Croatian Experiences with Evaluation of PPPs According to the Regulation (EC) No. 1107/2009

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History of PPP evaluation in Croatia

Until 2008

- PPP authorization based on Plant Protection Act (Official Gazette 10/94)
- IPP - biological testing of PPP
- IMROH - hazard assessment (no risk assessment)

2008 – 1st of July 2013

- evaluation based on Plant Protection Products Act (Official Gazette 70/05) within the Council Directive 91/414/EEC

History of PPP evaluation in Croatia

From 1st of July 2013

- Croatia joined the EU
- Implementation of Regulation (EC) 1107/2009

For requests submitted before 1st of July 2013

- registration and evaluation process under Council Directive 91/414/EEC

Institutions involved in evaluation

Croatian Centre for Agriculture, Food and Rural Affairs, Institute for Plant Protection

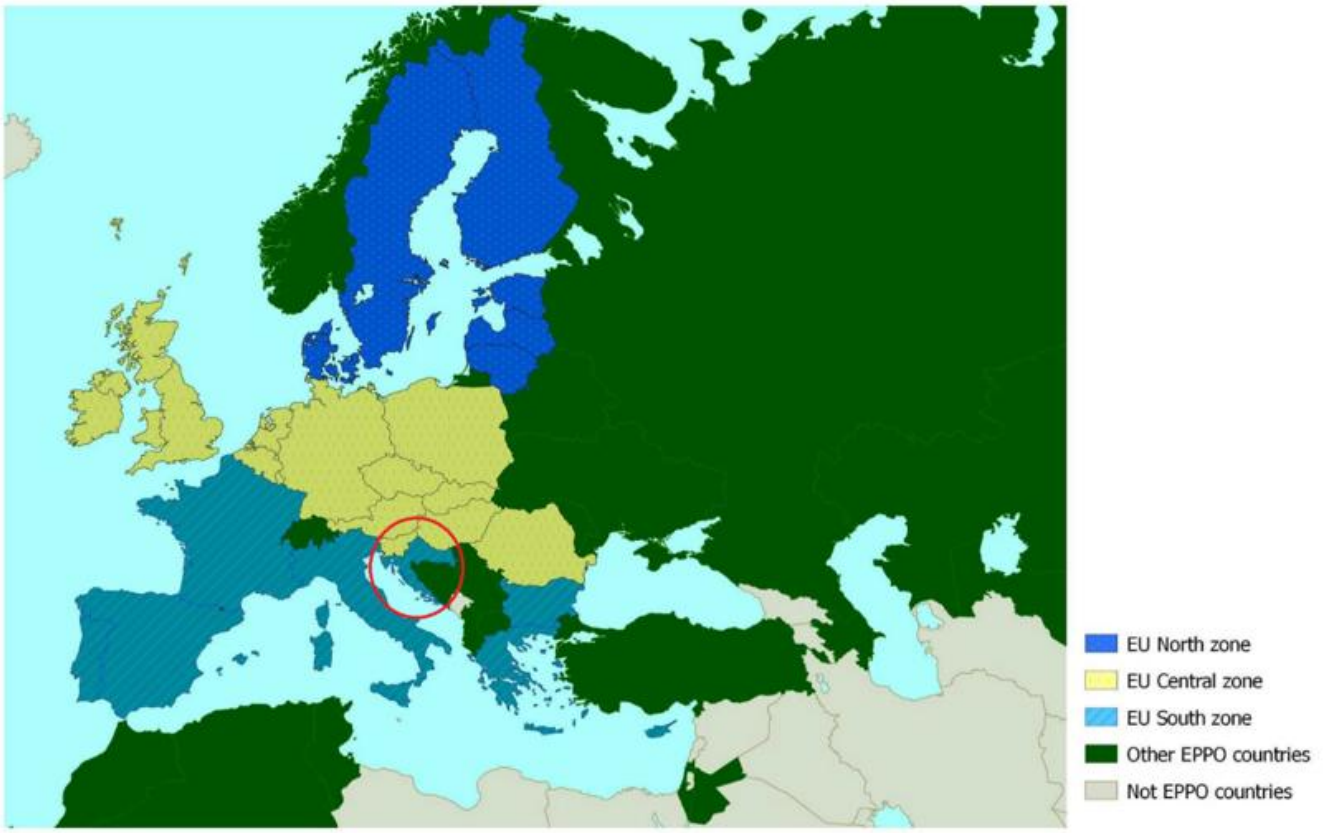
- Identity and physical-chemical properties
- Analytical methods
- Operator exposure
- Residues
- Fate and Behaviour
- Ecotoxicology
- Efficacy
- Technical coordination and preparation of Registration Reports

Institutions involved in evaluation

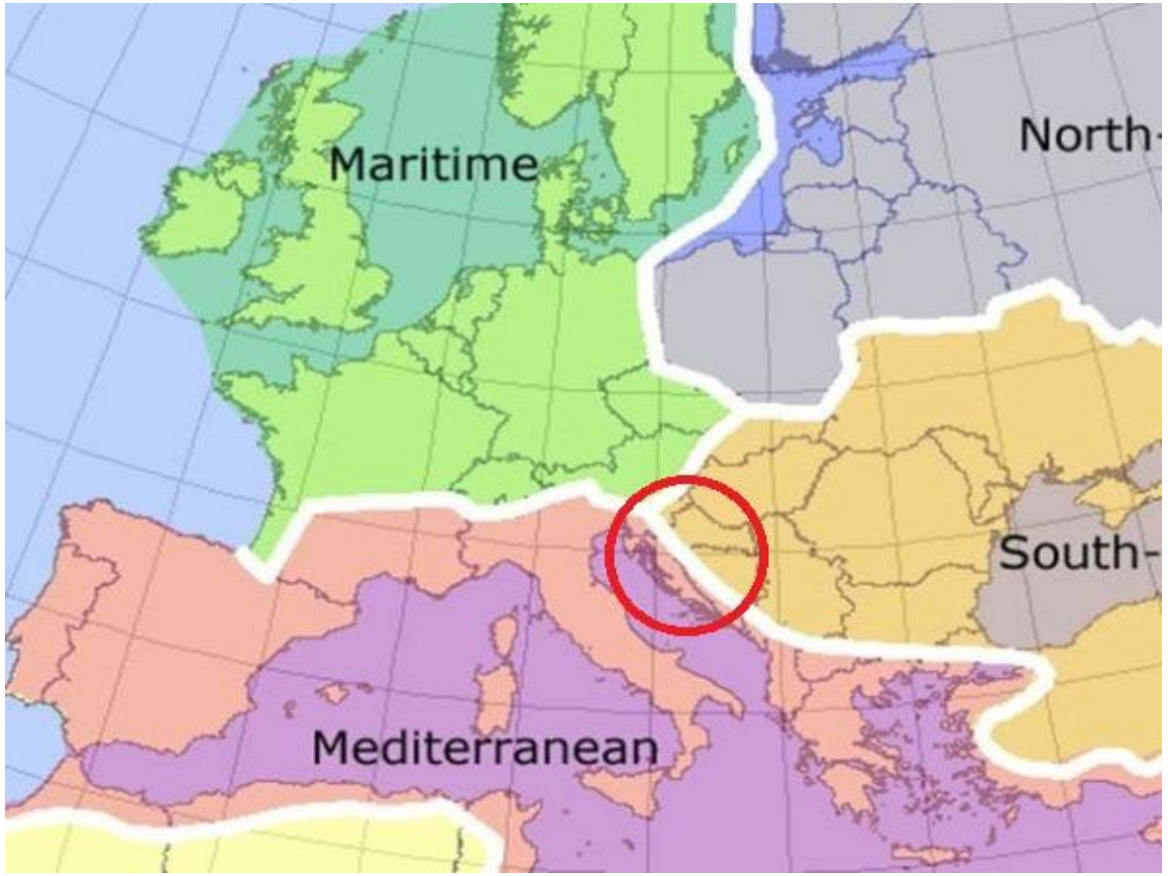
Institute for Medical Research and Occupational Health

- Mammalian toxicology
- Operator exposure
- Technical coordination and preparation of Registration Reports

Administrative position of Croatia



Agro-climatic position of Croatia (EPPO)

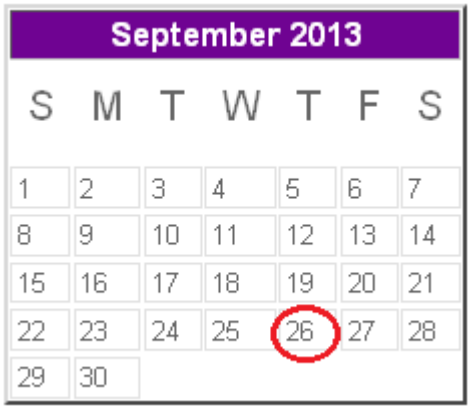


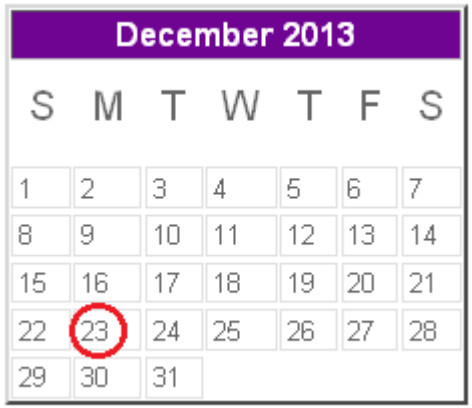
Experts involved in evaluation

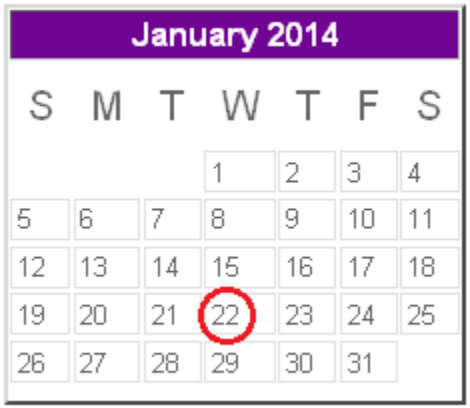
Area	No. of experts (25 + 1*)	Remark
Physical-chemical properties	3	2 experts 90 % (other lab for control of PPP) 1 expert 30 % (other fate and biocides)
Mammalian toxicology	1*	1 expert 25 % (other opex, coordination and poison control)
Operator exposure	1 + 1*	1 expert 20 % (other eff and diagnostics) 1 expert 25 % (other tox, coordination and poison control)
Residues	3	**2 experts 100 %** 1 expert 50 % (other coordination and diagnostics)
Fate and Behaviour	4	**2 experts 100 %** 1 expert 70 % (other phys-chem and biocides) 1 expert 80 % (other diagnostics)
Ecotoxicology	5	1 expert 80 % (other coordination) 1 expert 50 % (other coordination and diagnostics) 1 expert 80 % (other diagnostics) 1 expert 20 % (other diagnostics) 1 expert 20 % (other efficacy)
Efficacy	12	1 expert 90% (other RFA) 1 expert 80% (other ecotox and RFA) All other experts 20-30 % evaluation
Technical coordination	3 + 1*	1 expert 50 % (other coordination, residues and diagnostics) 1 expert 50 % (other coordination, ecotox and diagnostics) 1 expert 10 % (other tox, opex and poison control) 1 expert 20 % (other ecotox)

* Institute for Medical Research and Occupational Health

First applications under Reg. (EC) 1107/2009







Applications and Reports under Reg. (EC) 1107/2009

Application type	Received	Reports
zRMS	3	1
cMS	4 have final RR by zRMS (83)	1
MR	57	27
Emergency situations	19	19
Research and development	12	12
Parallel trade	4	4

Other Reports from 1st of July 2013

Application type	Reports
Step 1	132
Evaluation for authorization (91/414)	11
MR (91/414)	28
Amendment of authorization	54

Experiences with evaluation process

National Addendum

- opex, residues, fate and ecotox
- not submitted
- not according to national requirements

Label proposal

- not according to Reg. (EU) 547/2011 regarding labelling requirements
- not according to (CLP) Reg. (EC) 1272/2008

Experiences with Evaluation Process

MR of PPPs registered under Directive 91/414 in reference MS

- RR, evaluated dRR or national evaluation not submitted or non existent / both
- MIII document or non evaluated dRR submitted

MR according to Central zone

- problems in all areas
- agro-climatic conditions not comparable
- efficacy trials from Maritime EPPO Zone
- residue trials from Northern Zone

Experiences with Evaluation Process

Part C

- not submitted
- manufacturing sites for active substance and formulation not submitted / not updated
- equivalence report not available on CIRCABC
- minor and major changes in composition of formulation not updated

Packaging

- not specified
- data not submitted (material, closure, size, opening)

Experiences with Evaluation Process

Analytical methods

- studies for active substance and relevant impurities in formulation not submitted – important for post-registration control of formulation analysis

IPP and IMROH Guidelines for applicants

- prepared, but waiting for confirmation from CA

Experiences with Evaluation Process

Problems with final Registration Reports by other zRMS

- risk for certain areas not resolved
- MR for PPPs set out for commenting before Croatia joined the EU

Data protection

- zRMS refers to data protection for another PPP evaluated on national level (e.g. this PPP registered in Croatia but not under UP)
- zRMS refers to the DAR and concludes that the use of this data by the applicant is questionable

Conclusions

- evaluations are time consuming
- often requests for additional documentation (even several times)
- assessments under Directive 91/414
- insufficient number of evaluators (evaluators engaged in other activities in IPP and IMROH)
- many evaluations still pending (cMS)

Thank you for your attention!

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