



**CropLife**  
EUROPE

**Active Substances  
evaluations and approvals**  
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6<sup>th</sup> March 2024

# Health and prognosis of EU farmers crop protection toolbox ?

**Attrition rate in  
AS renewals**

**Innovation rate  
from new AS  
approvals**

**Signs, Symptoms  
and Challenges**

**Opportunities**

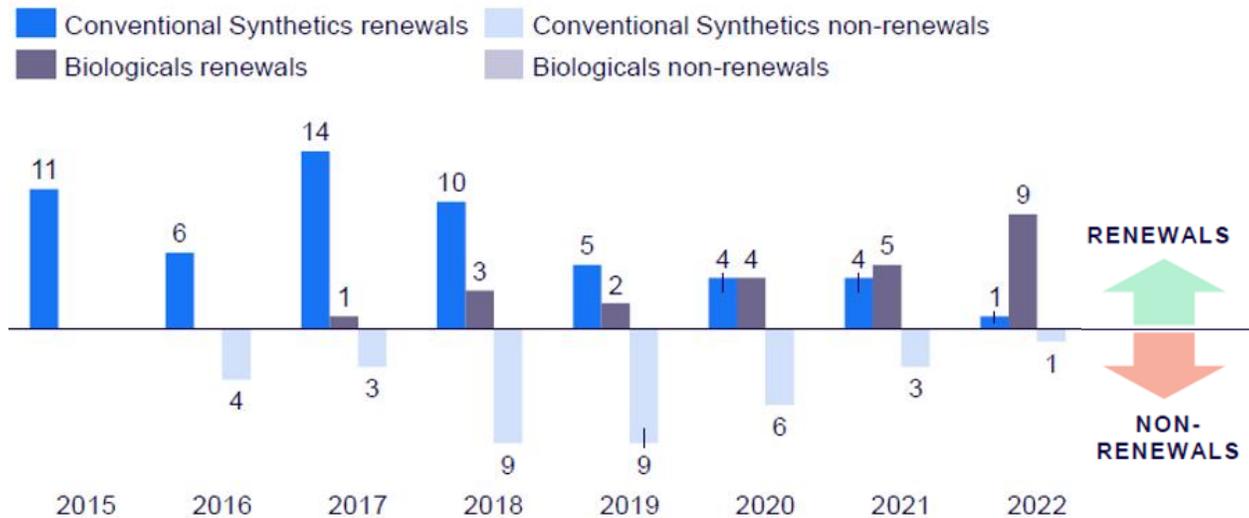


# Attrition rate in AS renewals

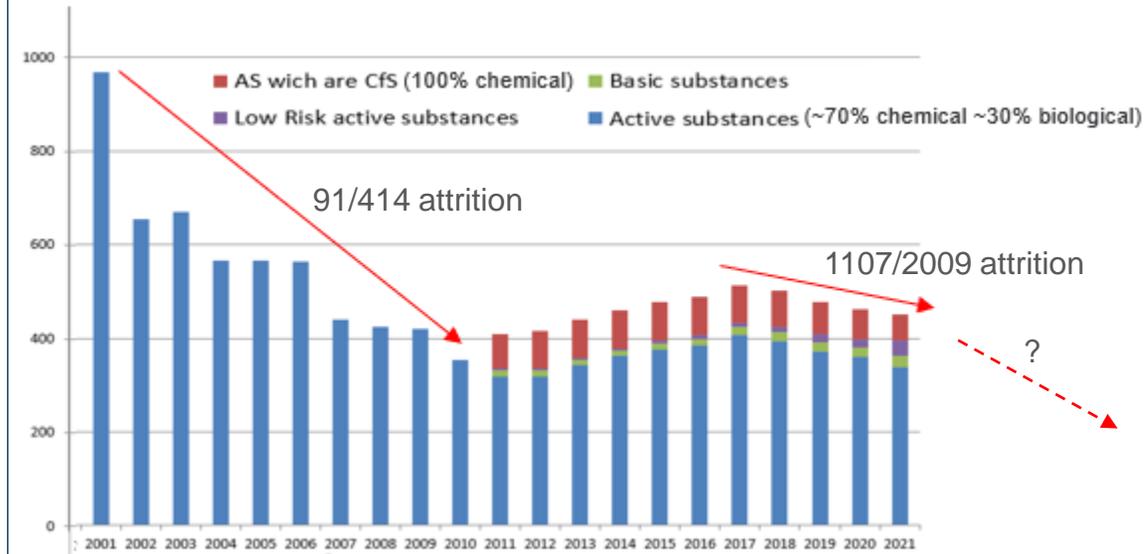
# Half of synthetic AS decisions = non-renewal / glasshouse use only

Average of 26 decisions per year (AS renewal and new ASs)

## Active Substances Renewal decisions



## Approved Active Substances evolution

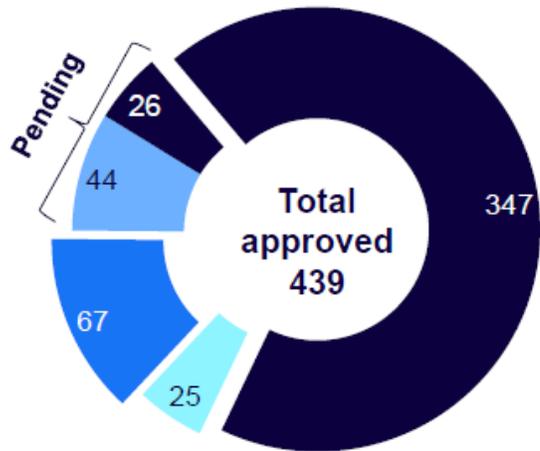


# 2/3<sup>rds</sup> of synthetic ASs pending expiry/renewal decision 2024-26

>100 decisions/expiry per year (222 synthetic ASs, 20 biological ASs and 70 new AS)

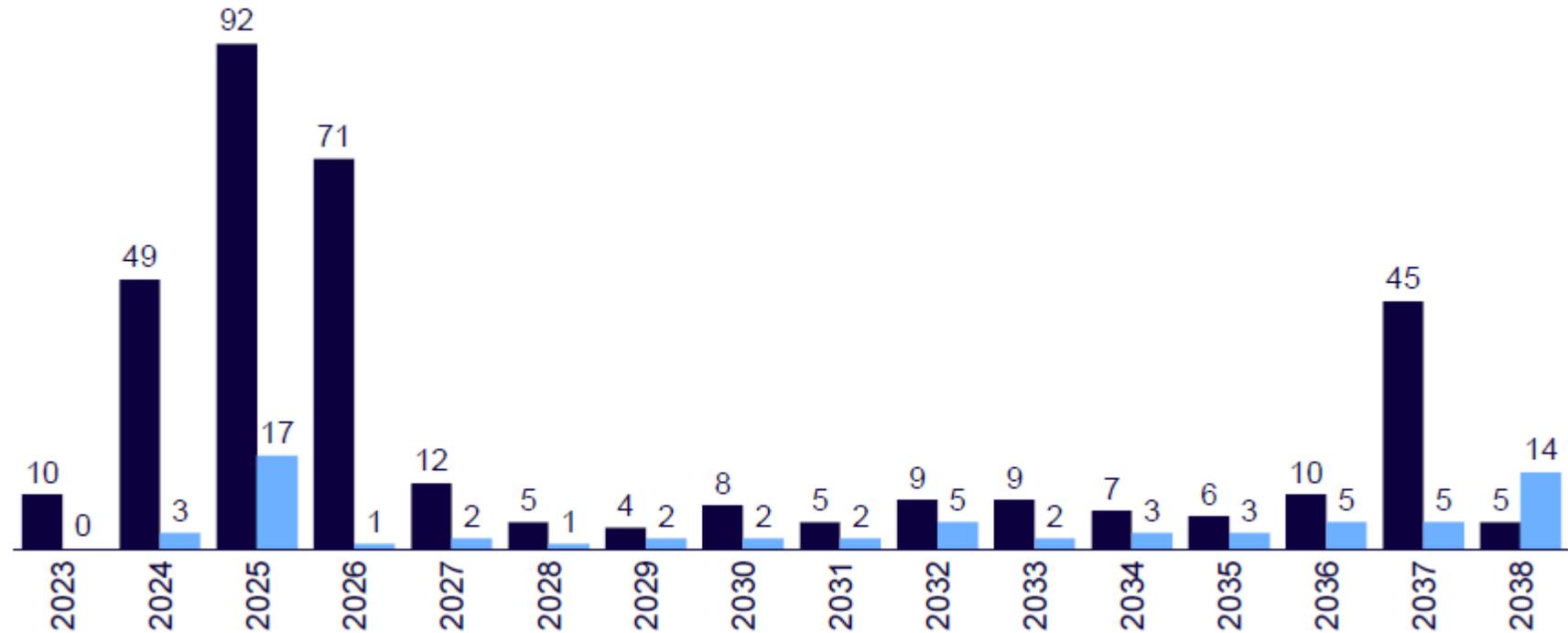
## Approved actives

- Approved synthetic AS
- Pending synthetic AS<sup>2</sup>
- Basic substances<sup>1</sup>
- Pending Biologicals
- Approved Biologicals



## Expiry dates of approved active substances

- Synthetic AS
- Biologicals





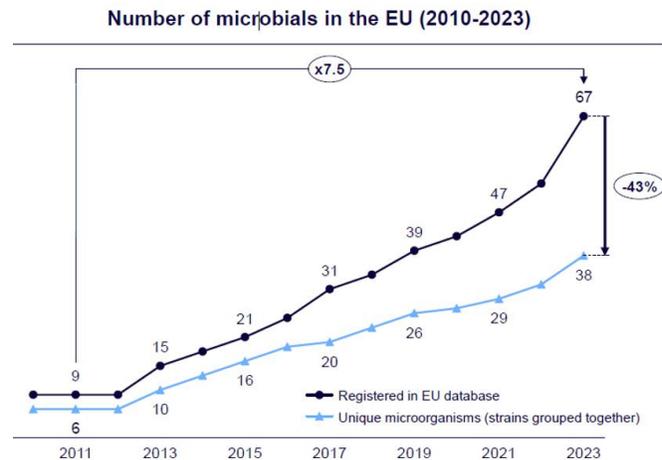
# Innovation rate from new AS approvals

# Trends in New active substance approvals

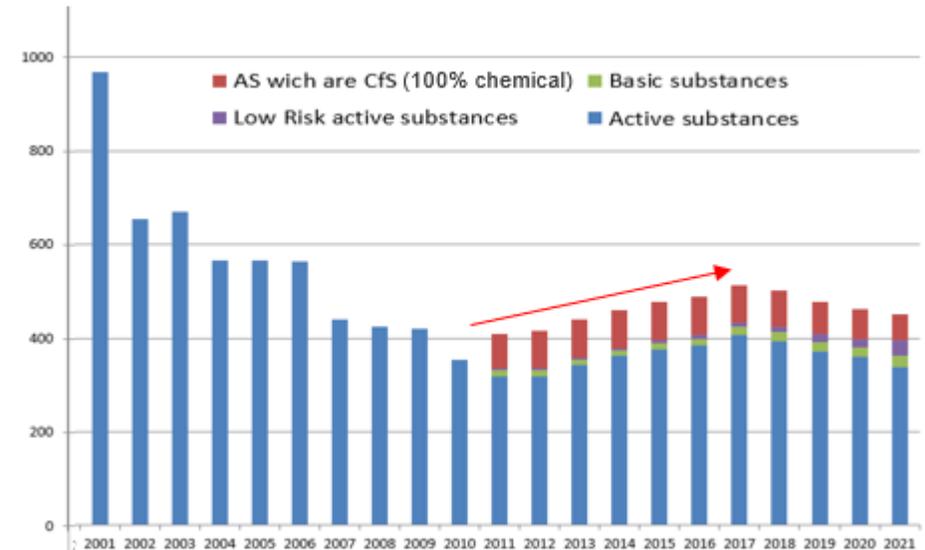
- 🌱 Dramatic reduction in new synthetic AS applications, last new synthetic AS approval Jul 2019
- 🌱 Steady stream of new biological AS applications, but insufficient approvals to off-set loss of ASs under AS renewal

## Other key drivers of Active Substance trends

- 🌱 Belated approval of >60 new AS submitted under 91/414 and available under national provisional authorisations
- 🌱 24 Basic active substances of limited professional ag utility
  - 🌱 Beer, Cow milk, Fructose, Salt, Sucrose, Sunflower oil, Vinegar, Whey
- 🌱 Listing of separate microorganism strains as unique entries



## Approved Active Substances evolution





# Signs, Symptoms and Challenges

# Welcome signs from Commission, MS and EFSA activity

- Differentiated data requirements and guidance for Microorganisms
- Similar work focussed on semiochemicals on-going
- Targeted funding for more biological experts in MS authorities
- Preparation of a compendium on risk mitigation measures RMMs
- EU Precision Application Task Force EUPAF
- Prioritisation of Guidance Document development

## Watchouts

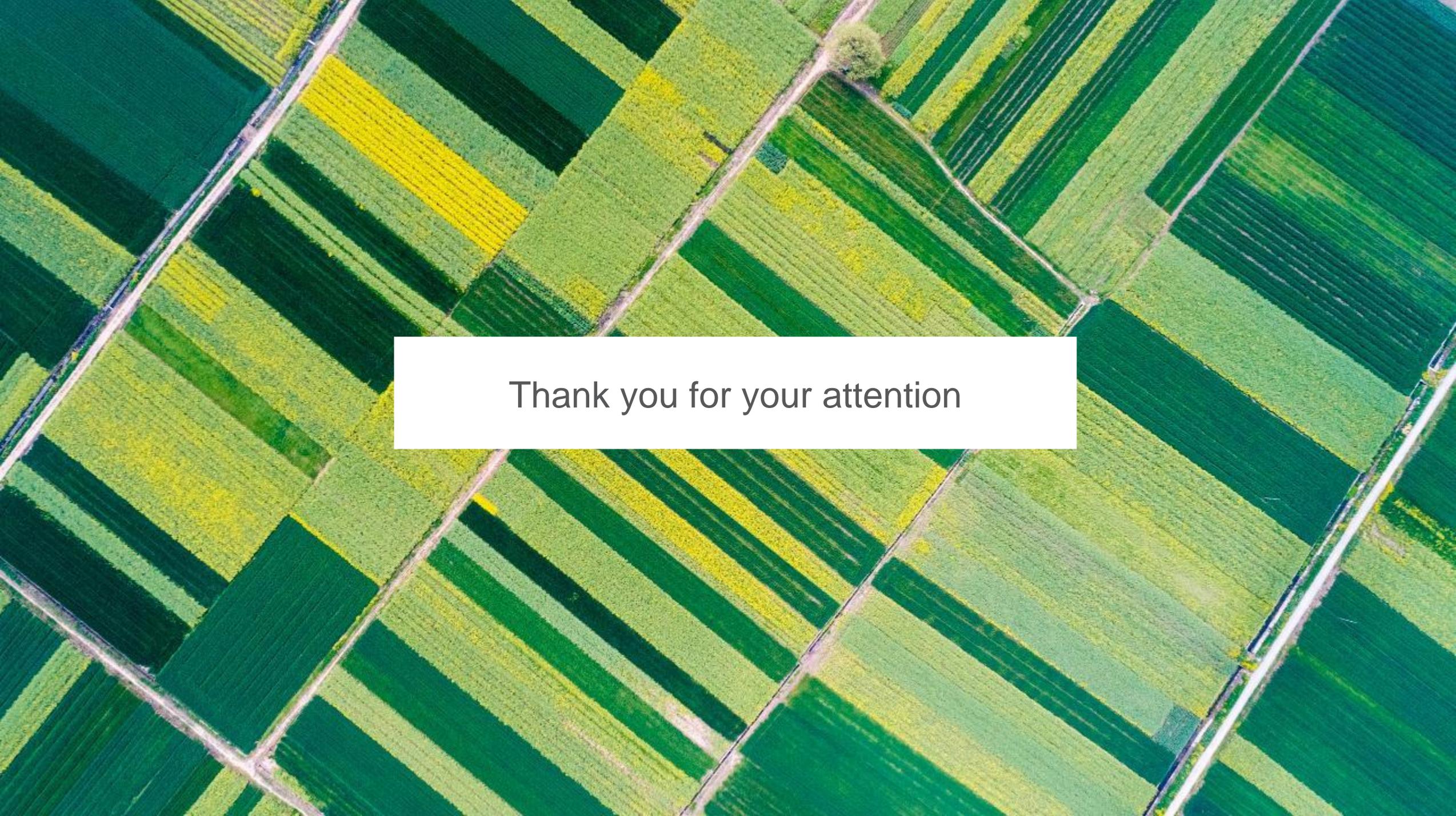
- Delay between EFSA receiving and accepting assessment/evaluation report threatens EFSA / ECHA timeline alignment
- Concern about divergence in ED guidance EFSA / ECHA
- Concerns about predictability and consistency of assessments
  - Reduced acceptance of tiered testing & assessment strategies to minimise animal use
  - Weight of evidence approach often not applied in practice
- Negative trends in AgbioInvestor time and cost to market study (discovery, development, and registration)<sup>9</sup>



# Opportunities

# Opportunities to mitigate threat to EU farmers CP toolbox

- Encouraged that ZAPID workshop tries to define further practical steps that can help encourage innovation
  - Low risk and biopesticide exploration projects to ensure timely assessment
  - Guidance Document feasibility check and periodic evaluation
- Additional guidance and targeted adaptation of data requirements for other biopesticide categories
- Look forward to publication and use of the RMM compendium to gain practical experience of this living document
- Meaningful guidance and practical use of all the derogations intended by the legislators
  - Negligible exposure
  - Art 4.7 on essential use
  - Art 51 extension of authorisations for minor uses
  - Art 53 emergency authorisations
  - Art 30 provisional authorisation



Thank you for your attention