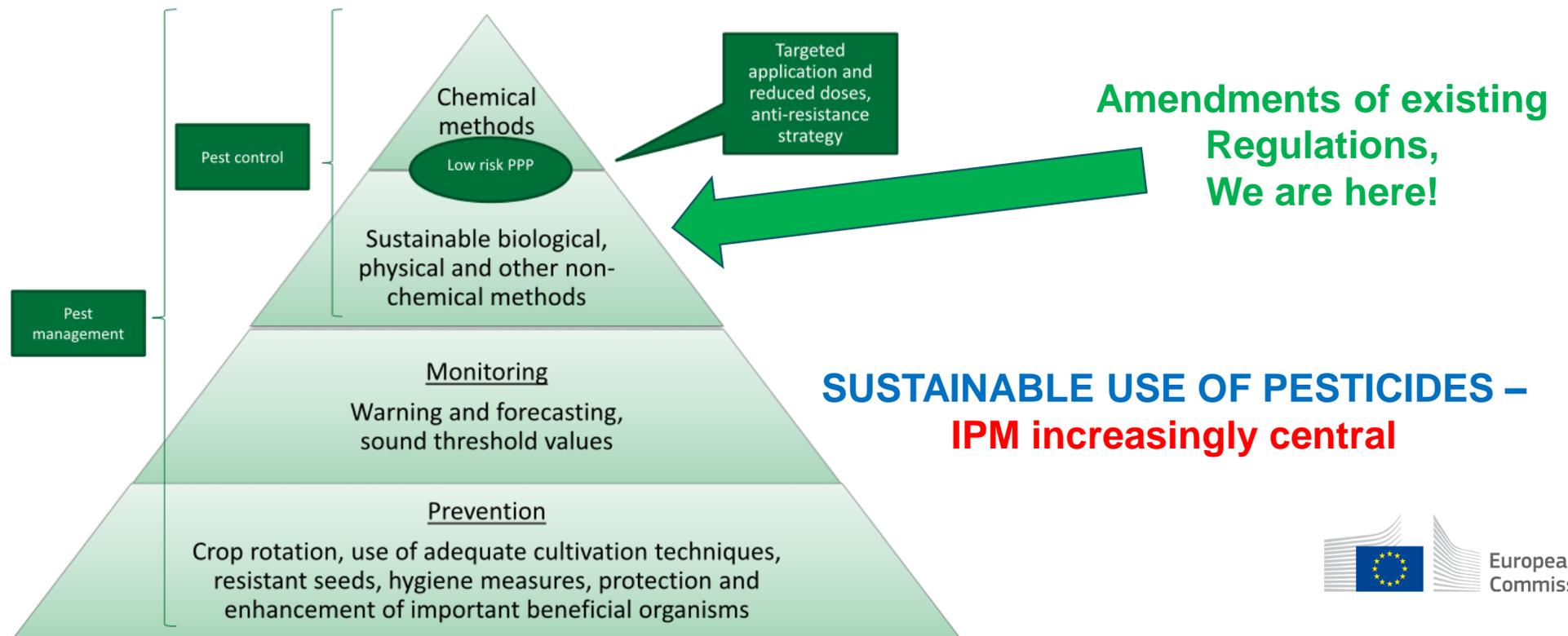
The use of pesticides in agriculture contributes to pollution of soil, water and air. The Commission will take actions to:

✓ 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.



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

Low hazard active substances approved in EU



# Reg involved in the amendment:

- ❑ **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**: «*how risk assessors should evaluate AS and PPP, and which are the decision making criteria?*»

# Principles of the revision

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

# Biological properties (Reg 283/2013)

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

## Biological properties (WoE)



# Tiered-based approach

Example on **pathogenicity** to humans (Section 5 Reg 283/2013)

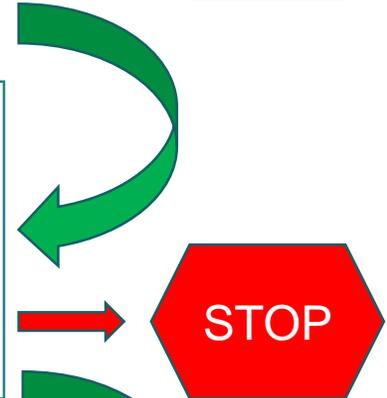
## 1- Weight of evidence approach (WoE)

- **Biological properties**
- **Medical data**
- Others



## 2- Pathogenicity and infectivity studies (new data generation)

- Acute oral, and/or
- Acute intratracheal/ intranasal, and/or
- Intravenous/Intraperitoneal or subcutaneous test

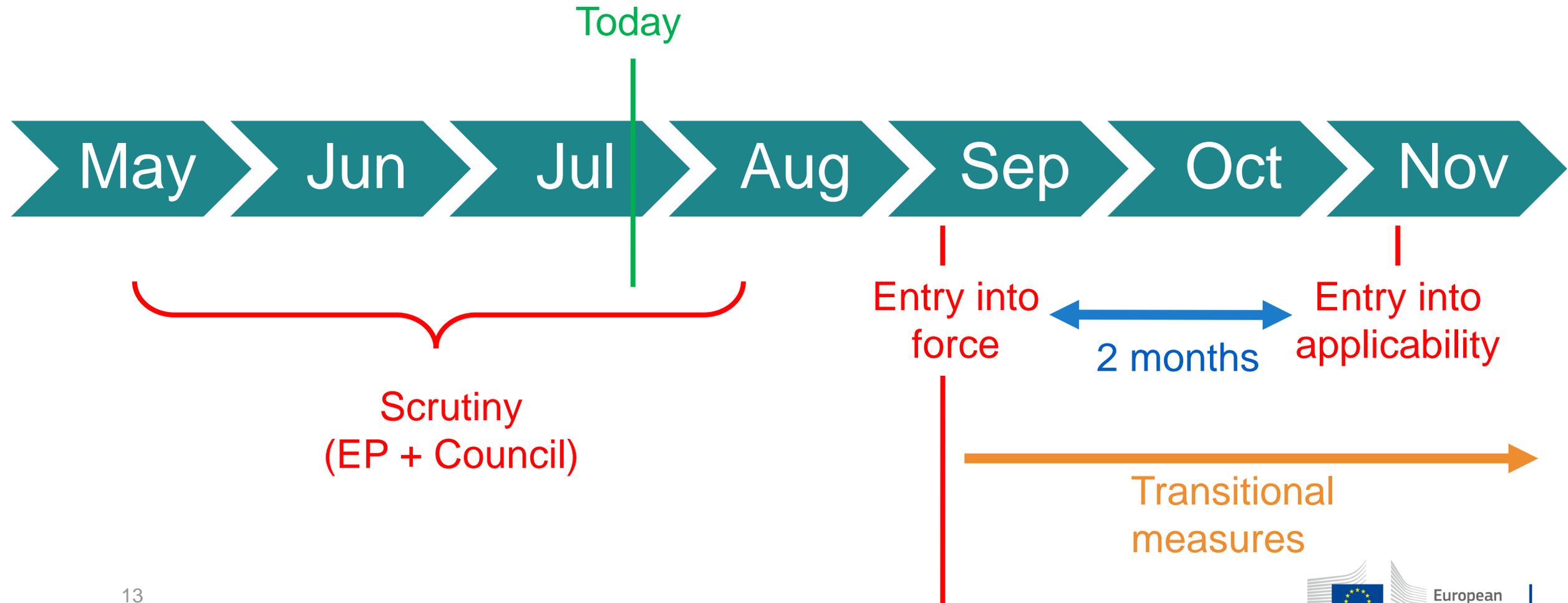


## 3- Specific pathogenicity and infectivity studies (new data generation)

- If WoE and pathogenicity and infectivity studies require further investigation



# Timings 2022



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# Thank you



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