Panel on General Standards on Efficacy Evaluation
INIA, Madrid, 2015-03-09/11

Plant Protection Products Unit
Technical Directorate for Evaluation of Plant Varieties and Plant Protection Products
**ZONAL EVALUATION**

**LEGISLATIVE FRAMEWORK**


ZONAL EVALUATION

LEGISLATIVE FRAMEWORK


ZONAL EVALUATION/AUTHORISATION

- Assessment of PPP on a zonal level is made by a Zonal Rapporteur Member State (zRMS)
- Dossier to be submitted for the authorisation and assessment of a PPP must fulfil the data requirements and uniform principles.
- Procedure (Evaluation)
- Period (Deadline)
Efficacy data must be provided under Regulation EC No 1107/2009.

The data submitted are presented in 3 documents:

- **dRR (draft registration report, part B Section 7 Efficacy)** - a critical concise summary of the BAD. Document prepared by the applicant following all relevant **EPPPO PP standards**.
- **BAD (Biological Assessment Dossier)** - a detailed summary. Specific Efficacy data requirements detailed in EU Regulation.
- **Annex**: Trials/study reports
Efficacy data must be provided under Regulation EC No 1107/2009. The data submitted are presented in 3 documents:

- **dRR (draft registration report, part B Section 7 Efficacy)** - a critical concise summary of the BAD. Document prepared by the applicant following all relevant *EPPPO PP standards*.
- **BAD (Biological Assessment Dossier)** - a detailed summary. Specific Efficacy data requirements detailed in EU Regulation.
- **Annex**: Trials/study reports

Zonal submissions are usually made to one of three **EU regulatory zones (Northern, Central and Southern)**. The dRR and the BAD must be adapted to each zone.

**Exceptions**: EU is considered as **one regulatory zone** for the purpose of use in greenhouses, as post-harvest treatment, for treatment of empty storage rooms and for seed treatment (Art.33)

Where there are particular National Requirements, further information and/or data could be addressed in accompanying **National Addenda**.
New changes in dRR revised and adapted to new data requirements

**dRR - Part B Section 3 – Efficacy**

3. Efficacy Data and Information on the PPP

3.0 Summary and conclusions of (z) RMS

3.1 Efficacy data

- Preliminary tests
- Minimum effective dose tests
- Efficacy tests

3.2 Resistance

3.3 Adverse effects on treated crops

- Phytotoxicity
- Effect on the yield
- Effects on the quality
- Effects on transformation processes
- Propagation

3.4 Observations on other undesirable or unintended side-effects

- Succeeding crops
- Adjacent crops
- Beneficial and other non-target organisms

**General Standards (e.g.)**

- PP1/225 Minimum effective dose
- PP1/152 Design and analysis of efficacy evaluation trials
- PP1/269 Comparable climates on global level
- PP1/181 Conduct and reporting of efficacy trials, including good experimental practice
- PP1/214 Principles of acceptable efficacy
- PP1/223 Introduction to the efficacy evaluation of plant protection products
- PP1/226 Number of efficacy trials
- PP1/243 Effects of plant protection products on transformation processes
- PP1/135 Phytotoxicity assessment
- PP1/256 Effects on adjacent crops
- PP1/213 Resistance risk analysis
- PP1/207 Effects on succeeding crops

**Specific Standards (e.g.)**

- PP1/262 Take-all of cereals
- PP1/280 Bactrocera oleae – bait application
- PP1/137 Weeds in cotton
- PP1/184 Regulation of growth in citrus
- PP1/096 Slugs in field crops
- PP1/025 Globodera and Heterodera spp.
- PP1/199 Rodent seed repellents
- PP1/170 Side-effects on honeybees
First experiences with zonal evaluation in the Southern Zone (ES)
Problems and future actions

Example 1: Efficacy should be proved to the relevant EPPO Zone of zRMS and cMS. In many cases insufficient trials are performed in South-East and Maritime EPPO Zone.

Southern Zone (European zone (Reg. (EC) 1107/2009) correspond to three EPPO Zone (Maritime, Mediterranean and South-East Zone)

Could Number of trials "per EPPO Zone" be specified in the Standard EPPO PP1/226 Number of efficacy trials?

Table 1 Basic number of direct efficacy trials in an area of similar conditions required (for further explanation, see four bullet points in section on Reduced number of trials)

<table>
<thead>
<tr>
<th>Fully supportive results required</th>
</tr>
</thead>
<tbody>
<tr>
<td>Major pest on major crop</td>
</tr>
<tr>
<td>Minor uses</td>
</tr>
<tr>
<td>Major pest; protected conditions</td>
</tr>
</tbody>
</table>

Number of trials per EPPO Zone in which authorization is sought.

Table 3-7. Presentation of trials (efficacy trials, preliminary trials...) e.g.

<table>
<thead>
<tr>
<th>Crop(s) (1)</th>
<th>Target(s) (1)</th>
<th>Country</th>
<th>Years</th>
<th>Type of trial (2)</th>
<th>Number of trials (number of valid trials)</th>
<th>GEP, non-GEP, official</th>
</tr>
</thead>
<tbody>
<tr>
<td>Winter wheat</td>
<td>Grass weeds</td>
<td>France</td>
<td>2007</td>
<td>MED</td>
<td>1 (1)</td>
<td>GEP</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>2007-2010</td>
<td>MED + E</td>
<td>8 (6)</td>
<td>GEP</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>2010</td>
<td>E</td>
<td>3 (3)</td>
<td>GEP</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Bulgaria</td>
<td>2007-2010</td>
<td>MED + E</td>
<td>-</td>
<td>8 (8)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Spain</td>
<td>2008</td>
<td>MED + E</td>
<td>4 (3)</td>
<td>GEP</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Italy</td>
<td>2010-2011</td>
<td>E</td>
<td>-</td>
<td>4 (3)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>TOTAL</td>
<td></td>
<td>12 (10)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>11 (9)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>8 (8)</td>
<td></td>
</tr>
</tbody>
</table>
Example 2. A crop*pest is minor use in zRMS and major use in a cMS

- Major/minor status of intended uses (for all cMS and zRMS) are considered in the new changes in efficacy dRR. The new dRR improves this issue.

<table>
<thead>
<tr>
<th>Crop and/or situation</th>
<th>Crop status</th>
<th>Pests or group of pests controlled</th>
<th>Pest status</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Major</td>
<td></td>
<td>Major</td>
</tr>
<tr>
<td>Olive</td>
<td>EL, ES, IT</td>
<td>-</td>
<td>minor</td>
</tr>
<tr>
<td></td>
<td>-</td>
<td>FR</td>
<td></td>
</tr>
</tbody>
</table>

In any case, the applicant should consider a major crop/pest whether this situation is presented in one concerned Member State.
Example 2. A crop*pest is minor use in zRMS and major use in a cMS

- Major/minor status of intended uses (for all cMS and zRMS) are considered in the new changes in efficacy dRR. The new dRR improves this issue.

<table>
<thead>
<tr>
<th>Crop and/or situation</th>
<th>Crop status</th>
<th>Pests or group of pests controlled</th>
<th>Pest status</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Major</td>
<td></td>
<td>Major</td>
</tr>
<tr>
<td>Olive</td>
<td>minor</td>
<td></td>
<td>minor</td>
</tr>
<tr>
<td>EL, ES, IT</td>
<td>-</td>
<td></td>
<td></td>
</tr>
<tr>
<td>-</td>
<td>FR</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

In any case, the applicant should consider a major crop/pest whether this situation is presented in one concerned Member State.

Example 3: cMS request National Requirements in comment period

- The applicant should have provided a National Addenda.
- National requirements present a drawback to make progress in harmonization and provide additional workload for cMS.
- Are they strictly necessary? Would it be possible to reach an harmonization on national requirements in order to include them into the Core Dossier? It would facilitate the Mutual Recognition.
- Many cMS request additional data in comment period. Southern Zone Steering Committee agreed that additional data after comment period should be avoided.
Example 4: zRMS only evaluates for its country

- According to Regulation (EC) 1107/2009 Art. 33 and 35. The application shall be examined by the Member State proposed by the applicant to evaluate the application in the zone concerned.
- As a consequence: an increase of workload for cMS and lack of harmonization
Example 4: zRMS only evaluates for its country

- According to Regulation (EC) 1107/2009 Art. 33 and 35. The application shall be examined by the Member State proposed by the applicant to evaluate the application in the zone concerned.
- As a consequence: an increase of workload for cMS and lack of harmonization

Example 5: Seed treatment- All Zones. What is the better trials distribution?

Reg. (EC) 1107/2009 Art. 33 b. In the case of an application for seed treatment, only one Member State shall be proposed to evaluate the application taking account of all zones.

EPPO PP1/278(1) Principles of zonal data production and evaluation: "In the case of seed treatments, these are subject to the wide range of soil types and climatic conditions present across the authorization zone, as well as to variation in pest pressure and sensitivity. As such, it is considered that these treatments are more similar to conventional foliar plant protection products and a trials series should encompass the diverse conditions encountered in the authorization zone".

- Is trials location representative of 4 EPPO zones?

<table>
<thead>
<tr>
<th>Table A. Location and numbers of trials submitted (e.g.)</th>
</tr>
</thead>
<tbody>
<tr>
<td>North Eastern EPPO zone</td>
</tr>
<tr>
<td>-------------------------</td>
</tr>
<tr>
<td>Central Zone</td>
</tr>
<tr>
<td>PL</td>
</tr>
<tr>
<td>9</td>
</tr>
<tr>
<td>DK</td>
</tr>
<tr>
<td>2</td>
</tr>
<tr>
<td>6</td>
</tr>
</tbody>
</table>

Could EPPO define it?
## Points for discussion

1. Could number of trials "per EPPO Zone" be specified in the Standard EPPO PP1/226 _Number of efficacy trials_?

2. Consider a major crop/pest whether this situation is presented in one concerned Member State.

3. Would it be possible to reach an harmonization on national requirements in order to include them into the Core Dossier?

4. zRMS shall evaluate efficacy data for whole zone.

5. What is the better trials distribution in the case of evaluation taking account of all zones (e.g. seed treatment)?

6. Re-authorisation of PPPs under regulation (EC) no 1107/2009 after renewal of approval of an active substance (art. 43)

7. Comparative Assessment
Thank you for your attention