



# Implementation of the product authorisation procedures and the use of Article 53

Sustainable Solutions to Protect Crops, 2021

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# Outline

- Authorisation of products – challenges and successes
- Emergency authorisations – state of play and ongoing activities
- PPPAMS – state of play

# Authorisation of products

## Highs and lows



# Authorisation of products - what is working well?

- Effective coordination and work-sharing within zones:
  - common understanding leading to more harmonisation (PAI Group)
  - development of procedural or RA guidance:
    - *new version of the GD on Zonal Evaluation and MR (Jan 2021)*
    - *update to the GD on new data post (renewal of ) approval (ongoing)*
- Better use of mutual recognition
- Increased efforts to harmonise the acceptance of data under Article 43(6)
- Schemes to improve the quality of applications and facilitate a smoother process

# Authorisation of products – what is not working?

In general, the Zonal and Mutual Recognition process is not working optimally:

- Significant delays – resources, complexity of applications, inefficiencies
- Inadequate comparative assessment
- Mutual recognition – still not fully working as intended e.g. national requirements, trust issues, divergent views

## Consequences:

Impacts on other areas – ‘clogging’ of the system

Lack of pest management solutions – recourse to Article 53!

Availability of new and/or low-risk products is hampered



## Renewal of authorisation

Objective – to ensure a high level of protection for health and the environment

- Delays!
- Implementation of conditions of approval (esp. restrictions)
- Systematic prolongation (Article 43(6))
- Products remain on the market without an updated assessment

# Emergency authorisations granted under Article 53 of Regulation (EC) No 1107/2009

## **State of play and ongoing activities**



# The fundamentals

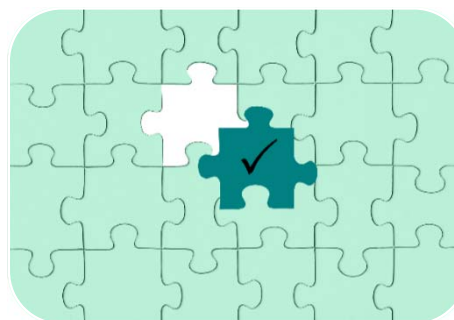
Article 53, read in conjunction with recital 32 of Regulation (EC) No 1107/2009



Last resort - all other reasonable means should be considered



Limited and controlled use



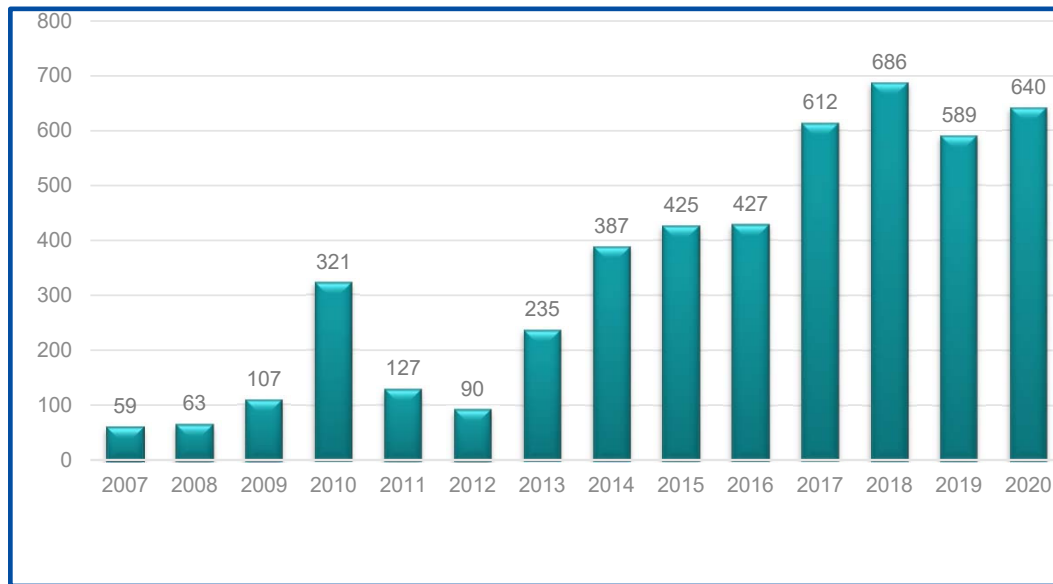
Fully justified – in particular for consumer safety



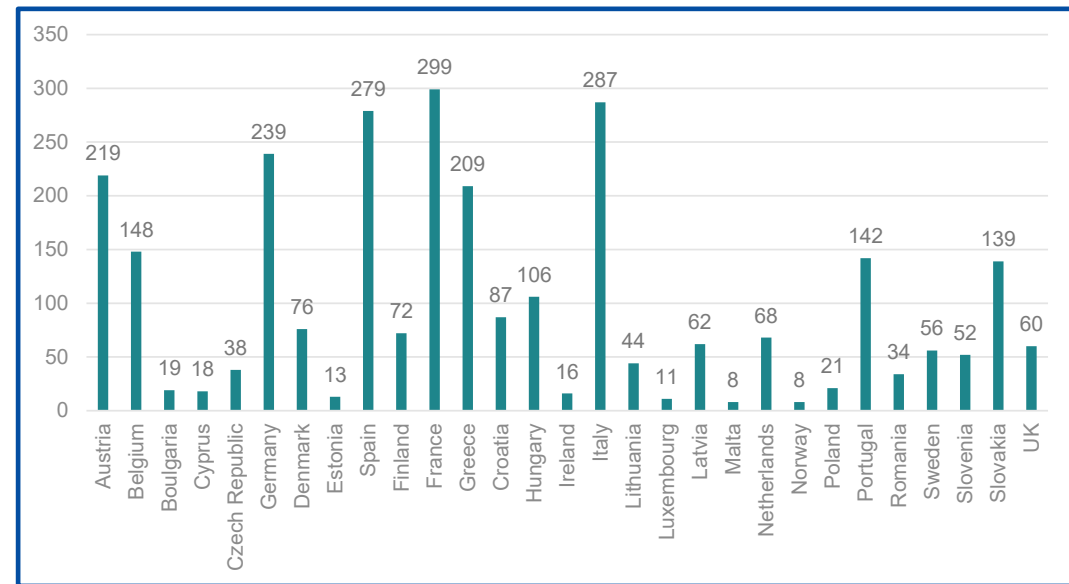
Notified to MS and the Commission



# Emergency authorisations in numbers

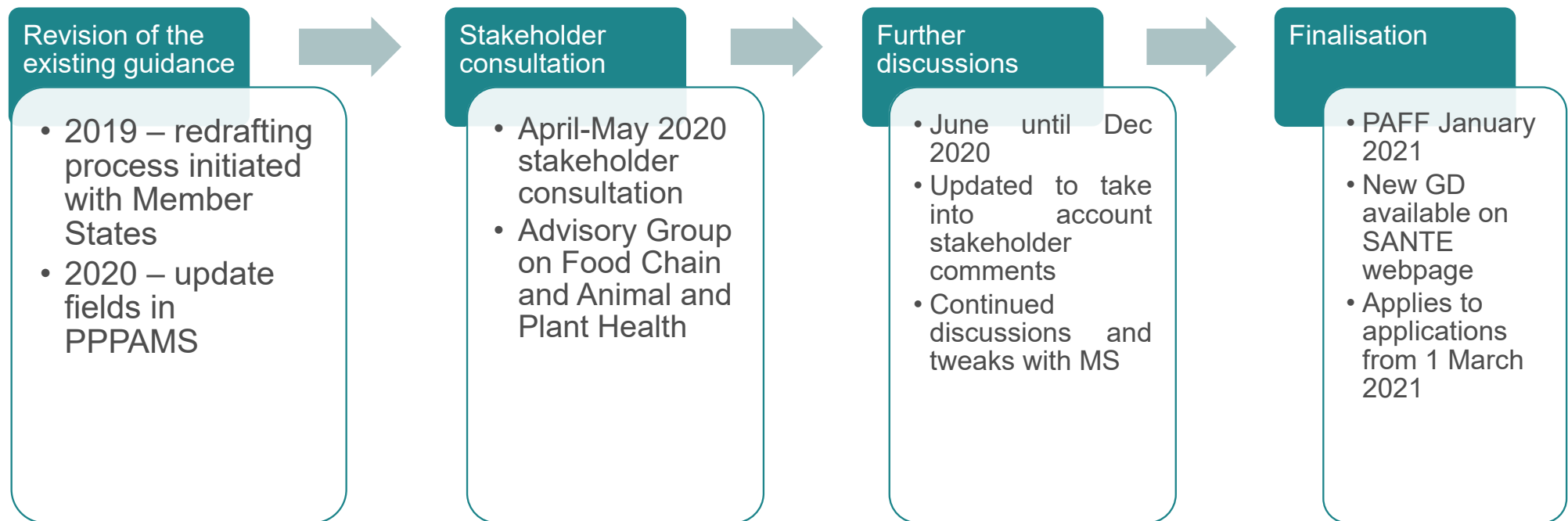


**Evolution of Emergency Authorisations  
2007-2020  
(MS + NO & UK)**



**Number of Emergency Authorisations  
PPPAMS: June 2016 - February 2021  
(MS + NO & UK)**

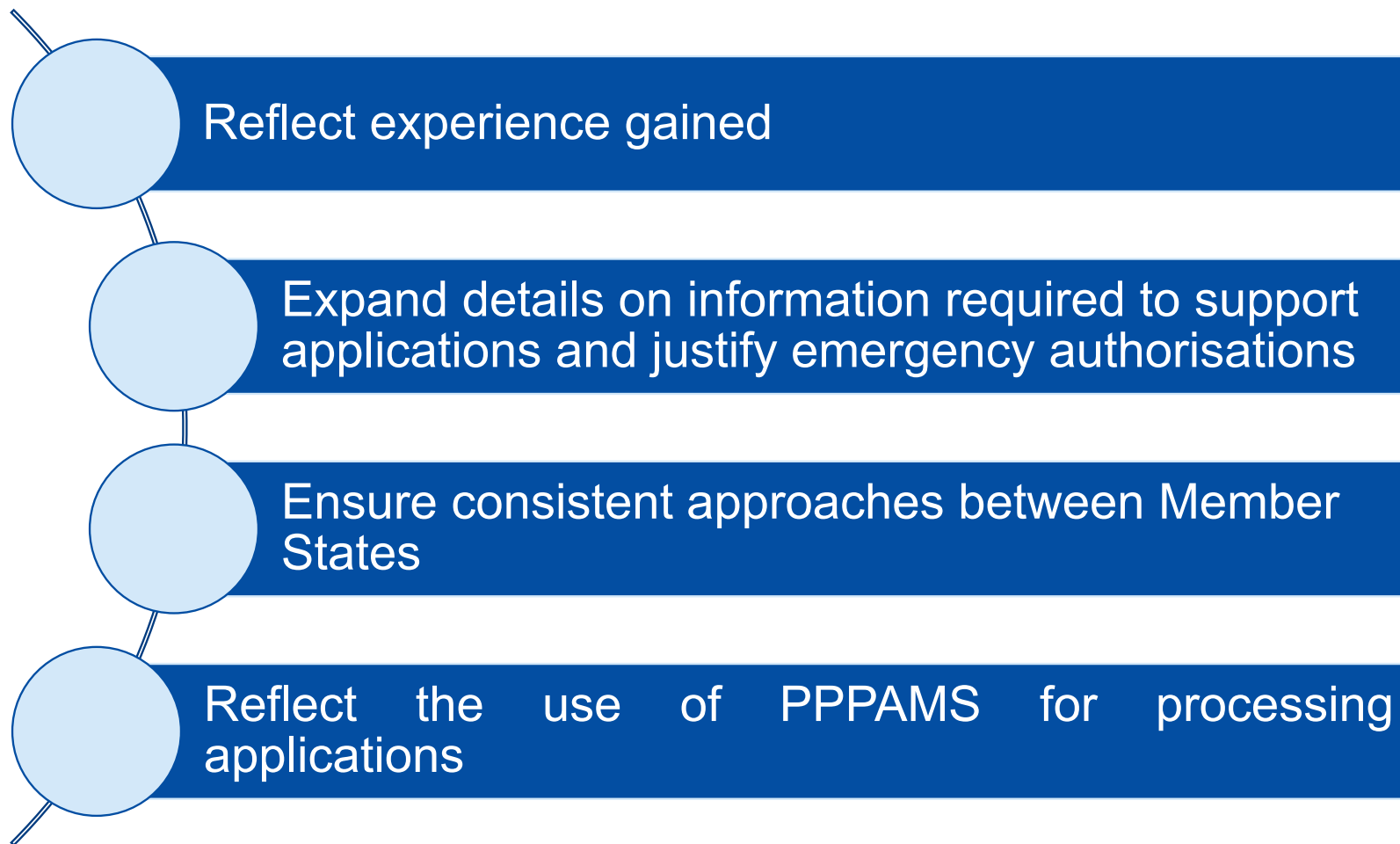
# Update of the guidance – state of play



The new guidance is available on the Pesticides pages on Europa:

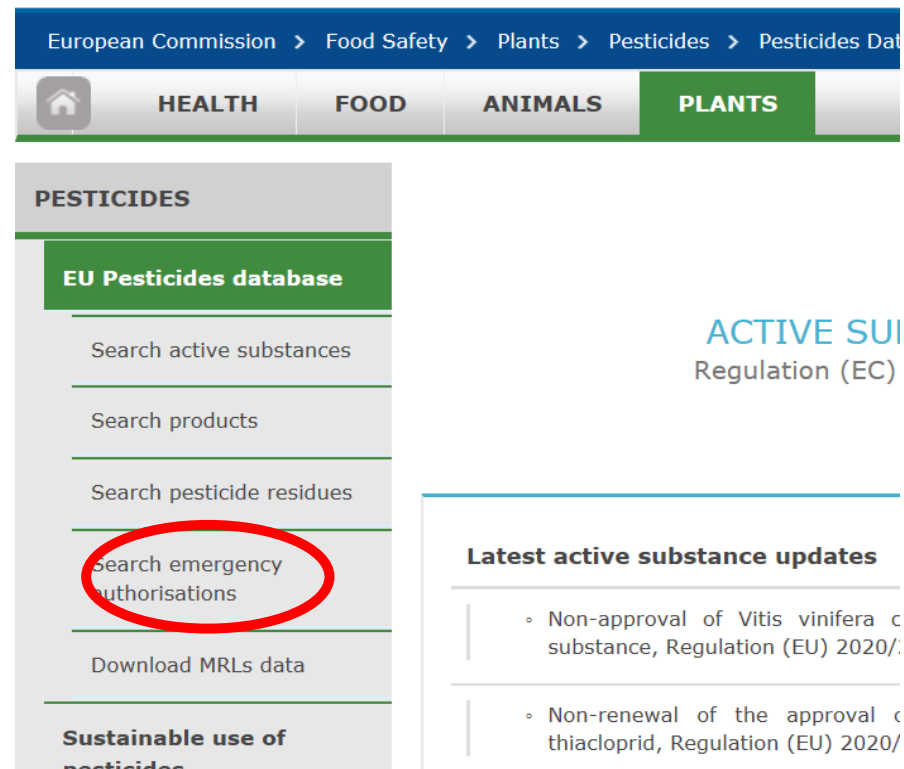
[https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides\\_aas\\_guidance\\_wd\\_emergency\\_authorisations\\_article53\\_post-210301.pdf](https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_aas_guidance_wd_emergency_authorisations_article53_post-210301.pdf)

# Update of the guidance – key points



# EU Pesticides Database – search tool for information on emergency authorisations

- Launched in February 2020
- Simple but powerful search tool
- Increased transparency



# Emergency authorisation database

## Search for Emergency Authorisations

### Search options

Keyword ?

Country ?

Active Substance ?

Authorised use ?

Valid from ?

Valid until ?

Search

Clear search options

### Emergency Authorisations (2111 matching records)

Download Excel file



Global Filter

1 2 3 4 5 10

Product company code ?	Trade name (s) ?	Active substances	Authorised in	Authorisation holder ?	Validity	Download pdf file	Download Excel file
A1412A	Reglone	Diquat	FI	Central Union of Agricultural Producers and Forest Owners (MTK)	01/05/2020 - 22/09/2020		
ProFume	ProFume	Sulfuryl fluoride	BE	Exponent International Limited	28/04/2020 - 30/04/2020		
CRUISER	Cruiser	Thiamethox...	BE	KDT	15/04/2020 - 12/08/2020		
Typosan P306	Typosan P306	4,6,6-Trimet... bicyclo[3.1.1] hept-3-en-ol, ((S)-cis-verbenol)	SE	Plantskydd AB	15/04/2020 - 13/08/2020		
Conviso One	Conviso One	Foramsulfur... Thiencarbazone methyl	SK	BAYER	01/04/2020 - 31/05/2020		
Force 1.5 GR	Force 1.5 GR	Tefluthrin	BE	KDT	01/04/2020 - 29/07/2020		
Sherpa 0,8 GR	Sherpa 0.8 GR	Cypermethrin	BE	KDT	01/04/2020 - 29/07/2020		

# Enhanced scrutiny



- Emergency authorisation (EA) should not be used in place of regular authorisation procedures – delays should be reduced and research activities should be initiated to find solutions
- The Commission has and will continue to monitor cases where (repeated) EAs are issued without sound justification
- If EAs are not fully justified, the Commission may adopt a decision to prohibit the repetition of the same EA (same crop/pest combination)
- February 2020 - the Commission adopted two decisions prohibiting the granting of repeated EAs by Romania (clothianidin and imidacloprid) and Lithuania (thiamethoxam) for certain crop-pest combinations
- October 2020 - the Commission mandated EFSA to assess the EAs granted for the use of clothianidin, imidacloprid, thiamethoxam and/or thiacloprid in sugarbeet for the 2020 growing season

# The Plant Protection Products Application Management System (PPPAMS)

<http://ec.europa.eu/pppams>

# Current status and future activities

PPPAMS can currently be used to submit applications for:

- ***new PPPs*** (zonal)
- ***mutual recognition*** of PPPs processed via PPPAMS
- ***emergency authorisations***

2020: some new features (GAP upload tool)

- Applicants are strongly encouraged to work with MS to submit applications for new PPPs – gain experience

## What is next?

- Development of the system to manage other application types is ongoing – authorisations will be built up over time
- Full implementation 2022 onwards



# Keep in touch



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[https://ec.europa.eu/food/plant/pesticides/refit\\_en](https://ec.europa.eu/food/plant/pesticides/refit_en)

# Thank you



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