

Online event | Tuesday, 30 November 2021 | Presentation



“Emergency authorisations of neonicotinoid pesticides 2020-21”

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**Information session to present
the work done by EFSA on the
emergency authorisations
granted by 11 Member States for
the use of neonicotinoid-based
insecticides on sugar beet in
2020/21**

Chris Lythgo | Ciro Gardi

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1. Legislative background
2. EFSA protocol for Article 4.7 assessments
3. Overview of what was identified in the technical reports
4. Reflections resulting from the assessments

*“... , in special circumstances a **Member State** may authorise, for a **period not exceeding 120 days**, the placing on the market of plant protection products, ... **because of a danger which cannot be contained by any other reasonable means.**”*

Available Framework:

- SANCO/10087/2012 rev.0 of 1 February 2013 Working document on emergency situations according to article 53 of Regulation (EC) No 1107/2009
- SANCO/10087/2012 rev.1 of 26 January 2021 Guidance on emergency authorisations according to article 53 of Regulation (EC) No 1107/2009. Applicable from 1 March 2021

https://ec.europa.eu/food/system/files/2021-03/pesticides_aas_guidance_wd_emergency_authorisations_article53_post-210301.pdf

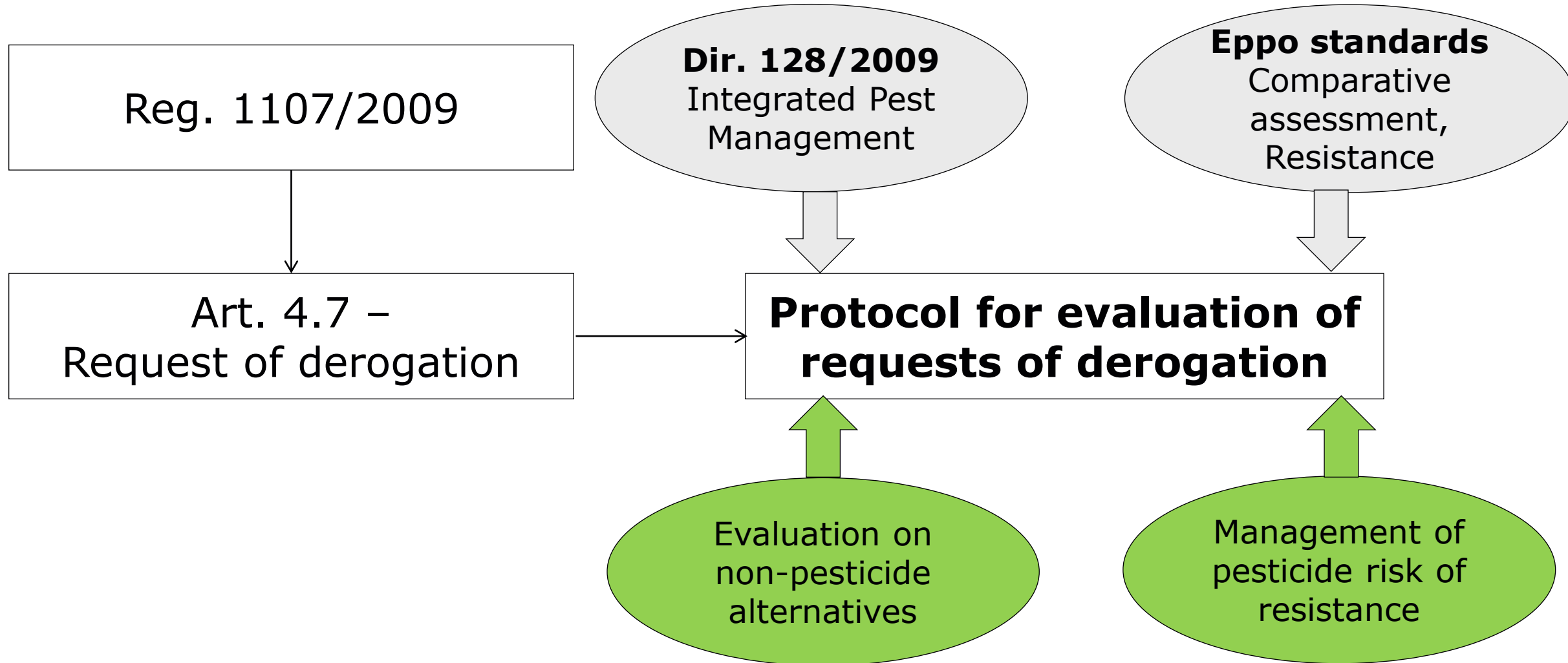
- Some approval criteria for plant protection products active substances (a.s.) are linked to the so-called "**cut-off criteria**"
- However certain **derogations** apply: negligible exposure and Article 4.7
- → **Art 4.7** = Derogation from normal criteria, for some types of substances with defined hazardous properties

In the absence of any clear direction regarding the application of art.53, art. 4.7 is considered the best **available** proxy

Comparison of the articles

	Art 53 Emergency Situations	Art 4 A.S. approval criteria, point 7
What	Authorise use of a product in a situation different to its authorised uses. The provision can be applied for both approved but also not approved active substances	Approve an active substance even if it does not satisfy the criteria set out in points 3.6.3, 3.6.4, 3.6.5 or 3.8.2 of Annex II, i.e. approval cut off criteria.
When	Because of a danger which cannot be contained by any other reasonable means	To control a serious danger to plant health which cannot be contained by other available means including non-chemical methods
Who	Member States	European Commission with qualified majority Member states can then authorise products following the uniform principles.
For how long	120 days max	5 years max
Available framework	<ul style="list-style-type: none"> SANCO/10087/2012 rev.0 of 1 February 2013 Working document on emergency situations according to article 53 of Regulation (EC) No 1107/2009 SANCO/10087/2012 rev.1 of 26 January 2021 Guidance on emergency authorisations according to article 53 of Regulation (EC) No 1107/2009. Applicable from 1 March 2021 	"...provided that the use of the active substance is subject to risk mitigation measures to ensure that exposure of humans and the environment is minimised. For such substances maximum residue levels shall be set in accordance with Regulation (EC) No 396/2005."

Protocol for the evaluation of art. 4.7 requests



COLLECT ALL AVAILABLE INSECTICIDE METHODS, ASSESS RESISTANCE

Max number of applications per crop	IRAC group/MoA ³	Insecticide risk of resistance ⁴		
		Global	National	Overall classification

of lue)	Notes			Evaluation of insecticide alternatives (z/x value)
	Agronomic issues	Bee and environmental restrictions	Other information	
				#DIV/0!

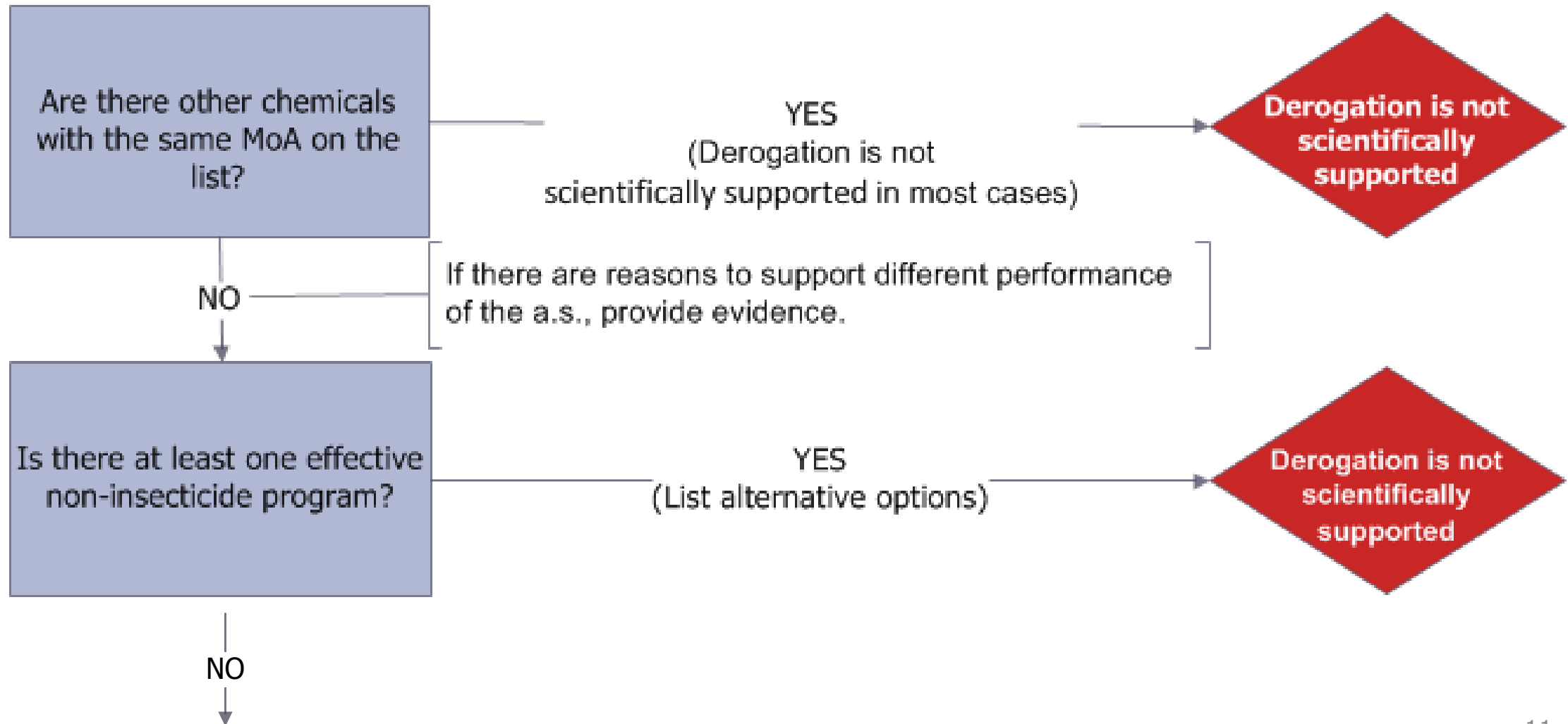
IRAC=Insecticide resistance action committee
 MoA=resistance mode of action

COLLECT AVAILABLE NON INSECTICIDE METHODS, QUALITATIVELY ASSESS

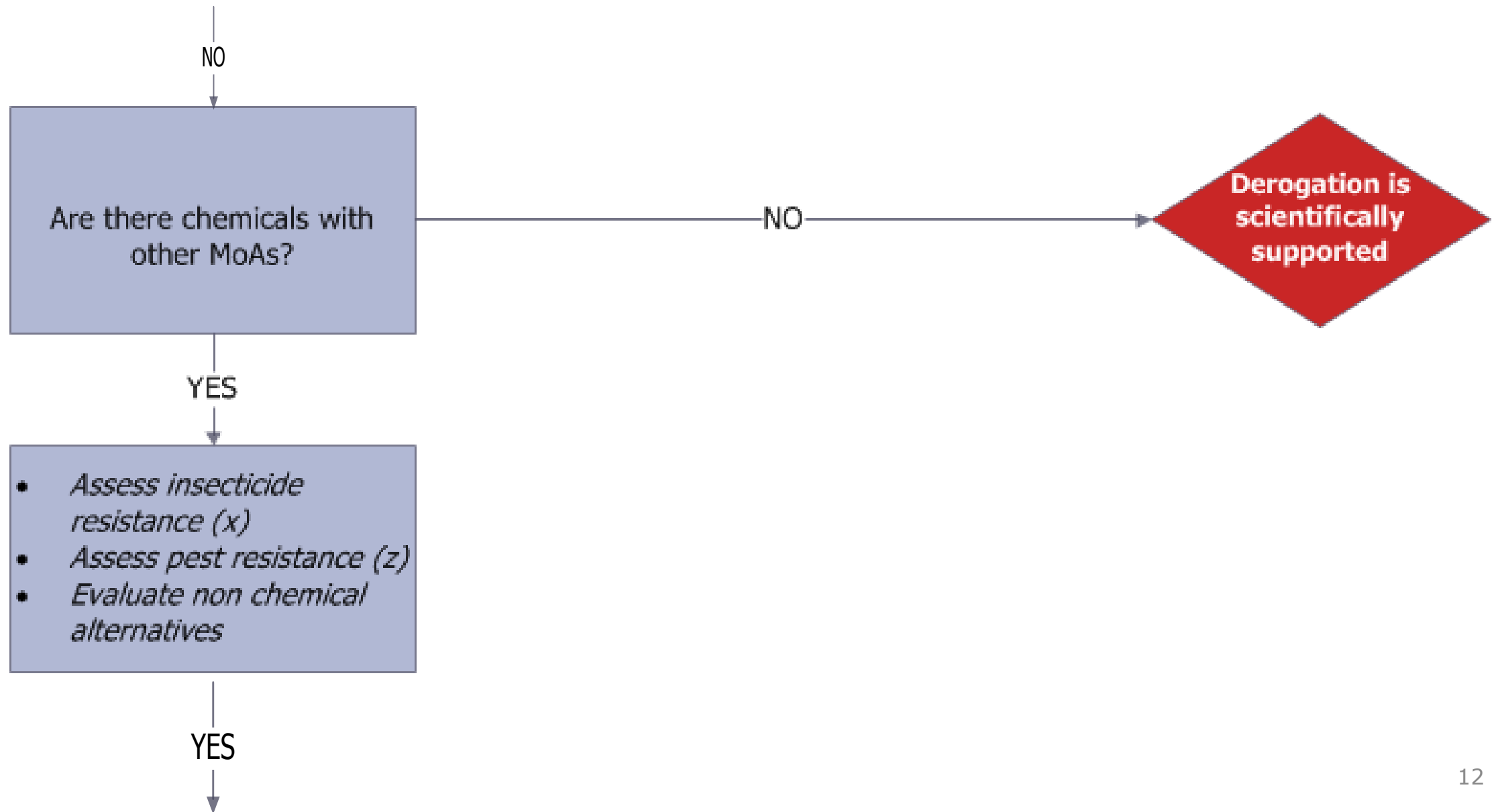
	Practised Usage	Feasibility	Evaluation	Notes	
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A					
P					
	Physical control	Others			

- EFSA uses the information provided by Member States (MS) and accepts that it is reliable, and no further research is done for the validation of these data.
- MS have the full responsibility for the accuracy and correctness of the data provided to EFSA to perform the assessment regarding:
 - which are the non-insecticide alternatives
 - list of authorised insecticide a.s.
 - the pest resistance situation in their territory (whilst a valid and up to date resistance data bank such as planned by EPPO is unavailable)

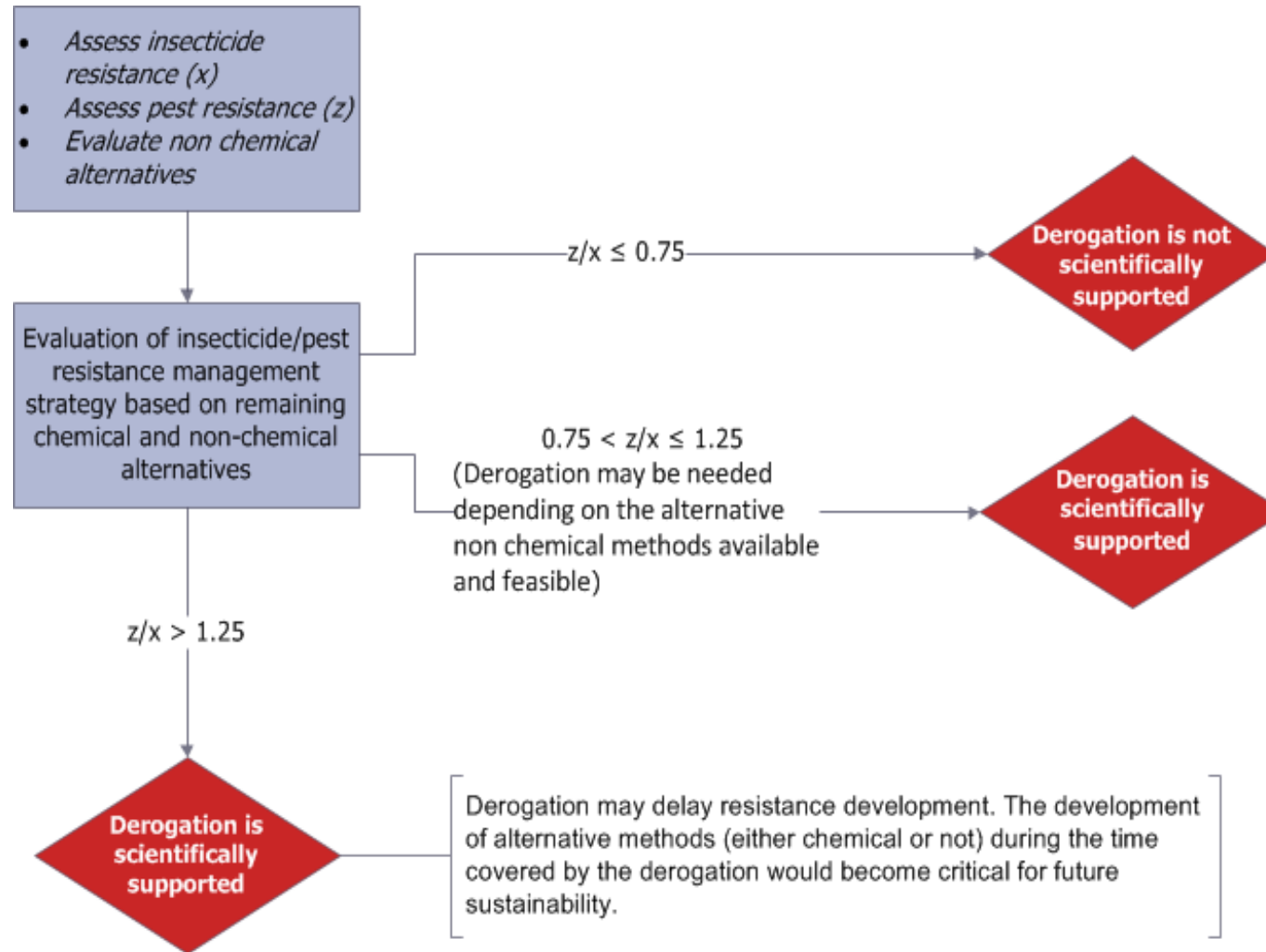
Protocol for the evaluation of art. 4.7 requests



Protocol for the evaluation of art. 4.7 requests



Protocol for the evaluation of art. 4.7 requests



- Whether the Member State provided information on research activities into alternatives to these neonicotinoid active substances has been indicated in the technical reports
- Experts provided input whether alternative methods might have been missed by the member states
- Clarified with a commentary when a non-insecticidal method had been assessed as effective for a pest when it can be widely practiced (e.g. crop rotation), but the authorisation had anyway been granted. This situation can be regarded as a deviation from the protocol considering integrated pest management principles are behind the protocol

The assessments of the 17 emergency authorisations using the art. 4.7 protocol gave the indication that they were justified

- Why effective and available non chemical methods were not considered appropriate to be practiced everywhere in a member state? Crop rotation in Belgium (2 pests), Denmark (some soil and seedling pests) and Slovakia (all 3 pests considered)
- For Croatia an assessment relating to aphid species as pests was missing, though Croatia had included aphids as a pest family for which the treating of seed had been authorised

- More emphasis on assessing what is practiced in adjoining countries and regions especially those not needing neonicotinoid emergency authorisations (topic is covered / possible with the existing protocol)
- What other assessable criteria than the comparative assessment of resistance to maintain effectiveness for alternative chemicals might be important in the emergency authorisation context, considering their 120 day duration?
- Seems clear there is consensus that it is essential that non-chemical methods remain a key consideration also in line with sustainability policies

- Article 53 pertains to: Emergency situations in plant protection
 - **SMART definition agreed by stakeholders: what are emergency situations in plant protection**
 - Once defined, information needs to assess this, might then be developed
- Article 53 specifies danger which cannot be contained by any other reasonable means
 - **SMART definition agreed by stakeholders: what is reasonable means**
 - All available means including those in adjacent members states (article 4.7 approach) might be considered reasonable? But maybe also SMART criteria for available could be useful?
 - If something different to the article 4.7 approach be defined, information needs to assess this, might then be developed



Perspectives and opportunities

Manuela Tiramani

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Opportunities to move the assessment forward?

**Art 4.7 protocol
vs art. 53**

SUSTAINABILITY

**Definition by risk managers
of what emergency
situations in plant
protection are (need of a
benchmark?)**

**"Danger which cannot be
contained by any other
reasonable means"
What is reasonable?**



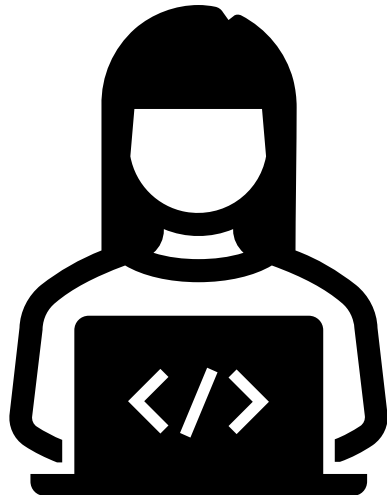
**What other assessable
criteria might be important
in the emergency
authorisation context,
considering their 120 day
duration?**

**Non-chemical methods:
What are the peculiarities
that might make their
applications different from
country to country?**

**What is practiced in
adjacent countries/regions
especially those not
needing neonicotinoid
emergency authorisations?**

An online tool

- Single entry for all EA requests



Benefits:



- ✓ harmonisation across MSs
- ✓ transparency (tool open to viewers)
- ✓ language
- ✓ timeliness (real time application)
- ✓ efficiency gain
- ✓ reconsideration of technical aspects

Could it also serve as a platform to share best practices across regions/MSs





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