Regulation No. 1107/2009 (EC)- Implementation in Slovak republic

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Structure of authorisation bodies and expertal workingplaces in Slovak republic

- Ministry of Agriculture and Rural Development of the Slovak republic
- Central Control and Testing Institute in Agriculture in Bratislava
- Department of Pesticide Registration

- Assessment of Biological efficacy (BAD) (5 experts)
- Assesment of Identity and Physical-chemical Properties (3 experts)
- Assessment of Analytical methods (1 expert)
- Coordination and Legislative(8 members)

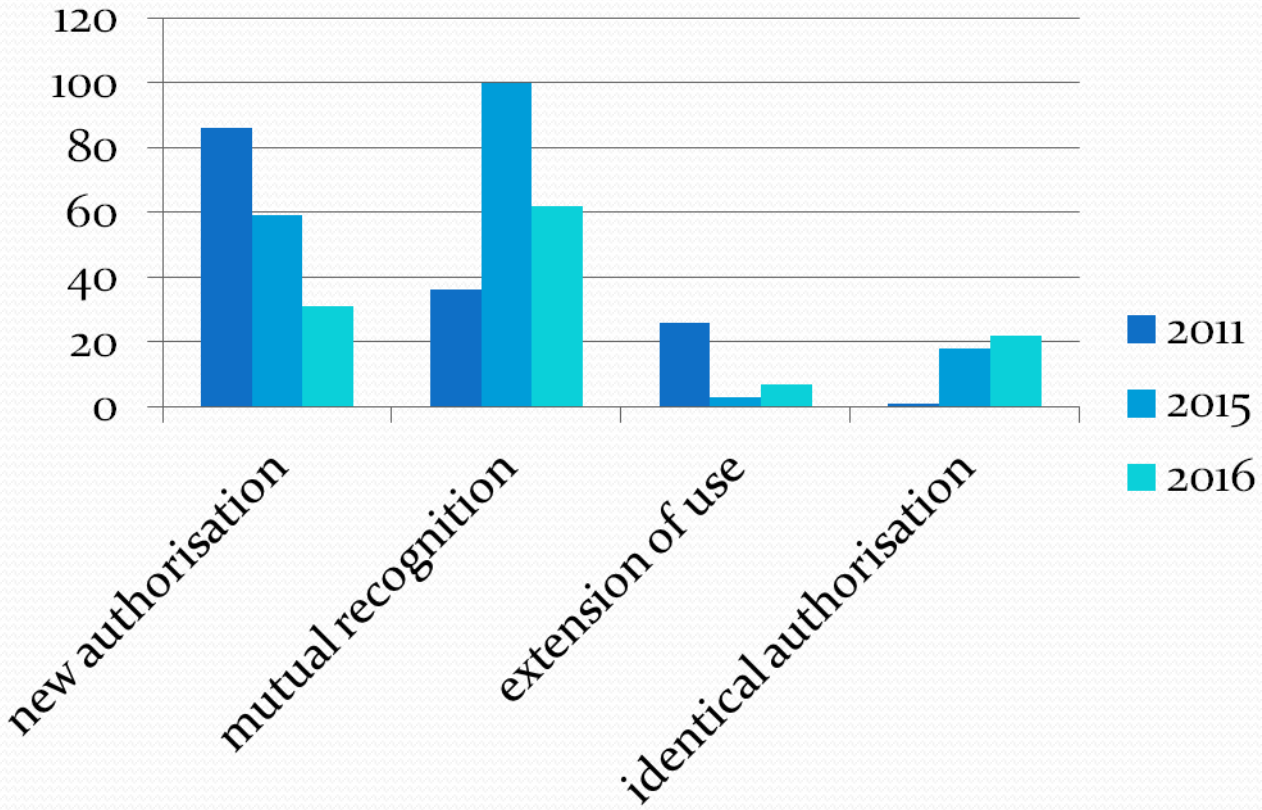
Cooperation with external workingplaces

- Ruled by 3 different ministries
- **Ecotoxicology**- Institute of Apiculture, NRL for Pesticides (University of Veterinary Medicine)
- **Toxicology, Operator exposure, Residues**- Public Health Authority
- **Fate and Behaviour** (Groundwaters and soils)- Water Research Institute
- **Fate and Behaviour** (Surfacewaters and air)- Slovak Hydrometheorological Institute

Number of applications received under Reg. 1107/2009

Applications under 1107/2009				
	2014	2015	2016	Summary
Other change	335	239	72	646
Notification of authorisation	2	26	12	40
Renewal of authorisation		0	53	53
Parallel trade (placed on market)	75	65	59	199
New authorisation	81	59	31	171
Re-registration (Step I)	8	2	1	11
Re-registration (Step II)	47	20		67
Extension of use	12	3	7	22
Parallel trade (providing information)	24	17	10	51
Mutual recognition	83	100	62	245
Summary	332	531	307	1505

Applications submitted under Reg. 1107/2009



Slovakia in EPPO zones

Art. 40- Mutual recognition- specific requirements in slovak conditions

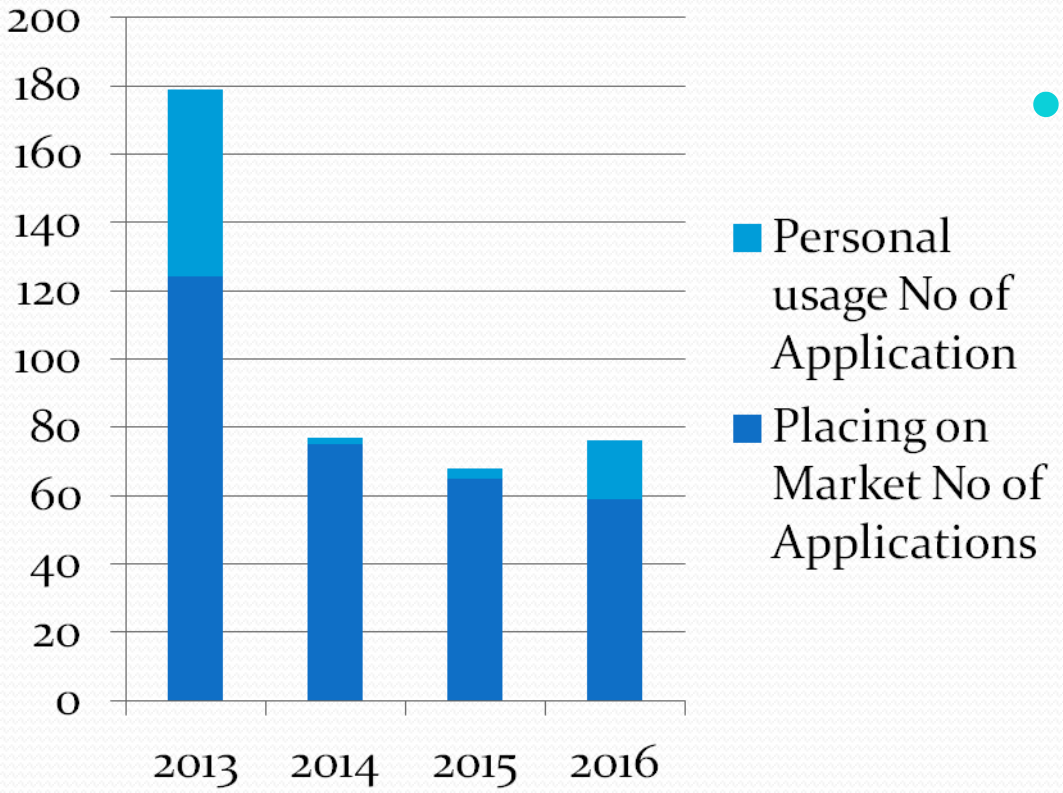
Fate section:	SK scenarios
ground water:	Used model: FOCUS PEARL, FOCUS PELMO Relevant Scenarios for Slovakia: Kremsmunster, Chateaudun, Hamburg (Piacenza only as a helping scenario, not essential). National requirements: none Note: Using of specific national methodics for risk assessment for ground water in case of using products in golf greens (combination of FOCUS models and GMS or MT3DMS).
surface water:	FOCUS SW modelling approach, Step 1, Step 2 (North Europe); Step 3: SWASH, models: PRZM, MACRO and TOXSWA, Relevant scenarios: D4, D5 and R1 (document SANCO/4802/2001) Step 4: SWAN National requirements: none Note: Greenhouses and covered crops (combination of FOCUS models and FOCUS drift calculator (0.1% of the dose rate as drift input to surface water)

Mutual recognition-BAD

- None efficacy trials from SE EPPO zone, authorisation is granted when there are comparable agricultural conditions
- How to deal it?
- The differences between MR and new authorisations (Art. 33)

Parallel trade (Art. 52)

- Placed on market vs Personal usage



- Problems with information request- 10 days period in not meet

Comparative assessment (Art. 50)

- Since 1.8.2015 is of force
- Already made 10 comparisons, next in procedures
- 40% prepared by UKSUP and 60% prepared by applicant, none was considered as Candidate for Substitution
- Problems by MR, when the CA is not prepared by applicant no chance to prepare registration within 120 days

Renewal of authorisation- Art. 43

- After renewal of active substances 53 applications
- SK is not considered as zRMS, just cMS
- Still waiting for RR
- Sometimes problems with documentation
- In some cases under presure re-registration is on-going + renewal

New authorisation (Art.41)

- In most cases SK is considered as cMS
- 1 application in 2015- SK is zRMS
- Problems- commenting period- detected no Efficacy trials or not sufficient number of trials
- PPP is not recomended for authorisation
- After stopping the procedure- application for MR

Conclusion

- Parallel trade- increasing of personal usage, it should be simplified procedure
- Mutual recognition- requirements for Fate and Behaviour and Efficacy sections
- Renewal-not enough practical experiences
- Work overload

Thank you for your attention