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 – 1\textsuperscript{st} of July 2013

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
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)
<table>
<thead>
<tr>
<th>Area</th>
<th>No. of experts (25 + 1*)</th>
<th>Remark</th>
</tr>
</thead>
</table>
| 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

<table>
<thead>
<tr>
<th>Application type</th>
<th>Received</th>
<th>Reports</th>
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<tr>
<td>zRMS</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td>cMS</td>
<td>4 have final RR by zRMS (83)</td>
<td>1</td>
</tr>
<tr>
<td>MR</td>
<td>57</td>
<td>27</td>
</tr>
<tr>
<td>Emergency situations</td>
<td>19</td>
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</tr>
<tr>
<td>Research and development</td>
<td>12</td>
<td>12</td>
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<tr>
<td>Parallel trade</td>
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<td>4</td>
</tr>
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</table>
# Other Reports from 1\textsuperscript{st} of July 2013

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<th>Application type</th>
<th>Reports</th>
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</thead>
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<td>Step 1</td>
<td>132</td>
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<tr>
<td>Evaluation for authorization (91/414)</td>
<td>11</td>
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<tr>
<td>MR (91/414)</td>
<td>28</td>
</tr>
<tr>
<td>Amendment of authorization</td>
<td>54</td>
</tr>
</tbody>
</table>
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).
- 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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