guidance 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**
NATIONAL ADDENDA – *the Netherlands*

**Applicant: Company name**

**Date: DD/MM/YYYY**

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# Table of Contents

# 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. It has been designed as an example of how a Part B Section 7 (Efficacy) National addendum could be prepared. This document does not contain a detailed example of a efficacy assessment but provides examples of how sections could be completed.

This document should be read in conjunction with the guidance for the core assessment Part B section 7 (efficacy). All details/examples provided in the core guidance/example are not repeated here. Only information that could be helpful in the preparation of a national addendum is provided.

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.

## IIIA1 6.1 Efficacy data

This national addendum has been prepared for <*insert product code/name*> in the Netherlands. This addendum should be read in conjunction with the core assessment part B7 efficacy.

Where there are no issues that are considered to be national a cross reference is made to the core assessment. Only issues that are relevant for the Netherlands are presented in this addendum.
For the efficacy evaluation as much data/information as possible should be in the Core. As a general rule, all data of all intended uses for each concerned member state should be summarised in the core dossier.
If national addenda are submitted, only limited additional data should be included. Examples for additional data which can be presented in the national addenda for efficacy are:

- no (EPPO) guidance available: e.g. rain fastness
- specific low dose rates because of national risk mitigation measures
- specific (regional use): cooperation/ with cMS is important

Or in cases that zRMS can not conclude it is also possible to add data in the national addendum e.g.:

- specific dose due to regional pest pressure, soil types, local resistance problems
- bridging trials / data protection
- statements referring to existing products
- national extrapolation possibilities
- national label: dose expression, water volume, crop/pest grouping, label warnings etc

In the Guidance Document 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 11-07/2009 of the EU parliament and council on placing of plant protection products on the market” more guidance is given about this subject.

### Introduction

This introductory section should include the following information:

- Justification why this national addendum is provided; e.g. explanation of the submission process, a short introduction of what the national addendum is about, all other information that could clarify

the context of the national addendum, explaining how national labels are derived and supported by the Core dosser, etc.

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.

### IIIA1 6.1.1 Preliminary range-finding tests

This information is considered to be relevant for all countries so please refer to core assessment.

Reference is made to the core assessment (Part B7).

### IIIA1 6.1.2 Minimum effective dose tests

Reference is made to the core assessment (Part B7).

In principle minimum effective dose is evaluated within the Core assessment. In that case reference can be made to the core assessment (Part B7). However, under the following circumstances (additional) information should be given in the national addendum. This list is not exhaustive.

1) Conversion of dose rate: Countries have different means of expressing the dose of plant protection products (e.g. for three-dimensional crops). If in the Core dossier under the chapter minimum effective dose test another dose rate is addressed than used in the Netherlands, provide justification for the dose rate applied for in the Netherlands. The following EPPO standard can be used: Dose expression for plant protection products (PP 1/239 (2). E.g. for apple in the Core dossier a dose rate in per ha leaf wall area (LWA) is justified, but for the Netherlands a dose rate in concentration is (%) is claimed on the WG (label).
2) Bridging trials: In case of bridging trials for demonstration of comparability of product formulations, applicants should check per country if data are indeed free of data protection or if a LOA (Letter Of Access) should be provided. The results of the trials should be addressed in the Core document, but since data protection is a national affair the ZRMS is not able to conclude on data protection issues for another member state. Therefore the final conclusion for dose justification has to be made on member state level.
3) Core GAP doesn't cover NLGAP. Under special circumstances (e.g. specific low dose rates because of national risk mitigation measures or specific regional uses) it is possible that the core GAP does not cover the NLGAP. In such a case address this crop (these crops). See also guidance Part B7 CORE how to describe this.
4) In case the zRMS is not conclusive for all point under "minimum effective dose" in the core, the open points should be addressed in the national addendum. E.g.
    a. If an extrapolation from a major crop to a minor crop not has been done in the Core dossier this point should be addressed in the National addendum. Extrapolation can be based on EPPO extrapolation tables (in conjunction with the EPPO 1/257 Efficacy and crop safety extrapolations for minor uses), the Dutch extrapolation document (this document can be found on the Ctgb website in the Evaluation Manual, chapter efficacy) or on an argumentation. In the particular case of "article 51" uses, please refer to the regulation 1107/2009, for the Netherlands no dose justification data are necessary for these uses.

### IIIA1 6.1.3 Efficacy tests

Reference is made to the core assessment (Part B7).

In principle “efficacy tests” is evaluated within the Core assessment. In that case reference can be made to the core assessment (Part B7). However, under the following circumstances (additional) information should be given in the national addendum. This list is not exhaustive.

1) Bridging trials: In case of bridging trials for demonstration of comparability of product formulations, applicants should check per country if data are indeed free of data protection or if a LOA (Letter Of Access) should be provided. The results of the trials should be addressed in the Core document, but since data protection is a national affair the ZRMS is not able to conclude on data protection issues for another member state. Therefore the final conclusion about the efficacy tests has to be made on member state level.
2) Core GAP doesn’t cover NLGAP. Under special circumstances it is possible that the core GAP does not cover the NLGAP. In such a case address this crop (these crops). See also guidance Part B7 CORE how to describe this.
3) In case the ZRMS is not conclusive for all points under ‘Efficacy tests’ in the core dossier, the open points should be addressed in the national addendum. E.g.
    a. If an extrapolation from a major crop to a minor crop not has been done in the Core dossier this point should be addressed in the National addendum. Extrapolation can be based on EPPO extrapolation tables (in conjunction with the EPPO 1/257 Efficacy and crop safety extrapolations for minor uses), the Dutch extrapolation document (this document can be found on the Ctgb website in the Evaluation Manual, chapter efficacy) or on an argumentation. In the particular case of “article 51” uses, please refer to the regulation 1107/2009, for the Netherlands no efficacy data are necessary.
    b. If extrapolation is necessary for one weed/disease/pest to another weed/disease/pest it should also be addressed; e.g. for the Netherlands if efficacy is shown for 3 broadleaved weeds than extrapolation can be done to the whole group of broadleaved weeds.
    c. If in principle not enough trials are available but zRMS left decision open to cMS, because for example expert judgement this can be possible.
4) If applicable specific efficacy related restriction or warning sentences for the Netherlands should be addressed.

## IIIA1 6.1.4 Effects on yield and quality

### IIIA1 6.1.4.1 Impact on the quality of plants or plant products

Reference is made to the core assessment (Part B7).

If applicable a specific national warning sentence“ on the directions for use (WG= Wettelijk Gebruiksvoorschrift) should be addressed.

### IIIA1 6.1.4.2 Effects on the processing procedure

Reference is made to the core assessment (Part B7).

If applicable a specific national warning sentence“ on the directions for use (WG= Wettelijk Gebruiksvoorschrift) should be addressed.

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

Reference is made to the core assessment (Part B7).

If applicable a specific national warning sentence“ on the directions for use (WG= Wettelijk Gebruiksvoorschrift) should be addressed.

## IIIA1 6.2 Adverse effects

Reference is made to the core assessment (Part B7).

### IIIA1 6.2.1 Phytotoxicity to host crop

Reference is made to the core assessment (Part B7).

In principle “Phytotoxicity to host crop” is evaluated within the Core assessment. In that case reference can be made to the core assessment (Part B7). However, under the following circumstances (additional) information should be given in the national addendum. This list is not exhaustive.

1) If applicable a specific national warning sentence“ on the directions for use (WG= Wettelijk Gebruiksvoorschrift) should be addressed.

2) In case the ZRMS is not conclusive for all points under ‘Phytotoxicity to host crop” in the core dossier, the open points should be addressed in the national addendum. E.g. If an extrapolation from a major crop to a minor crop not has been done in de Core dossier this point should be addressed in the National addendum. Extrapolation can be based on EPPO extrapolation tables (in conjunction with the EPPO 1/257 Efficacy and crop safety extrapolations for minor uses), the Dutch extrapolation document (this document can be found on the Ctgb website in the Evaluation Manual, chapter efficacy) or on an argumentation. In the particular case of “article 51” uses, please refer to the regulation 1107/2009, for the Netherlands no phytotoxicity data are necessary.

### IIIA1 6.2.2 Adverse effects on health of host animals

This is not an EC data requirement/ not required by Directive 1107/2009.

### IIIA1 6.2.3 Adverse effects on site of application

This is not an EC data requirement/ not required by Directive 1107/2009.

### 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 is made to the core assessment (Part B7).

If applicable a specific national warning sentence“ on the directions for use (WG= Wettelijk Gebruiksvoorschrift) should be addressed.

## IIIA1 6.2.6 Impact on succeeding crops

Reference is made to the core assessment (Part B7).

If applicable a specific national warning sentence“ on the directions for use (WG= Wettelijk Gebruiksvoorschrift) should be addressed.

## IIIA1 6.2.7 Impact on other plants including adjacent crops

Reference is made to the core assessment (Part B7).

If applicable a specific national warning sentence“ on the directions for use (WG= Wettelijk Gebruiksvoorschrift) should be addressed

## IIIA1 6.2.8 Possible development of resistance or cross-resistance

Reference is made to the core assessment (Part B7).

If applicable a specific national resistance management strategy on “ the directions for use (WG= Wettelijk Gebruiksvoorschrift) should be addressed.

It can be necessary to add information about specific crop systems and resistance for the Netherlands.

## 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

Reference is made to the core assessment (Part B7).

## 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

**None.**

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

Reference is made to the core assessment (Part B7).

Write a summary and a conclusion for the chapters 6.1 - 6.5. Take care that the conclusion is clear for the Netherlands. .

## IIIA1 6.7 List of test facilities including the corresponding certificates

Reference is made to the core assessment (Part B7).

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

Only applicable if trials are evaluated on national level. Normally under the zonal process this is not the case. Evaluation of trials has to be conducted in Core dossier Part B7.

| Annex point | Author | Year | Title<br>Source (where different from company)<br>Company, Report No.<br>GLP or GEP status (where relevant)<br>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 |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | |

## 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.**