Regulation 1107/2009/EC:

Current issues in the Slovak Republic

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Outline

- Stage of progress in Slovakia
- Issues and experience with the applications in EU MSs including zonal approvals

Regulation 1107/2009/EC - expectations and results within 3 years after coming into force

Aim:

- To speed up the authorisation procedures
- To eliminate duplication of work, saving capacity of experts
- To harmonize the system of authorisation
- Availability of similar PPP for farmers in all MS

Stage of progress

Where we were?

Where we are?

Unchanged

- SK Authorisation system – decentalized
- PPP evaluation: UKSUP plus 5 independent Institutes
- 6 Institutes belong to 4 different Ministries
- Divided areas for Ecotox and Fate do not facilitate the process

Consequences

= impossibility to determine/change priorities by UKSUP

= lack of control over assessments

= lack of harmonisation in assessments

= a complicated regulation of priorities and planning

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Stage of progress

Small change/Big change

- 2011 – built unproffesional database on MS Access (available only for UKSUP)
- zonal authorisations coordinated by UKSUP

Consequences

= MS Access database - quicker access to data + processing for statistics purposes - temporary solution in 2011, nowadays not sufficient

= annually List of PPP created manually

= process under control of authority

- Number of staff - still insufficiente in some areas / Fluctuation in expert area

Consequences

= missed deadlines within zonal processes

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Stage of progress

Evaluation capacity in SK /2014 (30,5 people)

	2008	2012	31/7/2014
Coordinators	4	**5**	5
Phys-chem, AM	2	2	**3.6**
Efficacy	3	**4**	4
Admin staff	2	1	3
Legislation	1	1	1
Tox	0.7	0.7	0.7
Res	0.7	0.5	0.5
Fate Gw	1	**2**	**7.2**
Fate Sw	0.7	**1.5**	**2.8**
Ecotox	1	0.7	1
Ecotox bee	0.5	**1**	1

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Stage of progress

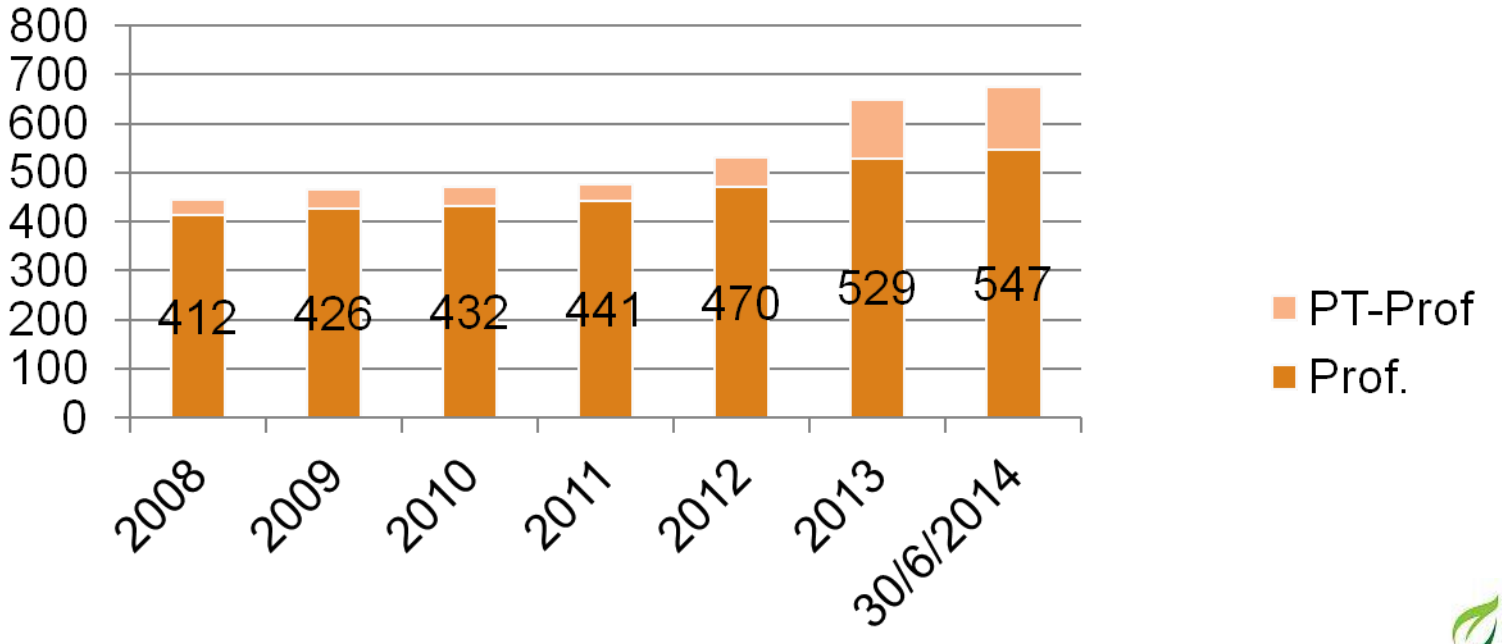
AS and PPP Statistics

by 30 June 2014

674 plant protection products

223 active substances

Number of PPP in the years 2008 - 2014



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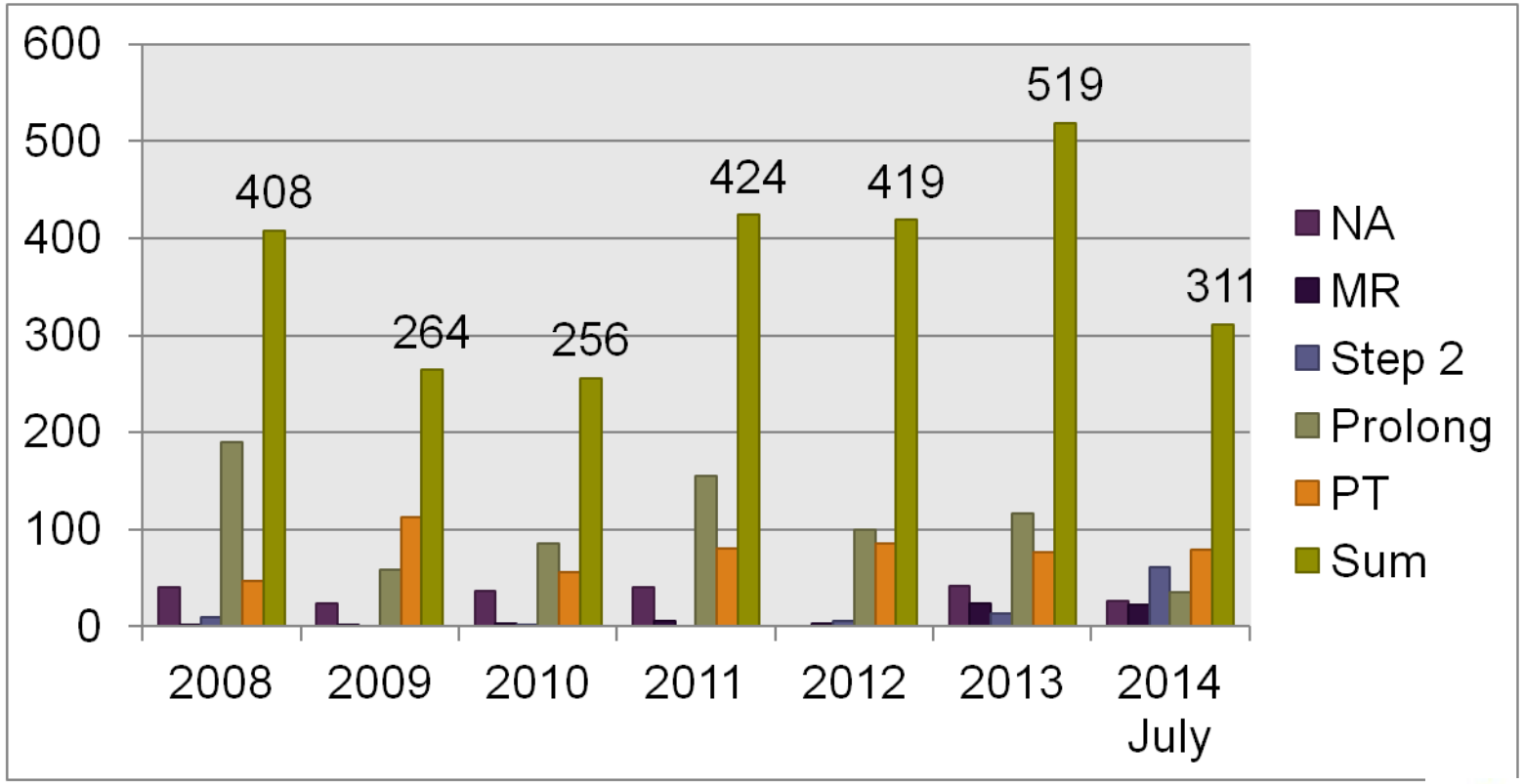
Stage of progress

No. of issued PPP Approvals 2008 - 2014



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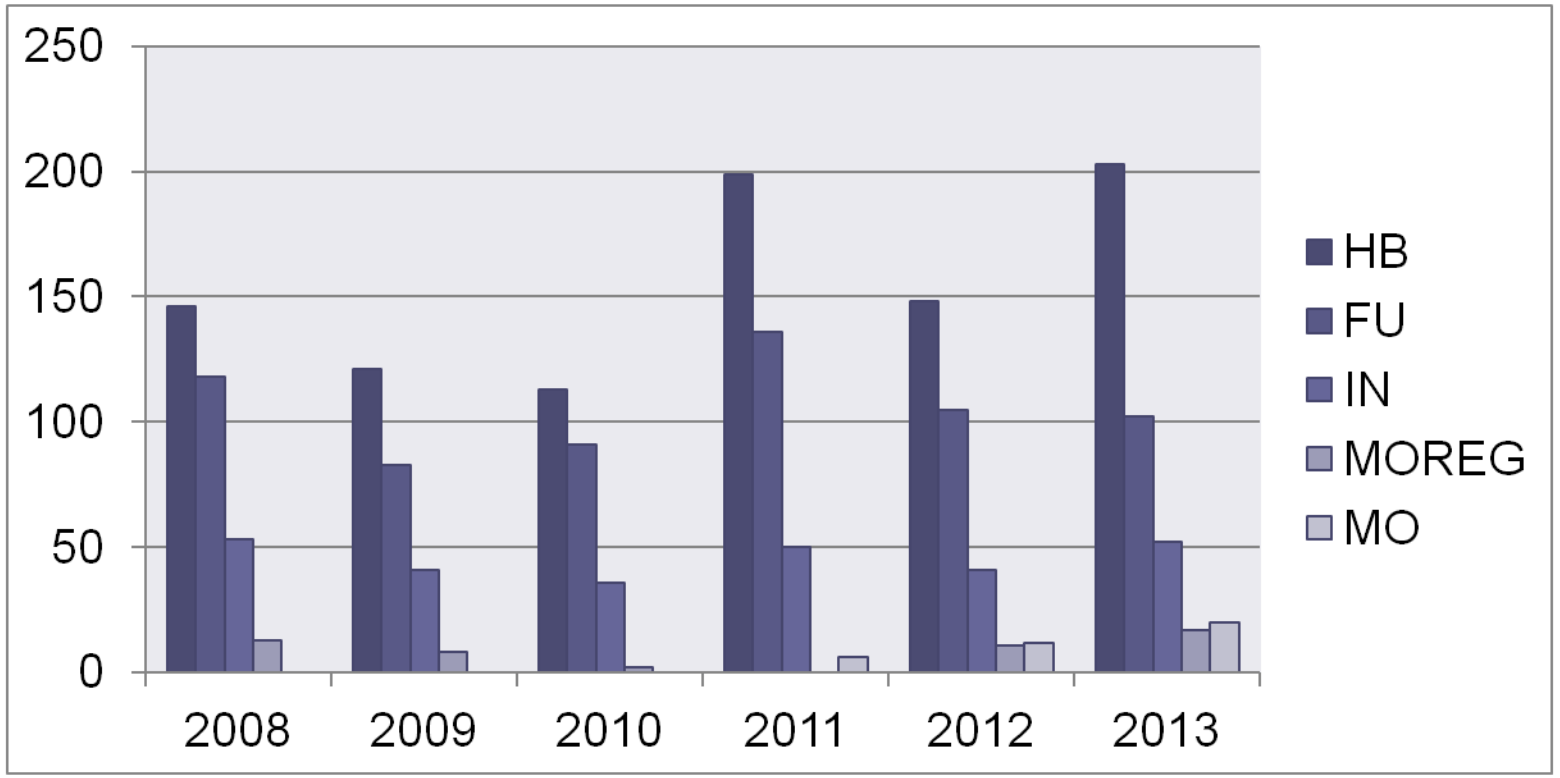
Stage of progress

PPP in terms of their functions



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Stage of progress

1107/2009/EC Applications 2012 - 2014:

SK zRMS

New authorisations	10
Label extension	1
Step 2	4

SK cMS

New authorisations	96
Step 2	52
Notifications for intended applications	121

National Applications in progress

New authorisations	91	Parallel trade	22
Step 2	173	Minor use	26
Mutual recognition	58	Label extension	22

- 834 applications in progress in 2014

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Stage of progress

MS Capacity 2015

5 applications for new product or Step 2/Renewal

Re-approval of AS

AIR I

■ Prohexadion (calcium)	SK (co-RMS), FR (RMS)	completed

AIR II

■ Prosulfuron	SK (co-RMS), FR (RMS)	being finalised
■ Glyphosate	SK (co-RMS), DE (RMS)	being finalised

AIR III

■ Foramsulfuron	SK (co-RMS), FI (RMS)	in progress
■ Metrafenone	SK (co-RMS), LV (RMS)	an application received
■ Methoxyfenozide	SK (co-RMS), UK (RMS)	an application received
■ **Boscalid**	**FR (co-RMS), SK (RMS)**	**2015**
■ Diflubenzuron	SK (co-RMS), EL (RMS)	2015

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Issues and experience with the applications in EU MSs

Submission of Application

- Incomplete/incorrect filled SK application

Study reports

- Incomplete CD – the lack of Study reports from diferent Sections

dRR for minor use

- Farmers submit applications for MU instead of holder of authorisations – authority should write dRR

Issues and experience with the applications in EU MSs

dRR

- Wrong indication of the manufacturer vs. manufacturing plant of AS or PPP
- More focused assessments are needed (often too extensive, e.g. dRR B7 more than 300 pages??)
- Lack of some EPPO zone within the zonal evaluation
- Requirement from MS to include zRMS comments in a green Table
- Different GAPs included in sections of dRR

Issues and experience with the applications in EU MSs

cMS - New product authorisation (Art 36) and MR (Art 40)

- Evaluation of national data if submitted (in case of Art 40 appl. 120 day can not be kept)
- Even nowadays we meet with Reg. report not in EN
- Reduction of national requirements – relevant fate scenarios and particular EPPO zone should be available
- SK has no national requirements

Relevant scenarios GW	**Relevant scenarios SW**
Kremsmunster, Chateaudun, Hamburg	FOCUS SW modelling
(Piacenza only as a helping scenario)	approach, Steps 1 – 4
Used models:	
PEARL 4.4.4, FOCUS PELMO 4.4.3	D4, D5 and R1

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Issues and experience with the applications in EU MSs

Parallel trade

- In SK - products only permitted, not authorised
- The time of permission can not be prolonged – new application needed
- SK does not allow re-packaging of parallel products

Generic products

- No experience
- Possible problem with PPP which did not come through Step 2
- Data protection must be over

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Conclusion

- Analysis of the authorisation process 2008 – 2014 indicates acceleration of the process in accordance with Regulation 1107/2009/EC in SK
- To increase resources to meet the demands of the regulation is needed
- Database system needed (SK)
- Regulation 1107/2009/EC gives good opportunities for saving capacities and work-sharing
- In near future MS to cope with incoming new demanding tasks (renewal, comparative assessment, …) where work-sharing and expert resources will be important

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Thank you for your attention!

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