



Minor uses and emergency authorizations

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Emergency use - legislation

- ❖ *Art. 53 Regulation (EC) 1107/2009*
- ❖ *§ 26 Act No. 405/2011 Coll. (Phytosanitary Act)*
- ❖ *§ 19 Decree MoARD No. 485/2011 Coll.*

Emergency use in practice

- *Permission is granted by Ministry of Agriculture and Rural Development*
- *Based on expert assessment in tox, ecotox, fate and behaviour section*
- *Free of charge ! but revision of this provision is needed*

Emergency use - applicants

Chemical companies

Associations of farmers, fruit growers

Individual entities

➤ *First step:*

Relevance of application is strictly examined

Permission

- ❑ *Approved label and/or instructions for safe use, risk mitigation measures*
- ❑ *Records of placing on the market and use are requested*

BUT

Never: *PPP with non-approved or banned active substances*

Always: *Use is in compliance with MRL, supported by residual trials (or extrapolation is possible)*

Emergency uses - needs

I. PPPs authorized in EU MS but not in the Slovak Republic

II. PPP authorized in the Slovak Republic but for other uses (major/minor use)

*III. Special needs of organic farming (authorization in the Slovak Republic is not supported by producer – economical reasons, application for mutual recognition by third party- **questionable!!!!**)*

PPPs authorized in EU MS

- 1. new PPPs, authorization in SR is envisaged*
- 2. old PPPs, authorization in SR has not economical significance for producer, authorization in SR is not expected*
- 3. PPPs authorized in SR in the past, but authorization was cancelled during re-registration process (not longer supported by authorization holder)*

CONFLICTS

1. *Misuse of emergency use permission -- the easiest way how to place PPPs on the market (new authorization is more expensive 😊)*
2. *Long term process for extension of existing authorizations - main problems are zonal approach, limited personal capacities (need for fast action 😊)*

BUT

! No other alternatives for farmers (discrimination, role of hostage in economical interests of stake)!

Minor uses – economical aspects

Slovak Republic – small market for PPPs

Attractive are only major crops

(oilseed rape, maize, cereals, sunflower)

Unattractive market for minor crops (definition of minor crop is based on the size of cultivated area)

Majority of crops in the Slovak Republic are minor, incl. apple trees, pears, sugar beet ...

Minor uses – obstacles

Applications are submitted by farmers

high costs for authorization versus low volumes of PPPs placed on the market (for organic farming cca 10 !!)

*Long term process if assessment in all areas is requested (limited personal capacities of expert institutions) and zonal approach is applied (assessment reports for future mutual recognitions have to be in ENGLISH!, commenting phase...) – **HIGHER COSTS TOO***

Possible ways for simplification?

*National extension of authorization for minor use **without** zonal assessment and commenting (mutual recognition in other MS is not possible, absence of assessment report in specific format, SK language)*

Risk assessment is performed, assessment report is in very simple format (risk mitigation measures), in Slovak, limiting factor is tox section – residues!



Cooperation between MS

1. *Use information from EUMUDA
(European Minor Use Database)*

(protected part – for Minor use trials and studies database – how to obtain access?), possible extension of information (GAP), legal aspects?

2. *Coordination between MS (discussed EU coordination facility – mainly focused on collection data from MS and update of EUMUDA???)*

Other ideas are welcome...

?????



***Thank you for your kind
attention!***

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