guicance document

Technical Guidance Paper
dRR - Part B Section 7 - Efficacy

Versie 1. (2015)

Technical guidance for applicants in preparing a concise efficacy summary as part of a draft Registration Report (dRR).

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Draft REGISTRATION REPORT
Part B

Section 7: Efficacy Data and Information

Product name(s): XXX

Product code: XXX

Active Substance(s): XXX
XXX g/L or g/kg

Northern / Central / Southern/ EU wide Zone

Zonal Rapporteur Member State: xxx

GUIDANCE
CORE - The Netherlands

Applicant: Company name

Date: DD/MM/YYYY

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IIIA1 6 Efficacy Data and Information (including Value Data) on the Plant Protection Product

This document is to be used by the applicant of a plant protection product for registration at Member State level (evaluation can be at the zonal level or the European level). The template is for all plant protection products, except for micro-organisms (because there is another chaptering for this type of product).
It has been designed to provide guidance on the preparation of Part B Section 7 (Efficacy Data and Information) of the draft registration report (dRR) and on the information required specifically for this section. The guidance is applicable to the core assessment.

Notes:
Text in blue provides general information/support and should be deleted when the document is finalized. Text in black shows the headers for each section. It also shows **example text**. The table format is not fixed; tables are provided as examples (columns can be added or deleted). They could be adapted to suit the product being evaluated. Moreover, some tables are not relevant for all products or all submission types: tables can be added or deleted.
Texts in yellow should be changed as specified.

IIIA1 6.1 Efficacy data

Transformation of the dRR (applicant version) into the RR (zRMS version)

Introduction

This introductory section should include the following information:

- The type of submission: new product, extension, renewal, etc.
- Explanations of the submission process: for the core dossier or the national addenda:
  - zRMS to which the dossier has been submitted.
  - Member States concerned by the registration (cMS = concerned Member State).
- If national addenda are submitted (only limited additional data should be included, as explained in the Guidance Document SANCO 10055/2013[1]):
  - Member States to which national addenda (for efficacy section) have been submitted.
  - Justification of the need for the national addenda. Add short information of what the national addenda contain, for the zRMS to have a broad overview of the dossier.
- All other information that could clarify the context of the request.

More information on the content of a dRR is available in the Guidance Document SANCO 10055/2013.

Description of active substances

The content of this section may vary depending on whether the product contains new or existing active substances.

[1] SANCO /10055/2013 "Guidance document on the Efficacy composition of Core Dossier and National Addenda submitted to support the authorization of plant protection products under Regulation (EC) No 1107/2009 of the EU Parliament and Council on placing of plant protection products on the market.

It is not necessary in this section to provide a summary of what follows in all other sections (section 1, 2, 4 to 8).

Mode of action:

Write some information on the mode of action, chemical group(s), biological properties, chemical and biological targets, mobility, uptake, persistence and any other biological properties that may be relevant.

Table 6-1. Details of the active substances

Active substance	AS1	AS2	ASn
Concentration (Unit: g/kg or g/L...)	200 g/L		
Chemical group	auxin		
Mode of action	IAA regulator		
Biological action	e.g. post-emergence herbicide		
...			

For further physico-chemical properties, reference should be made to Registration Report Part B Section 1: Identity, physical and chemical properties, other information.

Description of the plant protection product

A statement should be made regarding the product, its active components and concentration(s), and the formulation type.

Example:

Product is a e.g. emulsifiable concentrate (EC) containing number / unit active substance(s).

The data presented in this dRR are intended to support the label claim for product for the control of targets 1, 2 etc. in crop(s).

Table 6-2. Corresponding between product codes and product trade names in different EU Member States.

Product code	Product trade name(s)	Member State	Authorisation No.	Date of initial registration	Date of the last re-registration / approval

Table 6-3. Simplified table of currently registered uses and requested uses for the product code.

Uses		Member State	Currently registered rate(s)*	Requested rate(s)	Comments / Other relevant details on GAPs
Crop(s)	Target(s)				

*only for re-registration or extension of use. In case of a new preparation, the column "current registered rate" can be deleted.

Further details about the proposed uses (GAP) can be found in Part A, paragraph 2.3. (NL uses) or in part B.1, paragraph 3.3.1. (all MS uses) of the registration report.

Conversion table dose expressions

In case of high crops or for any other specific dose expression, a conversion table is necessary to convert the different dose expressions (e.g. application rate per hL into per ha). Refer to the guideline EPPO PP 1/239 Dose expression.

Description of the target pests

Table 6-4. Glossary of pests mentioned in the dossier.

EPPO code	Scientific name	Common name*

* optional.

It is preferable to use the scientific name or the EPPO codes in the text of the dRR, rather than the common name.

Applicant should describe the importance of pests and crops, and the growing situation in all the cMS where the product is applied for. It is essential information for the zRMS, in order to have an overview over the specific pest/crop situation and the growing practices in the cMS.

Table 6-5. 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
Winter wheat	DE, UK, FR, PL	-			
Spring wheat	DE, UK, FR, PL	-			
Spring durum wheat	-	DE, FR			

Concerning the minor/major status, RMS will comment the applicant proposal. During the commenting period, cMS are invited to comment the relevance of the applicant / zRMS proposal.

Compliance with the Uniform Principles

Indicate whether the overall assessment was performed according to the uniform principles and, if necessary, what deviations have been identified. These deviations must also be included in the relevant chapter.

Information on trials submitted (6.1 Efficacy data)

Table 6-6. Presentation of trials (efficacy trials, preliminary trials...)

It is possible to propose a single table for all uses or to propose separate tables.

Crop(s) (1)	Target(s) (1)	Country	Years	Type of trial (2)	Number of trials (number of valid trials)		GEP, non-GEP,	Comments (any other relevant
					Maritime	Mediterrane		

					zone	an zone	official	information)
Winter wheat	Grass weeds	France	2007	MED	1 (1)	-	GEP	
			2007 - 2010	MED + E	8 (6)	3 (3)	GEP	
			2010	E	3 (3)	-	GEP	
		Germany	2007 - 2010	MED + E	8 (8)	-	GEP	
		Belgium	2008	MED + E	4 (3)	-	GEP	
		Italy	2010 - 2011	E	-	4 (3)	GEP	
	TOTAL	-	2007 - 2011	-	24 (21)	7 (6)	-	
TOTAL	-	-		-			-	

(1) According to the GAP table.
(2) P = preliminary trial, MED = minimum effective dose, E = efficacy trial.

A map with trial location is recommended.

Applicant should provide a rationale for the number and distribution of trials (the presence of trials at this location and the absence of trials at that location), regarding crop growing areas, target pest status (major/minor), pest distribution, agricultural practices, "usual" growing periods, soil types and all relevant information linked to GAP (refer to EPPO guidelines 1/226, 1/241, 1/269, 1/278 and to relevant crop/pest-specific EPPO standards).

The applicant should justify the exclusion of trials - or their inclusion, in case of any deviation.

Table 6-7. Presentation of reference standards used in trials (efficacy trials, preliminary trials...)
It is possible to propose a single table for all uses or to propose separate tables.

Crop(s) * Target(s)	Reference standard	Country(ies) where the product is registered (1)	Registration number	Active substance(s)	Formulation		Registered application rate (3)	Application rate in trials (per treatment)	Remark (4)
					Type (2)	Concentration of a.s.			

(1) only on use(s) applied for (with the test product).
(2) e.g. WP (wettable powder), EC (emulsifiable concentrate), etc.
(3) dose(s) / dose range authorized on that use in the country.
(4) Other relevant information (e.g. uses, number of applications, spray volume, method of application, etc.).

If different formulations (e.g. former formulations) were used in trials, all formulations should be presented in a table. Applicant should justify the inclusion of data from other formulations.

General recommendations for trial grouping

Data should be preferably summarised by EPPO climatic zones. If it has been already established there is no significant difference seen between trials from different EPPO climatic zones, an additional synthesis of the whole relevant dataset is recommended, especially for MS divided in different EPPO climatic zones.

Data must be summarised by application timing (e.g. spring vs. autumn, pre-emergence vs. post-emergence) and by assessment timing (e.g. short term, mid-term, long term...).

Other trial grouping may be also appropriate. Data comparability may be addressed for a number of factors including edaphic, agronomic and biological factors. Examples of other grouping:

- Agronomic risk (pest pressure),
- Soil type,
- Resistance status,
- ...

It is important to describe and to justify how trial data has been grouped for summarisation. Grouping should be decided on a case-by-case basis. The data may be organized / grouped in different ways, e.g. if there are country-specific use rates or soil types, etc.

It should be noted that trial grouping is not always possible or relevant. In that case, a presentation trial per trial is possible.

IIIA1 6.1.1 Preliminary range-finding tests

A statement should be made regarding the availability or otherwise of results from preliminary tests. If no tests are available, this should be stated.

When test results are available, a short description of the number, nature and type of test carried out should be made. Minimum details should include: year conducted, location, type of study (e.g. laboratory, glasshouse, field), target organisms, pest stages, crop stages, water volumes, outline methodology (e.g. foliar herbicide, contact insecticide, preventative fungicide). It should be made clear if the tests were carried out according to GEP (not a requirement for preliminary tests) and the outcome and overall conclusion of the tests should be stipulated.

The information should be presented in the form of simple tables (an example of table is given in the chapter “efficacy tests”).

In function of the type of preparation or the type of demand, provide the appropriate data:

- Information on the biological activity of the active substance (herbicidal, insecticidal or fungicidal activity, spectrum of action) (For a new active ingredient)

- Mode of action of the active substance (for a new active ingredient)

- For co-formulated products, justification of the combination of several active and/or safener/synergistic substances.

If the product is a co-formulation, justify the use of each active substance in the mixture and show the advantages of the combination, e.g. improved efficacy, spectrum, or added persistency.

Specify and justify the minimum level of infestation used for validation of the trial and assessment timing. If statistical analysis is available on trial grouping (in the BAD), it is appropriate to provide this data in the table below (by adding columns).

Table 6-8. Efficacy of active substance components in test product

Target	Number of trials	Infestation of the untreated control (unit)		% control					
				Test product xxx g a.s./ha + xxx g a.s./ha		Product 1 Xxx g a.s./ha		Product 2 xxx g a.s./ha	
		Mean	Min. & Max.	Mean	Min. & Max.	Mean	Min. & Max.	Mean	Min. & Max.
Target 1									
Target 2									

Example of a justification of the advantages of each active ingredient:

In x trials, test product applied at dose (active substances) was compared to the straight product 1 (active substance) and the straight product 2 (active substance) at similar rates of the single active substances against target 1. According to the presented results, product provided better control than the single active substance products against target 1.

As diseases / weeds / pests often occur as complexes of several pathogens throughout a season, x application(s) of product at dose should therefore be used to efficiently control all pathogens claimed on the label.

- For co-formulated products, determination of the ratio of active and/or safener/synergistic substances

Argue on the choice of the ratio. The following table can be used.

Specify and justify the minimum level of infestation used for validation of the assessment / trial and assessment timing. If statistical analysis is available on trial grouping (in the BAD), it is appropriate to provide this data in the table below, by adding columns.

Table 6-9. % of control of the different ratios at timing of assessment. (e.g. 10 to 14 days after application).

Target	Number of trials	Infestation of the untreated control (unit)		% control					
				Ratio 1		Ratio 2		Ratio 3	
		Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max
Target 1*									
Target 2*									
Target 3*									

*EPPO codes (weed species / pest...).

Columns with the reference product(s) can be added.

Example:

In x trials, ratio 1 at dose (active substances) was compared to the ratio 2 (active substance) and ratio 3 (active substance) against target 1. According to the presented results, the ratio X/X provided better control than the other ratio against target 1.

Summary and conclusions on the preliminary trials

Write a summary and a conclusion on the entire chapter 6.1.1.

IIIA1 6.1.2 Minimum effective dose tests

A statement should be made regarding the availability or otherwise of results from tests describing the minimum effective dose. These may be the same tests as also used in chapter 6.1.3 to describe the efficacy of the proposed label rate(s).

Where test results are available, a short description of the number, nature and type of test carried out should be made. Minimum details should include: year conducted, location, type of study (e.g. glasshouse, field), trial design, target organisms, pest stages, crop stages, water volumes, outline methodology (e.g. foliar herbicide, contact insecticide, preventative fungicide).
It should be made clear if the tests were carried out according to GEP, or by officially-recognised testing organisations and the guidelines (e.g. EPPO) followed should be specified.

The information should be presented in the form of simple tables (an example of table is given in the chapter "efficacy tests").

Reference should be made to EPPO standard PP 1/225 '*Minimum effective dose'* which advices on the minimum requirements necessary to ensure consistency of decision making.

For each use, a distinct paragraph (title) should be provided including a synthesis table and comments. If no data is available, a rationale should be provided (at least) to justify to chosen dose(s) (based on extrapolation principles, concomitant use, major / minor status, harder / easier to control...).

Crop(s) 1 AND/OR Target(s) 1

X field trials were established in order to determine the minimum effective dose for the control of the crop(s) 1 / target(s) 1. Product was tested at xxx to xxx L/ha or kg/ha (xxx – xxx g of active substance) in crops for the control of targets. The rates reflect the proposed label rate and X% and Y% of the full recommended rate of product, in accordance with the EPPO standard PP 1/225 '*Minimum effective dose'*.
A summary of the dose response results is provided in table 3-10.

Specify and justify the minimum level of infestation used for validation of the assessment / trial and assessment timing. If statistical analysis is available on trial grouping (in the BAD), it is appropriate to provide this data in the table below (by adding columns).

Table 6-10. Minimum effective dose. Efficacy of product at proposed label rate, at X% and Y% dose rates on target 1 at assessment timing against "Crop(s) 1 AND/OR Target(s) 1".

Grouping *	Number of trials	Infestation of the untreated control (unit)		% control with product					
				Rate 1 (X% of full rate)		Rate 2 (Y% of full rate)		Rate 3 (Full rate)	
		Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max
All									
A									
B									
C									

*A, B, C can be a "trial group" (as defined in page 10, e.g. EPPO climatic zone 1) or a specific target (e.g. weed A, weed B...). In order to adapt the table to the data presented, it is possible:
- to add lines or columns,
- to duplicate the table (e.g. one table for "trial group 1", one table for "trial group 2", one table for "all").

For the timing of assessments, the dose of xxx L/ha or kg/ha of product provided a superior / inferior / similar control to the dose of xxx L/ha or kg/ha of product in x trials out of x trials.

Crop(s) 2 AND/OR Target(s) 2

Cf previous paragraph.

Summary and conclusions on the minimum effective dose

Example:
According to the presented results, the dose of xxx L/ha or kg/ha of product provided the optimum overall control and should be considered as effective against these number major pests, for which activity of product is claimed.

As diseases often occur as complexes of several pathogens throughout a season, x application(s) of product at xxx L/ha or kg/ha should therefore be used to efficiently control all the pathogens claimed on the label.

As a result, the proposed rate of xxx L/ha or kg/ha should be considered the minimum effective dose to deliver broad spectrum control of targets under a wide range of environmental conditions.

IIIA1 6.1.3 Efficacy tests

A short description of the number, nature and type of test carried out should be made. Minimum details should include: year conducted, location, type of study (e.g. glasshouse, field), trial design, target organisms, pest stages, crop stages, water volumes, outline methodology (e.g. foliar herbicide, contact insecticide, preventative fungicide).

It should be made clear if the tests were carried out according to GEP, by officially recognised testing organisations and the guidelines (e.g. EPPO) followed should be specified.

Information on trial methodology can be presented in the form of a table. An example of table is given below.

Table 6-11. Details on trial methodology

It is preferable to propose a table for each use.

Guidelines	General guidelines	EPPO PP 1/152 (2/3)...
	Specific guidelines	EPPO PP 1/93 (2), …
Experimental design	Plot design	RCBD (36),
	Plot size	9-15 m²
	Number of replications	3 (6) - 4 (30)
Crop	Trials per crop	Winter wheat (25) Spring wheat (6) Durum wheat (5)
	Varieties per crop	Winter wheat: Mulan, Türkis… Spring wheat: Passat… …
	Sowing period	Winter wheat: from October (01) to November (12). Spring wheat: March (05-15)… …

Application	Crop stage (BBCH) at application	Winter wheat: from BBCH 11 to BBCH 26. Spring wheat: from BBCH 12 to BBCH 15. …
	Timing Pest stage at application (1)	Post-emergence ALOMY (BBCH 11-14) ...
	Number of applications Intervals between applications	1 (31 trials) 2 (5 trials) with intervals of 15 - 35 days.
	Spray volumes	200 - 500 L/ha
Assessment	Assessment types	% of weed coverage, number of weeds/m², intensity, severity, % damaged fruits…
	Assessment dates	7 DAT, 14 DAT, 21 DAT, 45 DAT
Other relevant information	e.g. Soil type, pH (in case of soil active substance …)	
	e.g. Natural / artificial innoculation…	
	e.g. Field / Greenhouse...	
	...	

(1) BBCH for weeds, pre-emergence, preventive / curative application, insect stage…

For each crop(s) / target(s), a distinct paragraph (title) should be provided including a synthesis table and comments. Example: downy mildew of grapevine, control of grass weeds in cereals.

Crop(s) 1 AND/OR Target(s) 1

A total of x trials were carried out to evaluate the efficacy of product for the control of target(s) in crop(s).

Efficacy data for target(s) are presented from x efficacy trials assessed. x trials have been conducted between year and year in list countries.

This chapter should summarise all of the points addressed in the chapters of the BAD. However, it is often not necessary to provide details of individual trials either in text or tabular form – these are all available in the BAD.

Specify and justify the minimum level of infestation used for validation of the trial and assessment timing. If statistical analysis is available on trial grouping (in the BAD), it is appropriate to provide this data in the table below (by adding columns).

Table 6-12 shows a summary of the control of assessment type on crop part for target.

Table 6-12. Efficacy of product at the timing of assessment.

Target	Grouping *	Number of trials	Infestation in the untreated control (unit)		% control				Nb of trials where product is >, <, = compared to standard 1**
					Product at rate		Standard 1 at rate		
			Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	
Target 1	All								xxx trials > xxx trials = xxx trials <
	A								
	B								

	C								

*A, B, C can be a “trial group” (as defined in page 10, e.g. EPPO climatic zone A) or a specific target (e.g. weed A, weed B...). In order to adapt the table to the data presented, it is possible:
- to add lines or columns,
- to duplicate the table (e.g. one table for “trial group 1”, one table for “trial group 2”, one table for “all”).

** Optional.

The more appropriate(s) assessment timing(s) must be presented (justification of the choice will be appreciated).
Any other relevant data (such as statistical analysis…) can also be provided by the addition of supplemental columns. The “median” can be added (by implementation of a supplemental column), but should not replace the mean.

The role of the reference product(s) is described in the guideline PP 1/214 (2) “Principles of acceptable efficacy”. As much as possible, comparison between the test product and the reference product(s) (or very close reference products) should be “orthogonal”: compare the same number of trials, with both products on the same field site (site-by-site trials). If there is more than one reference product, this can be done for the main reference products. Only means of the same products should be calculated.

For example:

	Number of trials	% of control		
		Test product	Standard 1	Standard 2
Average of all trials with the test product	15	87	-	-
Orthogonal comparison, with main reference product(s)	6	90	93	-
	5	85	-	77

A summary of the results and a conclusion should be provided.

For example
Data demonstrated that the efficacy of the product at the proposed rate of xxx L/ha or kg/ha was inferior to / equivalent to / superior to the efficacy of standard 1 at rate 1 against target(s).
Data demonstrated that the efficacy of the product at the proposed rate of xxx L/ha or kg/ha was inferior to / equivalent to / superior to the efficacy of standard 2 at rate 2 against target(s).
The data also demonstrated that there was no difference in the performance of product when trial data was grouped as presented in table 6-xxx.

An indication of the % of achieved efficacy is necessary in the dRR (it can be a range). The % of efficacy was not proposed in the example text, because numeric data are expected in the tables of results. If not presented in tables, numeric data should be proposed in the text.
In the total absence of numeric data (e.g. when not possible), the applicant / (z)RMS should describe the efficacy seen in trials.

Appropriate reference should be made to other label statements pertaining to efficacy such as water volume, soil type etc. when relevant.

Crop(s) 2 / Target(s) 2

Cf previous paragraph.

Minor use

For each minor use, if data is not available, it should be mentioned the reference to the respective pest/crop of the existing extrapolation table (in conjunction with the EPPO 1/257 Efficacy and crop safety extrapolations for minor uses) or an argumentation, allowing to link the minor use to an intended use or a registered use (which is supported by sufficient data).

In the particular case of “article 51” uses, please refer to the regulation 1107/2009.

Summary and conclusion

Write a summary and a conclusion on the entire chapter 6.1.3.

IIIA1 6.1.4 Effects on yield and quality

IIIA1 6.1.4.1 Impact on the quality of plants or plant products

A statement should be made regarding the availability (or otherwise) of results from trials that evaluated the impact on quality. These trials may include phytotoxicity/yield trials (section 6.3) as well as efficacy trials. The individual assessments required for aspects of quality will be dependent on the proposed use in particular the crop. Reference may be made to individual EPPO standards and to EPPO PP standards 1/242 (taint test) and 1/135.

When test results are available, a brief description of experiments should be provided. Trials must be presented as described in efficacy chapter (table “details on trial methodology”).

X studies conducted between year and year in countries on crops revealed no negative impact / or describe them of product on quality of plants.

The results should be summarised, in tabular form if appropriate, and a conclusion drawn.

IIIA1 6.1.4.2 Effects on the processing procedure

The relevance of the product uses to processing procedures (brewing, fermentation, baking) should be described and a statement made regarding the availability or otherwise of trial results.

Reference may be made to EPPO standard PP 1/268 ‘*Study of unintentional effects of plant protection products on fermentation processes and characteristics of wine*’ and standard PP 1/243 *‘Effects of plant protection products on transformation processes’* which provides an indication of the circumstances under which data on transformation processes are required.

When test results are available, a brief description of experiments should be provided. Trials must be presented as described in efficacy chapter (table “details on trial methodology”)with at least dose, number of appl., interval between appl., PHI (time between last treatment and harvest), kind of transformation (e.g. fermentation with addition of pure yeast, spontaneous fermentation, distillation).

The results should be summarised, in tabular form, if appropriate, and a conclusion should be written.

IIIA1 6.1.4.3 Effects on the yield of treated plants and plant products

Yield (and relevant quality indicators), from efficacy trials (in the presence of challenging pest populations)

The aim is demonstrating the benefit of using the product. The submission of these data is not a requirement; it is additional information, where available or when it is an intended secondary effect (e.g. for cereal fungicides).

A summary of the yield data from efficacy trials is presented in table 6-13.

A total of x trials were carried out between year and year in countries. The objective was to confirm the yield response of product in the presence of pest / weed / disease.

Specify and justify the minimum level of infestation used for validation of the assessment / trial and assessment timing. If statistical analysis is available on trial grouping (in the BAD), it is appropriate to provide this data in the table below (by adding columns).

Table 6-13. Yield (quality) effect of product in efficacy trials on crop * target 1

Grouping	Number of trials	Untreated control Absolute figures (unit)		% yield relative to the untreated or absolute figures (unit)			
				Product at rate		Standard at rate	
		Mean	Min & Max	Mean	Min & Max	Mean	Min & Max
All							
A							
B							

A summary of the results and a conclusion should be provided.

For example

Product at the proposed label rate of xxx L/ha or kg/ha had a (describe) / no positive effect on the yield of crop in the presence of disease / weed / pest. In fact, there was a x% increase in yield over the untreated.

IIIA1 6.2 Adverse effects

The trials described in this chapter can also be relevant chapter 6.1.4.

Table 6-14. Presentation of trials (selectivity trials, transformation trials...)

It is possible to propose a single table for all crops or to propose distinct tables. Likewise, it is possible to present specific trials (e.g. transformation trials) in this table or in a specific one in the specific chapter.

Crop (1)	Country	Type of trial (2)	Number of trials		Years	GEP, non-GEP, official	Comments (any other relevant information)
			Maritime zone	Mediterranean zone			
Winter wheat	France	S	4	2	2007 - 2010	GEP	
		S + Y	2	-	2010	GEP	
		S + Y + Q	2	1	2009	GEP	
	Germany	S + Y	3	-	2007 - 2010	GEP	
	Italy	S + Y	-	2	2010 - 2011	GEP	
TOTAL	-	-	11	5	-	-	

(1) According to the GAP table.
(2) S = selectivity trial, Y = trial with yield assessment, Q = trial with quality assessment, T = trial on the basis of the study of impact on transformation process, P = trial with assessment of impact on propagation.

Table 6-15. Presentation of reference standards used in trials (selectivity trials, transformation trials...)

It is possible to propose a single table for all crops or to propose distinct tables.

Crop(s)	Reference standards	Country(ies) where the product is registered (1)	Registration number	Active substance(s) (a.s)	Formulation		Registered application rate (3)	Application rate in trials (per treatment)	Remark (3)
					Type (2)	Concentration of a.s.			

(1) only on use(s) applied for (with the test product).
(2) e.g.WP (wettable powder), EC (emulsifiable concentrate), etc.
(3) Dose / dose range authorized in the country.
(4) Other relevant information (e.g. uses, number of applications, spray volume, method of application…).

IIIA1 6.2.1 Phytotoxicity to host crop

Phytotoxicity

Data may be presented from efficacy trials conducted and/or from specific trials conducted to evaluate potential phytotoxicity.

EPPO standard PP 1/135 and 1/226 provides useful guidance on the number and type of trials in crops needed to demonstrate the crop safety of a plant protection product at the normal (N) and at twice the normal (2N) dose rate.

A short description of the number, nature and type of test carried out should be made. Minimum details should include: year conducted, location, type of study (e.g. glasshouse, field), trial design, crop stages, tested cultivars, water volumes and outline methodology (e.g. foliar herbicide, contact insecticide, preventative fungicide).
It should be made clear if the tests were carried out according to GEP, by officially recognised testing organisations and the guidelines (e.g. EPPO) followed.

The information should be presented in the form of simple tables (an example of table is given in the chapter “efficacy tests”).

Specify the threshold of acceptability for the phytotoxicity. Precise the number of trials where symptoms are observed and the number of trials where unacceptable symptoms were observed for each tested dose.

A summary of the trials where phytotoxicity was observed is provided in the table below. A table is not necessary in the dRR if no significant effect is seen (it will be available in the BAD).

In the presence or absence of a table presenting the data, the applicant should provide in the text a rationale and all evidences (concisely) that may be useful to the evaluation.

Table 6-16. Phytotoxicity of product

	Selectivity trials (20 trials)	Efficacy trials (x trials)

Number of trials with…		Test product		Standard 1		Test product	Standard 1
		N	2N (or other)	N	2N (or other)	N	N
Maximum of phytotoxicity recorded during the trials	0% to 5%	5	10	7	8		
	>5% to 10%	3	6	2	6		
	>10% to 15%	0	2	1	2		
	>15 %	0	0	0	0		
Level of symptoms at the last assessments	0% to 5%	2	2	1	1		
	>5% to 10%	0	0	0	0		
	>10% to 15%	0	0	0	0		
	>15 %	0	0	0	0		

In the text:

- add short description of symptoms observed and their evolution, and on which variety the highest symptoms occur,
- Explanation of the cause of highest phytotoxic levels in trials (climatic conditions, soil type, sensible varieties...),
- Possibly, proposal of warnings on the label and/or management measures to decrease the risk of phytotoxicity.

For each crop:

X trials were carried out on crop in countries from year-year on a wide range of commercially grown varieties.

If no phytotoxicity issues:

(No) phytotoxicity symptom caused by product at the proposed dose rate of xxx L/ha or kg/ha was recorded in all / the vast majority of / x trials out to y trials.

For each minor use, if data is not available, it should be mentioned the reference to the respective crop of the existing extrapolation table (in conjunction to EPPO 1/257 Efficacy and crop safety extrapolations for minor uses) or an argumentation, allowing to link the minor crop to an intended crop or a registered crop (which is supported by sufficient data).

In the particular case of “article 51” uses, please refer to the regulation 1107/2009.

Yield

This part concerns only trials in pest free conditions. The absence of negative effect seen in efficacy trials can offer supporting evidence (especially for fungicides and insecticides) when conducted in the absence of the pest, or where pest pressure is low.

If provided, yield results under challenging pest populations may be reported under effectiveness, as supporting evidence of benefit in treatment intended to show an increased yield.

A statement should be made regarding the availability (or otherwise) of results from trials that evaluated the impact on yield (refer to EPPO standard PP 1/135). The individual assessments required for aspects of yield will be dependent on the proposed use. The results should be summarised, in tabular form if appropriate, and a conclusion drawn.

Table 6-17. Relationship between phytotoxicity and yield.

Test report	Variety	Maximum phyto. at 1N rate (%) (DAA)		Maximum phyto. at 2N (or other) rate (%) (DAA)		Yield in the untreated control Absolute figures (unit)	Yield at 1N as % of untreated		Yield at 2N (or other) rate as % of untreated	
		Test product	Standard 1	Test product	Standard 1		Test product	Standard 1	Test product	Standard 1

Only for trials with a significant phytotoxicity or a negative impact on yield.

For crop, a total of x trials were carried out between year and year in countries.

For each dose of the product and each crop, precise the number of trials where the yield is significantly inferior / equal / superior to the yield of untreated control and/or the yield of the standard.

In x trials, product at the proposed label rate of xxx L/ha or kg/ha had no (or describe) negative effect on the yield of crop 1 in the absence of pest / weed / disease

IIIA1 6.2.2 Adverse effects on health of host animals

This is not an EC data requirement/ not required by Directive 91/414/EEC.

IIIA1 6.2.3 Adverse effects on site of application

This is not an EC data requirement/ not required by Directive 91/414/EEC.

IIIA1 6.2.4 Adverse effects on beneficial organisms (other than bees)

Detailed studies on the potential adverse effects to beneficial organisms are submitted in Part B Section 6 Annex Point IIIA 10.5 and IIIA 10.6 and summarised in the dRR Part B Section 6.

IIIA1 6.2.5 Adverse effects on parts of plant used for propagating purposes

Reference may be made to EPPO standard PP 1/135 'Phytotoxicity assessment' which provides an indication of the circumstances under which data on plant parts for propagation are required.

A brief description of experiments should be provided. Trials and results must be presented as described in the other parts of the dRR (efficacy, selectivity, etc.). The results should be summarised, in tabular form, if appropriate.

X studies conducted between year and year in countries on crops revealed no (or describe) negative impact of product on propagation material cereal seed, tubers, etc.

IIIA1 6.2.6 Impact on succeeding crops

A step-wise approach should be taken following the EPPO Standard PP 1/207 '*Effects on succeeding* crops'. A summary and a conclusion of this step-wise approach should be presented.

If no significant effects are seen, a summary of the rationale and a conclusion are sufficient in the dRR. In case of significant effects seen (usually, herbicides), a more detailed presentation of data in dRR may be useful. In that case, the following tables can be used (optional).

Table 6-18. PEC-values and TER-calculation of test product (active substance) based on EC10-values.

Succeeding crop (1)	Days after application (2)	EC10 mg/kg soil (3)	PEC (4)		TER (5)	
			mg/kg soil e.g. 5 cm	mg/kg soil e.g. 20 cm	EC10/PEC e.g. 5 cm	EC10/PEC e.g. 20 cm
BRSNW	e.g. 100					
SINAL	e.g. 100					
TRZAW	e.g. 120					
AVESA	e.g. 300					
BEAVA	e.g. 330					
ZEAMA	e.g. 360					

1 possible following crops in a regular crop rotation
2 adequate value for following crop in a regular crop rotation
3 EC10-values of succeeding crops
4 PEC (soil depth e.g. 5/20 cm)
5 TER (soil depth e.g. 5/20 cm)

If field trials are necessary, a brief description of experiments should be provided. Trials can be presented as described in the efficacy chapter (table "details on trial methodology).

Table 6.19. Results of field trials: Effects of test product on succeeding crops.

Treated crop (growth stage) (1)	Cultivation / Tillage	Succeeding crop (growth stage) (2)	Succ. crop sown X DAT (3)	Phytotoxicity and/or other side effects				Remarks (e.g. type of damage, yield...)
				Test product (dose)		Standard (dose) (4)		
				Nber of trials with phyto/total	Min-max	Nber of trials with phyto/total	Min-max	
Winter wheat (BBCH 12-14)	Plough (20-25 cm)	Maize (BBCH)	130 DAT	0/2	0%			
		Sugar beet (BBCH)	130 DAT	1/2	0-5%			
	Harrow (superficial work 5-7 cm)	Maize (BBCH)	130 DAT	0/2	0%			
		Sugar beet (BBCH)	130 DAT	2/2	5-20%			
		Mustard	270 DAT					

(1) Growth stage at application.
(2) Growth stage at observation time.
(3) DAT: days after treatment.
(4) If available (as described in EPPO standard PP 1/207).

X studies conducted between year and year in countries on crops revealed no or describe restrictions on following crops after application of product.

IIIA1 6.2.7 Impact on other plants including adjacent crops

A step-wise approach should be taken following EPPO Standard PP 1/256 '*Effects on adjacent crops'*. It is important to consider all crops which are likely to be present as adjacent crops (either already emerged or yet to emerge) across the zone. A summary and a conclusion of this step-wise approach should be presented.

If no significant effects are seen, a summary of the rationale and a conclusion are sufficient in the dRR. In case of significant effects seen (usually, herbicides), a more detailed presentation of data in dRR may be useful. In that case, the following tables can be used (optional).

Table 6-20: PEC-values (mg/ha) (drift)

Distance to adjacent crop (m)	% drift (1)	Drift *test product* (mg/ha)
1	2.77	
3	0.95	
5	0.57	
10	0.29	
15	0.20	

1 according to Ganzelmeier, BBA 1995.

Table 6-21: ED_{50}-values (mg/ha) of different test plants

Test plant		EPPO Code	ED_{50} *test product* (mg/ha)	
Common name	Scientific name (lat.)		Seedling-emergence-test	Vegetative-vigour-test
Soya bean	*Glycine max*	GLXMA		

In addition to drift, the volatility of the active substance (and if known the formulated product) should be considered, as this may affect adjacent crops.

If field (or semi-field) trials are necessary, a brief description of experiments should be provided. Trials can be presented as described in the efficacy chapter (table "details on trial methodology).

Table 6-22. Results of field trials (or semi-field trials): Effects of test product on adjacent crops.

Treated crop (growth stage) (1)	Adjacent crop (growth stage) (1)	Distance drift	Rate expected at this distance (2)	Phytotoxicity and/or other side-effects		Remarks
				Nber of trials with phyto / total	Min-max	
Winter wheat (BBCH 13-14)	Winter rape (BBCH 11-19)	1 m	4% N	3/3	7-25%	
		3 m	1% N	2/3	5-15%	
		5 m	0,6% N	0/3	0%	
		10 m	0,3%N	0/3	0%	
	Winter peas (BBCH 12-14)					

(1) At application.
(2) Dosage likely to reach the crop (e.g. according to Ganzelmeier scale).

X studies conducted between year and year in countries on crops revealed no or describe restrictions on adjacent crops after application of product.

Summary and conclusion

Write a summary and a conclusion on the entire chapter "6.2.1 - 6.2.7. "Adverse effects".
(It is possible to propose a single summary for the chapter 6.2.1 t/m 6.2.6 or to propose distinct summaries for 6.2.1, 6.2.2, 6.2.3 etc, placed at the end of each chapter).

IIIA1 6.2.8 Possible development of resistance or cross-resistance

EPPO Standard PP 1/213 'Resistance risk analysis' provides a framework for resistance risk assessment and resistance risk management. Each of the points that formed part of this section in the BAD should be briefly summarised ensuring it is clear what evidence is available and on what basis a particular decision was made.

Findings on the risk of resistance by use and suitable management measures must be provided for the entire zone and if necessary, for each Member State of the zone. If monitoring proves to be necessary, it may be performed at the national or zonal level.

IIIA1 6.3 Economics

This is not an EC data requirement/ not required by Directive 91/414/EEC.

IIIA1 6.4 Benefits

IIIA1 6.4.1 Survey of alternative pest control measures

This is not an EC data requirement/ not required by Directive 91/414/EEC.

IIIA1 6.4.2 Compatibility with current management practices including IPM

If trials were carried out, a brief description of experiments should be provided. Trials and results can be presented as described in the other parts of the dRR (efficacy, selectivity, etc.).

IIIA1 6.4.3 Contribution to risk reduction

This is not an EC data requirement/ not required by Directive 91/414/EEC.

IIIA1 6.5 Other/special studies

Tank cleaning

Tank cleaning will not be evaluated in the Netherlands, but some member states require data about tank cleaning.
Sufficient data should be submitted to demonstrate that residues of the plant protection product do not remain in the application equipment after cleaning, and that there is no risk to subsequently treated crops.
A brief description of experiments should be provided. Trials and results can be presented as described in the other parts of the dRR (efficacy, selectivity, etc.).

X studies conducted between year and year in countries on crops revealed no negative impact of product on crops treated after the tank cleaning.

Provide any additional information that is considered relevant and/or that support label claims / recommendations.

Studies that may be included are:

- Biological compatibility (if tank-mixes are recommended on the proposed label),
- Rain fastness,
- Justification for recommended water volumes.
- Impact of environmental and climatic conditions on the efficacy of the product or active substance (the effect of pH or temperature, etc.).

A brief description of experiments should be provided. Trials and results can be presented as described in the other parts of the dRR (efficacy, selectivity, etc.).

IIIA1 6.6 Summary and assessment of data according to point 6.1 to 6.5

Write a summary and a conclusion for the chapters 6.1 - 6.5.
(It is possible to propose a single summary for the chapter 6.1 - 6.5 or to propose distinct summaries for 6.1, 6.2., 6.3 etc.).
Take care that the conclusion for all different cMS-countries is clear. Try to make a conclusion per climatic zone (if possible).

IIIA1 6.7 List of test facilities including the corresponding certificates

Make a list of test facilities and specify whether a certificate exists. The corresponding certificates must be located in the BAD.

Table 3-23. List of test facilities

Test facilities	Address	Certificate (Yes or No)

860Appendix 1: List of data submitted in support of the evaluation

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Annex point	**Author**	**Year**	**Title** **Source (where different from company)** **Company, Report No.** **GLP or GEP status (where relevant)** **Published or Unpublished**	**Data protection claimed Y/N**	**Owner** (SYN = Syngenta)	**Application number***	**Date of submission***	**Data protection granted? Y/N**	**Studies relied on? Y/N**

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Appendix 2: Critical uses – justification and GAP tables

The proposed uses (GAP) can be found in Part A, paragraph 2.3. (NL uses) or in part B.1, paragraph 3.3.1. (all MS uses) of the registration report.

Appendix 3–9:

The appendix 3 to 9 should not be part of the dRR, but only in the BAD.