

SPECIALITY CROPS



MinorUses

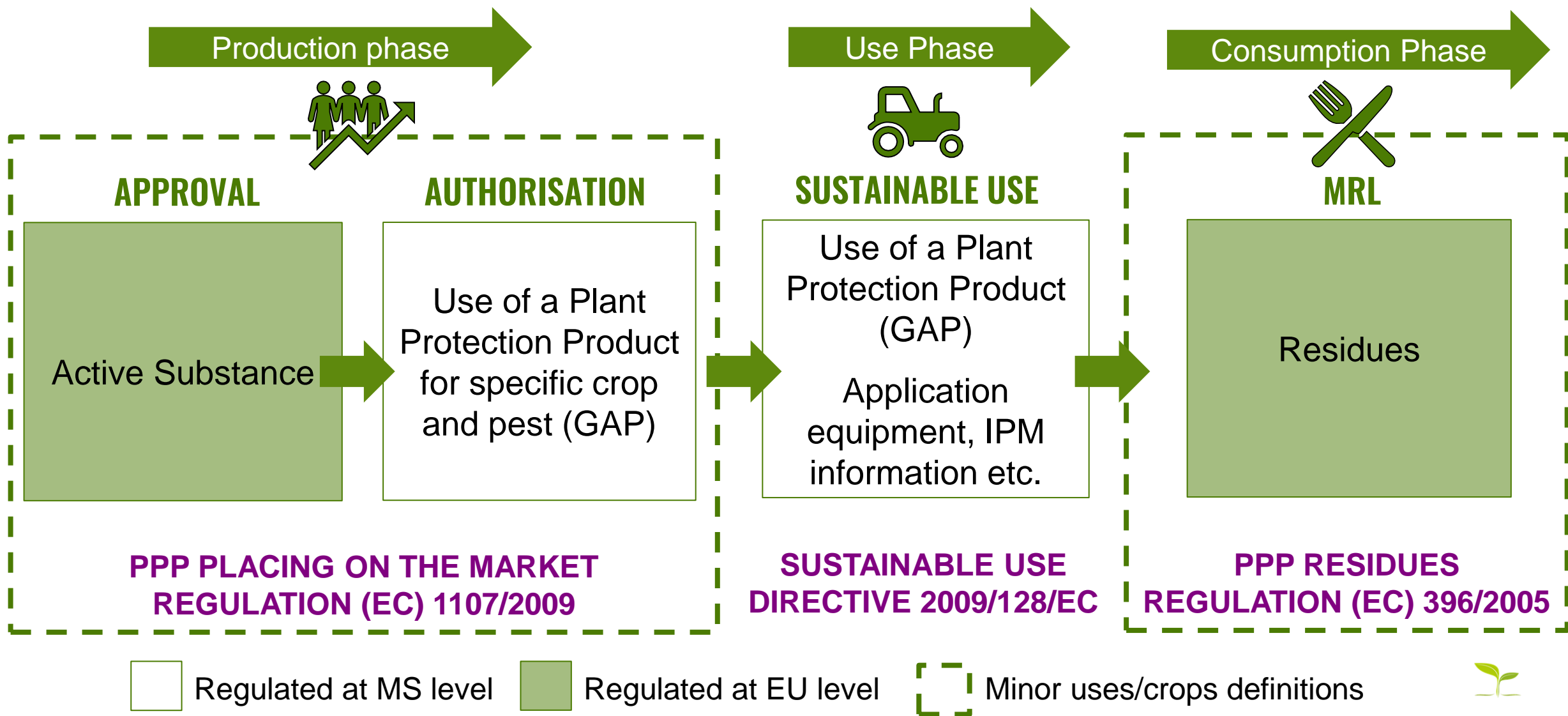
HOW IS THE PRODUCT AUTHORIZATION SYSTEM IMPACTING MINOR USES AUTHORIZATIONS?

**BETWEEN REGULATORY FRAMEWORK &
REALITY CHALLENGES**

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EU PESTIZIDE LEGISLATION

THE REGULATORY CYCLE OF A PLANT PROTECTION PRODUCT





WHAT ARE MINOR USES/ CROPS? DEFINITIONS

Regulation (EC) No 1107/2009 – Article 3(26):

Use of a plant protection product in a particular Member State on plants or plant products which are:

National dimension

(a) not widely grown in that Member State,
or

Minor crop

(b) widely grown to meet an exceptional
plant protection need

Minor use on a major crop

Minor crop refers to cultivation area

EPPO Standard PP 1/244(3) Principles of efficacy
evaluation of MU.

Minor crop refers to economic value of the crop





WHAT ARE MINOR USES/ CROPS? DEFINITIONS

TECHNICAL GUIDELINES: On data requirements for setting MRLs, comparability of residue trials and extrapolation for residue data on products from plant and animal origin (SANTE/2019/12752).

The following criteria were used for classifying a crop or a product as 'major' in the EU:

(a) **Daily intake contribution** > 0.125 g/kg bw/day and relevant cultivation area (> 20 000 ha) and/or production (> 400 000 tonnes per year) in the zone

or

(b) **Cultivation area** > 20 000 ha and production > 400 000 tonnes per year

All crops not defined as 'major crops' according to the criteria outlined above are minor crops.

Minor/major refers to daily intake in combination with cultivation area or production amount



REGULATORY VERSUS EPPO AND RESIDUE ZONES

Regulatory zones:

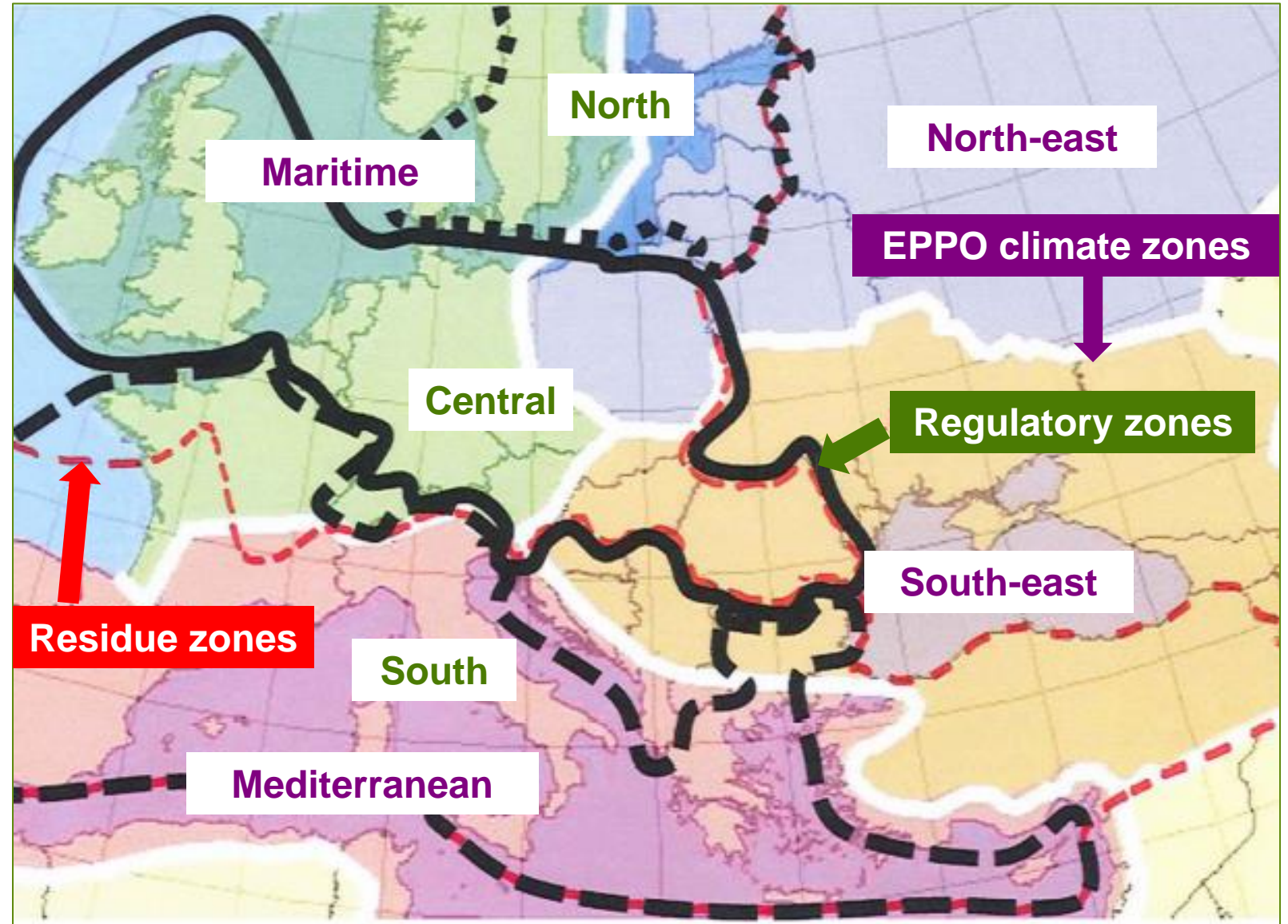
North, Central, South


EPPO climate zones:

Maritime, Mediterranean,
North-east, South-east

Residue zones (outdoor):

North and South





IS THIS A WORKABLE DEFINITION

Issues

- Leaves it up to MS to define what constitutes as "minor crop/use"
- Interferes with the zonal procedure and mutual recognition
- Use of mutual recognition for authorisation of PPPs varies greatly between MS and zones
 - additional national requirements
 - lack of harmonisation in the methodologies used for conducting evaluations
 - lack of cooperation and coordination
 - sub-optimal efforts spent on commenting on the work carried out by others during the zonal assessment process
- Use of zonal authorisations and mutual recognition would **reduce the duplication of work** and speed up market access for PPPs.

MINOR USES & SPECIALITY CROPS IN EUROPE ACTUAL STATE PART 1

- **lack of active substances** at MS level due to the relatively high registration process costs.
Sales versus data generation costs (MRL, efficacy data, application fees, etc.)
- The costs and workload involved in authorising PPPs within the three zones established by the PPP Regulation are not fairly distributed across MS. This also contributes to the existing delays as certain MS face a high workload.
- Off-Label Extension of Authorisation for Minor Uses (EAMU), or Emergency Use Authorisations are used as an interim solution.

The use of any product with an off-label EAMU approval is entirely at the **risk of the user!**



MINOR USES & SPECIALITY CROPS IN EUROPE ACTUAL STATE PART 2

Regulation (EU) No. 1107/2009 determines under article 53 that a MS can authorise a PPP on the market in **special circumstances** for limited (max. 120d) and controlled use.

- MUCF contacted a survey on Emergency Use Authorisations granted between 2017-19 in Europe & compared it with MU needs
 - A total of 311 substances were covered by 1753 authorisations.
 - **80% of the 50 first prioritized needs** are addressed in Europe with emergency authorization.
 - Insecticides were authorized 906 times, fungicides 442 times, herbicides 264 times, and others 141 times.
 - Most emergency authorisations granted for the **active substance cyantraniliprole (5%)**, and for the pest *Drosophila suzukii* (6%).



EMERGENCY AUTHORISATIONS COMPARISON TO MINOR USES NEEDS

Crop EPPO Code	Crop common name	Pest EPPO Code	Pest scientific name	Pest common name	Frequency	Priority total points	Member States	Area of use	Function	CEG	Number of Emerg. auth. on the period 2017-2019	
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PRNAV	sweet cherry	DROSSU	Drosophila suzukii	spotted drosophila	wing	10	39	Northern: DK Central: CH,DE,IE,NL,SI,UK Southern: CY,ES,PT	f,fg	insecticide	Fruits and Vegetables	63
RUBID	raspberry	DROSSU	Drosophila suzukii	spotted drosophila	wing	18	60	Northern: DK,EE,FI,NO,SE Central: AT,BE,CH,DE,HU,IE,NL,SI,SK,UK Southern: FR,IT,PT	f,fg	insecticide	Fruits and Vegetables	45
PRNDO	european plum	DROSSU	Drosophila suzukii	spotted drosophila	wing	8	12	Northern: EE,SE Central: DE,NL,SI,UK Southern: FR				
PRNCE	sour cherry	DROSSU	Drosophila suzukii	spotted drosophila	wing	3	9	Central: DE,SI Southern: FR				

- DK (2): Spinosad
- AT (9): lambda-Cyhalothrin, Pyrethrins, Spinosad
- BE (5): Cyantraniliprole, Dimethoate, Phosmet
- CH (18): Acetamipride, Calciumhydroxide, Kaolin, Pyrethrine, Spinosad, Thiadiprid
- DE (4): Cyantraniliprole, lambda-Cyhalothrin, Spinosad
- IE (2): Cyantraniliprole
- NL (3): Cyantraniliprole, Spinosad
- SI (3): Spinosad
- SK (5): Cyantraniliprole, Spinosad
- UK (5): Cyantraniliprole, Spinosad
- ES (3): Cyantraniliprole, Spinosad
- PT (1): Spinosad
- GR (3): Cyantraniliprole

The whole survey table is available:

www.eumuda.eu/database/table_minor_uses_and_art_53



CONCERNS & SOME POINTS FOR DISCUSSION

- As part of the GREEN DEAL commitment, in particular the Farm to Fork strategy to make food systems more sustainable and protect citizens from harmful substances, a reduction in the number of active substances approved at EU level has been observed
 - 2018: 488 approved active substances in Feb. 2021: 466 (65 out of them are candidates for substitution; 23 are Basic substances; 25 are Low risk substances)
 - 2020: 85 of non-renewed substances; 58 of renewed substances; 60 of new substances approved
- **diverse PPP toolbox** for farmers is needed (i.e. counteract pest resistance development, to competitively produce within the EU, to be competitive to imported produce)
- the very limited use of the simplification tools for minor uses (i.e. mutual recognition and extension of minor uses)
- the lack of incentives for industry to submit a dossier for minor uses authorisation
- Insufficient **Cooperation between MS**, coordination of trials and acceptance of residue data evaluated by other MS and acceptance of residue trials from outside the EU
- **Harmonized definition of 'minor crop/pest'** is needed to facilitate authorisations



SPECIALITY CROPS



THANK YOU FOR YOUR ATTENTION.



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