

guidance document

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**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).***

19

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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21

Table of Contents

22			
23			
24	IIIA1 6	Efficacy Data and Information (including Value Data) on the Plant Protection	
25	Product 3		
26	IIIA1 6.1	Efficacy data	3
27	IIIA1 6.1.1	Preliminary range-finding tests.....	4
28	IIIA1 6.1.2	Minimum effective dose tests	4
29	IIIA1 6.1.3	Efficacy tests.....	4
30	IIIA1 6.1.4	Effects on yield and quality.....	5
31	IIIA1 6.1.4.1	Impact on the quality of plants or plant products	5
32	IIIA1 6.1.4.2	Effects on the processing procedure.....	5
33	IIIA1 6.1.4.3	Effects on the yield of treated plants and plant products	5
34	IIIA1 6.2	Adverse effects	6
35	IIIA1 6.2.1	Phytotoxicity to host crop	6
36	IIIA1 6.2.2	Adverse effects on health of host animals.....	6
37	IIIA1 6.2.3	Adverse effects on site of application	6
38	IIIA1 6.2.4	Adverse effects on beneficial organisms (other than bees).....	6
39	IIIA1 6.2.5	Adverse effects on parts of plant used for propagating purposes	6
40	IIIA1 6.2.6	Impact on succeeding crops.....	7
41	IIIA1 6.2.7	Impact on other plants including adjacent crops	7
42	IIIA1 6.2.8	Possible development of resistance or cross-resistance	7
43	IIIA1 6.3	Economics	7
44	IIIA1 6.4	Benefits	7
45	IIIA1 6.4.1	Survey of alternative pest control measures.....	7
46	IIIA1 6.4.2	Compatibility with current management practices including IPM.....	7
47	IIIA1 6.4.3	Contribution to risk reduction.....	7
48	IIIA1 6.5	Other/special studies	7
49	IIIA1 6.6	Summary and assessment of data according to point 6.1 to 6.5	8
50	IIIA1 6.7	List of test facilities including the corresponding certificates	8
51	Appendix 1:	List of data submitted in support of the evaluation	8
52	Appendix 2:	Critical uses – justification and GAP tables	8
53	Appendix 3–9:	8
54			

55IIIA1 6 Efficacy Data and Information (including Value Data) on the 56Plant Protection Product

57

58

59This document is to be used by the applicant of a plant protection product for registration at Member
60State level. It has been designed as an example of how a Part B Section 7 (Efficacy) National
61addendum could be prepared. This document does not contain a detailed example of a efficacy
62assessment but provides examples of how sections could be completed.

63

64This document should be read in conjunction with the guidance for the core assessment Part B
65section 7 (efficacy). All details/examples provided in the core guidance/example are not repeated
66here. Only information that could be helpful in the preparation of a national addendum is provided.

67

68Notes:

69Text in blue provides general information/support and should be deleted when the document is
70finalized. Text in black shows the headers for each section. It also shows **example text**. The table
71format is not fixed; tables are provided as examples (columns can be added or deleted). They could
72be adapted to suit the product being evaluated. Moreover, some tables are not relevant for all
73products or all submission types: tables can be added or deleted.

75

76IIIA1 6.1 Efficacy data

77

78This national addendum has been prepared for <insert product code/name> in the Netherlands. This
79addendum should be read in conjunction with the core assessment part B7 efficacy.

80

81Where there are no issues that are considered to be national a cross reference is made to the core
82assessment. Only issues that are relevant for the Netherlands are presented in this addendum.
83For the efficacy evaluation as much data/information as possible should be in the Core. As a general
84rule, all data of all intended uses for each concerned member state should be summarised in the core
85dossier.

86If national addenda are submitted, only limited additional data should be included. Examples for
87additional data which can be presented in the national addenda for efficacy are:

88 - no (EPPO) guidance available: e.g. rain fastness

89 - specific low dose rates because of national risk mitigation measures

90 - specific (regional use): cooperation/ with cMS is important

91Or in cases that zRMS can not conclude it is also possible to add data in the national addendum
92e.g.:

93 - specific dose due to regional pest pressure, soil types, local resistance problems

94 - bridging trials / data protection

95 - statements referring to existing products

96 - national extrapolation possibilities

97 - national label: dose expression, water volume, crop/pest grouping, label warnings etc

98In the Guidance Document SANCO 10055/2013: "Guidance document on the efficacy composition
99of core dossier and national addenda submitted to support the authorization of plant protection
100products under regulation (EC) NO 11-07/2009 of the EU parliament and council on placing of plant
101protection products on the market" more guidance is given about this subject.

102

103

104Introduction

105

106This introductory section should include the following information:

107

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

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

112

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

115

116

117

118 IIIA1 6.1.1 Preliminary range-finding tests

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

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

121

122 IIIA1 6.1.2 Minimum effective dose tests

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

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

127 1) Conversion of dose rate: Countries have different means of expressing the dose of plant
128 protection products (e.g. for three-dimensional crops). If in the Core dossier under the
129 chapter minimum effective dose test another dose rate is addressed than used in the

130 Netherlands, provide justification for the dose rate applied for in the Netherlands. The
131 following EPPO standard can be used: Dose expression for plant protection products (PP

132 1/239 (2). E.g. for apple in the Core dossier a dose rate in per ha leaf wall area (LWA) is
133 justified, but for the Netherlands a dose rate in concentration is (%) is claimed on the WG

134 (label).

135 2) Bridging trials: In case of bridging trials for demonstration of comparability of product
136 formulations, applicants should check per country if data are indeed free of data protection or

137 if a LOA (Letter Of Access) should be provided. The results of the trials should be addressed
138 in the Core document, but since data protection is a national affair the ZRMS is not able to

139 conclude on data protection issues for another member state. Therefore the final conclusion
140 for dose justification has to be made on member state level.

141 3) Core GAP doesn't cover NLGAP. Under special circumstances (e.g. specific low dose rates
142 because of national risk mitigation measures or specific regional uses) it is possible that the
143 core GAP does not cover the NLGAP. In such a case address this crop (these crops). See

144 also guidance Part B7 CORE how to describe this.

145 4) In case the zRMS is not conclusive for all point under "minimum effective dose" in the core,
146 the open points should be addressed in the national addendum. E.g.

147 a. If an extrapolation from a major crop to a minor crop not has been done in the Core
148 dossier this point should be addressed in the National addendum. Extrapolation can

149 be based on EPPO extrapolation tables (in conjunction with the EPPO 1/257 Efficacy
150 and crop safety extrapolations for minor uses), the Dutch extrapolation document

151 (this document can be found on the Ctgb website in the Evaluation Manual, chapter
152 efficacy) or on an argumentation. In the particular case of "article 51" uses, please

153 refer to the regulation 1107/2009, for the Netherlands no dose justification data are
154 necessary for these uses.

155

156

157

158 IIIA1 6.1.3 Efficacy tests

159

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

161

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

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

191

192

193 IIIA1 6.1.4 Effects on yield and quality

194

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

196

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

198 If applicable a specific national warning sentence“ on the directions for use (WG= Wettelijk

199 Gebruiksvoorschrift) should be addressed.

200.

201

202 IIIA1 6.1.4.2 Effects on the processing procedure

203

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

205 If applicable a specific national warning sentence“ on the directions for use (WG= Wettelijk

206 Gebruiksvoorschrift) should be addressed.

207

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

209

210

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

212If applicable a specific national warning sentence“ on the directions for use (WG= Wettelijk
213Gebruiksvoorschrift) should be addressed.

214

215IIIA1 6.2 Adverse effects

216

217Reference is made to the core assessment (Part B7).

218

219IIIA1 6.2.1 Phytotoxicity to host crop

220

221Reference is made to the core assessment (Part B7).

222In principle “Phytotoxicity to host crop” is evaluated within the Core assessment. In that case

223reference can be made to the core assessment (Part B7). However, under the following

224circumstances (additional) information should be given in the national addendum. This list is not

225exhaustive.

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

228 2) In case the ZRMS is not conclusive for all points under ‘Phytotoxicity to host crop’ in the core
229 dossier, the open points should be addressed in the national addendum. E.g. If an
230 extrapolation from a major crop to a minor crop not has been done in de Core dossier this
231 point should be addressed in the National addendum. Extrapolation can be based on EPPO
232 extrapolation tables (in conjunction with the EPPO 1/257 Efficacy and crop safety
233 extrapolations for minor uses), the Dutch extrapolation document (this document can be
234 found on the Ctgb website in the Evaluation Manual, chapter efficacy) or on an
235 argumentation. In the particular case of “article 51” uses, please refer to the regulation
236 1107/2009, for the Netherlands no phytotoxicity data are necessary.

237

238IIIA1 6.2.2 Adverse effects on health of host animals

239

240This is not an EC data requirement/ not required by Directive 1107/2009.

241

242IIIA1 6.2.3 Adverse effects on site of application

243

244This is not an EC data requirement/ not required by Directive 1107/2009.

245

246

247IIIA1 6.2.4 Adverse effects on beneficial organisms (other than bees)

248

249Detailed studies on the potential adverse effects to beneficial organisms are submitted in Part B

250Section 6 Annex Point IIIA 10.5 and IIIA 10.6 and summarised in the dRR Part B Section 6.

251

252IIIA1 6.2.5 Adverse effects on parts of plant used for propagating purposes

253

254

255Reference is made to the core assessment (Part B7).

256If applicable a specific national warning sentence“ on the directions for use (WG= Wettelijk

257Gebruiksvoorschrift) should be addressed.

258

259 IIIA1 6.2.6 Impact on succeeding crops

260

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

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

264

265 IIIA1 6.2.7 Impact on other plants including adjacent crops

266

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

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

270

271 IIIA1 6.2.8 Possible development of resistance or cross-resistance

272

273

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

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

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

279

280 IIIA1 6.3 Economics

281

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

283

284 IIIA1 6.4 Benefits

285

286 IIIA1 6.4.1 Survey of alternative pest control measures

287

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

289

290 IIIA1 6.4.2 Compatibility with current management practices including

291 IPM

292

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

294 IIIA1 6.4.3 Contribution to risk reduction

295

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

297

298 IIIA1 6.5 Other/special studies

299

300 None.

301

302 IIIA1 6.6 Summary and assessment of data according to point 6.1 to 303 6.5

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

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

307 IIIA1 6.7 List of test facilities including the corresponding certificates

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

309

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

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

313

314

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

315

316 Appendix 2: Critical uses – justification and GAP tables

317

318 The proposed uses (GAP) can be found in Part A, paragraph 2.3. (NL uses) or in part B.1, paragraph
 319 3.3.1. (all MS uses) of the registration report.

320

321 Appendix 3–9:

322

323

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

325

326