Emergency authorisations and other complications

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Emergency authorisations

Article 53

Emergency situations in plant protection

1. By way of derogation from Article 28, in special circumstances a Member State may authorise, for a period not exceeding 120 days, the placing on the market of plant protection products, for limited and controlled use, where such a measure appears necessary because of a danger which cannot be contained by any other reasonable means

Free ride?

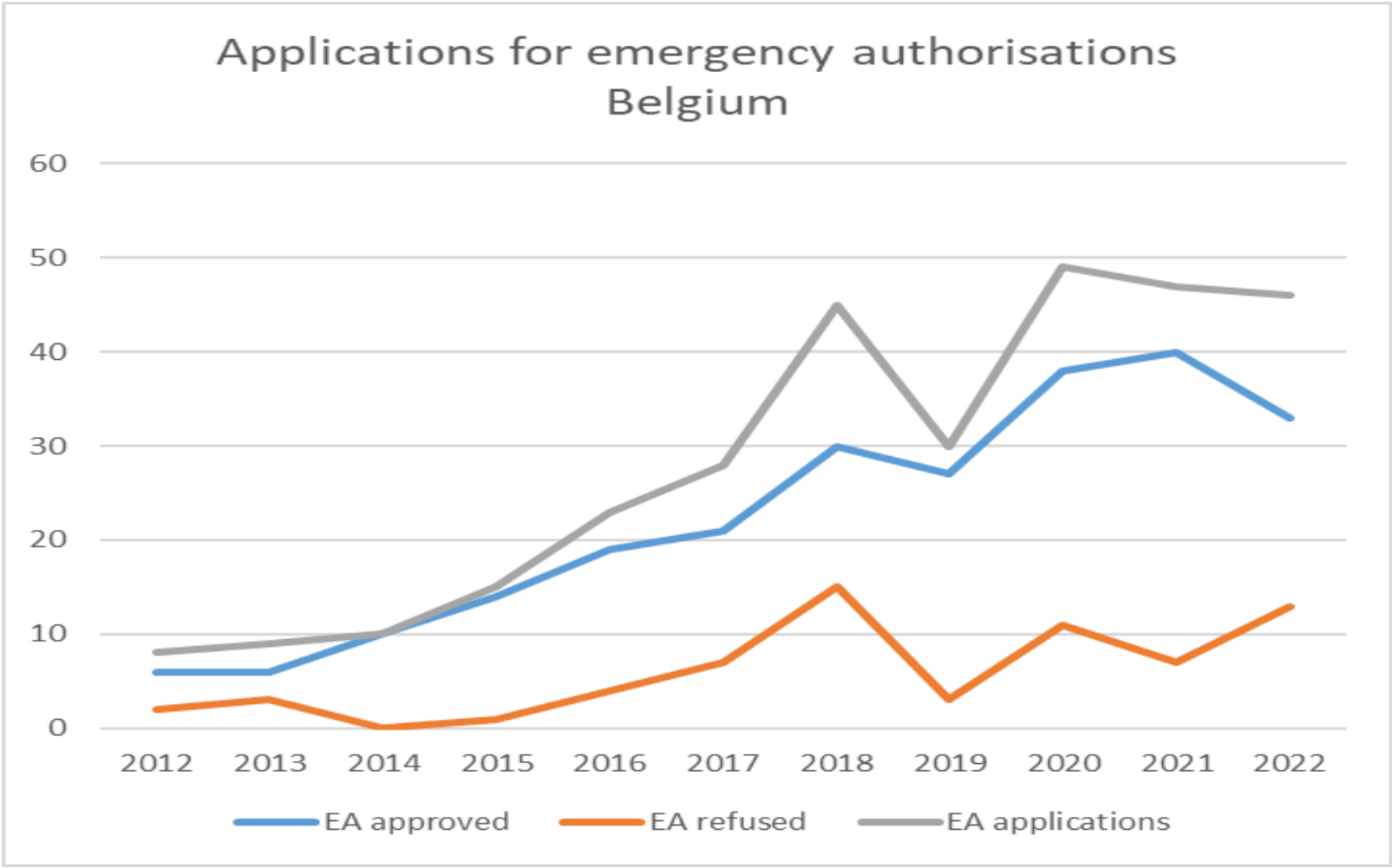
Derogation from authorisation conditions of art 28

⇒ MS permitted to grant any authorisation, for any active substance, for any use, even repetitive

⇒ Emergency authorisations to temporarily fill gaps in farmers toolbox

⇒ More and more needed, more and more applications

⇒ EU Guidance document on Emergency Authorisations Sanco/10087/2013 (under review)


Applications for emergency authorisations
Belgium
60
50
40
30
20
10
0
2012
2013
2014
2015
2016
2017
2018
2019
2020
2021
2022
EA approved
EA refused
EA applications

Good governance

MS have to take care and responsibility for their deeds

Agricultural need/lack of alternatives

Risk assessment for emergency authorisations

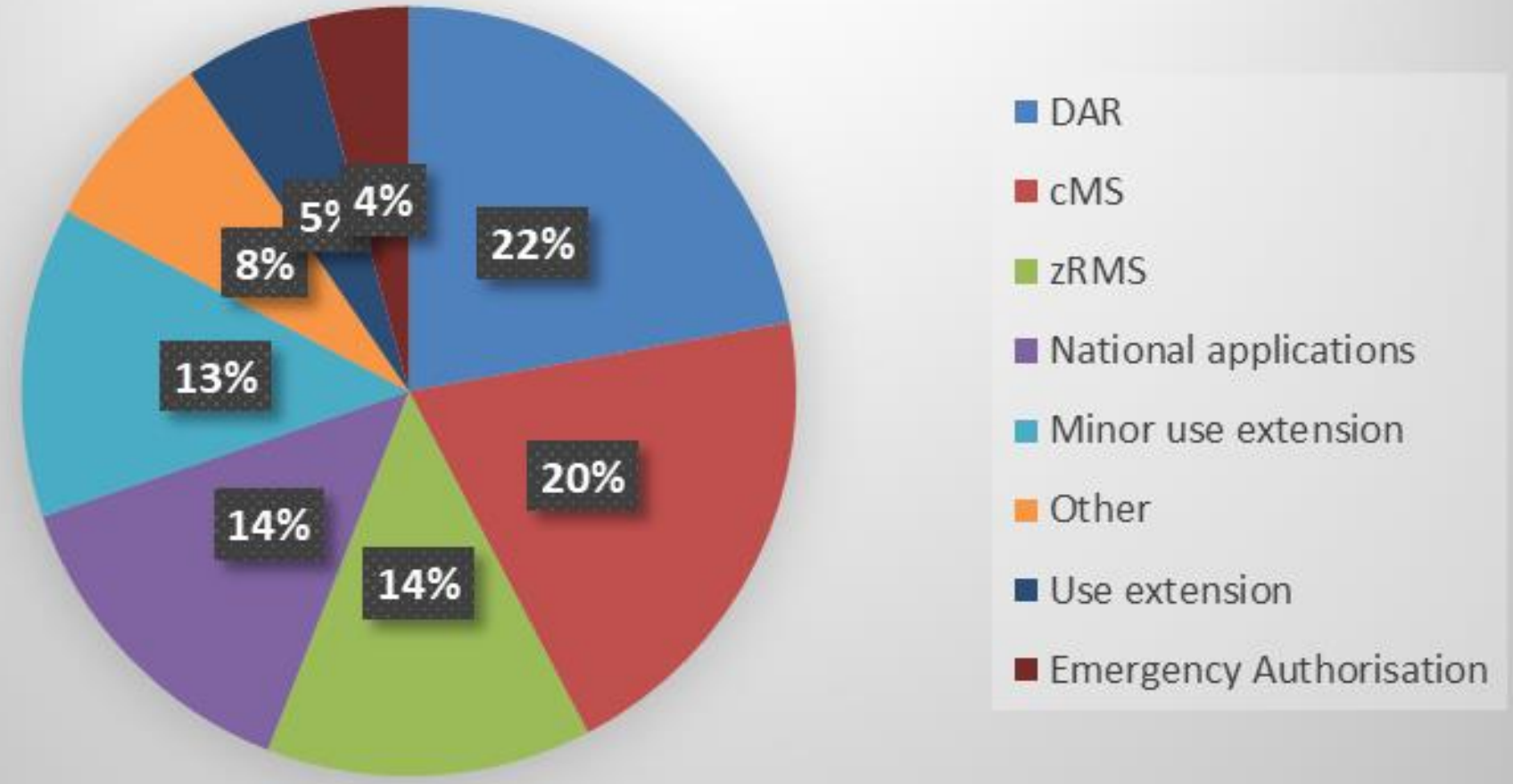
⇒ Data set mostly incomplete or not up to date

⇒ Which data to be used?

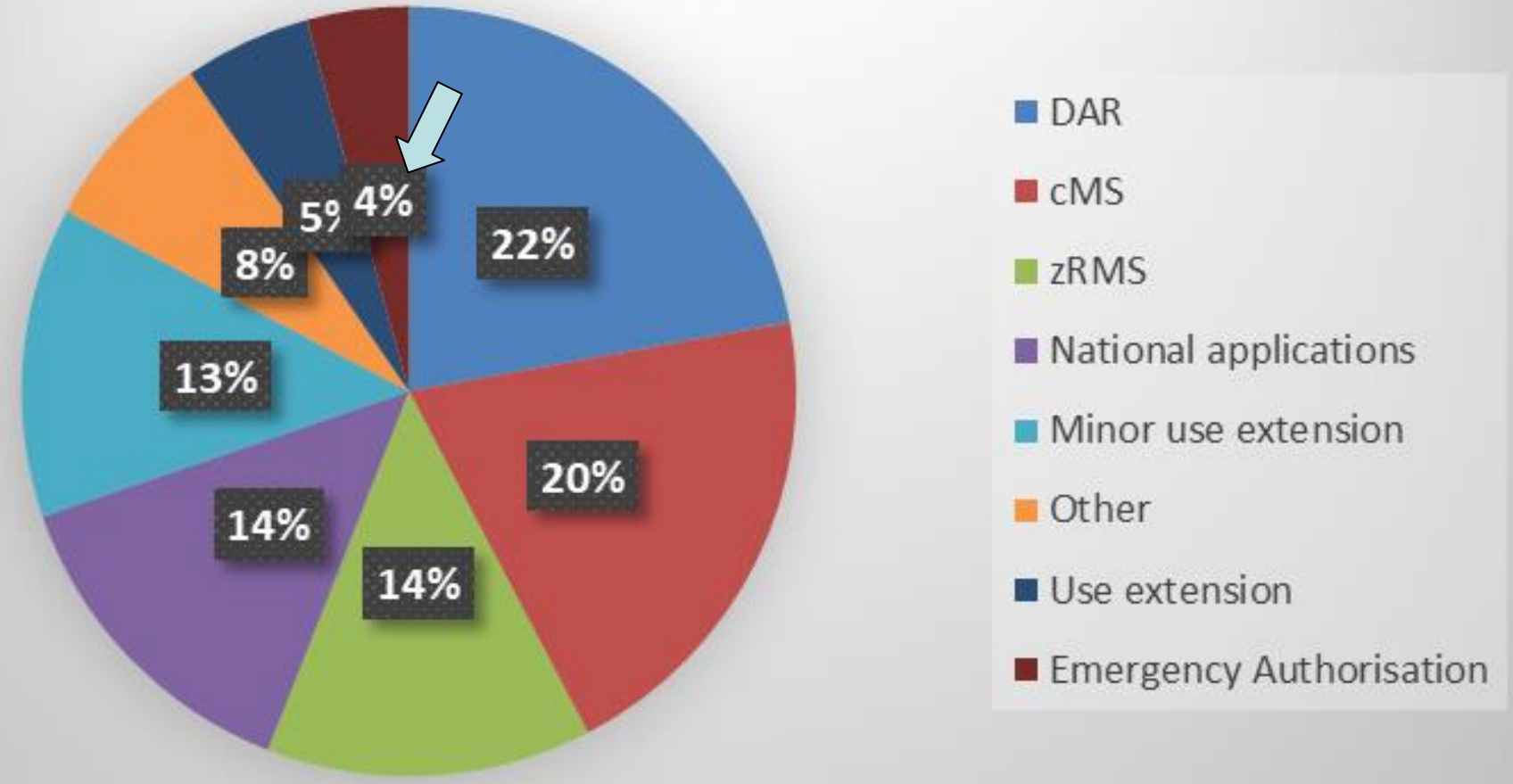
⇒ Which endpoints to be used?

⇒ Extra work, extra complex

Workload distribution - Belgium



Workload distribution - Belgium



Principles in Belgium

No RA if within risk envelope of existing autorisations (<period of grace) (as for minor use extension)

Otherwise full RA!

… but which endpoints?

Active substance:

- still approved : EU endpoints (approved by SCoPAFF)
- not yet approved (new): latest available data = at least a DAR + LoEP
- no longer approved (banned): most recent EFSA Conclusions + EP (even if not approved by SCoPAFF)

Neonics and Belgium

Clothianidin, thiamethoxam, imidacloprid

Banned on 29/05/2018 for sowing treated seeds outdoors

Divergence with national evaluations due to use of new EFSA GD

Non renewed on 31/01/19 (clo), 30/04/19 (thia), 1/12/20 (imi)

⇒ EA in 2019/2020 for thiamethoxam and clothianidin (sugar beet, carrot, lettuce)

⇒ EA in 2021/2022 for imidacloprid (sugar beet, lettuce)

⇒ Full RA including sowing of treated seeds, with risk mitigation for full crop rotation

⇒ Stopped two years after active substance non-renewal (= cfr regular period of grace)

Neonics and Belgium

EA for the seed treatment = use of a PPP = covered by art 53

EA for the sowing of the treated seeds (cfr GD for EA):

⇒ Sowing restricted to the national territory (<> free movement of seeds on EU market)

⇒ Sowing not covered by art. 53 but in spirit of Reg 1107 (as evaluation of sowing)

Courtcase

Reaction to EA after EU-wide ban of neonics

Council of State asked the EU Court of Justice for a preliminary ruling

Ruling of 19/01/23 : **Article 53(1) … must be interpreted as not permitting a Member State**

to authorise the placing on the market of plant protection products for seed treatment, or the placing on the market and use of seeds treated with those products,

where the placing on the market and use of seeds treated with those products have been expressly prohibited by an implementing regulation.

Difficulties in interpretation

Only for active substance banned for seed treatment and sowing? Or also if banned for use outdoors? Or if banned for a crop? Or…

And what about completely banned active substances ?

Also for treatment of seeds for export purposes ?

Restrictive interpretation (only treatment of seeds and sowing)?

… or broad (also plant protection products) ? = no EA for any use banned on EU-level

And do existing EA need to be revoked?

The future?

Everything depends of the reference uses

1! safe use is needed/sufficient for active substance approval

⇒ Non-safe reference uses are banned

⇒ But does that banned use include sowing of treated seeds?

⇒ Interpretation depending on the RA for the banned use?

But what about all other possible (comparable!) non-safe uses ?

Banned uses to be detailed

Or even beter: no longer ban of (reference) uses on EU level

⇒ MS need to do a full RA anyway

⇒ No need to lift restrictions

Thank you for your attention !

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