

The EU Compendium on conditions of use – status, development and further implementation

CEUREG Forum XXIV

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Unit E4 – Pesticides and Biocides

DG Health and Food Safety



Content

- Plant protection products (PPP): EU political context
- Type of conditions of pesticide use to reduce exposure and risk
- Regulatory context: How to integrate these conditions of use in the regulatory framework to place a pesticide in the market?
- Commission activities
- Take home messages

Political context - Farm to Fork Strategy: Pesticide reduction targets by 2030 (new Commission?)



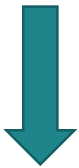
Reduce by 50% the overall use and risk of chemical pesticides



Reduce use by 50% of more hazardous pesticides



+




Pesticide reduction : some figures



Reduce use by 50%
of more hazardous
pesticides

In 2001 EU counted 979 active substances

Today we have:

1. 425 active substances approved and 
2. **965 NOT approved.**
3. **90 Candidates for Substitution**
3. 20 active substances are currently processed.
4. 71 are pending for a decision

More info in :

[Implementing Regulation \(EU\) No 540/2011](#)

And in our EU Pesticide Database.

Pesticide portfolio is evolving

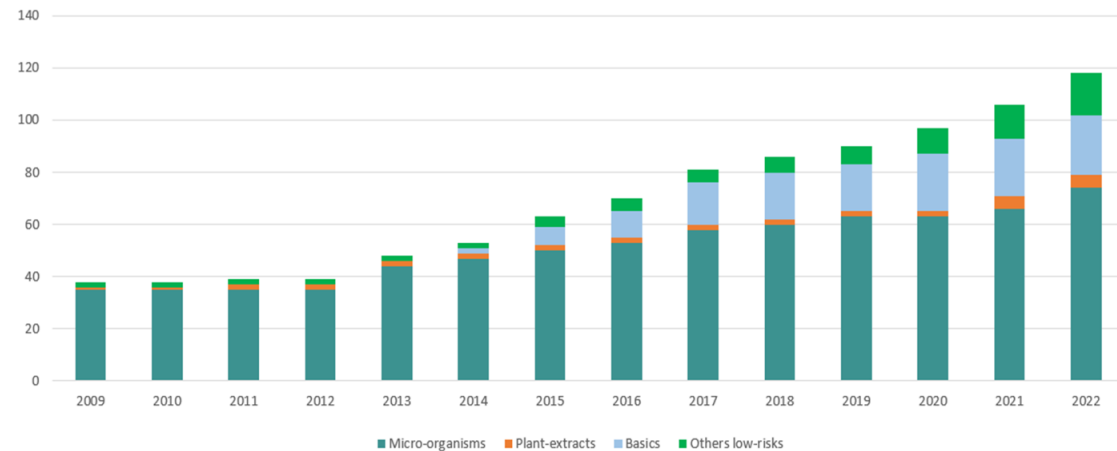


Reduce use by 50%
of more hazardous
pesticides = **rely on
more low-risk**



Availability of low-risk / non-chemical alternatives

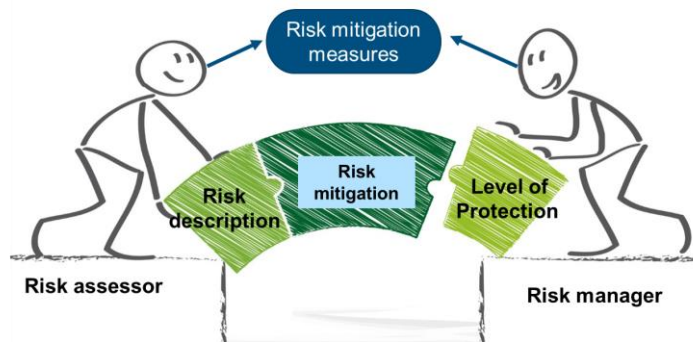
Low hazard active substances approved in EU



Pesticide use shall be evolving – mitigating the risks



Reduce by 50% the overall use and **risk** of chemical pesticides



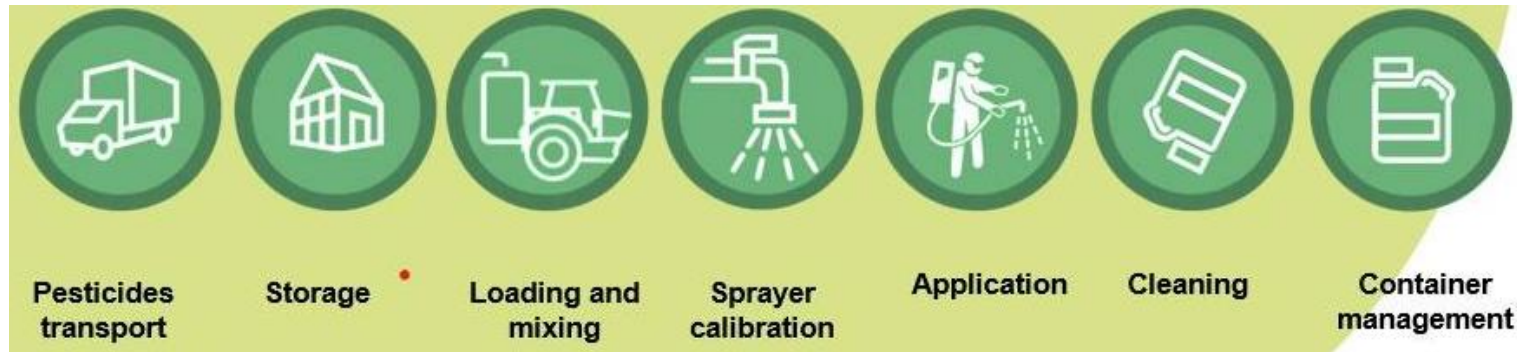
EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY
Food Safety, Sustainability, and Innovation
Pesticides and Biocides

PAFF-PPL-March 2024-Doc.A.07.02
23 May 2024

Compendium of conditions of use to reduce exposure and risk from plant protection products

Compendium of conditions of use

- Overall, reducing the risks = considering the whole life cycle



- Many risks can be addressed by:
 - Good practices implemented by various actors including the farmer
 - Generic risk mitigation or conditions of use (SUD)
 - Specific risk mitigation measures: (1) techniques or (2) application conditions = GAP

definition (1107/2009) **Compendium**

Compendium covers...

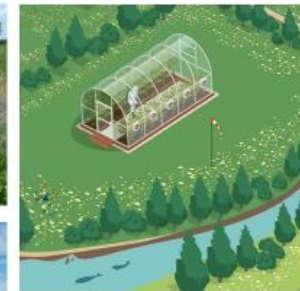
- Personal protective equipment
- Nozzles
- Technical conditions (different types of sprayers)
- Equipment for treated seeds
- Formulations
- Field management measures
- Restrictions of use

Technical measures



Other types of Risk Mitigation Measures

Field management measures



Awareness -raising tools



Technological measures



Compendium: « first (living) list » of techniques/practices reducing risks in the regulatory process. It gives a first ‘hit’ to make use of them in the regulatory process of approval of active substances and authorisations of PPP

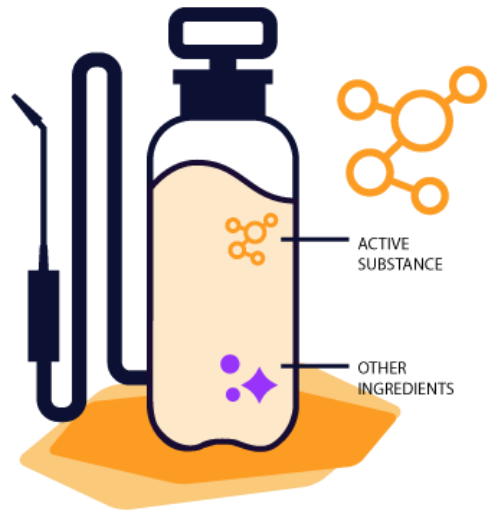


Moyens permettant de diminuer le risque de dérive de pulvérisation
Aide à l'identification des matériels

- Follow-up actions neededongoing discussion with MS/EFSA (memorandum)



YOU KNOW : Under Reg. (EC) No 1107/2009, two steps are needed to place a PPP on the EU market.
Conditions of use to reduce exposure and risk can be integrated in both.

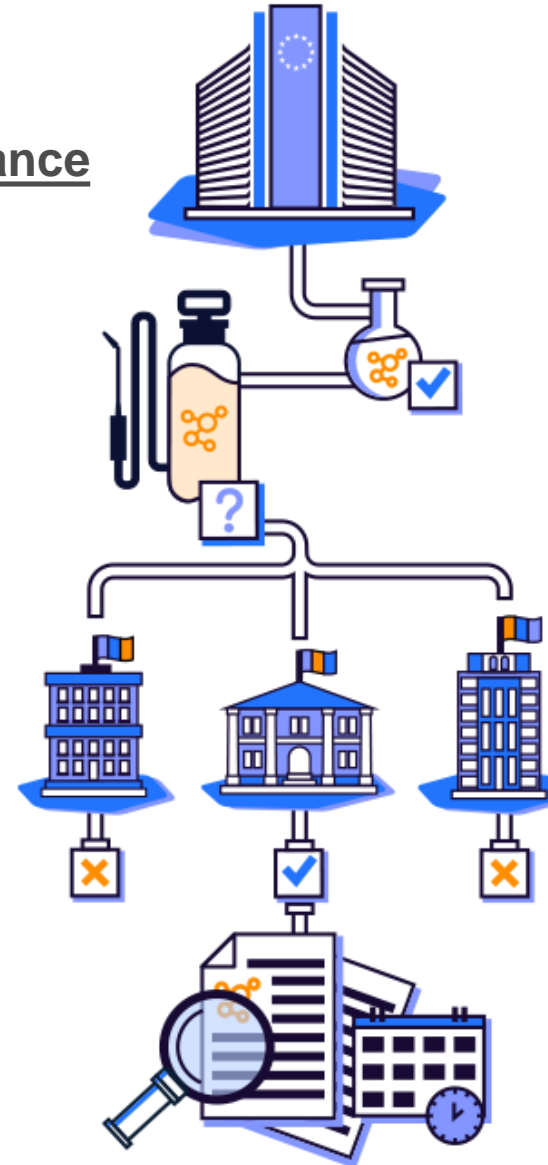


1

At EU level:
assessment of the active substance
for approval

2

At Member States (MS) level:
assessment of the plant protection product
containing the active
for authorisation



1

2

Conditions of use are described in the GAP table, which is the basis for the risk assessment of the active substance and the PPP. The user is obliged to implement these conditions.

Example the GAP table proposed by the applicant for the renewal of the active substance carbon dioxide.



Aligal-2

Crop and/or situation (a)	Member State	Product Name	F G I (b)	Pests or group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks (m)
					Type (d-f)	Conc of a.i. g/kg (i)	Method kind (f-h)	Growth stage and season (j)	Number max (k)	Interval between applications (min)	kg a.s./m ³ (or kg a.s./t)	Water l/ha min max	L product / ha a) max. rate per appl. b) max. total rate per crop/season		
Stored cereal grains (YCEST)	EU	Aligal-2	I	Insects	GA	999 g/kg	Fumigation (gas-tight silo unit without Circulatory fumigation)	Post-harvest (storage).	1	-	a) 10 -30 kg/t b) 10 -30 kg/t	n.a	n.a	n.a	20°C, 25 d Sufficient gas concentration of 70% CO ₂ above the cereal grains inside the top of silo.

The **applicant** should describe the uses in the GAP table and may include the conditions of use to reduce exposure. For new techniques:

- suitability for the specific use defended,
- effectiveness
- affordability for the user
- requirements for inspection
- controllability and enforceability

1

At EU level:
assessment of
the active substance

RMS and / or EFSA as risk assessor can propose conditions of use needed to ensure a safe use of the pesticide to fulfil the protection required under the Reg. 1107/2009.

Example the conditions of use proposed by EFSA for the renewal of the active substance carbon dioxide.



Risk mitigation measures (RMMs) identified following consideration of Member State (MS) and/or applicant's proposal(s) during the peer review, if any, are presented in this section. These measures applicable for human health and/or the environment leading to a reduction of exposure levels of operators, workers, bystanders/residents, environmental compartments and/or non-target organisms for the representative uses are listed below. The list may also cover any RMMs as appropriate, leading to an acceptable level of risks for the respective non-target organisms.

It is noted that final decisions on the need of RMMs to ensure the safe use of the plant protection product containing the concerned active substance will be taken by risk managers during the decision-making phase. Consideration of the validity and appropriateness of the RMMs remains the responsibility of MSs at product authorisation, taking into account their specific agricultural, plant health and environmental conditions at national level).

- Adequate ventilation (e.g. with a "certificate of gas clearance") before humans can re-enter treated and/or surrounding areas (i.e. chambers, buildings and silos) is recommended for all representative uses (please, refer to section 2).
- A 30 m buffer zone for resident (subjected to revision considering the wind-speeds in the different member states) is recommended for all representative uses (please, refer to section 2).



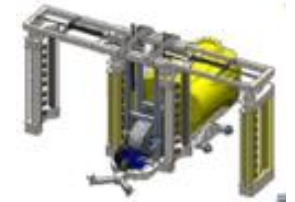
1

At EU level:
assessment of
the active substance

In the approval or renewal, specific provisions can apply to reduce the exposure and the risk of human/animal health and the environment. The user is obliged to implement them.

Conditions set during the renewal for the active substance **CAPTAN**

Common Name, Identification Numbers	IUPAC Name	Purity ¹	Date of approval	Expiration of approval	Specific provisions
<p><u>Captan</u> CAS No 133-06-2 CIPAC No 40</p>	<p>N- [(trichloromethyl) thio]cyclohex-4-ene-1,2-dicarboximide</p>	<p>≥ 930 g/kg</p> <p><u>perchloromethyl mercaptan:</u> ≤ 5 g/kg</p> <p>folpet: ≤ 10 g/kg</p> <p>carbon tetrachloride: ≤ 0.1 g/kg</p>	1 November 2024	31 October 2039	<p>For outdoor uses the following conditions shall apply:</p> <ul style="list-style-type: none"> – Only uses outside flowering of the crop and when no flowering weeds are present in the rows of the treated crops may be <u>authorised</u>; – Member States shall require that applications in <u>orchards (e.g., apples, cherries) are only done with application equipment that increases the precision and accuracy of the application (e.g. emission shields, shielded sprayers, hooded sprayers, tunnel sprayers, sensor controlled sensor-controlled sprayers)</u>, and, while maintaining the application rate on the target surfaces, achieves an average reduction of at least 61% of the applied plant protection product (per hectare) and a minimum of 20% reduction of plant protection product loss to the ground compared to applications via conventional application equipment and practice. <p>For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on <u>captan</u>, and in particular <u>Appendices I and II</u> thereto, shall be taken into account. In addition, risk mitigations such as no-spray buffer zones from field margins, shall be required, when appropriate, by the Member States <u>on the basis of</u> their risk assessment to protect bees and aquatic organisms.</p>



1

At EU level:
assessment of
the active substance

In the renewal of cypermethrin, specific provisions to reduce the exposure and the risk to the aquatic environment addressed to MS in view of authorisations.

Conditions set during the renewal for the active substance **CYPERMETHRIN**

ANNEX I

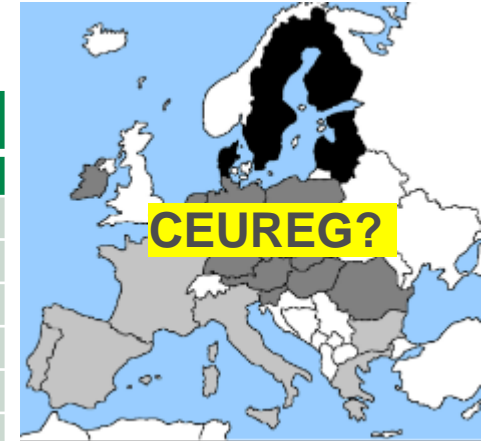
Date of approval	Expiration of approval	Specific provisions
1 February 2022	31 January 2029	<p>Authorisations shall be limited to professional users.</p> <p>When authorising plant protection products containing cypermethrin for spray applications outdoors, in order to ensure the protection of non-target organisms, in particular aquatic organisms and non-target arthropods, including bees:</p> <ul style="list-style-type: none">— risk mitigation measures achieving reduction of drift shall be required that lead to exposure $\leq 5,8$ mg a.s./ha in off-crop areas and, in addition, for spring applications to concentrations in water bodies $\leq 0,0038$ μg a.s./L,— only uses outside flowering of the crop and when no flowering weeds are present may be authorised.

2

At Member States level: assessment of the plant protection product containing the active

**Each National Authority of the MS impose the most appropriate risk mitigation measures according to the agricultural, plant health and environmental conditions and national regulations (SUD national plans).
The user is obliged to implement them.**

Possible surface water mitigation measures in the Member States of the Northern zone



F = Field crops
V = Vegetables,
O = Orchards,
B=Bush berries & nurseries



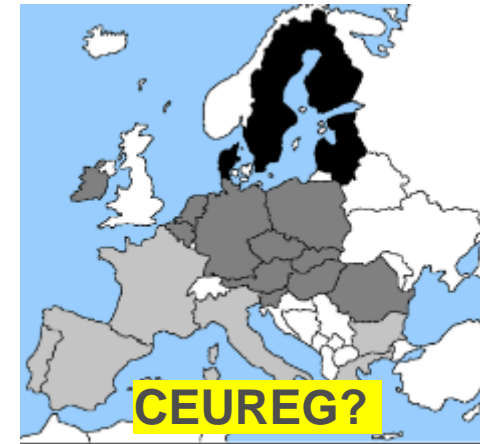
Dist. (m)	Denmark	Estonia	Finland	Latvia	Lithuania	Norway	Sweden*
Width of non-spray buffer zones to mitigate drift (m)							
2	FVOB						
3							
5	FVOB					FVOB	
10	FVOB		FVOB		FVOB		
15		FVOB		FVOB			FVB
20	FVOB			FVOB		FVOB	O
25							
30	VOB		OB		OB	FVOB	
35		OB					
40	O		O	OB			
45							
50	O		O	O			
Runoff vegetative buffer zone (m)**							
	-	10	10	10	10	10	-
Drift-reducing nozzles (%) *							
25	-	-	-	-	-	-	O
50	-	Yes	Yes	Yes	Yes	FVOB	FVOB
75	-	Yes	Yes	Yes	Yes	FV	FVOB
90	-	Yes	Yes	Yes	Yes	FV	FVOB
99	-	-	-	-	-	-	O

2

At Member States level:
assessment of the plant protection product
containing the active

National lists of risk mitigation measures

- **Czech Republic:** Information on personal protective equipment and Protective distances to protect people / buffer zones - people (bystanders, residents)
- **Belgium:** Recommendation towards protection of surface waters by professional users of Pesticides
- **The Netherlands:** Methodology to derive risk performance factors for drift reducing nozzles (DRN) and classes of DRN + Classes of purification stations of aquaponics systems in greenhouses
- **Germany:** Information on personal protective equipment and list of different drift reduction nozzles
- **OTHERS?**



Compendium = « first (living) list »

WHAT?

WHERE?

EMISSION
ROUTE

BENEFICIARIES ?

PERFORMANCE :

max. % exposure

reduction ? References

DATA?

Item	To be used in:	Nature of exposure/ risk	Compartment benefitting in the Risk Assessment					Performance (38)	References	Are harmonized exposure data available to be used in risk assessment?
	Horizontal crops (HC), Vertical crops (VC), granules (GR) or treated seeds (TS), indoor		Human Health ⁽³⁹⁾		Environment					
			Operators/ workers (professional)	Bystanders/residents (citizens)	Surface Water + Aquatic organisms	Terrestrial field area + non-target organisms	Groundwater			
Emission shields, shielded sprayers, hooded sprayers	HC + VC	DRIFT			X	X		90% for shields in Italy	Guidance document of Mitigation Measures for Surface water in Italy	Data should be provided to confirm the performance level of the chosen equipment for a specific condition of use
Tunnel sprayers	VC	DRIFT			X	X		Can mitigate 90-99% (depending on the possible combination with Drift Reduction Nozzles).	Guidance document of Mitigation Measures for Surface water in Italy	Data should be provided to confirm the performance level of the chosen equipment for a specific condition of use

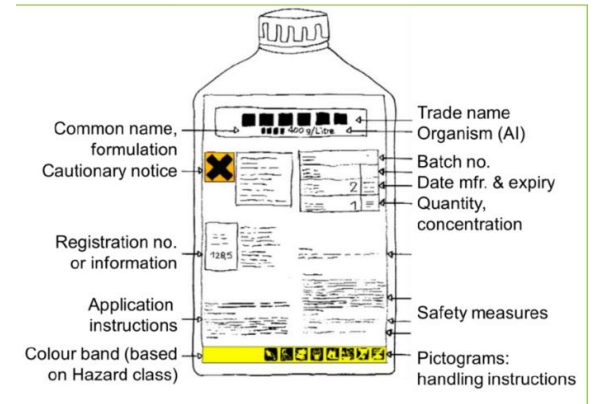
Memorandum to the Compendium: Follow-up actions needed

- **Procedural aspects** to include additional techniques or conditions of use, or further specification/description/definition of already listed ones:
 - Which data? From whom?
 - Mandating EFSA (under discussion)
- “Validation of performance values”: standard methods to test ?
Equivalence of techniques?
- Amendment of guidance documents: ceiling values to risk mitigation + combination of techniques?
- Availability, affordability reliability (certification?) of the techniques/machines
- **Product labelling requirements**

Amendment Regulation (EU) No 547/2011: Labelling requirements for Plant Protection Products (PPP) (under discussion)

Content of the proposal :

- **Annex I:** Information on the PPP identification and conditions of use
- **Annex II:** Standard phrases for safe disposal of the PPP
- **Annex III:** Standard phrase and pictogram for hazard communication of PPP containing chemicals: hazard for bees
- **Annex IV:** Standard phrase for hazard communication of PPP containing micro-organisms: sensitising effects
- **Annex V:** Standard phrases for risk mitigation measures: human health and environment
- **Annex VI:** Coloured scheme



Amendment **Labelling** requirements – **RMM** (under discussion)

Standard phrases are built according to a “modular” mode: few examples

- “SRu 1: To protect (human health, environmental compartment, group of organisms or species to be specified), (do not) use/apply (temporal restrictions or restrictions to growth stages to be specified).”
- “SPe 1: To protect (environmental compartment, group of organisms or species to be specified), use drift reduction technology ensuring at least x% of exposure reduction.”
- “SPe 3: To protect (environmental compartment, group of organisms or species to be specified) keep an untreated buffer zone/ vegetated field margin(s)/crop free zones of (width to be specified) to (for instance surface water, field margins).”

In the future? Encoded electronically machine-readable information to illustrate the RMM?



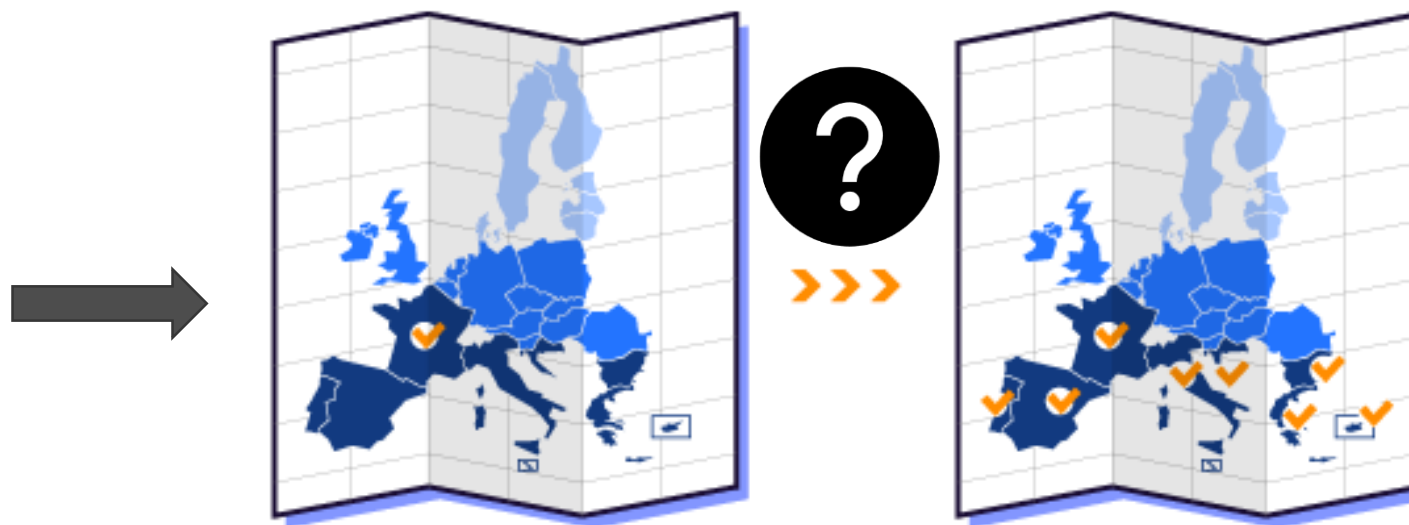
2

WHICH BENEFIT TO COLLABORATE IN A ZONE?

Harmonisation of similar conditions of use imposed as risk mitigation measures when authorising a PPP is needed to facilitate mutual recognition.

Member States	Responsible Authority	Drift Reduction Classification
BE	FOD	50, 75, 90 % (99% for orchards only)
DE	JKI	50, 75, 90, 95 %
FR	ZNT	66, 75, 90, 95% ²⁾
NL	TCT	DR Nozzles 75, 90, 95%, DR Technology (DRN + DRT) up to 99%

Source: CEMA, 2021



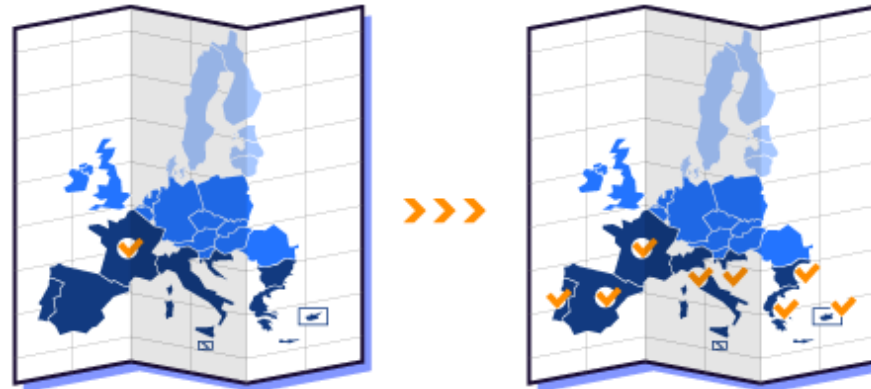
If the PPP is authorised in one MS, the authorisation in other MS can be quicker via **mutual recognition**.

Steps and on going activities

1. **Workshop 2020** with MS, EFSA, COM services and research experts: Reducing exposure to pesticides – experience so far and next steps towards more sustainable plant protection.
2. *“Compendium of conditions of use to reduce exposure and risk from plant protection products” - 2024*
3. **? Working Group with MS?** : how to implement specific conditions of use in the framework of the Reg. (EC) No 1107/2009?
4. Mandates to EFSA? PERA activities?
5. Revision of the **labelling regulation** & Implementing of **record keeping**.
6. Alignment with **EFSA’s research projects** to develop new exposure scenarios for application techniques.
7. Communication with **stakeholders (EUPAF, AGRIGUIDE, OECD)**.
8. Funding **research** on innovative techniques under Horizon 2020.
9. **Training:**
 1. existing already E- learning course on Risk Mitigation Measures
 2. To come in 2025-2026 : **3 BTSF workshops**

Take home messages

1. Conditions of use to reduce exposure can be integrated at EU level or national level during the preparation of the dossier, the risk assessment and/or risk management process.
2. MS can decide the most appropriate risk mitigation measures according to their national conditions.
3. Harmonisation of similar conditions of use is needed to facilitate mutual recognition.



Take home messages

New application techniques:

- Important to reach the reduction targets
- compilation, classification, validation and dissemination of quantitative and qualitative data is needed at national and EU level to develop exposure scenarios.
- Effectiveness to reduce exposure + information on their affordability, controllability and enforceability should be considered.
- Inspection, calibration and training of the users is essential.
- Should be available also for non chemical pesticides.
- Possibility of digital labels and the obligation of record keeping can encourage their use.



Check BTSF Academy website

E- learning course on Risk Mitigation Measures

Content

1. **Assessing the risks of pesticides**
 2. **Mitigating the risks of pesticides**
 3. **Techniques and practices in place to reduce risks**
 4. **Practical aspects of RMM**
 5. **Regulatory framework**
- **Duration:** 6 hours
 - **To whom:** authorities and stakeholders.
 - **Languages:** EN + few others to come

Thank you!



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