



# Product authorization

## Follow up to the ZAPID workshop

CropLife Europe Annual Conference

6 March 2024,

Brussels, Belgium

Zsuzsa König,  
Unit E4 – Pesticides and Biocides  
DG Health and Food Safety

# The problems



Not keeping the **regulatory deadlines**  
**(REFIT 2020)**

**(UN)AVAILABILITY** of Plant Protection  
Products at MS level

Slow **ACCESS** to the market and lack  
of (non-chemical) active substances  
**ALTERNATIVES**

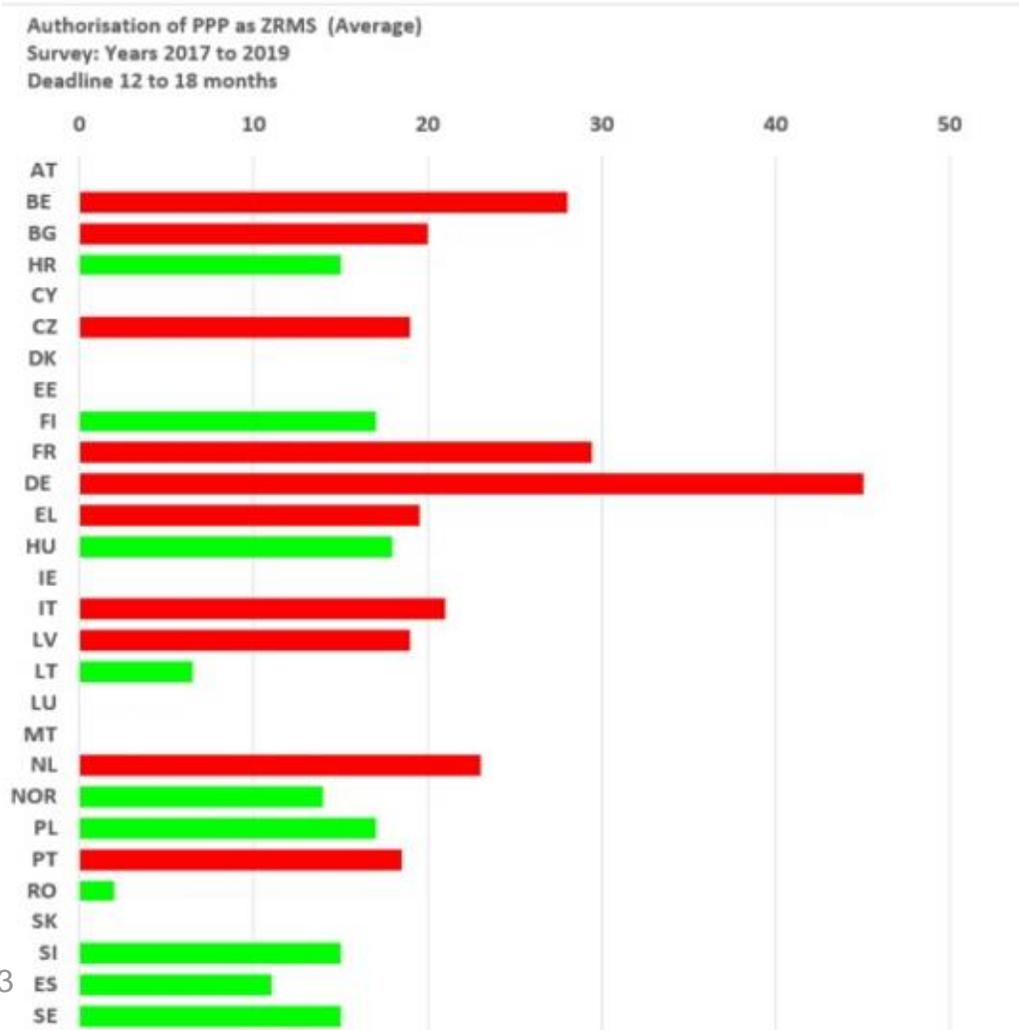
Less PPPs - more **RESISTANCE**

PPPs for **MINOR USES**

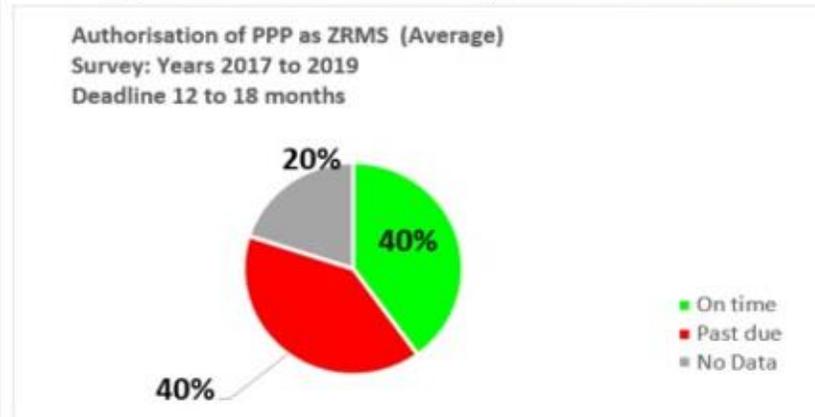
# Authorisation of a plant protection product - (legal deadline 12-18 months) #1

(COM staff working document 2022 - 1st survey: from 1 January 2017 to 31 December 2019)

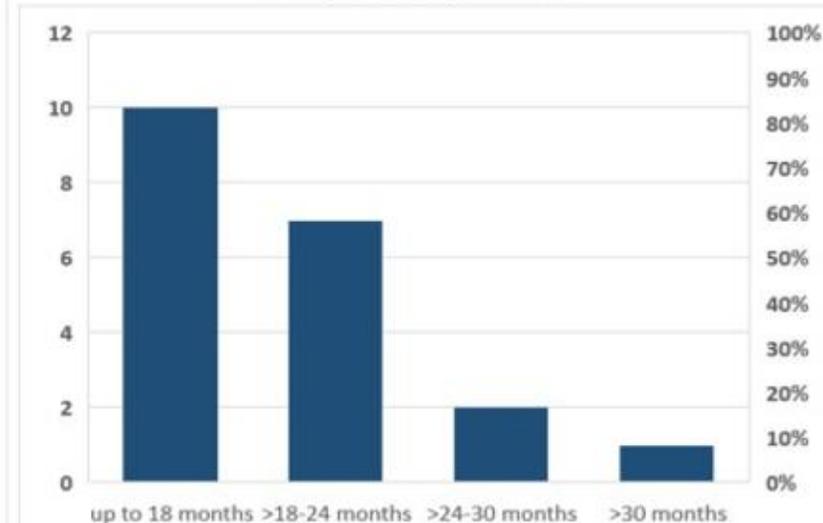
Average time per country to complete the procedure (months)



Percentage of countries within the legal deadline, exceeding the legal deadline and that did not provide information



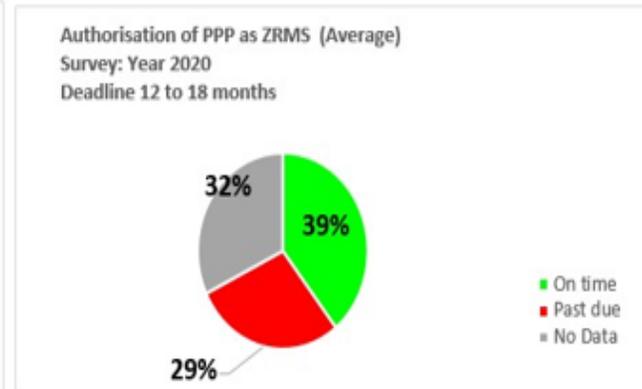
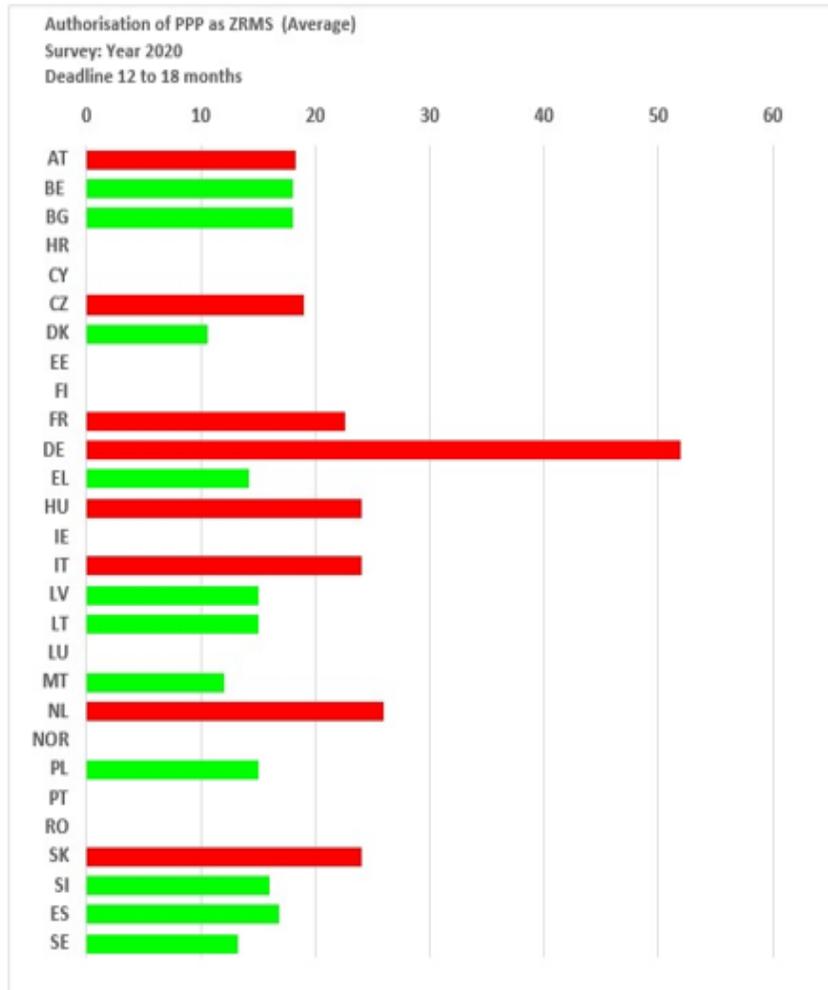
Number of countries grouped by the average timing in months to complete the procedure



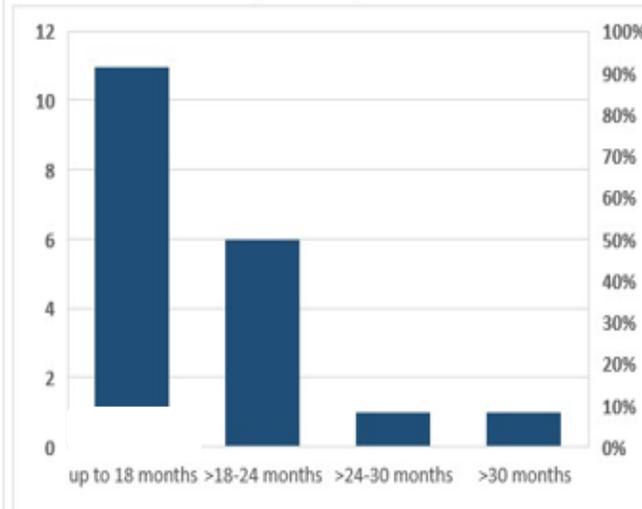
# COM staff working document 2022 - 2nd survey: from 1 January 2020 to 31 December 2020

## Average time in months per country to complete the procedure

## Compliance with the legal deadline



Number of countries grouped by the average time in months to complete the procedure

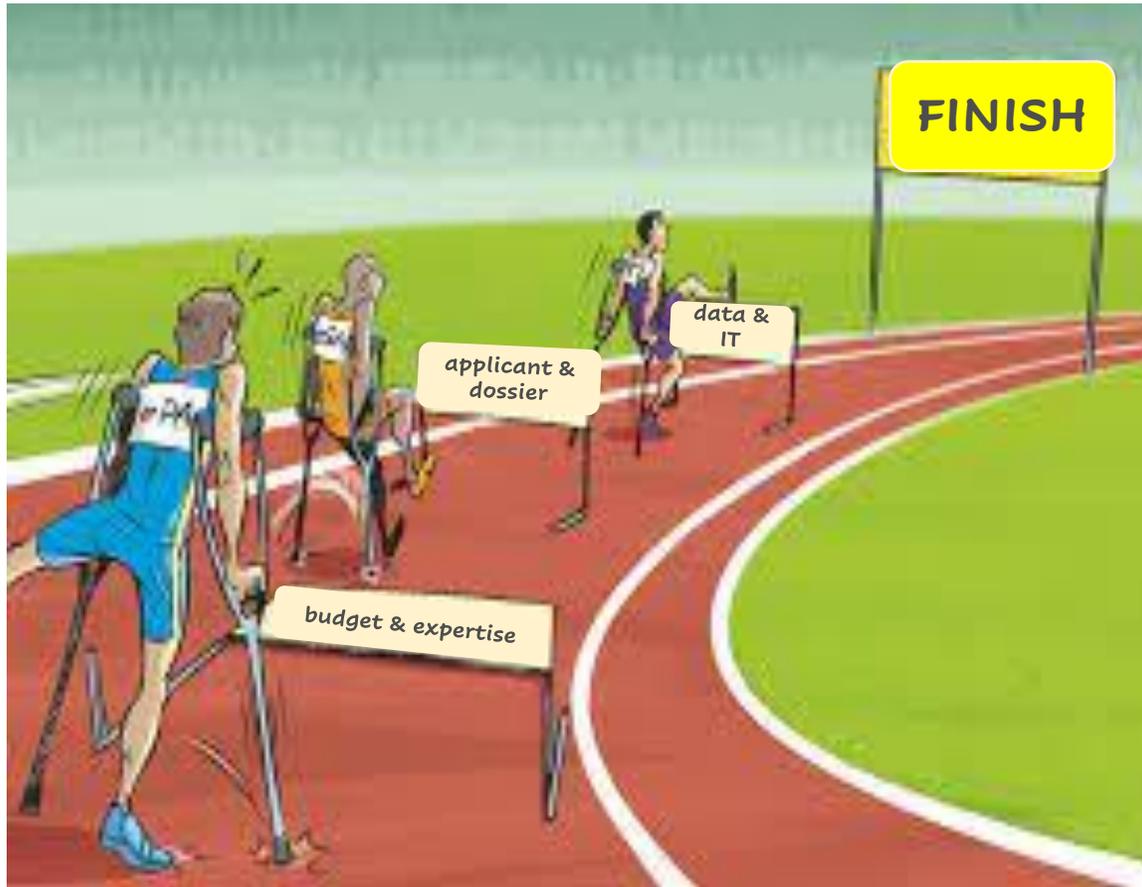


9

9

Authorisation of PPPs as ZRMS																											
EL	DE	FR	IT	PL	ES	AT	CZ	MT	NL	BE	SE	DK	LV	SI	LT	HR	HU	SK	BG	FI	IE	NO	PT	CY	EE	LU	RO
83	65	52	38	25	20	15	15	12	11	5	5	3	3	3	2	1	1	1	0	0	0	0	0	/	/	/	/

# Some Reasons/Hurdles



**DELAYS** (lack of staff/expertise? Administrative red-tape? Not sharing workload?)

**FEES**

**Lack of RINGFENCING of fees**

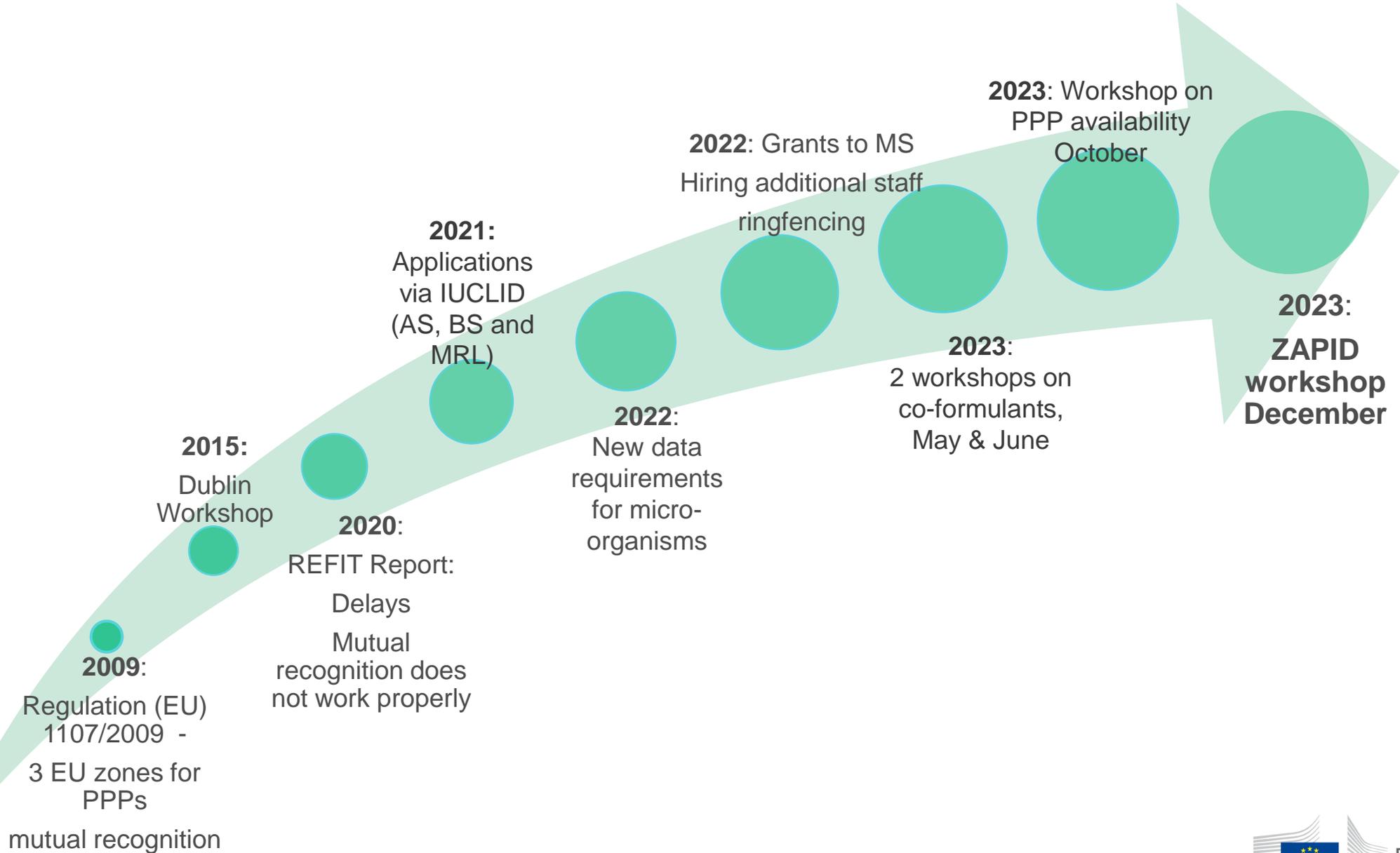
**(IN)COMPLETENESS** of AS/PPP dossiers

**IT related obstacles**

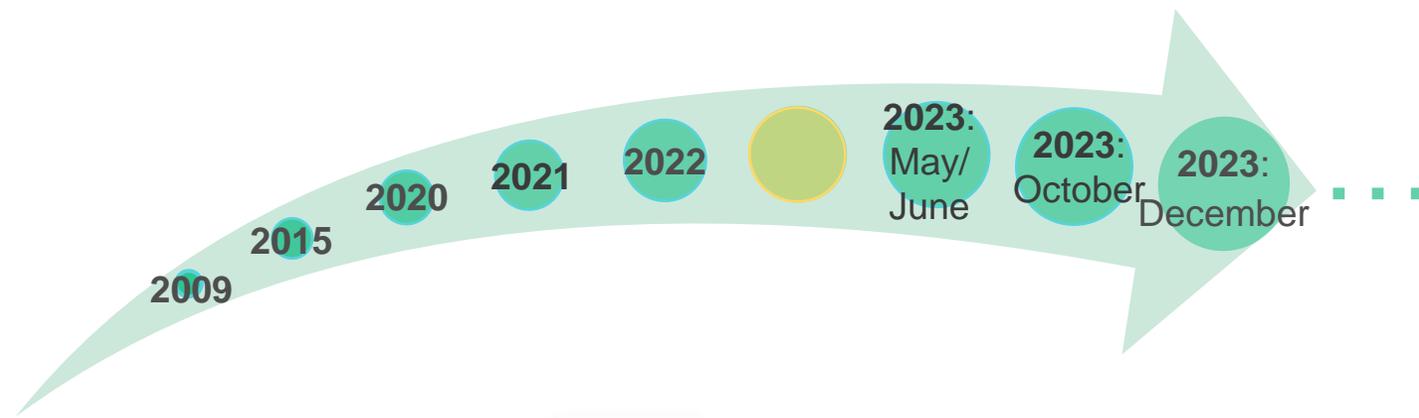
**INCREASING REQUIREMENTS** for the risk assessments

**APPLICANTS** do not ask for authorisation in MS (cost, administration)

Actual **USE** by the farmers



# 2022: Grants to MS



- Priorities:

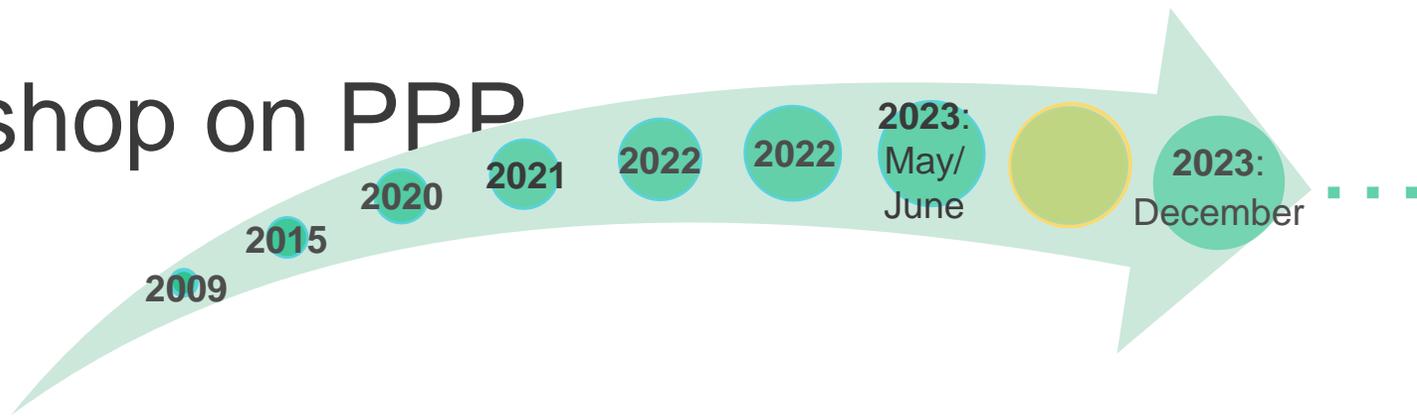
- to reduce delays in approval and authorisations
- to increase number of experts in microorganisms
- to ring fence the fees for the authorities actually carrying out the work

- Hiring additional staff

- €5 Million of total budget of 6 MS (AT, EE, ES, LT, LV, and SK)- € 3,4M EC contribution.



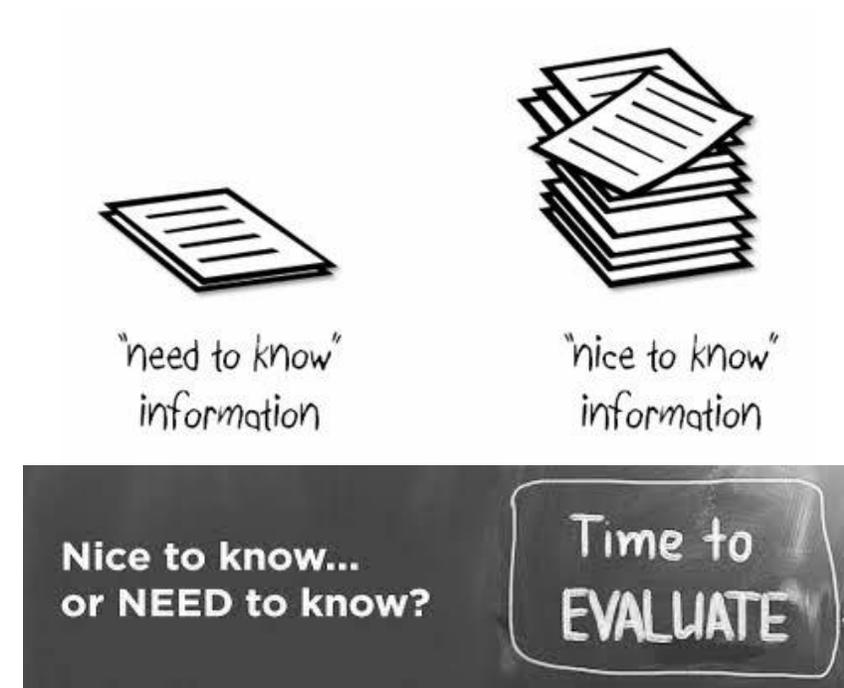
# 2023 October: Workshop on PPP



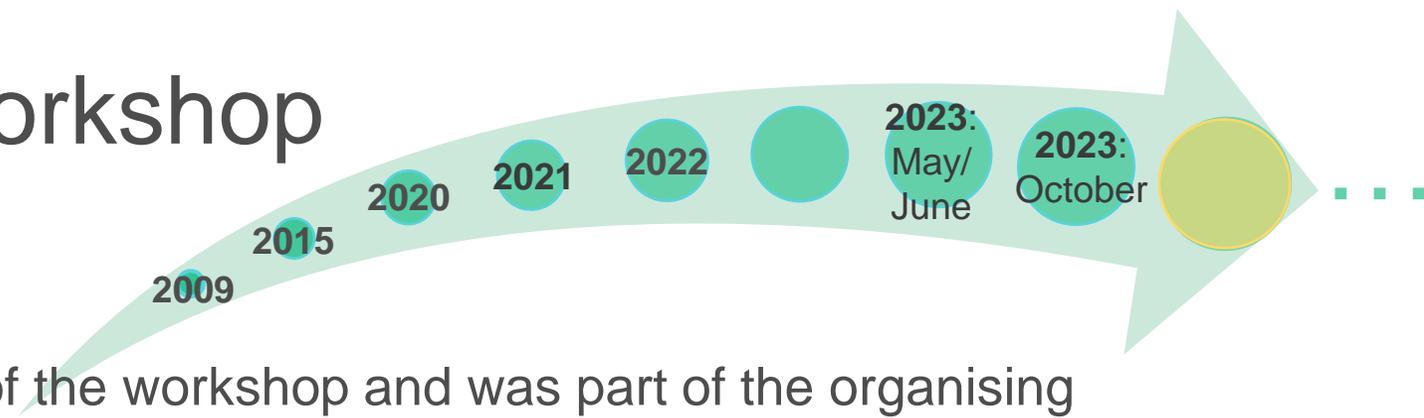
- focused primarily on availability of PPPs containing low risk and biocontrol substances
- an exchange of experience of Member States on barriers and also of good practices on use of current legal provisions on mutual recognition
- Report available: [82add5dc-043d-4cae-8f9d-6dd2b4817e20\\_en \(europa.eu\)](https://ec.europa.eu/pesticides/files/20230824/82add5dc-043d-4cae-8f9d-6dd2b4817e20_en.pdf)

# Some other actions so far

- Support MS to **enhance the capacity** of MS authorities to **evaluate biopesticides**.
  - BTSF
- Draft Compendium on application techniques (risk mitigation measures)
- Problem Formulation document (**need to know** vs. nice to know)
- Support MS to assess PPP formulations (Co-formulants)

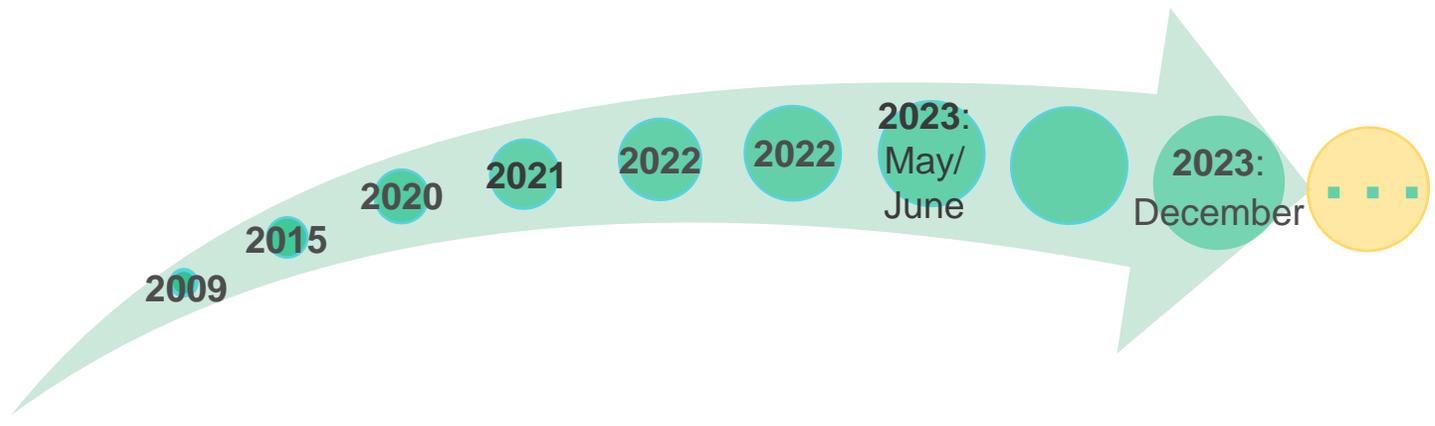


# 2023 Dec: ZAPID workshop



- COM supported the organisation of the workshop and was part of the organising committee
- Long due but because of COVID it could only take place in 2023
- Participants identified several follow-up actions in the 5 sessions:
  - Meeting legal requirements – Tackling delays
  - Harmonising zonal decision making – Special focus on Mutual Recognition, minor uses, and assessment of co-formulants
  - Work sharing on digital platforms
  - Implementation of new scientific and technical knowledge - Guidance Documents
  - Authorisation of ppp in the light of the Green Deal - Low risk, biocontrol and non-chemical ppp

# Next steps



- Report of ZAPID will be available asap: [Workshops/events - European Commission \(europa.eu\)](#)
- Part of the follow up activities identified at ZAPID to improve the zonal system could be considered by MS in the framework of PAI (Working Group on Post Approval Issues of SCoPAFF) where Commission is present and in the inter-zonal committees

## Workshops/events

- Workshop on the Zonal Authorisation Procedure – Improvement and Development (ZAPID), 5 to 7 December 2023, Braunschweig (DE) - [Agenda](#)
- Workshop on possibilities to increase availability of PPPs, 26 October 2023, online - [Report](#)
- Workshop Specific Protection Goals for the Environmental risk assessment of PPP – moving on with the EFSA method, 3 - 4 February 2020, Brussels (BE) - [Report](#)
- Workshop on Risk Mitigation Measures for Pesticides, 17 January 2020, Brussels (BE) - [Report](#)
- Workshop on Zonal Evaluation, Mutual Recognition and Re-authorisation, 2-4 June 2015, Dublin (IE) - [Report](#)

# Thank you



© European Union 2020

Unless otherwise noted the reuse of this presentation is authorised under the [CC BY 4.0](https://creativecommons.org/licenses/by/4.0/) license. For any use or reproduction of elements that are not owned by the EU, permission may need to be sought directly from the respective right holders.

