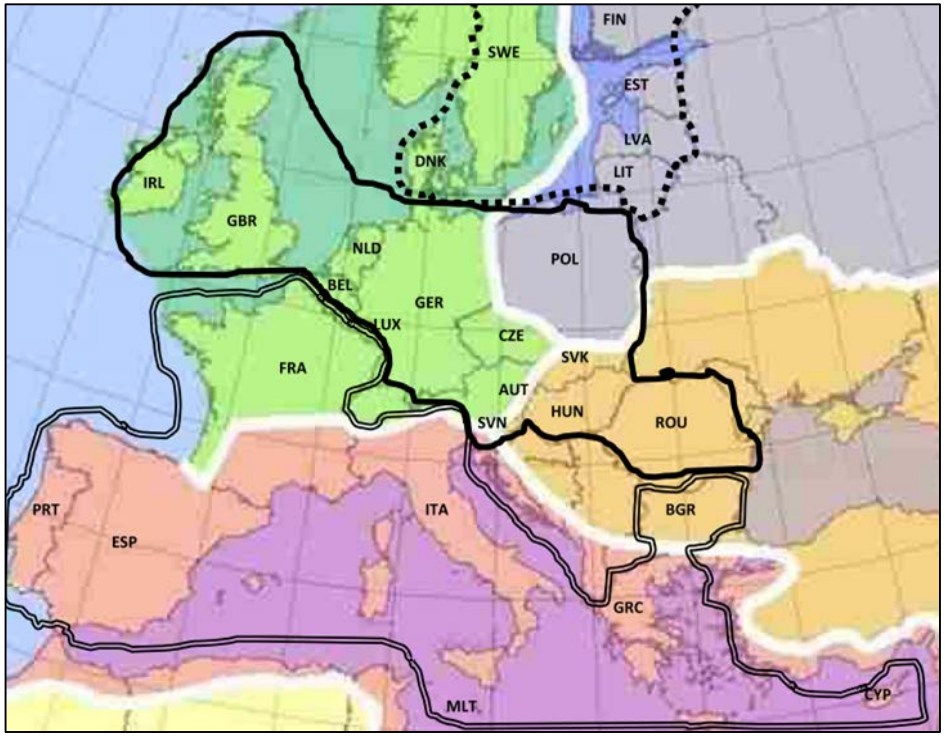
Panel on General Standards on Efficacy Evaluation

INIA, Madrid, 2015-03-09/11



Plant Protection Products Unit

Technical Directorate for Evaluation of Plant Varieties and Plant Protection Products

MINISTERIO DE ECONOMÍA Y COMPETITIVIDAD

INIA Instituto Nacional de Investigación y Tecnología Agraria y Alimentaria

ZONAL EVALUATION

LEGISLATIVE FRAMEWORK

- **Regulation EC No 1107/2009** of the European Parliament and of the Council concerning the **placing of plant protection products on the market** and repealing Council Directives 79/117/EEC and 91/414/EEC concerning the placing of plant protection products on the market.

- **Commission Regulation (EU) No 284/2013 (545/2011)** setting out the **data requirements** for plant protection products, in accordance with Regulation (EC) No 1107/2009
- **Commission Regulation (EU) 546/2011** implementing Regulation (EC) No 1107/2009 as regards **uniform principles** for evaluation and authorisation of plant protection products

ZONAL EVALUATION

LEGISLATIVE FRAMEWORK

- **Regulation EC No 1107/2009** of the European Parliament and of the Council concerning the **placing of plant protection products on the market** and repealing Council Directives 79/117/EEC and 91/414/EEC concerning the placing of plant protection products on the market.

- **Commission Regulation (EU) No 284/2013 (545/2011)** setting out the **data requirements** for plant protection products, in accordance with Regulation (EC) No 1107/2009
- **Commission Regulation (EU) 546/2011** implementing Regulation (EC) No 1107/2009 as regards **uniform principles** for evaluation and authorisation of plant protection products

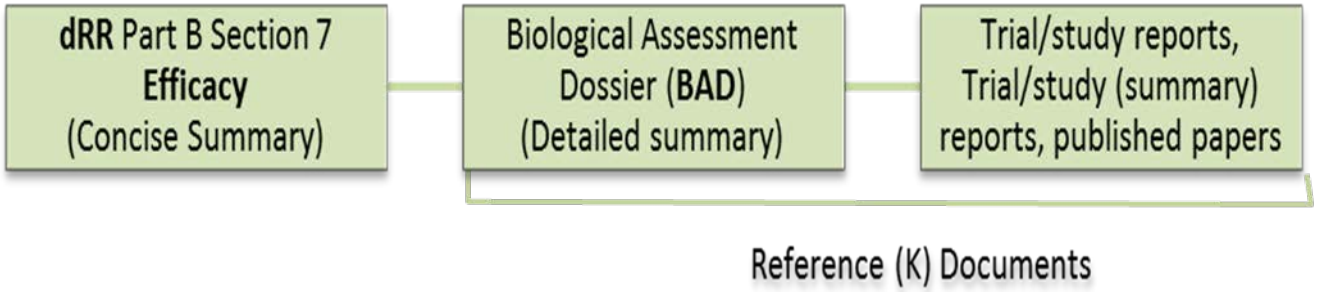
ZONAL EVALUATION/AUTHORISATION

- **Application** (Art. 33-39, Art. 43, Reg. (EC) 1107/2009)
- 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:

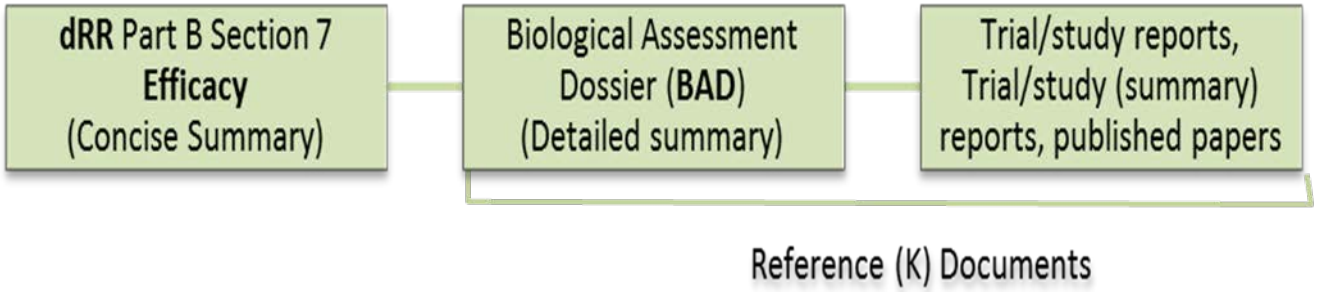
- **dRR (draft registration report, part B Section 7 Efficacy**) - a critical concise summary of the BAD. Document prepared by the applicant following all relevant ***EPPO PP standards***.
- **BAD** (**Biological Assessment Dossier**) - a detailed summary. Specific Efficacy data requirements detailed 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 ***EPPO 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**.

Efficacy Evaluation points

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

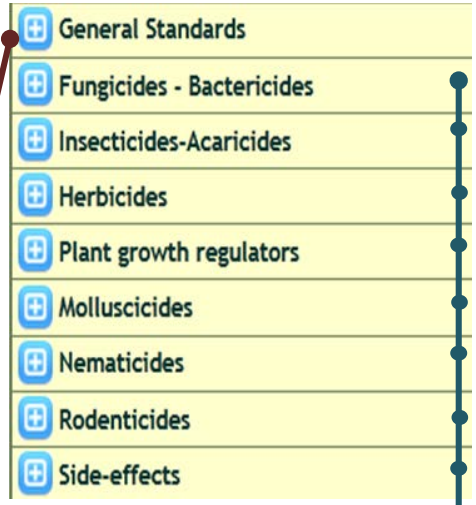
3.3 Adverse effects on treated crops

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

EPPO standard (PP1)- Efficacy evaluation of PPP



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)

	Fully supportive results required
Major pest on major crop	10 (range 6–15)
Minor uses	3 (range 2–6)
Major pest; protected conditions	6 (range 4–8)

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

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

Crop(s) (1)	Target(s) (1)	Country	Years	Type of trial (2)	Number of trials (number of valid trials)			GEP, non-GEP, official
					Maritime zone	Mediterranean zone	South-East zone	
Winter wheat	Grass weeds	France	2007	MED	1 (1)	-		GEP
			2007 - 2010	MED + E	8 (6)	3 (3)		GEP
			2010	E	3 (3)	-		GEP
		Bulgaria	2007 - 2010	MED + E		-	8 (8)	GEP
		Spain	2008	MED + E		4 (3)		GEP
		Italy	2010 - 2011	E	-	4 (3)		GEP
	TOTAL	-	2007 - 2011	-	12 (10)	11 (9)	8 (8)	-

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 3-6. Major / minor status of intended uses (for all cMS and zRMS).

Crop and/or situation	Crop status		Pests or group of pests controlled	Pest status	
	Major	minor		Major	minor
Olive	EL, ES, IT	-			
	-	FR			

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 3-6. Major / minor status of intended uses (for all cMS and zRMS).

Crop and/or situation	Crop status		Pests or group of pests controlled	Pest status	
	Major	minor		Major	minor
Olive	EL, ES, IT	-			
	-	FR			

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?

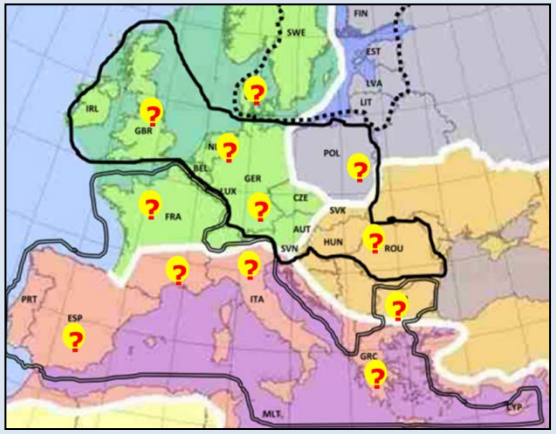
Reg. (EC) 1107/2009 Art. 33 b. *In the case of an application for seed treatment, only one Member State shall be proposed to evaluate the application taking account of all zones.*

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 A. Location and numbers of trials submitted (e.g.)

North Eastern EPPO zone	Maritime EPPO zone						Mediterranean EPPO zone	South Eastern EPPO zone
Central Zone				Northern Zone		Southern Zone		
PL	DE	UK	BE	DK	SE	FR North		
9	7	6	2	2	7	6	-----	-----



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