

REGISTRATION REPORT
Part B
Section 3
Efficacy Data and Information
Concise summary

Product code: 102000028562

Product name(s): deltamethrin + flupyradifurone EC 85
(10+75 g/L)

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(Authorization)

Applicant: Bayer Crop Science Division

Submission date: 01/08/2019 (intended)

MS Finalisation date: August 2020 (initial Core Assessment)
February 2022 (final Core Assessment)
May 2022 (update final Core Assessment)

Version history

When	What
August 2019	Original Bayer Crop Science Division submission
August 2020	Initial zRMS assessment. The report in the dRR format has been prepared by the Applicant, therefore all comments, additional evaluations and conclusions of the zRMS are presented in grey commenting boxes. Minor changes are introduced directly in the text and highlighted in grey. Not agreed or not relevant information are struck through and shaded for transparency .
February 2022	Final report (Core Assessment updated following the commenting period) Additional information/assessments included by the zRMS in the report in response to comments recieved from the cMS and the Applicant are highlighted in yellow. Information no longer relevant is struck through and shaded .
May 2022	Update final Core Assessment Correction by zRMS in 3 additional commenting boxes highlighted in yellow: 1) following the GAP table, p. 13-14, 2) following section 3.4.4, p. 96, 3) following section 3.4.5, p.97 .

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Table of Contents

3	Efficacy Data and Information (including Value Data) on the Plant Protection Product (KCP 6).....	5
3.1	Summary and conclusions of zRMS on Section 3: Efficacy (KCP 6).....	6
3.2	Efficacy data (KCP 6).....	15
3.2.1	Preliminary tests (KCP 6.1).....	26
3.2.2	Minimum effective dose tests (KCP 6.2)	43
3.2.3	Efficacy tests (KCP 6.2)	58
3.3	Information on the occurrence or possible occurrence of the development of resistance (KCP 6.3).....	91
3.4	Adverse effects on treated crops (KCP 6.4)	93
3.4.1.	Phytotoxicity to host crop (KCP 6.4.1)	93
3.4.2.	Effect on the yield of treated plants or plant product (KCP 6.4.2)	96
3.4.3	Effects on the quality of plants or plant products (KCP 6.4.3).....	96
3.4.4	Effects on transformation processes (KCP 6.4.4).....	96
3.4.5	Impact on treated plants or plant products to be used for propagation (KCP 6.4.5).....	97
3.5	Observations on other undesirable or unintended side-effects (KCP 6.5).....	97
3.5.1	Impact on succeeding crops (KCP 6.5.1)	97
3.5.2	Impact on other plants including adjacent crops (KCP 6.5.2)	97
3.5.3	Effects on beneficial and other non-target organisms (KCP 6.5.3).....	98
3.6	Other/special studies.....	98
3.7	List of test facilities including the corresponding certificates	98
Appendix 1	Lists of data considered in support of the evaluation.....	101

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

Reference:	KCP Section 6/01
Title:	Biological assessment dossier - Efficacy data and information - Detailed summary - Deltamethrin + flupyradifurone EC85 (85 g/L) - Central zone - Zonal rapporteur member state: Poland - Core assessment (authorization)
Report:	Van Waetermeulen, X.; Tossens, X.; 2019; M-665892-01-1
Authority registration No:	Not known at the present stage of evaluation (August 2020).
Guideline(s):	Reg 1107/2009; Section 7, Point 6; According to OECD format guidance for industry data submissions on plant protection products and their active substances
Deviations:	--
GLP/GEP:	No
Acceptability:	The extent of the zRMS acceptance of the dossier is described in detail in the zRMS abstract in the chapter 3.1 “Summary and conclusions of zRMS on Section 3: Efficacy (KCP 6)”, starting the next page.
Duplication (if vertebrate study):	Not applicable.

This document is a summary of the data submitted to support the registration of the plant protection product deltamethrin + flupyradifurone EC85 (10 g/L + 75 g/L) which is proposed to be commonly named as DLT+FPF EC85 to ease the reading on this dossier. It refers to the Zonal BAD “Summary of the Efficacy Data and Information on the Plant Protection Product for deltamethrin + flupyradifurone EC85 (10 g/L + 75 g/L)”.

Appendix 1 of this document contains the list of references included for support of the evaluation.

All other appendices are submitted together with the Biological Assessment Dossier and its respective studies or study compilations.

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

Comments of zRMS:

Conclusions from the assessment were prepared using grey commenting boxes placed at the end of each chapter and, when necessary, in the relevant places within a chapter. Textual changes were done using grey highlights in the text. The parts of the text amended or added by the zRMS evaluator are highlighted in grey, whereas the parts struck off are also ~~visibly marked with the grey font~~.

3.1 Summary and conclusions of zRMS on Section 3: Efficacy (KCP 6)

Abstract

Abstract of the evaluation, by the zRMS:

The Applicant has submitted efficacy dossier of the insecticide DLT+FPF EC85/Sivanto Energy, containing 10 g/l deltamethrin (DLT) (sodium channel modulators, IRAC group 3A) and flupyradifurone (FPF) (nicotinic acetylcholine receptor (NACHR) competitive modulators, IRAC group 4D). The product is intended to be used in the control of *Ceutorhynchus napi* (CEUTNA), *Ceutorhynchus quadridens (pallidactylus)* (CEUTQU), *Ceutorhynchus obstrictus (assimilis)* (CEUTAS), *Dasineura brassica* (DASYBR) and *Brassicogethes (Meligethes) aeneus* (MELIAE) in winter and spring oilseed rape (OSR) and in winter and spring mustard. The authorization is sought on the grounds of the art. 33, and only in case of Poland – for mustard/ *Brassicogethes (Meligethes) aeneus*, based on the art. 51, of the regulation (EC) No 1107/2009.

To date, FPF has not been authorized in Poland for any use in oilseed rape (OSR).

The applicant submitted results of **98 field efficacy trials** from 2014-2018 (41 trials for CEUTNA and CEUTQU, 24 trials for MELIAE and 33 trials for CEUTAS and DASYBR), majority of which were carried out in winter oilseed rape. All these trials were conducted in different locations in three EPPO climatic zones: the North-East, the South-East and the Maritime zone. Along with the data from the North-East and the South-East EPPO zones a number of supporting trials have been submitted, covering parts of the respective EPPO zones belonging to EU regulatory zones other than Central (North and South, respectively).

No special selectivity trials were presented, as the phytotoxicity symptoms had been recorded within the efficacy trials and none were observed.

Preliminary trials, concerned mostly with **mixture justification**, had justified the co-formulation of the DLT with FPF. In control of the stem weevils the test product performed better compared to the single actives FPF and DLT used alone. In control of the pollen beetle, the pod weevil and the pod midge, consecutive assessments were carried out in each trial, in order to show the initial and the long-lasting efficacy. The combination of deltamethrin and flupyradifurone proved to offer on average better efficacy, compared to the single-active formulations applied at comparable dose rates, and both in the control of MELIAE and in the combined control of CEUTAS and DASYBR, the residual effect of the mixture, compared to single actives, can be concluded.

Majority of the individual trials within the data set submitted by the applicant had been used for **MED** and **Efficacy** sections simultaneously. The minimum effective dose has been established for the uses 01-03 as follows: 0.75 L/ha DLT+FPF EC85 (85 g/L) to control stem weevils (USE01) and the pollen beetle (USE02), and 0.50 L/ha - to control the pod weevil and the pod midge (USE03).

The spray volume values claimed in the GAP table for each use have been corrected, by the zRMS, according to the true application data contained in the individual trial reports and summarized in all the tables “*Details on trial methodology*” pertaining to efficacy testing, for uses 01-03. This correction includes mustard crop (SINSS) too, although it may be noted that no trials were submitted in mustard, so there is no “trial methodology” as well. However, the pest species (MELIAE) and the BBCH (50-59) declared by the applicant describe the use precisely as one analogous to the use no 02 in winter OSR. Hence the analogous correction of the spray volume. Nevertheless the zRMS PL acknowledges that the decision may be reconsidered individually, in case the other concerned MS, Romania, decides to authorize this use.

Based on the submitted results of the **Efficacy** trials it can be concluded that the insecticide DLT+FPF EC85 (85 g/L) is effective in control of CEUTNA, CEUTQU, CEUTAS and DASYBR in winter oilseed rape, in control of MELIAE in winter oilseed rape and in control of MELIAE in spring oilseed rape (data from Poland only).

The efficacy of the test item at the dose rate of 0.75 L/ha in control of the stem weevils (CEUTNA and CEUTAS) in winter OSR can be described as good in the North-East, the South-East and the Maritime zones, except for the incidence (% plants infested) control of CEUTNA in the Maritime zone, where it is better called moderate. The efficacy of the test item at the dose rate of 0.75 L/ha in control of the pollen beetle (MELIAE) in winter OSR was good both in the North-East as in the South-East zone, with the delicate shift towards “moderate” at the later assessment dates (1-6 DAA *versus* 7-13 DAA, NE zone, 1-3 DAA *versus* 7 DAA, SE zone).

In **3** efficacy trials conducted in the North-East zone on **spring** OSR the efficacy of DLT+FPF EC85 was low and very low at the first and the second assessment respectively. Due to the limited number of efficacy trials conducted in spring OSR, this use was supported by efficacy trials carried out in winter OSR (extrapolation), and moderate control level was finally concluded in case of spring OSR.

No efficacy trials were carried out in spring oilseed rape in the South-East zone. In case of the registration of DLT+FPF EC85 for the use in spring oilseed rape against MELIAE in the South-East zone, the concerned MSs are kindly advised to consider individually the possible extrapolation of efficacy trial results from winter oilseed rape to the spring oilseed rape, according to their national requirements.

The efficacy of the test item at the dose rate of 0.50 L/ha in control of the pod weevil (CEUTAS) and the pod midge (DASYBR) in winter OSR should be described as good in the North-East, the South-East and the Maritime zones, with the exception for the North-East zone (including North EU regulatory zone), where DASYBR was controlled with moderate an efficacy.

No efficacy trials testing control of CEUTNA, CEUTQU, CEUTAS and DASYBR in **spring oilseed rape** were submitted in any of the EPPO climatic zones (North-East, South-East or Maritime). Due to spring oilseed rape being minor crop in Poland, it is possible to authorize this use in PL based on the art. 51 of EU Regulation 1107/2009. In case of registration of DLT+FPF EC85 to control CEUTAS and DASYBR in the South-East and Maritime zones, the concerned MSs are kindly advised to consider individually the possible extrapolation of efficacy trial results from winter oilseed rape to spring oilseed rape, according to their national requirements.

No efficacy trials were carried out in **mustard** (winter and spring). Use in this crop has been accepted for Poland, according to art. 51 of the 1107/2009. The other concerned MS - Romania - is kindly advised to consider individually the possibility of extrapolation of efficacy trial results, from winter oilseed rape to the other crops, according to their national requirements.

Quantitative and qualitative parameters of the yield were evaluated in 13 efficacy trials testing efficacy of DLT+FPF EC85 against CEUTNA and CEUTQU, in winter OSR, and in 24 efficacy trials conducted in winter OSR against CEUTAS and DASYBR, as well as in 6 field efficacy trials conducted in spring OSR against MELIAE. No negative effects were observed. DLT+FPF EC 85 applied at the proposed dose rates of 0,5 and 0,75 L/ha did not cause deterioration of yield quantity, moisture content in seeds, TKW or the oil content in seeds, as compared to untreated plots or the plots treated with reference products.

Resistance management

Inspection of two graphs showing results of the resistance monitoring study (2017), presented by the applicant in the document [M-659907-01-1](#) suggests clearly that DLT+FPF EC85 performs better than pyrethroids used alone. This leads to the conclusion that the potential for resistance to the first of the actives, DLT, should not be ignored, even though in the proposed product DLT has been co-formulated with the other active, FPF, the one new to the OSR pests. On the other hand, the absence of resistance cases reported for FPF in the OSR pests is likely the plain consequence of this active's absence in that crop. DLT+FPF EC85 may not be as immune to resistance selection as it seems at the first glance. The applicant has proposed the standard resistance management measures to be applied, which is largely accepted by the zRMS. The issue is explained in more detail in the commenting box following the Resistance Chapter (3.3).

Table 0-1: Acceptability of intended uses (and respective fall-back GAPs, if applicable)

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No. *	Mem- ber state(s)	Crop and/ or situation (crop destination / purpose of crop)	F, Fn, G, Gn, Gnp or I **	Pests or Group of pests controlled (additionally: develop- mental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/ synergist per ha, other dose rate expression, dose range (min-max)	zRMS Conclusion (efficacy)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between ap- plications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
Zonal uses (field or outdoor uses, certain types of protected crops)														
1	CZE	Rape, winter (BRSNW)	F	CEUTNA, CEUTQU	spraying (foliar)	30-49	a) 2 b) 2	14	a) 0.75 b) 1.5	a) DLT 7.5 + FPF 56.25 b) DLT 15 + FPF 112.5	200-600 250-300 200-600	as per growth stage		A
2	CZE	Rape, spring (Canola) (BRSNS)	F	CEUTNA, CEUTQU	spraying (foliar)	30-49	a) 2 b) 2	14	a) 0.75 b) 1.5	a) DLT 7.5 + FPF 56.25 b) DLT 15 + FPF 112.5	200-600	as per growth stage		C
3	CZE	Rape, winter (BRSNW)	F	CEUTAS, DASYBR	spraying (foliar)	65-79	a) 2 b) 2	14	a) 0.5 b) 1	a) DLT 5 + FPF 37.5 b) DLT 10 + FPF 75	200-600 250-400 200-600	45		A
4	CZE	Rape, spring (Canola) (BRSNS)	F	CEUTAS, DASYBR	spraying (foliar)	65-79	a) 2 b) 2	14	a) 0.5 b) 1	a) DLT 5 + FPF 37.5 b) DLT 10 + FPF 75	200-600	45		C
5	HUN	Rape, winter (BRSNW)	F	CEUTNA, CEUTQU	spraying (foliar)	30-49	a) 2 b) 2	14	a) 0.75 b) 1.5	a) DLT 7.5 + FPF 56.25 b) DLT 15 + FPF 112.5	200-600 250-300 200-600	as per growth stage		A
6	HUN	Rape, spring (Canola) (BRSNS)	F	CEUTNA, CEUTQU	spraying (foliar)	30-49	a) 2 b) 2	14	a) 0.75 b) 1.5	a) DLT 7.5 + FPF 56.25 b) DLT 15 + FPF 112.5	200-600	as per growth stage		C
7	NLD	Rape, winter (BRSNW)	F	CEUTNA, CEUTQU	spraying (foliar)	30-49	a) 2 b) 2	14	a) 0.75 b) 1.5	a) DLT 7.5 + FPF 56.25 b) DLT 15 + FPF 112.5	200-600 250-300 200-600	as per growth stage		A
8	NLD	Rape, spring (Canola)	F	CEUTNA, CEUTQU	spraying (foliar)	30-49	a) 2 b) 2	14	a) 0.75 b) 1.5	a) DLT 7.5 + FPF 56.25	200-600	as per growth		C

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No. *	Mem- ber state(s)	Crop and/ or situation (crop destination / purpose of crop)	F, Fn, G, Gn, Gnp or I **	Pests or Group of pests controlled (additionally: develop- mental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/ synergist per ha, other dose rate expression, dose range (min-max)	zRMS Conclusion (efficacy)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between ap- plications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
		(BRSNS)								b) DLT 15 + FPF 112.5		stage		
9	NLD	Rape, winter (BRSNW)	F	CEUTAS, DASYBR	spraying (foliar)	65-79	a) 2 b) 2	14	a) 0.5 b) 1	a) DLT 5 + FPF 37.5 b) DLT 10 + FPF 75	200-600 250-400 200-600	45		A
10	NLD	Rape, spring (Canola) (BRSNS)	F	CEUTAS, DASYBR	spraying (foliar)	65-79	a) 2 b) 2	14	a) 0.5 b) 1	a) DLT 5 + FPF 37.5 b) DLT 10 + FPF 75	200-600	45		C
11	POL	Rape, winter (BRSNW)	F	CEUTNA, CEUTQU	spraying (foliar)	30-49	a) 2 b) 2	14	a) 0.75 b) 1.5	a) DLT 7.5 + FPF 56.25 b) DLT 15 + FPF 112.5	200-600 250-300 200-600	as per growth stage		A
12	POL	Rape, spring (Canola) (BRSNS)	F	CEUTNA, CEUTQU	spraying (foliar)	30-49	a) 2 b) 2	14	a) 0.75 b) 1.5	a) DLT 7.5 + FPF 56.25 b) DLT 15 + FPF 112.5	200-600	as per growth stage	possible registra- tion as minor uses according to Arti- cle 51	N
13	POL	Rape, winter (BRSNW)	F	MELIAE	spraying (foliar)	50-59	a) 2 b) 2	14	a) 0.75 b) 1.5	a) DLT 7.5 + FPF 56.25 b) DLT 15 + FPF 112.5	200-600 250-300 200-600	as per growth stage		A
14	POL	Rape, spring (Canola) (BRSNS)	F	MELIAE	spraying (foliar)	50-59	a) 2 b) 2	14	a) 0.75 b) 1.5	a) DLT 7.5 + FPF 56.25 b) DLT 15 + FPF 112.5	200-600 250-300 200-600	as per growth stage		A
15	POL	Rape, winter (BRSNW)	F	CEUTAS, DASYBR	spraying (foliar)	65-79	a) 2 b) 2	14	a) 0.5 b) 1	a) DLT 5 + FPF 37.5 b) DLT 10 + FPF 75	200-600 250-400 200-600	45		A
16	POL	Rape, spring (Canola)	F	CEUTAS, DASYBR	spraying (foliar)	65-79	a) 2 b) 2	14	a) 0.5 b) 1	a) DLT 5 + FPF 37.5	200-600	45	possible registra- tion as minor uses	N

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No. *	Mem- ber state(s)	Crop and/ or situation (crop destination / purpose of crop)	F, Fn, G, Gn, Gnp or I **	Pests or Group of pests controlled (additionally: develop- mental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/ synergist per ha, other dose rate expression, dose range (min-max)	zRMS Conclusion (efficacy)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between ap- plications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
		(BRSNS)								b) DLT 10 + FPF 75			according to Arti- cle 51	
17	ROU	Rape, winter (BRSNW)	F	CEUTNA, CEUTQU	spraying (foliar)	30-49	a) 2 b) 2	14	a) 0.75 b) 1.5	a) DLT 7.5 + FPF 56.25 b) DLT 15 + FPF 112.5	200-600 250-300 200-600	as per growth stage		A
18	ROU	Rape, spring (Canola) (BRSNS)	F	CEUTNA, CEUTQU	spraying (foliar)	30-49	a) 2 b) 2	14	a) 0.75 b) 1.5	a) DLT 7.5 + FPF 56.25 b) DLT 15 + FPF 112.5	200-600	as per growth stage		C
19	ROU	Rape, winter (BRSNW)	F	MELIAE	spraying (foliar)	50-59	a) 2 b) 2	14	a) 0.75 b) 1.5	a) DLT 7.5 + FPF 56.25 b) DLT 15 + FPF 112.5	200-600 250-300 200-600	as per growth stage		A
20	ROU	Rape, spring (Canola) (BRSNS)	F	MELIAE	spraying (foliar)	50-59	a) 2 b) 2	14	a) 0.75 b) 1.5	a) DLT 7.5 + FPF 56.25 b) DLT 15 + FPF 112.5	200-600	as per growth stage		C
21	ROU	Rape, winter (BRSNW)	F	CEUTAS, DASYBR	spraying (foliar)	65-79	a) 2 b) 2	14	a) 0.5 b) 1	a) DLT 5 + FPF 37.5 b) DLT 10 + FPF 75	200-600 250-400 200-600	45		A
22	ROU	Rape, spring (Canola) (BRSNS)	F	CEUTAS, DASYBR	spraying (foliar)	65-79	a) 2 b) 2	14	a) 0.5 b) 1	a) DLT 5 + FPF 37.5 b) DLT 10 + FPF 75	200-600	45		C
23	SVK	Rape, winter (BRSNW)	F	CEUTNA, CEUTQU	spraying (foliar)	30-49	a) 2 b) 2	14	a) 0.75 b) 1.5	a) DLT 7.5 + FPF 56.25 b) DLT 15 + FPF 112.5	200-600 250-300 200-600	as per growth stage		A
24	SVK	Rape, spring (Canola)	F	CEUTNA, CEUTQU	spraying (foliar)	30-49	a) 2 b) 2	14	a) 0.75 b) 1.5	a) DLT 7.5 + FPF 56.25	200-600	as per growth		C

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No. *	Mem- ber state(s)	Crop and/ or situation (crop destination / purpose of crop)	F, Fn, G, Gn, Gnp or I **	Pests or Group of pests controlled (additionally: develop- mental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/ synergist per ha, other dose rate expression, dose range (min-max)	zRMS Conclusion (efficacy)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between ap- plications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
		(BRSNS)								b) DLT 15 + FPF 112.5		stage		
25	SVK	Rape, winter (BRSNW)	F	CEUTAS, DASYBR	spraying (foliar)	65-79	a) 2 b) 2	14	a) 0.5 b) 1	a) DLT 5 + FPF 37.5 b) DLT 10 + FPF 75	200-600 250-400 200-600	45		A
26	SVK	Rape, spring (Canola) (BRSNS)	F	CEUTAS, DASYBR	spraying (foliar)	65-79	a) 2 b) 2	14	a) 0.5 b) 1	a) DLT 5 + FPF 37.5 b) DLT 10 + FPF 75	200-600	45		C
27	SVN	Rape, winter (BRSNW)	F	CEUTNA, CEUTQU	spraying (foliar)	30-49	a) 2 b) 2	14	a) 0.75 b) 1.5	a) DLT 7.5 + FPF 56.25 b) DLT 15 + FPF 112.5	200-600 250-300 200-600	as per growth stage		A
28	SVN	Rape, spring (Canola) (BRSNS)	F	CEUTNA, CEUTQU	spraying (foliar)	30-49	a) 2 b) 2	14	a) 0.75 b) 1.5	a) DLT 7.5 + FPF 56.25 b) DLT 15 + FPF 112.5	200-600	as per growth stage		N
29	SVN	Rape, winter (BRSNW)	F	CEUTAS, DASYBR	spraying (foliar)	65-79	a) 2 b) 2	14	a) 0.5 b) 1	a) DLT 5 + FPF 37.5 b) DLT 10 + FPF 75	200-600 250-400 200-600	45		A
30	SVN	Rape, spring (Canola) (BRSNS)	F	CEUTAS, DASYBR	spraying (foliar)	65-79	a) 2 b) 2	14	a) 0.5 b) 1	a) DLT 5 + FPF 37.5 b) DLT 10 + FPF 75	200-600	45		N
31	POL	Mustard, winter (SINSS)	F	MELIAE	spraying (foliar)	50-59	a) 2 b) 2	14	a) 0.75 b) 1.5	a) DLT 7.5 + FPF 56.25 b) DLT 15 + FPF 112.5	200-600	as per growth stage	possible registra- tion as minor uses according to Arti- cle 51	N
32	POL	Mustard, spring (SINSS)	F	MELIAE	spraying (foliar)	50-59	a) 2 b) 2	14	a) 0.75 b) 1.5	a) DLT 7.5 + FPF 56.25	200-600	as per growth	possible registra- tion as minor uses	N

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No. *	Mem- ber state(s)	Crop and/ or situation (crop destination / purpose of crop)	F, Fn, G, Gnp or I **	Pests or Group of pests controlled (additionally: develop- mental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/ synergist per ha, other dose rate expression, dose range (min-max)	zRMS Conclusion (efficacy)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between ap- plications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
										b) DLT 15 + FPF 112.5		stage	according to Arti- cle 51	
33	ROU	Mustard, winter (SINSS)	F	MELIAE	spraying (foliar)	50-59	a) 2 b) 2	14	a) 0.75 b) 1.5	a) DLT 7.5 + FPF 56.25 b) DLT 15 + FPF 112.5	200-600	as per growth stage		C
34	ROU	Mustard, spring (SINSS)	F	MELIAE	spraying (foliar)	50-59	a) 2 b) 2	14	a) 0.75 b) 1.5	a) DLT 7.5 + FPF 56.25 b) DLT 15 + FPF 112.5	200-600	as per growth stage		C

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1.

** F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application

Remarks table heading:	(a)	e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)	(d)	Select relevant
	(b)	Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008	(e)	Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
	(c)	g/kg or g/l	(f)	No authorization possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.

Remarks columns:	1	Numeration necessary to allow references	8	The maximum number of application possible under practical conditions of use must be provided.
	2	Use official codes/nomenclatures of EU Member States	9	Minimum interval (in days) between applications of the same product
	3	For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)	10	For specific uses other specifications might be possible, e.g.: g/m ³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
	4	F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application	11	The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
	5	Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.	12	If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under "application: method/kind".
	6	Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.	13	PHI - minimum pre-harvest interval
	7	Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application	14	Remarks may include: Extent of use/economic importance/restrictions
			15	Overall conclusions - explanation for the column 15 is below ***
			n/a	Not applicable

*** Explanation for column 15 "Overall conclusions"

A	Acceptable
R	Acceptable with further restriction
C	To be confirmed by cMS
N	Not acceptable / evaluation not possible

Comments of zRMS – corrigendum to the GAP table:

In the GAP table above, for each one of the cMSs except for HU, PL and RO, the applicant had listed 2 application windows for the use in the oilseed rape, and had included the maximum of 2 applications per each use, *i.e.* *per* application window, as well as 2 applications *per* season. This notation is inconsistent with the anti-resistance strategy declared by the applicant further in the dRR (a total of 2 applications *per* growth season) and it should have been corrected in the course of evaluation.

As the zRMS, we apologize for the inconvenience. However, presenting the applicant's claim properly, in the GAP table, it would require remodelling of the table, first by altering the sequence of the uses to make all winter form uses or spring form uses neighbouring, and then by collating rows in columns 8-10, separately for winter and spring uses, in order to place one common statement for 2 or 3 uses, concerning no. of applications, interval and maximum dose rate *per* season. As it might be inappropriate to interfere so extensively with the GAP's original layout, we decided to make the corrigendum textual, without changing the GAP notation.

The GAP table must be interpreted as follows:

- 1) A single application of Sivanto Energy should be authorized in each separate application window / for each group of target pests, in the oilseed rape. At the same time, the maximum of two applications of Sivanto Energy *per* growth season must be authorized overall.
- 2) The interval between the applications carried out within the neighbouring application windows is claimed as ≥ 14 days, which is correct in the cMSs, in which only two relatively distant application windows are envisaged, one for the stem weevils and the other one - for the pod weevil and the pod midge.
- 3) The anti-resistance strategy assumed by the applicant, and explained in the respective chapter, holds it that no two consecutive applications should use Sivanto Energy. Therefore, in the cMSs with two application windows, one application must use an insecticide showing different MoA (MoAs listed in the zRMS comments

to resistance chapter). The recommendation of 2 applications per season using Sivanto energy may only suggest, that in those cMSs an additional, second application is allowed within the first window, or - preceding the second application of Sivanto - in the second window, with other MoA product, thus fulfilling the requirement of MoA rotation.

- 4) To the opinion of zRMS the single application window, that is provided for the control of stem weevils in Hungary, may not be long enough to contain repeated application, and even though, such application should then be using another product, if the assumptions of anti-resistance strategy are to be respected. Therefore the zRMS presumes that only a single application might have been meant, by the applicant, for Hungary.
- 5) In Poland and in Romania, where the additional application window is envisaged for MELIAE, the GAP has been interpreted as allowing choice of the maximum two application options, out of the three available, using Sivanto Energy, with a product of another MoA being used in between, as the third application, while still respecting the interval ≥ 14 days.
- 6) For the mustard crop (PL, RO), the number of applications with Sivanto Energy: “2” must be considered an error either, because it is the only pest claimed in that crop and the single application window envisaged, both in PL and in RO. As MELIAE is the important pest with high risk of resistance to pyrethroids, the proper anti-resistance strategy should be also extended over other crops infested by the species. Therefore if necessary, the second application in mustard must use an insecticide showing different MoA. The number of applications allowed in the mustard crop should be therefore 1 *per* growth season.

3.2 Efficacy data (KCP 6)

Introduction

The plant protection product DLT+FPF EC85 which contains the active substances deltamethrin + flupyradifurone is submitted for authorization as a new product in EU regulatory Central Zone on oilseed rape. It is submitted to be evaluated by Poland as zRMS. Authorisation of this product is claimed in EU member states belonging to the Maritime EPPO climatic zone (Czech Republic, the Netherlands), North-East EPPO climatic zone (Poland) and South-East EPPO climatic zone (Hungary, Romania, Slovakia and Slovenia).

Submission type : New product
Central zone RMS: Poland

c-MS	Nat Add (Y/N)	Justification for Nat Add
Czech Republic	N	
The Netherlands	N	
Poland	N	
Hungary	N	
Romania	N	
Slovakia	N	
Slovenia	N	

Description of active substances

This product contains the following active substances

deltamethrin	Existing*
flupyradifurone	Existing*

*Annex I listed

Mode of action

Table 0-1: Details of the active substances

Active substance	Deltamethrin	Flupyradifurone
Concentration	10 g/L	75 g/L
Chemical group	pyrethroids	butenolide
Mode of action	Sodium channel modulators (disturbs conduction of nerve impulse in insects by modifying the kinetics of voltage sensitive sodium channels). IRAC group 3A	Agonist of nicotinic acetylcholine receptor. IRAC group 4D
Biological action	Insecticide	Insecticide

Description of the plant protection product

DLT+FPF EC85 is an emulsifiable concentrate (EC) containing 10 grams per litre of deltamethrin and 75 grams per litre of flupyradifurone.

DLT+FPF EC85 is to be used on the pests *Ceutorhynchus napi* and *Ceutorhynchus quadridens* (*pallidactylus*) in spring and winter oilseed rape; on the pests *Brassicogethes* (*Meligethes*) *aeneus* in spring and winter oilseed rape, and in white and black mustard, and on the pests *Ceutorhynchus obstrictus* (*assimilis*) and *Dasineura brassica* in spring and winter oilseed rape. Further details concerning the requested uses for DLT+FPF EC85 are given in the Table 3.2-2 below.

Table 0-2: Simplified table of currently registered uses and requested uses for the product DLT+FPF EC85

Use		Member State	Requested rate(s)	Comments / Other relevant details on GAPs
Crop	Target			
Rape, winter (BRSNW) Rape, spring (BRSNS)	CEUTNA, CEUTQU	CZE HUN NLD POL ROU SVK SVN	0.75L/ha	Foliar application; Max. 2 applications/year; water 200-600 L/ha; BBCH 30-49
Rape, winter (BRSNW) Rape, spring (BRSNS); White mustard (BRSJU); Black mustard (BRSNI) Winter and spring mustard (SINSS)	MELIAE	POL ROU	0.75L/ha	Foliar application; Max. 2 applications/year; water 200-600 L/ha; BBCH 50-59
Rape, winter (BRSNW) Rape, spring (BRSNS)	CEUTAS, DASYBR	CZE HUN POL ROU SVK SVN	0.50L/ha	Foliar application; Max. 2 applications/year; water 200-600 L/ha; BBCH 65-79

Description of the crop

The Table 3.2-3 below presents an overview of the crop situation in the Czech Republic, The Netherlands, Poland, Romania, Hungary, Slovakia and Slovenia where the submission is intended, for the last available seasons (from 2013 to 2018).

Table 3.2-3: Oilseed rape (winter, spring and mustards) grown area by country (kha)-last available data

Country	CZE	NLD	POL	ROU	HUN	SVK	SVN
Year	2018	2013	2017	2018	2018	2018	2017
kHa	489,34	3	956	1.974,00	1.061,82	282,08	1145

Source: <http://ec.europa.eu/eurostat/data/database>

Description of the target pests

Eppo code	Scientific name	Common name and/or other name used in trial reports
CEUTNA	<i>Ceutorhynchus napi</i>	Cabbage stem weevil
CEUTQU	<i>Ceutorhynchus quadridens (pallidactylus)</i>	Cabbage seedstalk curculio
MELIAE	<i>Brassicogethes (Meligethes) aeneus</i>	Pollen beetle
CEUTAS	<i>Ceutorhynchus obstrictus (assimilis)</i>	Cabbage seed weevil
DYSABR	<i>Dasineura brassica</i>	Brassica pod midge

The Table 3.2-4 presents the the uses number and the countries claiming these uses

Table 3.2-4: Presentation of the use number and the countries claiming the use

No.	Crop (EPPO code)	Insect controlled (EPPO code)	Country claiming the use
Use 1	Winter rape (BRSNW)	<i>Ceutorhynchus napi</i> (CEUTNA)	Czech Republic
	Spring rape (BRSNS)	<i>Ceutorhynchus pallidactylus (quadridens)</i> (CEUTQU)	Hungary
			The Netherlands
			Poland
			Romania
			Slovakia
			Slovenia
Use 2	Winter rape (BRSNW)	<i>Brassicogethes (Meligethes) aeneus</i> (MELIAE)	Poland
	Spring rape (BRSNS);		Romania
	White mustard (BRSJU)		
	Black mustard (BRSNI)		
	Winter mustard (SINSS)		
	Spring mustard (SINSS)		
Use 3	Winter rape (BRSNW)	<i>Ceutorhynchus obstrictus (assimilis)</i> (CEUTAS)	Czech Republic
	Spring rape (BRSNS)	<i>Dasineura brassicae</i> (DASYBR)	Hungary
			Poland
			Romania
			Slovakia
			Slovenia

Table 0-5: Major / minor status of intended uses (for all cMS and zRMS).

The respective importance of the crops and targets that represent the intended uses is presented in table below.

Crop	Crop status		Pests or group of pests controlled	Pest status	
	Major	Minor		Major	Minor
Spring Oilseed Rape (BRSNS)	HUN	ROU; SVK; NLD; CZE; POL; SVN	Stem weevils <i>Ceutorhynchus napi</i> CEUTNA <i>Ceutorhynchus quadridens</i> CEUTQU	HUN ; ROU ; POL	SVK; CZE; NLD; SVN
			Pollen beetle <i>Brassicogethes aeneus</i> MELIAE	ROU; POL	–
			Cabbage seed weevil <i>Ceutorhynchus obstrictus</i> CEUTAS	HUN; POL	SVK; ROU; CZE; NLD; SVN
			Brassica pod midge <i>Dasineura brassicae</i> DASYBR	HUN; POL	SVK; ROU; CZE; NLD; SVN
Winter Oilseed Rape (BRSNW)	ROU; HUN; SVK; CZE; POL; SVN	NLD	Stem weevils <i>Ceutorhynchus napi</i> CEUTNA <i>Ceutorhynchus quadridens</i> CEUTQU	HUN; SVK; ROU; CZE; POL; SVN HUN; SVK; CZE; POL; SVN	NLD ROU; NLD
			Pollen beetle <i>Brassicogethes aeneus</i> MELIAE	ROU; POL;	–
			Cabbage seed weevil <i>Ceutorhynchus obstrictus</i> CEUTAS	HUN; SVK; CZE; POL; SVN	ROU; NLD
			Brassica pod midge <i>Dasineura brassicae</i> DASYBR	HUN; SVK; CZE; POL; SVN	ROU; NLD
White mustard (BRSJU); Black mustard (BRSNI)* Winter and spring mustard (SINSS)	–	ROU; HUN; SVK; CZE; POL; NLD; SVN	Pollen beetle <i>Brassicogethes aeneus</i> MELIAE	–	ROU; POL;

Master Label

A master draft label is prepared here to facilitate the understanding on the product and help in the construction of the country labels that are submitted in the Part A.

Deltamethrin + Flupyradifurone EC85 (85 g/L)

An emulsifiable concentrate (EC) containing 10 g/L deltamethrin and 75 g/L flupyradifurone.

CROPS

For use on oilseed rape

TARGETS

- For the control of *Ceutorhynchus napi*
- For the control of *Ceutorhynchus quadridens*
- For the control of *Brassicogethes (Meligethes) aeneus*
- For the control of *Ceutorhynchus obstrictus (assimilis)*
- For the control of *Dasineura brassica*

APPLICATION TIMING

- *Brassicogethes (Meligethes) aeneus* BBCH 50-59
- *Ceutorhynchus napi* and *Ceutorhynchus pallidactylus (quadridens)* BBCH 30-49
- *Ceutorhynchus obstrictus (assimilis)* and *Dasineura brassica* BBCH 65-79

NUMBER OF APPLICATIONS

- One or two applications per use, per crop and per season

RATE & WATER VOLUME

2x0.5L/ha - 2x0.75L/ha
Applied in 200-600 L/ha of water

APPLICATION DETAILS

- Foliar spraying

Compliance with the Uniform Principles

The studies summarised in this document were performed according to the Uniform Principles, being carried out following the EPPO recommendations and in accordance with GEP, by officially recognised testing organisations

A list of the test facilities including the corresponding certificates can be found in Chapter 3.7.

Deviations from EPPO standards that occurred in efficacy trials will be described in detail in Chapter 3.2.3 for the relevant uses. These deviations have been considered overall acceptable for efficacy evaluation purposes. Summary of these deviations is listed here below:

- Plot size in 1 efficacy trial against CEUTNA/CEUTQU was reduced from 25 m² recommended by EPPO standard PP1/219(1) to 20 m² to guarantee a better uniformity in the infestation level.
- In 3 trials in the North-East EPPO climatic zone against MELIAE, the application was done between BBCH 60-61 which is out of the GAP (BBCH 50 to BBCH 59) but not considered as a major deviation. In 2 supportive trials in spring oilseed rape, application was done very early (BBCH 21 and 35).
- In 2 trials in the South-East EPPO climatic zone against MELIAE, the product has been applied very early in two Hungarian trials (because the product has been applied against *Ceutorhynchus napi* which appears earlier in the development of oilseed rape). These trials are nevertheless presented as they provide useful information about the product efficacy against pollen beetle, when applied at an earlier timing.
- In trials against MELIAE, assessment have been done on 50 shoots except for 8 trials : where the number of insects have been counted on 20 or 25 shoots which is a deviation from the EPPO standards.
- In 1 trial in North-East EPPO climatic zone against CEUTAS and DASYBR, plot size was slightly lower (20 m²) than the recommendation of the EPPO standard (25m²).

Information on trials submitted (3.1 Efficacy data)

The efficacy trials implemented and reported in this dossier are presented in Table 3.2-6 below. Overall, results from 98 efficacy trials are presented in this BAD in order to demonstrate the efficacy of DLT+FPF EC85 at the target dose rates. Trials having low pest pressure or where the reference product did not perform according to expectation are considered not valid for efficacy evaluation purposes, but will be used for the evaluation of crop safety (chapter 3.4.1). Single trial reports are given in Compilation of trial reports (CTR) grouped as follows: [M-659525-01-1](#) is the compilation of trial reports for DLT+FPF EC85 - Efficacy trials on *Ceutorhynchus napi* and *Ceutorhynchus quadridens* on oilseed rape, [M-659528-01-1](#) is the compilation of trial reports for DLT+FPF EC85 - Efficacy trials on *Brassicogethes* (*Meligethes*) *aeneus* on oilseed rape, and M-659527-01-1 is the compilation of trial reports for DLT+FPF EC85 - Efficacy trials on *Ceutorhynchus obstrictus* (*assimilis*) and *Dasineura brassica* on oilseed rape. Trials are grouped according to countries and EPPO climatic zones defined by EPPO standard PP1/241(2) where they were conducted. The trials are distributed across the EPPO Maritime, North-East and South-East climatic zones representing the various agro-climatic conditions in the EU Regulatory Central zone. Additionally, several trials from EU regulatory Zone North and South (EPPO North-East and South-East climatic zones) are presented separately as supportive data.

Table 0-6: Presentation of trials (minimum effective dose MED, efficacy trials EFF, preliminary trials P)

Crop	Target	Country	Year	Type of trials*	Number of trials (number of valid trials)			GEP**
					EPPO North-East	EPPO South-East	EPPO Maritime	
BRSN W Rape, winter	CEUTN A/ CEUTQ U	Poland	2014	P + MED + EFF	2 (2)			Yes
			2015	P + MED + EFF	2 (2)			Yes
			2016	P + MED + EFF	2 (2)			Yes
			2017	P + MED + EFF	1 (1)			Yes
		Lithuania	2015	P + MED + EFF	1 (1) supp			Yes
			2017	P + MED + EFF	2 (2) supp			Yes
		Latvia	2015	P + MED + EFF	2 (2) supp			Yes
			2017	P + MED + EFF	2 (2) supp			Yes
		Hungary	2014	P + MED + EFF		2 (2)		Yes
			2015	P + MED + EFF		1 (1)		Yes
			2016	P + MED + EFF		2 (2)		Yes
			2017	P + MED + EFF		2 (2)		Yes
		Slovakia	2014	P + MED + EFF		3 (3)		Yes
			2015	P + MED + EFF		2 (2)		Yes
			2016	P + MED + EFF		1 (1)		Yes
		Romania	2015	P + MED + EFF		1 (1)		Yes

Crop	Target	Country	Year	Type of trials*	Number of trials (number of valid trials)			GEP**
					EPPO North-East	EPPO South-East	EPPO Maritime	
			2016	P + MED + EFF		1 (1)		Yes
			2014	P + MED + EFF		2 (2) supp		Yes
		Bul-garia	2015	P + MED + EFF		1 (1) supp		Yes
			2016	P + MED + EFF		2(2) supp		Yes
			2014	P + MED + EFF			4 (4)	Yes
		Czech republic	2016	P + MED + EFF			2 (2)	Yes
			2017	P + MED + EFF			1 (1)	Yes
		Total	2014-2016		14 (14)	20 (20)	7 (7)	
BRSN W Rape, winter	MELIAE	Poland	2014	P + MED + EFF	2 (2)			Yes
			2014	P + EFF	2 (2)			Yes
			2015	P + MED + EFF	3 (3)			Yes
			2016	P + MED + EFF	3 (3)			Yes
			2017	P + MED + EFF	2 (2)			Yes
		Hun-gary	2015	P + MED + EFF		1 (1)		Yes
			2016	P + MED + EFF		1 (1)		Yes
			2017	P + MED + EFF		2 (1)		Yes
		Slo-vakia	2014	P + MED + EFF		1 (1)		Yes
		Roma-nia	2017	P + MED + EFF		1 (1)		Yes
		Bul-garia	2017	P + MED + EFF		2 (2) supp		Yes
		Total	2014-2017		12 (12)	8 (7)		
BRSNS Rape, spring	MELIAE	Poland	2014	P + EFF	1 (1)			Yes
			2016	P + MED + EFF	1 (1)			Yes
		Latvia	2015	P + MED + EFF	1(0) supp			Yes
		Lithua-nia	2016	P + MED + EFF	1(1) supp			Yes
		Total	2014-2016		4 (3)			
BRSN W Rape, winter	CEU-TAS/DASYB R	Poland	2014	P + MED + EFF	1 (1)			Yes
			2015	P + MED + EFF	1 (1)			Yes
			2016	P + MED + EFF	2 (2)			Yes

Crop	Target	Country	Year	Type of trials*	Number of trials (number of valid trials)			GEP**
					EPPO North-East	EPPO South-East	EPPO Maritime	
			2017	P + MED + EFF	1 (1)			Yes
		Latvia	2017	P + MED + EFF	1 (1)			Yes
			2018	P + MED + EFF	1 (1)			Yes
		Lithuania	2017	P + MED + EFF	2 (2)			Yes
			2018	P + MED + EFF	1 (1)			Yes
		Hungary	2015	P + MED + EFF		2 (2)		Yes
			2016	P + MED + EFF		2 (2)		Yes
		Slovakia	2014	P + MED + EFF		3 (3)		Yes
			2015	P + MED + EFF		2 (2)		Yes
			2016	P + MED + EFF		1 (1)		Yes
		Bulgaria	2015	P + MED + EFF		1 (1)		Yes
			2016	P + MED + EFF		2 (2)		Yes
		Czech Republic	2014	P + MED + EFF			3 (3)	Yes
			2015	P + MED + EFF			4 (4)	Yes
			2016	P + MED + EFF			3 (3)	Yes
		Total	2014-2018		10 (10)	13 (13)	10 (10)	

* P = preliminary trial, MED = minimum effective dose, E = efficacy trial.

** GEP: Good Experimental Practices. Official: carried out by a national official organisation.

Reference standards used for the experimentation of DLT+FPF EC85.

The reference standards used for the experimentations are presented in Table 3.2-7 below.

Table 0-7: Presentation of reference standards used in trials (efficacy trials, preliminary trials...)

Reference standards	Countries (where the product is registered)	Authorization number	Active substance	Formulation type	Concentration of a.s. in the formulation	Target	Registered application rate	Applic. rate in trials (per treatment)	Remarks
Proteus OD110	Poland	R-10/2009	Deltamethrin Thiacloprid	OD	10 g/L 100 g/L	CEUTNA - CEUTQU MELIAE CEUTAS- DASBYR	0.5-0.6 L/ha	0.6L/ha 0.6-0.75 L/ha 0.6-0.75 L/ha	

Reference standards	Countries (where the product is registered)	Authorization number	Active substance	Formulation type	Concentration of a.s. in the formulation	Target	Registered application rate	Applic. rate in trials (per treatment)	Remarks
	Lithuania	03061/07				CEUTNA - CEUTQU MELIAE CEUTAS- DASBYR	0.6-0.75 L/ha	0.6L/ha 0.75 L/ha 0.75 L/ha	
	Latvia	275				CEUTNA - CEUTQU MELIAE CEUTAS- DASBYR	0.6-0.75 L/ha	0.6L/ha 0.75 L/ha 0.75 L/ha	
	Hungary	04.2/3745 -2/2014				CEUTNA - CEUTQU MELIAE CEUTAS- DASBYR	0.5-0.75 L/ha	0.5-0.75 L/ha 0.75 L/ha 0.75 L/ha	
	Slovakia	07-05- 0901				CEUTNA - CEUTQU MELIAE CEUTAS- DASBYR	0.5-0.7 L/ha	0.7-0.75 L/ha 0.75 L/ha 0.7-0.75 L/ha	
	Romania	2522				CEUTNA - CEUTQU MELIAE	0.6 L/ha	0.75L/ha 0.75L/ha	
	Bulgaria	0539- 3/28.04.2 016				CEUTNA - CEUTQU MELIAE CEUTAS- DASBYR	0.5 L/ha	0.5L/ha 0.75L/ha 0.5L/ha	
	Czech Republic	4607-1				CEUTNA - CEUTQU CEUTAS- DASYBR	0.5-0.75 L/ha 0.5-0.75 L/ha	0.75L/ha 0.75L/ha	
Decis EW15	Slovakia	07-05- 0876	Deltamethrin	EW	15g/L	CEUTNA - CEUTQU MELIAE CEUTAS- DASBYR	0.5 L/ha 0.35 L/ha 0.5 L/ha	0,33- 0.5L/ha 0,33- 0.5L/ha 0,33- 0.5L/ha	
	Czech Republic	4538-4				CEUTNA - CEUTQU CEUTAS- DASBYR	0.4-0.5 L/ha 0.4-0.5 L/ha	0,33- 0.5L/ha 0,33- 0.5L/ha	

Reference standards	Countries (where the product is registered)	Authorization number	Active substance	Formulation type	Concentration of a.s. in the formulation	Target	Registered application rate	Applic. rate in trials (per treatment)	Remarks
Decis EC100	Poland	R-59/2011	Deltamethrin	EC	100g/L	CEUTNA - CEUTQU	0.05-0.075 L/ha	0.05-0.075L/ha	
						MELIAE		0.05-0.075L/ha	
						CEUTAS-DASYBR		0.05-0.075L/ha	
	Lithuania					CEUTNA - CEUTQU CEUTAS-DASYBR		0.05-0.075L/ha 0.05 L/ha	Expired
	Latvia					CEUTNA - CEUTQU CEUTAS-DASYBR		0.05-0.075L/ha 0.05 L/ha	Expired
	Hungary	04.2/8155 -1/2015				CEUTNA - CEUTQU MELIAE - CEUTAS-DASYBR	0.075 L/ha	0.05-0.075L/ha 0.075 L/ha 0.05-0.075L/ha	
	Slovakia	19-00432-AU				CEUTNA - CEUTQU CEUTAS-DASYBR	0,0625L/ha 0.075 L/ha	0.075 L/ha 0.05-0.075L/ha	
	Romania	123PC/22.07.2015				CEUTNA - CEUTQU MELIAE	0.075 L/ha	0.075L/ha 0.075L/ha	
	Bulgaria	01180-2/28.12.2015				CEUTNA - CEUTQU MELIAE CEUTAS-DASYBR	0.05-0.2 L/ha	0.05-0.075L/ha 0.075L/ha 0.05-0.075L/ha	Not approved ?
	Czech Republic	5450-0				CEUTNA - CEUTQU	0,0625L/ha		

Reference standards	Countries (where the product is registered)	Authorization number	Active substance	Formulation type	Concentration of a.s. in the formulation	Target	Registered application rate	Applic. rate in trials (per treatment)	Remarks
						CEUTAS-DASYBR	0.075 L/ha	0.05-0.075L/ha	
Nurelle ECS50 Nurelle D 550 EC	Bulgaria	01462-2/15.05.2018	Chlorpyrifos-ethyl Cypermethrin	EC	500 g/l 50 g/l	CEUTNA - CEUTQU	0.6L/ha	0.6L/ha	
Decis Mega 50 EW	PL	R-369/2016d	deltamethrin	EW	50g/L	ATALCO , CEUTNA , MELIAE	0.15L/h	0.150L/ha	
Decis Expert	not known to zRMS at the time of submission	not known to zRMS at the time of submission	deltamethrin	EC	100g/L	not known to zRMS at the time of submission	not known to zRMS at the time of submission	0.075L/ha	
Fastac 100 EC	PL	R-412/2018d	alfacypermethrin	EC	100g/L	CEUTNA , CEUTQU , MELIAE	0.12L/ha	0.150L/ha	
Fastact Active 050 ME	PL	R - 52/2014	alfacypermethrin	ME	50g/L	CEUTNA , CEUTAS	0.25L/ha	0.150L/ha	
Mavrik 240 EW	PL	R - 462/2019d	tau-fluvalinate	EW	240g/L	CEUTNA , CEUTAS, MELIAE	0.20L/ha	0.200L/ha	
Karate Zeon 050 CS	PL	R-224/2019d	lambda-cyhalothrin	CS	50g/L	CEUTNA , CEUTQU , MELIAE	0.125-0.150L/ha	0.150L/ha	
Karate Zeon 100 CS	PL	R-600/2016d	lambda-cyhalothrin	CS	100g/L	CEUTNA , CEUTQU , CEUTAS	0.075L/ha	0.075L/ha 0.100L/ha 0.150L/ha	

Formulations codes used for the experimentation of DLT+FPF EC85

DLT+FPF EC85 has been evaluated under the following name/formulation:

Name	Formulation code
DELTAMETHRIN + BYI02960	SP102000028562
DLT+FPF EC85	
Sivanto eEnergy	

Principles for trial grouping

Considering that the trials presented in this document were implemented in the different countries of Europe belonging to the Southern and the Central EU regulatory zones, results are presented by climatic zones, according to EPPO standard 1/241 (2) - “Guidance on comparable climates”.

Formula used /efficacy calculations

Efficacy – Abbott

$$\% \text{ Efficacy} = [1 - (T/C)] * 100$$

Where T = mean infection level in the treated plots and C mean infection level in the untreated plots.

3.2.1 Preliminary tests (KCP 6.1)

Justification of the insecticide mixture

This chapter gathers all information related to the justification of the mixture, in accordance to the EPPO standards PP1/277(1) and PP1/306(1).

General presentation of the mixture justification

DLT+FPF EC85 is an insecticide mixture associating 2 different insecticides molecules having different properties, spectrum and mode of action. Deltamethrin, belonging to the pyrethroid chemical class (IRAC ~~group 9~~ group 3A) and flupyradifurone, from the butenolide chemical class (IRAC ~~group 4e~~ group 4D). Deltamethrin is a broad-spectrum insecticide, targeting piercing-sucking and chewing pests, acting by contact and ingestion against all mobile stages (larvae; adults), characterized also, as other pyrethroids, by a good knock-down effect. Effect on the target pests is obtained via direct contact on the pest, by residual activity (transfer of the insecticide from leaf cuticula to the insect, via tarsal or body contact) or by ingestion. Flupyradifurone is a systemic, xylem-mobile insecticide, with a higher activity after oral than after contact uptake, against adults and larvae of piercing-sucking pests (aphids, whiteflies, psyllids) and selected chewing pests, including coleopteran and dipteran pests. Its systemic property contributes to its lasting efficacy and ability to control difficult-to be reached pests. The mixture combines 2 active substances with opposite properties, in relation with temperature: there is a well-known negative thermodependency for pyrethroids, including deltamethrin whereas flupyradifurone has a positive thermodependency ([M-659248-01-1](#)); a combination of these 2 molecules has then the capability to be effective in a broad range of temperature conditions, from end of winter/beginning of spring (application against stem weevils) to spring/summer (seed pod pests application).

Comments of zRMS:

The effect of temperature on the efficacy of flupyradifurone was demonstrated in two aphids, in a simple laboratory test carried out in 2019, and has been briefly reported in [M-659248-01-1](#) document. The results have demonstrated that the efficacy was largely independent of temperature (15 °C vs 30 °C) at the full field dose rate of the active and, at the same time, clearly higher in 30 °C compared to 15 °C, at 0.0625 and 0.250 of the full dose rate. The target test

species were *Myzus persicae* on cabbage and *Aphis gossypii* on cotton plants.

Products containing deltamethrin, solo, or in mixture with another insecticides, are registered for the control of OSR insect pests, in Europe. There are no flupyradifurone containing products registered for the control of insect pests, in OSR. The target rates for DLT + FPF EC85 for the control of insect pests deliver same or lower deltamethrin rate than the currently registered rates of solo-deltamethrin containing products.

Depending on countries, several insecticides mixtures are registered for the control of insect pests in OSR. All are based on pyrethroid molecules, associated either with organo-phosphate (chlorpyrifos), or with group 4A insecticides (thiacloprid; thiametoxam).

In order to justify the mixture a series of field trials have been carried out by Bayer CropScience in Europe. The justification of the mixture is supported by field trials results against the stem weevils, *Ceutorhynchus napi*; *C. quadridens*, the pollen beetle, *Brassicogethes (Meligethes) aeneus*, and against the pod pests: *C. obstrictus (assimilis)* and *Dasineura brassicae*. In these trials the efficacy of the mixture was compared with the efficacy of the single active substances (flupyradifurone SL200; deltamethrin several formulations) in order to investigate the potential benefits as defined in the EPPO standard PP1/277: initial efficacy; length of control; potential to control pests complex; consistency of performances; overall better efficacy. The considerations of this insecticide mixture for resistance management are addressed in 3.3. Information on the occurrence or possible occurrence of the development of resistance.

Field trials results will be presented and discussed by target pests, in relation with the main timing of applications: stem weevils; pollen beetle; pod pests; and by EPPO climatic zone. When sufficient number of trial results are available, F-test is performed in order to determine whether there is a statistical difference between the mixture and the single active substances and efficacy results are summarized in graphs.

Justification of the mixture: stem weevils: *Ceutorhynchus napi* CEUTNA; *C. pallidactylus (quadridens)* CEUTQU

In order to justify the mixture DLT+FPF EC85 against CEUTNA and CEUTQU in oilseed rape, a series of field trials was implemented in Europe by Bayer CropScience between 2014 and 2017. The trials were carried out in countries belonging to the Central EU Regulatory Zone: in Poland - North-East EPPO climatic zone; in the Czech Republic - Maritime EPPO climatic zone; in Hungary; Slovakia; Romania - South-East EPPO climatic Zone. Supportive trials were implemented in countries belonging to different EU Regulatory Zones: in Lithuania; Latvia - part of Northern Zone and North-East EPPO climatic zone; in Bulgaria - belonging to South-East EPPO climatic zone and Southern EU regulatory Zone. All trials were carried out in field conditions, with natural infestations.

Trials were designed, conducted and reported in accordance to general EPPO standards PP1/135(2/4), PP1/152(3/4), PP1/225(2) and PP1/181(3/4), to the specific standard PP1/219(1) and comply with Good Experimental Practices. The testing facilities responsible for the conduct of these trials were the development teams of the country subsidiary organisations of Bayer CropScience and other testing organisations. They are listed under the point 3.7. All are GEP approved and copies of hyperlinks to the corresponding certificates are included under the same point. It has to be noticed that these trials are also part of the data package presented for Efficacy tests in chapter 3.2.3, where the methodology of the trials is described in details.

The damage caused by the stem weevils is in relation to egg-laying in the stems and larvae development inside, which can cause plant distortion or stem bursting. The assessment for the evaluation of the efficacy of the products consists of counting the number of larvae within the stems and counting the plants showing symptoms of infestation, from a minimum of 20 plants per plot. An infestation of a minimum of 10 % infested plants is considered for the validation of the trials.

As the biology of the ~~2~~ two stem weevils species is similar, single results on the two species will be presented in a same table, and averaged together. The results are analysed by EPPO climatic zone and then grouped together for an analysis.

To justify the mixture, the efficacy of DLT+FPF EC85 at the supported rate of 0.75 L/ha has been investigated, in comparison with to Decis (various formulations) and FPF SL200, at the dose rates delivering respectively the same amount of deltamethrin and flupyradifurone as DLT+FPF EC85, against the stem weevils. The tested rates are presented in Table 3.2.-8.

Table 3.2.-8: Tested rates of DLT+FPF EC85; FPF SL200 and DLT formulations against the stem weevils, for the justification of the mixture.

Product	Formulated product dosages	Single substances dosages (g a.s/ha)	
		Deltamethrin (DLT)	Flupyradifurone (FPF)
DLT+FPF EC85	0,75 L/ha	7,5	56,25
FPF SL200	0,28125 L/ha	-	56,25
DLT EC100	0,075 L/ha	7,5	-
DLT EW050	0,15 L/ha	7,5	-
DLT EW015	0,5 L/ha	7,5	-

While presenting the efficacy results in this chapter the results of DLT formulations are pooled together.

Results in the Maritime EPPO climatic Zone

The results from 8 assessments in 7 trials carried out in the Czech Republic between 2014 and 2017-Maritime EPPO climatic zone, assessments on infested plants, are presented in the Table 3.2.-9. All trials had sufficient infestation, with a minimum of 15 % damaged plants. The efficacy of With the FPF SL200 (mean 40.4 %; range 0-95.2 %), the lowest efficacy being was seen against CEUTQU (2 trials). DLT at 7,5 g a.i/ha performed better and more consistently than FPF SL200 in all trials.

The average efficacy of the mixture (mean 71.8%, range 33.8-100 %) (mean 72.4%, range 38.6-100 %) was only slightly above that of DLT (mean 66.1%; range 42.9-100 %). There was a statistically significant difference between the mixture and FPF SL200, in favour of the mixture, in one four of the trials. In one trial, the mixture efficacy was below DLT's, however with no statistical significance, and in one other trial the mixture performed significantly better compared to DLT. In all other trials, efficacy of the mixture was at same level or slightly above that of DLT, and better with at least a 5 % difference in 4 of the 8 trials, yet without statistical significance.

Table 3.2.-9. Efficacy of DLT+FPF EC85 against the stem weevils: justification of the mixture. % Efficacy on % of infested plants. Results from the Maritime EPPO climatic zone

EPPO climatic zone	EU regulatory zone	No. of trials	BBC H crop stage	Target (no of trials)	Sample Size	DA A	UNTREATED (% of Plant infested)		DLT+FPF EC85		DLT		FPF SL200	
									0,75 L/ha 7,5 + 56,25 g a.s/ha		7,5 g a.s/ha		56,25 g a.s/ha	
														% Efficacy (Abbott)
							Mean	Min-Max	Mean	Min-Max	Mean	Min-Max	Mean	Min-Max
Maritime	Central	8 7	65-79	CEUTN A (6)/ CEUTQU U (2)	20 PLANTS	20-54	49.7	15.0-82.5	71.8 72.4	33.8 38.6-100	66.1	42.9-100	40.4	0.0-92.5

A summary of the number of larvae counted in these trials is presented in Table 3.2-10. In all the trials, the efficacy provided by the mixture was at least equivalent to that of DLT, without any statistical differences. The average efficacy of the mixture reached 88,6 % (range 63.6- 100 %), whereas that of DLT was 84.9% (range 63.6- 100%). The performance of FPF SL200 (57.0 %) was below that of the mixture and DLT, the efficacy being the lowest against CEUTQU. In 50 % of the trials efficacy of DLT+FPF EC85 was better than DLT's with at least 5 % a difference. It can be noticed that, in trials where FPF SL200 performed moderately to good, the efficacy of the mixture was always superior to that of DLT, which is a hint that flupyradifurone brings an incremental efficacy to deltamethrin's in the mixture.* In one of the trial an assessment on the pollen beetle, MELIAE, 28 DAA, shows a significantly better efficacy of DLT+FPF EC85 than DLT and FPF SL200, expressing then a better residual efficacy and the possibility to control a pest complex.

*** Comments of zRMS:**

In fact, the opposite is true, it is DLT that enhances the efficacy of FPF, as can be seen in the single trial results (BAD) where DLT performs better than FPF, when working alone, in 7 trials out of 8, or works the level of FPF, in the remaining 8th trial. Also, the applicant do mention the fact themselves, while commenting the Fig. 3.2.-1 in BAD and summarizing the mixture justification for stem weevil control.

Table 3.2.-10. Efficacy of DLT+FPF EC85 against the stem weevils: justification of the mixture. % Efficacy on count of living larvae. Results from the Maritime EPPO climatic zone.

EPPO climatic zone	EU regulatory zone	No. of trials	BBC H crop stage	Target (no of trials)	Sample Size	DA A	UNTREATED (Living Larvae)		DLT+FPF EC85		DLT		FPF SL200	
									0,75 L/ha 7,5 + 56,25 g a.s/ha		7,5 g a.s/ha		56,25 g a.s/ha	
							% Efficacy (Abbott)							
Maritime	Central	87	65-79	CEUTNA (6)/CEUTQU (2)	20 PLANTS	20-54	24.6	2.8-58.3	88.6	63.6-100	84.9	63.6-100	57.0	0.0-96.0

Results in the South-East EPPO climatic zone

12 trials have been conducted between 2014 and 2017 in Hungary; Slovakia; Romania which are part of the claim. 5 supportive trials were carried out in Bulgaria (EU Southern regulatory Zone).*

*** Comments of zRMS:**

The assessment of plant infestation and larvae count in the SE EPPO zone and part of the South EU zone (Tables 3.2.-11 and 3.2.-12) are based on two sets of trials which do not overlap completely. The zRMS considers this acceptable.

In all trials a single application was carried out against CEUTNA since the presence of the weevils had been detected in yellow water traps. CEUTQU was present in none of the trials. Assessments consisted of count of infested plants and/or count of larvae in stems; in 2 trials (HUN 2014 and BGR 2015) only the assessment on infested plants is available, whereas in 3 trials (SVK 2014; 2015; 2016) only the assessment on larvae is available. This is not expected to have an influence on the analysis as there is a good correlation between the 2 assessment types.

Results are firstly presented and analyzed for the assessment on infested plants (Table 3.2.-11). Majority of the trials had a high level of infestation - 8 of them five out of ten trials in the Central zone and all five

BG trials had shown 90-100 % infestations. In these conditions of high infestation, more than one application would have been necessary for a better comparative evaluation of the products; with a single application, the average efficacy of DLT+FPF EC85 at 0.75 L/ha is 58.3%, higher than that of DLT (50.6 %) and FPF SL200 (42.3 %, with the highest variability) (as summarized for the complete data set of 15 trials including South EU portion of the SE EPPO zone, i.e. BG trials). There is a statistical difference between DLT+FPF EC85 and DLT in 2 trials, and a statistical difference with FPF SL200 in 3 trials. In 9 of the trials, there is at least a 5 % difference between DLT+FPF EC85 and DLT in favour of the mixture, and only 2 in favour of DLT.

Table 3.2.-11. Efficacy of DLT+FPF EC85 against the stem weevils CEUTNA: justification of the mixture. % Efficacy on % of infested plants. Results from the South-East EPPO climatic zone.

EPPO climatic zone	EU regulatory zone	Number of trials	BBC H crop stage	Sample Size	DA A	UNTREATED		DLT+FPF EC85		DLT		FPF SL200	
						(% of infested plants)		0,75 L/ha 7,5 + 56,25 g a.s/ha		7,5 g a.s/ha		56.25 g a.s/ha	
						Mean	Min-Max	% Efficacy (Abbott)					
								Mean	Min-Max	Mean	Min-Max	Mean	Min-Max
South-East	Central	14 10	65-69	20 PLANTS	23-96	75.1	37.5-100	64.1	10.3-100	56.1	7.7-100	50.3	4.1-100
	South Central + South	16 15	65-69	20 PLANTS	7-96	82.9	37.5-100	58.3	10.3-100	50.6	7.7-100	42.3	4.1-100

The results for the assessment on larvae are available in Table 3.2.-12. The average efficacy for all products is 80.2 %; 75.1 % and 67.2 % for DLT+FPF EC85; DLT and FPF SL200, respectively, with the largest variability for FPF SL200 and the lowest, and equivalent one, for DLT+FPF EC85 and DLT. There is a statistical difference between DLT+FPF EC85 and DLT, in favour of the mixture, in the most infested trial as well as in another trial which has a with much lower an infestation. There is a positive efficacy difference (at least +5%) between DLT+FPF EC85 and DLT, in 8 trials, and only one in the other direction. It can be concluded from the trials carried out in countries belonging to the South-East EPPO climatic zone that the efficacy of DLT+FPF EC85 against CEUTNA is better than that of DLT, with a statistical difference in about 10 % of the trials.

Table 3.2.-12. Efficacy of DLT+FPF EC85 against CEUTNA: justification of the mixture. % Efficacy on larvae. Results from the South-East EPPO climatic zone.

EU regulatory zone	Number of trials	BBCH stage	DAA	Sample size	UNTREATED (Living larvae)		DLT+FPF EC85		DLT		FPF SL200	
							0,75 L/ha 7,5 + 56,25 g a.s/ha		7.5 g a.s/ha		56.25 g a.s/ha	
					Mean	Min-Max	Efficacy (% Abbott)				Mean	Min-Max
Central	14 12	65 59-69	23-96	20 PLANTS	100.2	18.0-493.3	84.7	59.5-100	80.0	55.2-100	72.2	29.4-100
Central + South	18 16	65-69	14-96	20 PLANTS	150.4	18.0-493.3	80.2	59.5-100	75.1	55.0-100	67.2	29.4-100

Comments of zRMS to mixture justification results in the SE EPPO zone:

Within the complete data set as seen in the Tab 3.2.-5 BAD, there are 2 trials with significant advantage of the mixture compared to DLT (SK 2014 and RO 2016), and 4 trials with significant advantage of the mixture compared to FPF, three of them in HU, SK and RO (2016-2017), and one in BG (2014). The difference between the mixture and the DLT to the disadvantage of the mixture, mentioned by the applicant, is insignificant, similar to all the remaining comparisons.

The performance of FPF applied alone is more variable across the five BG trials, compared to HU, RO and SK trials in the SE part of the Central zone (CV 80.4% vs 66.4%). The opposite is true for the FPF+DLT mixture (CV 38.3% vs 44.4%, South zone, Central zone, respectively) and DLT (CV 31.7% vs 51.0%, respectively). Thus the more coherent efficacy of the mixture compared to less consistent performance of the FPF results in broader distance of efficacy values between the FPF and the mixture, in the BG trials (20.3% efficacy difference on average) compared to Central zone (13.7% difference, on average). In this way, incorporating of the BG trials allows to increase the average value of this distance to 16.0%, in the aggregated data set, and this makes the mixture justification a bit more obvious as, even though the mean values become lower, the differences between them show greater advantage of mixture formulation over the two actives used alone.

However, the efficacy results are less clear-cut in BG trials. In only one, out of five BG trials, the significant difference was shown between the mixture DLT+FPF and the FPF alone, in favour of the mixture. Otherwise, all the efficacy values are lower, in BG trials, compared to the Central zone, and those numerically high differences between the treatments are nevertheless statistically insignificant, suggesting lower replicate consistence (raw data unavailable in the single trial reports).

Yet, despite the above considerations, the ten trials that were carried out in the Central part of the SE EPPO zone provide, to the opinion of zRMS, fairly enough data to reliably justify co-formulation of FPF and DLT.

Results in the North-East EPPO climatic zone

The results against CEUTNA and CEUTQU from ~~15 trials~~ 12 trials (2014-2017) are available to justify the mixture in the North-East EPPO climatic zone. ~~8~~ 7 trials were carried out in Poland, which is part of the claim, and are supported by ~~7~~ 5 trials carried out in Lithuania and Latvia.* The trial with an infestation lower than 10 % of infested plants is excluded from the analysis, as well as trials with an infestation of larvae lower than 0.2 larvae and having being been assessed at a ~~timing where~~ time when larvae should still be present in the stems.

* Comments of zRMS:

The assessment of plant infestation and larvae count in the NE EPPO zone and part of the North EU zone (Tables 3.2.-13 and 3.2.-14) are based on 7 trials from PL, 3 trials from LT and 2 trials from LV. One trial from LT and one from LV were excluded, as explained by the applicant. The zRMS considers this acceptable. In the tables referred to, the number of data points may be higher than the number of trials, as in some of them data for CEUTNA and CEUTQU come from the same trial. The zRMS-corrected number of trials is always equal to the number of submitted trial reports.

The applicant repeatedly insists on treating the number of data points as the number of trials. Therefore if in doubts, please always refer to the **Table 3.2-49** (Efficacy tests chapter), or **Table 3.2-27** (Minimum effective dose chapter) for the correct, definite number of trials, as most of the trials presented in this submission have been used to support different chapters of B3 section simultaneously.

A summary of the results for the assessment on % of infested plants is expressed in Table 3.2.-13. Infestation level is generally lower than in the trials carried out in countries belonging to the South-East EPPO climatic Zone. In contrast with CEUTQU trials carried out in the maritime EPPO climatic zone, the efficacy of FPF SL200 against this target (3 results) seems to be not different from that against CEUTNA.

The average efficacy of DLT+FPF EC85 (mean 88.2%, range 47.6-100 %) is similar to DLT's (mean 86,5%, range 71.4- 100%) and above FPF SL200's (mean 77.1-range 18.8- 100 %). At single trial level, there is no statistical differences between DLT+FPF EC85 and DLT or FPF SL200. Nevertheless in 4 trials there is an efficacy benefit of DLT+FPF EC85, in comparison ~~with~~ to DLT.

Table 3.2.-13. DLT+FPF EC85 against stem weevils CEUTNA/CEUTQU: justification of the mixture. % Efficacy on infested plants. Results from the North-East EPPO climatic zone.

EU regulatory zone	Number of trials	BBC H crop stage	Target (no of trials)	DA A	Sample size	UNTREATED (% of Plant infested)		DLT+FPF EC85		DLT		FPF SL200	
								0,75 L/ha 7,5+56,25 g a.s/ha		7,5 g a.s/ha		0,28125 L/ha 56,25 g a.s/ha	
												% Efficacy (Abbott)	
						Mean	Min-Max	Mean	Min-Max	Mean	Min-Max	Mean	Min-Max
Central	11 7	65-69	CEUTN A (7)/ CEUTQU (3)	15-70	20 PLANTS	38.6	11.3-100	89.3 93.5	47.6 86.4-100	87.3 88.9	71.4 73.5-100	82.4 85.9	47.6 70.6-100
Central + North-ern	12 9	65-69	CEUTN A (8)/ CEUTQU (4)	15-70	20 PLANTS	36.8	11.3-100	88.2	47.6-100	86.5	71.4-100	77.1	18.8-100

Results expressed as % of efficacy calculated according to the count of larvae are presented in the Table 3.2.-14. According to this type of assessment, the average efficacy of DLT+FPF EC85, 91.6 % (range 70.3-100 %) is better than that of DLT (mean 86.3%; range 71.2-100 %) and of FPF SL200 (mean 70.1 %, range 12.0-100 %). In one trial, efficacy of the mixture was significantly better higher than that of the single active species substances, against the two weevils species. In 6 assessments there is at least 5% a positive efficacy difference between DLT+FPF EC85 and DLT; in four of them the difference is > 10%, including the assessments with statistical significance, in which the advantage of using mixture amounts to 16.9% or 14.7% compared to DLT, and 18.3% or 15.5%, compared to FPF (two separate estimates for CEUTQU and CEUTNA respectively).

Table 3.2.-14. DLT+FPF EC85 against stem weevils CEUTNA/CEUTQU: justification of the mixture. % Efficacy on number of larvae. Results from the North-East EPPO climatic zone

EU regulatory zone	Number of trials	BBC H crop stage	Target (no of trials)	Sample Size	D A A	UNTREATED (Living larvae)	DLT+FPF EC85 0,75 L/ha 7,5+56,25 g a.s/ha		DLT 7,5 g a.s/ha		FPF SL200 0,28125 L/ha 56,25 g a.s/ha	
							% Efficacy (Abbott)					
							Mean	Min-Max	Mean	Min-Max	Mean	Min-Max
Central	7	67-73	CEUTN A (4)/ CEUTQU U (5)	± 20 PLANTS	15-70	1	0.2-2.5 0.2-0.6	97.2 92.3-100	90.9	80.2-100	93	78.9-100
Central + North-eu	12	67-73	CEUTN A (4)/ CEUTQU U (10)	± 20 PLANTS	15-70	1.3	0.7-3.6	91.6 70.3-100	86.3	71.2-100	70.1	12.0-100

General conclusion on CEUTNA/CEUTQU trials results for the justification of the mixture.

Flupyradifurone, which has no registered use against stem weevils, has demonstrated to be effective. The mixture can be justified by an overall better efficacy, in comparison with to FPF SL200 and to deltamethrin formulations. A statistical analysis (F-test) carried out on the set of data shows that DLT+FPF EC85 is significantly better than both comparison single-component products used for comparison: FPF SL200 and deltamethrin formulations.

Comments of zRMS on mixture justification for the control of stem weevils CEUTNA and CEUTQU:

Overall, 37 trials demonstrating justification of the DLT+FPF mixture in control of CEUTNA and CEUTQU are used in the assessment in this part of the dossier. These trials taken together generated 35 data points in pest incidence (plant infestation) and 37 data points in pest severity (insect count *per* plant).

Considered the **PEST INCIDENCE**, in **17** out of 35 assessments the difference $\geq 5\%$ was demonstrated between the DLT+FPF mixture and DLT, to the advantage of the mixture. In **12** cases the difference was $\geq 10\%$ and **three of these** were statistically significant, with two of them coinciding with significant difference between the DLT+FPF mixture and FPF used alone, that was $>10\%$ to the advantage of the mixture. The difference $\geq 5\%$, between the DLT+FPF mixture and FPF, to the advantage of the mixture, was demonstrated in **25** out of 35 assessments. In **21** of them the difference was $>10\%$. That difference was statistically significant in **2** **another** cases, in addition to the three mentioned above, and these did not overlap with the difference between the the DLT+FPF mixture and DLT, in the respective trials.

Considered the **PEST SEVERITY**, in **17** out of 37 assessments the difference $\geq 5\%$ was demonstrated between the DLT+FPF mixture and DLT, to the advantage of the mixture. In **7** cases that difference was $>10\%$ and in **3** of them the difference was statistically significant, and coincided with significant difference between the DLT+FPF mixture and FPF used alone, that was $>10\%$ to the advantage of the mixture. The difference $\geq 5\%$ between the DLT+FPF mixture and FPF, to the advantage of the mixture, was demonstrated in **28** out of 37 assessments. In **23** cases it was $\geq 10\%$, including **4** **another** cases of statistical significance, in addition to the three mentioned above, which also did not overlap with the difference between the the DLT+FPF mixture and DLT, in the respective trials.

Justification of the mixture: the pollen beetle *Brassicogethes (Meligethes) aeneus* MELIAE

The previous section has shown that application with DLT+FPF EC85 at 0.75 L/ha targeting stem weevils can deliver significant control of first occurring pollen beetle, better than DLT and FPF SL200, in one trial. The damages caused by the pollen beetle can be important, ~~as if the adults feed on OSR flower buds, which cause~~ causing stamen abscission and “blind stalks”.

In order to justify the mixture DLT+FPF EC85 against MELIAE in oilseed rape, a series of field trials was implemented in Europe by Bayer CropScience between 2014 and 2017. The trials were carried out in countries belonging to the Central EU regulatory zone: Poland (North-East EPPO climatic zone), Hungary, Slovakia and Romania (South-East EPPO climatic zone). Supportive trials were implemented in countries belonging to different EU regulatory zones: Lithuania and Latvia, belonging to the Northern regulatory Zone and to the North-East EPPO climatic zone, and Bulgaria - belonging to the South-East EPPO climatic zone and the Southern regulatory zone. All trials were carried out in field conditions, with natural infestations. Trials were designed, conducted and reported in accordance to general EPPO standards PP1/135(2/4), PP1/152(3/4), PP1/225(2) and PP1/181(3/4), to the specific standard PP1/178(3) and comply with Good Experimental Practices. The testing facilities responsible for the conduct of these trials were the development teams of the country subsidiary organisations of Bayer CropScience and other testing organisations. They are listed under the point 3.7. All are GEP approved and copies of the corresponding certificates are included under the same point. It has to be noticed that these trials are also part of the data package presented for Efficacy tests in chapter 3.2.3, where the methodology of the trials is described in details.

To justify the mixture against the pollen beetle, the efficacy of DLT+FPF EC85 has been investigated at ~~the supported~~ its proposed rate of 0.75 L/ha, in comparison with to DLT (various formulations) at 7,5 g a.s/ha and to FPF SL200, at 52,5 or 56,25 g a.s/ha (Table 3.2.-16).

Table 3.2.-16: Tested rates of DLT+FPF EC85; FPF SL200; DLT formulations against the pollen beetle, for the justification of the mixture.

Product	Formulated product dosages	Single substances dosages (g a.s/ha)	
		Deltamethrin (DLT)	Flupyradifurone (FPF)
DLT+FPF EC85	0,75 L/ha	7,5	56,25
FPF SL200	0,26250-0,28125 L/ha	-	52,5-56,25
DLT EC100	0,075 L/ha	7,5	-
DLT EW050	0,15 L/ha	7,5	-
DLT EW015	0,5 L/ha	7,5	-

Results in the North-East EPPO climatic Zone

Twelve trials were carried out in Poland between 2014 and 2017, specifically targeting the pollen beetle. The results in the trial IA14XSTCW2POL2 are presented for 1 plot, and not 1 shoot. These results are not included in the overall calculation.

~~Trials or assessments with too low infestation (< 0,5 insects/shoot) and/or with non significant efficacy are generally not included in the average.~~ The results refer to 1 shoot or 1 plant.

DLT+FPF EC85 was tested at the supported-proposed rate, 0.75 L/ha, in comparison with DLT at 7.5 g a.s/ha and ~~or~~ FPF SL200 at 52.5 g a.s/ha (2 trials) or 56.25 g a.s/ha. As the difference between the 2 application rates for FPF SL200 is only 7 % (3.75 g/ha, i.e. 6.7%), which cannot have an influence on the efficacy, the results of the 2 rates are averaged together. The results of the assessment carried out on 1-2, 4-6, 11-13 and 15-17 Days After Application are presented in the Table -3.2.-17, with orthogonal comparisons between DLT+FPF EC85 and DLT or FPF SL200.

At 1 to 2 days after the application the average efficacy of the mixture DLT+FPF EC85 is not different from DLT and FPF SL200, which is confirmed by the single trials results. At 4 to 6 days after the application a slightly superior average efficacy of DLT+FPF EC85, in comparison with DLT, was observed - ~~72.9~~ 76.3% (range ~~31.6~~ 57.7-100 %) and ~~68.1~~ 71.1 % (range ~~36.8~~ 44.7- 89.5 %) respectively; there are statistical significant differences between the two products, in favour of the mixture, in 3 trials. The efficacy of FPF SL200 averaged ~~62.2~~ 63.7 % (range 36.3- 88.8 %) and the efficacy of the mixture was significantly better in one trial. At 11-13 days after the application the mixture DLT+FPF EC85 showed better an average efficacy with an average of ~~84.2~~ 84.1% (range ~~80.0~~ 80.0-87.5%) in comparison with DLT - ~~with an average efficacy of 60.6~~ 60.5% (range ~~35.5~~ 35.1-76.0%). A statistical significant difference was found in 2 trials out of the 3. The efficacy of the mixture was better than that of FPF SL200, with respectively 82.5% (range 80.0-84.9%) and 57.3% (range 48.0-66.5%), in 2 trials, and statistical significant difference was observed in 1 trial, in favour of the mixture.

Table 3.2.-17. Efficacy of DLT+FPF EC85 against MELIAE: justification of the mixture. Results from the North-East EPPO climatic zone.

EP PO cli- mat ic zon e	E U re gu la- tor y zo ne	Num ber of trials	BB CH cro p stag e at as- sessment	Sample Size	DA A	UNTREAT ED (Living Adults)		DLT+FPF EC85		FPF SL200		DLT	
						Me an	Min- Max	0,75 L/ha 7,5+56,25 g a,s/ha		52,5*- 56,25 g a,s/ha		7,5 g a,s/ha	
								% Efficacy (Abbott)					
								Mean	Min- Max	Mean	Min- Max	Mean	Min- Max
Nor th- East	Ce ntr al	10	51- 61	1 SHOOT	1-2	3,3 3,4	1,0- 7,1	83,5	62,1- 95,6			86,6 82,7	70,8 47,9-100
		7	51- 61	1 SHOOT	1-2	3,2	1,0- 7,1	84,9 85,0	68,1- 95,6	81,8 81,4	61,7- 92,9	84,2 82,3	10,9 47,9-100
		11	52- 63	1 SHOOT	4-6	3,1	0,4- 6,0	72,9 76,3	31,6 57,7-100			68,1 71,1	36,8 44,7-89,5
		8	52- 63	1 SHOOT	4-6	2,3	0,4- 4,8	69,8 74,6	31,6 57,7-100	62,2 63,7	36,3- 88,8	65,4 69,1	36,8 59,2-89,5
		3	63- 65	1 SHOOT/PL ANT	11- 13	1,7	0,3- 2,4	84,2 84,1	80,0- 87,5			60,6 60,5	35,5 35,1-76,0
		2	63- 65	1 SHOOT/PL ANT	11- 13		0,3- 2,4	82,5	80,0- 84,9	57,3	48,0- 66,5	73,2	70,3-76,0
		2	65- 67	1 SHOOT/PL ANT	15- 17		0,5- 0,8	75,1	56,8- 93,3	59,0	35,8- 82,2	66,0	36,4-95,6

Results in the South-East EPPO climatic zone

The results of 6 trials carried out either in Central EU regulatory zone and 2 supportive trials in Bulgaria (belonging to the South EU regulatory zone), are presented to demonstrate the justification of the mixture against MELIAE in the South-East EPPO climatic zone. Trials or assessments with too low infestation (< 0,5 insects/shoot) and/or with non significant efficacy are not included in the summaries.

The assessments which are presented aim to evaluate the initial efficacy and the lasting efficacy. At 1 to 3 days after the application (DAA), results show an average efficacy of DLT+FPF EC85 of 85.6 % (range 49.0- 98.9 %), slightly superior to that of FPF SL200 (average 79.4 %; range 63.9 -93.6 %) and to that of DLT 7.5 g a.s/ha (average 82.5%; range 33.0-97.7 %) in 6 trials. At 7 and 11 DAA, the superiority of the mixture is observed in 4 and 2 trials respectively. In one of the trials, there is a statistical significant difference between the mixture and DLT or FPF SL200, however efficacy of the mixture reaches here only 20% 19.4 % when while DLT or FPF SL200 are not effective. Yield is also presented in 2 supportive trials with a better yield for the mixture (statistical difference was found in 1 trial in favour of the mixture in comparison with DLT and FPF SL200).

Table 3.2.-18. Efficacy of DLT+FPF EC85 against MELIAE: justification of the mixture. Results from the South-East EPPO climatic zone.

South-East DLT+FPF climatic zone:													
EPPO climatic zone	EU regulatory zone	Number of trials	BB CH crop stage	Sample Size	DA A	UNTREATED (Living Adults)		DLT+FPF EC85		FPF SL200		DLT	
								0,75 L/ha 7,5+56,25 g a.s/ha		56,25 g a.s/ha		7,5 g a.s/ha	
								% Efficacy (Abbott)					
						Mean	Min-Max	Mean	Min-Max	Mean	Min-Max	Mean	Min-Max
South-East	Central	3-4	50-63	1 SHOOT/PLANT	1-3	3.0	1.0-7.2	79.0	49.0-97.4	76.0	63.9-93.6	75.1	33.0-96.8
	Central+Southern	6	50-63	1 SHOOT/PLANT	1-3	2.3	0.9-7.2	85.6	49.0-98.9	79.4	63.9-93.6	82.5	33.0-97.7
	Central+Southern	4	53-63	1 SHOOT/PLANT	7	1.9 2.0	0.8-4.5	72.5	19.4-93.7	62.9	4.5-87.4	66.9	9.6-92.1
	Southern	2	59-65	1 PLANT	11	0.7	0.7	86.0	85.1-86.8	73.3 73.5	73.0-73.3	71.9	71.6-72.1
	-					Yield (tons/ha)		% Relative to the untreated					
	South-east	2	Yield		72-86	2.15	1.9-2.4	108.75	108.2-109.3	104	103.8-104.2	104.7	104.4-105.0

Conclusion about justification of the mixture against the pollen beetle.

Flupyradifurone, which has no registered use against the pollen beetle, has demonstrated to be ~~intrinsically~~ effective against this pest. The mixture can be justified by a better lasting efficacy, in comparison with the single active substances, observed in countries belonging to the North-East EPPO Climatic zone and to the South-East EPPO climatic zone. The ability of DLT+FPF EC 85 to control pyrethroid-resistant populations of pollen beetle is considered in the point 3.3.

Comments of zRMS on mixture justification for the control of MELIAE:

“Flupyradifurone, which has no registered use against the pollen beetle, has demonstrated to be [...] effective against this pest “. However, more than in DLT, the insecticidal activity of FPF seems to fade gradually in time, which can be better seen in the NE zone trials (Table 3.2.-17), but is also discernible in the SE zone (Table 3.2.18), provided one observes the range values (min-max) instead of just means, in consecutive assessment dates. The phenomenon is far from obvious for the changeable number of trials representing particular assessment dates. Nevertheless, the co-formulation of FPF with DLT seems to offer the advantage of extending the insecticidal activity of the new product, compared to the two active substances used alone, as in both groups of trials (NE and SE) the difference in activity between the mixture and its single components becomes wider at the later assessment dates, compared to initial assessments.

Justification of the mixture: *C. obstrictus (assimilis)* and *D. brassicae*

In the previous section it was shown in a trial that an application with DLT+FPF EC85, targeting the pollen beetle, was able to control CEUTAS. The damages due to *D. brassicae* being linked to the activity of *C. obstrictus*, the results against these 2 pests are presented here in this section; furthermore in most of the trials the ~~2~~ two insects were present simultaneously. Only in minority of trials the infestation with DASYBR was not present. The larva of CEUTAS can feed on 5 seeds in a pod, on average; the larvae of DASYBR

feed on the pod wall, which becomes yellow, swollen and splits prematurely. The efficacy of DLT+FPF EC85 at the supported proposed rate of 0.5 L/ha- has been investigated, in comparison with DLT (various formulations, grouped together) and FPF SL200, at dose rates delivering the same amount of deltamethrin and flupyradifurone as DLT+FPF EC85, against these pod pests. In order to justify the mixture DLT+FPF EC85 against CEUTAS and DASYBR in oilseed rape, a series of field trials was implemented in Europe by Bayer. Field trials aiming to justify the mixture were carried out in the European regulatory central zone Central EU regulatory zone in the trial seasons 2014 to 2018 2017 in the Czech Republic, Poland, Hungary, and Slovakia, Romania. In addition, 2 supportive field trials from the European Regulatory South zone Southern EU regulatory zone carried out in Bulgaria in 2015 and 2016 as well as 5 trials carried out in the Northern EU regulatory zone (Latvia, Lithuania) in 2017 and 2018 are used in this dossier. The trials were implemented in farmer's fields under conditions of natural infestation. Trials were designed, conducted and reported in accordance to general EPPO standards PP1/135(2/4), PP1/152(3/4), PP1/225(2) and PP1/181(3/4) and comply with Good Experimental Practices. The testing facilities responsible for the conduct of these trials were the development teams of the country subsidiary organisations of Bayer CropScience and other testing organisations. They are listed under the point 3.7. All are GEP approved and copies of the corresponding certificates are included under the same point. It has to be noticed that these trials are also part of the data package presented for Efficacy tests in chapter 3.2.3, where the methodology is described in details. The tested rates are presented in Table 3.2.-19

Table 3.2.-19: Tested rates of DLT+FPF EC85; FPF SL200; DLT formulations, for the justification of the mixture.

Product	Formulated product dos-ages	Active substances dosages (g a.s/ha)	
		Deltamethrin (DLT)	Flupyradifurone (FPF)
DLT+FPF EC85	0,5 L/ha	5	37,5
FPF SL200	0,1875 L/ha	-	37,5
DLT EC100	0,05 L/ha	5	-
DLT EW050	0,1 L/ha	5	-
DLT EW015	0,333 L/ha	5	-

The trials are presented by EPPO climatic zone and by pest.

Results in the Maritime EPPO climatic Zone.

All 7 trials were carried out in the Czech Republic between 2014 and 2016. Only one application was carried out at BBCH 61-65, targeting adults of CEUTAS. Pre-count showed infestations of 0.2 to 0.7 insects/shoot, compatible with the application threshold of one weevil on 2 shoots. Adults were assessed just after the application at 1 to 2 DAA and 5 to 8 DAA while larvae were assessed after 4 weeks at 21 to 25 DAA. In the initial assessment, results show comparable average efficacy of the single active substances, deltamethrin (5 g a.s/ha) with 80.7% (range 34.2-96.9 %) and flupyradifurone (37.5 g a.s/ha, average 80.7 % average, range 60.0-92.9 %), the mixture being slightly more effective (average 87.5 %, min range 65.8-, max 100 %) The mixture has comparable performances as deltamethrin at the high rate of 7,5 g a.s/ha and performed statistically better than FPF SL200 in one trial. At 5 to 8 DAA, the average efficacy for the mixture is better with 85.8 % (range 61.9- 97.8 %); than that of FPF SL200, average of 74.2 % (range 42.9- 95.7 %) and of DLT, average of 77.2 % (range 52.4- 95.7 %). There is a statistical difference between the mixture and the single components, in 2 trials; the mixture is superior or equal to the single components in 6 of the 7 trials. Number of larvae was also assessed at 21 to 25 days after the application with average efficacy of the mixture of 98.5 % (range 95.0- 100 %), 91.9 % (range 76.9-100 %) for FPF SL200 and 88 87.8 % (range 70- 100 %) for DLT 5 g a.s/ha.

Table 3.2.-20 Efficacy of DLT+FPF EC85 against CEUTAS adults and larvae,: justification of the mixture.Results from the Maritime EPPO climatic zone.

Infectious from the Maritime EPPO climatic zone:														
EPPO climatic zone	EU regulatory zone	Number of trials	Sample Size	DAA	UN-TREATED (Living adults or larvae)		DLT+FPF EC85		FPF SL200		DLT		DLT	
							0,5 L/ha		37.5 g a.s/ha		5 g a.s/ha		7,5 g a.s/ha	
					% Efficacy (Abbott)									
					Me an	Min- Max	Me an	Min- Max	Me an	Min- Max	Me an	Min- Max	Me an	Min- Max
Maritime	Central	7	1 SHOOT	1-2.	0.5	0.1-0.9	87.5	65.8-100	80.7	60.0-92.9	80.7	34.2-96.9	91.2	78.9-100
	Central	7	1 SHOOT	5-8.	0.5	0.1-0.9	85.8	61.9-97.8	74.2	42.9-95.7	77.2	52.4-95.7	86.4	61.9-100
	Central	6	100 PODS	21-25	5.7	2.5-12.5	98.5	95.0-100	91.9	76.9-100	87.8	70.0-100	97	90.0-100

At 5 to 7 DAA, the mixture performed better against DASYBR with an efficacy average of 91.6% (range 86.5-100%) in comparison to DLT at 5g a.s./ha (mean average 79.5%; range 72.0-95.2%) and FPF SL200 (mean average 80.5 80.6%, range 66.7-100%). The results from this timing of assessment demonstrates a better larvicidal/curative efficacy of the mixture, in comparison with the single active substances at equivalent amount of a.s/ha. A better control of larvae (level and variability) with the mixture is also seen 2 weeks after application, which can be interpreted as a better lasting efficacy of the mixture in comparison with the single components, allowing to prevent new infestation of pods after application.

Table 3.2.-21: Efficacy of DLT+FPF EC85 against DASYBR,: justification of the mixture.Results from trials carried out in Maritime EPPO climatic Zone.

EPPO climatic zone	EU regulatory zone	Number of trials	0-DAA BBCH crop stage	Sample Size	DAA	UNTREATED (Infested pods)		DLT+FPF EC85		FPF SL200		DLT		DLT					
								0.5 L/ha 5 + 37.5 g a.s/ha		37.5 g a.s/ha		5 g a.s/ha		7,5 g a.s/ha					
						% Efficacy (Abbott)													
						Mean	Min-Max	Mean	Min-Max	Mean	Min-Max	Mean	Min-Max	Mean	Min-Max				
Maritime	Central	9 8	63-67	25 SHOOT	5-7	6.2 7.0	0.0-12.5 3.8-10.5	91.6	86.5-100	80.5 80.6	66.7-100	79.5	72.0-95.2	91.1	85.7-97.6				
	Central	9 10	65-75	25 SHOOT	14-16	18.7 17.9	3.3-99.5	83.3 84.0	61.5-91.9	70.9 72.6	38.5-96.7 95.7	63.3 65.3	25.1-91.9	77.6 78.7	43.0-94.6				

Results in the South-East Zone

Ten trials were carried out in the Central regulatory zone between 2014 and 2016; as well as 2 supportive trials in Bulgaria and 2 in the South regulatory zone, in 2015 and 2016, in order to demonstrate the justification of the mixture of DLT+FPF EC85 against CEUTAS. The trial IR14SVK125VK17 was not included in the overall calculation (at 4-7 DAA), because the number of infected pods was recorded in it, instead of

the number of living adults, as it was in the remaining trials. Adults were assessed just after the application, at 1 to 2 DAA and 4 to 7 DAA, while larvae were assessed after 4 to 6 weeks at 21 to 40 DAA. In 9 of the 12 trials DLT+FPF EC85 performed better than DLT (5 g a.s/ha) with statistically significant differences in 2 trials. In 11 of the 12 trials, DLT+FPF EC85 performed better than FPF SL200 at 37.5 g a.s/ha, the difference being statistically significant in 5 trials. At 4 to 7 DAA, the results showed that mixture efficacy was on average slightly superior (75.4 73.2%, range 13.0% -100 %) than the single components (mean average 68.7 66.5%, range 49.3 % -94.7 77.2 % for FPF SL200; average 65.9%, range 29.7-100 % for DLT 5 g a.s/ha). At 21 to 40 DAA the mixture was significantly more effective than at least one of the components, in 4 trials, and has an average efficacy of of 85.1 % (range 69.5-100 %), whereas FPF SL200 and DLT 5 g a.s/ha had shown the efficacy of 72.4% (range 44.4- 88.5 %) and 66.6 % (range 44.4- 82.5 %) respectively for FPF SL200 and DLT 5 g a.s/ha, respectively

Table 3.2.-22: Efficacy of DLT+FPF EC85 against CEUTAS adults and larvae: justification of the mixture. Results from the South-East EPPO climatic zone.

EU regulatory zone	Number of trials	DAA BBC H crop stage	Sample Size	DAA	UN-TREATED (Living adults and larvae)		DLT+FPF EC85		FPF SL200		DECIS		DECIS	
							0.5 L/ha 5+37.5 g a.s/ha		37.5 g a.s/ha		5 g a.s/ha		7.5 g a.s/ha	
							% Efficacy (Abbott)							
					Mean	Min-Max	Mean	Min-Max	Mean	Min-Max	Mean	Min-Max		
Central	10	0-8; 0-3- 1-2 59-71	1 SHOOT	1-2 3	0-6 0.8	0-1 0.2-1.4	86.4	65.6-100	72.1	40.6-100	78.6	55.9-100	86-6 86.7	66.7-100
Central +Southern	12	0-8; 0-3- 1-2 59-72	1 SHOOT	1-2 3	0-7 0.8	0-1 0.2-1.4	84.4	52.0-100	68.7	36.0-100	73.8	32.0-100	82-9 83.0	36.0-100
Central	10 9	61-71	1 SHOOT	4-6	0-9 0.7	0.2-2.3 1.4	72-9 69.9	13.0-99-6 97.2	68-7 65.8	49.3-94-7 77.2	70-4 67.1	29.7-100	78-5 76.2	43.2-100
Central +Southern	12 11	61-74	1 SHOOT	4-7	0-9 0.8	0.2-2.3 1.4	75-4 73.2	13.0-100	68-9 66.5	49.3-94-7 77.2	68-7 65.9	29.7-100	78-2 76.3	43.2-100
Central	10 9	69-80	100 PODS	21-40	31.8	2.3-117.0	84.5	69.5-100	71.2	44.4-88.5	68.4	44.4-82.5	83.9	66.7-100
Central +Southern	12 11	69-80	100 PODS	21-40	43.7	2.3-117.0	85.1	69.5-100	72.4	44.4-88.5	66.6	44.4-82.5	83.5	66.7-100

To determine the efficacy against the pod midge, the results of 8 trials carried out in Central EU regulatory zone are presented as well as a result of one trial carried out in Southern EU regulatory zone (Bulgaria) for the South-East EPPO climatic zone. At 4 to 6 DAA, DLT+FPF EC85 confirmed a better curative effect on DASYBR than both DLT 5 g a.s/ha and FPF SL200. In average, the efficacy of DLT+FPF EC85 reached 73.5 % (range 33.0 - 95.0 %), vs 70 69.8% (range 58.3-80 79.9%) and 59.2 % (range 33.3-75.2 %) for FPF SL200 and DLT 5 g a.s/ha, respectively.

At 14 to 26 DAA, the average efficacy (81.0 81.9 %, min range 60 %; max 95.2 %) of DLT+FPF EC85 remains better than FPF SL200 and DLT (71.1 70.9 %, min range 40.0 max 92.3 % and 69.7 %, min range 56.0, max 79.0 % respectively). DLT+FPF EC85 performed significantly better than DLT 5 g a.s/ha in 3 trials, including in the trial with the highest infestation, and significantly better than FPF SL200 in 2 trials.

Table 3.2.-23: Efficacy of DLT+FPF EC85 against DASYBR justification of the mixture. Results from trials carried out in South-East EPPO climatic Zone.

EU regulatory zone	Number of trials	DAA BBCH crop stage	Sample Size	DAA	UN-TREATED (Infested pods)		DLT+FPF EC85		FPF SL200		DLT		DLT	
							0,5 L/ha 5+37,5 g a.s/ha		37,5 g a.s/ha		5 g a.s/ha		7,5 g a.s/ha	
							% Efficacy (Abbott)							
					Mean	Min-Max	Mean	Min-Max	Mean	Min-Max	Mean	Min-Max		
Central	5	1.6; 1.2 61-71	25 SHOOTS	4-6.	21.9	1.5-64.5	71.5	33.3-95.0	69.1	58.3-79.9	56.4	33.3-75.2	78.1	66.7-89.9
Central + Southern	6	28.3; 1.6 61-71	25 SHOOTS	4-6.	63.5	1.5-271.3	73.5	33.3-95.0	69.8	58.3-79.9	59.2	33.3-75.2	78.6	66.7-89.9
Central	7	65-75	25 SHOOTS	14-26	27.0	1.3-83.3	82.5	60.0-95.2	71.1	40.0-92.3	69.7	56.0-79.0	86.5	80.0-88.1
Central + Southern	8	65-75	25 SHOOTS	14-26	105.7	1.3-656.3	81.2 81.9	60.0-95.2	70.8 70.9	40.0-92.3	69.7	56.0-79.0	85	74.1-88.1

Results in the North-East EPPO climatic Zone

Nine trials were carried out in countries belonging to the EPPO climatic Zone North-East EPPO climatic Zone-including 5 trials carried out in the Northern EU regulatory zone to demonstrate the justification of the mixture against CEUTAS. At timing of application, adult weevils were at a lower level (0.2 to 0.7 insects/shoot) than in the trials carried out in South-East and Maritime EPPO climatic Zones. Adults were assessed just after the application at 1 to 2 DAA and 5 to 7 DAA while larvae were assessed after 4 weeks at 22 to 28 DAA.

At 1 to 3 DAA it was however able possible to demonstrate a significative efficacy of the products in most of the trials. DLT and FPF SL200 and DLT 5 g a.s/ha, at rates equivalent to those in the mixture, demonstrated a comparable efficacy, here 66.3%-(range 28.6- 83.7%)- and 70.2%-(range 0.0-100 %) respectively, with the other efficacy zones. The trial where DLT was used at 5 g a.s/ha has 0.0 % efficacy is a trial with a low infestation, without significative efficacy of the products. The combination (i.e. mixture) was significantly better than one or the other of the single active substances in 2 trials and reached an average efficacy of 83.8 % (min range 62.7 % max 100 %), i.e. higher than that of the single active substances.

At 5-7 DAA, the infestation was low in most of the trials carried out in Northern EU regulatory zone; however the average performance of the mixture (mean of average 77.0 %, range 40.0-100 %) is still above that of the single active substances (mean of average 66.5 %, range 23.3-100 % for DLT 5 g a.s/ha and

At 22 to 28 days after the application, the highest efficacy of the mixture for the control of adults results in a better control of CEUTAS larvae; where in 4 trials the mixture performed significantly better than at least one of the single active substances. For this assessment type, the average efficacy of DLT+FPF EC85 is 75.4 % (range 47.4- 96.9 %) and that of DLT and FPF SL200, average 63.3 63.4% (range 44.7-90.6 %) and 59.2 %, range 11.3- 78.9 %), respectively.

EU regulatory zone	Trial number Number of trials	BBCH Crop stage	Sample Size	DAA	UNTREATED (Living adults or larvae)		DLT+FPF EC85		FPF SL200		DLT	
							0.5 L/ha		37.5 g a.s/ha		5 g a.s/ha	
											% Efficacy (Abbott)	
					Mean	Min-Max	Mean	Min-Max	Mean	Min-Max	Mean	Min-Max
Central	4	67	1 SHOOT	1-2.	0.5	0.3-0.8	87.5	81.1-98.3	69.0	60.0-81.7	76	67.6-83.3
Central+Northern	9	59-69	1 SHOOT	1-2.	0.4	0.1-0.8	83.8	62.7-100	66.3	28.6-83.7	70.2	0.0-100
Central	4	69-71	1 SHOOT	6	0.4	0.3-0.6	85.2	80.0-95.7	71.4	62.5-87.2	73.1	62.5-95.7
Central+Northern	9	63-72	1 SHOOT	5-7.	0.3	0.025-0.6	77.0	40.0-100	56.1	30.0-87.2	66.5	23.3-100
Central	4	77-79	100 PODS	24-28	12.1	8.0-17.8	81.6	79.2-84.2	54.5	11.3-78.9	56	44.7-69
Central+Northern	9	71-78	100 PODS	22-28	11.8	5.5-19	75.4	47.4-96.9	59.2	11.3-78.9	63.4	44.7-90.6

At 14 to 16 DAA, the average efficacy of DLT+FPF EC85 (mean average 68.67.9%; range 31.0-94.0 94.4 %) remained better than that of DLT (mean average 54.0%, range 29.4-72.2 %) and of FPF SL200 (mean average 50.4%, range 0.0-78.2 %), with statistical significant differences in 2 trials.

EU regu- latory zone	Nu mbe r of tri- als	BBC H crop stage at	Sample Size	DA A	UNTREATED (Infested pods)	DLT+FPF EC85	FPF SL200	DLT
						0.5 L/ha 5+37.5 g a.s/ha	37.5 g a.s/ha	5 g a.s/ha
						% Efficacy (Abbott)		

		as- sess- ment			Mea n	Min-Max	Mean	Min-Max	Mea n	Min-Max	Mea n	Min- Max
Central	5	69-71	25 SHOOTs	6	26.3	6.8-78.8	69.5	31.9-81.5	70.3	51.6-81.0	42.8	2.9-62.7
Central + North	6	63-71	25 SHOOTs	6-7	33.5	6.8-78.9 78.8	68.4 68.5	31.9-81.6 81.5	62.2	21.7-81.1 81.0	46.8	2.9-66.4
Central	5	73-77	25 SHOOTs	14-15	50.2	13.8-112.3	68.1	42.2-85.5	56.9	27.2-78.2	50.6	29.4-66.7
Central + North	8	73-77	25 SHOOTs	14-16	56.1	4.5-164.8	67.9	31.0-94.4	50.4	0.0-78.2	54.0	29.4-72.2

The results from the North-East EPPO climatic Zone are consistent with those observed in the Maritime and South-East EPPO climatic Zones. Flupyradifurone has shown to be intrinsically effective against the 2 two pod pests, for which it has no registered use. The results show that the mixture can be justified by an overall better control of the pod pests complex, which includes a better initial efficacy against adults weevils, better curative effect on the pod midge larvae and better residual efficacy against both pests. A statistical analysis (F-test) carried out on the set of data shows that DLT+FPF EC85 is very highly and significantly better than both comparison products, FPF SL200 and deltamethrin formulations.

Comments of zRMS on mixture justification for the control of CEUTAS and DASYBR:

For the pod weevil, *C. assimilis*, and the pod midge, *D. brassicae*, the evidence for the difference in activity, between the mixture and the single actives, gradually increasing in time, is not that much apparent as in control of the pollen beetle. It is more often that the maximum efficacy is visible already on 1-3 DAA and remains such, or fluctuates only slightly, until the last assessments.

Nevertheless, the trials carried out in the Maritime, North-East and the South-East EPPO zones all testify to the ability of the mixture to retain its insecticidal effect until as late as 21-40 (CEUTAS) or 14-26 DAA (DASYBR), at the level still considerably higher compared to the single actives used alone.

Comments of zRMS on mixture justification overall:

DLT+FPF EC85 is a new product, and one of its actives, FPF, has currently no authorization in Poland for pest control in OSR. Consequently, the mixture justification is not the least important part of the assessment.

For the justification of the mixture DLT+FPF EC85, a series of field trials have been submitted by the applicant, that were carried out in three EPPO zones (North-East, South-East and Maritime), mainly within the Central EU regulatory zone but also, additionally, in parts of the North and the South EU regulatory zones. Results from these trials reliably demonstrate the advantage of co-formulating the FPF and DLT in control of all the OSR pests on which the efficacy had been tested: CEUTNA, CEUTQU, MELIAE, CEUTAS and DASYBR.

In control of the stem weevils (CEUTNA, CEUTQU) the averaged efficacy values from the assessment dates between 7-96 DAA, for 35 different trials, make it possible to conclude that the test product performed better compared to the single actives FPF and DLT used alone. In control of the pollen beetle MELIAE, pod weevil CEUTAS and pod midge DASYBR on winter oilseed rape, 2 to 3 consecutive assessments were carried out in each trial, in order to demonstrate both the initial and the long-lasting efficacy, and the relation between them. The combination of deltamethrin and flupyradifurone proved to offer on average better efficacy, compared to the single-active formulations applied at comparable dose rates, and both in the control of MELIAE and in the combined control of CEUTAS and DASYBR, the residual effect of the mixture, compared to single actives, can be concluded. zRMS considers the FPF and DLT co-formulation justified.

3.2.2 Minimum effective dose tests (KCP 6.2)

USE 01: Minimum effective dose of DLT+FPF EC85 on oilseed rape against *Ceutorhynchus napi* (CEUTNA) and *Ceutorhynchus quadridens* (CEUTQU)

In order to demonstrate the minimum effective dose of DLT+FPF EC85 against *Ceutorhynchus napi* (CEUTNA) and *Ceutorhynchus quadridens* (CEUTQU) in winter oilseed rape, the following chapter summarizes the results from a series of 41 minimum effective dose field trials carried out in Poland (7) representing the North-East EPPO climatic zone in the European regulatory central zone, in Hungary (7), Romania (2) and Slovakia (6) representing the South-East EPPO climatic zone in the European regulatory central zone, and in the Czech Republic (7) representing the Maritime EPPO climatic zone in the European regulatory central. Seven additional trials from European regulatory Northern zone carried out in Latvia (4) and Lithuania (3) were added as supporting trials for North-East EPPO climatic zone. Moreover, five additional trials from European regulatory Southern zone carried out in Bulgaria were added as supporting trials for South-East EPPO climatic zone.

Single trial reports are given in Compilation of Trial Reports [M-659525-01-1](#) with the corresponding trial list. It has to be noticed that these trials are also part of the data package presented for Efficacy tests in chapter 3.2.3. The number of trials conducted in each climatic zone and country is shown in Table 3.2-27 below.

Table 3.2-27: Distribution of trials according to climatic zones and countries

Crop	EPPO climatic zone	Regulatory Zone	Country	Year	Number of trials	Total		
Winter oilseed rape	North-East	Central	Poland	2014	2	7		
				2015	2			
				2016	2			
				2017	1			
		Northern	Lithuania	2015	1	3	7	
				2017	2			
			Latvia	2015	2	4		
				2017	2			
	North-East EPPO climatic zone						14	
	South-East	Central	Romania	2015	1	2	15	
				2016	1			
			Hungary	2014	2	7		
				2015	1			
				2016	2			
				2017	2			
			Slovakia	2014	3	6		
				2015	2			
		2016		1				
		Southern	Bulgaria	2014	2	5	5	
				2015	1			
	2016			2				
	South-East EPPO climatic zone						20	
	Maritime	Central	Czech republic	2014	4	7		
				2016	2			
				2017	1			
Maritime EPPO climatic zone						7		
Total	All EPPO climatic zones		Winter oilseed rape			41		

Test product

DLT+FPF EC85 was tested at 40.0 % (0.4N); 66.7 % (0.67N); and 100% (N) of the proposed label rate, in accordance with the EPPO standard PP1/225 'Minimum effective dose'. The list of EPPO standards followed in the trials is presented in Table 3.2-28 below. The detailed methodology of these trials will be described in chapter 3.2.3 Efficacy tests since they are used in both chapters.

Table 3.2-28: EPPO standards followed in this chapter

EPPO standards	Titles
PP1/135(3)	Phytotoxicity assessment
PP1/152(4)	Design and analysis of efficacy evaluation trials
PP1/181(4)	Conduct and reporting of efficacy evaluation trials including GEP
PP1/225(2)	Minimum effective dose
PP1/178(3)	<i>Ceutorhynchus napi</i> and <i>Ceutorhynchus pallidactylus</i> on rape

Summary of the results

In the summary **Table tables** below, orthogonal comparisons between different tested dose rates of DLT+FPF EC85 are presented. Only trials/assessments considered as valid to evaluate the minimum effective dose of DLT+FPF EC85 against *C. napi* and *C. quadridens*, in which reference products behaved as expected and infestation levels were sufficient are included in trial groupings below. The number of larvae and plants infested were counted for the both pests and presented per EPPO climatic zone, per pest and both pests together. *C. napi* and *C. quadridens* being pests with similar biology on one side, and on the other side the application can target the 2 pests at the same time.

Results in North-East EPPO climatic zone

Assesment on living larvae – Table 3.2-29

In ~~ten~~ five out of seven trials carried out in Poland in the EU Central regulatory zone, the test product DLT+FPF EC85 showed a clear dose rate response from 0.5 L/ha to 0.75L/ha in the control of larvae of CEUTNA and CEUTQU. The dose rate response from 0.5 L/ha to 0.75L/ha is confirmed in the efficacy results from the supportive trials conducted in Latvia and Lithuania (EU Northern regulatory zone). The dose rate 0.3L/ha was also tested in 6 trials. The results showed a clear dose response between the two lower doses and the proposed dose of 0.75L/ha.

Table 3.2-29: MED of DLT+FPF EC85 on winter oilseed rape according to number of larvae of CEUTNA and CEUTQU-Summary of the results in North-East EPPO climatic zone

Table 1. Summary of the results in North-East DTPC climatic zone													
EP P O cli- ma- tic zo- ne	Tar- get	EU reg- ula- tory zon- e	Trial-numbers Number of tri- als	Sample Size	DAA	UNTREATED (Living larvae)		DLT+ FPF EC 85		DLT+ FPF EC 85		DLT+ FPF EC 85	
								0.3 L/ha		0.5 L/ha		0.75 L/ha	
												% Efficacy (Abbott)	
						Mean *	Min- Max	Mea n	Min - Ma x	Mea n	Min - Ma x	Mea n	Min - Max
No rth - Ea st	CE UT NA	Cen- tral	5	20 or 25 PLANTS	29-70	0.9	0.2-1.6			92.2	85.4 - 100	98 .2	95.7 -100
		Cen- tral + Nort hern	7	20, 25 or 40 PLANTS	29-70	0.7	0.2-1.6	81.8		52- 100	93 .7	80- 100	
	CE UT QU	Cen- tral	2	20 PLANTS	45-70	1.5	0.4-2.5	82.3	76. 5- 88. 2	97.5	95.1 - 100	97 .5	95,1 -100

EP P O cli- ma- tic zo- ne	Tar- get	EU reg- ula- tory zon- e	Trial numbers	Sample Size	DAA	UNTREATED (Living larvae)		DLT+ FPF EC 85		DLT+ FPF EC 85		DLT+ FPF EC 85	
			Number of tri- als					0.3 L/ha		0.5 L/ha		0.75 L/ha	
			% Efficacy (Abbott)										
			Mean *			Min- Max	Mea n	Min - Ma x	Mea n	Min - Ma x	M ea n	Min - Max	
	5	20 or 25 PLANTS	15-70	1.2	0.4-2.5	89.5		82.4 - 100	96 .3	92.3 -100			
	Central + Nort hern	6	20 or 25 PLANTS	28-70	2.3	0.4-3.6	71.6	43. 2- 88. 2	74.9	34.2 - 100	86 .4	70.3 -100	
		10	1 PLANT	15-70	1.7	0.2-3.6	77.9		34.2 - 100	87 .4	69.2 -100		
		2 trials, 3 data points	1 PLANT	28-70	1.1	0.2-2.5	80.4	76. 5- 88. 2	98.4	95.1 - 100	98 .4	95.1 -100	
	CE UT NA + CE UT QU	Central	7 trials 10 data points	1 PLANT	15- 70	1.0	0.2-2.5	90.8		82.4 - 100	97 .3	92.3 -100	
		Central + Nort hern	6 trials, 7 data points	1 PLANT	25-70	2.0	0.2-3.6	72.3	43. 2- 88. 2	78.5	34.2 - 100	88 .3	70.3 -100
			13 trials 17 data points	1 PLANT	15- 70	1.3	0.2-3.6	79.5		34.2 - 100	90 .0	69.2 -100	

* Mean per 1 plant

Assesment on plant infested – Table 3.2-30

The number of infested plants by CEUTNA and CEUTQU was also assessed in these trials. In ten two of the seven trials conducted in Poland in the in the EU Central regulatory zone, the test product DLT+FPF EC85 showed a small dose rate response from 0.5 L/ha to 0.75L/ha in the control of infested plants by CEUTNA and CEUTQU. A clear dose response was shown with the addition of trials conducted in the EU Northern regulatory zone in the control of infested plants by CEUTNA and CEUTQU. The dose rate 0.3L/ha was also tested in 3 trials with a clear dose response between the three doses.

Table 3.2-30: MED of DLT+FPF EC85 on winter oilseed rape according to plants infested by of CEUTNA and CEUTQU-Summary of the results in North-East EPPO climatic zone

EP PO cli- ma- tic zon e	Tar- get	EU reg ula tor y zon e	Number of trials	Sample Size	DA A	UNTREATED (% of Plant in- fested)		DLT+ FPF EC 85		DLT+ FPF EC 85			
								0.3 L/ha		0.5 L/ha		0.75 L/ha	
								% Efficacy (Abbott)					
						Mea- n	Min- Max	Me- an	Min- Max	Me- an	Min- Max	Me- an	Min- Max

North-East	CEU TNA	Ce ntra l	2	20 PLANT S	28-70	55.6	11.3-100	75.1	72.5-77.8	93.1	86.3-100	94.3	88.6-100
			7	20 PLANT S	15-70	41.9	11.3-100			88.7	76.5-100	93.5	86.4-100
		Ce ntra l + Norther n	9	20-40 PLANT S	15-70	36.4	5.0-100			77.1	25-100	88.0	62.5-100
	CEU TQU	Ce ntra l	3	20 PLANT S	29-70	23.1 30.8	16.3-45.0			86.9	80-100	93.6	88.9-100
		Ce ntra l + Norther n	4	20-25 PLANT S	23-70	29.7	23.8 16.3 - 45.0			77.0	47.6-100	82.1	47.6-100
	CEU TNA-CEU TQU	Ce ntra l	2 trials, 3 data points	20 PLANT S	28-70	42.5	11.3-100	73.2	69.2-77.8	95.4	86.3-100	96.2	88.6-100
			10	20-25 PLANT S	15-70	38.6	11.3-100			88.1	76.5-100	93.5	86.4-100
		Ce ntra l + Norther n	13	20-40 PLANT S	15-70	34.4	5.0-100			77.1	25-100	86.2	47.6-100

Results in South-East EPPO climatic zone

Assesment on living larvae – Table 3.2-31

Concerning the eighteen trials carried out in countries belonging in the EU Central regulatory zone in the South-East EPPO climatic zone, the test product DLT+FPF EC85 showed a clear dose rate response from 0.5 L/ha to 0.75L/ha in the control of larvae of CEUTNA and CEUTQU. The dose rate response from 0.5 L/ha to 0.75L/ha is confirmed in the efficacy results from the supportive trials conducted in Bulgaria (EU Southern regulatory zone). The dose rate 0.3L/ha was also tested in 8 trials, results showed a clear dose response between the two lower doses and the proposed dose of 0.75L/ha.

Table 3.2-31: MED of DLT+FPF EC85 on winter oilseed rape according to number of larvae of CEUTNA and CEUTQU-Summary of the results in South-East EPPO climatic zone

EPP O cli- mati c zone	Target	EU reg- ula- tory zone	Tri al nu mb er	Sample Size	DA A	UNTREATED (Living larvae)		DLT+ FPF EC 85		DLT+ FPF EC 85		DLT+ FPF EC 85					
								0.3 L/ha		0.5 L/ha		0.75 L/ha					
						% Efficacy (Abbott)											
						Me an	Min- Max	Me an	Min- Max	Me an	Min- Max	Me an	Min- Max				
Sout h- East	CEUT NA	Central	5	20 PLANTS	28- 96	26.6	18-40.8	75.2	62.6- 92.9	83.8	68.7- 100	85. 2	66.9- 100				
			14	20 PLANTS	23- 96	119. 3	18- 505.5		73.2	38.2- 100	81. 6	59.2- 100					
		Central + Sout hern	7	20 PLANTS	28- 96	124. 6	18- 406.5	68.9	53.0- 92.9	76.6	56.9- 100	78. 8	60-100				
			19	20 PLANTS	7- 96	172. 3	185- 505.5		71.0	38.2- 100	77. 6	59.2- 100					

	CEUT QU	Central	4	20 PLANTS	28- 41	40.1	12.8- 79.5		83.8	73.7- 93.6	93.2	90.6- 96.1	
	CEUT NA + CEUT QU	Central	6	20 PLANTS	28- 96	24.7	12.8- 40.8	72.5	58.8- 92.9	84.8	52.9- 100	87	59.2- 100
			18	20 PLANTS	23- 96	101. 7	12.8- 505.5		75.5	38.2- 100	84.2	59.2- 100	
		Central + Sout hern	8	20 PLANTS	28- 96	110. 9	12.8- 406.5	67.7	53.0- 92.9	78.3	56.9- 100	80.9	60.0- 100
			23	20 PLANTS	jul/ 96	149. 3	12.8- 505.5		72.8	38.2- 100	80.3	59.2- 100	

Assessment on plant infested – Table 3.2-32

In twelve trials conducted in the in countries belonging in the EU Central regulatory zone in the South-East EPPO climatic zone, the test product DLT+FPF EC85 showed a dose rate response from 0.5 L/ha to 0.75L/ha in the control plants infested by of CEUTNA and CEUTQU. The dose rate response from 0.5 L/ha to 0.75L/ha is confirmed in the efficacy results from the supportive trials conducted in Bulgaria (EU Southern regulatory zone). The dose rate 0.3L/ha was also

Table 3.2-32: MED of DLT+FPF EC85 on winter oilseed rape according to plants infested by CEUTNA and CEUTQU-Summary of the results in South-East EPPO climatic zone

EPPO climatic zone	Target	EU regulatory zone	Number of trials	Sample Size	DAA	UNTREATED (% of Plant infested)		DLT+ FPF EC 85		DLT+ FPF EC 85		DLT+ FPF EC 85	
								0.3 L/ha		0.5 L/ha		0.75 L/ha	
								% Efficacy (Abbott)					
						Mean	Min-Max	Mean	Min-Max	Mean	Min-Max	Mean	Min-Max
South-East	CEU TNA	Central	4	20 PLANTS	28-96	62.2	37.5-98.8	62.7	47.5-91.1	76.6	52.5-100	79.5	57.5-100
			8	20 PLANTS	23-96	70.3	37.5-100		68.2	24.3-100	74.2	45.9-100	
		Central + Southern	6	20 PLANTS	28-96	74.8	37.5-100	47.6	7.5-60	60.0	20.0-90.0	63.9	27.5-96.7
			13	20 PLANTS	7-96	81.2	37.5-100		58.5	20.0-100	63.6	27.5-100	
	CEU TQU	Central	3	20 PLANTS	34-41	63.8	22.5-97.5		53.3	20.5-83.3	71.5	41.0-94.4	
	CEU TNA-CEU TQU	Central	5	20 PLANTS	28-96	52.3	12.8-98.8	61.9	47.5-91.1	79.3	52.5-100	82.8	57.5-100
			12	20 PLANTS	23-96	60.2	12.8-100		73.4	24.3-100	80.5	45.9-100	
		Central + Southern	7	20 PLANTS	28-96	65.9 70.5	12.8 22.5-100	49.2 60.1	7.5 47.5-91.1	64.3 62.7	20.0 20.5-100	68.5 70.5	27.5 41.0-100
			17	20 PLANTS	7-96	71.5 78.5	12.8 22.5-100		64.4 61.9	20.0 20.5-100	70.6 69.7	27.5 41.0-100	

Results in Maritime EPPO climatic zone

Assessment on living larvae – Table 3.2-33

In the trials carried out in the Czech Republic in the EU Central regulatory zone (Maritime EPPO climatic zone), the test product DLT+FPF EC85 showed a clear dose rate response from 0.5 L/ha to

0.75L/ha in the control of larvae of CEUTNA and CEUTQU. The dose rate 0.3L/ha was also tested in 5 trials, results showed a clear dose response between the two lower doses and the proposed dose of 0.75L/ha tested in 7 trials, results showed a clear dose response between the two lower doses and the proposed dose of 0.75L/ha.

Table 3.2-33: MED of DLT+FPF EC85 on winter oilseed rape according to number of larvae of CEUTNA and CEUTQU-Summary of the results in Maritime EPPO climatic zone

EPPO climatic zone	Target	EU regulatory zone	Trial number	Sample Size	DAA	UNTREATED (Living larvae)		DLT+ FPF EC 85		DLT+ FPF EC 85		DLT+ FPF EC 85	
								0.3 L/ha		0.5 L/ha		0.75 L/ha	
						Mean	Min-Max	Mean	Min-Max	Mean	Min-Max	Mean	Min-Max
% Efficacy (Abbott)													
						Mean	Min-Max	Mean	Min-Max	Mean	Min-Max	Mean	Min-Max
Maritime	CEUTNA	Central	3	20 PLANTS	39-54	24.8	6.3-58.3	70.1	62.5-76.0	89.3	82.5-96.0	96.0	90.6-100
			6	20 PLANTS	20-54	23.7	3.8-58.3			87.4	79.9-96.0	93.3	83.5-100
	CEUTQU		2	20 PLANTS	42-54	27.3	2.8-51.8	73.8	72.7-74.9	39.8	9.1-70.5	74.8	63.6-86.0
	CEUTNA+CEUTQU		5	20 PLANTS	39-54	25.8	2.8-51.8 58.3	71.6	62.5-76.0	69.5	9.1-96.0	87.5	63.6-100
			8	20 PLANTS	20-54	24.6	2.8-58.3			75.5	9.1-96.0	88.6	63.6-100

In the trials carried out in the Czech Republic in the EU Central regulatory zone (Maritime EPPO climatic zone), the test product DLT+FPF EC85 showed a clear dose rate response from 0.5 L/ha to 0.75L/ha in the control of larvae of CEUTNA and CEUTQU. The dose rate 0.3L/ha was also tested in 5 trials, results showed a clear dose response between the two lower doses and the proposed dose of 0.75L/ha

Assessment on plants infested – Table 3.2-34

Table 3.2-34: MED of DLT+FPF EC85 on winter oilseed rape according to plants infested by CEUTNA and CEUTQU-Summary of the results in Maritime EPPO climatic zone

EPP O climatic zone	Target	E U re gul ato ry zo ne	Nu mb er of tri als	Sample Size	DA A	UN- TREATED (% of Plant infested)		DLT+ FPF EC 85		DLT+ FPF EC 85		DLT+ FPF EC 85	
								0.3 L/ha		0.5 L/ha		0.75 L/ha	
						Me an	Min- Max	Me an	Min- Max	Me an	Min- Max	Mean	Min-Max
Mari- time	CEUT NA	Ce ntr al	3	20 PLANT S	39- 54	53. 3	26.3- 78.8	59. 8	47.7- 76.2	78. 3	68.2- 95.2	86.0	76.2-100
			6	20 PLANT S	20- 54	45. 8	15.0- 82.5			68. 5	42.9- 95.2	77.5	59.1-100
	CEUT QU		2	20 PLANT S	42- 54	61. 3	55- 67.5	40. 1	22.7- 57.4	41. 3	36.4- 46.3	54.8	33.8-75.9
	CEUT NA- CEUT QU		5	20 PLANT S	39- 54	56. 5	26.3- 78.8	51. 9	22.7- 76.2	63. 5	36.4- 95.2	73.5 74.5	33.8 38.6-100
			8	20 PLANT S	20- 54	49. 7	15.0- 82.5				61. 7	36.4- 95.2	71.8 72.4

Out of all these forty-one trials (all EU regulatory zones), the mean efficacy at the proposed dose rate of 0.75L/ha was better than at lower tested dose rates both of 0.5 L/ha and of 0.3 L/ha. According to the presented results of reliable trials carried out in Maritime, South-East and North-East EPPO climatic zone, the dose rate of 0.75 L/ha (N) of DLT+FPF EC85 provided the optimum overall control and should be considered as effective against the pests CEUTNA and CEUTQU, two majors pests of oilseed rape.

Conclusion of the Minimum effective dose of DLT +FPF EC85 against CEUTNA and CEUTQU

According to the presented results, the dose of 0.75 L/ha of DLT+FPF EC85 provided the optimum overall control and should be considered as effective against these two major pests, for which activity of DLT+FPF EC85 is claimed. As a result, the proposed rate of 0.75 L/ha should be considered the minimum effective dose to deliver broad spectrum control of CEUTNA and CEUTQU under a wide range of environmental conditions.

Comments of zRMS:

The applicant submitted the results from 41 field efficacy trials to justify the MED for the control of stem weevils: *Ceutorhynchus napi* (CEUTNA) and *Ceutorhynchus quadridens* (CEUTQU) in winter oilseed rape: 14 trials in the North-East EPPO climatic zone (including 7 in the North EU regulatory zone), 7 in the Maritime zone (all in Czech Republic) and 20 - in the South-East EPPO climatic zone (including 5 in the South EU regulatory zone). In all of these trials the proposed, target dose rate of 0,75 L/ha was tested along with the 0,50 L/ha dose rate. In 17 trials the dose rate of 0,30 L/ha was tested as well: in 4 trials in the Maritime zone, in 7 – in the South-East zone (including 2 in BG), and in 6 trials in the North-East zone (including 4 in LT and LV). In two trials in Poland (North-East zone) the dose response was evident only between the 0,30 L/ha and 0,50 L/ha dose rates while the efficacy at 0,50 and 0,75 L/ha was comparable. The observation concerns CEUTNA and may be attributed to low infestation level (11,3 % - 16,3 % plants infested, 0,2 -0,4 larvae per plant, UNCK, 70 DAA) which could bias the results by selecting, even though from the treated plots, the plants which had never been infested, before or after treatment. Unfortunately, no data on pest incidence or severity before treatment is available from these two trials.

In the South-East zone the dose response between the 0,50 and 0,75 L/ha becomes “clear” when results are averaged across the large sets of trials, whereas it is less clear in the less abundant sets, that include the 0,30 L/ha dose rate trials (there the 0,30 / 0,50 L/ha dose response is more evident).

Otherwise, i.e. when averaged within the three EPPO zones concerned, and also when extended with the results from the North and South EU regulatory zones, the data essentially show the dose response clear and wide enough to consider the 0,75 L/ha dose rate as the minimum effective dose to control stem weevils in winter oilseed rape.

USE 02: Minimum effective dose of DLT+FPF EC85 on oilseed rape against *Brassicogethes aeneus* (MELIAE)

Brassicogethes aeneus (MELIAE) is a major pest for oilseed rape in all concerned member states ~~except in The Netherlands~~ (Romania and Poland). Spring oilseed rape (BRSNS) is a major crops only in Hungary. Winter oilseed rape is a minor crops only in the Netherlands. Nevertheless, with regard to cultivated acreages, spring oilseed rape and mustards (~~BRSJU, BRSNI~~ SINSS) can be considered as minor crops. The same insect species (MELIAE) attacks both winter (BRSNW) and spring oilseed rape (BRSNS), as well as mustard (~~BRSJU, BRSNI~~ SINSS), and the application conditions and timing based on crop growth stage are identical. Therefore, results obtained on winter oilseed rape will be used to support also the use on spring oilseed rape and mustard.

Minimum effective dose against MELIAE on winter oilseed rape

In order to demonstrate the minimum effective dose of DLT+FPF EC85 against *Brassicogethes aeneus* (MELIAE) in winter oilseed rape, the following chapter summarizes the results from a series of ~~18-20~~ minimum effective dose field trials carried out in Poland (~~10~~ 12) representing the North-East EPPO climatic zone in the European regulatory Central zone and in Hungary(4), Romania (1) and Slovakia (1) representing the South-East EPPO climatic zone in the European regulatory Central zone. Two additional trials from European regulatory Southern zone carried out in Bulgaria were added as supporting

trials for South-East EPPO climatic zone. Single trial reports are given in Compilation of Trial Reports [M-659528-01-1](#) with the corresponding trial list. It has to be noticed that these trials are also part of the data package presented for Efficacy tests in chapter 3.2.3. The number of trials conducted in each climatic zone and country is shown in Table 3.2-35 below.

Table 3.2-35: Distribution of trials according to climatic zones and countries

EPPO climatic zone	Regulatory Zone	Country	Year	Number of trials	Total		
North-East	Central	Poland	2014	2	12		
			2015	3			
			2016	3			
			2017	2			
South-East	Central	Romania	2017	1	1	8	
		Hungary	2015	1	4		
			2016	1			
			2017	2			
		Slovakia	2014	1	1		
	Southern	Bulgaria	2017	2	2		
	All EPPO climatic zones						20

Test product

DLT+FPF EC85 was tested at 40.0 % (0.4N); 66.7 % (0.67N); and 100% (N) of the proposed label rate, in accordance with the EPPO standard PP 1/225 'Minimum effective dose'. The list of EPPO standards followed in the trials is presented in Table 3.2-36 below.

Table 3.2-36: EPPO standards followed in this chapter.

EPPO standards	Titles
PP1/135(3)	Phytotoxicity assessment
PP1/152(4)	Design and analysis of efficacy evaluation trials
PP1/181(4)	Conduct and reporting of efficacy evaluation trials including GEP
PP1/225(2)	Minimum effective dose
PP1/178(3)	<i>Meligethes aeneus</i> on rape

The detailed methodology of these trials will be described in chapter 3.2.3 Efficacy tests since they are used in both chapters.

Summary of the results

In the summary tables below, orthogonal comparisons between different tested doses rates of DLT+FPF EC85 are presented. Only trials/assessments considered as valid to evaluate the minimum effective dose of DLT+FPF EC85 against *B. aeneus* in which reference products behaved as expected and infestation levels were sufficient, are included in trial groupings below. Ten trials were conducted in the North-East and eight - in the South-East EPPO climatic zone against *B. aeneus* on winter oilseed rape. The results of the trial number IA14XSTCW2POL2 are presented for 1 plot, not 1 shoot. In the trials IR14POLR08007I and IR14POLR08UP01 (assessment at the day of application) the dose rate of 0.5 L/ha or lower dose rate were not tested. These trials are therefore not included in the overall calculation. The efficacy of the test product DLT+FPF EC85 was evaluated at different timing assessments times according to the EPPO guidance PP1/178(3) *Meligethes aeneus* on rape. Results of living adults are presented by EPPO climatic zone.

Results in North-East EPPO climatic zone – Table 3.2-37

In ten trials in North-East EPPO climatic zone at 1-2 days after application of DLT+FPF EC85 applied at full propose dose rate (0.75L/ha) provides an average of 82.9% of reduction of insects

per shoot while the 0.5L/ha dose rate showed a reduction of insects of 81.1%. In the last assessment done in these trials (11-13 DAA), the application of the test product DLT+FPF EC85 at the proposed dose rate (0.75L/ha) provides ~~84.2~~ 84.1% (80.0-87.5%) of reduction of insects per shoot/plant while the 0.5L/ha dose rate (0.67N) showed a reduction of insects of 77.8% (range 72.0-81.3%) in 3 trials.

Table 3.2-37: MED of DLT+FPF EC85 on winter oilseed rape against MELIAE-Summary of the results in North-East EPPO climatic zone

North-East EPP Climate zone												
EPP O climati c zone	EU reg ula tor y zo ne	Nu mbe r of tri als	BBC H crop stage at as sessm t	DA A	UNTREATED		DLT+ FPF EC 85		DLT+ FPF EC 85		DLT+ FPF EC 85	
					(Living Adults/shoot)		0.3 L/ha		0.5 L/ha		0.75 L/ha	
							% Efficacy (Abbott)					
					Mea n	Min- Max	Me an	Min- Max	Mean	Min-Max	Mean	Min-Max
Nort h- East	Ce ntr al	10 9	51-61	0	2.7	0.4-7.3	na		na		na	
		9 8	51-61	1-2	3.5 3.6	1.0-7.1	-		81.1	59.3-92.9	82.9 82.8	62.1-95.6
		10 9	52-63	4-6	2.9 3.1	0.4-6.0	-		64.5 71.5	1.1 24.4- 96.6	72.7 77.2	31.6 57.7- 100
		6 5	61-64 63	7-9	2.4 2.8	0.7 1.2- 3.8	-		59.5 61.4	32.6 33.2- 88.5	61.5 66.9	17.0-97.3
		3	63-65	11- 13	1.6 1.7	0.3-2.4	-		77.8	72.0-81.3	84.2 84.1	80.0-87.5

Results in South-East EPPO climatic zone – Table 3.2-38

In six trials in South-East EPPO climatic zone at 1-3 days after the application, DLT+FPF EC85 applied at the full proposed N dose rate (0.75 L/ha) provided a greater reduction of the number of insects per shoot compared to the 0.5 L/ha dose rate (0.67N) showing respectively an average efficacy of 85.6% vs. 79.6%. At 2 days after the application, DLT+FPF EC85 at 0,3 L/ha (0,4N) was tested in one trial. No significant differences were observed, between the full proposed dose rate (N), and this lower dose rate. In four trials at 7 days after the application, DLT+FPF EC85 applied at the full proposed N dose rate (0.75L/ha) achieved a good efficacy level (~~72.7~~ 72.5%) compared to the 0.5L/ha dose rate (0.67N). A clear trend in dose response is visible despite no significant differences were visible in the trials.

Table 3.2-38: MED of DLT+FPF EC85 on winter oilseed rape against MELIAE-Summary of the results in South-East EPPO climatic zone

South-East EPP O climatic zone												
EPP O climati c zone	EU regu- la- tory zone	Num ber of tri- als	BBC H crop stage at as- essm t	DA A	UNTREATED		DLT+ FPF EC 85		DLT+ FPF EC 85		DLT+ FPF EC 85	
					(Living Adults/shoot)		0.3 L/ha		0.5 L/ha		0.75 L/ha	
							% Efficacy (Abbott)					
					Mea n	Min- Max	Mea n	Min- Max	Mea n	Min- Max	Mean	Min- Max
South -East	Central	2	62-63	0	1.8 1.9	0.8-2.9	na		na		na	
		6	31-63	0	2.0	0.0-6.6	na		na		na	
	Central + South ern	8	31-63	0	1.7	0.0-6.6	na		na		na	
	Central	1	63	2	2.4	-	91.5	-	94.5	-	97.4	-
	Central	4	50- 63	1-3	3.0	1.0-7.2	-		73.3	44.0- 94.5	79.0	49.0- 97.4
	Central + South ern	6	50- 63	1-3	2.3	0.9-7.2	-		79.6	44.0- 94.5	85.6	49.0- 98.9
	Central	2	52 65	6	2.0	1.6-2.3	54.8	29.9- 79.6	71.6	59.9- 83.3	60.1	33.2- 87.0

Central	2	53-63	7	3.0 3.1	1.6-4.5	-	48.7	7.1-90.3	56.5 56.6	19.4-93.7
Central + Southern	4	53-63	7	1.9 2.0	0.8-4.5	-	64.9	7.1-90.3	72.5	19.4-93.7

Out of all these ~~eighteen~~ twenty trials (all EU regulatory zones), the ~~mean~~ average efficacy at the proposed dose rate of 0.75L/ha was better than at lower tested dose rates both of 0.5 L/ha and of 0.3 L/ha. On the basis of the presented results it is justified that DLT+FPF EC85 applied at the full dose of 0.75L/ha provides a better control of *Brassicogethes aeneus* (MELIAE) on winter ~~and spring~~ oilseed rape, ~~and mustards~~ according to the proposed label.

Conclusion of the Minimum effective dose of DLT +FPF EC85 against MELIAE

According to the presented results, the dose of 0.75 L/ha of DLT+FPF EC85 provided the optimum overall control and should be considered as effective against this major pest, for which activity of DLT+FPF EC85 is claimed. As a result, the proposed rate of 0.75 L/ha should be considered the minimum effective dose to deliver broad spectrum control of MELIAE under a wide range of environmental conditions.

Comments of zRMS:

The applicant submitted the results from 20 field efficacy trials to justify MED for the control of *Brassicogethes aeneus* (MELIAE) on winter oilseed rape (12 trials in the North-East EPPO climatic zone and 8 in the South-East EPPO climatic zone). Clear dose response between the dose rates of 0,5 L/ha and 0,75 L/ha of DLT+FPF EC85 was recorded in both EPPO climatic zones. The dose rate of 0.3 L/ha was tested in only one efficacy trial, therefore it was not included in the final conclusions. An average efficacy of the tested product was higher for the dose rate 0,75 L/ha compared to the lower dose rate of 0,5 L/ha in North-East EPPO climatic zone and in the South-East EPPO climatic zone. The dose rate of 0,75 L/ha can therefore be regarded as minimum effective dose to the control of MELIAE in winter oilseed rape.

USE 03: Minimum effective dose of DLT+FPF EC85 on oilseed rape against *Ceutorhynchus obstrictus* (CEUTAS) and *Dasineura brassica* (DASYBR)-

In order to demonstrate the minimum effective dose of DLT+FPF EC85 against *Ceutorhynchus obstrictus* (CEUTAS) and *Dasineura brassica* (DASYBR) in winter oilseed rape, the following chapter summarizes the results from a series of 33 minimum effective dose field trials carried out in Poland (5) representing the North-East EPPO climatic zone in the European regulatory central zone, in Hungary (4), Slovakia (6) representing the South-East EPPO climatic zone in the European regulatory central zone and in the Czech Republic (10) representing the Maritime EPPO climatic zone in the European regulatory central. Five additional trials from European regulatory northern zone carried out in Latvia (2) and Lithuania (3) were added as supporting trials for North-East EPPO climatic zone. Moreover, three additional trials from European regulatory southern zone carried out in Bulgaria were added as supporting trials for South-East EPPO climatic zone. Single trial reports are given in Compilation of Trial Reports M-659527-01-1, with the corresponding trial list. It has to be noticed that these trials are also part of the data package presented for Efficacy tests in chapter 3.2.3. The number of trials conducted in each climatic zone and country is shown in Table 3.2-39 below.

Table 3.2-39: Distribution of trials according to climatic zones and countries

Crop	EPPO climatic zone	Regulatory Zone	Country	Year	Number of trials	Total	
Winter oilseed rape	North-East	Central	Poland	2014	1	5	10
				2015	1		
				2016	2		
				2017	1		

		Northern	Latvia	2017	1	5		
				2018	1			
			Lithuania	2017	2			
				2018	1			
	North-East EPPO climatic zone							10
	South-East	Central	Hungary	2015	2	4	13	
				2016	2			
			Slovakia	2014	3	6		
				2015	2			
		2016		1				
		Southern	Bulgaria	2015	1	3		
				2016	2			
			South-East EPPO climatic zone					
	Maritime	Central	Czech Republic	2014	3	10		
				2015	4			
				2016	3			
Maritime EPPO climatic zone							10	
Total	All EPPO climatic zones			Winter oilseed rape			33	

Test product

DLT+FPF EC85 was tested at 60.0 % (0.6N) and 100% (1N) of the proposed label rate, in accordance with the EPPO standard PP 1/225 'Minimum effective dose'. The list of EPPO standards followed in the trials is presented in Table 3.2-40 below.

Table 3.2-40: EPPO standards followed in this chapter.

EPPO standards	Titles
PP1/135(3/4)	Phytotoxicity assessment
PP1/152(3/4)	Design and analysis of efficacy evaluation trials
PP1/181(4)	Conduct and reporting of efficacy evaluation trials including GEP
PP1/107(3)	<i>Ceutorhynchus assimilis</i>
PP1/220(1)	<i>Dasineura brassicae</i>

The detailed methodology of these trials will be described in chapter 3.2.3 Efficacy tests since they are used in both chapters. In the summary table xx below, orthogonal comparisons between different tested doses rates of DLT+FPF EC85 are presented. Only trials/assessments considered as valid to evaluate the minimum effective dose of DLT+FPF EC85 against *Ceutorhynchus obstrictus* (CEUTAS) and *Dasineura brassicae* (DASYBR) in which reference products behaved as expected, infestation levels were sufficient are included in trial groupings below.

Summary of the results

In the summary table below, orthogonal comparisons between different tested doses rates of DLT+FPF EC85 are presented. Only trials/assessments considered as valid to evaluate the minimum effective dose of DLT+FPF EC85 against *Ceutorhynchus obstrictus* (CEUTAS) and *Dasineura brassicae* (DASYBR) in which reference products behaved as expected and infestation levels were sufficient are included in trial groupings below. Results are presented per pest and after per EPPO climatic zone, number of living adults and larvae are presented for CEUTAS and infested pods and living larvae - for DASYBR.

Results of MED of DLT+FPF EC85 against CEUTAS

Results in North-East EPPO climatic zone – Table 3.2-41

In 4 trials in the Central EU regulatory zone in the North-East EPPO climatic zone, DLT+FPF EC85 sprayed once was evaluated after 1-2 days, 5-7 days and 22-28 DAA at the dose of 0.3 L/ha and 0.5 L/ha. The test product DLT+FPF EC85 showed a dose rate response from 0.3 L/ha to 0.5 L/ha in the control of CEUTAS. The test product applied at the dose 0.5 L/ha gave, on the 1-2 DAA, an average

efficacy 87.5% included between (range 81.1-98.3%) and 90% which is 10 to 20% more than the efficacy of the dose 0.3 L/ha in Central EU regulatory zone. The dose rate response from 0.3 L/ha to 0.5 L/ha is confirmed in the efficacy results from the 5 supportive trials conducted in Latvia and Lithuania (EU Northern EU regulatory zone). At the same time of assessment (1-2 DAA), an average efficacy at the dose of 0.5 L/ha in both Central and Northern EU regulatory zones was 83.8% (range 62.7-100%).

Table 3.2-41: MED of DLT+FPF EC85 on winter oilseed rape against CEUTAS-Living adults- Summary of the results in North-East EPPO climatic zone

of the results in North-East EA & O climatic zone											
EPP O cli- matic zone	EU regu- la- tory zone	Num ber of tri- als	BBC H Crop Stage at as- sess- ment	Sample Size	DA A	UNTREATED (Living adults)		DLT+ FPF EC 85		DLT+ FPF EC 85	
								0.3 L/ha		0.5 L/ha	
										Efficacy (% Abbott)	
						Mea n	Min- Max	Mean	Min-Max	Mean	Min- Max
North -East	Central	4	62-67	1 SHOOT	0	0.4	0.2-0.7	na		na	
	Central + North ern	9	59-67	1 SHOOT	0	0.3	0.0-0.7	na		na	
	Central	4	67	1 SHOOT	1-2.	0.5	0.3-0.8	77.2	70.3-88.3	87.5	81.1- 98.3
	Central + North ern	9	59-69	1 SHOOT	1-2.	0.4	0.1-0.8	63.2 69.1	60.0 25.0- 100	83.8	62.7-100
	Central	4	69-71	1 SHOOT	6	0.4	0.3-0.6	76.6	68.6-95.7	85.2	80.0- 95.7
	Central + North ern	8	63-72	1 SHOOT	5-7 .	0.3	0.1-0.6	69.3	30.0-100	77.0 74.2	40.0-100

Results in South-East EPPO climatic zone – Table 3.2-42

In the average of 10 trials conducted in Central EU regulatory zone and 2 trials in Southern EU regulatory zone, a clear dose response is visible between the dose of 0.3L/ha and 0.5L/ha in the control of CEUTAS in the South-East EPPO climatic zone. In the trial IR14SVK125VK17 the number of infested pods was assessed, and not the number of living adults at the day of application, 6 DAA and 16 DAA. The results from this trial are therefore not included in the overall calculation. In trials in the Central EU regulatory zone, DLT+FPF EC 85 at dose 0.5 L/ga gave an average efficacy of 86.4% (range ~~65.5~~ 65.6-100%) for the first assessment (1-3 DAA), and ~~79.5~~ 69.9% (range ~~37.8~~ ~~99.6~~ 13.0-97.2%) for the second assessment (4-6DAA), whereas the lower dose rate 0.3 L/ha provided 74.5% (range ~~53.2~~ 53.1-98.6%) and ~~72.2~~ 66.1% (range 33.8-96.2%) respectively.

Table 3.2-42: MED of DLT+FPF EC85 on winter oilseed rape against CEUTAS- Living adults- Summary of the results in Sout-East EPPO climatic zone

EPP O cli- mati c zone	EU regu- la- tory zone	Nu mbe r of tri- als	BBCH Crop Stage at as- sess- ment	Sample Size	DA A	UNTREATED (Living adults)		DLT+ FPF EC 85		DLT+ FPF EC 85	
								0.3 L/ha		0.5 L/ha	
								Efficacy (% Abbott)			
						Mea n	Min- Max	Mean	Min- Max	Mean	Min-Max
Sout h- East	Central	10 9	55-69	1 SHOOT	0	0.7 0.8	0.2-1.7	na		na	
	Central + Sout hern	12 11	55-71	1 SHOOT	0	0.8	0.2-1.7	na		na	
	Central	10	59-71	1 SHOOT	1-3 .	0.6 0.8	0.1 0.2- 1.4	74.5	53.1- 98.6	86.4	65.6-100

	Central + Southern	12	59-72	1 SHOOT	1-3	0.7 0.8	0.1-0.2-1.4	72.3	44.0-98.6	84.4	52.0-100
	Central	9	61-71	1 SHOOT	4-6	0.9 0.7	0.2-2.3-1.4	72.2 66.1	33.8-96.2	79.5 69.9	37.8-99.6 13.0-97.2
	Central + Southern	11 10	61-74	1 SHOOT	4-7	0.9 0.8	0.2-2.3-1.4	72.4 67.4	33.8-96.2	81.0 73.2	37.8-13.0-100
	Central	2 1	65-79 69	1 SHOOT	16-21	1.0 1.5	0.4-1.5	78.7 57.4	57.4-100	95.5 91.0	91.0-100

Results in Maritime EPPO climatic zone – Table 3.2-43

In 7 trials performed in the Czech Republic (Central EU regulatory zone-Maritime EPPO climatic zone), a clear dose response is visible between the dose 0.3L/ha and 0.5L/ha in 2 assessment done 1 to 2 and 5 to 8 days after the application. Statistical difference was found in 2 out of 7 trials but a clear trend is observed in the different trials.

Table 3.2-43: MED of DLT+FPF EC85 on winter oilseed rape against CEUTAS- Living adults- Summary of the results in Maritime EPPO climatic zone

of the Results in Maritime EPPO climatic zone											
EPPO climatic zone	EU regulatory zone	Number of trials	BBC H Crop Stage at assessment	Sample Size	DAA	UNTREATED (Living adults)		DLT+ FPF EC 85		DLT+ FPF EC 85	
								0.3 L/ha		0.5 L/ha	
								Efficacy (% Abbott)			
						Mean	Min-Max	Mean	Min-Max	Mean	Min-Max
Maritime	Central	7	61-65	1 SHOOT	- 1 - 0	0.4	0.2-0.7	na		na	
		7	61-65	1 SHOOT	1- 2	0.5	0.1-0.9	80.5	51.3-100	87.5	65.8-100
		7	63-67	1 SHOOT	5- 8	0.5	0.1-0.9	76.7	42.9-95.7	85.8	61.9-97.9 97.8

Assessment on larvae-All EPPO climatic zones – Table 3.2-44

Number of living larvae of CEUTAS was also assessed in the end of the trials on 100 pods. A clear dose response is visible in the three EPPO climatic zones between the dose rate 0.3L/ha and 0.5L/ha. In trials in the Central EU regulatory zone of the three EPPO climatic zones, the test product DLT+FPF EC85 applied at the higher dose gave on average the efficacy by 15% superior in the control of larvae of CEUTAS than compared to the lower dose rate (66.6% vs 81.6% in the North-East EPPO climatic zone, 70.2% vs 84.5% in the South-East EPPO climatic zone and 84.0% vs 98.5% in the Maritime EPPO climatic zone).

Table 3.2-44: MED of DLT+FPF EC85 on winter oilseed rape against CEUTAS- Living larvae- Summary of the results in all EPPO climatic zones

EPPO climatic zone	EU regulatory zone	Number of trials	BBC H Crop Stage at assessment	Sample Size	DA A	UNTREATED (Living larvae)		DLT+ FPF EC 85		DLT+ FPF EC 85					
								0.3 L/ha		0.5 L/ha					
												Efficacy (% Abbott)			
						Mean	Min-Max	Mean	Min-Max	Mean	Min-Max				
North-East	Central	4	77-79	100 PODS	24-28	12.1	8.0-17.8	66.6	62.3-73.2	81.6	79.2-84.2				
	Central + Northern	9	71-79	100 PODS	22-28	11.8	5.5-19.0	69.5	45.4-45.5-100	75.4	47.4-96.9				

South-East	Central	9	69-80	100 PODS	21-40	31.8	2.3-117	70.2	44.4-93.8	84.5	69.5-100
	Central + Southern	11	69-80	100 PODS	21-40	43.7	2.3-117	71.9	44.4-93.8	85.1	69.5-100
Maritime	Central	6	67-73	100 PODS	21-25	5.7	2.5-12.5	84.0	60.0-100	98.5	95.0-100

Results of MED of DLT+FPF EC85 against DASYB

Results in the North-East EPPO climatic zone – Table 3.2-45

In the untreated check, the number of pods infested by DASYBR was ~~weak~~ low to moderate from 0.0 to 12.5 per 25 shoots. In 5 trials in the Central EU regulatory zone a clear dose response of the 0.5L/ha dose rate of the test product DLT+FPF EC85 applied at was found, with an efficacy on average of 69.5% (range 31.9-81.5%), vs 55.2% (range 8.8-69.0%) for the lower dose 0.3 L/ha. At 14 to 16 15 days after the application, a clear dose response was still visible between the 2 doses (68.1% vs 51.6%).

Table 3.2-45: MED of DLT+FPF EC85 on winter oilseed rape against DASYBR- Infested pods- Summary of the results in North-East EPPO climatic zone

for the results in North-East EPPO climatic zone											
EPPO climatic zone	EU regulatory zone	Number of trials	BBC H crop stage at assessment	Sample Size	DA A	UNTREATED		DLT+ FPF EC 85		DLT+ FPF EC 85	
								0.3 L/ha		0.5 L/ha	
						Infested pods		% Efficacy (Abbott)			
								Mean	Min-Max	Mean	Min-Max
North-East	Central	5	62-67	25 SHOOTs	0	2.5	0.0-12.5	na		na	
	Central + North ern	6	62-67	25 SHOOTs	0	2.1	0.0-12.5	na		na	
	Central	5	69-71	25 SHOOTs	6	26.3	6.8-78.8	55.2	8.8-69.0	69.5	31.9-81.5
	Central + North ern	6	63-71	25 SHOOTs	6-7	33.5	6.8-78.8	55.1	8.8-69.0	68.4 68.5	31.9-81.5
	Central	5	73-77	25 SHOOTs	14-15	50.2	13.8-112.3	51.6	15.0-70.9	68.1	42.2-85.5
	Central + North ern	8	67-77	25 SHOOTs	14-16	56.0 56.1	4.4 4.5- 164.8	51.8	0.1 0.9- 88.9	67.9	31.0-94.4

~~In the untreated check, before application, the number of pods infested by DASYBR was low to moderate from 0.0 to 12,5 per 25 shoots.~~

Results in the South-East EPPO climatic zone – Table 3.2-46

In the untreated check, the number of pods infested by DASYBR was ~~weak~~ low to moderate from 0.0 to 2,0 per 25 shoots and high in the Southern EU ~~central~~ regulatory zone with 161.8 infested pods per 25 shoots. A dose rate response was recorded, to the test product DLT+FPF EC85, applied at the rates of 0.3 L/ha to 0.5L/ha, in the control of pods infested by of DASYBR in the Central EU regulatory zone, with an efficacy average of 71.5% (range 33.3-95.0%) for the higher dose rate and 59.8% (50.0-80.6%) for the lower dose rate, at 4 to 6 days after the application. Dose response was also found 14 to 16 26 days after the application with an efficacy average of 82.5% (range 60.0-~~95.6~~ **95.2%**) for the higher dose and 68.9% (57.1-78.6%) for the lower dose. The dose rate response from 0.5 L/ha to 0.75L/ha is confirmed in the efficacy results from the supportive trial in ~~EU~~ the Southern ~~EU~~ regulatory zone.

Table 3.2-46: MED of DLT+FPF EC85 on winter oilseed rape against DASYBR- Infested pods- Summary of the results in the South-East EPPO climatic zone

for the Results in the South-East LTP Climatic zone											
EPPO climatic zone	EU regulatory zone	Number of trials	BBC H crop stage at assessment	Sample Size	DA A	UNTREATED		DLT+ FPF EC 85			
								0.3 L/ha		0.5 L/ha	
						Infested pods		% Efficacy (Abbott)			
						Mean	Min-Max	Mean	Min-Max	Mean	Min-Max
South-East	Central	7	55-69	25 SHOOTs	0	1.1 1.2	0.0-2.0	na		na	
	Central + Sout hern	8	55-69	25 SHOOTs	0	21.2	0.0-161.8	na		na	
	Central	5	55-69 61-71	25 SHOOTs	4-6	21.9	1.5-64.5	59.8	50.0-80.6	71.5	33.3-95.0
	Central + Sout hern	6	55-69 61-71	25 SHOOTs	4-6	63.5	1.5-271.3	62.8	50.0-80.6	73.5	33.3-95.0
	Central	7	65-75	25 SHOOTs	14-26	27.0	1.3-88.3 83.3	68.9	57.1-78.6	82.5	60.0-95.6 95.2
	Central + Sout hern	8	55-69 65-75	25 SHOOTs	14-26	105.7	1.3-656.3	69.2	57.1-78.6	81.2 81.9	60.0-95.6

In the untreated check, before application, the number of pods infested by DASYBR was low to moderate;

Results in the Maritime EPPO climatic zone – Table 3.2-47

In ten trials conducted in the Czech Republic, the number of pods infested by DASYBR in the untreated check was weak low to good high from 0.0 to 20.0 per 25 shoots. A clear dose response is visible between the dose rate 0.3L/ha and 0.5L/ha in 2 assessments at 5 to 8 days after the application and at 14 to 16 days after the application. The test product DLT+FPF EC85 provides a very good on average efficacy of 92.5% (range 86.5-100%) in the first assessment and 83.3 84.0% (range (61.5-91.9%) for at the second assessment, compared to 79.2% (range 62.5-97.5%) and 71.0 72.5% (range 53.8-87.2%) respectively, provides by the lower dose.

Table 3.2-47: MED of DLT+FPF EC85 on winter oilseed rape against DASYBR-Maritime EPPO climatic zone

EPPO climatic zone	EU regulatory zone	Number of trials	BBC H crop stage at assessment	Sample Size	DA A	UNTREATED		DLT+ FPF EC 85		DLT+ FPF EC 85	
								0.3 L/ha		0.5 L/ha	
						Infested pods		% Efficacy (Abbott)			
						Mean	Min-Max	Mean	Min-Max	Mean	Min-Max
Maritime	Central	10	61-65	25 SHOOTs	-1-0	7.0	0.0-20.0	na		na	
		9	65-69	25 SHOOTs	5-8	7.3	3.8-10.5	79.2	62.5-97.5	92.5	86.5-100
		10	65-71	25 SHOOTs	14-16	18.7-17.9	3.3-99.5	71.0-72.5	53.8-87.2	83.3-84.0	61.5-91.9

Assessment on larvae – the North-East and the Maritime EPPO climatic zones – Table 3.2-48

The number of living larvae of DASYBR was also assessed in the end of the trials on 100 pods. A dose response is visible in the Maritime EPPO climatic zone between the dose rate 0.3L/ha and 0.5L/ha. In 4 trials in the Central EU regulatory zone of the Maritime EPPO climatic zone, test product DLT+FPF

EC85 applied at the higher dose gave ~~in~~ on average the efficacy of 96.6% (range 93.3-100%) at the 0.5 L/ha proposed dose rate, and 86.9% ~~the lower dose rate~~ (range 79.2% ~~vs~~ 98.6%) at the lower dose. In one of those 4 trials a statistically significant difference was found between the dose rates. A smaller dose response was found in the 4 trials in Central and Northern EU regulatory zone of the North-East EPPO climatic zone.

Table 3.2-48: MED of DLT+FPF EC85 on winter oilseed rape against CEUTAS- Living larvae- Summary of the results in North-East and Maritime EPPO climatic zones

EPPO climatic zone	EU regulatory zone	Trial number	BBC H crop stage at assessment	Sample Size	DAA	UNTREATED		DLT+ FPF EC 85		DLT+ FPF EC 85	
								0.3 L/ha		0.5 L/ha	
						Living larvae		% Efficacy (Abbott)			
						Mean	Min-Max	Mean	Min-Max	Mean	Min-Max
North-East	Central + Northern	4	71-73	100 PODS	21-28	17.9	14.0-26.3	61.7	23.3-87.5	67.7	37.0-91.1
Maritime	Central	4	67-77	100 PODS	21-28	83.9	13.5-161.3	86.9	79.2-98.6	96.6	93.3-100

Out of all these thirty-three trials (all EU regulatory zones), the ~~mean~~ average efficacy at the proposed dose rate of 0.5L/ha was ~~better~~ higher than at the lower tested dose rates ~~both~~ of 0.3 L/ha. According to the presented results of reliable trials carried out in Maritime, South-East and North-East EPPO climatic zone, the dose rate of 0.5 L/ha (1N) of DLT+FPF EC85 provided the optimum overall control and should be considered as effective against the pests CEUTAS and DASYBR, two majors pests of oilseed rape.

Conclusion on the Minimum effective dose of DLT +FPF EC85 against CEUTAS and DASYBR

According to the presented results, the dose rate of 0.5 L/ha of DLT+FPF EC85 provided the optimum overall control and should be considered as effective against these two major pests, for which activity of DLT+FPF EC85 is claimed. As a result, the proposed rate of 0.5 L/ha should be considered the minimum effective dose to deliver broad spectrum control of CEUTAS and DASYBR under a wide range of environmental conditions.

Comments of zRMS:

The applicant submitted the results from 33 field efficacy trials to justify the MED for the control of *Ceutorhynchus obstrictus* (CEUTAS) and *Dasineura brassica* (DASYBR) on winter oilseed rape (10 trials in the North-East EPPO climatic zone, 13 - in the South-East EPPO climatic zone and 10 trials in the Maritime EPPO climatic zone). Clear dose response between the doses 0,3 L/ha and 0,5 L/ha of DLT+FPF EC85 was recorded in all three EPPO climatic zones. An average efficacy of tested product was higher for the dose rate 0.5 L/ha compared to the lower dose rate 0,3 L/ha for both CEUTAS (in control of living adults and living larvae) and DASYBR (considered the number of infested pods and the control of living larvae) in all three EPPO climatic zones. The dose rate of 0,5 L/ha can be regarded as the minimum effective dose for the control of CEUTAS and DASYBR in winter oilseed rape.

3.2.3 Efficacy tests (KCP 6.2)

Efficacy test information is covered in the following chapter, which includes: testing organisations, locations of trials, methodologies and result summaries. Efficacy data are presented by USE as listed in the Table 3.2-4. For each use, data are grouped per each EPPO climatic zone. Efficacy data are then summarized by assessment type and timing, depending on the target pest and EPPO recommendations. The data enclosed in the summary tables are fully detailed in the documents referenced as [M-659525-01-1](#), [M-659528-01-1](#), M-659527-01-1. Detailed summary tables with single trials results and statistical analysis are presented in the BAD (Please refer to Doc. [M-665892-01-1](#)).

USE01: Efficacy of DLT+FPF EC85 on oilseed rape against *Ceutorhynchus napi* (CEUTNA) and *Ceutorhynchus quadridens* (CEUTQU)

In order to demonstrate the efficacy of DLT+FPF EC85 against *Ceutorhynchus napi* (CEUTNA) and *Ceutorhynchus quadridens* (CEUTQU) in oilseed rape, the following chapter summarizes the results from a series 41 efficacy field trials (all in winter oilseed rape). Twenty-nine trials were carried out in the European Central regulatory zone (7 in Poland, 2 in Romania, 7 in Hungary, 6 in Slovakia and 7 in the Czech Republic). In addition, 7 field trials carried out in the European Northern regulatory zone (3 in Lithuania and 4 in Latvia) and 5 in the European ~~Northern~~ Southern regulatory zone (in Bulgaria) were added to support the North-East and South-East EPPO climatic zone. The trials were implemented in farmer's fields under conditions of natural infestation and were distributed across the three EPPO climatic zones. The single trial reports are included in Compilation of Trial Reports [M-659525-01-1](#) with the corresponding trial list. The number of trials conducted in each climatic zone and country is shown in Table 3.2-49 below.

Table 3.2-49: Distribution of trials according to the crops, the climatic zones and countries

Crop	EPPO climatic zone	Regulatory Zone	Country	Year	Number of trials	Total					
Winter oilseed rape	North-East	Central	Poland	2014	2	7					
				2015	2						
				2016	2						
				2017	1						
		Northern	Lithuania	2015	1	3	7				
				2017	2						
			Latvia	2015	2	4					
				2017	2						
				North-East EPPO climatic zone						14	
				South-East	Central	Romania		2015	1	2	15
	2016	1									
	Hungary	2014	2			7					
		2015	1								
		2016	2								
		2017	2								
		Slovakia	2014				3	6			
	2015		2								
	2016		1								
	Southern	Bulgaria	2014		2	5	5				
			2015		1						
			2016		2						
	South-East EPPO climatic zone						20				
	Maritime	Central	Czech republic		2014	4	7				
				2016	2						
				2017	1						
	Maritime EPPO climatic zone						7				
	Total	All EPPO climatic zones		Winter oilseed rape			41				

* Details of the methodology

A general overview of the methodology in efficacy trials carried out in oilseed rape CEUTNA and CEUTQU is presented in Table 3.2-50 which follows. Trials are also used in section 3.2.1. Preliminary part and in section 3.2.2. Minimum effective dose.

Table 3.2-50: Details on trial methodology (38 field trials) – CEUTNA and CEUTQU

Guidelines	General guidelines	PP1/135(3) Phytotoxicity assessment PP1/152(4) Design and analysis of efficacy evaluation trials PP1/181(4) Conduct and reporting of efficacy evaluation trials including GEP PP/225(2) Minimum effective dose
	Specific guidelines	PP1/219(1) <i>Ceutorhynchus napi</i> and <i>Ceutorhynchus pallidactylus</i> on rape
Experimental design	Plot design	Randomized Complete Block, RCB, RCBD
	Plot size	20 to 250 M ²
	Number of replications	4
Crop	Trials per crop	<i>Brassica napus</i> L. ssp. <i>napus</i> (winter) (41)
	Varieties per crop	Alister ; Atenzo; Armstrong; Arsenal; Artoga ; Aviator; Bagira ; Callifornium; Cantate; Canti; DA vinci; Digger (2); DK Exception; DK Exquisite; DK Imminent CL; DK Impression; Dribbler; Duplex; Kodiak, Konkret; Kuga; KWS Hybrirock ; Manitoba; Marathon; Ontario; PT 205; PR45D05; Raffines; Rescator; Rohan (3); Slaki CS; Sunset ; SY Saveo; Technic; Triangle; Visby (3)
	Sowing dates	August us to September
Application	Crop stage (BBCH) at application	BBCH 21 to BBCH 63 64
	Number of applications	1
	Spray volumes	250L/ha to 300L/ha
Assessment	Assessment types	Living larvae; Infested plants
	Assessment timings	North-East EPPO climatic zone: CEUTNA: Living larvae 29-70DAA; Infested plants 16 15-70DAA CEUTQU: Living larvae 15-70DAA; Infested plants 23-70DAA South-East EPPO climatic zone CEUTNA: Living larvae 7-96DAA; Infested plants 14-96DAA CEUTQU: Living larvae and Infested plants 34-41DAA Maritime EPPO climatic zone CEUTNA: Living larvae; Infested plants 20-54DAA CEUTQU: Living larvae; Infested plants 42-54DAA
Other relevant information	Infestation	Natural
	Site type	Field

Assessment was tested in line with EPPO standard requirements with exception of 1 trials with a small deviation. In all except one trial the experimental plots consisted of an overall plot area between ~~20~~ 25-250 m², which ~~is not~~ conforms for 1 trial to the minimal plot area recommended by EPPO standard PP1/219(1) (25 m²) to guarantee a better uniformity in the infestation level. The single trial in question, IR14POLR07006I, had the plot area of 20 m². DLT+FPF EC85 was tested at 0.75 L/ha on oilseed rape to control CEUTNA and CEUTQU. This rate reflects the proposed label rate. Efficacy was tested under a range of environmental conditions to fully challenge the product. DLT+FPF EC85 was compared to different insecticides Proteus and Nurelle.

Summary of the results

In the summary Table below, orthogonal comparisons between the supported dose rate of DLT+FPF EC85 and the reference product are presented. Only trials/assessments considered as valid to evaluate the efficacy of DLT+FPF EC85 against *C. napi* and *C. quadridens*, i.e. those in which reference products behaved as expected and infestation levels were sufficiently high, are included in trial groupings below. The number of larvae and plants infested were counted for the both pests and presented per EPPO

climatic zone, per pest and both pests together. *C. napi* and *C. quadridens* being pests with similar biology on one side, and on the other side the application can target the 2 pests at the same time.

Results in the North-East EPPO climatic zone – the number of larvae – Table 3.2-51

In 5 trials in the Central EU regulatory zone in the North-East EPPO climatic zone, DLT+FPF EC85 showed the efficacy on average similar compared to the test product (98.2% vs 95.4%) in the control of CEUTNA. The control of CEUTQU was evaluated in 5 trials in the Central EU regulatory zone with a similar average efficacy between the test product and the reference product (96.3% vs 94.1%). These results are confirmed with the supportive trials conducted in Latvia and Lithuania (EU Northern regulatory zone).

Table 3.2-51: Efficacy of DLT+FPF EC85 on winter oilseed rape against larvae of CEUTNA and CEUTQU-Summary of the results in North-East EPPO climatic zone

Summary of the Results in North-East EP PO climatic zone												
EP PO cli- mat- ic zon- e	Target	EU reg- ula- tor- y zon- e	Trial number	BB CH cro p stag- e	Sam- ple Size	DAA	UN- TREATED (Living In- sects)		DLT+ FPF EC 85		Proteus OD110	
									0.75 L/ha		0.6-0.75 L/ha	
									% Efficacy (Abbott)			
Me- an	Min- Max											
Nor- th- East	CEUT NA	Central	5	67- 73	1 PLA NT	29-70 DAA	0.9	0.2- 1.6	98.2	95.7-100	95.4	85.3-100
		Central + Nor- ther- n	7	67- 73	1 PLA NT	29-70 DAA	0.7	0.2- 1.6	93.7	80-100	89.7	68.0-100
	CEUT QU	Central	5	67- 69	1 PLA NT	15-70 DAA	1.2	0.4- 2.5	96.3	92.3-100	94.1	85.9-100
		Central + Nor- ther- n	10	67- 69	1 PLA NT	15-70 DAA	1.7	0.2- 3.6	87.4	69.2-100	83.4	61.5-100
	CEUT NA+ CEUT QU	Central	10	67- 73	1 PLA NT	15- 70 DAA	1.0	0.2- 2.5	97.3	92.3-100	94.7	85.3-100
		Central + Nor- ther- n	14, 17 data points	67- 73	1 PLA NT	15- 70 DAA	1.3	0.2- 3.6	90.0 92.1	69.2 70.3-100	86.0 89.6	61.5 63.5-100

Results in the North-East EPPO climatic zone – the % of plants infested– Table 3.2-52

In 7 trials in the Central EU regulatory zone in the North-East EPPO climatic zone, DLT+FPF EC85 showed a similar or higher on average efficacy in the control of plants infested by CEUTNA in comparison with the test product (93.5% vs 90.5%). The control of CEUTQU was evaluated in 3 trials in the Central EU regulatory zone, with a similar on average efficacy between the test product and the reference product (93.6% vs 91.9%). These results are confirmed with the supportive trials conducted in Latvia and Lithuania (EU Northern regulatory zone).

Table 3.2-52: Efficacy of DLT+FPF EC85 on winter oilseed rape against plants infested by CEUTNA and CEUTQU-Summary of the results in North-East EPPO climatic zone

EPP O	Target		Nu- mb	BBC H	Sample Size	DA A		DLT+ FPF EC 85	Proteus OD110
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cli- mati c zone		EU reg- ula- tory zone	er of tri- als	crop stage			UNTREATED (% of Plant in- fested)		0.75 L/ha		0.6-0.75 L/ha	
							% Efficacy (Abbott)					
							Mean	Min- Max	Me an	Min- Max	Mean	Min- Max
Nort h- East	CEUT NA	Central	7	65-69	20 PLANTS	15- 70	41.9	11.3- 100	93.5	86.4- 100	90.5	72.7- 100
		Central + Nort hern	9	65-69	20-40 PLANTS	15- 70	36.4	5.0-100	88.0	62.5- 100	84.5	50.0- 100
	CEUT QU	Central	3	67-69	20 PLANTS	29- 70	23.1	16.3- 45.0	93.6	88.9- 100	91.9	84.0- 100
		Central + Nort hern	4	67-71	20-25 PLANTS	23- 70	29.7	23.8 16.3- 45.0	82.1	47.6- 100	77.3	33.3- 100
	CEUT NA- CEUT QU	Central	10	65-69	20-25 PLANTS	15- 70	38.6	11.3- 100	93.5	86.4- 100	90.9 91.4	72.7- 100
		Central + Nort hern	13	65-69 71	20-40 PLANTS	15- 70	34.4 39.6	5.0 3.6- 100	86.2	47.6- 100	72.8 83.5	33.3- 100

Results in South-East EPPO climatic zone – the number of larvae – Table 3.2-53

In 11 trials in the Central EU regulatory zone, DLT+FPF EC85 showed a similar average efficacy than the reference product Proteus in the control of the larvae of CEUTNA: 85.0% and 86.5%, respectively. These results are confirmed with the supportive trials conducted in Bulgaria (Southern EU regulatory zone). Similar efficacy was also found between the test product (93.2%) and the reference product Proteus (87.9%) in the control of CEUTQU larvae, in 4 trials carried out in the Central EU regulatory zone. In 2 trials in the Central EU regulatory zone, DLT+FPF EC85 showed a similar the on average efficacy of 74.6%, than comparable to the reference Nurelle D 550EC (69.3%) in the control of plants infested by CEUTNA larvae. These results are confirmed with the 2 supportive trials conducted in Bulgaria (Southern EU regulatory zone).

The results on efficacy data against CEUTNA and CEUTQU are presented together (both pests being similar). Similar efficacy average was found in 15 trials in the Central EU regulatory zone between DLT+FPF EC 85 (87.2% 85.7%) and the reference Proteus (86.9%). These results are confirmed with the 3 supportive trials conducted in Bulgaria (Southern EU regulatory zone).

Table 3.2-53: Efficacy of DLT+FPF EC85 on winter oilseed rape against larvae of CEUTNA and CEUTQU- Summary of the results in South-East EPPO climatic zone

EP PO cli- ma- tic zon e	Tar- get	EU reg- ula- tor y zon e	Nu mber of trials	BB CH cro p sta ge	Sam- ple Size	D A A	UNTREATED (Living larvae)		DLT+FPF EC85		NURELLE D 550 EC		PROTEUS OD110	
									0.75 L/ha		0.6 L/ha		0.5-0.7-0.75 L/ha	
									% Efficacy (Abbott)					
							Mean	Min- Max	Mea n	Min- Max	M ea n	Min- Max	Mea n	Min- Max
So uth- Eas t	CEU TNA	Central	11	59-69	20 PLAN TS	23-96	99.7	18.0-493.3	85.0	59.5-100	86.5		70.9-100	
		Central + Southern	14	59-69	20 PLAN TS	7-96.	156.8	18.0-505.5	80.6	59.2-100	81.3		54.4-100	

		Central	2	65	20 PLAN TS	28-33	33.8	26.8-40.8	74.6	66.9-82.2	69.3	58.3-80.4
		Central + Southern	4	65-67	20 PLAN TS	28-37	201.6	26.8-406.5	68.7	60.0-82.2	66.3	58.3-80.4
	CEU TQU	Central	4	61-69	20 PLAN TS	28-41	40.1	12.8-79.5	93.2	90.6-96.1	87.9	83.3-92.3
	CEU TNA-CEU TQU	Central	15	59-69	20 PLAN TS	23-96	83.8 77.9	12.8-493.3	87.2 85.7	59.5-100	86.9	70.9-100
		Central + Southern	18	59-69	20 PLAN TS	7-96	117.9 109.2	12.8-493.3	84.1 81.2	59.5 59.2-100	82.8 83.9	54.4 60.1-100
		Central	2	65	20 PLAN TS	28-33	33.8	26.8-40.8	74.6	66.9-82.2	69.3	58.3-80.4
		Central + Southern	4	65-67	20 PLAN TS	28-37	201.6	26.8-406.5	68.7	60.0-82.2	66.3	58.3-80.4
		Central	2	65	20 PLAN TS	28-33	33.8	26.8-40.8	74.6	66.9-82.2	69.3	58.3-80.4
		Central + Southern	4	65-67	20 PLAN TS	28-37	201.6	26.8-406.5	68.7	60.0-82.2	66.3	58.3-80.4
		Central	2	65	20 PLAN TS	28-33	33.8	26.8-40.8	74.6	66.9-82.2	69.3	58.3-80.4

Results in South-East EPPO climatic zone– the % of plants infested – Table 3.2-54

In 11 trials in the Central EU regulatory zone, DLT+FPF EC85 showed a similar average efficacy than the reference product Proteus for the control of CEUTNA larvae with respectively 85.0% and 86.5%.

In 5 trials in the Central EU regulatory zone, DLT+FPF EC85 showed a similar average efficacy than to the reference product Proteus, in the reduction of plants infested by CEUTNA with respectively 78.7% and 75.3%. These results are confirmed with the 4 supportive trials conducted in Bulgaria (Southern EU regulatory zone). Similar efficacy was also found between the test product (71.5%) and the reference product Proteus (67.3%) in the control of plants infested by the pest CEUTQU in 3 trials in the Central EU regulatory zone.

In 2 trials in the Central EU regulatory zone, DLT+FPF EC85 showed a similar average efficacy (60.8%) than to the reference Nurelle D 550EC (61.0%) in the control of plants infested by CEUTNA larvae. These results are confirmed with the 2 supportive trials conducted in Bulgaria (Southern EU regulatory zone).

The results on efficacy data against CEUTNA and CEUTQU are presented together (both pest being similar), similar efficacy average was found in 10 trials in the Central EU regulatory zone between DLT+FPF EC 85 (85.5% 72.9%) and the reference Proteus (80.3% 71.8%). These results are confirmed with the 3 supportive trials conducted in Bulgaria (Southern EU regulatory zone).

Table 3.2-54: Efficacy of DLT+FPF EC85 on winter oilseed rape against plants infested by CEUTNA and CEUTQU-Summary of the results in South-East EPPO climatic zone

CEU FFG - Summary of the results in South-East EPP O climatic zone														
EPP O cli- mati- c zone	Tar- get	EU regu- la- tor y zone	Nu m be r of tri- als	BB CH cro- p sta- ge	Sam- ple Size	D A A	UNTREATED (% of infested plants)		DLT+FPF EC85		NURELLE D 550 EC		PROTEUS OD110	
									0.75 L/ha		0.6 L/ha		0.5-0.7-0.75 L/ha	
									% Efficacy (Abbott)					
Sout h-Est	CEU TNA	Ce ntr al	5	65- 69	20 PLAN TS	23 - 96	75	37.5- 100	78.7	45.9- 100	75.3		44.6- 100	

		Ce ntr al + So uth ern	9	65- 69	20 PLAN TS	7- 96	82.5	37.5- 100	71.1	43.2- 100	64.6	28.4- 100
		Ce ntr al	2	65	20 PLAN TS	28 - 33	56.3	50- 62.5	60.8	57.5- 64	61. 0	60- 62
		Ce ntr al + So uth ern	4	65- 67	20 PLAN TS	28 - 37	78.1	50-100	46.6	27.5- 64	46. 8	28.8 - 62.0
	CEU TQU	Ce ntr al	3	61- 69	20 PLAN TS	34 - 41	63.8	22.5- 97.5	71.5	41- 94.4	67.3	39.7- 83.3
	CEU TNA + CEU TQU	Ce ntr al	10	65- 69	20 PLAN TS	23 - 96	61.0 68.3	12.8 22.5- 100	84.5 72.9	45.9 41.0- 100	80.3 71.8	44.6 39.7- 100
		Ce ntr al + So uth ern	13	65- 69	20 PLAN TS	7- 96	69.4 75.0	12.8 22.5- 100	77.9 69.0	43.2 41.0- 100	71.7 64.7	28.4- 100
		Ce ntr al	2	65	20 PLAN TS	28 - 33	56.3	50- 62.5	60.8	57.5- 64	61. 0	60- 62
		Ce ntr al + So uth ern	4	65- 67	20 PLAN TS	28 - 37	78.1	50-100	46.6	27.5- 64	46. 8	28.8 - 62

Results in Maritime EPPO climatic zone – the number of larvae – Table 3.2-55

In 8 7 trials in EU regulatory zone in the Maritime EPPO climatic zone, DLT+FPF EC85 showed similar efficacy in the control of CEUTNA to the reference Proteus; the average efficacy from 6 trials was 93.3% (range 83.5-100%) and 94.4% (range 91.2-100%), respectively. A similar efficacy was also found in 2 trials for the control of CEUTQU, with the average efficacy values of 74.8% (range 63.6-86.0%) for the test product and 77.7% (range 63.6-91.8%) for the reference Proteus.

Table 3.2-55: Efficacy of DLT+FPF EC85 on winter oilseed rape against larvae of CEUTNA and CEUTQU- Summary of the results in Maritime EPPO climatic zone

EPPO cli- matic zone	Target	EU reg ula tor y zo ne	Number of trials	BBC H crop stag e	Sample Size	DA A	UN- TREATED (Living lar- vae)		DLT+ FPF EC 85		PROTEUS OD110	
									0.75 L/ha		0.75 L/ha	
							% Efficacy (Abbott)				Me an	Min- Max
Mari- time	CEUTN A	Ce ntr al	6	65- 79	20 PLANT S	20- 54	23. 7	3.8- 58.3	93.3	83.5- 100	94. 4	91.2- 100
	CEUTQ U		2	65- 69	20 PLANT S	42- 54	27. 3	2.8- 51.8	74.8	63.6- 86.0	77. 7	63.6- 91.8

	CEUTN A+ CEUTQ U		8 data points, 7 trials	65- 79	20 PLANT S	20- 54	24. 6	2.8- 58.3	88.6	63.6- 100	90. 2	63.6- 100
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Results in Maritime EPPO climatic zone – the % of plants infested – Table 3.2-56

In 8 trials in EU regulatory zone in the Maritime EPPO climatic zone, DLT+FPF EC85 showed a an inferior efficacy of plants infested by CEUTNA in 6 trials with an efficacy average of 77.5 % (range 59.1-100%) for the test product and 86.5% (range 71.4-100%) for the reference Proteus. Only one statistical difference was found in these 6 trials between the test product and the reference product. A similar efficacy was found in 2 trials for the control of CEUTQU with an efficacy average of 54.8% (range 33.8-75.9%) for the test product and 56.4% (range 38.6-74.1%) for the reference Proteus.

In 7 trials carried out in the Maritime EPPO climatic zone, DLT+FPF EC85 had shown, on average, the efficacy inferior to the standard reference product Proteus, in reduction of the number of plants infested by CEUTNA. The mean efficacy of the test item from 6 trials was 77.5 % (range 59.1-100%), compared to the efficacy of Proteus: 86.5% (range 71.4-100%). However, in only one, out of those six trials, the statistically significant difference was found between the test and the reference product. A similar efficacy of the test and reference product was found in 2 trials concerned with the plants infested by CEUTQU, with the mean efficacy of 57.3% (range 38.6-75.9%) for DLT+FPF EC 85 and 56.4% (range 38.6-74.1%) - for Proteus.

Table 3.2-56: Efficacy of DLT+FPF EC85 on winter oilseed rape against plants infested by CEUTNA and CEUTQU-Summary of the results in Maritime EPPO climatic zone

CEUT QU Summary of the Results in Maritime EPP O climatic zone												
EPP O climatic zone	Tar- get	E U re gul ato ry zo ne	Number of trials	BB CH crop stag e	Sample Size	DA A	UN- TREATED (% of Plant infested)		DLT+ FPF EC 85		PROTEUS OD110	
									0.75 L/ha		0.75 L/ha	
							% Efficacy (Abbott)		Me an	Min- Max	Mean	Min- Max
Mari- time	CEUT NA	Ce ntr al	6	65- 79	20 PLANT S	20- 54	45. 8	15.0- 82.5	77.5	59.1-100	86. 5	71.4- 100
	CEUT QU		2	65- 69	20 PLANT S	42- 54	61. 3	55- 67.5	54.8 57.3	33.8 38.6-75.9	56. 4	38.6- 74.1
	CEUT NA + CEUT QU		8 data points, 7 trials	65- 79	20 PLANT S	20- 54	49. 7	15.0- 82.5	71.8 72.4	33.8 38.6-100	79. 0	38.6- 100

When efficacy was calculated according to the % of infested plants, in 6 trials in EU regulatory zone in the Maritime EPPO climatic zone, DLT+FPF EC85 showed an inferior efficacy, with an efficacy average of 77.5 % (range 59.1-100%) for the test product and 86.5% (range 71.4-100%) for the reference Proteus.

Conclusion of the Efficacy of DLT +FPF EC85 against *C. napi* and *C. quadridens*

Against *C. napi* and *C. quadridens*, 41 fields trials were implemented in the period of 2014-2017 to evaluate the efficacy of DLT+FPF EC85. All the trials were conducted to GEP by officially recognized testing organisations and followed the appropriate EPPO standards. From these trials, it was demonstrated that the application of DLT+FPF EC85 at 0.75 L/ha, provides effective and consistent control of population and damages of *C. napi* and *C. quadridens* at a level of performance similar to that of the different standard products. It can therefore be concluded that a label claim for the use of DLT+FPF EC85 in oilseed rape against CEUTNA and CEUTQU at 0.75 L/ha in the European regulatory Central zone has been fully justified by the data discussed above.

Comments of zRMS:

The applicant submitted results from 41 field efficacy trials to demonstrate the efficacy of the test product in control of the stem weevils, CEUTNA and CEUTQU, in the winter oilseed rape. The efficacy of the DLT+FPF EC85, at its proposed dose rate of 0.75 L/ha, aggregated for the two pest species and averaged within the EPPO zones plus their parts belonging to other EU administrative zones, can be summarized as follows, for pest severity (number of larvae per plant) and pest incidence (% of plants infested):

14 trials in the North East EPPO plus North EU (LT, LV), severity:	92.1 % (70.3-100 %) (Table 3.2-51)
13 trials in the North East EPPO plus North EU (LT, LV), incidence:	86.2 % (47.6-100 %) (Table 3.2-52)
18 trials in the South East EPPO plus South EU (BG), severity:	81.2 % (59.2-100 %) (Table 3.2-53)
13 trials in the South East EPPO plus South EU (BG), incidence:	69.0 % (41.0-100 %) (Table 3.2-54)
7 trials in the Maritime EPPO, severity:	88.6 % (63.6-100 %) (Table 3.2-55)
7 trials in the Maritime EPPO, incidence:	72.4 % (38.6-100 %) (Table 3.2-56)

Furthermore, the summaries (Tables 3.2-51 – 3.2-56) have shown that the test product performed the level comparable to the standard Proteus (in all zones), and exceeded the level of performance of another standard, Nurelle (in the South East zone).

The numerically lower efficacy of the test item compared to Proteus, observed in the Maritime zone, was confirmed as statistically significant in only one trial, IR16CZE231TU01, out of six carried out in that zone and concerned with CEUTNA. The five remaining trials in that set demonstrate the statistical homogeneity between the efficacy of the test item and the standard product, even though in some of them the test item performed at

slightly lower a level, compared to standard. On the contrary, the two Maritime zone trials concerned with CEUTQU show the efficacy of DLT+FPF EC85 equivalent to the standard Proteus.

In order to avoid any ambiguity, the four tables showing individual trial data on the stem weevil control in the Maritime zone, showing the homogenous group markings, were pasted below, from the BAD. Please note, that in the table 3.2-111 (CEUTQU, incidence) the efficacy for the test product has been corrected, because the applicant had erroneously used the percentage of plants infested (on average 6.75 plants per sample of 20 = 33.8%) instead of efficacy value according to Abbott formula (in this case: 38.6%, as on average 11.0 plants were infested in the UNCK). The Table 3.2-56 in dRR (this document), presenting mean values, already takes this correction into account.

BAD, Table 3.2-108, **CEUTNA, efficacy on severity (no of living larvae)** (Maritime zone)

trial number	BBCH on assessm.	sample size	assessm. date	UNCK (living larvae)		DLT+FPF EC85 0.75 L/ha		PROTEUS OD110 0,75 L/ha	
IR14CZE321KL01	69	20 PLANTS	54 DAA	10.0	a	97.5	d	92.5	cd
IR14CZE321NE01	67	20 PLANTS	39 DAA	6.3	a	100	b	100	b
IR14CZE321TR01	65	20 PLANTS	42 DAA	58.3	a	90.6	c	93.6	c
IR16CZE231KL01	69	20 PLANTS	52 DAA	3.8	a	100	b	93.3	b
IR16CZE231TU01	79	20 PLANTS	51 DAA	41.0	a	83.5	d	95.7	e
IR17CZE230NE01	65	20 PLANTS	20 DAA	22.8	a	87.9	c	91.2	c

BAD, Table 3.2-109, **CEUTNA, efficacy on incidence (% infested plants)** (Maritime zone)

trial number	BBCH on assessm.	sample size	assessm. date	UNCK (% of in-fested plants)		DLT+FPF EC85 0.75 L/ha		PROTEUS OD110 0,75 L/ha	
IR14CZE321KL01	69	20 PLANTS	54 DAA	55.0	a	81.8	ef	84.1	f
IR14CZE321NE01	67	20 PLANTS	39 DAA	26.3	a	100	b	100	b
IR14CZE321TR01	65	20 PLANTS	42 DAA	78.8	a	76.2	b	82.5	b
IR16CZE231KL01	69	20 PLANTS	52 DAA	15.0	a	83.3	b	91.7	b
IR16CZE231TU01	79	20 PLANTS	51 DAA	82.5	a	59.1	b	89.4	c
IR17CZE230NE01	65	20 PLANTS	20 DAA	17.5	a	64.3	ab	71.4	b

BAD, Table 3.2-110, **CEUTQU, efficacy on severity (no of living adults)** (Maritime zone)

trial number	BBCH on assessm.	sample size	assessm. date	UNCK (% of in-fested plants)		DLT+FPF EC85 0.75 L/ha		PROTEUS OD110 0,75 L/ha	
IR14CZE321KU01	69	20 PLANTS	54 DAA	2.8	-	63.6	-	63,6	-
IR14CZE321TR01	65	20 PLANTS	42 DAA	51.8	a	86.0	c	91,8	c

BAD, Table 3.2-111, **CEUTQU, efficacy on incidence (% infested plants)** (Maritime zone)

trial number	BBCH on assessm.	sample size	assessm. date	UNCK (% of in-fested plants)		DLT+FPF EC85 0.75 L/ha		PROTEUS OD110 0,75 L/ha	
IR14CZE321KU01	69	20 PLANTS	54 DAA	55	ab	33.8 38,6	bc	38.6	bc
IR14CZE321TR01	65	20 PLANTS	42 DAA	67.5	a	75.9	b	74.1	b

Overall, it may be concluded that the test product, DLT+FPF EC85, applied in winter oilseed rape at the dose rate of 0.75 L/ha against the stem weevils CEUTNA and CEUTQU had, on average, demonstrated good level of control of the stem weevils, in majority of trials across the three EPPO zones concerned. Only in the Maritime EPPO zone the level of control should be called rather moderate, but this only with respect to pest incidence. With respect to severity in the Maritime zone (Table 3.2-108, CEUTNA) it may be noticed that the efficacy in the individual trials is largely comparable (*i.e.* insignificantly lower) and sometimes numerically equal to, or higher, compared to that of the standard. Therefore, despite some flaws to the individual trials, the general overview offered by the complete data set on stem weevils allows to declare that the applicant's claim concerning the USE01 in winter oilseed rape is justified.

USE02: Efficacy of DLT+FPF EC85 on oilseed rape against *Brassicogethes aeneus* (MELIAE)

In order to demonstrate the efficacy of DLT+FPF EC85 against *Brassicogethes aeneus* (MELIAE) in oilseed rape, the following chapter summarizes the results from a series of 24 efficacy field trials (20 in winter oilseed rape and 4 in spring oilseed rape). Twenty trials were carried out in the European Central EU regulatory zone and 2 supportive field trials carried out in the European Southern EU regulatory zone and 2 in the European Northern EU regulatory zone. The trials were implemented in farmer's fields under conditions of natural infestation and were distributed across the EPPO North-East and South-East EPPO climatic zones. No trials carried out in the Maritime EPPO climatic zone have been submitted as no countries belonging to this EPPO climatic zone are supported this use in this submission. Single trial reports are included in Compilation of Trial Reports [M-659528-01-1](#) with the corresponding trial list. The number of trials conducted in each climatic zone and country is shown in Table 3.2-57 below.

Table 3.2-57: Distribution of trials according to the crops, the climatic zones and countries

Table 5.2-37: Distribution of trials according to the crops, the climatic zones and countries									
Crop	EPPO climatic zone	Regulatory Zone	Country	Year	Number of trials	Total			
Winter oilseed rape	North-East	Central	Poland	2014	4	12			
				2015	3				
				2016	3				
				2017	2				
	South-East	Central	Romania	2017	1	1	8		
			Hungary	2015	1	4			
				2016	1				
				2017	2				
			Slovakia	2014	1	1			
		Southern	Bulgaria	2017	2	2			
Sum	All EPPO climatic zones					20			
Spring oilseed rape	North-East	Central	Poland	2014	1	2	4		
				2016	1				
		Northern	Latvia	2015	1	2			
			Lithuania	2016	1				
Sum	North-East EPPO climatic zone					4			
Total	All EPPO climatic zones		Winter and spring oilseed rape					24	

Testing facilities and organisations

The testing facilities responsible for the conduct of GEP trials were the development teams of the country subsidiary organisations of Bayer CropScience and external testing organisations. All these organizations were officially recognized by the competent authorities to be able to carry out field registration trials in accordance with the principles of GEP. They are listed under Chapter 3.7 and copies of the corresponding and relevant certificates are included in the BAD under the same Chapter 3.7.

Methodology

Methodology used in the efficacy trials is shown in Tables 3.2-xx 58. ~~As one trial was often infested by more than one claimed disease species, details on trial methodologies are not presented per claimed disease species, but per EPPO climatic zone.~~ As partly different assessment intervals and in most cases different numbers of assessments were used in the trials, depending on the infestation evolution, specific time windows were defined for the overall efficacy assessment of DLT+FPF EC85. Therefore, to be able to compare trials with different assessment schemes the following time windows were defined:

Assessments 1 - 3 days after application – immediate effect

Assessment 4 - 6 days after application – midterm effect

Assessments 7 – 13 days after application – long term effect

*Details of the methodology

A general overview of the methodology in efficacy trials carried out in oilseed rape against MELIAE is presented in Table 3.2-58 which follows. These trials are also used in section 3.2.1. Preliminary Preliminary part and section 3.2.2. Minimum effective dose.

Table 3.2-58: Details on trial methodology (field trials) – MELIAE

Guidelines	General guidelines	PP1/135(3) Phytotoxicity assessment PP1/152(4) Design and analysis of efficacy evaluation trials PP1/181(4) Conduct and reporting of efficacy evaluation trials including GEP PP1/225(2) Minimum effective dose
	Specific guidelines	PP1/178(3) <i>Meligethes aeneus</i> on rape
Experimental design	Plot design	Randomized Complete Block, RCB,RCBD
	Plot size	25 to 450 100 m ²
	Number of replications	4
Crop	Trials per crop	<i>Brassica napus</i> L. ssp. <i>napus</i> (winter) (BRSNW) (20) <i>Brassica napus</i> L. ssp. <i>napus</i> (spring) (BRSNS) (5 4)
	Varieties per crop	BRSNW: 1022; Abakus ; Alister; Artoga; Atora ; Digger; Dribbler; DK Imagine; DK Imminent CL (2); DK Impression SL; DK Exception; Garou; Hibrirock; Jumper; Ladora; NK Technik ; Rohan ; Sherlock; Starter; Vectra; Vision BRSNS: Bios; DK71-30CL ; Kaldera; Majong H ; SW Svinto
	Sowing dates	BRSNW: August to September BRSNS: April to May
Application	Crop stage (BBCH) at application	BRSNW: from BBCH 31 to BBCH 63 BRSNS: from BBCH 21 to BBCH 57 60
	Number of applications	BRSNW: 1 BRSNS: 1-4
	Spray volumes	250-300 L/ha
Assessment	Assessment types	Number of living adults
	Assessment timings	BRSNW: North-East EPPO climatic zone: 0; 1-2 3; 4-6; 7-9; 11-13; 15-17; 21-28 days after application South-East EPPO climatic zone: 0; 1-3; 6; 7days after application BRSNS: North-East EPPO climatic zone: BRSNS North-East EPPO climatic zone: First application :0; 1-2; 4-6; 8-9 days after application Second application: 1-9 days after application
Other relevant	information Infestation	Natural
	Site type	Field

Assessments were performed were in line with the EPPO standard PP1/178(3) requirements with exception of few trials with several deviations. For the North-East EPPO climatic zone, the first assessment ±, corresponding to the day of the application, was done between BBCH 51-61 which is out of the GAP (BBCH 50 to BBCH 59) for three trials, but not considered as a major deviation. In 2 supportive trials in spring oilseed rape, application was done very early (BBCH 21 and 35).

The product has been applied very early in two Hungarian trials (because the product has been applied against *Ceutorhynchus napi* which appears earlier in the development of oilseed rape). These trials are

nevertheless presented as they provide useful information about the product efficacy against pollen beetle, when applied at an earlier timing.

Assessment have been done on 50 shoots except for 8 trials: where the number of insects have been counted on 20 or 25 shoots which is a deviation from the EPPO standards. In the efficacy tables, the number of insects is reported to 1 shoot to have the same sample size for all trials.

DLT+FPF EC85 was tested at 0.75 L/ha on oilseed rape to control MELIAE. This rate reflects the proposed label rate. Efficacy was tested under a range of environmental conditions to fully challenge the product. DLT+FPF EC85 was compared to different insecticides Proteus.

Summary of the results

In the summary tables below, orthogonal comparisons between the supported dose rate of DLT+FPF EC85 and the reference product are presented. Only trials/assessments considered as valid to evaluate the efficacy of DLT+FPF EC85 against *B. aeneus*, in which reference products behaved as expected, infestation levels were sufficient are included in trial groupings below. Results are presented per EPPO climatic zone. Degree of shoot infestation severity (n. of insect/shoot) in the trials was variable, from medium to high, whatever the EPPO climatic zone.

Results in winter oilseed rape – the North-East EPPO climatic zone – Table 3.2-59

In the 12 trials conducted in the North-East EPPO climatic zone in the Central EU regulatory zone, test product DLT+FPF EC85 applied at the proposed dose 0.75L/ha showed a similar efficacy than as the reference product Proteus applied at 0.6-0.75L/ha in first assessments (83.5% vs 86.3 86.6% at 1 to 2 days after the application) until the last assessment (65.4% vs 63.7% at 11 to 13 days after the application)

Table 3.2-59: Efficacy of DLT+FPF EC85 on winter oilseed rape against MELIAE- Summary of the results in North-East EPPO climatic zone

in North-East EPPO climatic zone											
EPP O clil- mati c zone	EU reg ula tor y zon e	Nu mbe r of tri als	BBCH crop stage at as- essmt	Sample Size	DA A	UNTREATED		DLT+ FPF EC 85		PROTEUS OD110	
						(Living Adults/shoot)		0.75 L/ha		0.6 L/ha- 0.75 L/ha	
								Efficacy (% Abbott)			
						Mea n	Min- Max	Mean	Min-Max	Mean	Min-Max
Nort h- East	Ce ntra l	12 11	51-61	1 SHOOT / PLANT	0	2.7	0.4-7.3	na		na	
		11 10	51-61	1 SHOOT	1-2	3.3 3.4	1.0-7.1	83.5	62.1-95.6	86.3 86.6	68.0-97.4
		12 11	52-63	1 SHOOT / PLANT	4-6	2.9	0.4-6.0	72.6 76.3	31.6 57.7- 100	68.9 72.0	35.3 44.5- 96.2
		8 7	60-65 63	1 SHOOT	7-9	2.1 2.5	0.7 1.2- 3.8	55.3 65.5	4.6 17.0- 97.3	55.5 59.2	6.0-89.5
		3 5	63-62 - 65	1 SHOOT / PLANT	11-13	1.6 1.2	0.3-2.4	65.4	11.2-87.5	63.7	27.1-96.0

Results in winter oilseed rape – the South-East EPPO climatic zone – Table 3.2-60

In 8 trials conducted in the South-East EPPO climatic zone, DLT+FPF EC85 showed a slightly weaker lower efficacy compared to the reference product Proteus in the first assessments (1-3; and 6 DAA) but a similar efficacy in the last assessment (7 DAA). It has been noticed that the weaker lower efficacy found 1 to 3 days after the application is essentially due to the weaker lower efficacy found in one Hungarian trial IR17HUNWR1LB01 (% efficacy of the tested product at 0.75 L/ha - 49.0% after 3 DAA).

Table 3.2-60: Efficacy of DLT+FPF EC85 on winter oilseed rape against MELIAE- Summary of the results in South-East EPPO climatic zone

In South-East LFPO climatic zone											
EPP O cli- mati- c zone	EU regu- la- tory zone	Num ber of tri- als	BBC H crop stage at as- essm t	Sample Size	DA A	UNTREATED (Living Adults/shoot)		DLT+ FPF EC 85		PROTEUS OD110	
								0.75 L/ha		0.6 L/ha- 0.75 L/ha	
								Efficacy (% Abbott)			
South -East	Central	6	31-63	1 SHOOT/ PLANT	0	2.0	0.0-6.6	na		na	
	Central + South ern	8	31-63	1 SHOOT/ PLANT	0	1.7	0.0-6.6	na		na	
	Central	4	50- 63	1 SHOOT/ PLANT	1-3	3.0	1.0-7.2	79.0	49.0- 97.4	88.2 90.1	82.5-92.0 95.6
	Central + South ern	6	50- 63	1 SHOOT/ PLANT	1-3	2.3	0.9-7.2	85.6	49.0- 98.9	93.0	82.5-98.9
	Central	2	52-65	1 SHOOT	6	2.0	1.6-2.3	60.1	33.2- 87.0	74.0	65.2-82.5 82.7
	Central	2	53- 63	1 SHOOT/ PLANT	7	3.0 3.1	1.6-4.5	56.5 56.6	19.4- 93.7	59.6	25.8-93.4
	Central + South ern	4	53- 63	1 SHOOT/ PLANT	7	1.9 2.0	0.8-4.5	72.5	19.4- 93.7	72.8	25.8-93.4

Results in spring oilseed rape – the South-East EPPO climatic zone – Table 3.2-61

Concerning the 4 3 trials conducted in spring oilseed rape in the North-East EPPO climatic zone, DLT+FPF EC85 showed a slightly weaker lower efficacy compared to the reference product Proteus in the first assessments (1-2; 4-6 DAA) but a similar efficacy in the last assessment (8-9 DAA). Two applications of the test product DLT+FPF EC85 were done in 2 trials in the EU Northern EU regulatory zone with weak low efficacy for the test product and the reference product, which includes contains thiacloprid, an active substance for which no pollen beetle resistance has been described.

Table 3.2-61: Efficacy of DLT+FPF EC85 on spring oilseed rape against MELIAE- Summary of the results in North-East EPPO climatic zone

EP PO cli- mati- c zone	EU regu- latory zone	Number of trials	BBC H crop stage at as- sessm ent	Sample Size	DAA	UNTREATED		DLT+FPF EC 85		PROTEUS OD110	
						Living insect		0.75 L/ha		0.75 L/ha	
						Mean	Min-Max	Mean	Min- Max	Mean	Min- Max
Nor- th- Eas- t	Central	2 1	51- 57	50 SHOO TS	0 DAA	165.9 143.5	143.5- 188.3	na		na	
	Central + North- ern	5 3	21- 57 51	50 SHOO TS	0 DAA	163.6 155.3	105.0- 217.5	na		na	
	Central	2 1	51- 59	50 SHOO TS	1 DAA	175.0 147.5	147.5- 202.5	57.2 56.9	56.9- 57.4	73.1 78.1	68.0- 78.1
	Central +	4 3	23- 57 51	50 SHOO TS	1-2 DAA	181.1 173.9	107.5- 266.8	52.4 50.7	34.9- 60.2	70.3 71.1	61.0- 78.1

North- ern										
Central	≥ 1	57- 62	50 SHOO TS	4-6 DAA	106.8 142.8	70.8-142.8	47.4 64.1	30.7- 64.1	61.4 76.2	46.6- 76.2
Central + North- ern	4 3	51- 62 57	50 SHOO TS	4-6 DAA	143.6 167.9	70.8 127.0- 233.8	33.0 33.7	0.0-64.1	41.9 40.4	0.0-76.2
Central+N orthern	2	60- 62- 67	50 SHOO TS	8-9 DAA	57.5 117.5	46.0 69.0- 166.0	46.4 26.8	39.1 0.0-53.6	45.7 29.7	32.1 0.0-59.4
North- ern	2	62- 67 57- 60	50 SHOO TS	1-2 DAB	178.9	122.5- 235.3	26.4	17.3- 35.5	39.8	27.3- 52.3
	1	64	50 SHOO TS	6 DAB	100.5	-	14.4		15.4	-

, which includes thiacloprid, an active substance for which no pollen beetle resistance has been described.

Conclusion on the Efficacy of DLT +FPF EC85 against *B. aeneus*

Against *B. aeneus*, 24 fields trials (20 in winter oilseed rape and 4 in spring oilseed rape) were implemented in the period of 2014-2017 to evaluate the efficacy of DLT+FPF EC85. All the trials were conducted to GEP by officially recognized testing organisations and followed the appropriate EPPO standards. From these trials, it was demonstrated, that the application of DLT+FPF EC85 at 0.75 L/ha provides effective and consistent control of population of adults MELIAE at the level of performance similar to that of the different standard products. It can therefore be concluded that a label claim for the use of DLT+FPF EC85 in oilseed rape against MELIAE at 0.75 L/ha in Poland and Romania has been fully justified by the data discussed above.

Comments of zRMS:

24 field efficacy trials (20 trials in winter oilseed rape and 4 trials in spring oilseed rape) conducted in time period of 2014-2017 are presented to demonstrate the efficacy of DLT+FPF EC85 against *Brassicogethes aeneus* (MELIAE) in the North-East EPPO climatic zone and South-East EPPO climatic zone. The results of trials no IA14XSTCW2POL1 and IA14XSTCW2POL2 (carried out in Poland, the North-East climatic zone) were recorded from 1 plot, and not from 50 shoots. According to the EPPO guideline PP 1/178(3), the number of beetles should be recorded on at least 50 main shoots, selected at random from the centre of each plot. For this deviation, the efficacy values from these trials were not included, by the zRMS, in the overall calculation, but the results from these trials are presented below:

Spring oilseed rape

Trial number	BBCH crop stage at application/assessment	Sample size	DAA	UN-TREATED (Living adults)	DLT+FPF EC85 0.75 L/ha	PROTEUS OD110 0.75 L/ha
					% Efficacy (Abott)	
IA14XSTCW2POL1	57	1 PLOT	0 DAA	188.3	na	na
	59	1 PLOT	1 DAA	202.5	57.4	68.0
	62	1 PLOT	6 DAA	70.8	30.7	46.6
	67	1 PLOT	9 DAA	46.0	39.1	32.1

Winter oilseed rape

Trial number	BBCH crop stage at application/assessment	Sample size	DAA	UN-TREATED (Living adults)	DLT+FPF EC85 0.75 L/ha	PROTEUS OD110 0.75 L/ha
					% Efficacy (Abott)	

IA14XSTCW2POL2	57	1 PLOT	0 DAA	2.7	2.6	2.6
	57	1 PLOT	1 DAA	127.5	84.1	83.5
	62	1 PLOT	6 DAA	47.5	31.6	35.3
	64	1 PLOT	8 DAA	34.5	50.7	30.4

The results from 11 field efficacy trials carried out in winter oilseed rape in countries belonging to the North-East EPPO climatic zone show good efficacy of DLT+FPF EC 85 applied at the dose rate 0,75 L/ha, on 1-2 DAA and 4-6 DAA, with an average of 83,5% and 76,3% respectively. In the last assessments (7-9 and 11-13 DAA), the efficacy was lower but still on the moderate level (>65%). No statistically significant differences between the tested and the reference products were noted.

The results from 8 field efficacy trials carried out in winter oilseed rape in countries belonging to the South-East climatic zone show good efficacy of DLT+FPF EC85 applied at the dose rate 0,75 L/ha, on 1-3 DAA, with an average of 79% (in case of countries belonging to the Central EU regulatory zone) or 85,6% (in case both Central and Southern EU regulatory zones data are aggregated). In the last assessment (7 DAA) in four efficacy trials (from the Central+Southern regulatory zones) the efficacy of the tested product was still on the moderate level (72,5%). The reference product Proteus OD110 applied at the dose rate 0,75 L/ha gave slightly higher efficacy.

Only 3 field efficacy trials conducted in countries belonging to the North-East EPPO climatic zone on spring oilseed rape were submitted. The efficacy of DLT+FPF EC85 was low in the first assessment (1-2 DAA) with an average of 50,7%. On 4-6 DAA the efficacy of tested product has decreased to 33,7%. The reference product Proteus OD110 was more effective, especially in the initial period after application. Due to the limited number of efficacy trials conducted in spring OSR, this use was supported by efficacy trials carried out in winter OSR (extrapolation), and moderate control level was finally concluded for spring OSR

No efficacy trials were carried out in spring oilseed rape in the South-East EPPO climatic zone. In case of the registration of DLT+FPF EC85 for the use in spring oilseed rape against MELIAE in the South-East zone, the concerned MS are kindly advised to consider individually the possible extrapolation of efficacy trial results from winter oilseed rape to the spring oilseed rape, according to their national requirements.

USE03: Efficacy of DLT+FPF EC85 on oilseed rape against *Ceutorhynchus obstrictus* (CEUTAS) and *Dasineura brassica* (DASYBR)

In order to demonstrate the efficacy of DLT+FPF EC85 against of *Ceutorhynchus obstrictus* (CEUTAS) and *Dasineura brassica* (DASYBR) in oilseed rape, the following chapter summarizes the results from a series of 33 efficacy field trials (all in winter oilseed rape). Twenty-five trials were carried out in the ~~European~~ Central EU regulatory zone, 3 supportive field trials were carried out in the ~~European~~ Southern EU regulatory zone and 5 - in the ~~European~~ Northern EU regulatory zone. The trials were implemented in farmer's fields under conditions of natural infection and were distributed across the ~~EPPO~~ North-East, South-East, Maritime EPPO climatic zones. Single trial reports are given in Compilation of Trial Reports M-659527-01-1 with the corresponding trial list. The number of trials conducted in each climatic zone and country is shown in Table 3.2-62 below:

Table 3.2-62: Distribution of trials according to the crops, the climatic zones and countries

Crop	EPPO climatic zone	Regulatory Zone	Country	Year	Number of trials	Total	
Winter oilseed rape	North-East	Central	Poland	2014	1	5	10
				2015	1		
				2016	2		
				2017	1		
		Northern	Latvia	2017	1	5	
				2018	1		
			Lithuania	2017	2		

				2018	1		
	North-East EPPO climatic zone						10
	South-East	Central	Hungary	2015	2	4	13
				2016	2		
			Slovakia	2014	3	6	
				2015	2		
				2016	1		
		Southern	Bulgaria	2015	1	3	
				2016	2		
		South-East EPPO climatic zone					
	Maritime	Central	Czech Republic	2014	3	10	
				2015	4		
				2016	3		
Maritime EPPO climatic zone						10	
Total	All EPPO climatic zones		Winter oilseed rape			33	

Details of the methodology

A general overview of the methodology in efficacy trials carried out in oilseed rape against CEUTAS and DASYBR is presented in Table 3.2-63 which follows. Trials are also used in section 3.2.1. ~~Preliminary~~ Preliminary part and section 3.2.2. Minimum effective dose.

Table 3.2-63: Details on trial methodology (38 33 field trials) – CEUTAS and DASYBR

Guidelines	General guidelines	PP1/135(3/4) Phytotoxicity assessment PP1/152(3/4) Design and analysis of efficacy evaluation trials PP1/181(4) Conduct and reporting of efficacy evaluation trials including GEP PP1/225(2) Minimum effective dose
	Specific guidelines	PP1/107(3) Ceutorhynchus <i>Ceutorhynchus assimilis</i> PP1/220(1) <i>Dasineura brassicae</i>
Experimental design	Plot design	Randomized Complete Block, RCB,RCBD
	Plot size	20 to 150 100 m ²
	Number of replications	4
Crop	Trials per crop	<i>Brassica napus</i> L. ssp. <i>napus</i> (winter) (BRSNW) (33)
	Varieties per crop	Arsenal; Artoga; Bourbon ES; Callifornium; Cantate; Canti; Cult; D-03; Da Vinci; DK Imagine; DK Imminent CL; DK Impression ; Elvis; ES Mercurij; Felter CL; Goya; Ivan; Konkret; Kuga(2); Muller NK ; NK Ontario(2); Pioneer(2); PR45D03; Raffines; Rescator (2); Rohan(2); Sherpa; Visby
	Sowing dates	August to September
Application	Crop stage (BBCH) at application	From BBCH55 to BBCH 73
	Number of applications	4
	Spray volumes	250- 300 400 L/ha
Assessment	Assessment types	CEUTAS: Number of living adults and larvae; DASYBR: Infested pods and Number of living larvae
	Assessment timings	North-East EPPO climatic zone: CEUTAS: Living adults 1-2, 5-7DAA; Living Larvae 22-28DAA DASYBR: Infested pods 6-7,14-16DAA Living larvae 21-28DAA; South-East EPPO climatic zone

		CEUTAS: Living adults 1-3, 4-7, 16-21DAA; Living Larvae 21-40DAA DASYBR: Infested pods 4-6,14-16DAA Maritime EPPO climatic zone CEUTAS: Living adults 1-2, 5-8DAA; Living Larvae 21-25DAA DASYBR: Infested pods 5-8,14-16DAA Living larvae 21-28DAA
Other relevant information	information Infestation	Natural
	Site type	Field

Assessments performed were in line with EPPO standard PP1/107(3) and PP1/220(1) requirements with exception of 1 trial with a slight deviation: In the North-East EPPO climatic zone, plot size was compliant with the recommendation of the 25 m², with the exception of one trial where the plot size was slightly lower (20 m²).

DLT+FPF EC85 was tested at 0.5 L/ha on oilseed rape to control CEUTAS and DASYBR. This rate reflects the proposed label rate. Efficacy was tested under a range of environmental conditions to fully challenge the product. DLT+FPF EC85 was compared to different insecticides Proteus.

Summary of the results

In the summary tables **xx** below, orthogonal comparisons between different tested doses rates of DLT+FPF EC85 are presented. Only trials/assessments considered as valid to evaluate the efficacy of DLT+FPF EC85 against *Ceutorhynchus obstrictus* (CEUTAS) and *Dasineura brassica* (DASYBR) in which reference products behaved as expected, infestation levels were sufficient are included in trial groupings below. Results are presented per pest and after per EPPO climatic zone, number of living adults and larvae are presented for CEUTAS and infested pods and living larvae for DASYBR.

Results of Efficacy of DLT+FPF EC85 against CEUTAS

Results in the North-East EPPO climatic zone – Table 3.2-64

Adults were assessed just after the application at 1 to 2 DAA and 5 to 7 DAA while larvae were assessed after 4 weeks at 22 to 28 DAA. In 4 trials in the Central EU regulatory zone in the North-East EPPO climatic zone, DLT+FPF EC85 showed a similar control of CEUTAS compared to reference product at 1-2 days after the application (87.5% vs 91.0%), at 6 days after the application (85.3 vs 85.2% vs 88.3%) and at 24 to 28 days after application (81.6% vs 88.3%) in the number of living larvae assessed in 100 pods. This similar efficacy is confirmed in the efficacy results from the 5 supportive trials conducted in the Northern EU regulatory zone.

Table 3.2-64: Efficacy of DLT+FPF EC85 on winter oilseed rape against CEUTAS-Living adults (assessments 0-7 DAA) and larvae (assessment 22-28 DAA)- Summary of the results in North-East EPPO climatic zone

EPPO climatic zone	EU regulatory zone	Number of trials	BBC H Crop Stage at assessment	Sample Size	DAA	UNTREATED (Living adults or larvae)		DLT+ FPF EC 85		PROTEUS OD110	
								0.5 L/ha		0.6 L/ha - or 0.75 L/ha	
						Mean	Min-Max	Efficacy (% Abbott)			
						Mean	Min-Max	Mean	Min-Max	Mean	Min-Max
North-East	Central	4	62-67	1 SHOOT	0	0.4	0.2-0.7	na		na	
	Central + Northern	9	59-67	1 SHOOT	0	0.3	0.0-0.7	na		na	
	Central	4	67	1 SHOOT	1-2	0.5	0.3-0.8	87.5	81.1-98.3	91.0	78.8-97.1
	Central +	9	59-69	1 SHOOT	1-2	0.4	0.1-0.8	83.8	62.7-100	80.5	42.9-97.1

	North ern										
	Central	4	69-71	1 SHOOT	6	0.4	0.3-0.6	85.2	80.0- 95.7	88.3	73.0-97.9
	Central + North ern	8	63-72	1 SHOOT	5-7	0.3	0.1-0.6	77.0 74.2	40.0-100	72.2 72.3	34.8-100
	Central	4	77- 79	100 PODS	24- 28	12.1 12.2	8.0-17.8	81.6	79.2- 84.2	88.3	71.1- 100
	Central + North ern	9	71- 79	100 PODS	22- 28	11.8	5.5-19.0	75.4	47.4- 96.9	84.8	64.5- 100

Results in the South-East EPPO climatic zone – Table 3.2-65

Adults were assessed just after the application at 1 to 3 DAA, 4 to 7 DAA and 16-21 DAA while larvae were assessed at 21 to 40 DAA. In the trial IR14SVK125VK17 at the day of application, 6 DAA and 16 DAA, only the number of infested pods was assessed, and not the number of living adults. This trial was not included in the overall calculations. In 10 trials in the Central EU regulatory zone in the South-East EPPO climatic zone, DLT+FPF EC85 showed a similar control of CEUTAS compared to referene product at 1-3 days after the application (86.4% vs 88.2%), at 4 to 6 days after the application (~~79.5~~ 77.0% vs ~~81.2~~ 78.8%) in ~~9~~ 8 trials, and at 16 to 21 days after application (~~95.5~~ 91.0% for the both) in ~~3~~ 1 trials and at 21 to 40 days after application (84.5% vs 88.4%) in 9 trials in which number of living larvae was assessed in 100 pods. This similar efficacy is confirmed in the efficacy results from the 2 supportive trials conducted in the Southern EU regulatory zone.

Table 3.2-65: Efficacy of DLT+FPF EC85 on winter oilseed rape against CEUTAS-Living adults and larvae-Summary of the results in South-East EPPO climatic zone

Summary of the results in South-East EPO climatic zone											
EPP O cli- mati- c zone	EU reg- ula- tory zone	Nu mbe r of tri- als	BBCH crop stage at as- sess- ment	Sample Size	DA A	UNTREATED (Living adults or larvae)		DLT+ FPF EC 85		PROTEUS OD110	
								0.5 L/ha		0.5- or 0.7- or 0.75 L/ha	
						Efficacy (% Abbott)				Mean	Min-Max
Sout h- East	Central	10 9	55-69	1 SHOOT	0	0.7 0.8	0.2-1.7	na	na	na	na
	Central + Sout hern	12 11	55-71	1 SHOOT	0	0,8	0.2-1.7	na	na	na	na
	Central	10	59-71	1 SHOOT	1-3	0.6 0.8	0.1 0.2- 1.4	86,4	65.6-100	88,2	66.7-100
	Central + Sout hern	12	59-72	1 SHOOT	1-3	0.7 0.8	0.1 0.2- 1.4	84,4	52.0-100	85,2	44.0-100
	Central	9 8	61-71	1 SHOOT	4-6	0.9 0.7	0.2- 2.3 1.4	79.5 77.0	37.8- 99.6 97.2	81.2 78.8	40.5- 100 92.6
	Central + Sout hern	11 10	61-74	1 SHOOT	4-7	0.9 0.8	0.2- 2.3 1.4	81.0 79.2	37.8-100	81.0 79.1	40.5- 100 96.4
	Central	2 1	65-79 69	1 SHOOT	16 21	1.0 1.5	0.4-1.5	95.5 91.0	91.0-100	95.5 91.0	91.0-100
	Central	9	69-80	100 PODS	21- 40	31.8	2.3- 117.0	84.5	65.9 69.5- 100	88.4	82.4-100
	Central + Sout hern	11	69-80	100 PODS	21- 40	43.7	2.3- 117.0	85.1	65.9 69.5- 100	87.6	72.2-100

Results in the Maritime EPPO climatic zone – Table 3.2-66

Adults were assessed just after the application at 1 to 2 DAA and 5 to 8 DAA while larvae were assessed 3-4 weeks after, at 21 to 25 DAA. In 7 trials in Central EU regulatory zone in Maritime EPPO climatic zone, DLT+FPF EC85 showed a similar control of CEUTAS compared to reference product at 1-2 days after the application (87.5% vs 88.3%), at 5 to 8 days after the application (85.8% vs 87.9%) and at 21 to 25 days after application (98.5% vs 97.4%) in 6 trials in which number of living larvae was assessed in 100 pods.

Table 3.2-66: MED Efficacy of DLT+FPF EC85 on winter oilseed rape against CEUTAS-Living adults and larvae- Summary of the results in Maritime EPPO climatic zone

EPPO climatic zone	EU regulatory zone	Trial number	BBC H crop stage at assessment	Sample Size	DAA	UNTREATED		DLT+ FPF EC 85		PROTEUS OD110	
						(Living adults or larvae)		0.5 L/ha		0.75 L/ha	
								Efficacy (% Abbott)			
						Mean	Min-Max	Mean	Min-Max	Mean	Min-Max
Maritime	Central	7	61-65	1 SHOOT	- 1 - 0	0.4	0.2-0.7	na		na	
		7	61-65	1 SHOOT	1- 2	0.5	0.1-0.9	87.5	65.8-100	88.3	71.1-100
		7	63-67	1 SHOOT	5- 8	0.5	0.1-0.9	85.8	61.9-97.9 97.8	87.9	71.4-100
		6	67-73	100 PODS	21- 25	5.7	2.5-12.5	98.5	95.0-100	97.4	88.5-100

Adults number were assessed just after the application at 1 to 2 DAA and 5 to 8 DAA while larvae were assessed 3-4 weeks after at 21 to 25 DAA. In 7 trials in Central EU regulatory zone in Maritime EPPO climatic zone, DLT+FPF EC85 showed a similar control of CEUTAS at 1-2 days after the application (87.5% vs 88.3%), at 5 to 8 days after the application (85.8% vs 87.9%) and at 21 to 25 days after application (98.5% vs 97.4%) in 6 trials in which number of living larvae was assessed in 100 pods.

Results of Efficacy of DLT+FPF EC85 against DASYBR

Results in the North-East EPPO climatic zone – Table 3.2-67

In 5 trials in the Central EU regulatory zone, the test product DLT+FPF EC85 showed a weaker lower efficacy when applied at 0.5L/ha dose rate than the reference product Proteus (69.5% vs 81.8%), when it applied at 0.5L/ha than the reference product Proteus at 6 days after the application. However, no statistical differences were found in these trials. At 14 to 16 15 days after the application, a similar efficacy was found for the test product and the reference product (68.1% vs 69.8%). In only one trial in the Central EU regulatory zone a very low efficacy of 37% was recorded, at 21 days after the application, when reduction of the number of living larvae was assessed in 100 pods.

Table 3.2-67: Efficacy of DLT+FPF EC85 on winter oilseed rape against DASYBR- Infested pods- Summary of the results in North-East EPPO climatic zone

EPPO climatic zone	EU regulatory zone	Number of trials	BBC H crop stage at assessment	Sample Size	DAA	UNTREATED		DLT+ FPF EC 85	PROTEUS OD110
								0.5 L/ha	0.6 L/ha 0.75 L/ha
								% Efficacy (Abbott)	
						Infested pods			
North-East	Central	5	62-67	25 SHOOT S	0	2.5	0.0-12.5	na	na

Cent ral + Nort hern	6	62- 67	25 SHOOT S	0	2.1	0.0-12.5	na		na	
Cent ral	5	69- 71	25 SHOOT S	6	26.3	6.8-78.8	69.5	31.9- 81.5	81.8	68.6-92.6
Cent ral + Nort hern	6	63- 71	25 SHOOT S	6-7	33.5	6.8-78.8	68.4 68.5	31.9- 81.5	84.3	68.6-92.6 96.8
Cent ral	5	73- 77	25 SHOOT S	14-15	50.2	13.8- 112.3	68.1	42.2- 85.5	69.8	39.9-94.4
Cent ral + Nort hern	8	67- 77	25 SHOOT S	14-16	56.0 56.1	4.4 4.5 - 164.8	67.9	31.0- 94.4	78.6	39.9-99.7
Cent ral	1	-	100 PODS	21 DAA	15.9	-	37.0	-	30.8	-
Cent ral+ Nort hern	4	71- 73	100 PODS	21-28 DAA	17.9	14.0-26.3	67.7	37.0- 91.1	70.7	30.8-87.5

Results in the Souh-East EPPO climatic zone – Table 3.2-68

In 7 trials in the Central EU regulatory zone, DLT+FPF EC85 showed a ~~weaker~~ lower efficacy compared to the reference product Proteus; ~~was found with respectively an efficacy on~~ average 71.5% (range 33.3-95.0%) and 87.4% (range 83.3-93.4%), respectively, at 4 to 6 days after the application. In the second assessment, the average efficacy ~~between~~ of DLT+FPF EC85 is similar to the reference Proteus, at 14 to 26 days after the application; ~~with~~ respectively 82.5% (range 60.0-95.6 ~~95.2~~%) and 86.9% (range 80.0-91.7%).

Table 3.2-68: Efficacy of DLT+FPF EC85 on winter oilseed rape against DASYBR- Infested pods- Summary of the results in South-East EPPO climatic zone

EPPO climatic zone	EU reg- ula- tory zone	Nu mbe r of tri- als	BBC H crop stage at as- sess- ment	Sample Size	DA A	UNTREATED		DLT+ FPF EC 85		PRO- TEUS OD11 0	PRO- TEUS OD110
								0.5 L/ha		0.6 0.7 L/ha	0.75 L/ha
						Infested pods		% Efficacy (Abbott)			
						Mea n	Min-Max	Mean	Min-Max	Mean	Min-Max
South- East	Cent- ral	7	55- 69	25 SHOOTS	0	1.1 1.2	0.0-2.0	na		na	
	Cent- ral + Sout hern	8	55- 69	25 SHOOTS	0	21.2	0.0-161.8	na		na	
	Cent- ral	5	55- 69	25 SHOOTS	4-6	21.9	1.5-64.5	71.5	33.3-95.0	87.4	83.3- 93.4
	Cent- ral + Sout hern	6	55- 69	25 SHOOTS	4-6	63.5	1.5-271.3	73.5	33.3-95.0	87.0	83.3- 93.4
	Cent- ral	7	65- 75	25 SHOOTS	14- 26	27.0	1.3-88.3 83.3	82.5	60.0-95.6 95.2	86.9	80.0- 91.7
	Cent- ral	8	55- 69	25 SHOOTS	14- 26	105. 7	1.3-656.3	81.2 81.9	60.0-95.6 95.2	86.0	79.9- 91.7

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Results in the Maritime EPPO climatic zone – Table 3.2-69

In 10 trials in the Central EU regulatory zone in Maritime EPPO climatic zone, a similar efficacy in the control of pods infested by DASYBR was found between in DLT+FPF EC85: with an efficacy on average of 92.5% (range 86.5-100%) and in the reference product Proteus: with an efficacy average of 90.7% (range 80.0-100%). A similar efficacy was also found at 14 to 26 days after the application between in the test product (83.3 84.0%) and in the reference product (88.8 89.9%).

Table 3.2-69: Efficacy of DLT+FPF EC85 on winter oilseed rape against DASYBR- Infested pods and living larvae- Summary of the results in Maritime EPPO climatic zone

EPPO climatic zone	EU regulatory zone	Number of trials	BBC H crop stage at assessment	Sample Size	DAA	UNTREATED		DLT+ FPF EC 85		PRO-TEUS OD110	PROTEUS OD110
								0.5 L/ha		0.6 L/ha	0.75 L/ha
						Infested pods		% Efficacy (Abbott)			
						Mean	Min-Max	Mean	Min-Max	Mean	Min-Max
Maritime	Central	10	61-65	25 SHOOTs	1-10	7.0	0.0-20.0	na		na	
		9	65-69	25 SHOOTs	5-8	7.3	3.8-10.5	92.5	86.5-100	90.7	80.0-100
		10	65-71	25 SHOOTs	14-16	18.7 17.9	3.3-99.5	83.3 84.0	61.5-91.9	88.8 89.9	76.5-100
		4	67-77	100 PODs	21-28	83.9	13.5-161.3	96.6	93.3-100	91.0	81.5-99.8

Conclusion on the Efficacy of DLT +FPF EC85 against *Ceutorhynchus obstrictus* (CEUTAS) and *Dasineura brassica* (DASYBR)

Against *C. obstrictus* and *D. brassica*, 33 fields trials were implemented in the period of 2014-2018 to evaluate the efficacy of DLT+FPF EC85. All the trials were conducted accordingly to GEP by officially recognized testing organisations and followed the appropriate EPPO standards. From these trials, it was demonstrated that the application of DLT+FPF EC85 at 0.5 L/ha, provides an effective and consistent control of population and damages by *C. obstrictus* and *D. brassica*, at the level of performance similar to that of the different standard products. It can therefore be concluded that a label claim for the use of DLT+FPF EC85 in oilseed rape against CEUTAS and DASYBR at 0.5 L/ha in the European Central EU regulatory central zone has been fully justified by the data discussed above.

Comments of zRMS:

33 field efficacy trials (10 trials in the North-East EPPO climatic zone, 13 trials in the South-East EPPO climatic zone and 10 trials in the Maritime EPPO climatic zone) conducted in time period of 2014-2018 are presented to demonstrate the efficacy of DLT+FPF EC 85 against *Ceutorhynchus obstrictus* (CEUTAS) and *Dasineura brassica* (DASYBR) in winter oilseed rape.

The results from 9 field efficacy trials carried out in the countries belonging to the North-East EPPO climatic zone for the control of CEUTAS, show good efficacy of DLT+FPF EC 85 applied at the dose rate 0,5 L/ha after 1-2 DAA and 5-7 DAA, with an average of 83,8% and 74,2% (in both the Central and the Northern EU regulatory zones) respectively. In the last assessments (22-28 DAA), the efficacy was still on sufficient level (75,4%). No significant differences between the tested and reference products were noted.

The results from 12 field efficacy trials carried out in the countries belonging to the South-East EPPO climatic zone for the control of CEUTAS, show good efficacy of DLT+FPF EC 85 applied at the dose rate 0,5 L/ha after

1-3 DAA and 4-7 DAA with an average of 84,4% and 79,2% (in both the Central and the Southern EU regulatory zones) respectively. In the last assessments (21-40 DAA), the efficacy was still high (85,1%). No significant differences between the tested and reference products were noted.

The results from 7 field efficacy trials carried out in the countries belonging to the Maritime EPPO climatic zone for the control of CEUTAS, show good efficacy of DLT+FPF EC 85 applied at the dose rate 0,5 L/ha after 1-2 DAA and 5-8 DAA, with an average of 87,5% and 85,8% respectively. In the last assessments (21-25 DAA), the efficacy was still high (98,5%). No significant differences between the tested and reference products were noted.

The results from 8 field efficacy trials carried out in the countries belonging to the North-East EPPO climatic zone for the control of DASYBR, show moderate efficacy of DLT+FPF EC 85 applied at the dose rate 0,5 L/ha after 6-7 DAA and 14-16 DAA, with an average of 68,5% and 67,9% (in both the Central and the Northern EU regulatory zones) respectively. In the last assessments (21-28 DAA), the efficacy was still on the same level (67,7%). The reference product Proteus OD110 applied at the dose rate of 0,75 L/ha had shown slightly higher efficacy.

The results from 8 field efficacy trials carried out in the countries belonging to the South-East EPPO climatic zone for the control of DASYBR, show good efficacy of DLT+FPF EC 85 applied at the dose rate 0,5 L/ha after 4-6 DAA and 14-26 DAA with an average of 73,5% and 81,9% (in both the Central and the Southern EU regulatory zones) respectively. The reference product Proteus OD110 applied at the dose rate 0,7 or 0,75 L/ha had shown slightly higher efficacy at the time of the first assessment.

The results from 10 field efficacy trials carried out in the countries belonging to the Maritime EPPO climatic zone for the control of DASYBR, show good efficacy of DLT+FPF EC 85 applied at the dose rate of 0,5 L/ha after 5-8 DAA and 14-16 DAA, with an average of 92,5% and 84% respectively. In the last assessments (21-28 DAA), the efficacy was still high (96,6%). No significant differences between the tested and reference products were noted.

No efficacy trials testing control of CEUTAS and DASYBR in spring oilseed rape were submitted in any of the EPPO climatic zones (North-East, South-East or Maritime). In case of registration of DLT+FPF EC85 to control CEUTAS and DASYBR in the South-East and Maritime EPPO climatic zone, the concerned MSs are kindly advised to consider individually the possible extrapolation of efficacy trial results from winter oilseed rape to spring oilseed rape, according to their national requirements.

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

According to the EPPO standard PP1/278(3), quantitative and qualitative data are not required. However, data has been collected from some oilseed rape efficacy trials in the presence of pest populations.

Winter Oilseed rape

Results of yield in efficacy trials conducted against CEUTNA and CEUTQU

Quantitative and qualitative parameters were evaluated in 13 efficacy trials (6 in the North-East, 4 in South-East EPPO and 3 in the Maritime EPPO climatic zone) of DLT+FPF EC85 against CEUTNA and CEUTQU, in winter oilseed rape. Yield was measured in 13 trials (Table 3.2-70), as well as % of moisture, in 12 trials (Table 3.2-71). TKW (Thousand Kernel Weight) was recorded in 6 trials (Table 3.2-72) and % of oil content - in 1 trial (Table 3.2-73).

Yield data

Yield was measured in 13 trials conducted in North-East, South-East and Maritime EPPO climatic zone from trial seasons 2014 to 2017. The test product DLT+FPF EC85 at 0.75 L/ha was compared to the test standard reference product Proteus® applied at the recommended dose rate of 0.50, 0.60 or 0.75L/ha.

No negative impact on the yield was detected after the application of DLT+FPF EC85 at the proposed dose rate of 0.75L/ha. Higher yield with statistically significant differences, compared to the untreated control, was detected in the 2 trials in the North-East, in 1 trial in the South-East and in 1 trial in the Maritime EPPO climatic zone, after the application of DLT+FPF EC85. Yield average of 116.2% compared to the untreated check was measured in all EPPO climatic zones, in the same range level than as the reference product Proteus®.

Table 3.2-70: Yield effect of DLT+FPF EC85 in efficacy trials on winter oilseed rape against CEUTNA/CEUTQU-Summary of all EPPO climatic zones

CEUT NA/ CEUT QU - Summary of all EPPO climatic zones									
EPPO climatic zone	EU regulatory zone	Number of trials	Target	UN-TREATED (Tons/ha)		DLT+FPF EC85		PROTEUS OD110	
						0.75 L/ha		0.6-0.75 L/ha	
				Mean	Min-Max	% Relative of untreated			
North-East	Central	4	CEUT NA	3.7	3.2-4.5	103.6	101.2-106.4	103.8 105.9	100.8-109.6 114.4
	Central + Northern	6	CEUT NA/ CEUT QU	3.5	2.9-4.5	112.9	101.2-135.1	110.6	100.8-130.3
South-East	Central	2	CEUT NA/ CEUT QU	3.4	2.9-3.9	106.5	102.7-110.3	106.5	102.4-110.7
	Central + Southern	4	CEUT NA/ CEUT QU	2.8	1.7-3.9	128.5	102.7-179.1	126.3	102.4-172.5
Maritime	Central	3	CEUT NA	3.5	2.9-4.0	106.6 107.5	102.1 102.3-110.2 112.0	106.9	103.2-109.3
All EPPO climatic zones	All EU regulatory zones	13	CEUT NA/ CEUT QU	3.3	1.7-4.5	116.2 116.5	101.2-179.1	114.5 113.4	100.8-172.5

Quality parameters

Moisture content

Percentage of moisture content was measured in 12 efficacy trials conducted against the pests CEUTNA and CEUTQU. No negative effect was found after the application of the test product DLT+FPF EC85 at 0.75 L/ha, compared to the untreated control and the reference product Proteus® applied at recommended dose rate.

Table 3.2-71: Effect of DLT+FPF EC85 on the moisture content in efficacy trials on winter oilseed rape against CEUTNA/CEUTQU -Summary of all EPPO climatic zones

EPPO climatic zone	EU regulatory zone	Number of trials	Target	UNTREATED	DLT+FPF EC85	PROTEUS OD110
					0.75 L/ha	0.6-0.75 L/ha
				Moisture content (%)		

				Mean	Min-Max	Mean	Min-Max	Mean	Min-Max
North-East	Central	4	CEUTNA	7.7	6.6-8.3	7.6	6.5-8.3	7.6	6.4-8.3
	Central+Northern	6	CEUTNA/ CEUTQU	8.3	6.6-9.6	8.6	6.5-11.9	8.4 8.6	6.4-11.1 11.3
South-East	Central	2	CEUTNA / CEUTQU	8.0	6.6-9.5	8.1 8.2	6.8-9.5	7.9	6.4-9.5
	Central+Southern	3 4	CEUTNA / CEUTQU	8.0 8.1	6.6-9.5	8.1 8.2	6.8-9.5	8.0	6.4-9.5
Maritime	Central	3	CEUTNA	8.0	6.0-9.9	8.1	6.1-10.0	7.9	5.6 5.7-9.8
All EPPO climatic zones	All EU regulatory zones	12	CEUTNA/ CEUTQU	8.0 8.1	6.0-9.9	8.3	6.1+-11.9	8.1 8.4	5.6 5.7-11.1

TKW (Weight Thousand Kernel)

TKW was measured in 6 trials (3 in the North-Est, 1 in the South-East and 2 in the Maritime EPPO climatic zone). No negative effect was found after the application of test product DLT+FPF EC85, compared to the untreated check.

Table 3.2-72: Effect of DLT+FPF EC85 on the TKW in efficacy trials on winter oilseed rape against CEUTNA/CEUTQU -Summary of all EPPO climatic zones

Summary of an EPPO climatic zones											
EPPO climatic zone	EU regulatory zone	Number of trials	Target	UNTREATED		DLT+FPF EC85		PROTEUS OD110			
						0.75 L/ha		0.6-0.75 L/ha			
				TKW		% Relative of untreated					
				Mean	Min-Max	Mean	Min-Max	Mean	Min-Max		
North-East	Central + Northern	3	CEUTNA/CEUTQU	5.2	5.2-5.3	98.0 97.6	96.4-100.3	99.3 98.4	96.4 92.6-102.2		
South-East	Central	1	CEUTNA	4.2	-	106.5	-	105.8	-		
Maritime	Central	2	CEUTNA	4.4	3.6-5.1	100.9	100.4-101.4	100.5	100.2-100.7		
All EPPO climatic zones	All EU regulatory zones	6	CEUTNA/CEUTQU	4.8	3.6-5.3	100.4	96.4-101.4	100.8	96.4-102.2		

Oil content

Percentage of oil content was measured in 1 trial in Maritime EPPO climatic zone. No difference was found after the application of test Product DLT+FPF EC85, compared to the untreated control and to the reference product Proteus®, applied at recommended dose rate.

Table 3.2-73: Effect of DLT+FPF EC85 on the oil content in efficacy trials on winter oilseed rape against CEUTNA/CEUTQU -Summary of all EPPO climatic zones

EPPO climatic zone	EU regulatory zone	Number of trial	Target	DAA	UN-TREATED (Oil content)	DLT+ FPF EC 85	PROTEUS OD110
						0.75 L/ha	0.75 L/ha
						% Relative of untreated	
Maritime	Central	1	CEUTNA/ MELIAE	97 DAA	44.3	99.3	101.1

The results presented above show that DLT+FPF EC85 did not produce any negative effects on this quality parameter of harvested seed, in the presence of pest and is therefore not likely to cause detrimental effects on the quality of harvested seeds, when used according to the proposed label recommendations.

Results of yield in efficacy trials conducted against MELIAE

Two efficacy trials against MELIAE conducted in the North-East and two - in the South-East EPPO climatic zone, from trial seasons 2014 and 2017, were harvested. Yield was evaluated in 4 trials (Table 3.2-74), the % of moisture content - in 4 trials (Table 3.2-75), TKW (Thousand Kernel Weight) - in 2 trials (Table 3.2-76) and the % of oil content - in 2 trials (Table 3.2-77).

Yield data

Yield was measured in 2 efficacy trials against MELIAE in the North-East and 2 in the South-East EPPO climatic zone. No negative impact on the yield was detected after the application of DLT+FPF EC85 at the proposed dose rate of 0.75L/ha. Higher yield with statistically significant differences in the South-East EPPO climatic zone was detected after the application of DLT+FPF EC85 at the proposed dose rate of 0.75L/ha. Yield average of 105.5% compared to the untreated check was measured in the average of the two EPPO climatic zones, within the same range level than the reference product Proteus®.

Table 3.2-74: Yield effect of DLT+FPF EC85 in efficacy trials on winter oilseed rape against MELIAE-Summary of all EPPO climatic zones

EPPO climatic zone	EU regulatory zone	Number of trials	Target	UNTREATED (Tons/ha)		DLT+FPF EC85		PROTEUS OD110	
						0.75 L/ha		0.6-0.75 L/ha	
						% Relative of untreated			
				Mean	Min-Max	Mean	Min-Max	Mean	Min-Max
North-East	Central	2	MELIAE	4.7	3.4-5.9	102.0 102.1	98.5-105.6	99.4	98.3-100.5
South-East	Southern	2	MELIAE	2.1 2.2	1.9-2.4	108.7 108.8	108.7 108.2-109.3	107.6 107.7	107.4-107.9
All EPPO climatic zones	All EU regulatory zones	4	MELIAE	3.4 3.5	1.9-5.9	105.5	98.5-109.3	103.5 103.6	98.3-107.9

The results presented above show that DLT+FPF EC85 did not produce any negative effects on this quantity parameter for harvested seed in the presence of pest and is therefore not likely to cause detrimental effects on the yield of harvested seeds, when used according to the proposed label recommendations.

Quality parameters

Moisture content

The results presented above show that DLT+FPF EC85 did not produce any negative effects on this quantity quality parameter for in the harvested seed in the presence of pest and is therefore not likely to cause detrimental effects on the yield of harvested seeds, when used according to the proposed label recommendations. No negative effect was observed, on the moisture content, in 2 trials in the North-East and 2 trials in the South-East EPPO climatic zone.

Table 3.2-75: Effect of DLT+FPF EC85 on the moisture content in efficacy trials on winter oilseed rape against MELIAE -Summary of all EPPO climatic zones

EPPO climatic zone	EU regulatory zone	Trial Number	Target	UN-TREATED		DLT+FPF EC85	PROTEUS OD110		
						0.75 L/ha	0.6-0.75 L/ha		
						Moisture content (%)			
North-East	Central	2	MELIAE	6.6	6.3-6.9	6.5	6.2-6.8	6.7	6.2-6.5-6.8

South-East	Southern	2	MELIAE	7.8	7.7-7.9	7.8	7.7-7.9	7.8	7.7-7.9
All EPPO climatic zones	All EU regulatory zones	4	MELIAE	7.2	6.3-7.9	7.15 7.2	6.2-7.9	7.15 7.3	6.2 6.5 -7.9

TKW (Thousand Kernel Weight)

TKW was evaluated in 2 trials in the North-East EPPO climatic zone. No negative effect was observed after the application of the test product DLT+FPF EC85 at 0.75 L/ha compared to the untreated control and the reference product Proteus®.

Table 3.2-76: Effect of DLT+FPF EC85 on the TKW in efficacy trials on winter oilseed rape against MELIAE -Summary of North-East EPPO climatic zone

EPPO climatic zone	EU regulatory zone	Trial Number	Target	UNTREATED (TKW)		DLT+FPF EC85		PROTEUS OD110	
						0.75 L/ha		0.6-0.75 L/ha	
				TKW		% Relative of untreated			
North-East	Central	2	MELIAE	5.0	4.8-5.1	101.0 101.1	98.4-103.7	99.1	96.8-101.4

Oil content

Percentage of oil content was measured in 2 trials in South-East EPPO climatic zone. No difference was found after the application of test product DLT+FPF EC85 compared to the untreated control and the reference product Proteus® applied at recommended dose rate

Table 3.2-77: Effect of DLT+FPF EC85 on the oil content in efficacy trials on winter oilseed rape against MELIAE -Summary of Sout-East EPPO climatic zone

EPP O cli- matic zone	EU reg- ula- tor y zon e	Trial Num- ber	Cro p Stag e at as- sess- men t	Tar- get	DAA	UNTREATED (Oil content)		DLT+ FPF EC85		PROTEUS OD110	
								0.75 L/ha		0.75 L/ha	
								% Relative of untreated			
South -East	Cent ral	Mean of 2 trials	99	ME- LIA E	62-69 DAA	41. 0	40.9- 41.0	104. 6	104.1- 105.1	103. 8	103.5- 104.0

~~The results presented above show that DLT+FPF EC85 did not produce any negative effects on this quality parameter for harvested seed in the presence of pest and is therefore not likely to cause detrimental effects on the quality of harvested seeds, when used according to the proposed label recommendations.~~

Results of yield in efficacy trials conducted against CEUTAS/DASYBR

In **total**, 24 efficacy trials conducted against CEUTAS and DASYBR in the North-East (8 **trials**), in the South-East (6 **trials**) and in Maritime EPPO climatic zone (10 **trials**), from trial seasons 2014 to 2018, were harvested.

Yield data

Yield was evaluated in **24** trials (Table 3.2-78), % of moisture content - in **24** trials (Table 3.2-79), TKW (Weight Thousand Kernel) - in **23** trials (Table 3.2-80) and % of oil content - in **12** trials (Table 3.2-81). Yield was measured in 24 efficacy trials against CEUTAS and DASYBR. No negative impact on the

yield was detected after the application of DLT+FPF EC85 at the proposed dose rate of 0.5L/ha. Higher yield with statistically significant differences was detected in 1 trial in the North-East, 5 trials in the South-East and 4 trials in the Maritime EPPO climatic zone was detected after the application of DLT+FPF EC85 at the proposed dose rate of 0.5L/ha. Yield average of 113.8 112.9%, compared to the untreated check, was measured in all EPPO climatic zones, within the same range level than the reference product Proteus®.

Table 3.2-78: Yield effect of DLT+FPF EC85 in efficacy trials on winter oilseed rape against CEU-TAS/DASYBR-Summary of all EPPO climatic zones

TAS/EC85 DLT Summary of an EPPO climatic zones									
EPPO climatic zone	EU regulatory zone	Number of trials	Target	UNTREATED (Tons/ha)		DLT+FPF EC85		PROTEUS OD110	
						0,5 L/ha		0-5-0,6-0,75 L/ha	
						% Relative of untreated			
				Mean	Min-Max	Mean	Min-Max	Mean	Min-Max
North-East	Central	5	CEU-TAS/ DASYBR	3.4	2.4-5.1	106.9	94.4-117.0	110.5	107.1-115.3
	Central + Northern	8	CEU-TAS/ DASYBR	3.6	2.4-5.1	106.5	94.4-117.0	108.9	107.1-105.5-115.3
South-East	Central	3	CEU-TAS/ DASYBR	3.5	2.4-4.2	116.0	108.0-126.5	122.2	107.4-144.2
	Central + Southern	6	CEU-TAS/ DASYBR	2.8-2.9	1.0-4.2	135.1	108.0-205.0	137.2	107.4-191.2
Maritime	Central	10	CEU-TAS/ DASYBR	3.8-3.9	2.9-5.2	107.2-106.8	100.4-114.5	107.9-107.4	103.6-103.3-117.5
	Central	3	DASYBR	3.9	3.1-5.0	106.8-105.8	100.4-114.5-102.6-110.3	106.1	103.3-110.9
All EPPO climatic zone	All EU regulatory zone	24	CEU-TAS/ DASYBR	3.5-125-3.5	1.0-5.2	113.8-112.9	94.4-205.0	114.9-115.4	103.3-191.2

together, in the same range level than the reference product Proteus®.

The results presented above show that DLT+FPF EC85 did not produce any negative effects on this quantity parameter for of the harvested seed in the presence of pest at different infestation levels - low to high, and is therefore not likely to cause detrimental effects on the yield of harvested seeds, when used according to the proposed label recommendations.

The results presented above show that DLT+FPF EC85 did not produce any negative effects on this quantity parameter for harvested seed in the presence of pest and is therefore not likely to cause detrimental effects on the yield of harvested seeds, when used according to the proposed label recommendations.

Quality parameters

Moisture content

No negative effect on the moisture content was observed in 24 trials in the North-East, South-East and Maritime EPPO climatic zone.

Table 3.2-79: Effect of DLT+FPF EC85 on the moisture content in efficacy trials on winter oilseed rape against CEUTAS/DASYBR -Summary of all EPPO climatic zones

Against CEU-TAS/DASYB R - Summary of an EPPO climatic zones									
EPPO climatic zone	EU regulatory zone	Number of trials	Target	UNTREATED		DLT+FPF EC85		PROTEUS OD110	
						0.5 L/ha		0.5-0.6-0.7-0.75 L/ha	
				Moisture content (%)					
				Mean	Min-Max	Mean	Min-Max	Mean	Min-Max
North-East	Central	5	CEU-TAS/DASYB R	8.0	7.0-8.7	7.8	6.9-8.7	8.0	6.9-8.7
	Central + Northern	8	CEU-TAS/DASYB R	8.7 8.8	7.0-8.7 12.3	8.6	8.6 6.9-12.0	8.6	6.9-11.1
South-East	Central	3	CEU-TAS/DASYB R	9.4 9.3	9.1-9.7	9.4	9.1-9.8	9.4	9.2-9.8
	Central + Southern	6	CEU-TAS/DASYB R	8.3	6.5-9.7	8.3	6.4-9.8	8.4	6.7-9.8
Maritime	Central	7 10	CEU-TAS/DASYB R	8.9	6.9-10.1	9.1 9.0	9.1-10.0 7.0-10.4	9.1 9.0	7.1-10.1
	Central	3	DASYB R	8.9 8.8	8.7-8.9	8.7 8.8	8.5-9.0 9.1	8.7	8.5-9.0
All EPPO climatic zone	All EU regulatory zone	24	CEU-TAS/DASYB R	8.7	6.5-10.1 12.3	8.6 8.7	6.4-12.0	7.7 8.7	6.9 6.7-11.1

TKW (Thousand Kernel Weight)

TKW was evaluated in 23 trials in the North-East, South-East and Maritime EPPO climatic zone. No negative effect was observed after the application of the test product DLT+FPF EC85 at 0.5 L/ha compared to the untreated control and the reference product Proteus®.

Table 3.2-80: Effect of DLT+FPF EC85 on the TKW in efficacy trials on winter oilseed rape against CEUTAS/DASYBR -Summary of all EPPO climatic zones

EPPO climatic zone	EU regulatory zone	Number of trials	Target	UNTREATED (TKW)		DLT+FPF EC85		PROTEUS OD110	
						0.5 L/ha		0.6-0.7-0.75 L/ha	
				TKW		% Relative of untreated			
				Mean	Min-Max	Mean	Min-Max	Mean	Min-Max
North-East	Central	5	CEU-TAS/DASYBR	4.8	4.3-5.2	101.1	98.0-105.0	101.4	98.3-107.7 107.4
	Central + Northern	8	CEU-TAS/DASYBR	4.9	4.3-5.2 5.3	100.9	98.0-105.0	101.5	98.3-107.7 107.4
South-East	Central	3	CEU-TAS/	5.1	5.0-5.2	102.4	99.8-105.9	104.0	99.6-110.7

	Central + Southern	5	DASYB R CEU-TAS/ DASYB R	5.2	4.2-6.8	106.7	99.8-120.5	108.9	99.6-124.1
Maritime	Central	7 10	CEU-TAS/ DASYB R	5 4.9	4.3-6.3	100 102.1	96.1-102.1 97.6-104.0	99.8 100.6	96.1-102.3 103.0
	Central	3	DASYB R	4.7 4.6	4.3-5.0	104.3 102.3	101.3-106.6 104.0	102.6	101.9-103.0
All EPPO climatic zone	All EU regulatory zone	23	CEU-TAS/ DASYB R	4.9	4.2-6.8	102.4 102.6	96.1-105.0 97.6-120.5	103.2	96.1-124.1

Oil content

Percentage of oil content was measured in 23 12 trials in the North-East, the South-East and the Maritime EPPO climatic zone. No difference was found after the application of test Product DLT+FPF EC85 compared to the untreated control and the reference product Proteus® applied at recommended dose rate.

Table 3.2-81: Effect of DLT+FPF EC85 on the oil content in efficacy trials on winter oilseed rape against CEUTAS/DASYBR -Summary of all EPPO climatic zones

EPPO climatic zone	EU regulatory zone	Number of trials	Target	UNTREATED (Oil content)		DLT+ FPF EC85		PROTEUS OD110	
						0.5 L/ha		0.6-0.7-0.75 L/ha	
						% Relative of untreated			
				Mean	Min-Max	Mean	Min-Max	Mean	Min-Max
North-East	Central	5	CEU-TAS/ DASYBR	45.7	42.2-49.2	99.6	98.5-100.7	99.3	98.0-100.8
South-East	Central	2	CEU-TAS/ DASYBR	43.1	40.2-46.0	102.7	99.8-105.5	103.3	99.9-106.7
Maritime	Central	5	CEU-TAS/ DASYBR	45.2	41.0-46.5	100.4 100.3	98.7-101.4	100.3	97.4-102.8
All EPPO climatic zone	Central	12	CEU-TAS/ DASYBR	41.3 44.7	40.2-49.2	94.2 100.9	98.5-105.5	94.4 101.0	97.4-106.7

The results presented above show that DLT+FPF EC85 did not produce any negative effects on this quality parameter for harvested seed in the presence of pest and is therefore not likely to cause detrimental effects on the quality of harvested seeds, when used according to the proposed label recommendations

Spring oilseed rape

Plot was harvested in one two efficacy trials conducted against MELIAE in spring oilseed rape, in Poland and in Lithuania, in 2016. Yield (tons/ha), moisture content and TKW (Thousand Kernel Weight) was assessed and are presented in Table 3.2-82, Table 3.2-83 and Table 3.2-84 respectively.

Yield data

Table 3.2-82: Effect of DLT+FPF EC85 on the yield in efficacy trials against MELIAE in the North-East EPPO climatic zone

					UNTREATED (Tons/ha)		DLT+FPF EC85		PROTEUS OD110	
Trial number	Country	Variety	Crop Stage at assess- ment	DAA			0.75 L/ha		0.6 L/ha	
							% Relative of untreated			
IR16POLR03PR01	Poland	BIOS	89	78 DAA	1.6	b	114.4	a	115.1	a
IR16LTUSP- BRS03	Lithua- nia	MA- JONG H	89	62 DAA	2.7		110.2		103.9	
Mean of 2 trials				62-	2.2		112.3		109.5	
Min	-	-	89	78	1.6		110.2		103.9	
Max				DAA	2.7		114.4		115.1	

DAA=Days After Application. Treatments followed by same letter are not statistically different (p =0.05; Student-Newman-Keuls)

Quality parameters

Moisture content

Table 3.2-83: Effect of DLT+FPF EC85 on the moisture content in efficacy trials against MELIAE in the North-East EPPO climatic zone

North East LTFC climatic zone										
					UN-TREATED		DLT+FPF EC85		PROTEUS OD110	
Trial number	Country	Variety	Crop Stage at assessment	DAA			0.75 L/ha		0.6 L/ha	
					Moisture content (%)					
IR16POLR03PR01	Poland	BIOS	89	78 DAA	6.55	-	5.85	-	6.125	-
IR16LTUSP-BRS03	Lithuania	MA-JONG H	89	62 DAA	20.0		18.0		17.7	
Mean of 2 trials	-	-	89	62-	13.3	12.0		11.9		
Min				78	5.9		6.1			
Max				DAA	18.0		17.7			

DAA=Days After Application. Treatments followed by same letter are not statistically different (p =0.05; Student-Newman-Keuls)

TKW (Thousand Kernel Weight)

Table 3.2-84: Effect of DLT+FPF EC85 on the TKW in efficacy trials against MELIAE in the North-East EPPO climatic zone

LTP Climate zone										
					UNTREATED (TKW)		DLT+FPF EC85		PROTEUS OD110	
Trial number	Country	Variety	Crop Stage at assess- ment	DAA			0.75 L/ha		0.6 L/ha	
							% Relative of untreated			
IR16POLR03PR01	Poland	BIOS	89	78 DAA	3.3	-	102.8	-	101.9	-
IR16LTUSP- BRS03	Lithua- nia	MA- JONG H	99	64 DAA	3.6		110.4		110.3	
Mean of 2 trials				64-	3.5		106.6		106.1	
Min	-	-	89-99	78	3.3		102.8		101.9	
Max				DAA	3.6		110.4		110.3	

DAA=Days After Application. Treatments followed by same letter are not statistically different (p =0.05; Student-Newman-Keuls)

Summary of yield data in efficacy trials against MELIAE in spring oilseed rape

In ~~one~~ **two** trials conducted in Poland and Lithuania in 2016 in spring oilseed rape against MELIAE, yield data was assessed. No negative effect was found after the application of the test product DLT+FPF EC85 at 0.75L/ha. Higher yield with statistically significant differences was found with the untreated control (+14 ~~12~~%), whereas the results of yield, moisture content and TKW ~~was~~ **were** comparable - without statistically significant differences as compared to the reference Proteus® applied at the recommended dose.

Conclusion on yield data in efficacy trials in winter and spring oilseed rape

Plots were harvested in 17 efficacy trials in the North-East EPPO climatic zone (16 in winter oilseed rape and 1 in spring oilseed rape), in 12 efficacy trials in the South-East EPPO climatic zone, and in 13 efficacy trials in the Maritime EPPO climatic zone, in winter oilseed rape. Weight and moisture of seeds from each plot were measured. The yield of seeds ~~were~~ **was** recalculated to the evaluated moisture and presented as t/ha. In these trials, the sub-samples were taken for measuring the weight and moisture of seeds. The results were recalculated to standard 9% moisture content and presented as gram of 1000 seeds as TKW. In conclusion, DLT+FPF EC85 applied at the proposed dose rate of 0.5 L/ha and

0.75L/ha, sprayed once, caused no negative effects on yield in situations of low to high pests infestations and was comparable, without significant differences, to the reference product Proteus® applied at the recommended dose rate.

Comments of zRMS:

Quantitative and qualitative parameters of the yield were evaluated in 13 efficacy trials altogether, 6 of them in the North-East zone, 4 - in the South-East and 3 - in the Maritime EPPO climatic zone, testing efficacy of DLT+FPF EC85 against CEUTNA and CEUTQU, in winter oilseed rape. The application of the test item at the proposed dose rate of 0.75 L/ ha against the stem weevils did not affect the yield quantity or quality in any negative way, compared to the untreated plots or to the standard reference products.

The quality and quantity parameters of yield were also assessed in field efficacy trials carried out in winter and spring oilseed rape in all EPPO climatic zones (North-East, South-East and Maritime). In 24 field efficacy trials conducted in winter oilseed rape against CEUTAS and DASYBR and 6 field efficacy trials conducted in spring oilseed rape against MELIAE, no negative effects were observed. DLT+FPF EC 85 applied at the proposed dose rates of 0,5 and 0,75 L/ha did not cause deterioration of yield quantity, moisture content in seeds, TKW or the oil content in seeds, as compared to untreated crops.

3.3 Information on the occurrence or possible occurrence of the development of resistance (KCP 6.3)

M-659907-01-1

The resistance statement to support the use of DLT+FPF EC85 against insects pests in oilseed rape is reported in the document [M-659907-01-1](#). A summary of this document is available below. Resistance in arthropod pest species comprises a change in the genetic composition of a population in response to selection by pesticides, such that control in the field may be impaired repeatedly at recommended application rates. The report includes resistance management information regarding key invertebrate pests in oilseed rape in the central zone (CZ), such as stem weevils, pollen beetle and pod pests, e.g. *Ceutorhynchus assimilis* (syn. *obstrictus*) and *Dasineura brassicae* targeted with formulations containing the insecticidal ingredients flupyradifurone and deltamethrin (DLT+FPF EC85).

Mode of action

DLT+FPF EC85 is a mixture of two chemically different insecticides complementing each other in numerous properties and belonging to distinct mode of action classes, i.e. acting on different molecular target-sites. Flupyradifurone belongs to the new butenolide class of chemistry and acts agonistically by reversible binding on insect nicotinic acetylcholine receptors (nAChR) located in the central nervous system. It belongs to IRAC mode of action sub-group 4D, including other, but different “Nicotinic acetylcholine receptor (nAChR) competitive modulators”. However due to its new butenolide pharmacophore as a novel bioactive scaffold it is chemically different from other sub-groups such as neonicotinoids (4A). Deltamethrin is a pyrethroid insecticide acting on voltage-gated sodium channels and belongs to IRAC mode of action sub-group 3A (sodium channel modulators).

Mechanisms of resistance

No metabolic or target-site mediated mechanisms of resistance in any of the coleopteran pests mentioned above are yet described for flupyradifurone and any other chemical class belonging to IRAC mode of action group 4. Resistance to pyrethroid insecticides has been described for different crop pests and the major mechanisms of resistance were identified as either metabolic (esterases and monooxygenases) or knock-down-resistance (kdr) due to a mutation in the IIS6 domain of the voltage-gated sodium channel. Some of the pest insects intended to be targeted by deltamethrin in DLT+FPF EC85 are not listed as high risk pests within EPPO's Std. PP1/213 on resistance risk analysis and haven't been included for a detailed survey, primarily due to a lack of any resistance issues in the past, including stem weevils (*Ceutorhynchus* spp.) and *D. brassicae*. Resistance to pyrethroids is known and well-described in pollen beetle populations throughout Europe. Pyrethroid resistance in cabbage seed pod weevil is regionally known.

Cross resistance

Cross-resistance is principally expected to occur between all members of chemical classes belonging to a single IRAC mode of action group, but not between mode of action classes, such as IRAC groups 3 and 4. No flupyradifurone cross-resistance is yet published for any pest covered in the statement. Cross-resistance between pyrethroids in pollen beetle and cabbage seed pod weevil has been described in the past.

Evidence of resistance, sensitivity data and resistance risk

Flupyradifurone belongs to a new class of chemistry and pests targeted in oilseed rape have not yet been exposed to this insecticide under applied conditions in oilseed rape. Resistance to deltamethrin as well as other pyrethroids is described in pollen beetle and cabbage seed pod weevil, but not stem weevils and pod midges. Adult vial tests according to IRAC Method #011 were conducted with DLT+FPF EC85 at different field rates to assess the susceptibility of field-collected pollen beetle populations. The mixture showed superior activity when compared with a pyrethroid solo application.

Acceptability of the resistance risk

In addition to the specific insecticide risk the inherent invertebrate pest risk is a second factor that determines the overall resistance risk of DLT+FPF EC85. None of the covered pests is classified as higher risk pest, though pollen beetle has developed pyrethroid resistance levels often impairing field efficacy of pyrethroid applications. However, apart from this fact wherever possible the installment of resistance management strategies as outlined or based on regularly updated IRAC documents (annual pollen beetle resistance survey) are recommended in order to lower the risk of resistance development in any of the pests targeted by Sivanto Energy.

Resistance management strategy and use pattern

General resistance management guidelines for insecticides as published by IRAC should be followed with DLT+FPF EC85 and regionally adapted as necessary. To prevent possible resistance development against flupyradifurone, consecutive spray applications with compounds of the same mode of action Group are not recommended, and should only be considered in rotational spray applications when interrupted with treatments by insecticides of other mode of action (MoA) classes, or if other alternatives are not available. Such a resistance management strategy is also known as “MoA treatment windows” approach.

Communication and implementation of the management strategy

Bayer AG is an active member of IRAC International and its Working Groups since many years. The anti-resistance strategy for flupyradifurone/deltamethrin-based products is communicated to the advisory and the farmer's level essentially on the label. In addition, leaflets and brochures which describe the product also include recommendations for resistance management.

Comments of zRMS:

Flupyradifurone (FPF) has been originally designed and intended against different piercing-sucking pest species and it has been so far used only in crops other than oilseed rape (OSR). Consequently, the insect species targeted by the DLT+FPF EC85 have not been exposed yet to the mode of action of FPF. By the same token it is this active, and not deltamethrin (DLT), that constitutes the critical component of the new product in OSR protection.

It may be noticed that, contrary to DLT, which represents MoA shared by tens of other actives within the 3A group, FPF is, as a compound, distinct - in structural terms - from the remaining members of the group 4, including the most numerous subgroup 4A, neonicotinoids, even though it targets the same nAChR. Its efficacy has been so far compared to the actives of the 4A group, mostly to imidacloprid, only with respect to sucking pests, and in some species, *e.g.* in some strains of *Phorodon humuli* or *Bemisia tabaci*, it performed orders of magnitude better than imidacloprid. The applicant thus argues that the resistance risk inherent in FPF should be considered moderate at most, and perhaps even low – taking into account the assumed low risk inherent in the target pests of the OSR, that were so far exposed only to the notorious 4A group.

Following that reasoning the applicant presents the results of the resistance monitoring study, carried out on samples collected in 2017 from 28 populations of MELIAE in the Central EU administrative zone (F, DE, HU). The collected beetles had been exposed to the concentrations of the test item, DLT+FPF EC85, equivalent to 100% (0.1 µg cm² DLT and 0.5625 µg cm⁻² FPF) and 20% of the field rate (0.02 µg cm⁻² DLT and 0.1125 µg cm² FPF), according to the experimental protocol described as “modified IRAC no 11 ‘Pollen beetle susceptibility monitoring bioassay – synthetic pyrethroids’ “. The test results are compared to the study named “Pyrethroid sensitivity monitoring data for pollen beetle populations collected in 2017 in the central zone”, following the same protocol.

Inspection of two graphs presented in the document [M-659907-01-1](#) suggests clearly that DLT+FPF EC85 performs better than pyrethroids used alone, leading to a conclusion that the potential for DLT resistance should not be ignored, even though in the proposed DLT+FPF EC85 product it has been co-formulated with the FPF, the active new to the OSR pests. On the other hand, the absence of resistance cases reported for FPF in the OSR pests is likely the plain consequence of this active's absence in the OSR crop.

In recognition of the above-mentioned facts the applicant has proposed that standard management strategy “as published by IRAC” must be used, which the zRMS PL generally accepts. To the opinion of zRMS, a little more specific information and guidance should be placed in the product label, including critical issues affecting the product's efficacy in the long term, as collected below in points 1-6 (points 4-6 come here in exact wording by the applicant, after the document [M-659907-01-1](#)). The MSs are nevertheless kindly encouraged to adopt or adjust the wording, according to their local circumstances and requirements.

DLT+FPF EC85 / Sivanto Energy contains two active substances: flupyradifurone – a nAChR modulator belonging to the group 4D, IRAC, (butenolides), and deltamethrin – sodium channel modulator belonging to the group 3A, IRAC (pyrethroids). In order to avoid resistance build-up in populations of the pests targeted by this product, the following rules should be observed:

- 1) The maximum number of applications of the DLT+FPF EC85 / Sivanto Energy per season is 2. In case when more applications are necessary, products containing actives belonging to other IRAC groups and showing other modes of action should be applied.*
- 2) In any case, an application of DLT+FPF EC85 / Sivanto Energy should not be followed directly by the application of any insecticide showing MoA of the IRAC groups 3A, or 4D. Instead, a product with an active(s) belonging to other MoA groups, e.g. 1B, 4A, 9B, or 22A, should be utilized.*
- 3) The dose rates should be observed strictly, according to the label recommendation for particular uses.*
- 4) If pyrethroid resistant pollen beetles are known to be present in the target crop, then non-pyrethroid insecticides should be the primary choice for pollen beetle control.*
- 5) The use of insecticide mixtures containing pyrethroids for the control of pyrethroid resistant pollen beetle is generally not recommended, unless no other options are available and the second mixture component is still fully effective.*
- 6) Non-chemical control options should be considered as part of any pest management strategy. Insecticide use does not replace the need for resistant crop varieties, good agronomic practice, plant hygiene/sanitation etc.*

3.4 Adverse effects on treated crops (KCP 6.4)

Phytotoxicity assessments were obtained in efficacy trials and no phytotoxicity was observed. Therefore, according to the EPPO standard PP1/135(3): Phytotoxicity assessment, no specific crop safety trials were needed with DLT+FPF EC85 on oilseed rape.

Phytotoxicity assessments performed in 92 efficacy trials conducted with DLT+FPF EC85 is presented in Chapter 3.4.1. Crop safety assessments (88 in winter oilseed rape and 4 in spring oilseed rape).

3.4.1. Phytotoxicity to host crop (KCP 6.4.1)

As phytotoxicity assessments were obtained in efficacy trials and no phytotoxic effect was observed here, no specific crop safety trials were performed with DLT+FPF EC85. The general phytotoxicity of DLT+FPF EC85 on the crop was evaluated using the following scale:

% General Phytotoxicity	Description
0%	no symptoms
1-5 %	very slight symptoms, negligible in practice
6-10 %	slight symptoms
11-15 %	obvious symptoms (acceptable)
16-20 %	strong symptoms (usually no more acceptable)
20-30 %	strong symptoms, clearly unacceptable
> 30 %	very strong symptoms
100%	the crop is destroyed.

*15% of visual damage is the maximum damage that Bayer CropScience considers as acceptable.

On oilseed rape, 92 efficacy trials (88 in winter oilseed rape and 4 in spring oilseed rape) were implemented across different countries in Europe (Poland, Lithuania, Latvia, Czech Republic, Hungary, Slovakia, Romania and Bulgaria) and phytotoxicity assessments were made in addition to efficacy assessments. Table 3.4.-1 show the ~~list~~ number of efficacy trials with phytotoxicity assessments, and ~~Table 3.4.-1~~ the varieties tested within these efficacy trials.

Table 3.4.-1: Winter and spring oilseed rape - List of varieties tested in efficacy trials with DLT+FPF EC85

Crop	EPPO climatic zone	EU regulatory zone	Variety	Country	Number of Trials
Winter Oilseed rape BRSNW	North-East EPPO climatic zone	Central EU regulatory zone	VECTRA	Poland	1
			NK TECHNIK	Poland	1
			DIGGER	Poland	3
			TECHNIC	Poland	1
			SHERLOCK	Poland	1
			VISBY	Poland	1
			CALLIFORNIUM	Poland	2
			ALISTER	Poland	1
			VISION	Poland	1
			STARTER	Poland	1
			KONKRET	Poland	2
			PT 205	Poland	1
			BOURBON ES	Poland	1
			HIBRIROCK	Poland	1
			GAROU	Poland	1
			ROHAN	Poland	1
			PIONEER	Poland	1
			ATORA	Poland	1
			1022	Poland	1
			BERNY	Poland	1
			ARTOGA	Poland	1
		Northern EU regulatory zone	VISBY	Lithuania	1
			VISBY	Latvia	1
			KUGA	Lithuania	3
			RAFFINES	Lithuania	2
			ARMSTRONG	Latvia	1
			MARATHON	Latvia	1
			PIONEER	Latvia	1
			CULT	Latvia	1
			25 varieties	3 countries	35 trials
			SY SAVEO	Hungary	1
			DK EXQUISITE	Hungary	1

	South-East EPPO cli- matic zone	Central EU regulatory zone	GOYA	Slovakia	1
			ONTARIO	Slovakia	2
			ROHAN	Slovakia	1
			MANITOBA	Slovakia	1
			AVIATOR	Hungary	1
			DK IMAGINE	Hungary	± 2
			D-03	Hungary	1
			BAGIRA	Romania	1
			ARTOGA	Slovakia	2
			CANTATE	Slovakia	2
			KODIAK	Slovakia	1
			DK IMMINENT CL	Hungary	2
			KWS HYBRIROCK	Hungary	1
			ELVIS	Hungary	1
			TRIANGLE	Romania	1
			ARSENAL	Slovakia	2
			DK EXCEPTION	Hungary	1
			DRIBBLER	Hungary	1
			JUMPER	Romania	±
		Southern EU regulatory zone	DUPLEX	Bulgaria	1
			VISBY	Bulgaria	1
			SUNSET	Bulgaria	1
			FELTER CL	Bulgaria	1
			DK IMPRESSION	Bulgaria	3
			PR45D05	Bulgaria	1
			ES MERCURIJ	Bulgaria	1
			DK IMMINENT CL	Bulgaria	1
				28 27 varieties	4 countries
	Maritime EPPO cli- matic zone	Central EU regulatory zone	MULLER NK	Czech Republic	1
			CANTI	Czech Republic	2
			DA VINCI	Czech Republic	2
			ATENZO	Czech Republic	1
			ROHAN	Czech Republic	3
			ONTARIO	Czech Republic	1
			RESCATOR	Czech Republic	3
			PR45D03	Czech Republic	1
IVAN			Czech Republic	1	
SHERPA			Czech Republic	1	
SLAKI CS			Czech Republic	1	
			11 varieties	1 country	17 trials
All climatic zones		61 varieties	8 countries	88 trials	
Spring Oilseed rape BRSNS	North-East EPPO cli- matic zone	Central EU regulatory zone	SW SVINTO	Poland	1
			KALDERA	Latvia	1
			MAJONG H	Lithuania	1
			BIOS	Poland	1
					4 varieties
BRSNW & BRSNS	All climatic zones		65 varieties	8 countries	92 trials

Results of phytotoxicity on winter oilseed rape

Phytotoxicity assessments were obtained in 88 efficacy trials conducted in winter oilseed rape; 61 varieties of winter oilseed rape were tested. Trials were performed in the North-East EPPO climatic zone (23 in Poland, 6 in Latvia and 6 in Lithuania for a total of 35 trials), in the South-East EPPO climatic zone (11 in Hungary; 12 in Slovakia, 3 in Romania and 10 in Bulgaria for a total of 36 trials) and in the Maritime EPPO climatic zone (17 in the Czech Republic). Two dose rates of the test product DLT+FPF EC85 (0.5L/ha and 0.75L/ha) are presented to show the phytotoxicity assessments and compared to the reference product Proteus® at 0.6L/ha and 0.75L/ha. Test product DLT+FPF EC85 was applied in a rather broad range of crop stages from BBCH 21 to BBCH 73. No phytotoxicity was observed at any of the assessment timings in these trials after 1 or 2 applications carried out at crop stages corresponding to the supported GAPs in winter oilseed rape.

Results of phytotoxicity on spring oilseed rape

Phytotoxicity assessments were carried out in 4 efficacy trials conducted in spring oilseed rape. All trials were performed in the North-East EPPO climatic zone (2 trials in Poland, 1 in Latvia and 1 in Lithuania), test product DLT+FPF EC85 was applied 1 or 2 times, at 0.5L/ha and 0.75L/ha and compared to the reference product Proteus® at 0.75L/ha. ~~Any~~ No phytotoxicity was observed at any of the assessment timings in these trials after 1 and 2 applications in spring oilseed rape.

Conclusion of phytotoxicity on winter and spring oilseed rape

In conclusion, ~~any~~ no phytotoxicity was observed after the first and second application of the test product at the dose 0.5L/ha and 0.75L/ha in winter and spring oilseed rape in a number of commercially important varieties.

Comments of zRMS:

Phytotoxicity was assessed in a total of 88 efficacy trials on winter and spring oilseed rape. No specific disease free trials were carried out. The phytotoxicity symptoms were not observed in any of these trials in plots treated with the tested product DLT+FPF EC85 as well as in plots treated with the reference product, in none of the assessment dates. Based on the submitted data it can be concluded that use of DLT+FPF EC85 at the indicated dose rates is safe for winter and spring oilseed rape.

3.4.2. Effect on the yield of treated plants or plant product (KCP 6.4.2)

Since no phytotoxicity symptoms were observed with DLT+FPF EC85 in all efficacy trials (section 3.4.1), no dedicated crop safety trial was conducted, in accordance with EPPO standard PP 1/135(4) “*Phytotoxicity assessment*”. Effects of DLT+FPF EC85 on yield were measured in the efficacy trials (section 3.2.3), in situations of low to high pests pressure. In no situation, ~~any~~ negative effect on yield could be observed. It can be therefore concluded that when used according to the label it is unlikely that DLT +FPF EC85 would have a detrimental effect on yield.

3.4.3 Effects on the quality of plants or plant products (KCP 6.4.3)

Since no phytotoxicity symptoms were observed with DLT+FPF EC85 in all efficacy trials (section 3.4.1), no dedicated crop safety trials were conducted, in accordance with the EPPO standard PP1/135(4) “*Phytotoxicity assessment*”. ~~Since no phytotoxicity symptoms were observed in field, it can be stated that DLT+FPF EC85 will not have any detrimental effect on quality of crops, when applied according to the recommendations for use.~~ Quality results (oil content in seeds) under variable pest populations densities (low to high) are reported under ~~effectiveness~~ efficacy chapter, as supporting evidence of the benefit of the treatment. No adverse effects on quality of plants or plant products are reported. For a summary of the yield quality data from the efficacy trials, please refer to section 3.2.3.

3.4.4 Effects on transformation processes (KCP 6.4.4)

As from the EPPO standard PP1/243(2) “Effects of plant protection products on transformation processes”, oilseed rape is not included in the list of crops which may be subjected to transformation processes, therefore no specific study was conducted.

Comments of zRMS:

Since the extraction of oil from the oilseed rape seeds does not involve any kind of transformation vulnerable to pesticide residue, the non-submission of any specific study is acceptable.

3.4.5 Impact on treated plants or plant products to be used for propagation (KCP 6.4.5)

As DLT and FPF are insecticides, they show no herbicidal or PGR activity. As reported in section 3.4.1, no phytotoxicity effects have ever been reported in any of the DLT+FPF EC85 efficacy trials performed in oilseed rape after foliar spray which corresponds to the supported uses. Thus, no dedicated crop safety trials were conducted, in accordance with EPPO standard PP1/135(4) “*Phytotoxicity assessment*”. Therefore, it is reasonable to conclude that there will be negligible risk of adverse effects on plant parts used for propagating purposes.

Comments of zRMS:

The applicant's reasoning is correct and has been accepted by zRMS. No impact on propagative material should be expected.

3.5 Observations on other undesirable or unintended side-effects (KCP 6.5)

3.5.1 Impact on succeeding crops (KCP 6.5.1)

The effects of DLT+FPF EC85 on non-target plants are included in the dRR part B Section 9 Ecotoxicology. Evidence generated from application of DLT +FPF EC85, at 1.25 L/ha, measuring seedling emergence and possible phytotoxic symptoms on a representative range of crop seeds (sugar beet; oilseed rape rapeseed; cucumber; soybean; sunflower; tomato; onion; barley; spring wheat; maize) resulted in no effect (document [M-554592-01-1](#)). Therefore, no adverse effect to succeeding crops is expected when DLT+FPF EC85 is applied according to the recommendations for use.

Comments of zRMS:

The applicant submitted final reports on effects on the seedling emergence of non-target terrestrial plant species under greenhouse conditions. The study was conducted according to OECD 208 guideline for the testing of chemicals, Terrestrial Plant Test: Seedling Emergence and Seedling Growth Test (July 2006) and it considered the recommendations of US EPA Ecological Effects Test Guideline OCSPP 850.4100. Conclusions:

- no statistically significant effects on seedling emergence compared to the control was observed for any of the plant species tested on all assessment days,
- the most sensitive species was onion with an inhibition of 10,5% at the application rate of 1250 mL product/ha on day 21,
- no mortality occurred in any of the plant species tested except onion,
- no symptoms of phytotoxicity were observed for any of the plant species tested on all assessment days,
- no statistically significant inhibition on dry weight of shoot was observed for any species tested, except for cucumber and tomato at the test item rate of 1250 mL product/ha
- the highest inhibition on dry weight of shoot was observed for the species onion, followed by sunflower

A test of seedling emergence after application of DLT+FPF EC85 demonstrated that some effects occurred for two of the tested species (onion, cucumber, tomato and sunflower) at the application rates 1,25 L/ha, whereas the dose rates indicated in the GAP table are 0,5 and 075 L/ha. Consequently, it can be concluded that no adverse effects to succeeding crops are expected when tested product is applied according to the recommendations for use.

3.5.2 Impact on other plants including adjacent crops (KCP 6.5.2)

The effects of DLT+FPF EC85 on non-target plants are evaluated in the dRR part B Section 9 Ecotoxicology. A study ([M-554604-01-1](#)) has been conducted to evaluate the effects of DLT+FPF EC85 on a representative range of crop (sugar beet; rapeseed oilseed rape; cucumber; soybean; sunflower; tomato; onion; barley; spring wheat; maize). A statistically significant reduction of dry weight of shoot

was reported in 3 crops (~~rapeseed~~ oilseed rape; sugarbeet, tomato) as well as a light phytotoxicity (sugarbeet, ~~rapeseed~~ oilseed rape). However, the product was applied at a higher dose (1.25 L/ha, whereas 0.75 L/ha is supported) and at BBCH 12-14, whereas an application from BBCH30 is supported. In the field trials there was never any phytotoxicity observed with DLT+FPF EC85, when applied according to the recommendations. Therefore, no adverse effect to adjacent crops is expected when DLT+FPF EC85 is applied according to the recommendations for use.

Comments of zRMS:

The applicant submitted final reports on the effects on the vegetative vigour, of non-target terrestrial plant species and under greenhouse conditions. The study was conducted according to OECD 227 guideline for the testing of chemicals, Terrestrial Plant Test: Vegetative vigour (July 2006) and it considered the recommendations of US EPA Ecological Effects Test Guideline OCSPP 850.4150. Conclusions:

- no mortality occurred for any species tested,
- light symptoms of phytotoxicity could be observed for sugar beet and oilseed rape at the test item rate of 1250 mL product/ha. On day 21 after application, the BBCH growth stage of sugar beet was slightly lower in the test item group than in the control group,
- an application of DLT+FPF EC85 at the dose rate of 1250 mL product/ha resulted in a statistically significant inhibition of dry weight of shoot, for the plant species sugar beet, oilseed rape and tomato.

A test of vegetative vigour after application of DLT+FPF EC85 demonstrated that some effects occurred for some of the tested species (oilseed rape, sugar beet and tomato) at the application rates of 1,25 L/ha, whereas the dose rates indicated in GAP table are 0,5 and 0,75 L/ha. It can therefore be concluded that no adverse effects to adjacent crops should be expected when tested product is applied according to the recommendations for use.

3.5.3 Effects on beneficial and other non-target organisms (KCP 6.5.3)

Detailed studies on the possible adverse effects to beneficial and other non-target organisms are submitted and summarised in Part B, Section 9 (Ecotoxicology).

3.6 Other/special studies

No other studies are reported.

3.7 List of test facilities including the corresponding certificates

Organisation	Town	Country	Valid From	Valid To	Link
Agreco Sp. z o.o.	Wroclaw	Poland	11-Mar-2013	31/dec/00	1d618d48b391d6550357d9
Anadiag Romania	Bucharest	Romania	20/aug/15	20/aug/20	1d618d48afc
Bayer Hungaria Kft.	Budapest	Hungary	31/dec/14	31/dec/19	1d618df38a5
Bayer Sp. z o. o.	Warszawa	Poland	16/jun/10	31/dec/00	1d618d48985
BAZ - PAn Protection and Soil Conservation, Governmental Office, Borsod-Abauj-Zemplen	Miskolc	Hungary	3/aug/11	3/aug/16	1d618df37c5
Biotek Agriculture Polska Sp. Z o.o.	Olawa	Poland	10-Mar-2011	31/dec/19	1d618d486c3
Eurofins Agrosience Services EOOD (Bulgaria)	Letnica	Bulgaria	28-May-2015	28-May-2025	1d618d48b01
Eurofins Agrosience Services EOOD (Bulgaria)	Letnica	Bulgaria	1/jun/10	1/jun/15	1d618d487e5

Fundulea National Institute for Agricultural Research and Development	jud. Calarasi	Romania	20-Aug-2015	20-Aug-2020	1d6550358fd
Fundulea National Institute for Agricultural Research and Development	Fundulea	Romania	30-Jun-2010	30-Jun-2015	1d655035626
FYSE, S.r.o. Odd. Agrolab Kolare	Kolare	Slovakia	28/jan/11	28/jan/16	1d618d48703
Gemerprodukt Valice ovocinar-sko-vinohradnicke druzstvo	Rimavska Sobota	Slovakia	12/apr/16	12/apr/21	1d618d48b4d
Gemerprodukt Valice ovocinar-sko-vinohradnicke druzstvo	Rimavska Sobota	Slovakia	8-Mar-2013	15/feb/16	1d618d487c9
Governmental Office, Komarom-Esztergom	Tatabanya	Hungary	30-May-2012	30-May-2017	1d618df38af
Institute of Agriculture, Lithuanian Research Centre for Agriculture and Forestry	Akademija, Kedainiai district	Lithuania	12/dec/13	12/dec/19	1d618d48a6e
Institute of Agriculture, Lithuanian Research Centre for Agriculture and Forestry	Akademija, Kedainiai district	Lithuania	12/dec/07	12/dec/13	1d618d48858
Institute of Plant Protection - National Research Institute in Poznan	Poznan	Poland	11-May-2011	31/dec/19	1d618d486d9 1d65503536d
Instytut Ochrony Roslin, Panstwowy Instytut Badawczy, Oddzial Sosnicowice	Sosnicowice	Poland	23/jun/08	31/dec/19	1d618d486e2
Krasne Udoli, Ing. Jitka Mareckova	Touzim	Czech Republic	1/sep/16	31/aug/21	1d618df3a69
Krasne Udoli, Ing. Jitka Mareckova	Touzim	Czech Republic	28/jul/11	31/dec/19	1d618df3392
Latvian Plant Protection Research Centre Ltd./ SIA Latvijas Augu aizsardzibas petniecibas centrs	Riga	Latvia	28/sep/16	27/sep/21	1d618d48bc6
Latvian Plant Protection Research Centre Ltd./ SIA Latvijas Augu aizsardzibas petniecibas centrs	Riga	Latvia	20/sep/11	19/sep/16	1d618d48963
Nograd Megyei Kormanyhivatal Növény- és Talajvédelmi Igazgatósága	Balassagyarmat	Hungary	4-Dec-2012	3-Dec-2017	1d65503566a
PLANT-ART RESEARCH Kft.	Budaörs	Hungary	18-May-2015	18-May-2017	1d655035865
Poznan University of Life Sciences Experimental and Didactic Section of Tillage and Plant Cultivation Gorzyn Department of Agronomy	Poznan	Poland	14-Oct-2010	31/dec/00	1d618d48bba
SGS Polska Sp. z o.o.	Warszawa	Poland	16-May-2011	31/dec/19	1d618d486e9
Staphyt Sp. z o.o.	Poznan	Poland	25/sep/12	25/sep/17	1d618d48c3e
Syntech Research Hungary Kft.	Taplanszentkereszt	Hungary	22/sep/17	22/sep/22	1d618d48c30

Syntech Research Hungary Kft.	Taplanszentkereszt	Hungary	8/aug/11	7/aug/16	1d618d48787
UKSUP Kosice	Bratislava	Slovakia	15-Dec-2010	15-Dec-2015	1d6550353a7
Vyzkumny ustav picninarsky, spol. S r.o.	Troubsko	Czech Republic	31-Mar-2009	1/sep/16	1d618d48536
Vyzkumny ustav picninarsky, spol. S r.o.	Troubsko	Czech Republic	1/sep/16	1/sep/21	1d618d48bdf
Zemedelska zkusebni stanice Kujavy, s.r.o.	Kujavy	Czech Republic	14/apr/09	14/apr/16	1d618d48537
ZKUŠEBNÍ STANICE Trutnov s.r.o.	Trutnov	Czech Republic	20-Mar-2009	31/dec/00	1d618d48b51
Zkusebni stanice Kluky, spol. S r.o.	Kluky u Pisku	Czech Republic	1/sep/16	31/aug/21	1d618d48b84
Zkusebni stanice Kluky, spol. S r.o.	Kluky u Pisku	Czech Republic	15-Mar-2010	31/dec/00	1d618d48954
Zkusebni stanice Nechanice s.r.o.	Nechanice	Czech Republic	7/aug/09	7/aug/16	1d618d48b48
Zkusebni stanice Nechanice s.r.o.	Nechanice	Czech Republic	1-Sep-2016	31-Aug-2021	1d655035829
Zkusebni Stanice Trutnov. s.r.o.	Trutnov	Czech Republic	1/sep/16	1/sep/21	1d618d48bb6

Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

Data Point	Author(s)	Year	Title Company Report No. Source GLP or GEP status published or not	Vertebrate study Y/N	Owner
KCP Section 6 / 01	Van Waetermeulen, X.; Tossens, X.	2019	Biological assessment dossier - Efficacy data and information - Detailed summary - Deltamethrin + flupyradi-furone EC85 (85 g/L) - Central zone - Zonal rapporteur member state: Poland - Core assessment (authorization) Report No.: M-665892-01-1 Bayer S.A.S., Crop Science Division, Lyon, France GLP/GEP: n.a. unpublished	No	Bayer
KCP 6.1 / 01	Malsam, O.	2019	Study report for PPF SL200 - Greenhouse study - Myzus persicae in cabbage; Aphis gossypii in cotton Report No.: M-659248-01-1 Bayer AG, Crop Science Division, Monheim, Germany GLP/GEP: No unpublished	No	Bayer
KCP 6.2 / 01 ... also filed: KCP 6.4 / 02	Tossens, X.	2019	Compilation of trial reports for DLT+FPF EC85 - Efficacy trials on Brassicogethes (Meligethes) aeneus on oilseed rape Report No.: M-659528-01-1 Bayer AG, Crop Science Division, Monheim, Germany GLP/GEP: Yes unpublished	No	Bayer
KCP 6.2 / 02 ... also filed: KCP 6.4 / 03	Tossens, X.	2019	Compilation of trial reports for DLT+FPF EC85 - Efficacy trials on Ceutorhynchus obstrictus (assimilis) and Dasineura brassica on oilseed rape Report No.: M-659527-01-1 Bayer AG, Crop Science Division, Monheim, Germany GLP/GEP: Yes unpublished	No	Bayer
KCP 6.2 / 03 ... also filed: KCP 6.4 / 01	Tossens, X.	2019	Compilation of trial reports for DLT+FPF EC85 - Efficacy trials on Ceutorhynchus napi and Ceutorhynchus quadridens on oilseed rape Report No.: M-659525-01-1 Bayer AG, Crop Science Division, Monheim, Germany GLP/GEP: Yes unpublished	No	Bayer

Data Point	Author(s)	Year	Title Company Report No. Source GLP or GEP status published or not	Vertebrate study Y/N	Owner
KCP 6.3 / 01	Nauen, R.	2019	Information on the occurrence or possible occurrence of the development of resistance to DLT+FPF EC85 for the control of insects pests in oilseed rape, in central zone Report No.: M-659907-01-1 Bayer AG, Crop Science Division, Monheim, Germany GLP/GEP: No unpublished	No	Bayer
KCP 6.4 / 01 ... also filed: KCP 6.2 / 03	Tossens, X.	2019	Compilation of trial reports for DLT+FPF EC85 - Efficacy trials on Ceutorhynchus napi and Ceutorhynchus quadridens on oilseed rape Report No.: M-659525-01-1 Bayer AG, Crop Science Division, Monheim, Germany GLP/GEP: Yes unpublished	No	Bayer
KCP 6.4 / 02 ... also filed: KCP 6.2 / 01	Tossens, X.	2019	Compilation of trial reports for DLT+FPF EC85 - Efficacy trials on Brassicogethes (Meligethes) aeneus on oilseed rape Report No.: M-659528-01-1 Bayer AG, Crop Science Division, Monheim, Germany GLP/GEP: Yes unpublished	No	Bayer
KCP 6.4 / 03 ... also filed: KCP 6.2 / 02	Tossens, X.	2019	Compilation of trial reports for DLT+FPF EC85 - Efficacy trials on Ceutorhynchus obstrictus (assimilis) and Dasineura brassica on oilseed rape Report No.: M-659527-01-1 Bayer AG, Crop Science Division, Monheim, Germany GLP/GEP: Yes unpublished	No	Bayer
KCP 6.4 / 04 ... also filed: KCP 6.5.2 / 01	Ripperger, D.	2016	Deltamethrin + flupyradifurone EC 85 (10+75 g/L): Effects on the vegetative vigour of non-target terrestrial plant species under greenhouse conditions Report No.: S15-01671, Edition Number: M-554604-01-1 Eurofins Agroscience Services EcoChem GmbH, Niefern-Oeschelbronn, Germany GLP/GEP: Yes unpublished	No	Bayer
KCP 6.4 / 05 ... also filed: KCP 6.5.1 / 01	Ripperger, D.	2016	Deltamethrin + flupyradifurone EC 85 (10+75 g/L): Effects on the seedling emergence of non-target terrestrial plant species under greenhouse conditions Report No.: S15-01670, Edition Number: M-554592-01-1 Eurofins Agroscience Services EcoChem GmbH, Niefern-Oeschelbronn, Germany GLP/GEP: Yes unpublished	No	Bayer

Data Point	Author(s)	Year	Title Company Report No. Source GLP or GEP status published or not	Vertebrate study Y/N	Owner
KCP 6.5.1 / 01 ... also filed: KCP 6.4 / 05	Ripperger, D.	2016	Deltamethrin + flupyradifurone EC 85 (10+75 g/L): Effects on the seedling emergence of non-target terrestrial plant species under greenhouse conditions Report No.: S15-01670, Edition Number: M-554592-01-1 Eurofins Agroscience Services EcoChem GmbH, Niefern-Oeschelbronn, Germany GLP/GEP: Yes unpublished	No	Bayer
KCP 6.5.2 / 01 ... also filed: KCP 6.4 / 04	Ripperger, D.	2016	Deltamethrin + flupyradifurone EC 85 (10+75 g/L): Effects on the vegetative vigour of non-target terrestrial plant species under greenhouse conditions Report No.: S15-01671, Edition Number: M-554604-01-1 Eurofins Agroscience Services EcoChem GmbH, Niefern-Oeschelbronn, Germany GLP/GEP: Yes unpublished	No	Bayer

List of data submitted or referred to by the applicant and relied on, but already evaluated at EU peer review

Please note that all data mentioned as part of DAR, RAR, or EFSA journals are considered as relied on.

List of data submitted by the applicant and not relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
-	-	-	-	-	-

List of data relied on not submitted by the applicant but necessary for evaluation

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
-	-	-	-	-	-