

CEUREG
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CROATIAN PROGRESS REPORT
Authorisations and permits of PPPs
according to Regulation (EC) No. 1107/2009

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MINISTRY OF AGRICULTURE

Directorate of Food Quality and Phytosanitary Policy

Sector of Phytosanitary Policy

Service for Plant Protection Products, Department for Plant Protection Products

A close-up photograph of a vibrant green leaf with several clear water droplets of varying sizes. The leaf's veins are visible, and the background is softly blurred. This image occupies the top-left portion of the slide, partially overlapping a light green curved banner that contains the title and list.

Content

- Competent authority
- Responsibilities
- Report
- Plans
- Resources
- Main challenges and aims

Competent authority (CA)

Ministry of Agriculture

Directorate for Food Quality and Phytosanitary Policy

Sector of Phytosanitary Policy

Service for Plant Protection Products

Department for Plant Protection Products

Evaluation of dossiers

Croatian Centre for Agriculture, Food and
Rural Affairs - Plant Protection Institute
- evaluation of all areas except toxicology

Institute for Medical Research and
Occupational Health
- toxicology and OPEX

Responsibilities of CA

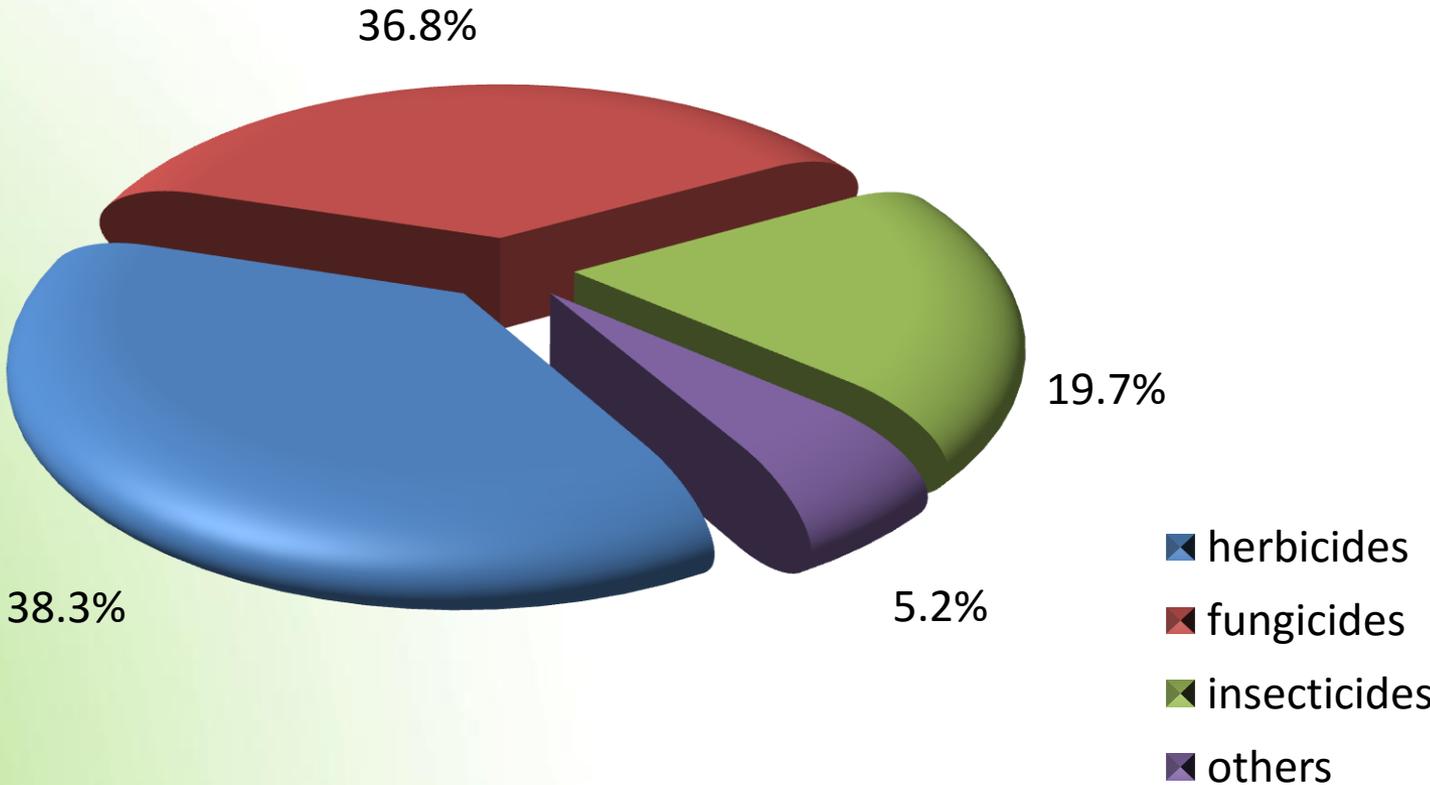
- policy in the area of PPPs
- enforcement of the provisions of the Regulation (EC) No. 1107/2009 at national level
- coordinates the process of authorisation, renewal and re-registration of PPPs
 - from submission of the documentation to the issuance of authorisation
- carries out completeness check
- issues authorisations and permits of PPPs
- maintenance of Phytosanitary information system (database on authorized PPPs)
- Phytosanitary information system:
<http://fis.mps.hr/trazilicaszb/>



Authorisation of PPPs

- from 1st July 2013 → in force Regulation (EC) No. 1107/2009 in Croatia
- before 1st July 2013 → Act on Plant Protection Products (OG 70/2005)
 - in line with the Directive 91/414/EEC

PPPs statistics



Number of authorised PPPs: 478
Number of active substances: 227



Authorisations issued according to Regulation (EC) No. 1107/2009 (July 2013 – October 2015)

Type of authorisation	Authorisations
HR - zRMS	1
HR - cMS (zonal and interzonal)	0
Mutual recognition	19
Clones	8
TOTAL	28

Ongoing applications submitted according to Regulation (EC) No. 1107/2009

Type of authorisation	Applications
HR - zRMS	2
HR - cMS (zonal and interzonal)	106
Mutual recognition	52
Clones	0
TOTAL	160



Permits issued according to Regulation (EC) No. 1107/2009 (July 2013 – October 2015)

Type of permit	Permits
Emergency situations (article 53)	36
Parallel trade (article 52)	1
Research and development (article 54)	93
TOTAL	130



Planned workload

Type of authorisation	Plan for 2016 – 2017
HR - zRMS	10 (accepted submissions)
HR - cMS (zonal and interzonal)	cca 100
Mutual recognition	cca 60 – 70



Planned workload

Evaluation of active substances	Plan for 2018 – 2021
HR – RMS	4 in 2019 1 in 2021
HR – coRMS	1 in 2018 1 in 2020 2 in 2021

Resources

Institution	No. of staff / experts
Ministry of Agriculture	6
CAFRA – Plant Protection Institute	24
Institute for Medical Research and Occupational Health	2



Main challenges

- timelines
- capacities issues
- increasing workload due to the obligations from Regulation (EC) No. 1107/2009
- switch to EU PPPAMS IT tracking tools for tracking progress from the submission of application to the issuing approval/permit
- new elements in the registration procedure – comparative assessment

Main challenges

- backlogs under the Directive 91/414/EEC
 - backlogs related to the re-registration program of PPPs according to uniform principles which started in 2008

Type of application related to the Directive 91/414/EEC	Applications
„Standard” (evaluation of Annex III dossier)	14
Recognition of authorisations	35



Comparative assessment

- Article 50 of Regulation (EC) No 1107/2009
 - Article 50.1 – comparative assessment related to other PPPs
 - Article 50.2 – comparative assessment of any PPP with non-chemical control and prevention method
 - List of candidates for substitution – Regulation (EU) No 2015/408
 - Comparative assessment should be included in Part A of dRR
- In HR guidance for comparative assessment is drafted
 - applications for new authorization
 - extension of authorization (only new uses)
 - renewal
 - mutual recognition
 - it will contain the list of major/minor crops



Midterm aims

- strengthen the administrative capacities
- increasing the involvement in the zonal process as zRMS
- revise national data requirements
- upgrade of Phytosanitary information system
 - used as a national PPPs database
 - keeping records on training of professional users, advisors and distributors, sales of PPPs, reporting to EFSA on pesticide residue monitoring



Thank you for your attention

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