



Ministry of Agriculture and Rural Development

Department of Plant Breeding and Plant Protection

**Selected issues of Plant Protection
Products registration in Poland.**

***Organisation, structure and current
problems.***

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DEPARTMENT of Plant Breeding and Plant Protection

UNIT OF PPP MARKETING

- active substances issues,
- post authorisation administrative changes and formulation changes,
- parallel trade,
- emergency authorisations,
- permits for trial purposes (research and development),
- approval of expert units.

UNIT OF REGISTRATION OF PPP

- risk management for plant protection products,
- administration and coordination of authorisation process,
- renewal of PPP
- extension of use,
- minor uses issues.
- Control and harmonisation of experts evaluation

Legislation
Cooperation with EC, MSs
Public access to information

...and 5 other units

Competent authority

UNIT OF PPP MARKETING - number of staff: 9

UNIT OF REGISTRATION OF PPP - number of staff: 13

Commission for Plant Protection Products

- opinions to authorisation project submitted by Unit
- members - 7

Expert's units

- entitled to perform evaluations or comments on a dossier of as/PPP and risk assessment.
- 10 units entitled.
- Number of staff performing evaluations (active) ~50

Currently granted 2373 authorizations for PPP (398 parallel trade) with 336 active substances

Plant protection products – Article 33/34

650 applications (ZRMS and cMS)

Mutual recognition – Article 40

55 applications

Extension of authorisations

100 applications – art. 45 (80% - ZRMS only for PL)

60 applications – minor uses art. 51

Current problems and challenges

- 1. Exemption from the submission of studies (art. 34)**
- 2. Minor uses**
- 3. PPP for seed treatment**
- 4. Low-risk plant protection products**

Art. 34 - access to the protected data/expired data protection period.

- Increasing number of applications
- Mutual recognition with art. 34. Data protection is national – in Poland the uses, crops, application periods are taken from product authorised in Poland.

Plan for future: to refuse when there are significant differences among Polish and reference MS label (reason: different data, different protection)

Comparable products?

- According to art. 34 2c on the request of the MS, the applicant submits data needed to demonstrate that the plant protection product has comparable effects to the plant protection product for which they show access to the protected data.
- SANCO/12638/2011 Guidance document on significant and non-significant changes of the chemical composition.
- Yet, no case while MARD asked for efficacy studies to confirm comparability but this is under discussion.
- Not possible to use expired data protection when the reference product is not authorised – the authorisation expired or was withdrawn.
- Not possible to change composition or reference product while the administrative process already started.

Minor uses – requirements

- Part B must be submitted for sections where new data or evaluations are necessary
- Each application is investigated case by case
- Decision which sections should be evaluated is made individually
- Efficacy – not evaluated
- Residues – always evaluated, evaluations prepared in other MS are acceptable. Administrative extrapolation is not approved.
- PL accepts mutual recognition for minor uses

Minor uses protection – facilitations in PL

- Minor uses are granted at the same time when Zonal Registration or Mutual Recognition authorisation is granted.
- The evaluation is conducted in core dossier
- Crop must be on the list in national regulation on minor uses – the list is very long, only few crops are not there (for instance only apple among horticultural crops)
- The administrative fee is only 120 Euro per application

Seed treatment

- Lack of products for seed treatment after withdrawal of some active substances – in particular for vegetables and oilseed rape.
- Seed treatment in forest cultivation – lack of products and alternative methods.
- Need for alternatives for neonicotinoids – oilseed rape, sugar beet.

Low – risk Plant Protection Products – Polish position


- Still very short list of approved low risk active substances for IPM and organic farming
- Requirements for data package of low risk substances should be reduced
- Too short period of approval

Low – risk Plant Protection Products – current situation in PL

- Fees are reduced
- Pre – submission meeting is free of charge
- Separate queue for applications.
- Facilitations for MR



Most wanted applications in PL ...

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- New PPP for seed treatment
 - PPP for minor uses (low economical importance)
 - PPP with active substances still not authorised in PL
 - PPP for organic farming

