Ministry of Agriculture and Rural Development

Department of Plant Breeding and Plant Protection

Practical effects of implementation of Regulation No 1107/2009 in Poland

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Statistical data

Currently granted 1297 authorizations for PPP:

264 - parallel trade

687 - according to uniform principles

257 - active substances in PPP

583 - herbicides – 45 %

415 - fungicides – 32 %

185 - insecticides – 14 %

62 - plant growth regulators - 5 %

52 - others - 4 %

Law

Regulation 1107/2009

Directive 2009/128/WE

ACT of 8 March 2013 on Plant Protection Products
- registration of PPPs
- trade of PPPs
- use of PPPs
- IPM

ACT of 18 December 2003 on Plant Protection
- phytosanitary issues
- organiztion of SPHSIS

17 Regulations

National Action Plan (NAP)

Competent authority

Ministry of Aagriculture and Rural Development

1. Legislation EU/national
2. Administration and coordination of authorisation, risk assessment and risk management for:
   - active substances
   - plant protection products, safeners, synergists, adjuvants
   - post approval issues
3. Cooperation with COM, EFSA, MS (exchange of information, work-sharing)
4. Public access to information – internet data base of authorized PPPs
5. Approval and control of Expert's units
6. **Number of staff – 19**

Commission for Plant Protection Products

- opinions and comments to RR and documents submitted by MARD
- **members - 7**

Expert's units

- entitled to elaborate evaluations or comments on a dossier of as/PPP and risk assessment
- **10 units** - number of staff - **230 experts**

Approval of active substances – Articles 4 - 21

- RMS for garlic extract
- AIR 2 (RMS for **1** as, coRMS for **2** as)
- AIR 3 (RMS for **9** as (11 **-** 2), coRMS for **7** as)
- New active substances – **0**

Advantages:

- free experts resources

Disadvantages:

- language requirements
- lack of experience
- formal problems in commenting DARs

Approval of active substances – Articles 22 – 27, 47, 49, 58

- low risk active substances and PPP
- basic substances
- candidates for substitution
- safeners and synergists
- unacceptable coformulants
- comparative assessment of PPP containing candidates for substitution
- adjuvants

Advantages:

- further risk reduction

Disadvantages:

- lack of experience and new problems
- additional work
- additional staff

Plant protection products – Articles 28 - 39

- 506 applications to evaluate – on June 14, 2011
- 589 applications submitted since June 14, 2011
- 590 applications in a cue (118 old, 159 RMS, 319 CMS)
- 150 authorizations granted this year
- 332 applications under evaluation
- 258 applications still waiting for evaluation

Advantages:

- zonal system
- less of work where PL is CMS
- a large number of experts

Disadvantages:

- huge delays in evaluations of applications
- lack of staff in MARD
- lack of harmonization of procedures in sections 5, 6 and 7

Mutual recognition of authorisation – Articles 40 - 42

- 127 applications submitted since June 14, 2011
- 86 applications in a cue
- 10 authorisations in this year
- 83 applications under evaluation
- 3 applications still waiting for evaluation

Advantages:

- harmonization of PPP market in Europe

Disadvantages:

- all submitted applications granted according to Directive 91/414/EEC
- new procedure in Poland
- huge delays in evaluations of applications
- problems with authorisation process when report has not been commented

Renewal, withdrawal and amendment – Articles 43 - 46

- 2088 applications submitted since June 14, 2011
- 963 applications in a cue (578 CLP)
- 367 decisions granted this year
- 638 applications under evaluation
- 325 applications still waiting for evaluation

Advantages:

- none

Disadvantages:

- foreseen significant number of applications in future

Placing on the market of treated seeds – Article 49

Advantages:

- significant facility for seed market
- interzonal registration system

Disadvantages:

- problem with use of PPP registered in third countries for seed intended for their market

Extension of authorisations for minor uses – Article 51

- 85 applications submitted since June 14, 2011
- 44 applications in a cue
- 20 authorisations in this year
- 40 applications under evaluation
- 4 applications still waiting for evaluation

Advantages:

- possibility for approval holders to submit applications
- zonal registration system

Disadvantages:

- lack of harmonization of procedures
- lack of commitment of farmers associations
- unsatisfactory fund for minor uses

Parallel trade – Article 52

- 382 applications submitted since June 14, 2011
- 32 applications in a cue
- 54 permits granted this year (46 applications rejected)
- 32 applications under evaluation
- 0 applications still waiting for evaluation

Advantages:

- equalization of prices on the PPP market in Europe

Disadvantages:

- lack of full control of trade
- abuse in trade

Emergency situations in plant protection – Article 53

- 24 applications submitted since June 14, 2011
- 0 applications in a cue
- 0 authorisations granted this year (3 applications rejected)
- 0 applications under evaluation
- 0 applications still waiting for evaluation

Advantages:

- good possibilities to solve emergency problems

Disadvantages:

- none

Research and development – Article 54

- 3096 applications submitted since June 14, 2011
- 56 applications in a cue
- 948 decisions granted this year
- 56 applications under evaluation
- 0 applications still waiting for evaluation

Advantages:

- control of experiments or test

Disadvantages:

- huge amount of applications
- unsatisfactory evaluation process of applications

Data protection vs confidentiality – Article 59 vs 63

Advantages:

- for approval holder

Disadvantages:

- formal problems witch applications
- time consuming processes

Conclusions

Regulation No 1107/2009

is a significant step forward

Thank You For Your Attention