

REGISTRATION REPORT

Part B **Section 3** **Efficacy Data and Information**

Concise summary

Product code: 102000007779

Product name(s): FFA SC 508.8 G
(Active substance(s)) Flufenacet 508.8 g a.s/L

Central Zone
Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(Authorization)

Applicant: Bayer Crop Science Division

Submission date: 30 June 2021

MS Finalisation date: February 2022 (initial Core Assessment)
June 2023 (final Core Assessment)

Version history

When	What
June 2021	Original Bayer Crop Science Division submission
February 2022	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.
June 2023	Final report (Core Assessment updated following the commenting period) No additional information or assessments after the commenting period.

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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 - FFA SC 508.8 - Flufenacet, 508.8 g/L - Central zone - Zonal rapporteur member state: Poland - Core assessment (authorization)
Report:	Feuerhahn, I.; Nielsen, T.; Bartlett, M.; 2021; M-767892-01-1
Authority registration No:	
Guideline(s):	Regulation (EC) No. 1107/2009
Deviations:	--
GLP/GEP:	not applicable
Acceptability:	
Duplication (if vertebrate study):	

This document is a summary of the data submitted to support the authorization of the plant protection product Flufenacet SC 508.8 G which is commonly named as FFA SC 508.8 G. To ease the reading on this dossier, Flufenacet SC 508.8 G will be referred to as FFA SC508.8. It refers to the BAD “BIOLOGICAL ASSESSMENT DOSSIER Efficacy Data and Information Detailed summary Flufenacet SC 508.8 G”.

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

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. 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 ~~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:

This application has been submitted for the authorization of new product FFA SC 508.8 G (formulation code: 102000007779) in Poland, Slovakia, Belgium and Ireland. FFA SC 508.8 G contains one active substance: flufenacet (508,8 g/l). This product is intended to use as a herbicide for weeds control in winter cereals (wheat, wheat durum, wheat spelt, barley, triticale and rye).

MED

Taking into account the results from all EPPO climatic zones, the dose rate of 0,24 l/ha can be considered the minimum effective dose to control of grasses and some dicotyledonous weeds in winter cereals, either in pre- and post-emergence application. However, the dose rate of 0,48 l/ha can be considered the minimum effective dose to control of ALOMY and LOLMU/LOLSS. Moreover, this dose rate can be also recommended to control of grasses in winter cereals in difficult growing conditions or in case of high level of weed pressure.

Efficacy

Based on the efficacy trial results it can be concluded that herbicide FFA SC 508.8 G is effective in control of grass weeds (ALOMY, APESV, POAAN, LOLSS/LOLMU) in winter cereals, at dose rates 0,24 l/ha and 0,48 l/ha, either in pre- or post-emergence application .

Selectivity

Based on the phytotoxicity assessment in efficacy and selectivity trials, it can be concluded that FFA SC 508.8 G applied at 0.24 L/ha (USE001 and USE003) in winter wheat, winter barley, rye, triticale, spelt and durum wheat will not cause any significant adverse effects, when applied according to the recommendations for pre- or post-emergence uses. Wheares, the application of FFA SC 508.8 G applied at 0.48 l/ha (USE002 and USE004) can cause some adverse effects i.a. thinning, stunting or volume reduction, which are transient. These symptoms do not negatively affect on quality or quantity of yield.

Resistance risk

The inherent risk of flufenacet is considered to be low. Taking into account limited resistant cases and small infested area, the resistance risk can be established as low. Based on the current cases of resistance but also benefit of FFA SC 508.8 G application in winter cereals, the zRMS proposes to include the recommendations to the product label which are presented in the chapter 3.3. The cMSs should consider these recommendations on the national level.

Table 3.1-1: 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. *	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F, Fn, Fnp G, Gn, Gnp or I **	Pests or Group of pests controlled (additionally: devel- opmental 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 applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg 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)														
29	POL	Wheat, winter (TRZAW)	F	ALOMY, POAAN, APESV, LOLSS , LOLMU , BBBBB , TTTDS , MATIN, PAPRH, VERPE	spraying (broadcast, overall)	00-09	a) 1 b) 1	-	a) 0.48 b) 0.48	a) FFA 244.2 b) FFA 244.2	100-400	as per growth stage		A
30	POL	Wheat, winter (TRZAW)	F	ALOMY , POAAN, APESV, LOLSS , LOLMU , BBBBB , TTTDS	spraying (broadcast, overall)	10-13	a) 1 b) 1	-	a) 0.48 b) 0.48	a) FFA 244.2 b) FFA 244.2	100-400	as per growth stage		A
31	POL	Wheat, winter (TRZAW)	F	ALOMY , POAAN, APESV, LOLSS , BBBBB , TTTDS	spraying (broadcast, overall)	00-09	a) 1 b) 1	-	a) 0.24 b) 0.24	a) FFA 122.1 b) FFA 122.1	100-400	as per growth stage		A
32	POL	Wheat, winter (TRZAW)	F	ALOMY , POAAN, APESV, LOLSS , BBBBB , TTTDS	spraying (broadcast, overall)	10-13	a) 1 b) 1	-	a) 0.24 b) 0.24	a) FFA 122.1 b) FFA 122.1	100-400	as per growth stage		A
33	POL	Triticale, winter (TTLWI)	F	ALOMY, POAAN, APESV, LOLSS , LOLMU , BBBBB , TTTDS , MATIN, PAPRH, VERPE	spraying (broadcast, overall)	00-09	a) 1 b) 1	-	a) 0.48 b) 0.48	a) FFA 244.2 b) FFA 244.2	100-400	as per growth stage		A
34	POL	Triticale, winter (TTLWI)	F	ALOMY , POAAN, APESV, LOLSS , LOLMU , BBBBB , TTTDS	spraying (broadcast, overall)	10-13	a) 1 b) 1	-	a) 0.48 b) 0.48	a) FFA 244.2 b) FFA 244.2	100-400	as per growth stage		A
35	POL	Triticale, winter (TTLWI)	F	ALOMY , POAAN, APESV, LOLSS , BBBBB , TTTDS	spraying (broadcast, overall)	00-09	a) 1 b) 1	-	a) 0.24 b) 0.24	a) FFA 122.1 b) FFA 122.1	100-400	as per growth stage		A
36	POL	Triticale, winter (TTLWI)	F	ALOMY , POAAN, APESV, LOLSS , BBBBB , TTTDS	spraying (broadcast, overall)	10-13	a) 1 b) 1	-	a) 0.24 b) 0.24	a) FFA 122.1 b) FFA 122.1	100-400	as per growth stage		A

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No. *	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F, Fn, Fnp G, Gn, Gnp or I **	Pests or Group of pests controlled (additionally: devel- opmental 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 applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
37	POL	Barley, winter (HORVW)	F	ALOMY, POAAN, APESV, LOLSS LOLMU , BBBBB , TTTDS , MATIN, PAPRH, VERPE	spraying (broadcast, overall)	00-09	a) 1 b) 1	-	a) 0.48 b) 0.48	a) FFA 244.2 b) FFA 244.2	100-400	as per growth stage		A
38	POL	Barley, winter (HORVW)	F	ALOMY , POAAN, APESV, LOLSS LOLMU , BBBBB , TTTDS	spraying (broadcast, overall)	10-13	a) 1 b) 1	-	a) 0.48 b) 0.48	a) FFA 244.2 b) FFA 244.2	100-400	as per growth stage		A
39	POL	Barley, winter (HORVW)	F	ALOMY , POAAN, APESV, LOLSS , BBBBB , TTTDS	spraying (broadcast, overall)	00-09	a) 1 b) 1	-	a) 0.24 b) 0.24	a) FFA 122.1 b) FFA 122.1	100-400	as per growth stage		A
40	POL	Barley, winter (HORVW)	F	ALOMY , POAAN, APESV, LOLSS , BBBBB , TTTDS	spraying (broadcast, overall)	10-13	a) 1 b) 1	-	a) 0.24 b) 0.24	a) FFA 122.1 b) FFA 122.1	100-400	as per growth stage		A
89	POL	Rye (SECCW)	F	ALOMY, POAAN, APESV, LOLSS LOLMU , BBBBB , TTTDS , MATIN, PAPRH, VERPE	spraying (broadcast, overall)	00-09	a) 1 b) 1	-	a) 0.48 b) 0.48	a) FFA 244.2 b) FFA 244.2	100-400	as per growth stage		A
90	POL	Rye (SECCW)	F	ALOMY , POAAN, APESV, LOLSS LOLMU , BBBBB , TTTDS	spraying (broadcast, overall)	10-13	a) 1 b) 1	-	a) 0.48 b) 0.48	a) FFA 244.2 b) FFA 244.2	100-400	as per growth stage		A
91	POL	Rye (SECCW)	F	ALOMY , POAAN, APESV, LOLSS , BBBBB , TTTDS	spraying (broadcast, overall)	00-09	a) 1 b) 1	-	a) 0.24 b) 0.24	a) FFA 122.1 b) FFA 122.1	100-400	as per growth stage		A
92	POL	Rye (SECCW)	F	ALOMY , POAAN, APESV, LOLSS , BBBBB , TTTDS	spraying (broadcast, overall)	10-13	a) 1 b) 1	-	a) 0.24 b) 0.24	a) FFA 122.1 b) FFA 122.1	100-400	as per growth stage		A
93	POL	Durum wheat (TRZDW)	F	ALOMY, POAAN, APESV, LOLSS LOLMU , BBBBB , TTTDS	spraying (broadcast, overall)	00-09	a) 1 b) 1	-	a) 0.48 b) 0.48	a) FFA 244.2 b) FFA 244.2	100-400	as per growth stage		A

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No. *	Member 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: devel- opmental 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)
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				TTTTDS , MATIN, PAPRH, VERPE										
94	POL	Durum wheat (TRZDW)	F	ALOMY , POAAN, APESV, LOLSS LOLMU , BBBBB , TTTTDS	spraying (broadcast, overall)	10-13	a) 1 b) 1	-	a) 0.48 b) 0.48	a) FFA 244.2 b) FFA 244.2	100-400	as per growth stage		A
95	POL	Durum wheat (TRZDW)	F	ALOMY , POAAN, APESV, LOLSS , BBBBB , TTTTDS	spraying (broadcast, overall)	00-09	a) 1 b) 1	-	a) 0.24 b) 0.24	a) FFA 122.1 b) FFA 122.1	100-400	as per growth stage		A
96	POL	Durum wheat (TRZDW)	F	ALOMY , POAAN, APESV, LOLSS , BBBBB , TTTTDS	spraying (broadcast, overall)	10-13	a) 1 b) 1	-	a) 0.24 b) 0.24	a) FFA 122.1 b) FFA 122.1	100-400	as per growth stage		A
129	POL	Spelt (TRZSP)	F	ALOMY , POAAN, APESV, LOLSS LOLMU , BBBBB , TTTTDS , MATIN, PARH, VERPE	spraying (broadcast, overall)	00-09	a) 1 b) 1	-	a) 0.48 b) 0.48	a) FFA 244.2 b) FFA 244.2	100-400	as per growth stage		A
130	POL	Spelt (TRZSP)	F	ALOMY , POAAN, APESV, LOLSS LOLMU , BBBBB , TTTTDS	spraying (broadcast, overall)	10-13	a) 1 b) 1	-	a) 0.48 b) 0.48	a) FFA 244.2 b) FFA 244.2	100-400	as per growth stage		A
131	POL	Spelt (TRZSP)	F	ALOMY , POAAN, APESV, LOLSS , BBBBB , TTTTDS	spraying (broadcast, overall)	00-09	a) 1 b) 1	-	a) 0.24 b) 0.24	a) FFA 122.1 b) FFA 122.1	100-400	as per growth stage		A
132	POL	Spelt (TRZSP)	F	ALOMY , POAAN, APESV, LOLSS , BBBBB , TTTTDS	spraying (broadcast, overall)	10-13	a) 1 b) 1	-	a) 0.24 b) 0.24	a) FFA 122.1 b) FFA 122.1	100-400	as per growth stage		A

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
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53	SVK	Wheat, winter (TRZAW)	F	ALOMY, POAAN, APESV, L OLSS, L OLMU, BBBBB , TTTTDS , MATIN, PAPRH, VERPE	spraying (broadcast, overall)	00-09	a) 1 b) 1	-	a) 0.48 b) 0.48	a) FFA 244.2 b) FFA 244.2	100-400	as per growth stage		C
54	SVK	Wheat, winter (TRZAW)	F	ALOMY, POAAN, APESV, L OLSS, L OLMU, BBBBB , TTTTDS	spraying (broadcast, overall)	10-13	a) 1 b) 1	-	a) 0.48 b) 0.48	a) FFA 244.2 b) FFA 244.2	100-400	as per growth stage		C
55	SVK	Wheat, winter (TRZAW)	F	ALOMY , POAAN, APESV, L OLSS, BBBBB , TTTTDS	spraying (broadcast, overall)	00-09	a) 1 b) 1	-	a) 0.24 b) 0.24	a) FFA 122.1 b) FFA 122.1	100-400	as per growth stage		C
56	SVK	Wheat, winter (TRZAW)	F	ALOMY , POAAN, APESV, L OLSS, BBBBB , TTTTDS	spraying (broadcast, overall)	10-13	a) 1 b) 1	-	a) 0.24 b) 0.24	a) FFA 122.1 b) FFA 122.1	100-400	as per growth stage		C
57	SVK	Triticale, winter (TTLWI)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTTDS	spraying (broadcast, overall)	00-09	a) 1 b) 1	-	a) 0.48 b) 0.48	a) FFA 244.2 b) FFA 244.2	100-400	as per growth stage		C
58	SVK	Triticale, winter (TTLWI)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTTDS	spraying (broadcast, overall)	10-13	a) 1 b) 1	-	a) 0.48 b) 0.48	a) FFA 244.2 b) FFA 244.2	100-400	as per growth stage		C
59	SVK	Triticale, winter (TTLWI)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTTDS	spraying (broadcast, overall)	00-09	a) 1 b) 1	-	a) 0.24 b) 0.24	a) FFA 122.1 b) FFA 122.1	100-400	as per growth stage		C

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No. *	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F, Fn, Fnp G, Gn, Gnp or I **	Pests or Group of pests controlled (additionally: devel- opmental 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 applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
60	SVK	Triticale, winter (TTLWI)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTDS	spraying (broadcast, overall)	10-13	a) 1 b) 1	-	a) 0.24 b) 0.24	a) FFA 122.1 b) FFA 122.1	100-400	as per growth stage		C
61	SVK	Barley, winter (HORVW)	F	ALOMY, POAAN, APESV, LOLSS, LOLMU, BBBBB, TTDS, MATIN, PAPRH, VERPE	spraying (broadcast, overall)	00-09	a) 1 b) 1	-	a) 0.48 b) 0.48	a) FFA 244.2 b) FFA 244.2	100-400	as per growth stage		C
62	SVK	Barley, winter (HORVW)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTDS	spraying (broadcast, overall)	10-13	a) 1 b) 1	-	a) 0.48 b) 0.48	a) FFA 244.2 b) FFA 244.2	100-400	as per growth stage		C
63	SVK	Barley, winter (HORVW)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTDS	spraying (broadcast, overall)	00-09	a) 1 b) 1	-	a) 0.24 b) 0.24	a) FFA 122.1 b) FFA 122.1	100-400	as per growth stage		C
64	SVK	Barley, winter (HORVW)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTDS	spraying (broadcast, overall)	10-13	a) 1 b) 1	-	a) 0.24 b) 0.24	a) FFA 122.1 b) FFA 122.1	100-400	as per growth stage		C
97	SVK	Rye (SECCW)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTDS	spraying (broadcast, overall)	00-09	a) 1 b) 1	-	a) 0.48 b) 0.48	a) FFA 244.2 b) FFA 244.2	100-400	as per growth stage		C
98	SVK	Rye (SECCW)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTDS	spraying (broadcast, overall)	10-13	a) 1 b) 1	-	a) 0.48 b) 0.48	a) FFA 244.2 b) FFA 244.2	100-400	as per growth stage		C
99	SVK	Rye (SECCW)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTDS	spraying (broadcast, overall)	00-09	a) 1 b) 1	-	a) 0.24 b) 0.24	a) FFA 122.1 b) FFA 122.1	100-400	as per growth stage		C
100	SVK	Rye (SECCW)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTDS	spraying (broadcast, overall)	10-13	a) 1 b) 1	-	a) 0.24 b) 0.24	a) FFA 122.1 b) FFA 122.1	100-400	as per growth stage		C
101	SVK	Durum wheat	F	ALOMY, POAAN,	spraying	00-09	a) 1	-	a) 0.48	a) FFA 244.2	100-400	as per		C

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No. *	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F, Fn, Fnp G, Gn, Gnp or I **	Pests or Group of pests controlled (additionally: devel- opmental 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 applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
		(TRZDW)		APESV, LOLSS, BBBBB, TTTDS	(broadcast, overall)		b) 1		b) 0.48	b) FFA 244.2		growth stage		
102	SVK	Durum wheat (TRZDW)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTTDS	spraying (broadcast, overall)	10-13	a) 1 b) 1	-	a) 0.48 b) 0.48	a) FFA 244.2 b) FFA 244.2	100-400	as per growth stage		C
103	SVK	Durum wheat (TRZDW)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTTDS	spraying (broadcast, overall)	00-09	a) 1 b) 1	-	a) 0.24 b) 0.24	a) FFA 122.1 b) FFA 122.1	100-400	as per growth stage		C
104	SVK	Durum wheat (TRZDW)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTTDS	spraying (broadcast, overall)	10-13	a) 1 b) 1	-	a) 0.24 b) 0.24	a) FFA 122.1 b) FFA 122.1	100-400	as per growth stage		C
133	SVK	Spelt (TRZSP)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTTDS	spraying (broadcast, overall)	00-09	a) 1 b) 1	-	a) 0.48 b) 0.48	a) FFA 244.2 b) FFA 244.2	100-400	as per growth stage		C
134	SVK	Spelt (TRZSP)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTTDS	spraying (broadcast, overall)	10-13	a) 1 b) 1	-	a) 0.48 b) 0.48	a) FFA 244.2 b) FFA 244.2	100-400	as per growth stage		C
135	SVK	Spelt (TRZSP)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTTDS	spraying (broadcast, overall)	00-09	a) 1 b) 1	-	a) 0.24 b) 0.24	a) FFA 122.1 b) FFA 122.1	100-400	as per growth stage		C
136	SVK	Spelt (TRZSP)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTTDS	spraying (broadcast, overall)	10-13	a) 1 b) 1	-	a) 0.24 b) 0.24	a) FFA 122.1 b) FFA 122.1	100-400	as per growth stage		C
65	BEL	Wheat, winter (TRZAW)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTTDS MATIN, PAPRH, VERPE	spraying (broadcast, overall)	00-09	a) 1 b) 1	-	a) 0.48 b) 0.48	a) FFA 244.2 b) FFA 244.2	100-400	as per growth stage		A ALOMY, APESV, LOLSS, POAAN, PAPRH C MATIN, VERPE

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No. *	Member 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: devel- opmental 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 applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
66	BEL	Wheat, winter (TRZAW)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTDS	spraying (broadcast, overall)	10-13	a) 1 b) 1	-	a) 0.48 b) 0.48	a) FFA 244.2 b) FFA 244.2	100-400	as per growth stage		A <i>ALOMY, LOLSS, POAAN</i>
67	BEL	Wheat, winter (TRZAW)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTDS	spraying (broadcast, overall)	00-09	a) 1 b) 1	-	a) 0.24 b) 0.24	a) FFA 122.1 b) FFA 122.1	100-400	as per growth stage		A
68	BEL	Wheat, winter (TRZAW)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTDS	spraying (broadcast, overall)	10-13	a) 1 b) 1	-	a) 0.24 b) 0.24	a) FFA 122.1 b) FFA 122.1	100-400	as per growth stage		A
69	BEL	Triticale, winter (TTLWI)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTDS	spraying (broadcast, overall)	00-09	a) 1 b) 1	-	a) 0.48 b) 0.48	a) FFA 244.2 b) FFA 244.2	100-400	as per growth stage		C
70	BEL	Triticale, winter (TTLWI)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTDS	spraying (broadcast, overall)	10-13	a) 1 b) 1	-	a) 0.48 b) 0.48	a) FFA 244.2 b) FFA 244.2	100-400	as per growth stage		C
71	BEL	Triticale, winter (TTLWI)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTDS	spraying (broadcast, overall)	00-09	a) 1 b) 1	-	a) 0.24 b) 0.24	a) FFA 122.1 b) FFA 122.1	100-400	as per growth stage		C
72	BEL	Triticale, winter (TTLWI)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTDS	spraying (broadcast, overall)	10-13	a) 1 b) 1	-	a) 0.24 b) 0.24	a) FFA 122.1 b) FFA 122.1	100-400	as per growth stage		C
73	BEL	Barley, winter (HORVW)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTDS MATIN, PAPRH, VERPE	spraying (broadcast, overall)	00-09	a) 1 b) 1	-	a) 0.48 b) 0.48	a) FFA 244.2 b) FFA 244.2	100-400	as per growth stage		C

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No. *	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F, Fn, G, Gnp or I **	Pests or Group of pests controlled (additionally: devel- opmental 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 applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
74	BEL	Barley, winter (HORVW)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTTDS	spraying (broadcast, overall)	10-13	a) 1 b) 1	-	a) 0.48 b) 0.48	a) FFA 244.2 b) FFA 244.2	100-400	as per growth stage		C
75	BEL	Barley, winter (HORVW)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTTDS	spraying (broadcast, overall)	00-09	a) 1 b) 1	-	a) 0.24 b) 0.24	a) FFA 122.1 b) FFA 122.1	100-400	as per growth stage		C
76	BEL	Barley, winter (HORVW)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTTDS	spraying (broadcast, overall)	10-13	a) 1 b) 1	-	a) 0.24 b) 0.24	a) FFA 122.1 b) FFA 122.1	100-400	as per growth stage		C
105	BEL	Rye (SECCW)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTTDS	spraying (broadcast, overall)	00-09	a) 1 b) 1	-	a) 0.48 b) 0.48	a) FFA 244.2 b) FFA 244.2	100-400	as per growth stage		C
106	BEL	Rye (SECCW)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTTDS	spraying (broadcast, overall)	10-13	a) 1 b) 1	-	a) 0.48 b) 0.48	a) FFA 244.2 b) FFA 244.2	100-400	as per growth stage		C
107	BEL	Rye (SECCW)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTTDS	spraying (broadcast, overall)	00-09	a) 1 b) 1	-	a) 0.24 b) 0.24	a) FFA 122.1 b) FFA 122.1	100-400	as per growth stage		C
108	BEL	Rye (SECCW)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTTDS	spraying (broadcast, overall)	10-13	a) 1 b) 1	-	a) 0.24 b) 0.24	a) FFA 122.1 b) FFA 122.1	100-400	as per growth stage		C
109	BEL	Durum wheat (TRZDW)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTTDS	spraying (broadcast, overall)	00-09	a) 1 b) 1	-	a) 0.48 b) 0.48	a) FFA 244.2 b) FFA 244.2	100-400	as per growth stage		C
110	BEL	Durum wheat (TRZDW)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTTDS	spraying (broadcast, overall)	10-13	a) 1 b) 1	-	a) 0.48 b) 0.48	a) FFA 244.2 b) FFA 244.2	100-400	as per growth stage		C
111	BEL	Durum wheat (TRZDW)	F	ALOMY, POAAN, APESV, LOLSS,	spraying (broadcast,	00-09	a) 1 b) 1	-	a) 0.24 b) 0.24	a) FFA 122.1 b) FFA 122.1	100-400	as per growth		C

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No. *	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F, Fn, Fnp G, Gn, Gnp or I **	Pests or Group of pests controlled (additionally: devel- opmental 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 applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
				BBBBB, TTDS	overall)							stage		
112	BEL	Durum wheat (TRZDW)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTDS	spraying (broadcast, overall)	10-13	a) 1 b) 1	-	a) 0.24 b) 0.24	a) FFA 122.1 b) FFA 122.1	100-400	as per growth stage		C
137	BEL	Spelt (TRZSP)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTDS	spraying (broadcast, overall)	00-09	a) 1 b) 1	-	a) 0.48 b) 0.48	a) FFA 244.2 b) FFA 244.2	100-400	as per growth stage		C
138	BEL	Spelt (TRZSP)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTDS	spraying (broadcast, overall)	10-13	a) 1 b) 1	-	a) 0.48 b) 0.48	a) FFA 244.2 b) FFA 244.2	100-400	as per growth stage		C
139	BEL	Spelt (TRZSP)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTDS	spraying (broadcast, overall)	00-09	a) 1 b) 1	-	a) 0.24 b) 0.24	a) FFA 122.1 b) FFA 122.1	100-400	as per growth stage		C
140	BEL	Spelt (TRZSP)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTDS	spraying (broadcast, overall)	10-13	a) 1 b) 1	-	a) 0.24 b) 0.24	a) FFA 122.1 b) FFA 122.1	100-400	as per growth stage		C
77	IRL	Wheat, winter (TRZAW)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTDS MATIN, PAPRH, VERPE	spraying (broadcast, overall)	00-09	a) 1 b) 1	-	a) 0.48 b) 0.48	a) FFA 244.2 b) FFA 244.2	100-400	as per growth stage		A ALOMY, APESV, LOLSS, POAAN, PAPRH
														C MATIN, VERPE
78	IRL	Wheat, winter (TRZAW)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTDS	spraying (broadcast, overall)	10-13	a) 1 b) 1	-	a) 0.48 b) 0.48	a) FFA 244.2 b) FFA 244.2	100-400	as per growth stage		A ALOMY, LOLSS, POAAN
														C APESV
79	IRL	Wheat, winter (TRZAW)	F	ALOMY, POAAN, APESV, LOLSS,	spraying (broadcast,	00-09	a) 1 b) 1	-	a) 0.24 b) 0.24	a) FFA 122.1 b) FFA 122.1	100-400	as per growth		A

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No. *	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F, Fn, Fnp G, Gn, Gnp or I **	Pests or Group of pests controlled (additionally: devel- opmental 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 applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
				BBBBB, TTDS	overall)							stage		
80	IRL	Wheat, winter (TRZAW)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTDS	spraying (broadcast, overall)	10-13	a) 1 b) 1	-	a) 0.24 b) 0.24	a) FFA 122.1 b) FFA 122.1	100-400	as per growth stage		A
81	IRL	Triticale, winter (TTLWI)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTDS	spraying (broadcast, overall)	00-09	a) 1 b) 1	-	a) 0.48 b) 0.48	a) FFA 244.2 b) FFA 244.2	100-400	as per growth stage		C
82	IRL	Triticale, winter (TTLWI)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTDS	spraying (broadcast, overall)	10-13	a) 1 b) 1	-	a) 0.48 b) 0.48	a) FFA 244.2 b) FFA 244.2	100-400	as per growth stage		C
83	IRL	Triticale, winter (TTLWI)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTDS	spraying (broadcast, overall)	00-09	a) 1 b) 1	-	a) 0.24 b) 0.24	a) FFA 122.1 b) FFA 122.1	100-400	as per growth stage		C
84	IRL	Triticale, winter (TTLWI)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTDS	spraying (broadcast, overall)	10-13	a) 1 b) 1	-	a) 0.24 b) 0.24	a) FFA 122.1 b) FFA 122.1	100-400	as per growth stage		C
85	IRL	Barley, winter (HORVW)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTDS MATIN, PAPRH, VERPE	spraying (broadcast, overall)	00-09	a) 1 b) 1	-	a) 0.48 b) 0.48	a) FFA 244.2 b) FFA 244.2	100-400	as per growth stage		C
86	IRL	Barley, winter (HORVW)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTDS	spraying (broadcast, overall)	10-13	a) 1 b) 1	-	a) 0.48 b) 0.48	a) FFA 244.2 b) FFA 244.2	100-400	as per growth stage		C
87	IRL	Barley, winter (HORVW)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTDS	spraying (broadcast, overall)	00-09	a) 1 b) 1	-	a) 0.24 b) 0.24	a) FFA 122.1 b) FFA 122.1	100-400	as per growth stage		C
88	IRL	Barley, winter (HORVW)	F	ALOMY, POAAN, APESV, LOLSS,	spraying (broadcast,	10-13	a) 1 b) 1	-	a) 0.24 b) 0.24	a) FFA 122.1 b) FFA 122.1	100-400	as per growth		C

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No. *	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F, Fn, Fnp G, Gn, Gnp or I **	Pests or Group of pests controlled (additionally: devel- opmental 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 applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
				BBBBB, TTTDS	overall)							stage		
113	IRL	Rye (SECCW)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTTDS	spraying (broadcast, overall)	00-09	a) 1 b) 1	-	a) 0.48 b) 0.48	a) FFA 244.2 b) FFA 244.2	100-400	as per growth stage		C
114	IRL	Rye (SECCW)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTTDS	spraying (broadcast, overall)	10-13	a) 1 b) 1	-	a) 0.48 b) 0.48	a) FFA 244.2 b) FFA 244.2	100-400	as per growth stage		C
115	IRL	Rye (SECCW)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTTDS	spraying (broadcast, overall)	00-09	a) 1 b) 1	-	a) 0.24 b) 0.24	a) FFA 122.1 b) FFA 122.1	100-400	as per growth stage		C
116	IRL	Rye (SECCW)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTTDS	spraying (broadcast, overall)	10-13	a) 1 b) 1	-	a) 0.24 b) 0.24	a) FFA 122.1 b) FFA 122.1	100-400	as per growth stage		C
117	IRL	Durum wheat (TRZDW)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTTDS	spraying (broadcast, overall)	00-09	a) 1 b) 1	-	a) 0.48 b) 0.48	a) FFA 244.2 b) FFA 244.2	100-400	as per growth stage		C
118	IRL	Durum wheat (TRZDW)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTTDS	spraying (broadcast, overall)	10-13	a) 1 b) 1	-	a) 0.48 b) 0.48	a) FFA 244.2 b) FFA 244.2	100-400	as per growth stage		C
119	IRL	Durum wheat (TRZDW)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTTDS	spraying (broadcast, overall)	00-09	a) 1 b) 1	-	a) 0.24 b) 0.24	a) FFA 122.1 b) FFA 122.1	100-400	as per growth stage		C
120	IRL	Durum wheat (TRZDW)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTTDS	spraying (broadcast, overall)	10-13	a) 1 b) 1	-	a) 0.24 b) 0.24	a) FFA 122.1 b) FFA 122.1	100-400	as per growth stage		C
141	IRL	Spelt (TRZSP)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTTDS	spraying (broadcast, overall)	00-09	a) 1 b) 1	-	a) 0.48 b) 0.48	a) FFA 244.2 b) FFA 244.2	100-400	as per growth stage		C
142	IRL	Spelt (TRZSP)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTTDS	spraying (broadcast, overall)	10-13	a) 1 b) 1	-	a) 0.48 b) 0.48	a) FFA 244.2 b) FFA 244.2	100-400	as per growth stage		C

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No. *	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F, Fn, Fnp G, Gn, Gnp or I **	Pests or Group of pests controlled (additionally: devel- opmental 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 applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
143	IRL	Spelt (TRZSP)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTDS	spraying (broadcast, overall)	00-09	a) 1 b) 1	-	a) 0.24 b) 0.24	a) FFA 122.1 b) FFA 122.1	100-400	as per growth stage		C
144	IRL	Spelt (TRZSP)	F	ALOMY, POAAN, APESV, LOLSS, BBBBB, TTDS	spraying (broadcast, overall)	10-13	a) 1 b) 1	-	a) 0.24 b) 0.24	a) FFA 122.1 b) FFA 122.1	100-400	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, Fnp: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gnp: professional and non-professional greenhouse use, I: indoor application

Column 15: zRMS conclusion,

A	Acceptable
R	Acceptable with further restriction
C	To be confirmed by CMS
N	Not acceptable / evaluation not possible
n.r.	Not relevant for section 3

3.2 Efficacy data (KCP 6)

Introduction

Submission type: authorization
Central Zone RMS: Poland

c-MS	Nat Add (Y/N)	Justification for Nat Add
Central Zone	N	no
Belgium	N	no
Poland	N	no
Slovakia	N	no
Ireland	N	no

Description of active substances

This product contains the following active substances

Flufenacet	existing
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Mode of action

Table 3.2-1: Details of the active substances

Active substance	flufenacet
Concentration (Unit: g/kg or g/L...)	508.8 g/L
Chemical group	Oxyacetamide
Mode of action	Inhibition of cell division (HRAC group : K3)
Biological action	Pre-emergence and early post-emergence herbicide

Description of the plant protection product

FFA SC508.8 is a soluble concentrate (SC) containing 508.8 grams per litre (g/L) flufenacet, whose specification number is 102000007779. FFA SC508.8 is to be used on winter cereals at two different application timings in the autumn (either pre-emergence crop BBCH 00-09 or post-emergence at crop BBCH 10-13) for the control of grass weeds and broad-leaved weeds.

Trials presented in this submission contain FFA SC508.8 tested at different dose rates. Some trials tested the target dose rates of 0.24 L/ha and 0.48 L/ha respectively. Other trials tested 0.25 L/ha and 0.5 L/ha, respectively. The dose rate difference between the two formulations is below 5% and therefore considered minor and they should therefore be considered equivalent. Hence, trials are presented together in tables under the respective target dose rates of 0.24 L/ha and 0.48 L/ha in order to ease the reading of this document.

FFA SC508.8 has been evaluated under the following synonyms in field trials:

Name	Formulation Code
FFA SC508.8	102000007779
FFA SC500	
Cadou	

Further details concerning the requested uses for FFA SC508.8 are presented in Table 3.0-2

Table 3.2-2: Simplified table of intended uses for product FFA SC508.8

Use N° in GAP table	USE N°	Uses		Member State	Currently registered rate(s)	Requested rate(s)	Comments / Other relevant details on GAPs
		Crop(s)	Target(s)				
67	USE001	TRZAW	APESV POAAN	BEL	-	0.24 L/ha	Pre-emergence; BBCH 00-09
71		TTLWI					
75		HORVW					
111		TRZDW					
139		TRZSP					
107		SECCW					
31		TRZAW		POL			
35		TTLWI					
39		HORVW					
95		TRZDW					
131		TRZSP					
91		SECCW					
55		TRZAW		SVK			
59		TTLWI					
63		HORVW					
103		TRZDW					
135		TRZSP					
99		SECCW					
79		TRZAW		IRL			
83		TTLWI					
87		HORVW					
115		TRZDW					
119		TRZSP					
143		SECCW					
65	USE002	TRZAW	ALOMY POAAN APESV high infestation LOLSS MATIN PAPRH VERPE	BEL	-	0.48 L/ha	Pre-emergence; BBCH 00-09
69		TTLWI					
73		HORVW					
109		TRZDW					
137		TRZSP					
105		SECCW					
29		TRZAW		POL			
33		TTLWI					
37		HORVW					
93		TRZDW					
129		TRZSP					
89		SECCW					
53		TRZAW		SVK			
57		TTLWI					
61		HORVW					
101		TRZDW					
133		TRZSP					
97		SECCW					
77		TRZAW		IRL			
81		TTLWI					
85		HORVW					
113		TRZDW					
117		TRZSP					
141		SECCW					
68	USE003	TRZAW	APESV POAAN	BEL	-	0.48 L/ha	Post-emergence;
72		TTLWI					

Use N° in GAP table	USE N°	Uses		Member State	Currently registered rate(s)	Requested rate(s)	Comments / Other relevant details on GAPs BBCH 10-13					
		Crop(s)	Target(s)									
76		HORVW		POL								
112		TRZDW										
140		TRZSP										
108		SECCW										
32		TRZAW										
36		TTLWI										
40		HORVW										
96		TRZDW										
132		TRZSP										
92		SECCW										
56		TRZAW										
60		TTLWI										
64		HORVW										
104		TRZDW										
136		TRZSP										
100		SECCW										
80		TRZAW										
84		TTLWI										
88		HORVW										
116		TRZDW										
120		TRZSP										
144		SECCW										
66		USE004		TRZAW				ALOMY POAAN APESV high infestation LOLSS MATIN PAPRH VERPE	BEL	-	0.48 L/ha	Post-emergence; BBCH 10-13
70				TTLWI								
74	HORVW											
110	TRZDW											
138	TRZSP		POL									
106	SECCW											
30	TRZAW											
34	TTLWI											
38	HORVW		SVK									
94	TRZDW											
130	TRZSP											
90	SECCW											
54	TRZAW		IRL									
58	TTLWI											
62	HORVW											
102	TRZDW											
134	TRZSP											
98	SECCW											
78	TRZAW											
82	TTLWI											
86	HORVW											
114	TRZDW											
118	TRZSP											
142	SECCW											

Further details are in the table “All intended uses” in Part B - Section 0.

Description of the target pests

Table 3.2-3: Glossary of pests mentioned in the dossier.

EPPO code	Scientific name	EPPO code	Scientific name
Grass weeds			
ALOMY	<i>Alopecurus myosuroides</i>	LOLSS	<i>Lolium</i> sp.
APESV	<i>Apera spica-venti</i>	LOLPE	<i>Lolium perenne</i>
LOLMU	<i>Lolium multiflorum</i>	POAAN	<i>Poa annua</i> L.
Broad-leaved weeds			
MATIN	<i>Tripleurospermum inodorum</i>	PAPRH	<i>Papaver rhoeas</i>
VERPE	<i>Veronica persica</i>		

The following provides general background information on the biology and importance of the target weeds.

Table 3.2-4: Major / minor status of intended uses (for all CMS and zRMS).

Crop and/or situation	Crop status		Pests or group of pests controlled	Pest status	
	Major	minor		Major	minor
Winter soft wheat	BEL, POL, SVK, IRL	-	ALOMY	BEL, POL, SVK, IRL	-
			APESV	BEL, POL, SVK, IRL	
			LOLSS	BEL, POL , SVK, IRL	POL
			POAAN	BEL, POL , SVK, IRL	POL
			TTTDS	P BEL, POL, SVK, IRL	-
Winter barley	BEL, POL, SVK, IRL	-	ALOMY	BEL, POL, SVK, IRL	-
			APESV	BEL, POL, SVK, IRL	
			LOLSS	BEL, POL , SVK, IRL	POL
			POAAN	BEL, POL , SVK, IRL	POL
			TTTDS	BEL, POL, SVK, IRL	-
Winter triticale	POL, SVK	BEL, IRL	ALOMY	POL, SVK	BEL, IRL
			APESV	POL, SVK	BEL, IRL
			LOLSS	POL , SVK	BEL, IRL, POL
			POAAN	POL , SVK	BEL, IRL, POL
			TTTDS	POL, SVK	BEL, IRL
Winter rye	POL, SVK	BEL, IRL	ALOMY	SVK	BEL, POL, IRL
			APESV	POL, SVK	BEL, IRL
			POAAN	POL , SVK	BEL, IRL, POL
			LOLSS	POL , SVK	BEL, IRL, POL
			TTTDS	POL, SVK	BEL, IRL
Winter durum wheat	SVK	BEL, POL, IRL	ALOMY	SVK	BEL, POL, IRL
			APESV	SVK	BEL, POL, IRL
			LOLSS	SVK	BEL, POL, IRL
			POAAN	SVK	BEL, POL, IRL
			TTTDS	SVK	BEL, POL, IRL
Spelt	-	BEL, POL, SVK, IRL	ALOMY	-	BEL, POL, SVK, IRL
			APESV	-	BEL, POL, SVK, IRL
			LOLSS	-	BEL, POL, SVK, IRL

			POAAN	-	BEL, POL, SVK, IRL
			TTTDS	-	BEL, POL, SVK, IRL

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 into Part A,

Flufenacet SC508.8 (508.8 g/L)

A suspension concentrate (SC) containing 508.8 g/L flufenacet

CROPS

For use on winter soft wheat, winter triticale, winter barley, winter rye, spelt and winter durum wheat

TARGETS

For control of grasses weeds:

Alopecurus myosuroides - ALOMY

Apera spica-venti - APESV

Lolium sp. - LOLSS

Poa annua - POAAN

For control of annual broad-leaved weeds (MATIN, PAPRH, VERPE)

APPLICATION TIMING

Pre-emergence at:

Crop BBCH 00-09 in BEL, SVK, POL, IRL

Post-emergence at:

Crop BBCH 10-13 in BEL, SVK, POL, IRL

NUMBER OF APPLICATIONS

1 application:

0.24 L/ha

or

0.48 L/ha

RATE & WATER VOLUME

100 – 400 L/ha in BEL, POL, SVK, IRL

APPLICATION DETAILS

Foliar application

Compliance with the Uniform Principles

The assessment is performed according to the uniform principles.

Information on trials submitted (3.1 Efficacy data)

The trials implemented and reported to support effectiveness of FFA SC508.8 into this dossier for minimum effective dose and efficacy data are presented in the tables below. More than one weed species can occur per trial, therefore instead of total number of trials, data points are presented for MED and efficacy. The trials are clustered according to USE and EPPO climatic zone.

Table 3.2-5: Presentation of efficacy trials.

Crop(s) *	Target(s)*	Country	Years	Type of trial**	Number of trials (number of valid trials)			GEP, non-GEP, official'***	Remarks
					Maritime zone	North-East zone	South-East zone		
Winter wheat, USE 001	Weeds	Austria	2018	MED+E	1(1)			GEP	
		Belgium	2018	MED+E	1(1)			GEP	
				2020	MED+E	1(1)			GEP
		Czech Republic	2018	MED+E	1(1)			GEP	
			2019	MED+E	1(1)			GEP	
			2020	MED+E	2(2)			GEP	
			MED+E						
		France	2020	E	9(9)			GEP	
		Germany	2019	E	1(1)			GEP	
		United Kingdom	2019	E	3(3)			GEP	
				MED+E	3(3)			GEP	
			2020	MED+E	1(1)			GEP	
		Poland	2020	MED+E		9(9)		GEP	
		Slovakia	2020	MED+E			1(1)	GEP	
Winter barley, USE 001	Weeds	Austria	2018	MED+E	1(1)		GEP		
		Czech Republic	2020	MED+E	1(1)		GEP		
		Slovakia	2020	MED+E			1(1)	GEP	
				E			1(1)	GEP	
		TOTAL USE 001		-	2018-2020	MED+E	23(23)	9(9)	3(3)
Winter wheat, USE 002	Weeds	Belgium	2020	MED+E	1(1)			GEP	
		Czech Republic	2019	MED+E	1(1)			GEP	
			2020	MED+E	2(2)			GEP	
		France	2020	MED+E	12(12)			GEP	
			2020	MED	1(1)			GEP	
		Germany	2019	MED+E	5(5)			GEP	

Crop(s) *	Target(s)*	Country	Years	Type of trial**	Number of trials (number of valid trials)			GEP, non-GEP, official'***	Remarks
					Maritime zone	North-East zone	South-East zone		
		United Kingdom	2018	E	1(1)			GEP	
			2019	E	3(3)			GEP	
			2019	MED	1(1)			GEP	
			2019	MED+E	3(3)			GEP	
		United Kingdom	2020	MED+E	1(1)			GEP	
		Poland	2020	MED+E		7(7)		GEP	
		Slovakia	2020	MED+E			1(1)	GEP	
		Winter barley, USE 002	Weeds	Belgium	2018	E	1(1)		
2020	MED+E				1(1)			GEP	
Czech Republic	2020			MED+E	1(1)			GEP	
Slovakia	2020			MED+E			1(1)	GEP	
E				1(1)	GEP				
TOTAL USE 002		-	2018-2020	MED+E	34(34)	7(7)	3(3)	-	
winter wheat, use003		Austria	2018	MED+E	1(1)			GEP	
		Belgium	2018	MED+E	1(1)			GEP	
			2018	MED+E	1(1)			GEP	
		Czech Republic	2019	MED+E	1(1)			GEP	
			2020	MED+E	2(2)			GEP	
		Germany	2019	E	10(10)			GEP	
		United Kingdom	2019	MED+E	3(3)			GEP	
			2020	MED+E	1(1)			GEP	
		Poland	2020	MED+E		6(6)		GEP	
		Slovakia	2020	MED+E			1(1)	GEP	
winter barley, use003	Weeds	Austria	2018	MED+E	1(1)			GEP	
			2019	MED+E	1(1)			GEP	
		Czech Republic	2020	MED+E	1(1)			GEP	

Crop(s) *	Target(s)*	Country	Years	Type of trial**	Number of trials (number of valid trials)			GEP, non-GEP, official'***	Remarks
					Maritime zone	North-East zone	South-East zone		
		Slovakia	2020	MED+E			1(1)	GEP	
TOTAL USE 003		-	2018-2020	MED+E	22(22)	6(6)	2(2)	-	
winter wheat, USE 004	Weeds	Czech Republic	2019	MED+E	1(1)			GEP	
			2020	MED+E	2(2)			GEP	
		France	2020	MED+E	13(13)			GEP	
		United Kingdom	2020	MED+E	1(1)			GEP	
		Poland	2020	MED+E		6(6)		GEP	
Slovakia	2020	MED+E			1(1)	GEP			
Austria	2019	MED+E	1(1)			GEP			
Belgium	2020	MED+E	2(2)			GEP			
Czech Republic	2020	MED+E	1(1)		1(1)	GEP			
Slovakia	2020	MED+E				GEP			
TOTAL USE 004		-	2018-2020	MED+E	21(21)	6(6)	2(2)	-	-

* According to the GAP table. Timing of the application(s) can be added if relevant (e.g. Pre-mergence vs post-emergence, spring vs autumn).

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

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

Testing facilities and organization

The testing facilities responsible for the trials implementation were the development teams of the country subsidiary organization of Bayer CropScience. Additionally, some trials were contracted by Bayer CropScience to different local or official institutes. All these organisations have GEP certificates entitling them to carry out these studies. A list of the testing facilities and copies of their GEP certificates when relevant can be found in chapter 3.7.

Table 3.2-6: Presentation of reference standards used in trials (preliminary trials, efficacy trials , selectivity trials)

Crop(s)	Reference standard	Country(ies) where the product is registered ⁽¹⁾	Authorization number	Active substance(s)	Formulation		Registered application rate ⁽³⁾	Application	Remark ⁽⁴⁾
					Type ⁽²⁾	Concentr. of a.s.		rate in trials (per treatment)	
Winter cereals	Bacara Forte SC360	AUT	3090-0	Diflufenican	SC	120	0.8-1 L/ha	0.8 L/ha (1N)	Use expired 2019
				Flurtamone		120			
		DEU	06369-0	Flufenazet		120			
Winter cereals	Boxer EC800	CZE	4566-0	Prosulfocarb	EC	800	4 L/ha	3 L/ha (1N) and 6 L/ha (2N)	BBCH 0-13
		DEU	033838-00				5 L/ha		
		POL	R-88/2015				3 L/ha		
		SVK	2000868-AU						
Winter cereals	Herold SC600	BEL	9533P/B	Diflufenican	SC	200	0.6 L/ha	0.6 L/ha (1N) and 1.2 L/ha (2N)	BBCH 11-13
		POL	R-192/2015	Flufenazet		400	0.25-0.35 L/ha		
Winter cereals	Liberator SC500	BEL	9681P/B	Diflufenican	SC	100	0.6 L/ha	0.6 L/ha (1N)	BBCH 0-9
		GBR	15206	Flufenazet		400	0.6 L/ha		BBCH 0-13
Winter cereals	Stomp 400	BEL	7957P/B	Pendimethalin	SC	400	2 L/ha	4.1 L/ha (1N)	Use expired
		GBR	13405				3.3-2.5 L/ha		
		CZE	3699-6				3.3-4.1 L/ha		BBCH 13-21
Winter cereals	Stomp Aqua	BEL	9839P/B	Pendimethalin	CS	455	2 L/ha	1.76 L/ha (1N)	BBCH 11-12
		CZE	5003-0				3.5 L/ha		BBCH 00-13
		DEU	2090011				3.5-4.4 L/ha		
		SVK	15-11-1653				2.9-3.5 L/ha		
		GBR	14664				2.2-2.9 L/ha		

(1) only on use(s) applied for (with the test product).

(2) e.g. WP (wetttable powder), EC (emulsifiable concentrate), etc.

(3) dose(s) / dose range authorized on that use in the country.

(4) Other relevant information (e.g. uses, number of applications, spray volume, method of application, etc.).

(5) some trial with 0.6 L/ha Biopower.

Statistical analyses of the data

All data (transformed as appropriate to follow a normal variance distribution) were analysed by analyses of the variance (AOV). Statistical comparisons of treatments were performed using Student-Newman & Keuls test. When another test is used at trial report level and reported as well in summary tables, it will be clearly mentioned under the concerned summary tables

The statistical separation of means was at the 5% probability level on all occasions providing that the AOV Treatment probability, P (F) was significant. In the results tables, means followed by the same letter do not significantly differ (P=0.05) according to concerned test comparison.

Statistical analysis is not performed if:

- it has fewer than 5 different values;
- it is a visual assessment of phytotoxicity, discrete scales, measures of time, poorly-defined units, judgement scales, currency values or treatment averages.

For all assessments (counting number of plants or ears/m² and % converage), efficacy calculations vs. untreated, the Abbott formula was used.

Principles for data grouping

All presented trials for minimum effective dose and effectiveness were performed in the EPPO climatic zone Maritime, North-East and South-East for the EU regulatory Central Zone.

Data are summarised according to the below uses:

- “USE001” where the recommended dose rate of FFA SC508.8 on winter wheat, winter barley, winter triticale and winter durum wheat is 0.24 L/ha at crop BBCH 0-09; applied pre-emergence in the autumn against APESV and POAAN.
- “USE002” where the recommended dose rate of FFA SC508.8 on winter wheat, winter barley, winter triticale and winter durum wheat is 0.48 L/ha at crop BBCH 0-09; applied pre-emergence in the autumn against ALOMY, APESV, POAAN, LOLSS and the broad-leaved weeds MATIN, PAPRH and VERPE.
- “USE003” where the recommended dose rate of FFA SC508.8 on winter wheat, winter barley, winter triticale and winter durum wheat is 0.24 L/ha at crop BBCH 10-13; applied post-emergence in the autumn against APESV and POAAN.
- “USE004” where the recommended dose rate of FFA SC508.8 on winter wheat, winter barley, winter triticale and winter durum wheat is 0.48 L/ha at crop BBCH 10-13; applied post-emergence in the autumn against ALOMY, APESV, POAAN and LOLSS.

and by assessment timing:

- for grass weeds at flowering/heading of grasses
- for annual broad-leaved weeds at crop BBCH 21-32, early spring assessment

In case of an insufficient number of trials in the EPPO zone North-East or South-East, supportive data (mostly from the Maritime EPPO climatic zone) were calculated together with existing trials of both zones to reach a sufficient number of trials.

More detailed information are presented in each chapter.

3.2.1 Preliminary tests (KCP 6.1)

Justification of the active ingredient content & ratio

For FFA SC508.8 no specific preliminary range finding tests are presented here since this product contains one active substance. The active substance flufenacet has been used for approximately 20 years and the herbicidal effects are well known. An overview of current registrations of FFA SC508.8 can be seen below:

Table 3.2.1-1: Current EU registrations of FFA SC508.8

Member State	Registration number number	Registered dose rate
AUT	3941	0.3-0.5 L/ha
CZE	5818-0	0.24-0.5 L/ha
DEU	005908-00	0.24-0.5 L/ha

Comments of zRMS:

Taking into account that flufenacet is known active substance in Europe and the product FFA SC 508.8 G contains only one active substance, in opinion of zRMS the preliminary tests are not necessary.

3.2.2 Minimum effective dose tests (KCP 6.2)

Methodological Instruction No. 2/2014” from UKSUP is presented in document [M-630120-01-1](#).

An experimentation program was scheduled and conducted in order to determine the Minimum Effective Dose (MED) of FFA SC508.8 in the North-East, Maritime- and South-East EPPO climatic zones.

Since trials used for MED determination are also used for efficacy evaluation of FFA SC508.8 methodology applied is the same and discussed in chapter 3.2.3 Efficacy tests. Efficacy is tested under a range of environmental conditions to fully challenge the product.

As well as an evaluation of the data, a general overview of the main characteristics of the methodology is presented for the trials reported for each USE. For more details on methodology or on the data generated from each individual trial please refer to the relevant “Single Trial Reports” and for the site description to Appendix 2 of this BAD.

Standards and trial design in minimum effective dose trials

The trials followed requirements of the EPPO standards PP1/225(2) and PP1/093(3). These standards mainly recommend the following:

- a trial design with minimum 3 to 4 replicates randomly distributed (3 replicates in case of trial series, according to EPPO PP1/152(3/4)),
- a plot size at least 10 m² for weed control and at least 12 m² for selectivity,
- a minimum of 3 assessments timings:
 - for post-emergence application: 1st up to 2 weeks after treatment, 2nd at BBCH 21-29 and 3rd at BBCH 37-39. A 4th optional assessment timing could be performed shortly before harvest.
 - at least one lower dose rate than the one recommended should be included in efficacy trials.

Trials were established following a Randomised Complete Block design. They were conducted with 3 to 4 replicates. As specified in EPPO standard PP1/093(3) the number of replicates in weed control trials can be reduced to 3 if 3 replicates ensure 12 degrees of freedom. In all trials conducted and used for efficacy evaluation this requirement strictly has been followed.

Reference products

Reference products are mainly used to validate a trial and not needed to justify the proposed dose rate in Minimum effective dose trials, therefore not presented in this chapter.

The evaluation of the product complies with the Uniform Principles.

Regarding the methodology instruction for Slovakia (also valid for Slovenia) “Methodological Instruction No. 2/2014” from UKSUP (ústredný kontrolný a skúšobný ústav poľnohospodársky Bratislava) from 1st of January 2016 ([M-630120-01-1](#)), trials from the B zone - middle (Central zone): Belgium, Czech Republic, Germany, Ireland, Luxembourg, Hungary, Netherlands, Austria, Poland, Romania, Slovenia, Slovakia, and United Kingdom are also acceptable for demonstrating effectiveness.

For Poland, countries belonging to another EPPO zone but neighbouring with Poland (the Czech Republic and Germany) were added as supportive data.

Data are grouped according to the proposed uses

- “USE001” where the recommended dose rate of FFA SC508.8 on winter wheat, winter barley, winter triticale and winter durum wheat is 0.24 L/ha at crop BBCH 00-09; applied pre-emergence in the autumn against APESV and POAAN.
- “USE002” where the recommended dose rate of FFA SC508.8 on winter wheat, winter barley, winter triticale and winter durum wheat is 0.48 L/ha at crop BBCH 00-09; applied pre-emergence in the autumn against ALOMY, APESV, POAAN, LOLSS and the broad-leaved weeds MATIN, PAPRH and VERPE.
- “USE003” where the recommended dose rate of FFA SC508.8 on winter wheat, winter barley, winter triticale and winter durum wheat is 0.24 L/ha at crop BBCH 10-13; applied post-emergence in the autumn against APESV and POAAN.
- “USE004” where the recommended dose rate of FFA SC508.8 on winter wheat, winter barley, winter triticale and winter durum wheat is 0.48 L/ha at crop BBCH 10-13; applied post-emergence in the autumn against ALOMY, APESV, POAAN and LOLSS.

The evaluation of the product complies with the Uniform Principles.

USE001: Minimum effective dose of FFA SC508.8 at 0.24 L/ha against APESV and POAAN; on TRZAW, HORVW, TTLWI, TRZDU, SECCW and TRZSP; pre-emergence at BBCH 00 – 09 ([M-761917-01-1](#)).

Single trial reports are available in the Compilation of trials reports.

In order to determine the minimum effective dose for FFA SC508.8 against weeds in winter cereals, a total of 21 trials were performed, 2 trials in Austria, 2 trials in Belgium, 5 in the Czech Republic, 7 trials in Poland, and 2 trials in Slovakia between 2018 and 2020. A general overview of the methodology used in Minimum effective dose trials of USE001 is shown in chapter 3.2.3. A general overview of the site description is presented in Appendix 2 of this BAD.

Test product and dose rates tested

FFA SC508.8 was applied once by spray application on winter wheat and winter barley under field conditions in 26 trials Austria, Belgium, Czech Republic, Great Britain, Poland and Slovakia during crop stage BBCH 00 to BBCH 09 and at a spray volume of 150-300 L/ha.

FFA SC508.8 was applied at rates of:

- | | |
|---|------|
| - 0.24 L/ha (equivalent to 122.1g FFA/ha) | 100% |
| - 0.2 L/ha (equivalent to 101.8g FFA/ha) | 83% |
| - 0.15 L/ha (equivalent to 76.3 g FFA/ha) | 62% |

for the control of grass weeds and annual broad-leaved weeds on winter cereals.

Since APESV and POAAN are part of the required GAP for USE001 and all mentioned weed species are considered to be important in all countries presented in this dossier, they were chosen for MED evaluation.

Table 3.2- 1a: Summary of Minimum effective dose of FFA SC508.8 at proposed label rate, at 83% and 63% dose rate on major grass weeds in winter cereals.

Target	Grouping (EPPO climatic zone)	Number of trials	Infestation of the untreated control			% control with FFA SC508.8								
			(% coverage / plants/)			0.15 L/ha			0.20 L/ha			0.24 L/ha		
						(63% of full rate)			(83% of full rate)			(Full rate)		
			Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	Mean	Min	Max
APESV	Central zone	18	83.5	4.3	297.3	89.5	40.4	100.0	93.2	58.6	100.0	95.3	74.2	100.0
	North-East	7	61.2	10.0	187.7	89.7	71.0	99.3	95.1	73.3	100.0	96.0	78.3	100.0
	POL+ supp.	12	71.3	4.3	187.7	92.9	71.0	100	96.8	73.3	100	97.5	78.3	100
	Maritime	9	103.9	4.3	297.3	97.1	92.6	100	98.1	94.9	100	99.4	97.1	100
	South-East	2	69.8	35.0	104.5	55.2	40.4	70.0	64.3	58.6	70.0	74.6	74.2	75.0
POAAN	Central zone	7	9.3	3	23.7	83.3	46.4	100	87.4	50	100	88.7	50	100
	Central zone excl 2 trials*	5	9.3	3	23.7	96.3	90	100	99.5	97.3	100	99.9	99.3	100
	Supp. For POL	3	13.6	7	23.7	78.8	46.4	100	88.1	64.3	100	90.5	71.4	100
	Maritime	6	9.7	3	23.7	89.5	55	100	91.2	50	100	91.6	50	100
	Maritime excl 1**	5	9.3	3	23.7	96.3	90	100	99.5	97.3	100	99.9	99.3	100
	South-East	1	7	-	-	46.4	-	-	63.3	-	-	71.4	-	-

*mean without excluded trials

**mean without excluded trial

Table 3.2- 2b: Summary of Minimum effective dose of FFA SC508.8 at proposed label rate, at 83% and 63% dose rate on major grass weeds in winter wheat and winter barley (USE 001)

Target	Grouping (EPPO climatic zone)	Number of trials	Infestation of the untreated control (on the day of assessment)			% control with FFA SC508.8								
			(% coverage / plants/)			0.15 L/ha			0.20 L/ha			0.24 L/ha		
						(63% of full rate)			(83% of full rate)			(Full rate)		
			Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	Mean	Min	Max
APESV in winter wheat	POL+ supp.	7	61.2	10.0	187.7	89.7	71.0	99.3	95.1	73.3	100	96.0	78.3	100
	Maritime	7	118.7	6.4	297.3	96.5	92.6	100	97.6	94.9	100	99.2	97.1	100
	South-East	1	104.5	-	-	40.4	-	-	58.6	-	-	74.2	-	-
APESV in winter barley	POL+ supp.	2	19.7	4.3	35.0	85.0	70.0	100	85.0	70.0	100	87.5	75.0	100
	Maritime	2	52.2	4.3	100	99.2	98.3	100	99.9	99.7	100	100	100	100
	South-East	1	35.0	-	-	70.0	-	-	70.0	-	-	75.0	-	-

POAAN in winter wheat	POL+ supp.	2	15.4	7.0	23.7	73.2	46.4	100	82.2	64.3	100	85.7	71.4	100
	Maritime**	4	9.1	3.0	23.7	97.9	91.7	100	99.3	97.3	100	99.8	99.3	100
	South-East	1	7.0	-	-	46.4	-	-	64.3	-	-	71.4	-	-
POAAN in winter barley	POL+ supp.	1	10.0	-	-	90.0	-	-	100	-	-	100	-	-
	Maritime	1	10.0	-	-	90.0	-	-	100	-	-	100	-	-

Summary and conclusions on the minimum effective dose, USE001

According to the presented results, the dose of 0.24 L/ha of FFA SC508.8 provided the optimum overall control against APESV and POAAN and should be considered as effective against major weeds for which activity of FFA SC508.8 is claimed.

As a result, the recommended rate of 0.24 L/ha should be considered the minimum effective dose to ensure broad spectrum control of grass weeds under a wide range of environmental conditions.

Comments of zRMS:

The Applicant has submitted a range of efficacy trials to determine the minimum effective dose for FFA SC 508.8 G against weeds in winter cereals for pre-emergence application. Because the trials have been conducted only in winter wheat and winter barley, the zRMS decided to present the results for every crop separately (the table 3.2- 58b). In the Maritime EPPO zone, the test product achieved effectiveness on the level >90% after application at dose rates of 0,15-0,24 l/ha against APESV and POAAN in winter wheat and winter barley. In the South-East EPPO zone, the test product achieved the highest effectiveness after application at dose rate of 0,24 l/ha: 74,2% for APESV/TRZAW, 75% for APESV/HORVW and 71,4% for POAAN/TRZAW. The efficacy of the dose rates 0,15 and 0,2 l/ha was significant lower. In the North-East EPPO zone, the test product achieved effectiveness on the level >85% after application at dose rates of 0,15 and 0,2 l/ha against APESV in winter wheat and winter barley and POAAN in winter barley. The dose rate of 0,24 l/ha was the most effective to control of POAAN in winter wheat (85,7%).

Taking into account the results from all EPPO climatic zones, the dose rate of 0,24 l/ha can be considered the minimum effective dose to control of grasses in winter cereals in pre-emergence application.

USE002: Minimum effective dose of FFA SC508.8 at 0.48 L/ha against ALOMY APESV, POAAN; LOLSS, MATIN, PAPRH and VERPE on TRZAW, HORVW, TTLWI, TRZDU, SECCW, TRZSP; pre-emergence at BBCH 00 – 09 ([M-761917-01-1](#)).

Single trial reports are available in the Compilation of trials reports.

All 38 trials used for minimum effective dose USE002 are also used for efficacy of FFA SC508.8 therefore, the methodology is the same and discussed in chapter 3.2.3.

In order to determine the minimum effective dose for FFA SC508.8 against weeds in winter cereals, in total 38 trials were conducted: 2 trials in Belgium, 4 trials in the Czech Republic, 5 trials in Germany, 5 trials in United Kingdom, 13 trials from France, 7 trials from Poland and 2 trials from Slovakia, between 2018 to 2020. A general overview of the methodology used in Minimum effective dose trials of USE002 is shown in Table 3.4-11. A general overview of the site description is presented in Appendix 2 of the BAD.

Test product and dose rates tested

FFA SC508.8 has been applied once by spray application on winter wheat and winter barley under field conditions in 26 trials Austria, Belgium, Czech Republic, Great Britain, Poland and Slovakia during crop stage BBCH 00 to BBCH 09 and at a spray volume of 150-300 L/ha.

FFA SC508.8 was applied at rates of:

- 0.48 L/ha (equivalent to 244.2 g FFA/ha) 100%
- 0.36 L/ha (equivalent to 183.2 g FFA/ha) 75%
- 0.24 L/ha (equivalent to 122.1 g FFA/ha) 50%

for the control of grass weeds and annual broad-leaved weeds on winter cereals.

Since ALOMY APESV, POAAN; LOLSS, MATIN, PAPRH and VERPE were reported in the majority of the trials and all mentioned weed species are considered to be important in all countries where the application is intended for, they were chosen for MED evaluation.

**Summary and evaluation of trial results –pre-emergence application of FFA SC508.8 0.48 L/ha
(Minimum effective dose trials – USE002)**

Grass weed - pre-emergence application of FFA SC508.8 0.48 L/ha

Table 3.2- 3a: Summary: Minimum effective dose, Efficacy of FFA SC508.8 at proposed label rate, at 75% and 50% dose rate on major grass-weeds in winter cereals.

Target	Grouping	Number of trials	Infestation of the untreated control			% control with FFA SC508.8								
	(EPPO climatic zone)		(% coverage / plants/m ²)			0.24 L/ha (1 N and 50% of 1N)			0.36 L/ha (75% of 1N)			0.48 L/ha (1N)		
			Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	Mean	Min	Max
ALOMY	Central zone	16	296.1	15.0	1891.7	67.6	0.6	97.8	72.3	1.5	99.5	87.8	69.3	99.8
	North-East	1	25			70			76.7			80		
	POL + supportive data	10	179.1	16.0	383.3	65.8	0.6	97.8	67.6	1.5	99.5	87.4	69.3	99.8
	Maritime	15	315.4	15.0	1891.7	67.5	0.6	97.8	72.0	1.5	99.5	88.3	69.3	99.8
APESV	Central zone	14	85.6	4.3	297.3	94.2	74.2	100.0	96.6	80.0	100.0	97.5	81.7	100.0
	North-East	7	61.2	10.0	187.7	96.0	78.3	100.0	96.8	80.0	100.0	97.2	81.7	100.0
	POL + supportive data	13	69.3	4.3	187.7	93.8	74.2	100	96.3	80.0	100	97.4	81.7	100
	Maritime	5	126.2	4.3	297.3	99.46	99	100	100	100	100	100	100	100
	South-East	2	69.8	35.0	104.5	74.6	74.2	75.0	87.2	80.0	94.3	92.5	85.0	100.0
POAAN	Central zone	7	8.4	3	23.7	92.6	50	100	97.1	81.7	100	98.7	91.7	100
	Central zone*	5	9.3	3	23.7	99.9	99.3	100	99.9	99.3	100	100.0	100	100
	POL + supportive data	4	13.6	7	23.7	90.5	71.4	100	96.4	89.3	100	100.0	100	100
	Maritime	6	8.4	3	23.7	92.6	50	100	97.1	81.7	100	98.7	91.7	100
	Maritime*	5	9.3	3	23.7	99.9	99.3	100	99.9	99.3	100	100.0	100	100
	South-East	2	7.4	7	7.8	68.0	64.5	71.4	88.2	87.1	89.3	98.4	96.8	100
LOLPE LOLMU/LOLSS	Central zone	10	349.6	48.3	1493.3	66.6	16.7	97.7	77.1	20	98	81.9	38.3	99.1
	Central zone**	8	137.8	48.3	535.3	78.7	43.3	97.7	87.6	60	98	91.4	80	99.1
	POL + supportive data	3	62.3	59	69	76.5	64.8	86.8	92.2	86.7	98	96.0	91.9	99.1

* mean without excluded trials

**mean without excluded trials

Table 3.2- 4b: Summary: Minimum effective dose, Efficacy of FFA SC508.8 at proposed label rate, at 75% and 50% dose rate on major grass-weeds in winter wheat and winter barley (USE 002).

Target	Grouping	Number of trials	Infestation of the untreated control (on the day of assessment)			% control with FFA SC508.8								
	(EPPO climatic zone)		(% coverage / plants/m ²)			0.24 L/ha (1 N and 50% of 1N)			0.36 L/ha (75% of 1N)			0.48 L/ha (1N)		
			Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	Mean	Min	Max
ALOMY	POL + support-	9		5.0	383.3	71.0	0.6	97.8	69.2	1.5	99.5	89.4	70.8	99.8

in winter wheat	ive data													
	Maritime	13	291.9	5.0	1891.7	71.6	0.6	97.8	72.3	1.5	99.5	89.4	70.8	99.8
ALOMY in winter barley	POL + support-ive data	1	245.3	-	-	18.8	-	-	52.4	-	-	69.3	-	-
	Maritime	2	313.3	245.3	381.3	40.8	18.8	62.8	70.5	52.4	88.6	81.3	69.3	93.2
APESV in winter wheat	POL + support-ive data	7	61.2	10.0	187.7	96.0	78.3	100	96.8	80.0	100	97.2	81.7	100
	Maritime	4	156.7	6.4	297.3	99.3	99.0	100	100	100	100	100	100	100
	South-East	1	104.5	-	-	74.2	-	-	94.3	-	-	100	-	-
APESV in winter barley	POL + support-ive data	2	19.7	4.3	35.0	87.5	75.0	100	90.0	80.0	100	92.5	85.0	100
	Maritime	1	4.3	-	-	100	-	-	100	-	-	100	-	-
	South-East	1	35.0	-	-	75.0	-	-	80.0	-	-	85.0	-	-
POAAN in winter wheat	POL + support-ive data	3	10.6	1.0	23.7	90.1	71.4	100	96.1	89.3	100	99.7	99.0	100
	Maritime	6	8.2	1.0	23.7	91.4	50.0	100	96.7	81.7	100	98.5	91.7	100
	South-East	1	7.0	-	-	71.4	-	-	89.3	-	-	100	-	-
POAAN in winter barley	POL + support-ive data	2	8.9	7.8	10.0	82.3	64.5	100	93.6	87.1	100	98.4	96.8	100
	Maritime	1	10.0	-	-	100	-	-	100	-	-	100	-	-
	South-East	1	7.8	-	-	64.5	-	-	87.1	-	-	96.8	-	-
LOLMU in winter wheat	POL + support-ive data	2	64.0	59.0	69.0	82.3	77.8	86.8	95.0	91.9	98.0	95.5	91.9	99.1
	Maritime	3	62.3	59.0	69.0	87.4	77.8	97.7	95.7	91.9	98.0	95.3	91.9	99.1
LOLMU in winter barley	POL + support-ive data	1	59.0	-	-	64.8	-	-	86.7	-	-	97.1	-	-
	Maritime	1	59.0	-	-	64.8	-	-	86.7	-	-	97.1	-	-
LOLSS in winter wheat	Maritime	4	214.2	48.3	535.3	75.6	43.3	96.3	81.7	60.0	97.3	87.0	80.0	96.0

Summary and conclusions on the minimum effective dose, grasses USE002

According to the presented results, the dose of 0.48 L/ha of FFA SC508.8 provided the optimum overall control against ALOMY and LOLPE/LOLSS and should be considered as effective against major weeds for which activity of FFA SC508.8 is claimed.

The minimum effective dose rate against APESV and POAAN is rather flat between 0.24 L/ha and 0.48 L/ha. However, trials have proven situations with difficult growing conditions, i.e. high levels of weed pressure, poor soil preparation or dry weather conditions, when the high dose is necessary to provide a high level of control.

As a result, the recommended rate of 0.48 L/ha should be considered the minimum effective dose to ensure broad spectrum control of grass weeds under a wide range of environmental conditions.

Comments of zRMS:

The Applicant has submitted a range of efficacy trials to determine the minimum effective dose for FFA SC 508.8 G against weeds in winter cereals for pre-emergence application. Because the trials have been conducted only in winter wheat and winter barley, the zRMS decided to present the results for every crop separately (the table 3.2- 68b). In the Maritime EPPO zone, the test product achieved effectiveness on the level >85% after application at dose rates of 0,24 l/ha against APESV in winter wheat and winter barley, LOLMU in winter wheat, POAAN in winter wheat and winter barley and VERPE in winter wheat. The dose rate of 0,36 l/ha was effective on the same level to control of also LOLMU in winter barley and PAPRH in winter wheat. The test product at 0,48 l/ha achieved the best results in control of ALOMY in winter wheat and winter barley (89,4% and 81,3%), LOLSS in winter wheat (87%) and MATIN in winter wheat and winter barley (75,5% and 85%). In the South-East EPPO zone, the test product achieved the effectiveness on the level >85% after application at dose rate of 0,36 l/ha in case of APESV in winter wheat and POAAN in winter wheat and winter barley. The dose rate 0,48 l/ha was the most effective to control of APESV in winter barley (85%). In the North-East EPPO zone, the test product achieved effectiveness on the level >85% after application at dose rate of 0,24 l/ha against APESV in winter wheat and winter barley and POAAN in winter wheat. The dose rate of 0,36 l/ha was significant better to control of LOLMU in winter wheat and winter barley, POAAN in winter barley, MATIN, PAPRH and VERPE in winter wheat. The dose rate of 0,48 l/ha is the most effective to control of ALOMY in winter wheat (89,4%) and MATIN in winter barley (85%).

Taking into account the results from all EPPO climatic zones, the dose rate of 0,48 l/ha can be considered the minimum effective dose to control of ALOMY and LOLMU/LOLSS. Moreover, this dose rate can be also recommended to control of grasses in winter cereals in difficult growing conditions or in case of high level of weed pressure.

**Summary and evaluation of trial results –pre-emergence application of FFA SC508.8 0.48 L/ha
(Minimum effective dose trials – USE002)**

Broad-leaved weeds - pre-emergence application of FFA SC508.8 at 0.48 L/ha

Table 3.2-xa: Summary: Minimum effective dose, Efficacy of FFA SC508.8 at proposed label rate, at 75% and 50% dose rate on major broad-leaved weeds in winter cereals.

Target	Grouping	Number of trials	Infestation of the untreated control			% control with FFA SC508.8								
	(EPPO climatic zone)		(% coverage / plants/m ²)			0.24 L/ha (50% of 1N)			0.36 L/ha (75% of 1N)			0.48 L/ha (1N)		
			Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	Mean	Min	Max
MATIN	Central zone	6	5.9	2	10.7	67.8	36.7	96.7	81.9	46.7	100	87.3	53.3	100
	North-East	3	3.0	2	4.7	68.9	43.3	96.7	88.9	83.3	100	95.9	90	100
	Maritime	3	8.8	7	10.7	66.7	36.7	83.3	74.9	46.7	94.7	78.7	53.3	97.7
PAPRH	Central zone	7	12.2	6.7	17.7	64.9	5	96.7	81.2	26.7	99.3	82.2	15	100
	North-East	2	11.15	10	12.3	66.65	63.3	70	81.7	76.7	86.7	83.35	66.7	100
	POL + supportive data	4	9.1	6.7	12.3	67.4	40	96.3	88.1	76.7	99	90.4	66.7	100
	Maritime	5	12.7	6.7	17.7	64.3	5	96.7	81.0	26.7	99.3	81.7	15	99.7
VERPE	Central zone	7	6.2	2.3	10	72.3	35.3	93.3	82.6	40.7	100	83.8	40.7	100
	North-East	4	5	2.3	9.7	73.7	53.3	93.3	85.9	71.7	100	87.5	73.3	98.3
	Maritime	2	9.35	8.7	10	87.9	85.7	90	97.2	94.3	100	97.9	95.7	100
	South-East	1	5	-	-	35.3	-	-	40.7	-	-	40.7	-	-

Table 3.2-xb: Summary: Minimum effective dose, Efficacy of FFA SC508.8 at proposed label rate, at 75% and 50% dose rate on major broad-leaved weeds in winter wheat and winter barley (USE 002).

Target	Grouping	Number of trials	Infestation of the untreated control (on the day of assessment)			% control with FFA SC508.8								
	(EPPO climatic zone)		(% coverage/ plants/m ²)			0.24 L/ha (50% of 1N)			0.36 L/ha (75% of 1N)			0.48 L/ha (1N)		
			Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	Mean	Min	Max
MATIN	POL +	3	3.0	2.0	4.7	68.9	43.3	96.7	88.9	83.3	100	95.9	90.0	100

in winter wheat	supportive data													
	Maritime	2	8.9	7.0	10.7	60.0	36.7	83.3	70.7	46.7	94.7	75.5	53.3	97.7
MATIN in winter barley	POL + supportive data	1	8.7	-	-	80.0	-	-	83.3	-	-	85.0	-	-
	Maritime	1	8.7	-	-	80.0	-	-	83.3	-	-	85.0	-	-
PAPRH in winter wheat	POL + supportive data	4	9.1	6.7	12.3	67.4	40.0	96.3	88.1	76.7	99.0	90.4	66.7	100
	Maritime	4	12.1	6.7	17.7	79.1	40.0	96.7	94.6	90.0	99.3	98.4	95.0	99.7
VERPE in winter wheat	POL + supportive data	4	5.0	2.3	9.7	73.7	53.3	93.3	85.9	71.7	100	87.5	73.3	98.3
	Maritime	2	9.4	8.7	10.0	87.9	85.7	90.0	97.2	94.3	100	97.9	95.7	100
VERPE in winter barley	POL + supportive data	1	5.0	-	-	35.5	-	-	40.7	-	-	40.7	-	-
	South-East	1	5.0	-	-	35.5	-	-	40.7	-	-	40.7	-	-

Summary and conclusions on the minimum effective dose, broadleaved weeds - USE002

According to the presented results, the dose of 0.48 kg/ha of FFA SC508.8 provided the optimum overall control against MATIN, PAPRH and VERPE and should be considered as effective against major weeds for which activity of FFA SC508.8 is claimed.

As a result, the recommended rate of 0.48 L/ha should be considered the minimum effective dose to ensure broad spectrum control of weeds under a wide range of environmental conditions.

Comments of zRMS:

The Applicant has submitted a range of efficacy trials to determine the minimum effective dose for FFA SC 508.8 G against broadleaved weeds in winter cereals for pre-emergence application. Because the trials have been conducted only in winter wheat and winter barley, the zRMS decided to present the results for every crop separately (the table 3.2- xb). In the Maritime EPPO zone, the test product at dose rate of 0,48 l/ha achieved the highest effectiveness compared to the lower dose rates: 75,5% in case of MATIN/TRZAW, 85% in case of MATIN/HORVW, 98,4% in case of PAPRH/TRZAW and 97,9% in case of VERPE/TRZAW. The dose rate of 0,36 l/ha was effective on level >85% in control of PAPRH and VERPE in winter wheat. In the South-East EPPO zone, only one efficacy trial has been submitted to determine MED. The test product achieved insufficient effectiveness (35,3% and 40,7%) in control of VERPE in winter barley. The cMS is kindly asked to decide whether to accept these results or to use trial results from other countries at national level. In the North-East EPPO zone, the test product achieved effectiveness on the level >85% after application at dose rate of 0,48 l/ha against MATIN in winter wheat and winter barley, PAPRH and VERPE in winter wheat. The dose rate of 0,36 l/ha was sufficient to control of MATIN, PAPRH and VERPE in winter wheat

Taking into account the results from all EPPO climatic zones, the dose rate of 0,48 l/ha can be considered the minimum effective dose to control of broadleaved weeds in winter cereals in pre-emergence application.

USE003: Minimum effective dose of FFA SC508.8 at 0.24 L/ha against APESV and POAAN on TRZAW, HORVW, TTLWI, TRZDU, SECCW and TRZSP; post-emergence at BBCH 10-13 ([M-761933-01-1](#)).

Single trial reports are available in the Compilation of trials reports.

As all 21 trials used for minimum effective dose are also used for efficacy of FFA SC508.8, the methodology is discussed in chapter 3.2.3.

In order to determine the minimum effective dose for FFA SC508.8 against weeds in winter cereals, a total of 3 trials were conducted in Austria, 1 trial was performed in Belgium, 4 trials in the United Kingdom, 5 trials in the Czech Republic, 2 trials in Slovakia, and 6 trials in Poland between 2018 and 2020. A general overview of the methodology used in Minimum effective dose trials of USE003 is shown chapter 3.2.3. A general overview of the site description is presented in Appendix 2 of the BAD.

Test product and dose rates tested

FFA SC508.8 has been applied once by spray application on winter wheat and winter barley under field conditions in Austria, the United Kingdom, Belgium, the Czech Republic, Slovakia and Poland during crop stage BBCH 10 - 13. Four trials were sprayed at crop BBCH 21 and 22, however APESV were at BBCH 11 and 12 at application timing, which corresponds to the expected weed BBCH for the recommended application timing. The spray volume used was 150-300 L/ha.

FFA SC508.8 was applied at rates of:

- | | |
|--|-------|
| - 0.24 L/ha (equivalent to 122.1 g FFA/ha) | 100% |
| - 0.2 L/ha (equivalent to 101.8 g FFA/ha) | 83.3% |
| - 0.15 L/ha (equivalent to 76.3 g FFA/ha) | 62.5% |

for the control of grass weeds on winter cereals.

Since APESV and POAAN are part of the GAP table and all mentioned weed species are considered to be important in all countries where the application is intended for, they were chosen for MED evaluation.

**Summary and evaluation of trial results –post-emergence application of FFA SC508.8
(Minimum effective dose trials – USE003)**

Grass weeds - post-emergence application of FFA SC508.8 at 0.24 L/ha

Table 3.2- 5a: Minimum effective dose, Efficacy of FFA SC508.8 at proposed label rate (0.24 L/ha), at 83.3% and 62.5% dose rate on major grass-weeds in winter cereals.

Target	Grouping (EPPO climatic zone)	Number of data points	Infestation of the untreated control			% control with FFA SC508.8								
			(% coverage / plants/m ²)			0.15 L/ha (62,5 % of 1N)			0.2 L/ha (83,3% of 1 N)			0.24 L/ha (1N)		
			Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	Mean	Min	Max
APESV	Central zone	16	79.1	4.0	195.0	83.1	26.7	100.0	87.6	41.7	100.0	90.4	56.7	100.0
	North-East	6	81.1	43.3	195.0	74.2	26.7	98.0	82.4	41.7	98.7	85.6	56.7	98.7
	Maritime (AUT, BEL, CZE)	8	78.3	4.0	153.3	98.4	94.8	100.0	98.7	96.2	100.0	99.5	97.7	100.0
	South-East	2	76.5	35.0	118.0	49.3	28.6	70.0	58.9	47.7	70.0	68.4	61.7	75.0
	S-E + supportive data	7	79.2	4.0	153.3	84.9	28.6	100.0	88.1	47.7	100.0	90.9	61.7	100.0
POAAN	Central zone	8	10.3 pl/m2/19%	5.7 pl/m2/3.3%	17 pl/m2/33.3%	85.9	29.0	100.0	86.6	51.6	100.0	94.8	64.5	100.0
	North-East	-	-	-	-	-	-	-	-	-	-	-	-	-
	N-E supportive data	2	11.4	5.7	17.0	97.1	94.1	100.0	97.1	94.1	100.0	100.0	100.0	100.0
	Maritime (AUT, CZE, GBR)	7	10.9 pl/m2/19%	5.7 pl/m2/3.3%	17 pl/m2/33.3%	85.3	53.3	100.0	91.5	71.7	100.0	97.4	88.3	100.0
	South-East	1	7.8	-	-	29.0	-	-	51.6	-	-	64.5	-	-
	S-E + supportive data	4	11.4	5.7	17.0	80.8	29.0	100.0	86.4	51.6	100.0	91.1	64.5	100.0

N-E = North-East EPPO climatic zone
S-E = South-East EPPO climatic zone

Table 3.2- 6b: Minimum effective dose, Efficacy of FFA SC508.8 at proposed label rate (0.24 L/ha), at 83.3% and 62.5% dose rate on major grass-weeds in winter wheat and winter barley (USE 003).

Target	Grouping (EPPO climatic zone)	Number of data points	Infestation of the untreated control			% control with FFA SC508.8								
			(% coverage / plants/m ²)			0.15 L/ha (62,5 % of 1N)			0.2 L/ha (83,3% of 1 N)			0.24 L/ha (1N)		
			Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	Mean	Min	Max
APESV in winter wheat	POL + supportive data	6	81.1	43.3	195.0	74.2	26.7	98.0	82.4	41.7	98.7	85.6	56.7	98.7
	Maritime	7	75.2	4.0	153.3	98.1	94.8	100	98.6	96.2	100	99.4	97.7	100
	South-East	1	35.0	-	-	70.0	-	-	70.0	-	-	75.0	-	-
APESV in winter barley	POL + supportive data	1	118.0	-	-	28.6	-	-	47.7	-	-	61.7	-	-
	Maritime	1	100.0	-	-	100	-	-	99.7	-	-	100	-	-

barley	South-East	1	118.0	-	-	28.6	-	-	47.7	-	-	61.7	-	-
POAAN in winter wheat	POL + supportive data	1	17.0	-	-	100	-	-	100	-	-	100	-	-
	Maritime	5	6.5pla/18.9%	6.0pla/3.3%	17.0pla/33.3%	80.7	53.3	100	89.3	71.7	100	96.4	88.3	100
POAAN in winter barley	POL + supportive data	2	6.8	5.7	7.8	61.6	29.0	94.1	72.9	51.6	94.1	82.3	64.5	100
	Maritime	2	10.4	5.7	15.0	97.1	94.1	100	97.1	94.1	100	100	100	100
	South-East	1	7.8	-	-	29.0	-	-	51.6	-	-	64.5	-	-

Conclusion on the minimum effective dose, USE003

According to the presented results, the dose of 0.24 L/ha of FFA SC508.8 applied post-emergence provided the optimum overall control against APESV and POAAN and should be considered as effective against major weeds for which activity of FFA SC508.8 is claimed.

As a result, the recommended rate of 0.24 L/ha applied post-emergence should be considered the minimum effective dose to ensure broad spectrum control of weeds under a wide range of environmental conditions.

Comments of zRMS:

The Applicant has submitted a range of efficacy trials to determine the minimum effective dose for FFA SC 508.8 G against grass weeds in winter cereals for post-emergence application. Because the trials have been conducted only in winter wheat and winter barley, the zRMS decided to present the results for every crop separately (the table 3.2-79b). In the Maritime EPPO zone, the test product at dose rate of 0,2 and 0,24 l/ha achieved the effectiveness on the level >85% in control of APESV and POAAN in winter wheat and winter barley. In the South-East EPPO zone, the dose rate of 0,24 l/ha was the most effective in control of APESV in winter wheat and winter barley and against POAAN in winter barley. In the North-East EPPO zone, FFA SC 508.8 G at dose rate of 0,24 l/ha achieved the effectiveness on the level >85% in control of APESV and POAAN in winter wheat. It was also the most effective against POAAN in winter barley (82,3%).

Taking into account the results from all EPPO climatic zones, the dose rate of 0,24 l/ha can be considered the minimum effective dose to control of grass weeds in winter cereals in post-emergence application.

USE004: Minimum effective dose of FFA SC508.8 at 0.48 kg/ha against ALOMY, APESV, LOLSS, and POAAN on TRZAW, HORVW, TTLWI, TRZDU, SECCW and TRZSP; post-emergence at BBCH 10-13 ([M-761933-01-1](#)).

Single trial reports are available in the Compilation of trials reports.

As all 32 trials used for minimum effective dose are also used for efficacy of FFA SC508.8, the methodology is the same and discussed in chapter 3.2.3.

In order to determine the minimum effective dose for FFA SC508.8 against weeds in winter cereals, 1 trial was conducted in Austria, 2 trials in Belgium, 4 trials in the Czech Republic, 4 trials in the United Kingdom, 13 trials in France, 6 trials in Poland, and 2 trials in Slovakia 2017 and 2019, giving a total of 32 trials. A general overview of the methodology used in Minimum effective dose trials of USE004 is shown in chapter 3.2.3. A general overview of the site description is presented in Appendix 2 of this BAD.

Test product and dose rates tested

FFA SC508.8 has been applied once by spray application on winter soft wheat under field conditions in Austria, Belgium, the Czech Republic, United Kingdom, Poland and Slovakia during crop stage BBCH 10 to BBCH 13, 4 trials were sprayed at crop BBCH 21 - 22, however POAAN was at BBCH 11 - 12.

FFA SC508.8 was applied at rates of:

- 0.48 L/ha (equivalent to 244.2 g FFA/ha)	100%
- 0.36 L/ha (equivalent to 183.2 g FFA/ha)	75%
- 0.24 L/ha (equivalent to 122.1 g FFA/ha)	50%

for the control of grass weeds on winter cereals.

Since ALOMY, APESV, LOLSS, and POAAN are part of the GAP table, and all mentioned weed species are important in all countries where the application is intended for, they were chosen for MED evaluation.

**Summary and evaluation of trial results –post-emergence application of FFA SC508.8
(Minimum effective dose trials – USE004)**

Grass weeds - post-emergence application of FFA SC508.8 at 0.48 L/ha

Table 3.2- 7a: Minimum effective dose, Efficacy of FFA SC508.8 at proposed label rate, at 75% and 50% dose rate on major grass weeds in winter cereals.

Target	Grouping (EPPO climatic zone)	Number of data points	Infestation of the untreated control			% control with FFA SC508.8								
			(% coverage / plants/m ²)			0.15 0.24 L/ha (62,5 % of 1N)			0.2 0.36 L/ha (83,3% of 1 N)			0.24 0.48 L/ha (1N)		
			Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	Mean	Min	Max
ALOMY	Central zone	11	481.1	15.0	2781.3	65.9	40.0	93.7	80.4	58.3	96.3	87.4	68.3	98.7
	Maritime (CZE, BEL, FRA)	11	481.1	15.0	2781.3	65.9	40.0	93.7	80.4	58.3	96.3	87.4	68.3	98.7
	Maritime CZE, supportive for POL	4	209.4	15.0	333.3	66.1	48.3	88.9	80.0	65.7	94.7	85.7	71.1	98.7
	Maritime (east CZE), Supportive for SVK	2	244.7	221.3	333.3	51.3	48.3	54.2	65.9	65.7	66.0	74.1	71.1	77.1
APESV	Central zone	23	110.5	4.0	470.0	92.6	56.7	100.0	95.8	73.3	100.0	97.0	85.0	100.0
	North-East	6	81.1	43.3	195.0	85.6	56.7	98.7	92.1	73.3	100.0	97.3	86.1	100.0
	Maritime CZE 2019 and 2020	4	85.2	4.0	153.3	99.5	98.4	100.0	99.7	98.9	100.0	99.8	99.3	100.0
	South-East (SVK)	2	76.5	35.0	118.0	68.4	61.7	75.0	84.7	80.0	89.4	90.7	85.0	96.4
	S-E + supportive data	5	80.5	4.0	153.3	87.3	61.7	100.0	93.9	80.0	100.0	96.3	85.0	100.0
LOLSS/LOLMU	Central zone	8	66.2	21.7	142.8	77.4	58.3	97.0	86.5	78.3	98.3	88.5	78.3	97.3
	N-E supportive data	4	60.0	28	142.8	67.7	58.3	81.0	83.9	81.3	86.9	88.1	85.4	92.2
	Maritime (CZE, FRA, LOLMU)	5	52.3	21.7	142.8	71.8	58.3	88.3	82.8	78.3	86.9	89	85.4	92.3
	Maritime (FRA LOLSS)	3	89.4	58.3	130.0	86.8	75.0	97.0	92.8	87.3	98.3	87.8	78.3	97.3
	Maritime (FRA LOLMU+LOLSS)	4	72.5	21.7	130.0	87.2	75.0	97.0	89.2	78.3	98.3	88.9	78.3	97.3
POAAN	Central zone	8	10.3 pl/m2/19%	5.7 pl/m2/3.3%	17 pl/m2/33.3%	93.3	64.5	100.0	95.8	86.7	100.0	98.8	96.0	100.0
	Maritime (CZE), N-E supportive data	2	11.4	5.7	17.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
	Maritime (AUT, CZE, GBR)	7	10.9 pl/m2/19%	5.7 pl/m2/3.3%	17 pl/m2/33.3%	97.4	88.3	100.0	97.1	86.7	100.0	99.1	96.0	100.0
	South-East	1	7.8	-	-	64.5	-	-	87.1	-	-	96.8	-	-
	S-E + supportive data	4	11.4	5.7	17.0	91.1	64.5	100.0	96.8	87.1	100.0	99.2	96.8	100.0

N-E = North-East EPPO climatic zone

S-E = South-East EPPO climatic zone

Table 3.2- 8b: Minimum effective dose, Efficacy of FFA SC508.8 at proposed label rate, at 75% and 50% dose rate on major grass weeds in winter wheat and winter barley (USE 004).

Target	Grouping (EPPO climatic zone)	Number of data points	Infestation of the untreated control			% control with FFA SC508.8								
			((% coverage/plants/m ²)			0.24 L/ha (62,5 % of 1N)			0.36 L/ha (83,3% of 1 N)			0.48 L/ha (1N)		
			Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	Mean	Min	Max
ALOMY	POL + supportive data	3	189.9	15.0	333.3	72.0	54.2	88.9	84.8	66.0	94.7	88.6	71.1	98.7

in winter wheat	Maritime	8	503.7	15.0	2781.3	69.1	40.0	93.7	80.8	58.3	96.3	87.6	68.3	98.7
ALOMY in winter barley	POL + supportive data	1	268.0	-	-	48.3	-	-	65.7	-	-	77.1	-	-
	Maritime	3	420.9	268.0	540.0	57.4	48.3	62.5	79.3	65.7	86.9	86.8	77.1	92.2
APESV in winter wheat	POL + supportive data	6	81.1	43.3	195	85.6	56.7	98.7	92.1	73.3	100	97.3	86.7	100
	Maritime	3	112.3	91.3	153.3	99.3	98.4	100	99.6	98.9	100	99.8	99.3	100
	South-East	1	35.0	-	-	75.0	-	-	80.0	-	-	85.0	-	-
APESV in winter barley	POL + supportive data	2	61.0	4.0	118.0	80.9	61.7	100	94.7	89.4	100	98.2	96.4	100
	Maritime	1	4.0	-	-	100	-	-	100	-	-	100	-	-
	South-East	1	118.0	-	-	61.7	-	-	89.4	-	-	96.4	-	-
LOLMU in winter wheat	POL + supportive data	3	70.6	32.0	142.8	63.2	58.3	68.3	82.9	81.3	84.7	88.9	85.4	92.2
	Maritime	4	58.4	21.7	142.8	69.5	58.3	88.3	81.8	78.3	84.7	89.8	85.4	92.3
LOLMU in winter barley	POL + supportive data	1	28.0	-	-	81.0	-	-	86.9	-	-	85.7	-	-
	Maritime	1	28.0	-	-	81.0	-	-	86.9	-	-	85.7	-	-
LOLSS in winter wheat	Maritime	3	89.4	58.3	130.0	86.8	75.0	97.0	92.8	87.3	98.3	87.8	78.3	97.3
POAAN in winter wheat	POL + supportive data	1	17.0	-	-	100	-	-	100	-	-	100	-	-
	Maritime	5	18.9%/11.5pla	3.3%/6pla	33.3%/17pla	96.4	88.3	100	95.9	86.7	100	98.7	96.0	100
POAAN in winter barley	POL + supportive data	2	6.8	5.7	7.8	82.3	64.5	100	93.6	87.1	100	98.4	96.8	100
	Maritime	2	10.4	5.7	15.0	100	100	100	100	100	100	100	100	100
	South-East	1	7.8	-	-	64.5	-	-	87.1	-	-	96.8	-	-

Summary and conclusion on the minimum effective dose, USE004

According to the presented results, the dose rate of 0.48 L/ha of FFA SC508,8 applied in post emergence provided the optimal overall control against ALOMY and LOLSS/LOLMU. It should be considered as an effective dose against other major weeds, including APESV and POAAN for which activity of FFA SC508,8 is claimed. Although FFA SC508,8 applied at 0.24 L/ha is demonstrated to be an effective dose for the control of APESV and POAAN (see USE 003) for situations where weed infestation is high, or soil and environmental conditions are poor then the higher dose rate of 0.48 L/ha may be required to reach an acceptable level of control.

Comments of zRMS:

The Applicant has submitted a range of efficacy trials to determine the minimum effective dose for FFA SC 508.8 G against grass weeds in winter cereals for post-emergence application. Because the trials have been conducted only in winter wheat and winter barley, the zRMS decided to present the results for every crop separately (the table 3.2-90b). In the Maritime EPPO zone, the dose rate of 0,24 l/ha was sufficient in case of control of APESV in winter wheat and winter barley, LOLSS in winter wheat and POAAN in winter wheat and winter barley. The level of effectiveness was >85%. However, the dose rate of 0,48 l/ha is the most effective against ALOMY in winter wheat and barley and LOLMU in winter wheat. In the South-East EPPPO zone, the test product at dose rate of 0,48 l/ha achieved the effectiveness >85% in control of APESV in winter wheat and barley and POAAN in winter barley. In the North-East EPPO zone, the dose rate of 0,24 l/ha was sufficient against APESV and POAAN in winter wheat (85,6% and 100%). FFA SC 508.8 G was the most effective in control of ALOMY in winter wheat and barley (88,6% and 77,1%), LOLMU in winter wheat (88,9%) and POAAN in winter barley (98,4%).

Taking into account the results from all EPPO climatic zones, the dose rate of 0,48 l/ha can be considered the minimum effective dose to control of ALOMY and LOLSS/LOLMU in winter cereals in post-emergence application. Moreover, this dose rate can be also recommended to control of grasses in winter cereals in difficult growing conditions or in case of high level of weed pressure.

3.2.3 Efficacy tests (KCP 6.2)

The Efficacy trials conducted are summarised and evaluated below according to the proposed uses i.e.:

- “USE001” where the recommended dose rate of FFA SC508.8 on winter wheat, winter barley, winter triticale and winter durum wheat is 0.24 L/ha at crop BBCH 00-09; applied pre-emergence in the autumn against APESV and POAAN.
- “USE002” where the recommended dose rate of FFA SC508.8 on winter wheat, winter barley, winter triticale and winter durum wheat is 0.48 L/ha at crop BBCH 00-09; applied pre-emergence in the autumn against ALOMY, APESV, POAAN, LOLSS and the broad-leaved weeds MATIN, PAPRH and VERPE.
- “USE003” where the recommended dose rate of FFA SC508.8 on winter wheat, winter barley, winter triticale and winter durum wheat is 0.24 L/ha at crop BBCH 10-13; applied post-emergence in the autumn against APESV and POAAN.
- “USE004” where the recommended dose rate of FFA SC508.8 on winter wheat, winter barley, winter triticale and winter durum wheat is 0.48 L/ha at crop BBCH 10-13; applied post-emergence in the autumn against ALOMY, APESV, POAAN and LOLSS.

As well as an evaluation of the data a general overview of the main characteristics of the methodology is presented for the trials reported for per USE. For more details on methodology or on the data generated from each individual trial please refer to the Single Trial Report, for the site description to Appendix 2 and for summary tables to Appendix 3.

Methodology

Trials followed the requirements of the efficacy EPPO standard PP1/093(3) “Weeds in cereals”. The list of EPPO standards followed in the trials is presented in the following table.

Table 3.2- 9: List of the EPPO standards followed in efficacy / minimum effective dose trials.

EPPO standard	Title
PP1/093(3)	<i>Weeds in cereals</i>
PP1/135(4)	<i>Phytotoxicity assessment</i>
PP1/152(4)	<i>Design and analysis of efficacy evaluation trials</i>
PP1/181(4)	<i>Conduct and reporting of efficacy evaluation trials including GEP</i>
PP1/225(2)	<i>Minimum effective dose</i>

Trials followed requirements of the EPPO standard PP1/093(3). This standard mainly recommend the following:

- a trial design with minimum 3 to 4 replicates randomly distributed (3 replicates in case of trial series, according to EPPO PP1/152(4)),
- a plot size at least 10 m² for weed control and at least 12 m² for selectivity,
- a minimum of 3 assessments timings:
 - for post-emergence application: 1st up to 2 weeks after treatment, 2nd at BBCH 21-29 and 3rd at BBCH 37-39. A 4th optional assessment timing could be performed shortly before harvest.

The Methodological Instruction No. 2/2014” from UKSUP is presented in the document [M-630120-01-1](#), *Methodological instruction no. 2/2014 on submission of the number of biological effectiveness experiments for an applicant for authorisation, extension of an authorisation, change or amendment to an authorisation, or re-assessment of a plant protection products authorisation.*

Regarding the Methodology Instruction for Slovakia (also valid for Slovenia) “Methodological Instruction No. 2/2014” from UKSUP (ústredný kontrolný a skúšobný ústav poľnohospodársky Bratislava) from 1st of January 2016 ([M-630120-01-1](#)), trials from the B zone - middle (Central zone):

Belgium, Czech Republic, Germany, Ireland, Luxembourg, Hungary, Netherlands, Austria, Poland, Romania, Slovenia, Slovakia, and United Kingdom are also valid for effectiveness.

For Poland, countries belonging to another EPPO zone but neighbouring with Poland (the Czech Republic, Slovakia and Germany) were clustered as supportive data.

The evaluation of the product complies with the Uniform Principles.

USE001: Efficacy of FFA SC508.8 at 0.24 L/ha against APESV and POAAN on TRZAW, HORVW, TTLWI, TRZDU, SECCW and TRZSP; pre-emergence at BBCH 00– 09 ([M-761917-01-1](#)).

Single trial reports are available in the document Compilation of trial reports.

A total of ~~24~~ 23 trials (2 from Austria, + 2 from Belgium, 5 trials from the Czech Republic, 4 trials from United Kingdom, ~~6~~ 7 trials from Poland, 3 trials from Slovakia) was carried out between 2018 and 2020 to evaluate the efficacy of FFA SC508.8 applied pre-emergence at 0.24 L/ha for the control of grass weeds in winter cereals. Trials were carried out in winter soft wheat and winter barley.

Trials set and methods

The main characteristics of the methodology, number and location of trials conducted and their distribution across countries and years is given in the following tables.

Table 3.2-7: Distribution and number of trials conducted, Maritime, North-East, South-East EPPO climatic zone, winter soft wheat and winter barley; pre-emergence, USE001

Country	EPPO climatic zone	2018	2019	2020	Sum trials	Sum per EPPO zone
Poland	North-East			9 7	9 7	9 7
Czech Republic	Maritime	1	1	3	5	26 13
Austria		2			2	
Belgium		1		1	2	
France				9	9	
United Kingdom			6 3	1	7 4	
			4		4	
Slovakia	South-East			3	3	3
Total Sum		4 3	8 4	26 14	38 23	

Table 3.2-8: Details on trial methodology - USE001

Guidelines	General guidelines	EPPO PP1/135(4), PP1/152(4), PP1/181(4), PP1/225(2)
	Specific guidelines	EPPO PP1/093(3)
Experimental design	Plot design	RCBD (24 23 trials)
	Plot size	10-27 m ²
	Number of replications	4 (2 trials), 3 (49 21 trials)
Crop	Trials per crop	TRZAW: 47 19 trials HORVW: 4 trial
	Varieties per crop	TRZAW AUT: GENIUS (1) BEL: ANAPOLIS (1), BERGHAMO (1) CZE: AVENUE (2), ANNIE (1), ENERGO (1) SVK: ANTONIUS (1) GBR: ELICIT (1), GRAHAM (1), KWS SISKIN (1), SKYFALL (1) POL: ATRIST (1), DEPOT (1), JOKER (1), LINUS (4 2), OSTROGA (1), PATRAS (1) HORVW: AUT: VERSUCHSSORTE (1) CZE: LEOPARD (1) SVK: ZOO (1), SCALA (1)
	Sowing period	TRZAW: AUT: October (1) BEL: November (1), October (1) CZE: September (2) to October (2) GBR: September (2), October (2) POL: September (4 5), October (1), (1 trial no data) SVK: October (1) HORVW: AUT: October (1) CZE: October (1) SVK: October (2)
Application	Crop stage (BBCH) at application	Post Pre-emergence TRZAW AUT: BBCH 00 BEL: BBCH 03-09 CZE: BBCH 03-07 GBR: BBCH 00-05 POL: BBCH 00-09 SVK: BBCH 00 HORVW AUT: BBCH 09 CZE: BBCH 05 SVK: BBCH 01-10
	Timing Pest stage at application	Pre-emergence <u>Grass weeds:</u> APESV: BBCH 00-05

Assessment	Number of applications	POAAN: BBCH 00-05
	Intervals between applications	1 (24 23 trials)
	Spray volumes	150 - 300 L/ha
	Assessment types	<p>2 to 5 efficacy and/or selectivity assessments</p> <p><u>Efficacy:</u></p> <ul style="list-style-type: none"> - Estimation of weed coverage in % per weed in untreated. Weed control (0% = no weed control, 100% =full weed control) of treated plots is estimated by comparison with untreated. - Counting of ears (only grasses) on basis square meter in untreated. Two possibilities for estimation of grass control: <ul style="list-style-type: none"> - Estimation of grass control (0% = no weed control, 100% = full weed control) of treated plots by comparison with untreated. - Counting of ears on basis square meter in treated followed by a calculation by comparison with untreated to express gras control in %. <p><u>Selectivity:</u></p> <ul style="list-style-type: none"> - Estimation of crop damage in % versus untreated plants as phytotoxicity general (PHYGEN). Each symptom assessed is reported individually.
	Assessment dates	<p><u>1 to 5 assessments</u></p> <p>A0: At application: Preliminary assessment of crop cover & weed population if present</p> <p>A1: BBCH 11-12 crop stage in untreated plots: Selectivity</p> <p>A2: BBCH 21-29: Selectivity and efficacy</p> <p>A3: BBCH 37-39: Selectivity</p> <p>A4: Heading or flowering of grass weeds: Efficacy. Additional assessments can be added if necessary (for example if one needs to distinguish vegetation stop (autumn) and vegetation start(spring).</p>
		<p>AUT: Silt (1), Sandy loam (1)</p> <p>BEL: no data (1), <u>sandy loam (1)</u></p> <p>CZE: Silty Clay Loam (2), Sandy Loam (2), Silty Clay (1)</p> <p>GBR: Loamy sand (2), Sandy Loam (1), Silty Clay Loam (1)</p> <p>POL: Gravelly Clay Loam(1), Loamy Sand (2), Sandy Clay (1), Sandy Loam (± 2), Silty sand (1)</p> <p>SVK: Loam (2), Sandy clay (1)</p>
	e.g. Natural / artificial inoculation...	Natural infestation
	e.g. Field / Greenhouse...	field trials

A map of trial locations is presented in the Biological Assessment Dossier.

An overview about all weed species observed in these trials are presented in the Biological Assessment dossier.

Weed coverage in the untreated plots before application and at presented assessment timing (for broad-leaved weeds at beginning of vegetation; for grass weeds at flowering of grasses) as % coverage or number of ears per square meter are presented in the Table below.

Table 3.2-9: Weed coverage in the untreated control at application and at assessment timing (grass weeds & broadleaved weeds)

Weed species	[%] coverage at application in untreated control	Weed BBCH at application	[ears/m ²] or [%] coverage at assessment in untreated control	Weed BBCH at assessment
Grass weeds				

APESV	0%	BBCH 00-09	4.3-297.3 plants/m2	BBCH 59-89
POAAN	0%	BBCH 00-05	3-23.7 plants/m2	BBCH 61

Reference products

FFA SC508.8 was compared with different standard reference products, depending on trial, Stomp 400 applied at 4.1 L/ha, Stomp Aqua applied at 1.76 L/ha, Herold applied at 0.6 L/ha, Liberator applied at 0.6 L/ha, Bacara forte applied at 0.8 L/ha and Boxer 3 L/ha was used as standard products.

Trial clustering

For each weed species data from each EPPO climatic zone is presented separately. If different references were used, trials are first clustered per reference used and additionally as Climate Zone Total, followed by adding of additional supportive data in case of the North-East- and South-East EPPO climatic zone. At the end, a summary of the Central zone is presented.

Summary and conclusion on the efficacy grass- and broad-leaved weeds - USE001

For each weed species data from each EPPO climatic zone is presented separately and then mean (average) of all trials is calculated.

Table 3.2-10: Summary: Efficacy of FFA SC 508.8 applied at 0.24 L/ha against major grass weeds in winter cereals.

Tar- get	Grouping*	Num- ber of trials	Infestation of the untreated control			FFA SC 508.8			BOXER			BACARA FORTE			HEROLD SC			LIBERATOR			STOMP 400		
	(EPPO climatic zone)		(% coverage / plants/m ²)			0.24 L/ha (1N)			3 L/HA			0.8 L/HA			0.6 L/HA			0.6 L/HA			4.1 L/HA		
			Mea n	Mi n	Ma x	Mean	Min	Max	Mea n	Mi n	Ma x	Mea n	Mi n	Ma x	Mean	Min	Max	Mea n	Mi n	Ma x	Mea n	Mi n	Ma x
APES V	Central zone	18	83.5	4.3	297. 3	95.3	74.2	100	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	North-East	7	61.2	10. 0	187. 7	96.0	78.3	100	92.9	77. 8	99. 7	-	-	-	-	-	-	-	-	-	-	-	-
	POL+supportive data (POL+CZE)	12	71.3	4.3	187. 7	97.5	78.3	100	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Maritime total	9	103. 9	4.3	297. 3	99.4	97.1	100	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Maritime (AUT)	2	76.0	52. 0	100. 0	100	100	100	-	-	-	100	10 0	100	-	-	-	-	-	-	-	-	-
	Maritime (BEL)	1	297. 3	-	-	99.0	-	-	-	-	-	-	-	-	100	-	-	100	-	-	-	-	-
	Maritime (CZE)	5	85.5	4.3	180. 0	99.7	99.0	100	-	-	-	-	-	-	-	-	-	-	-	-	98.3	91. 5	100
	Maritime (BEL+CZE)	4	112. 8	4.3	297. 3	99.3	99.0	100	-	-	-	-	-	-	100	100	100	100	10 0	100	-	-	-
	South-East	2	69.8	35. 0	104. 5	74.6	74.2	75.0	-	-	-	-	-	-	95.0	99.0	100	95.0	99. 0	100	-	-	-
	SVK+supportive data (CZE+AUT+SV K)	7	88.4	4.3	180. 0	92.6	74.2	100	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
POA AN	Central zone	7	9.3	3.0	23.7	88.7	50.0	100	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Maritime total	6	9.7	3.0	23.7	91.6	50.0	100	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Maritime (CZE)	2	16.9	10	23.7	100	100	100	-	-	-	-	-	-	-	-	-	-	-	-	100	10 0	100
	Maritime (GBR)	4	6.1	3.0	11.7	87.3	50.0	100	-	-	-	-	-	-	-	-	-	99.8	99. 3	100	-	-	-
	South-East	2	7.0 7.4	- 7.0	- 7.8	71.4 68.0	- 64.5	71.4	-	-	-	-	-	-	100 95.2	- 90.3	- 100	-	-	-	-	-	-
	POL/SVK+supp ortive data (CZE, SVK)	4	13.6 12.1	7.0	23.7	90.5 84.0	71.4 64.5	100	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

*Groupings are done according to climatic zone and reference product

Conclusions on the efficacy, USE001

Data shows that FFA SC508.8 applied at 0.24 L/ha at BBCH 00-09 is an effective product for the control of APESV and POAAN as presented in the table below.

The proposed label weed species spectrum and efficacy level of FFA SC508.8 per EPPO climatic zone (including supportive data) is indicated in the table below. Weeds susceptibility is ranked according to document SANCO/10055/2013 Rev. 4 as:

- Highly Susceptible: 95%-100% efficacy
- Susceptible: 85%-94.9% efficacy
- Moderately Susceptible: 70%-84.9% efficacy
- Moderately Tolerant: 50%-69.9%
- Tolerant: 0%-49.9 %.

Table 3.2-11: Proposed label target list and dose rates of FFA SC508.8 applied at 0.24 L/ha at crop BBCH 00-09

Target		North-East	Maritime	South-East
		0.24 L/ha		
Grass weeds				
APESV	<i>Apera spica-venti</i> (L.) BEAUV.	Highly susceptible	Highly susceptible	Highly Susceptible
POAAN	<i>Poa annua</i>	Highly susceptible Moderately Susceptible	Highly Susceptible	Highly susceptible Moderately Tolerant

Comments of zRMS:

23 field efficacy trials have been conducted in the three EPPO climatic zones: Maritime, South-East and North-East. FFA SC 508.8 G was tested at dose rate of 0,24 l/ha, once in growing season, in pre-emergence application (BBCH 00-09). Because the trials have been carried out only in winter wheat and winter barley, the zRMS decided to separate results from these crops. The cMSs are asked to consider this solution and use of extrapolation in case of weeds noted in the limited number of trials.

- A total of 13 efficacy trials were carried out in **the Maritime EPPO climatic zone** in the following countries: Czech Republic (5 trials), Austria (2 trials), Belgium (2 trials) and United Kingdom (4 trials). The classification of weed susceptibility for each weed species, which have been located in the Maritime zone is presented below.

Target	Crop	No of trials	Efficacy of FFA SC 508.8 G 0,24 l/ha	Susceptibility
APESV	TRZAW	7	99,2%	HS
APESV	HORVW	2	100%	HS
POAAN	TRZAW	5	89,8%	S
POAAN	HORVW	1	100%	HS

- A total of 7 efficacy trials were carried out in **the North-East EPPO climatic zone**, all in Poland. The trials conducted in the neighbour countries (Czech Republic, Germany and Slovakia) have been also included to the final calculation of efficacy.

Target	Crop	No of trials	Efficacy of FFA SC 508.8 G 0,24 l/ha	Susceptibility
APESV	TRZAW	7	96%	HS
APESV	HORVW	2	87,5%	S
POAAN	TRZAW	2	85,7%	S
POAAN	HORVW	2	82,3%	MS

- A total of 3 efficacy trials were carried out in **the Sout-East EPPO climatic zone**, all in Slovakia. Because the number of submitted trials is limited, the trials conducted in the neighbour countries (Austria and Czech Republic) have been also included to the final calculation of efficacy.

Target	Crop	No of trials	Efficacy of FFA SC 508.8 G	Susceptibility
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			0,24 l/ha	
APESV	TRZAW	6	95,4%	HS
APESV	HORVW	3	91,7%	S
POAAN	TRZAW	2	85,7%	S
POAAN	HORVW	2	82,3%	MS

USE002: Efficacy of FFA SC508.8 at 0.48 L/ha against ALOMY, LOLPE/LOLSS, POAAN, APESV and annual broad-leaved weeds MATIN , PAPRH and VERPE on TRZAW, HORVW, TTLWI, TRZDU, SECCW and TRZSP pre-emergence at BBCH 00-09 ([M-761917-01-1](#)).

Single trial reports are available in the document Compilation of trial reports.

A total of 42 trials (3 trials from Belgium, 4 trials from the Czech Republic, 5 trials from Germany, 12 trials from France, 8 trials from United Kingdom, 7 trials from Poland and 3 trials from Slovakia) were performed between 2018 and 2020 to evaluate the efficacy of FFA SC508.8 applied pre-emergence at 0.48 L/ha for the control of grass weeds and broad-leaved weeds. Trials were carried out in winter soft wheat and winter barley.

Trials set and methods

The main characteristics of the methodology, number and location of trials conducted and their distribution across countries and years is given below. In a separate column, the crop BBCH stage at application is presented per trial to justify the trials for USE002 (crop BBCH 00-09).

Table 3.2-12 Distribution and number of trials conducted, Maritime, North-East, South-East EPPO climatic zone, winter soft wheat and winter barley; pre-emergence, USE002

Country	EPPO	2018	2019	2020	Sum	Sum per EP- PO zone
	climatic zone				trials	
Poland	North-East			7	7	7
Czech Republic	Maritime		1	3	4	34 32
Belgium		1		2	3	
France				13 12	13 12	
United Kingdom		1	7 6	1	9 8	
Germany	South-East		5		5	3
Slovakia				3	3	
Total Sum		2	13 12	29 28	44 42	

Table 3.2-13: Details on trial methodology - USE002

Guidelines	General guidelines	EPPO PP1/135(4), PP1/152(4), PP1/181(4), PP1/225(2)
	Specific guidelines	EPPO PP1/093(3)
Experimental design	Plot design	RCBD (42 trials)
	Plot size	10-27 m ²
	Number of replications	4 (2 trials), 3 (40 trials)
Crop	Trials per crop	TRZAW: 37 trials HORVW: 5 trial
	Varieties per crop*	TRZAW BEL: ANAPOLIS (1) CZE: AVENUE (2), ANNIE (1) DEU: ASANO (1), DEKAN(1), JULIUS (1), KWS TALENT (1), RGT REFORM (1) FRA: APRILIO (1), CHEVIGNON (1), FRUCTIDOR (1), LG AMSTRONG (1), LUMINON (1), LYRIK (1), MACARON (1), NEMO (1), PAS-TORAL (1), SYLLON (2), VELASKO (1) GBR: ELICIT (1), GRAHAM (1), KWS KERRIN (1), KWS SISKIN (3-1), KWS ZYATT (1), SISKIN (4-2), SKYFALL (2) POL: ARTIST ARTIST (1), DEPOT (1), JOKER (1), LINUS (2), OSTROGA (1), PATRAS (1) SVK: ANTONIUS (1) HORVW: BEL: WOOTAN (1), WODAN (1) CZE: LEOPARD (1) SVK: ZOO (1), SCALA (1)
	Sowing period	TRZAW: BEL: November (1) CZE: September (1) to October (2) DEU: September (3), October (2) FRA: October (10), November (2) GBR: September (2), October (6) POL: September (5-6), October (1), (1 trial no data) SVK: October (1) HORVW: BEL: September (2) CZE: October (1) SVK: October (2)
Application	Crop stage (BBCH) at application	Post-emergence TRZAW BEL: BBCH 03 CZE: BBCH 03-05 DEU: BBCH 03-09 FRA: BBCH 00-06 GBR: BBCH 00-05 POL: BBCH 00-09 SVK: BBCH 00 HORVW BEL: BBCH 07-09 CZE: BBCH 05 SVK: BBCH 04-00-10
	Timing Pest stage at application	Pre-emergence Grass weeds: ALOMY: BBCH 00-09 APESV: BBCH 00-09 LOLMU: BBCH 03-05 LOLSS: BBCH 00 POAAN: BBCH 00-10 <u>Dicots:</u> MATIN: BBCH 03-09 VERPE: BBCH 00-09

Assessment	Number of applications	1 (42 trials)
	Intervals between applications	
	Spray volumes	150 - 300 L/ha
	Assessment types	<p>2 to 5 efficacy and/or selectivity assessments</p> <p><u>Efficacy:</u></p> <ul style="list-style-type: none"> - Estimation of weed coverage in % per weed in untreated. Weed control (0% = no weed control, 100% =full weed control) of treated plots is estimated by comparison with untreated. - Counting of ears (only grasses) on basis square meter in untreated. Two possibilities for estimation of grass control: <ul style="list-style-type: none"> - Estimation of grass control (0% = no weed control, 100% = full weed control) of treated plots by comparison with untreated. - Counting of ears on basis square meter in treated followed by a calculation by comparison with untreated to express gras control in %. <p><u>Selectivity:</u></p> <ul style="list-style-type: none"> - Estimation of crop damage in % versus untreated plants as phytotoxicity general (PHYGEN). Each symptom assessed is reported individually.
	Assessment dates	<p>1 to 5 assessments</p> <p>A0: At application: Preliminary assessment of crop cover & weed population if present</p> <p>A1: BBCH 11-12 crop stage in untreated plots: Selectivity</p> <p>A2: BBCH 21-29: Selectivity and efficacy</p> <p>A3: BBCH 37-39: Selectivity</p> <p>A4: Heading or flowering of grass weeds: Efficacy.</p> <p>Additional assessments can be added if necessary (for example if one needs to distinguish vegetation stop (autumn) and vegetation start(spring).</p>
	e.g. Natural / artificial inoculation...	<p>BEL: Loam (+ 3), no data (-2)</p> <p>CZE: Silty Clay Loam (2), Sandy Loam (1), Silty Clay (1)</p> <p>DEU: Loam (1), Loamy clay (1), Loamy silt (1), Sandy Loam (1), Silt Loam (1)</p> <p>FRA: Clay Sandy Loam (= 1), Clayey Silt (+ 4), Fine Loam (1), Fine Sandy Loam (1), Loam (1), Loamy Clay sand (1), sandy clay loam (1), clay (1), no data (= 1)</p> <p>GBR: Clay (1), Clay Loam (1), Loamy sand (2), Sandy Clay Loam (1), Sandy Loam (1), Silty sand (+) silty clay loam (2)</p> <p>POL: Gravelly Clay Loam(1), Sandy Clay (1), Sandy Loam (2), Silty sand (1), loamy sand (2)</p> <p>SVK: Loam (2), Sandy clay (1)</p>
	e.g. Field / Greenhouse...	field trials

A map of trial locations is presented in the Biological Assessment Dossier,

An overview about all weed species observed in these trials are presented in the Biological Assessment dossier.

Weed coverage in the untreated plots before application and at presented assessment timing (for broad-leaved weeds at beginning of vegetation; for grass weeds at flowering of grasses) as % coverage or number of ears per square meter are presented in the Table below. Only weed species which occurred in more than 1 trial or are part of a plant family (e.g. MATSS – MATCH, MATIN) are presented.

Table 3.2-14: Weed coverage in the untreated control at application and at assessment timing (grass weeds & broadleaved weeds)

Weed species	[%] coverage at application in untreated control	Weed BBCH at application	[ears/m ²] or [%] coverage at assessment in untreated control	Weed BBCH at assessment
Grass weeds				
ALOMY	0%	BBCH 00-09	15-1891.7 plants/m ² / 5-58.3%	BBCH 61-81
APESV	0% 15-80 plants/m ²	BBCH 00-09	4.3-297.3 plants/m ²	BBCH 59-75
LOLMU	0%	BBCH 03-05	59-77 plants/m ²	BBCH 59
LOLSS	0%	BBCH 00	48.3-1493.3 plants/m ²	BBCH 59-65
POAAN	0-6.75%	BBCH 00-10	3-23.7 plants/m ²	BBCH 61
Broad-leaved weeds				
MATIN	0%/ 7-15 plants/m ²	BBCH 03-08	2-10.7%	BBCH 16-30
VERPE	0%/ 20 plants/m ²	BBCH 03-09	4-9.7%	BBCH 11-43
PAPRH	0%/ 20 plants/m ²	BBCH 00-09	6.7-28.3%	BBCH 16-41

Reference product

FFA SC508.8 was compared with different standard reference products, depending on trial, Stomp 400 applied at 4.1 L/ha, Stomp Aqua applied at 1.76 L/ha, Herold applied at 0.6 L/ha, Liberator applied at 0.6 L/ha, Bacara forte applied at 0.8 L/ha and Boxer 3 L/ha was used as standard products.

Efficacy of FFA SC508.8 against grass weeds

Assessment for the evaluation of efficacy was done when the target weed reached the heading growth stage. Panicles density per m² was counted in most of trials, then the Abbott formula has been used to calculate the efficacy expressed in % (0% – no efficacy, 100% – full control). In some trials, CONTRO assessment have been used to express efficacy. These trials are marked in the tables with a star.

Summary and conclusion on the efficacy grass weeds - USE002

In the following, the results table of each weed species is presented followed by a summary of the results for this weed species.

Table 3.2-15: Summary: Efficacy of FFA SC508.8 applied at 0.48 L/ha, against grass weeds in winter cereals.

Target	Grouping	Number of trials	Infestation of the untreated control			FFA SC 508.8			HEROLD SC			LIBERATOR			STOMP 400			BOXER		
	(EPPO climatic zone)		(% coverage / plants/m ²)			0.48 L/ha (1N)			0.6 L/HA			0.6 L/HA			4.1 L/HA			3 L/HA		
			Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	Mean	Min	Max
ALOMY	Central zone	20	298.5	15.0	1891.7	85.7	60.0	99.8	-	-	-	-	-	-	-	-	-	-	-	-
	Maritime Total	19	314.6	15.0	1891.7	85.9	60.0	99.8	-	-	-	-	-	-	-	-	-	-	-	-
	Maritime (GBR, DEU, BEL, CZE, FRA)	15	341.3	15.0	1891.7	87.6	69.3	99.8	88.9	70.6	99.8	-	-	-	-	-	-	-	-	-
	Maritime (GBR)	3	154.2	70.0	238.3	74.4	60.0	96.9	-	-	-	76.4	65.0	83.2						
	Maritime (CZE)	4	198.1	32.3	261.3	89.8	69.3	99.3	-	-	-	-	-	-	55.9	7.1	99.3			
	North-East Total	1	25.0	-	-	80.0	-	-	-	-	-	-	-	-	-	-	-	66.7	-	-
	POL + supportive data (POL, DEU, CZE)	10	179.1	16.0	383.3	87.4	69.3	99.8	-	-	-	-	-	-	-	-	-	-	-	-
	Supportive data for SVK (CZE)	3	253.3	245.3	261.3	86.6	69.3	95.9	-	-	-	-	-	-	-	-	-	-	-	-
APESV	Central zone	14	85.6	4.3	297.3	97.5	81.7	100	-	-	-	-	-	-	-	-	-	-	-	-
	Maritime total	5	126.2	4.3	297.3	100	100	100	-	-	-	-	-	-	-	-	-	-	-	-
	Maritime (BEL)	1	297.3	-	-	100	-	-	100	-	-	-	-	-	-	-	-	-	-	-
	Maritime (CZE)	4	83.4	4.3	180.0	100	100	100	-	-	-	-	-	-	100	100	100	-	-	-

	Maritime (BEL, CZE)	4	112.8	4.3	297.3	100	100	100	100	100	100	-	-	-	-	-	-	-	-
	North-East Total	7	61.2	10.0	187.7	97.2	81.7	100	-	-	-	-	-	-	-	-	92.9	77.8	99.7
	POL + supportive data	13	69.3	4.3	187.7	97.4	81.7	100	-	-	-	-	-	-	-	-	-	-	-
	South-East Total	2	69.8	35.0	104.5	92.5	85.0	100	95.0	90.0	100	-	-	-	-	-	-	-	-
	SVK + supportive data	5	93.4	4.3	180.0	97.0	85.0	100	-	-	-	-	-	-	-	-	-	-	-
POAAN	Central zone	8	9.1	3.0	23.7	98.6	91.7	100	-	-	-	-	-	-	-	-	-	-	-
	Maritime Total	6	9.7	3.0	23.7	98.6	91.7	100	-	-	-	-	-	-	-	-	-	-	-
	Maritime (CZE)	2	16.9	10.0	23.7	100	100	100	-	-	-	-	-	-	100	100	100	-	-
	Maritime (GBR)	4	6.1	3.0	11.7	97.9	91.7	100	-	-	-	99.8	99.3	100	-	-	-	-	-
	South-East Total	2	7.4	7.0	7.8	98.4	96.8	100	95.2	90.3	100	-	-	-	-	-	-	-	-
	SVK + supportive data for POL	4	12.1	7.0	23.7	99.2	96.8	100	-	-	-	-	-	-	-	-	-	-	-
LOLPE LOLMU/LOLS S	Central zone	10	349.6	48.3	535.3 1493.3	81.9	38.3	99.1	-	-	-	-	-	-	-	-	-	-	-
	Central zone*	8	137.8	48.3	535.3	91.4	80.0	99.1	-	-	-	-	-	-	-	-	-	-	-
	Maritime LOLMU (CZE)	3	62.3	59.0	69.0	82.3	80.1	99.1	-	-	-	-	-	-	97.3	83.8	95.2	-	-
	Maritime LOLMU (FRA)	1	59.0	-	-	95.0	-	-	100	-	-	-	-	-	-	-	-	-	-
	Maritime LOLSS (FRA)	6	541.7	48.3	1493.3	72.7	38.3	96.0	89.0	66.7	99.0	-	-	-	-	-	-	-	-

	Maritime (FRA)*	5	183.1	48.3	535.3	88.6	80.0	96.0	97.3	93.3	100	-	-	-	-	-	-	-	-	-
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*excluding two trials with very high infestation level of 900-1493.3 heads/m2

Efficacy of FFA SC508.8 against broad-leaved weeds

Weed control (0% = no weed control, 100% =full weed control) of treated plots is estimated by comparison with the untreated. Assessment for the evaluation of efficacy was done based either on counted plants per square meter or % coverage.

Summary and conclusion on the efficacy broad-leaved weeds - USE002

In the following, the results table of each weed species is presented followed by a summary of the results for this weed species.

[illegible]

	South-East Total	1	5.0	-	-	40.7	-	-	95.0	-	-	-	-	-	-	-	-	-	-	-
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*excluding two trials with very high infestation level of 900-1493.3 heads/m2

Conclusions on the efficacy, USE002

Data shows that FFA SC508.8 applied at 0.48 L/ha at BBCH 00-09 is an effective product for the control of the grasses ALOMY, APESV, LOLSS, POAAN and the broad-leaved weeds MATIN, PAPRH and VERPE as presented in the table below.

The proposed label weed species spectrum and efficacy level of FFA SC508.8 per EPPO climatic zone (including supportive data) is indicated in the table below. Weeds susceptibility is ranked according to document SANCO/10055/2013 Rev. 4 as:

- Highly Susceptible: 95%-100% efficacy
- Susceptible: 85%-94.9% efficacy
- Moderately Susceptible: 70%-84.9% efficacy
- Moderately Tolerant: 50%-69.9%
- Tolerant: 0%-49.9 %.

Table 3.2-17: Proposed label target list and dose rates of FFA SC508.8 applied at 0.48 L/ha at crop BBCH 00-09

Target		North-East	Maritime	South-East
		0.48 L/ha		
Grass weeds				
ALOMY	<i>Alopecurus myosuroides</i>	Susceptible	Susceptible	Susceptible
APESV	<i>Apera spica-venti</i>	Highly Susceptible	Highly Susceptible	Highly Susceptible
LOLSS	<i>Lolium sp.</i>	Susceptible	Susceptible	Susceptible
POAAN	<i>Poa annua</i>	Highly Susceptible	Highly Susceptible	Highly Susceptible
Broad-leaved weeds				
MATIN	<i>Tripleurospermum inodorum</i>	Moderately Highly Susceptible	Moderately Susceptible	Moderately Susceptible
PAPRH	<i>Papaver rhoeas</i>	Moderately Susceptible	Moderately Susceptible	Moderately Susceptible
VERPE	<i>Viola arvensis</i>	Moderately Susceptible	Moderately Susceptible	Moderately Susceptible

Comments of zRMS:

42 field efficacy trials have been conducted in the three EPPO climatic zones: Maritime, South-East and North-East. FFA SC 508.8 G was tested at dose rate of 0,48 l/ha, once in growing season in pre-emergence application (BBCH 00-09). Because the trials have been carried out only in winter wheat and winter barley, the zRMS decided to separate results from these crops. The cMSs are asked to consider this solution and use of extrapolation in case of weeds noted in the limited number of trials.

- A total of 32 efficacy trials were carried out in **the Maritime EPPO climatic zone** in the following countries: Czech Republic (4 trials), France (12 trials), Belgium (3 trials), Germany (5 trials) and United Kingdom (8 trials). The classification of weed susceptibility for each weed species, which have been noted in the Maritime zone is presented below.

Target	Crop	No of trials	Efficacy of FFA SC 508.8 G 0,48 l/ha	Susceptibility
ALOMY	TRZAW	17	86,5%	S
ALOMY	HORVW	2	81,3%	MS
APESV	TRZAW	4	100%	HS
APESV	HORVW	1	100%	HS
POAAN	TRZAW	5	98,3%	HS
POAAN	HORVW	1	100%	HS
LOLMU	TRZAW	3	95,3%	HS
LOLMU	HORVW	1	97,1%	HS
LOLSS	TRZAW	4	87%	S
MATIN	TRZAW	2	75,5%	MS

MATIN	HORVW	1	85%	S
PAPRH	TRZAW	5	97,4%	HS
VERPE	TRZAW	3	84,1%	MS

• A total of 7 efficacy trials were carried out in the **North-East EPPO climatic zone**, all in Poland. The trials conducted in the neighbour countries (Czech Republic, Germany and Slovakia) have been also included to the final calculation of efficacy.

Target	Crop	No of trials	Efficacy of FFA SC 508.8 G 0,48 l/ha	Susceptibility
ALOMY	TRZAW	9	89,4%	S
ALOMY	HORVW	1	69,3%	MT
APESV	TRZAW	7	97,2%	HS
APESV	HORVW	2	92,5%	S
POAAN	TRZAW	2	100%	HS
POAAN	HORVW	2	98,4%	HS
LOLMU	TRZAW	2	95,5%	HS
LOLMU	HORVW	1	97,1%	HS
MATIN	TRZAW	5	87,7%	S
MATIN	HORVW	1	85%	S
PAPRH	TRZAW	4	90,4%	S
VERPE	TRZAW	5	93,1%	S
VERPE	HORVW	1	40,7%	T

• A total of 3 efficacy trials were carried out in the **Sout-East EPPO climatic zone**, all in Slovakia. Because the number of submitted trials is limited, the trials conducted in the neighbour countries (Austria and Czech Republic) have been also included to the final calculation of efficacy.

Target	Crop	No of trials	Efficacy of FFA SC 508.8 G 0,48 l/ha	Susceptibility
ALOMY	TRZAW	3	96,6%	HS
ALOMY	HORVW	1	69,3%	MT
APESV	TRZAW	4	100%	HS
APESV	HORVW	2	92,5%	S
POAAN	TRZAW	2	100%	HS
POAAN	HORVW	2	98,4%	HS
LOLMU	TRZAW	2	95,5%	HS
LOLMU	HORVW	1	97,1%	HS
MATIN	TRZAW	2	75,5%	MS
MATIN	HORVW	1	85%	S
PAPRH	TRZAW	1	95%	HS
VERPE	TRZAW	2	97,9%	HS
VERPE	HORVW	1	40,7%	T

USE003: Efficacy of FFA SC508.8 at 0.24 L/ha against APESV and POAAN on TRZAW, HORVW, TTLWI, TRZDU, SECCW and TRZSP; post-emergence at BBCH 10 – 13 ([M-761933-01-1](#)).

Single trial reports are available in the Compilation of trial reports.

A total of 31 trials (3 trials Austria, 1 from Belgium, 5 trials from the Czech Republic, 10 trials from Germany, 4 trials from the United Kingdom, 6 trials from Poland and 2 trials from Slovakia) was performed between 2018 and 2020 to evaluate the efficacy of FFA SC508.8 applied post-emergence at 0.24 L/ha for the control of grass weeds in winter cereals. 27 trials were carried out in winter soft wheat and 4 trials in winter barley.

Trials set and methods

The main characteristics of the methodology, number and location of trials conducted and their

distribution across countries and years is given below. In a separate column, the crop BBCH stage at application is presented per trial to justify the trials for USE003 (crop BBCH 10-13).

Table 3.2-18: Distribution and number of trials conducted, Maritime, North-East, South-East EPPO climatic zone, winter soft wheat and winter barley; post-emergence, USE003

Country	EPPO climatic zone	2018	2019	2020	Sum trials	Sum per EP-PO zone
Poland	North-East			6	6	6
Czech Republic	Maritime	1	1	3	5	23
Austria		2	1		3	
Belgium		1			1	
United Kingdom			3	1	4	
Germany			10		10	
Slovakia	South-East			2	2	2
Total Sum		4	15	12	31	

Table 3.2-19: Details on trial methodology - USE003

Guidelines	General guidelines	EPPO PP1/135(4), PP1/152(4), PP1/181(4), PP1/225(2)
	Specific guidelines	EPPO PP1/093(3)
Experimental design	Plot design	RCBD (31 trials)
	Plot size	10-26.25 m ²
	Number of replications	4 (1 trial), 3 (30 trials)
	Trials per crop	TRZAW (27 trials) HORVW (4 trials)
Crop	Varieties per crop	TRZAW: AUT: GENIUS (1) BEL: BERGHAMO (1) CZE: ENERGO (1), AVENUE (2), ANNIE (1) FRA: MUSIC (1), RUBISCO (1) DEU: APOSTEL (1), DEKAN (2), JB ASANO (1), LINUS (2), OPAL (1), RGT REFORM (1), SPONTAN (1), GENIUS (1) GBR: ELICIT (1), RGT ILLUSTRIOUS (1), GRAHAM (1), KWS SISKIN (1) POL: ATRIST (1), BELISSA (1), LINUS (2), OSTROGA (1), PATRAS (1) SVK: GENIUS (1) HORVW: AUT: VERSUCHSSORTE (1), FINOLA KWS (1) CZE: LEOPARD (1) SVK: ZOO (1)
	Sowing period	TRZAW: AUT: October (1) BEL: October (1) CZE: September (2) to October (2) DEU: September (4), October (6) GBR: September (3), October (1) POL: September (6) SVK: September (1) HORVW: AUT: September (1), October (1) CZE: October (1) SVK: October (1)
Application	Crop stage (BBCH) at application	Post-emergence <u>Winter soft wheat:</u> AUT: BBCH 11 BEL: BBCH 12 CZE: BBCH 11-22 DEU: BBCH 10-12 GBR: BBCH 12-22

		POL: BBCH 11-13 SVK: BBCH 21 <u>Winter barley:</u> AUT: BBCH 09-13 CZE: BBCH 12 SVK: BBCH 10
	Timing Pest stage at application	Post-emergence <u>Grass weeds:</u> APESV: BBCH 10-11 POAAN: BBCH 10-21
	Number of applications Intervals between applications	1 (31 trials)
	Spray volumes	200 - 300 L/ha
Assessment	Assessment types	3 to 5 efficacy and/or selectivity assessments <u>Efficacy:</u> - Estimation of weed coverage in % per weed in untreated. Weed control (0% = no weed control, 100% =full weed control) of treated plots is estimated by comparison with untreated. - Counting of ears (only grasses) on basis square meter in untreated. Two possibilities for estimation of grass control: - Estimation of grass control (0% = no weed control, 100% = full weed control) of treated plots by comparison with untreated. - Counting of ears on basis square meter in treated followed by a calculation by comparison with untreated to express grass control in %. <u>Selectivity:</u> - Estimation of crop damage in % versus untreated plants as phytotoxicity general (PHYGEN). Each symptom assessed is reported individually.
	Assessment dates	Autumn application A0: At application: Preliminary assessment of crop stage and weed population A1: 10- 14 days after application: Selectivity A2: BBCH 21-29: Selectivity and efficacy A3: BBCH 37-39: Selectivity A4: Heading or flowering of grass weeds: Efficacy Additional assessments can be added if necessary (for example if one needs to distinguish vegetation stop (autumn) and vegetation start (spring).
Other relevant information	e.g. Soil type, pH (in case of soil active substance ...)	AUT: Silt (1), Sandy loam (1), Loamy silt (1) BEL: Sandy loam (1) CZE: Sandy Loam (2), Silty clay Loam (2), Silty Clay (1) DEU: Humic sand (1), Loamy sand (4), Sandy loam (3), Silt loam (2) GBR: Loamy sand (1), Sandy loam (1), Silty clay Loam (2) POL: Clay (1), Gravelly clay loam (1), Loamy sand (1), Sandy clay (1), Sandy loam (2)

	SVK: Loamy Sand (1), Loam (1)
e.g. Natural / artificial inoculation...	Natural infestation
e.g. Field / Greenhouse...	field trials

A map of trial locations is presented in the Biological Assessment Dossier.

An overview about all weed species observed in these trials are presented in the Biological Assessment dossier.

Weed coverage in the untreated plots before application and at presented assessment timing (grass weeds at flowering of grasses) as % coverage or number of ears per square meter are presented in the Table below.

Table 3.2-20: Weed coverage in the untreated control at application and at assessment timing (grass weeds)

Weed species	[%] coverage at application in untreated control	Weed BBCH at application	[ears/m ²] or [%] coverage at assessment in untreated control	Weed BBCH at assessment
Grass weeds				
APESV	0.0-4% or 9 pl/m ²	BBCH 00-12	4 - 308.3 ears/m ²	BBCH 59-75
POAAN	0.0-3% or 8-40 pl/m ²	BBCH 10-22	2-161.7 ears/m ² or 3.3-33.3%	BBCH 59-75

Reference product

FFA SC508.8 was compared with different standard reference products, depending on trial, Stomp 400 applied at 4.1 L/ha, Stomp Aqua applied at 1.76 L/ha, Herold applied at 0.6 L/ha, Liberator applied at 0.6 L/ha, Bacara forte applied at 0.8 L/ha and Boxer 3 L/ha were used as standard products.

Efficacy of FFA SC508.8 against grass weeds

Assessment for the evaluation of efficacy was done when the target weed reached the heading growth stage. Panicles density per m² was counted in most of trials, then the Abbott formula was used to calculate the efficacy expressed in % (0% – no efficacy, 100% – full control). In some trials, a visual CONTRO assessment have been used to express efficacy. These trials are marked in the tables with a star.

Summary and conclusion on the efficacy grass weeds - USE003

In the following, the results table of each weed species is presented followed by a summary of the results for this weed species.

Table 3.2-21: Summary: Efficacy of FFA SC508.8 applied at 0.24 L/ha, against major grass weeds in TRZAW and HORVW.

Target	Grouping (EPPO climatic zone)	Number of data points	Infestation of the untreated control			FFA SC508.8			Stomp 400			Stomp Aqua			Herold			Bacara forte			Boxer			Liberator		
			(ears/m ²)			0.24 L/ha (1N)			4.1 L/ha			1.76 L/ha			0.6 L/ha			0.8 L/ha			3 L/ha			0.6 L/ha		
			Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	Mean	Min	Max
APESV	Central European Regulatory zone	23	110.5	4.0	470.0	92.6	56.7	100.0	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
	North-East	6	81.1	43.3	195.0	85.6	56.7	98.7	-	-	-	-	-	-	-	-	-	-	-	95.7	91.3	98.7	-	-	-	
	Maritime (AUT, DEU)	9	158.5	11.3	470.0	98.3	91.0	100.0	-	-	-	-	-	-	-	-	99.2	95.7	100.0	-	-	-	-	-	-	
	Maritime (BEL)	1	71.0	-	-	97.7	-	-	-	-	-	71.4	-	-	-	-	-	-	-	-	-	-	-	-	-	
	Maritime (CZE)	5	80.7	4.0	153.3	99.6	98.4	100.0	96.3	86.2	100.0	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
	South-East	2	76.5	35.0	118.0	68.4	61.7	75.0	-	-	-	-	-	-	93.1	90.0	96.2	-	-	-	-	-	-	-	-	-
	S-E + supportive data	5	80.3	4.0	153.3	99.9	99.6	100.0	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
POAAN	Central European Regulatory zone	14	21.8pl/m2/19%	2 pl/m2/3.3%	161.7 pl/m2/33.3%	94.8	64.5	100.0	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	N-E sup- portive data	8	26.4	29.9	2.0	97.6	98.4	90.0	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Maritime (CZE)	2	11.4	5.7	17.0	100.0	100.0	100.0	100.0	100.0	100.0	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Maritime (AUT, DEU)	7	29.0	2.0	161.7	97.2	90.0	100.0	-	-	-	-	-	-	99.4	95.7	100.0	-	-	-	-	-	-	-	-	-
	Maritime (GBR)	4	18.9%/6 ears/m2	3.3%/-	33.3%/-	95.5	88.3	100.0	-	-	-	-	-	-	-	-	-	-	-	-	-	-	95.9	86.0	100.0	
	South-East	1	7.8	-	-	64.5	-	-	-	-	-	-	-	-	90.3	-	-	-	-	-	-	-	-	-	-	-
	S-E + supportive data	4	11.4	5.7	17.0	91.1	64.5	100.0	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

N-E = North-East EPPO climatic zone

S-E = South-East EPPO climatic zone

Conclusions on the efficacy, USE003

Data shows that FFA SC508.8 applied at 0.24 L/ha at BBCH 10-13 is an effective product for the control of APESV and POAAN as presented in the table below.

The proposed label weed species spectrum and efficacy level of FFA SC508.8 per EPPO climatic zone (including supportive data) is indicated in the table below. Weeds susceptibility is ranked according to document SANCO/10055/2013 Rev. 4 as:

- Highly Susceptible: 95%-100% efficacy
- Susceptible: 85%-94.9% efficacy
- Moderately Susceptible: 70%-84.9% efficacy
- Moderately Tolerant: 50%-69.9%
- Tolerant: 0%-49.9 %.

Table 3.2-22: Proposed label target list and dose rates of FFA SC508.8 applied at 0.24 L/ha at crop BBCH 10-13

16-15				
Target		North-East	Maritime	South-East
		0.24 L/ha		
Grass weeds				
APESV	<i>Apera spica venti</i>	Susceptible	Highly susceptible	Highly susceptible
POAAN	<i>Poa annua</i>	Highly susceptible	Highly susceptible	Susceptible

Comments of zRMS:

31 field efficacy trials have been conducted in the three EPPO climatic zones: Maritime, South-East and North-East. FFA SC 508.8 G was tested at dose rate of 0,24 l/ha, once in the growing season, in post-emergence application (BBCH 10-13). Because the trials have been carried out only in winter wheat and winter barley, the zRMS decided to separate results for these crops. The cMSs are asked to consider this solution and use of extrapolation in case of weeds noted in the limited number of trials.

- A total of 23 efficacy trials were carried out in **the Maritime EPPO climatic zone** in the following countries: Czech Republic (5 trials), Austria (3 trials), Belgium (1 trial), Germany (10 trials) and United Kingdom (4 trials). The classification of weed susceptibility for each weed species, which have been located in the Maritime zone is presented below.

Target	Crop	No of trials	Efficacy of FFA SC 508.8 G 0,24 l/ha	Susceptibility
APESV	TRZAW	13	98,5%	HS
APESV	HORVW	2	100%	HS
POAAN	TRZAW	11	97,4%	HS
POAAN	HORVW	2	100%	HS

- A total of 7 efficacy trials were carried out in **the North-East EPPO climatic zone**, all in Poland. The trials conducted in the neighbour countries (Czech Republic, Germany and Slovakia) have been also included to the final calculation of efficacy.

Target	Crop	No of trials	Efficacy of FFA SC 508.8 G 0,24 l/ha	Susceptibility
APESV	TRZAW	6	85,6%	S
APESV	HORVW	2	80,9%	MS
POAAN	TRZAW	6	98,2%	HS
POAAN	HORVW	2	82,3%	MS

- A total of 3 efficacy trials were carried out in **the Sout-East EPPO climatic zone**, all in Slovakia. Because the number of submitted trials is limited, the trials conducted in the neighbour countries (Austria and Czech Republic) have been also included to the final calculation of efficacy.

Target	Crop	No of trials	Efficacy of FFA SC 508.8 G	Susceptibility
--------	------	--------------	----------------------------	----------------

			0,24 l/ha	
APESV	TRZAW	6	95,5%	HS
APESV	HORVW	3	87,2%	S
POAAN	TRZAW	1	100%	HS
POAAN	HORVW	3	88,2%	S

USE004: Efficacy of FFA SC508.8 at 0.48 L/ha against ALOMY, APESV, LOLSS and POAAN on TRZAW, HORVW, TTLWI, TRZDU, SECCW and TRZSP; post-emergence at BBCH 10-13 ([M-761933-01-1](#)).

Single trial reports are available in the Compilation of trial reports.

A total of 37 trials (1 trial in Austria, 4 trials from the Czech Republic, 2 trials in Belgium, 9 trials from the United Kingdom, 13 trials from France, 6 trials from Poland and 2 trials from Slovakia) were performed between 2018 and 2020 to evaluate the efficacy of FFA SC508.8 applied post-emergence at 0.48 L/ha for the control of grass weeds in winter cereals. 33 trials were carried out in winter soft wheat and 4 trials in winter barley.

Trials set and methods

The main characteristics of the methodology, number and location of trials conducted and their distribution across countries and years is given below. In a separate column, the crop BBCH stage at application is presented per trial to justify the trials for USE004 (crop BBCH 10-13).

Table 3.2-23: Distribution and number of trials conducted, Maritime, North-East, South-East EPPO climatic zone, winter soft wheat and winter barley; post-emergence, USE004

Country	EPPO climatic zone	2018	2019	2020	Sum trials	Sum per EP-PO zone
Poland	North-East			6	6	6
Czech Republic	Maritime		1	3	4	29
Austria		1	1		1	
Belgium				2	2	
United Kingdom		3	5	1	9	
France				13	13	
Slovakia	South-East			2	2	2
Total Sum		4	7	27	37	

Table 3.2-24: Details on trial methodology - USE004

Guidelines	General guidelines	EPPO PP1/135(4), PP1/152(4), PP1/181(4), PP1/225(2)
	Specific guidelines	EPPO PP1/093(3)
Experimental design	Plot design	RCBD (37 trials)
	Plot size	10-24 m ²
	Number of replications	4 (1 trials), 3 (36 trials)
Crop	Trials per crop	TRZAW: 32 trials HORVW: 5 trial
	Varieties per crop	TRZAW CZE: AVENUE (2), ANNIE (1) SVK: GENIUS (1) FRA: ADVISOR (1), APRILIO (1), CHEVIGNON (1), FRUCTIDOR (1), LG AMSTRONG (1), LUMINON (1), LYRIK (1), MACARON (1), NEMO (1), PASTORAL (1), SYLLON (2), VELASKO (1) GBR: ELICIT (1), GALLANT (1), GRAHAM (1), KWS SISKIN (1), RGT ILLUSTRIOUS (1), SISKIN (2), SKYFALL (2) POL: ATRIST (1), BELISSA (1), LINUS (2), OSTROGA (1), PATRAS (1) HORVW: AUT: FINOLA KWS (1) BEL: WODAN (1), TONIC (1) CZE: LEOPARD (1) SVK: ZOO (1)
	Sowing period	TRZAW: CZE: September (1) to October (2) FRA: September (1), October (10), November (2) GBR: September (3), October (6) POL: September (6) SVK: September (1) HORVW: AUT: September (1) BEL: September (2) CZE: October (1) SVK: October (1)
Application	Crop stage (BBCH) at application	Post-emergence TRZAW: POL: from BBCH 23 10 to BBCH 30 13 SVK: BBCH 25 21 (from 18 to 22) DEU: from BBCH 23 to BBCH 29 CZE: from BBCH 11 to BBCH 22 FRA: from BBCH 10 to BBCH 13 GBR: from BBCH 11 to BBCH 22 SECCW POL: BBCH 29 HORVW: SVK: from BBCH 10 to BBCH 12 AUT: BBCH 13 CZE: BBCH 12 BEL: from BBCH 11 to BBCH 12
	Timing Pest stage at application	Post-emergence <u>Grass weeds:</u> ALOMY: BBCH 10-12 APESV: BBCH 00-12 LOLSS: BBCH 00-12 POAAN: BBCH 10-21
	Number of applications Intervals between applications	1 (37 trials)
	Spray volumes	150 - 300 L/ha
Assessment	Assessment types	2 to 5 efficacy and/or selectivity assessments <u>Efficacy:</u>

		<p>- Estimation of weed coverage in % per weed in untreated. Weed control (0% = no weed control, 100% =full weed control) of treated plots is estimated by comparison with untreated.</p> <p>- Counting of ears (only grasses) on basis square meter in untreated. Two possibilities for estimation of grass control:</p> <ul style="list-style-type: none"> - Estimation of grass control (0% = no weed control, 100% = full weed control) of treated plots by comparison with untreated. - Counting of ears on basis square meter in treated followed by a calculation by comparison with untreated to express grass control in %. <p><u>Selectivity:</u></p> <ul style="list-style-type: none"> - Estimation of crop damage in % versus untreated plants as phytotoxicity general (PHY-GEN). Each symptom assessed is reported individually.
	Assessment dates	<p>Autumn application</p> <p>A0: At application: Preliminary assessment of crop stage and weed population</p> <p>A1: 10- 14 days after application: Selectivity</p> <p>A2: BBCH 21-29: Selectivity and efficacy</p> <p>A3: BBCH 37-39: Selectivity</p> <p>A4: Heading or flowering of grass weeds: Efficacy</p> <p>Additional assessments can be added if necessary (for example if one needs to distinguish vegetation stop (autumn) and vegetation start (spring)).</p>
Other relevant information	e.g. Soil type, pH (in case of soil active substance ...)	<p>POL: Clay (2 1), Coarse sand (1), Gravelly clay loam (2 1), Loamy fine sand (1), Loamy sand (4 1), Loamy silt (1), Sandy clay (4 1), Sandy loam (4 2)</p> <p>AUT: Loamy silt (1)</p> <p>BEL: - loam (1), loamy clay (1)</p> <p>CZE: Silty Clay Loam (2), Sandy Loam (1), Silty Clay (1)</p> <p>FRA: Calcareous Clay Loam (1), Clay (1), Clay Sandy Loam (1), Clayey Silt (5), Fine Loam (1), Fine Sandy Loam (1), Loam (1), Sandy Clay Loam (1) , -loamy silt (1)</p> <p>POL: Clay (1), Gravelly Clay Loam(1), Loamy Sand (1), Sandy Clay (1), Sandy Loam (2)</p> <p>SVK: Loamy sand (1), Loam (1)</p> <p>GBR: Clay (1), Clay Loam (2), Loamy sand (1) Sandy Clay Loam (1), Sandy Loam (1), Silty Clay Loam (3)</p>
	e.g. Natural / artificial inoculation...	Natural infestation
	e.g. Field / Greenhouse...	field trials

A map of trial locations is presented in the Biological Assessment Dossier.

An overview about all weed species observed in these trials are presented in the Biological Assessment dossier.

Weed coverage in the untreated plots before application and at presented assessment timing (for grass weeds at flowering of grasses) as % coverage or number of ears per square meter are presented in the Table below.

Table 3.2-25: Weed coverage in the untreated control at application and at assessment timing (grass weeds)

Weed species	[%] coverage or plants/m ² at application in untreated control	Weed BBCH at application	[ears/m ²] or [%] coverage at assessment in untreated control	Weed BBCH at assessment
Grass weeds				
ALOMY	0.5-20% or 25-170 pl/m ²	BBCH 10-12	15-2781.3 ears/m ²	BBCH 61-81
APESV	0.0-4% or 9 pl/m ²	BBCH 00-12	4 - 308.3 ears/m ²	BBCH 59-75
LOLMU	1-10% or 10 pl/m ²	BBCH 10-12	21.7-142.8 ears/m ²	BBCH 59-61
LOLSS	1-3% or 75 pl/m ²	BBCH 00-11	58.3-1333.3 ears/m ²	BBCH 59-61
POAAN	0.0-3% or 8-40 pl/m ²	BBCH 10-22	2-161.7 ears/m ² or 3.3-33.3%	BBCH 59-75

Reference product

FFA SC508.8 was compared with different standard reference products, depending on trial, Stomp 400 applied at 4.1 L/ha, Stomp Aqua applied at 1.76 L/ha, Herold applied at 0.6 L/ha, Liberator applied at 0.6 L/ha, Bacara forte applied at 0.8 L/ha and Boxer 3 L/ha was used as standard products.

Efficacy of FFA SC508.8 against grass weeds

Assessment for the evaluation of efficacy was done when the target weed reached the heading growth stage. Panicles density per m² was counted in most of trials, then the Abbott formula has been used to calculate the efficacy expressed in % (0 – no efficacy, 100 – full control). In some trials, CONTRO assessment have been used to express efficacy. These trials are marked in the tables with a star.

Summary and conclusion on the efficacy grass weeds - USE004

In the following, the results table of each weed species is presented followed by a summary of the results for this weed species.

[illegible]

Target	Grouping (EPPO climatic zone)	Number of data points	Infestation of the untreated control			FFA SC508.8			Stomp 400			Herold			Boxer			Liberator		
			(ears/m ²)			0.48 L/ha			4.1 L/ha			0.6 L/ha			3 L/ha			0.6 L/ha		
			Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	Mean	Min	Max
	N-E supportive data	2	11.4	5.7	17.0	100.0	100.0	100.0	100.0	100.0	100.0	-	-	-	-	-	-	-	-	-
	Maritime (CZE)	2	11.4	5.7	17.0	100.0	100.0	100.0	100.0	100.0	100.0	-	-	-	-	-	-	-	-	-
	Maritime (AUT)	1	15.0	-	-	100.0	-	-	-	-	-	100.0	-	-	-	-	-	-	-	-
	Maritime (GBR)	4	18.9%/6 ears/m2	3.3%/-	33.3%/-	98.7 98.4	96.0	100.0	-	-	-	-	-	-	-	-	-	95.9	86.0	100.0
	South-East	1	7.8	-	-	96.8	-	-	-	-	-	90.3	-	-	-	-	-	-	-	-
	S-E + supportive data	4	11.4	5.7	17.0	99.2	96.8	100.0	-	-	-	-	-	-	-	-	-	-	-	-

N-E = North-East EPPO climatic zone
S-E = South-East EPPO climatic zone

Conclusions on the efficacy, USE004

Data shows that FFA SC508.8 applied at 0.48 L/ha at BBCH 10-13 is an effective product for the control of ALOMY, APESV, LOLSS and POAAN as presented in the table below.

The proposed label weed species spectrum and efficacy level of FFA SC508.8 per EPPO climatic zone (including supportive data) is indicated in the table below. Weeds susceptibility is ranked according to document SANCO/10055/2013 Rev. 4 as:

- Highly Susceptible: 95%-100% efficacy
- Susceptible: 85%-94.9% efficacy
- Moderately Susceptible: 70%-84.9% efficacy
- Moderately Tolerant: 50%-69.9%
- Tolerant: 0%-49.9 %.

Table 3.2-27: Proposed label target list and dose rates of FFA SC508.8 applied at 0.48 L/ha at crop BBCH 10-13

Target		North-East	Maritime	South-East
		0.48 L/ha		
Grass weeds				
ALOMY	<i>Alopecurus myosuroides</i>	Susceptible	Moderately susceptible	Moderately susceptible
APESV	<i>Apera spica venti</i>	Highly susceptible	Highly susceptible	Highly susceptible
LOLMU/LOLSS	<i>Lolium</i> spp.	Susceptible	Susceptible	Susceptible
POAAN	<i>Poa annua</i>	Highly susceptible	Highly susceptible	Highly susceptible

Comments of zRMS:

37 field efficacy trials have been conducted in the three EPPO climatic zones: Maritime, South-East and North-East. FFA SC 508.8 G was tested at dose rate of 0,48 l/ha, once in the growing season, in post-emergence application (BBCH 10-13). Because the trials have been carried out only in winter wheat and winter barley, the zRMS decided to separate results for these crops. The cMSs are asked to consider this solution and use of extrapolation in case of weeds noted in the limited number of trials.

- A total of 29 efficacy trials were carried out in **the Maritime EPPO climatic zone** in the following countries: Czech Republic (4 trials), Austria (1 trial), Belgium (2 trials), France (13 trials) and United Kingdom (9 trials). The classification of weed susceptibility for each weed species, which have been noted in the Maritime zone is presented below.

Target	Crop	No of trials	Efficacy of FFA SC 508.8 G 0,48 l/ha	Susceptibility
ALOMY	TRZAW	13	80,7%	MS
ALOMY	HORVW	3	86,8%	S
APESV	TRZAW	3	99,8%	HS
APESV	HORVW	1	100%	HS
LOLMU	TRZAW	4	88,1%	S
LOLMU	HORVW	1	92,3%	S
LOLSS	TRZAW	3	87,8%	S
POAAN	TRZAW	5	98,7%	HS
POAAN	HORVW	2	100%	HS

- A total of 6 efficacy trials were carried out in **the North-East EPPO climatic zone**, all in Poland. The trials conducted in neighbour countries (Czech Republic, Germany and Slovakia) have been also included to the final calculation of efficacy.

Target	Crop	No of trials	Efficacy of FFA SC 508.8 G	Susceptibility
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			0,48 l/ha	
ALOMY	TRZAW	3	88,6%	S
ALOMY	HORVW	1	77,1%	MS
APESV	TRZAW	6	97,3%	HS
APESV	HORVW	2	98,2%	HS
LOLMU	TRZAW	4	88,1%	S
POAAN	TRZAW	1	100%	HS
POAAN	HORVW	2	98,4%	HS

• A total of 2 efficacy trials were carried out in **the Sout-East EPPO climatic zone**, all in Slovakia. Because the number of submitted trials is limited, the trials conducted in neighbour countries (Austria and Czech Republic) have been also included to the final calculation of efficacy.

Target	Crop	No of trials	Efficacy of FFA SC 508.8 G 0,48 l/ha	Susceptibility
ALOMY	TRZAW	3	88,6%	S
ALOMY	HORVW	1	77,1%	MS
APESV	TRZAW	4	96,1%	HS
APESV	HORVW	2	98,2%	HS
LOLMU	TRZAW	4	88,1%	S
POAAN	TRZAW	1	100%	HS
POAAN	HORVW	3	98,9%	HS

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

[M-759325-01-1](#)

EPPO Standard PP 1/213(3) ‘Resistance Risk Analysis’ provides a framework for resistance risk assessment and resistance risk management (Anonymous, 2012). To a great extent the resistance risk assessment considers the inherent risk of resistance evolution and depends on various factors, some of which are associated with the product and others with the weed. A detailed analysis of the risk of resistance and its management has been prepared and this document follows the framework presented within the guideline PP1/213(3) and specific details on plant protection products reported in Appendix II. In addition to the analysis, the summary is presented below.

The active ingredient flufenacet belong to the chemical class of oxyacetamide, HRAC classification 15/K3: very long chain fatty acid inhibitors.

Flufenacet SC 508.8 is formulated as SC (suspension concentrate) and is used as a pre-emergence (BBCH 00-09) and early post-emergence (BBCH 10-13) in autumn treatment. It contains 508.8 g L⁻¹ flufenacet.

Depending on the dose and the weed phonological stage, flufenacet SC 508.8 is a powerful residual herbicide designed to give effective control in winter cereals (wheat, triticale, barley and rye) over a wide range of grasses like *Alopecurus myosuroides*, *Apera spica-venti*, *Poa annua*, *Lolium* spp. and annual broad-leaved weeds.

Flufenacet SC 508.8 is proposed for the use in cereals in autumn in pre-emergence application at the dose rate of 0.24, and 0.48 L ha⁻¹ and early post-emergence application at the same dose rates for the registration in the Central and Southern zone, while a dose of 0.035 L ha⁻¹ is proposed for the Northern zone. One application of Flufenacet SC 508.8 is proposed per season.

Abstract

Mode of Action

Flufenacet belong to the chemical group of oxyacetamide (Long chain fatty acid inhibitors according to HRAC). It is an effective inhibitor of cell division (inhibition of very long chain fatty acids, VLCFAs). The compound is taken up mainly through the root system and the hypocotyls and is transported to the meristematic tissue of the roots and of the young shoots, leading to distortion of elongating tissue, halting of growth and plant death after a certain period (generally 1-2 weeks). Flufenacet is taken up also partly through the leaves when used in post-emergence treatments. The compound is effective in soil for a certain time and affects also grasses and broad-leaved weeds emerging later. Following the compound classification of the Herbicide Resistance Action Committee (HRAC), flufenacet has been assigned to Group 15 in the latest classification or Group K3 of the old classification. This mode of action group contains five different sub-groups, which differentiate in direction of resistance selection and cross-resistance patterns.

Cross-Resistance

Cross-resistance among K3 herbicides has not been reported so far and concerning multiple resistance to other modes of action two cases are reported in literature involving ACCase-, ALS-, PSII-inhibiting herbicides (Heap, 2020).

Evidence of Resistance, Sensitivity Data and Resistance Risk

The cell division inhibitors (HRAC group 15/K3) are divided into five chemical structure subclasses. In addition to the Oxyacetamides, the other subclasses include the Acetamides, Chloroacetamides, Tetrazolinones and a fifth sub-group referred to as “Others”. These compounds typically affect susceptible weeds before emergence, but do not inhibit seed germination.

Flufenacet controls mainly grass weed species (*Alopecurus myosuroides*, *Apera spica-venti*, *Lolium* spp., *Digitaria* spp., *Echinochloa crus-galli*, *Poa annua* and *Setaria* spp.) in very early growth stages and is persistent in soil for a limited time. Resistance to the chemical HRAC group 15/K3 to a global database has been reported in Europe in only in one case in Germany (Table 2.1; Heap, 2020). Resistance was described for a blackgrass (*Alopecurus myosuroides*) population in wheat, covering a very small infested area. Further investigations of Bayer AG based on different studies and results from field trials which have been carried out so far reveal that in certain *Lolium* spp. populations resistance levels could reach agronomic relevance due to detoxification by glutathione transferases. In addition, blackgrass (*Alopecurus myosuroides*) populations from Germany survived a treatment with the flufenacet field rate registered for the use in cereals (Dücker, 2019). Due to the limited resistant cases reported and the long presence in the market, a low risk associated can be associated with this mode of action to select for resistance. According to EPPO (Anonymous, 2012) this categorization is justified if no relevant spread of resistance was noted after use of the active ingredient over many years. In general, pre-emergent herbicides kill weeds directly after they germinate (i.e. after a radicle emerges from the seed), and/or before or directly after the seedling emerges from the soil. There are several characteristics of pre-emergent herbicides that influence how they should be used.

Acceptability of the Resistance Risk

An acceptable practical risk of selecting resistant biotypes is suggested when the product is used following the rotation of herbicide mode of action and crop rotation in the cropping system. Moreover, the inherent risk of flufenacet is considered to be low.

Resistance Management Strategy and Use Pattern

To avoid the selection of resistance it is recommended to perform one application of Flufenacet SC 508.8 at the recommended dose(s) in winter cereals per season according to the phenological stage of the weeds to control.

Communication and Implementation of the Management Strategy

The anti-resistance strategy for the product Flufenacet SC 508.8 is communicated to the advisory and at farmer's level essentially on the product label. In addition, leaflets and brochures that describe the product properties in a detailed manner contain the essential anti-resistance strategy points.

Comments of zRMS:

FFA SC 508.8 G contains only one active substance: flufenacet. This active belongs to the chemical group of oxyacetamides (HRAC Group 15 (legacy K3)). Resistance to flufenacet has been reported in France (*Lolium perenne* ssp. *multiflorum*, 2018), Germany (*Alopecurus myosuroides*, 2007), United Kingdom (*Lolium perenne* ssp. *multiflorum*, 2018) and United States (*Lolium perenne* ssp. *multiflorum*, 2005 and 2018) in wheat. Moreover, the resistance was described for *Alopecurus myosuroides* population in wheat in case of other actives from the Group 15/K3 in Sweden (2011). The inherent risk of flufenacet is considered to be low. Taking into account limited resistant cases and small infested area, the resistance risk can be established as low. Moreover, flufenacet as pre-emergent herbicide is used for control of germinate weeds which is already related to specific requirements. Based on the current cases of resistance but also benefit of FFA SC 508.8 G application in winter cereals, the zRMS proposes to include the below recommendations to the product label:

1. FFA SC 508.8 G should be applied according to the label directions, including time and number of applications and the recommended dose rate,
2. FFA SC 508.8 G should be used alternately with other compounds from different chemical groups and with different mode of action as well as within the whole crop rotation,
3. The product should be applied in tank-mixtures or in sequence with other herbicides if possible, to increase the efficacy on special weed species, which are insufficiently controlled,
4. A wide and diverse crop rotation should be practised. All possibilities of good agronomic measures should be followed (i.a. ploughing cultivation, sowing time)

3.4 Adverse effects on treated crops (KCP 6.4)

Table 3.4-1: Presentation of reference standards used in trials (weed-free selectivity, yield and quality)

Crop(s)	Reference standard	Country(ies) where the product is registered ⁽¹⁾	Authorization number	Active substance(s)	Formulation		Registered application rate ⁽³⁾	Application rate in trials (per treatment) ₂	Remark ⁽⁴⁾
					Type ⁽²⁾	Concentr. of a.s.			
Winter cereals	Boxer EC800	CZE	4566-0	Prosulfocarb	EC	800	4 L/ha	3 L/ha (1N) and 6 L/ha (2N)	BBCH 0-13
		DEU	033838-00				5 L/ha		
		POL	R-88/2015				3 L/ha		
		SVK	2000868-AU						
Winter cereals	Herold SC600	BEL	9533P/B	Diflufenican	SC	200	0.6 L/ha	0.6 L/ha (1N) and 1.2 L/ha (2N)	BBCH 11-13
		POL	R-192/2015	Flufenazet		400	0.25-0.35 L/ha		

(1) only on use(s) applied for (with the test product).

(2) e.g. WP (wetable powder), EC (emulsifiable concentrate), etc.

(3) dose(s) / dose range authorized on that use in the country.

(4) Other relevant information (e.g. uses, number of applications, spray volume, method of application, etc.).

3.4.1 Phytotoxicity to host crop (KCP 6.4.1)

FFA SC508.8 has been applied on a wide range of winter cereals at different geographical locations across the Central zone.

Assessments

For each observation, a percentage of general phytotoxicity was estimated, taking into account the intensity of the different symptoms observed: discoloration, volume reduction, thinning. The visual estimation of general phytotoxicity is expressed as a percentage, in comparison with the untreated control. When phytotoxicity reactions were noticed, the % general phytotoxicity was completed by assessing specifically the % of stunting, necrosis, yellowing and a particular attention paid to thinning which has potentially more yield relevance.

The maximum and the last general phytotoxicity observed in the trials are presented below. When no phytotoxicity symptoms occurred, the maximum and last assessment are grouped together, e.g. “PHYGEN Max / Last”.

Methodology

Table 3.4-2: List of the EPPO standards followed in crop tolerance trials.

EPPO standard	Title
PP1/093(3)	<i>Weeds in cereals</i>
PP1/135(4)	<i>Phytotoxicity assessment</i>
PP1/152(4)	<i>Design and analysis of efficacy evaluation trials</i>
PP1/181(4)	<i>Conduct and reporting of efficacy evaluation trials including GEP</i>

The evaluation of the product complies with the Uniform Principles.

Trial grouping and USE evaluation

In the following sections phytotoxicity assessments from efficacy trials and selectivity trials will be presented. Crop safety assessments recorded in efficacy trial results will be evaluated for all uses. Selectivity trials will be presented in USE002 and USE004 respectively, presenting the results for the higher dose rates. Taking a risk envelope approach these results are deemed to be valid to cover the potential phytotoxicity for USE001 and USE003, respectively where the product application rate is lower. An overview of the sections is given below:

- “USE001” where the recommended dose rate of FFA SC508.8 on winter wheat, winter barley, winter triticale and winter durum wheat is 0.24 L/ha at crop BBCH 00-09. Efficacy trial results on phytotoxicity assessments will be shown.
- “USE002” where the recommended dose rate of FFA SC508.8 on winter wheat, winter barley, winter triticale and winter durum wheat is 0.48 L/ha at crop BBCH 00-09. Efficacy and selectivity trial results on phytotoxicity will be shown. Selectivity trials in USE002 cover USE001.
- “USE003” where the recommended dose rate of FFA SC508.8 on winter wheat, winter barley, winter triticale and winter durum wheat is 0.24 L/ha at crop BBCH 10-13. Efficacy trial results on phytotoxicity assessments will be shown.
- “USE004” where the recommended dose rate of FFA SC508.8 on winter wheat, winter barley, winter triticale and winter durum wheat is 0.48 L/ha at crop BBCH 10-13. Efficacy and selectivity trial results on phytotoxicity will be shown. Selectivity trials in USE003 cover USE004.

USE001: FFA SC508.8 applied at 0.24 L/ha (1N rate), selectivity assessments from efficacy trials; BBCH 00-09 ([M-761917-01-1](#)).

Single trial reports (Efficacy trials) are available in the document Compilation of trial reports.

General informations on efficacy trials is presented in the efficacy chapter.

Phytotoxicity of FFA SC508.8 applied (BBCH 00-09) pre-emergence in winter wheat and winter barley, Efficacy trials, USE001

The methodology, distribution and location of efficacy trials, performed in the Austria, the Czech Republic, Belgium, Germany, France, the United Kingdom, Poland and Slovakia are presented in chapter 3.2.3. All trials were conducted in winter wheat and winter barley. These trials were carried out in the years 2018 to 2020.

Phytotoxicity to host crops was evaluated in all 37 efficacy trials (33 in winter wheat and 4 in winter barley) in which any visual crop effects (e.g. colour change, stunting) were evaluated after application of 0.24 L/ha FFA SC508.8.

Table 3.4-3: List of varieties in TRZAW tested in Efficacy trials - USE001

Crop	Variety	Maritime zone						North-East zone	South East zone	Sum
		AUT	CZE	BEL	DEU	FRA	GBR	POL	SVK	
TRZAW	ANAPOLIS			1						1
	ANNIE		2							2
	ANTONIUS								1	1
	APRILJO					2				2
	ATRIST							1		1
	AVENUE		1							1
	BERGHAMO			1						1
	DEKAN				1					1
	DEPOT							1		1
	ELICIT						1			1
	ENERGO		1							1
	FRUCTIDOR					2				2
	GENIUS	1								1
	GRAHAM						1			1
	JOKER							1		1
	KWS SISKIN						1			1
	KWS ZYATT						1			1
	LG AM-STRONG					1				1
	LINUS							1		1
	LYRIK					1				1
	MACARON					1				1
	NEMO					1				1
	OSTROGA							1		1
	PATRAS							1		1
	SISKIN						1			1
	SKYFALL						2			2
	SYLLON					3				3
TOTAL	27 varieties	1	4	2	1	11	7	6	1	33

Table 3.4-4: List of varieties in HORVW tested in Efficacy trials - USE001

Crop	Variety	Maritime zone		South East zone	Sum
		AUT	CZE	SVK	
HORVW	VERSUCHSSORTE	1			1
	LEOPARD		1		1
	SCALA			1	1
	ZOO			1	1
TOTAL	4 varieties	1	1	2	4

In the results tables, crop effects are clustered according to EPPO climatic zones and orthogonal according to the standard reference product. Reference products for efficacy trials are presented in the efficacy chapter 3.2.3.

Summary of phytotoxicity in Efficacy trials

Data is presented by crop and EPPO climatic zone.

Table 3.4-5: Phytotoxicity of FFA SC508.8 in winter cereals, Maritime EPPO climatic zone – USE001

Number of trials with		Efficacy trials	
		Test product	Standard
		N	N
TRZAW		Efficacy trials (23 trials)	
Maximum of phytotoxicity recorded during the trials	0% to 5%	20	16
	>5% to 10%	2	1
	>10% to 15%	-	1
	>15 %	1	5
Level of symptoms at the last assessments	0% to 5%	23	17
	>5% to 10%	-	-
	>10% to 15%	-	2
	>15 %	-	4
HORVW		Efficacy trials (2 trials)	
Maximum of phytotoxicity recorded during the trials	0% to 5%	2	2
	>5% to 10%	-	-
	>10% to 15%	-	-
	>15 %	-	-
Level of symptoms at the last assessments	0% to 5%	2	2
	>5% to 10%	-	-
	>10% to 15%	-	-
	>15 %	-	-

* Bacara Forte applied at 0.8 L/ha, Herold SC applied at 0.6 L/ha, Liberator applied at 0.6 L/ha, Stomp Aqua applied at 1.76 L/ha, Stomp 400 applied at 4.1 L/ha

Table 3.4-6: Phytotoxicity of FFA SC508.8 in winter cereals, North East EPPO climatic zone – USE001

Number of trials with		Efficacy trials	
		Test product	Standard*
		N	N
TRZAW		Efficacy trials (6 trials)	
Maximum of phytotoxicity recorded during the trials	0% to 5%	6	5
	>5% to 10%	-	1
	>10% to 15%	-	-
	>15 %	-	-
Level of symptoms at the last assessments	0% to 5%	6	6
	>5% to 10%	-	-
	>10% to 15%	-	-
	>15 %	-	-

*Boxer applied at 3 L/ha

Table 3.4-7: Phytotoxicity of FFA SC508.8 in winter cereals, South East EPPO climatic zone – USE001

Number of trials with		Efficacy trials	
		Test product	Standard*
		N	N
TRZAW		Efficacy trials (1 trial)	
Maximum of phytotoxicity recorded during the trials	0% to 5%	1	1
	>5% to 10%	-	-
	>10% to 15%	-	-
	>15 %	-	-
Level of symptoms at the last assessments	0% to 5%	1	1
	>5% to 10%	-	-
	>10% to 15%	-	-

	>15 %	-	-
HORVW		Efficacy trials	
		(2 trials)	
Maximum of phytotoxicity recorded during the trials	0% to 5%	2	2
	>5% to 10%	-	-
	>10% to 15%	-	-
	>15 %	-	-
Level of symptoms at the last assessments	0% to 5%	2	2
	>5% to 10%	-	-
	>10% to 15%	-	-
	>15 %	-	-

*Herold SC applied at 0.6 L/ha

Overall conclusion of phytotoxicity in Efficacy trials, USE001

It is concluded that application of FFA SC508.8 applied at 0.24 L/ha in winter wheat and winter barley as tested in a range of climatic and soil conditions, will not cause any significant adverse effects, when applied according to the recommendations for use at crop BBCH 00-09.

Comments of zRMS:

The Applicant has submitted results from 37 efficacy trials (33 trials in winter wheat and 4 in winter barley) for phytotoxicity assessment of FFA SC 508.8 G at dose rate of 0,24 l/ha in pre-emergence application. In the Maritime EPPPO climatic zone, the phytotoxicity on a level from 0% to 5% has been noted in the most of efficacy trials (in 20 out of 23 trials) conducted in winter wheat. Volume reduction was observed with 18,3% at 111 DAA in only 1 trials. The acceptable phytotoxicity level has been persisted until the last assessment in the all trials. No crop effects were detected in the trials conducted in winter barley. In the North-East EPPO climatic zone, the phytotoxicity on a level from 0% to 5% has been noted in all efficacy trials (6 trials in winter wheat), either during the trials and the last assessment. In the South-East EPPO climatic zone, no negative impact has been noted in 1 efficacy trial conducted in winter wheat and in 2 efficacy trials conducted in winter barley, either during the trials and the last assessment. It can be concluded that FFA SC 508.8 G is safe for winter wheat and winter barley if it is applied at dose rate of 0,24 l/ha in pre-emergence application. The slight symptoms of phytotoxicity were transient.

USE002: FFA SC508.8 applied at 0.48 L/ha (1N rate), selectivity assessments from efficacy trials; BBCH 00-09 ([M-761917-01-1](#)).

Single trial reports (Efficacy trials) are available in the document Compilation of trial reports.

Phytotoxicity of FFA SC508.8 applied ~~post~~ pre-emergence in winter wheat and winter barley, Efficacy trials, USE002

The methodology, distribution and location of efficacy trials, performed in the Czech Republic, Belgium, Germany, France, the United Kingdom, Poland and Slovakia are presented in chapter 3.2.3. All trials were conducted in winter wheat and winter barley. These trials were carried out in the years 2018 to 2020.

Phytotoxicity to host crops was evaluated in all 41 efficacy trials (36 in winter wheat and 5 in winter barley) in which any visual crop effects (e.g. colour change, stunting) were evaluated after application of ~~0.24~~ 0.48 L/ha FFA SC508.8.

Table 3.4-8: List of varieties in TRZAW tested in Efficacy trials - USE002

Crop	Variety	Maritime zone					North-East zone	South East zone	Sum
		CZE	BEL	DEU	FRA	GBR	POL	SVK	
TRZAW	ANAPOLIS		1						1
	ANNIE	1							1
	ANTONIUS							1	1
	APRILIO				1				1
	ASANO			1					1
	ATRIST						1		1
	AVENUE	1							1

	CHEVIGNON				1			1
	DEKAN			1				1
	DEPOT					1		1
	ELICIT				1			1
	FRUCTIDOR			1				1
	GRAHAM				1			1
	JOKER					1		1
	JULIUS		1					1
	KWS KERRIN				1			1
	KWS SISKIN				1			1
	KWS TALENT		1					1
	KWS ZYATT				1			1
	LG AM-STRONG			1				1
	LINUS					1		1
	LUMINON			1				1
	LYRIK			1				1
	MACARON			1				1
	NEMO			1				1
	OSTROGA					1		1
	PASTORAL			1				1
	PATRAS					1		1
	RGT REFORM		1					1
	SISKIN				1			1
	SKYFALL				2			2
	SYLLON			3				3
	VELASKO			1				1
TOTAL	33 varieties	2	1	5	13	8	6	36

Table 3.4-9: List of varieties in HORVW tested in Efficacy trials - USE002

Crop	Variety	Maritime zone		South East zone	Sum
		CZE	BEL	SVK	
HORVW	WODAN		2		2
	LEOPARD	1			1
	SCALA			1	1
	ZOO			1	1
TOTAL	4 varieties	1	2	2	5

In the results tables, crop effects are clustered according to EPPO climatic zones and orthogonal according to the standard reference product. Reference products for efficacy trials are presented in the efficacy chapter 3.2.3.

The trial location is presented in the Biological Assessment Dossier.

Summary of phytotoxicity in Efficacy trials

Data is presented by crop and EPPO climatic zone.

Table 3.4-10: Phytotoxicity of FFA SC508.8 in winter wheat, Maritime EPPO climatic zone – USE002

Number of trials with		Efficacy trials	
		Test product	Standard*
		N	N
TRZAW		Efficacy trials (30 trials)	
Maximum of phytotoxicity recorded during the trials	0% to 5%	22	20
	>5% to 10%	2	2
	>10% to 15%	2	2
	>15 %	4	6
Level of symptoms at the last assessments	0% to 5%	25	21
	>5% to 10%	2	1
	>10% to 15%	2	3
	>15 %	1	3

* Bacara Forte applied at 0.8 L/ha, Herold SC applied at 0.6 L/ha, Liberator applied at 0.6 L/ha, Stomp Aqua applied at 1.76 L/ha, Stomp 400 applied at 4.1 L/ha

Table 3.4-11: Phytotoxicity of FFA SC508.8 in winter wheat, North-east EPPO climatic zone – USE002

Number of trials with		Efficacy trials	
		Test product	Standard
		N	N
TRZAW		Efficacy trials	
		(6 trials)	
Maximum of phytotoxicity recorded during the trials	0% to 5%	5	5
	>5% to 10%	1	1
	>10% to 15%	-	-
	>15 %	-	-
Level of symptoms at the last assessments	0% to 5%	5	5
	>5% to 10%	-	-
	>10% to 15%	-	-
	>15 %	-	-

* Boxer applied at 3 L/ha

Table 3.4-x: Phytotoxicity of FFA SC508.8 in winter wheat, South-East EPPO climatic zone – USE002

Number of trials with		Efficacy trials	
		Test product	Standard
		N	N
TRZAW		Efficacy trials	
		(1 trial)	
Maximum of phytotoxicity recorded during the trials	0% to 5%	1	1
	>5% to 10%	-	-
	>10% to 15%	-	-
	>15 %	-	-
Level of symptoms at the last assessments	0% to 5%	1	1
	>5% to 10%	-	-
	>10% to 15%	-	-
	>15 %	-	-

Table 3.4-12: Phytotoxicity of FFA SC508.8 in winter barley, Maritime EPPO climatic zone – USE002

Number of trials with		Test product	Standard*
		N	N
HORVW		Efficacy trials	
		(2 trials)	
Maximum of phytotoxicity recorded during the trials	0% to 5%	2	1
	>5% to 10%	-	1
	>10% to 15%	-	-
	>15 %	-	-
Level of symptoms at the last assessments	0% to 5%	2	2
	>5% to 10%	-	-
	>10% to 15%	-	-
	>15 %	-	-

* Bacara Forte applied at 0.8 L/ha, Herold SC applied at 0.6 L/ha, Liberator applied at 0.6 L/ha, Stomp Aqua applied at 1.76 L/ha, Stomp 400 applied at 4.1 L/ha

Overall conclusion of phytotoxicity in Efficacy trials, USE002

It is concluded that application of FFA SC508.8 applied at 0.48 L/ha in winter wheat and winter barley as tested in a range of climatic and soil conditions, will not cause any significant adverse effects, when applied according to the recommendations for use at crop BBCH 00-09.

Table 3.4-13: Phytotoxicity of FFA SC508.8 in winter barley, South-East EPPO climatic zone – USE002

Number of trials with		Efficacy trials	
		Test product	Standard*
		N	N
HORVW		Efficacy trials	
		(2 trials)	
Maximum of phytotoxicity recorded during the trials	0% to 5%	2	2
	>5% to 10%	-	-
	>10% to 15%	-	-
	>15 %	-	-
Level of symptoms at the last		2	2

assessments	>5% to 10%	-	-
	>10% to 15%	-	-
	>15 %	-	-

* Herold SC applied at 0.6 L/ha

Comments of zRMS:

The Applicant has submitted results from 41 efficacy trials (36 trials in winter wheat and 5 in winter barley) for phytotoxicity assessment of FFA SC 508.8 G at dose rate of 0,48 l/ha in pre-emergence application. In the Maritime EPPPO climatic zone, the phytotoxicity on a level from 0% to 5% has been noted in 22 out of 30 efficacy trials conducted in winter wheat. General phytotoxicity above 15% was observed in four efficacy trials. Volume reduction and thinning on a level of 40-50% were detected in two efficacy trials, however the results of reference product were similar. The acceptable phytotoxicity level has been persisted until the last assessment in 25 trials. No crop effects were observed in the trials conducted in winter barley. In the Nort-East EPPO climatic zone, no negative symptoms have been noted in 5 out of 6 efficacy trials conducted in winter wheat. Color change on a level of 10% at 18 DAA was noted in one trial. In the South-East EPPO climatic zone, no negative impact has been noted in 1 efficacy trial conducted in winter wheat and in 2 efficacy trials conducted in winter barley, either during the trials and the last assessment. It can be concluded that FFA SC 508.8 G is safe for winter wheat and winter barley if it is applied at dose rate of 0,48 l/ha in pre-emergence application. The slight symptoms of phytotoxicity were transient.

USE 001 & USE002 Phytotoxicity of FFA SC508.8 applied **post** pre-emergence in winter cereals,

Crop tolerance trials, USE002 (M-761947-01-1).

Single trial reports (crop tolerance trials) are available in the document Compilation of trial reports.

Phytotoxicity of FFA SC508.8 applied **post** pre-emergence in winter cereals, crop tolerance trials, USE002

Phytotoxicity to host crops was evaluated in all 68 crop tolerance trials in which any visual crop effects (e.g. colour change, stunting) was evaluated after application of 0.48 L/ha FFA SC508.8 (1N USE002) and 0.96 L/ha FFA SC508.8 (2N USE002).

General informations on efficacy- and crop tolerance trials submitted for USE002 are presented in the table below.

Table 3.4-14: Presentation of trials – for selectivity – USE002

Table 3.4-14. Presentation of trials – for selectivity – CSE002								
Crops	Country	Type of trial*	Trials			Years	GEP, non-GEP, official	Remarks
			(number of valid trials)					
			Maritime zone	North-East zone	South-East zone			
TRZAW	BEL	S+Y+Q	1 (1)			2020	GEP	
	CZE	S+Y+Q	2 (2)			2020	GEP	
	DEU	S+Y+Q*	5 (5)			2003	GEP	
	DEU	S+Y+Q*	5 (5)			2004	GEP	
	FRA	S+Y+Q	4 (4)			2020	GEP	
	POL	S+Y+Q		4 (4)		2020	GEP	

	TOTAL	-	17 (17)	4 (4)	0 (0)	2003, 2004, 2020	-	
HORVW	BEL	S+Y+Q	1 (1)			2020	GEP	
	CZE	S+Y+Q	1 (1)			2020	GEP	
	DEU	S+Y+Q*	4 (4)			2003	GEP	
	DEU	S+Y+Q*	5 (5)			2004	GEP	
	FRA	S+Y+Q	4(4)			2020	GEP	
	POL	S+Y+Q		3 (3)		2020	GEP	
	TOTAL	-	15 (15)	3 (3)	0 (0)	2003, 2004, 2020	-	
TTLWI	DEU	S+Y+Q*	4 (4)			2003	GEP	
	DEU	S+Y+Q*	5 (5)			2004	GEP	
	Total	-	9 (9)	0 (0)	0 (0)	2003, 2004	-	
TRZDW	DEU	S+Y+Q	2 (2)			2015	GEP	
	DEU	S+Y+Q	4 (4)			2019	GEP	
		S+Y+Q						
	Total	-	6 (6)	0 (0)	0 (0)	2015, 2019	-	
TRZSP	DEU	S+Y+Q	2 (2)			2015	GEP	
	DEU	S+Y+Q	4 (4)			2018	GEP	
	Total	-	6 (6)	0 (0)	0 (0)	2015, 2018		
SECCW	DEU	S+Y+Q*	3 (3)			2003	GEP	
	DEU	S+Y+Q*	5 (5)			2004	GEP	
	Total		8 (8)	0 (0)	0 (0)	2003, 2004		
TOTAL	-	-	61 (61)	7 (7)	0 (0)	2003, 2004, 2015, 2019, 2020	-	

S = selectivity trial, Y = trial with yield assessment, Q = trial with quality assessment; Q=only TGW, no HLW, S(e)
=selectivity in efficacy trials

Table 3.4- 1: Details on trial methodology for trials from 2003-2004 in Crop tolerance trials, winter cereals - USE002

Guidelines	General guidelines	-
	Specific guidelines	-
Experimental design	Plot design	RCBD (36 trials)
	Plot size	15.75 m2 (1 trial) 20 m2 (5 trials) 22.5 m2 (4 trials) 25 m2 (27-26 trials)
	Number of replications	3 (31 trials) 4 (5 trials)
Crop	Trials per crop	TRZAW: 10 trials SECCW 8 trials TTLWI: 9 trials HORVW: 9 trials
	Varieties per crop**	TRZAW: Aspirant (1), Biscay (1), Cubus (1), Dekan (1), Ritmo (1), Totonto (1), Vivant (2), Drifter (1), N.A. (2-1) SECCW: Avanti (3), Picasso (5) TTLWI: Kitaro (1), Lamberto (2), Modus (2), Mundo (1), Santop (1), Triamant (1), Vitalis (1) HORVW: Candessa (3), Duett (1), Elbany (1), Franziska (1), Lomerit (1), Lomerit (1), Theresa (1), N.A.(1)
	Sowing period	TRZAW DEU: 19.09-7.11 SECCW DEU: 17.09-20.10 TTLWI DEU: from 17.09 - 18.10 HORVW DEU: from 18.09 - 02.10
Application	Crop stage (BBCH) at application	TRZAW DEU: BBCH 00-09 SECCW BBCH 00-09 TTLWI DEU: BBCH 00-09 HORVW BBCH 00-09
	Timing	Weed-free plots
	Pest stage at application	
	Number of applications	1 (36 trials)
	Intervals between applications	
	Spray volumes	250 – 400 L/ha
Assessment	Assessment types	% phytotoxicity, Yield, TGW
	Assessment dates	A0: At application: Assessment of crop stage only A1: 6-19 days after application A2: 13-36 days after application A3: 21-54 days after application A4: 31-62 days after application A5: at vegetation end in winter A6: at vegetation start in spring A7: Flower A8: Heading A9: Lodgin H1: harvest
Other relevant information	e.g. Soil type, pH (in case of soil active substance ...)	DEU: Fine Clay Loam (3), Fine Sand (1), Fine Sandy Loam (2), Humic Sand (4-3), Loamy Sand (7), Sand (= 3), Sandy Loam (15), Silty Sand (2)
	e.g. Natural / artificial inoculation...	weed-free
	e.g. Field / Green-house...	field

Table 3.4-16: Details on trial methodology for trials from 2015-2020 in Crop tolerance trials, winter cereals - USE002

Guidelines	General guidelines	PP1/135(4) Phytotoxicity assessment PP1/152(4) Design and analysis of efficacy evaluation trials PP1/181(4) Conduct and reporting of efficacy evaluation trials including GEP
	Specific guidelines	PP1/093(3) Weeds in cereals
Experimental design	Plot design	RCBD (32 trials)
	Plot size	12-15 m2 (11 trials): (12 m2 (2 trials), 12.5 m2 (3 trials), 12.825 m2 (1 trial), 13.5 m2 (2 trials), 15 m2 (3 trials)) 16-20 m2 (17 trials): 16 m2 (1 trial), 17.5 m2 (5 trials), 18 m2 (1 trial), 18.5 m2 (1 trial), 18.75 m2 (1 trial), 20 m2 (6 trials) 20.25-22.5 m2 (5 trial): 20.25 m2 (1 trial), 21 m2 (2 trials), 22 m2 (1 trial), 22.5 m2 (1 trial) 30 m2 (1 trial)
	Number of replications	4 (32 trials)
Crop	Trials per crop	TRZAW: 11 trials HORVW: 9 trials TRZDW: 6 trials TRZSP: 6 trials
	Varieties per crop**	TRZAW: Airbus (1), Apache (1), Aprilio (1), Bergahamo (1), Fructidor (1), Julie (1), Moschun (1), Opal (1), Ostroga (1), Rotax (1), Scenario (1) HORVW: Augusta (1), Carmina (1), Kosmos (1), KWS Borrelly (1), KWS Faro (1), KWS Meridian (1), Orbit (1), Visuel (1), Zenek (1) TRZDW: Elsadur (1), Sambadur (1), Wintergold (4) TRZSP: Badensonne (1), Badenstern (2), Franckenkorn (1), Zollernspelz (2)
	Sowing period	TRZAW BEL: 29.10., CZE: 18.10.-23.10., FRA: 14.10.-30.10., POL: 17.09.-08.10. HORVW BEL: 13.10., CZE: 20.09., FRA: 14.10.-27.10., POL: 11.09.-26.09. TRZDW DEU: 29.09. - 26.10. TRZSP DEU: 26.09. - 20.10.
Application	Crop stage (BBCH) at application	TRZAW BEL: BBCH 05, CZE: BBCH 00-03, FRA: BBCH 00-05, POL: BBCH 00-07 (10) HORVW BEL: BBCH 03, CZE: BBCH 00, FRA: BBCH 00-05, POL: BBCH 00-09 TRZDW DEU: BBCH 01-07 TRZSP DEU: BBCH 00-07
	Timing	Weed-free plots
	Pest stage at application	
	Number of applications	1 (32 trials)
	Intervals between applications	
	Spray volumes	150 – 300 L/ha
Assessment	Assessment types	% phytotoxicity, Yield, quality
	Assessment dates	WINTER CEREALS/ Pre-emergence applications

		A1: BBCH 11-12: phytotox + crop stage in untreated plots A2: at vegetation end in winter A3: at vegetation start in spring A4: BBCH 21-29: phytotox A5: BBCH 37-39: phytotox A6: Flower A7: Heading A8: Lodgin H1: harvest
Other relevant information	e.g. Soil type, pH (in case of soil active substance ...)	BEL: Loam (± 2), sandy loam (1)
		CZE: Loamy Sand (± 2), Sandy Loam (1)
		DEU: Clay Loam (1), Fine Silty Clay Loam (1), Loamy Sand (2), Sandy Loam (7), Silt (1)
		FRA: Calcarous Clay (1), Clay Loam (1), Clayey Silt (1), Loam (1), Loamy Clay Sand (1), Silt (1), N.A. (± 1)
		POL: Clay (1), Gravally Clay Loam (1), Loamy Sand (4), N.A. loamy fine sand (1)
	e.g. Natural / artificial inoculation...	weed-free
	e.g. Field / Green-house...	field

Reference products

In all crop tolerance trials conducted in the Maritime EPPO climatic zone, Herold applied at 0.6 L/ha (N rate) and 1.2 L/ha (2N rate) was used as the reference standard. In all crop tolerance trials conducted in the North East EPPO climatic zone, Boxer was applied at 3 L/ha (N rate) and 6 L/ha (2N rate) as the reference.

Table 3.4- 2: List of varieties in TRZAW tested in Crop safety trials - USE002

Crop	Variety	Maritime zone				North-East zone	Sum
		CZE	BEL	DEU	FRA	POL	
Winter wheat - TRZAW	AIRBUS	1					1
	APACHE				1		1
	APRILIO				1		1
	Aspirant				1		1
	Bergamo		1				1
	Biscay			1			1
	Cubus			1			1
	Dekan			1			1
	Drifter			1			1
	FRUCTIDOR				1		1
	JULIE	1					1
	MOSCHUN					1	1
	OPAL					1	1
	OSTROGA					1	1
	Ritmo			1			1
	ROTAX					1	1
	SCENARIO				1		1
	Totonto			1			1
	Vivant			2			2
	N.A.			± 1			± 1
TOTAL	20 varieties	± 2	1	± 9	5	4	± 21

Table 3.4-18: List of varieties in HORVW tested in Crop safety trials - USE002

Crop	Variety	Maritime zone				North-East zone	Sum
		CZE	BEL	DEU	FRA	POL	
HORVW	AUGUSTA				1		1

	CANDESSA			3			3
	CARMINA					1	1
	Duett			1			1
	ELBANY			1			1
	Franziska			1			1
	KOSMOS					1	1
	KWS BORRELLY				1		1
	KWS FARO				1		1
	KWS MERIDIAN	1					1
	LOMERIT/LOMMERIT			2			2
	ORBIT		1				1
	THERESA			1			1
	VISUEL				1		1
	ZENEK					1	1
TOTAL	15 varieties	1	1	9	4	3	18

Table 3.4-19: List of varieties in TTLWI tested in Crop safety trials - USE002

Crop	Variety	Maritime zone	Sum
		DEU	
TTLWI	Kitaro	1	1
	Lamberto	2	2
	Modus	2	2
	Mundo	1	1
	Santop	1	1
	Triamant	1	1
	VERONIKA	±	±
	Vitalis	1	1
TOTAL	8 7 varieties	10 9	10 9

Table 3.4-20: List of varieties in TRZSP tested in Crop safety trials - USE002

Crop	Variety	Maritime zone	Sum
		DEU	
TRZSP	BADENSONNE	± 1	± 1
	BADENSTERN	2	2
	FRANCKENKORN	1	1
	ZOLLERNPELZ	2	2
TOTAL	± 4 varieties	6	6

Table 3.4-21: List of varieties in TRZDW tested in Crop safety trials - USE002

Crop	Variety	Maritime zone	Sum
		DEU	
TRZDW	ELSADUR	1	1
	SAMBADUR	1	1
	WINTERGOLD	4	4
TOTAL	3 varieties	6	6

Table 3.4-22: List of varieties in SECCW tested in Crop safety trials - USE002

Crop	Variety	Maritime zone	Sum
		DEU	
SECCW	Avanti	3	3
	Picasso	5	5
TOTAL	8 2 varieties	8	8

The maximum and the last general phytotoxicity observed in selectivity and efficacy trials after post-emergence application with FFA SC508.8 applied at 0.48 L/ha (N rate) and 0.96 L/ha (2N rate) are presented below.

Summary of phytotoxicity in crop tolerance trials

Data is presented by crop and EPPO climatic zone.

Table 3.4-23: Summary: Phytotoxicity of FFA SC508.8, Maritime EPPO climatic zone - USE002

Number of trials with		Selectivity trials				Efficacy trials	
		Test product		Standard*		Test prod- uct	Standard**
		N	2N	N	2N	N	N
TRZAW		Selectivity trials (17 trials)				Efficacy trials (30 trials)	
Maximum of phytotoxicity recorded during the trials	0% to 5%	11	9	11	6	22	20
	>5% to 10%	0	-		1	2	2
	>10% to 15%	2	-	2	2	2	2
	>15 %	4	8	4	8	4	6
Level of symptoms at the last assessments	0% to 5%	11	9	11	6	25	21
	>5% to 10%	3			2	2	1
	>10% to 15%	1	4	3	2	2	3
	>15 %	2	4	3	7	1	3
HORVW		Selectivity trials (15 trials)				Efficacy trials (2 trials)	
Maximum of phytotoxicity recorded during the trials	0% to 5%	12	8	7	3	2	1
	>5% to 10%	-	2	4	2	-	1
	>10% to 15%	2	-	1	2	-	-
	>15 %	1	5	3	8	-	-
Level of symptoms at the last assessments	0% to 5%	13	11	9	8	2	2
	>5% to 10%	-	-	2	1	-	-
	>10% to 15%	2	-	1	-	-	-
	>15 %	-	4	3	6	-	-
SECCW		Selectivity trials (8 trials)				Efficacy trials (0 trials)	
Maximum of phytotoxicity recorded during the trials	0% to 5%	5	2	5	1	-	-
	>5% to 10%	1	1	-	-	-	-
	>10% to 15%	-	-	-	1	-	-
	>15 %	2	5	3	6	-	-
Level of symptoms at the last assessments	0% to 5%	6	3	5	2	-	-
	>5% to 10%	-	1	1	1	-	-
	>10% to 15%	-	-	-	-	-	-
	>15 %	2	4	2	5	-	-
TTLWI		Selectivity trials (9 trials)				Efficacy trials (0 trials)	
Maximum of phytotoxicity recorded during the trials	0% to 5%	3	2	4	1	-	-
	>5% to 10%	1	-	-	-	-	-
	>10% to 15%	3	1	1	1	-	-
	>15 %	2	6	4	7	-	-
Level of symptoms at the last assessments	0% to 5%	7	5	6	4	-	-
	>5% to 10%	-	-	-	-	-	-
	>10% to 15%	-	1	1	-	-	-
	>15 %	2	3	2	5	-	-
TRZDW		Selectivity trials (* 6 trials)				Efficacy trials (0 trials)	
Maximum of phytotoxicity recorded during the trials	0% to 5%	4	2	4	1	-	-
	>5% to 10%	1	2	1	1	-	-
	>10% to 15%	-	-	-	1	-	-
	>15 %	1	2	1	3	-	-
Level of	0% to 5%	4	3	4	2	-	-

symptoms at the last assessments	>5% to 10%	1	1	1	1	-	-
	>10% to 15%	-	-	-	-	-	-
	>15 %	1	2	1	3	-	-
TRZSP		Selectivity trials				Efficacy trials	
		(9 6 trials)				(0 trials)	
Maximum of phytotoxicity recorded during the trials	0% to 5%	≤ 5	≤ 4	≤ 3	≤ 2	-	-
	>5% to 10%	-	1	1	1	-	-
	>10% to 15%	1	1	+ 2	+	-	-
	>15 %	-	-	-	4 3	-	-
Level of symptoms at the last assessments	0% to 5%	≤ 5	≤ 4	≤ 3	≤ 2	-	-
	>5% to 10%	-	+ 2	1	1	-	-
	>10% to 15%	1	-	+ 2	+	-	-
	>15 %	-	-	-	≤ 3	-	-

*Standard products in Crop tolerance trials = Herold 0.6 L/ha (N rate) and at 1.2 L/ha (2N rate)

**Standard product in Efficacy trials = Bacara Forte applied at 0.8 L/ha, Herold SC applied at 0.6 L/ha, Liberator applied at 0.6 L/ha, Stomp Aqua applied at 1.76 L/ha, Stomp 400 applied at 4.1 L/ha

Table 3.4-24: Summary: Phytotoxicity of FFA SC508.8, North-East EPPO climatic zone - USE002

Number of trials with		Selectivity trials				Efficacy trials	
		Test product		Standard		Test product	Standard
		N	2N	N	2N	N	N
TRZAW		Selectivity trials				Efficacy trials	
		(≤ 4 trials)				(6 trials)	
Maximum of phytotoxicity recorded during the trials	0% to 5%	4	4	3	3	5	5
	>5% to 10%	-	-	1	1	1	1
	>10% to 15%	-	-	-	-	-	-
	>15 %	-	-	-	-	-	-
Level of symptoms at the last assessments	0% to 5%	4	4	3	3	≤ 6	≤ 6
	>5% to 10%	-	-	1	1	-	-
	>10% to 15%	-	-	-	-	-	-
	>15 %	-	-	-	-	-	-
HORVW		Selectivity trials				Efficacy trials	
		(3 trials)				(0 trials)	
Maximum of phytotoxicity recorded during the trials	0% to 5%	3	3	3	3	-	-
	>5% to 10%	-	-	-	-	-	-
	>10% to 15%	-	-	-	-	-	-
	>15 %	-	-	-	-	-	-
Level of symptoms at the last assessments	0% to 5%	3	3	3	3	-	-
	>5% to 10%	-	-	-	-	-	-
	>10% to 15%	-	-	-	-	-	-
	>15 %	-	-	-	-	-	-

*Standard product in Crop tolerance trials = Boxer 3.0 L/ha (N rate) and at 6.0 L/ha (2N rate)

**Standard product in Efficacy trials = Boxer 3.0 L/ha

Table 3.4-25: Summary: Phytotoxicity of FFA SC508.8, South-East EPPO climatic zone - USE002

Number of trials with		Selectivity trials				Efficacy trials	
		Test product		Standard		Test product	Standard*
		N	2N	N	2N	N	N
HORVW		Selectivity trials				Efficacy trials	
		(0 trials)				(2 trials)	
Maximum of phytotoxicity recorded during the trials	0% to 5%	-	-	-	-	2	2
	>5% to 10%	-	-	-	-	-	-
	>10% to 15%	-	-	-	-	-	-
	>15 %	-	-	-	-	-	-

Level of symptoms at the last assessments	0% to 5%					2	2
	>5% to 10%						
	>10% to 15%						
	>15 %						

*Standard product in Efficacy trials = Herold 0.6 L/ha

Overall conclusion of phytotoxicity in Efficacy- and Crop tolerance trials, USE001 and USE002

It is concluded that application of FFA SC508.8 applied at 0.24 L/ha (USE001) ~~or 0.48 L/ha (USE002)~~ in winter cereals as tested in a range of climatic and soil conditions, will not cause any unacceptable adverse effects, when applied according to the recommendations for use at crop BBCH 00-09. The trial results present that application of FFA SC508.8 applied at 0.48 l/ha (USE002) can cause some unacceptable adverse effects which are transient.

Comments of zRMS:

The Applicant has submitted results from 68 selectivity trials (36 trials conducted in 2003-2004 and 32 trials conducted in 2018-2020) for phytotoxicity assessment of FFA SC 508.8 G at dose rates of 0,48 l/ha and 0,96 l/ha (1N and 2N respectively) in pre-emergence application. These trials were carried out in winter wheat, winter barley, winter triticale, rye, wheat durum and spelt in the two EPPO climatic zones: Maritime and North-East. Because no selectivity trials have been submitted from the South-East zone, the cMS is asked to consider the USE001 and USE002 based on the results from other EPPO zones on the national level. Furthermore, it should be emphasized that the acceptance of trials conducted only in the years 2003-2004 is an exception due to the fact that the active substance flufenacet is known for winter triticale and winter rye. In the future, for the renewal of FFA SC 508.8 G, more recent selectivity trials would have to be submitted.

In the Maritime EPPO climatic zone, 17 selectivity trials were carried out in **winter wheat**. 10 crop tolerance trials were carried out in 2003-2004. The general phytotoxicity on a level >5% was noted in 2 trials at dose rate of 0,48 l/ha (1N) and in 4 trials at dose rate of 0,96 l/ha (2N). In 4 out of 7 selective trials from 2020, colour change, thinning, volume reduction and general phytotoxicity were detected on a level >5% at dose rate 1N. The negative impacts on the plants were noted also in case of dose rate 2N in the above trials. These symptoms were not transient and have been observed also in the last assessments. 15 selectivity trials were carried out in **winter barley**. In 2 out of 9 trials from 2003-2004, the general phytotoxicity and thinning on a level >5% were noted at dose rate of 0,46 l/ha. In one selectivity trial from 2020, volume reduction 7,3%, thinning and general phytotoxicity above 15% were observed. The crop effects at above 15% at the 2N rate were in 5 trials (4 in the years 2003-2004 and 1 in 2020). 8 selectivity trials were carried out in **winter rye** in the years 2003-2004. The general phytotoxicity and thinning were noted on a level >5% in 2 trials at dose rate of 0,48 l/ha and in 6 trials at dose rate of 0,96 l/ha. 9 selectivity trials were carried out in **winter triticale** in the years 2003-2004. The general phytotoxicity or thinning on a level >5% were observed in 6 at dose rate of 0,48 l/ha and in 7 out of 9 crop tolerance trials at dose rate of 0,96 l/ha. These symptoms were noted either as max and last assessments. 6 selectivity trials were carried out in **durum wheat** in 2015 and 2019. In one trial the phytotoxicity symptoms (thinning, stunting and general phytotoxicity) were on a level 17,5% and in one trial on a level 6,5% (thinning and general phytotoxicity) at the dose rate 1N. The level of symptoms >15% at dose rate 2N was noted in 2 trials. 6 selectivity trials were carried out in **spelt** in 2015 and 2019. The negative impact (thinning and general phytotoxicity) on a level >10% at dose rate of 0,48 l/ha was noted in one selective trial. Thinning, chlorosis and general phytotoxicity after an application of dose rate of 0,96 l/ha were observed in 2 trials.

In the North-East EPPO climatic zone, 4 selectivity trials were carried out in **winter wheat**. The general phytotoxicity and thinning on an acceptable level were noted in all trials at dose rate 0,48 l/ha. The phytotoxicity symptoms on a level 10,5% were after application of test product at dose rate of 0,96 l/ha in one trial. 3 crop tolerance trials have been conducted in **winter barley**. No phytotoxicity symptoms were noted in these trials, either for 1N and 2N dose. No selectivity trials have been conducted in winter rye, winter triticale, wheat durum and spelt in the North-East EPPO zone. Because flufenacet is a known active substance for winter cereals in Poland, the zRMS decided to use of the trials conducted in the neighbour countries (Czech Republic and Germany) for assessment. In 2 out of 5 selectivity trials from 2004 in **winter rye**, the test product at dose rate of 0,48 l/ha caused general phytotoxicity and thinning on a level >5%. The most of trials showed negative impacts on plants at dose rate of 0,96 l/ha. In 3 out of 5 selectivity trials in **winter triticale**, the phytotoxicity symptoms (PHYGEN and PHYTHI) were on a level >10% at dose rates of 0,48 and 0,96 l/ha. 6 selectivity trials were carried out in **durum wheat** in Germany. In one trial the phytotoxicity symptoms (thinning, stunting and general phytotoxicity) were on a level 17,5% and in one trial on a level 6,5% (thinning and general phytotoxicity) at the dose rate 1N. The level of symptoms >15% at dose rate 2N was noted in 2 trials. 6 selectivity trials were carried out in **spelt** in 2015 and 2019 in Germany. The negative impact (thinning and general phytotoxicity) on a level >10% at dose rate of 0,48 l/ha was noted in one selective trial. Thin-

ning, chlorosis and general phytotoxicity after application of dose rate of 0,96 l/ha were observed in 2 trials. It can be concluded that FFA SC 508.8 G at dose rate of 0,48 l/ha applied pre-emergence can cause some transient phytotoxicity symptoms i.a. thinning, stunting or volume reduction on winter cereals. In the opinion of zRMS this warning should be included to the product label. The efficacy trial results show that the dose rate of 0,24 l/ha is safe for the winter cereals.

USE003: FFA SC508.8 applied at 0.24 L/ha (N rate); BBCH 10-13 Efficacy trials (M-761933-01-1)

Single trial reports (Efficacy trials) are available in the document Compilation of trial reports.

General informations on efficacy trials is presented in efficacy chapter.

Phytotoxicity of FFA SC508.8 applied post-emergence in winter cereals, Efficacy trials, USE003

The methodology, distribution and location of efficacy trials, performed in Belgium, the Czech Republic, France, Germany, the United Kingdom, Poland and Slovakia are presented in chapter 3.2.3. 52 43 out of 62 49 trials were conducted in winter soft wheat and 10 6 trials in winter barley. These trials were carried out in the years 2018 to 2020.

Phytotoxicity to host crops was evaluated in all 54 49 efficacy trials in which any visual crop effects (e.g, colour change, stunting) was evaluated after application of 0.24 L/ha FFA SC508.8.

General informations on efficacy trials submitted for USE003 are presented in the table below.

The methodology and trial location of 52 49 efficacy trials are presented in chapter 3.2.3.

Table 3.4-26: List of varieties in winter wheat tested in Efficacy trials - USE003

Crop	Variety	Maritime EPPO climatic zone						North-East EPPO climatic zone POL	Sum
		AUT	CZE	GBR	DEU	FRA	BEL		
Winter soft wheat (TRZAW)	ADVISOR					1			1
	APOSTEL				1				1
	APRILIO					2 1			2 1
	ATRIST						1		1
	AVENUE		2						2
	BELISSA						1		1
	BERGHAMO						1		1
	CESARIO	-	-	-	-	+	-	-	+
	CHEVIGNON					2 1			2 1
	DEKAN				2				2
	ELICIT			1					1
	ENERGO		1						1
	EUCLIDE	-	-	-	+	-	-	-	+
	FRUCTIDOR					1			1
	GALLANT			1					1
	GENIUS	1			1				2
	GRAHAM			1					1
	JB ASANO				1				1
	KWS KERRIN			1					1
	LG AMSTRONG					1			1
	LINUS				2			2	4
	LUMINON					1			1
	LYRIK					1			1
	MACARON					1			1
	NEMO					1			1
	OPAL				1				1
	OSTROGA							1	1
	PASTORAL					1			1

Crop	Variety	Maritime EPPO climatic zone						North-East EPPO climatic zone	Sum
		AUT	CZE	GBR	DEU	FRA	BEL	POL	
	PATRAS							1	1
	RGT ILLUSTRIOUS			1					1
	RGT REFORM				1				1
	RGT SACRAMENTO	-	-	-	-	+	-	-	+
	SISKIN			2					2
	SKYFALL			+					+
	SMARAGD	-	-	-	+	-	-	-	+
	SPONTAN				1				1
	SYLLON					+			+
	VELASKO					1			1
TOTAL sum TRZAW	38 34 varieties	1	3	11 9	12 10	18 13	1	6	52 43

Table 3.4- 27: List of varieties in winter barley tested in Efficacy trials - USE003

Crop	Variety	Maritime EPPO climatic zone			North-East EP-PO climatic zone	South-East EP-PO climatic zone	Sum
		AUT	CZE	BEL	POL	SVK	
Winter barley (HORVW)	AZRAH	+	-	-	-	-	+
	FINOLA KWS	1					1
	KOSMOS	-	-	-	+	-	+
	LEOPARD		1				1
	TONIC			+			+
	VERSUCHSSORTE	1					1
	WODAN			1			1
	ZENEK	-	-	-	+	-	+
	ZOO					1	1
TOTAL sum HORVW	9 6 varieties	3	1	3 2	2	1	10 6

Summary of phytotoxicity in Efficacy trials

Data is presented by crop and EPPO climatic zone.

Table 3.4- 28: Phytotoxicity of FFA SC508.8 in winter soft wheat, Maritime, North-East and South-East-EPPO climatic zone – Efficacy trials - USE003

Maritime EPPO climatic zone			
		Efficacy trials	
Number of trials with		FFA SC508.8	Standard*
		N	N
TRZAW		Efficacy trials	
		(45 37 trials)	
Maximum of phytotoxicity recorded during the trials	0% to 5%	44 36	33
	>5% to 10%	1	2
	>10% to 15%	-	1
	>15 %	-	1
Level of symptoms at the last assessments	0% to 5%	45 37	37
	>5% to 10%	-	-
	>10% to 15%	-	-
	>15 %	-	-
North-East EPPO climatic zone			
		Efficacy trials	
Number of trials with		FFA SC508.8	Standard*
		N	N
TRZAW		Efficacy trials	
		(5 6 trials)	

Maximum of phytotoxicity recorded during the trials	0% to 5%	≤ 6	≤ 6
	>5% to 10%	-	-
	>10% to 15%	-	-
	>15 %	-	-
Level of symptoms at the last assessments	0% to 5%	≤ 6	≤ 6
	>5% to 10%	-	-
	>10% to 15%	-	-
	>15 %	-	-
South-East EPPO climatic zone			
		Efficacy trials	
Number of trials with		FFA SC508.8	Standard*
		N	N
TRZAW		Efficacy trials	
		(1 trial)	
Maximum of phytotoxicity recorded during the trials	0% to 5%	+	+
	>5% to 10%	-	-
	>10% to 15%	-	-
	>15 %	-	-
Level of symptoms at the last assessments	0% to 5%	+	+
	>5% to 10%	-	-
	>10% to 15%	-	-
	>15 %	-	-

*Standard: Herold SC600 0.6 L/ha, STOMP AQUA 1.76 L/ha, BOXER 3 L/ha, BACARA FORTE 0.8 L/ha, Liberator 0.6 L/ha

Table 3.4- 3: Phytotoxicity of FFA SC508.8 in winter barley, Maritime, North-East and South-East- EPPO climatic zone – Efficacy trials - USE003

Maritime EPPO climatic zone			
		Efficacy trials	
Number of trials with		FFA SC508.8	Standard*
		N	N
HORVW		Efficacy trials	
		(7 5 trials)	
Maximum of phytotoxicity recorded during the trials	0% to 5%	7 5	7 5
	>5% to 10%	-	-
	>10% to 15%	-	-
	>15 %	-	-
Level of symptoms at the last assessments	0% to 5%	7 5	7 5
	>5% to 10%	-	-
	>10% to 15%	-	-
	>15 %	-	-
North-East EPPO climatic zone			
		Efficacy trials	
Number of trials with		FFA SC508.8	Standard*
		N	N
HORVW		Efficacy trials	
		(2 trials)	
Maximum of phytotoxicity recorded during the trials	0% to 5%	2	2
	>5% to 10%	-	-
	>10% to 15%	-	-
	>15 %	-	-
Level of symptoms at the last assessments	0% to 5%	2	2
	>5% to 10%	-	-
	>10% to 15%	-	-
	>15 %	-	-
South-East EPPO climatic zone			
		Efficacy trials	
Number of trials with		FFA SC508.8	Standard*
		N	N
HORVW		Efficacy trials	
		(1 trial)	
Maximum of phytotoxicity recorded during the trials	0% to 5%	1	1
	>5% to 10%	-	-
	>10% to 15%	-	-
	>15 %	-	-

Level of symptoms at the last assessments	0% to 5%	1	1
	>5% to 10%	-	-
	>10% to 15%	-	-
	>15 %	-	-

*Standard: Herold SC600 0.6 L/ha, STOMP AQUA 1.76 L/ha, BOXER 3 L/ha, BACARA FORTE 0.8 L/ha, Liberator 0.6 L/ha

Overall conclusion of phytotoxicity in Efficacy trials, USE003

It is concluded that application of FFA SC508.8 applied at 0.24 L/ha in winter soft wheat and winter barley as tested in a range of climatic and soil conditions, will not cause any significant adverse effects, when applied according to the recommendations for use at crop BBCH 10-13.

Comments of zRMS:

The Applicant has submitted results from 49 efficacy trials (43 trials in winter wheat and 6 in winter barley) for phytotoxicity assessment of FFA SC 508.8 G at dose rate of 0,24 l/ha in post-emergence application. In the Maritime EPPPO climatic zone, the phytotoxicity on a level from 0% to 5% was noted in 36 out of 37 efficacy trials conducted in winter wheat. The maximum general phytotoxicity of 8,3% was observed in one efficacy trial. Also volume reduction on a level of 12,7% was detected in this efficacy trial, however the reference product caused the phytotoxicity on higher level. No crop effects were observed in the trials conducted in winter barley. In the North-East EPPPO climatic zone, no negative symptoms were noted in all 6 efficacy trials conducted in winter wheat, either during the trials and the last assessment. In the South-East EPPPO climatic zone, no negative impact was noted in 1 efficacy trial conducted in winter barley, either during the trials and the last assessment. It can be concluded that FFA SC 508.8 G is safe for winter wheat and winter barley if it is applied at dose rate of 0,24 l/ha in post-emergence application.

USE004: FFA SC508.8 applied at 0.48 L/ha (1N rate) and at 0.96 L/ha (2N rate); BBCH 10-13, Efficacy trials (M-761933-01-1).

Single trial reports (Efficacy trials) are available in the document Compilation of trial reports.

Phytotoxicity of FFA SC508.8 applied post-emergence in winter cereals, Efficacy trials, USE004

The methodology, distribution and location of efficacy trials, performed in Austria, Belgium, Czech Republic, United Kingdom, France, Poland and Slovakia, are presented in chapter 3.2.3. Out of these 43 35 trials, 35 30 were conducted in winter soft wheat and 8 5 trials in winter barley. These trials were carried out in the years 2018 to 2020.

Phytotoxicity to host crops was evaluated in all 44 35 efficacy trials in which any visual crop effects (e.g. colour change, stunting) were evaluated after application of 0.48 L/ha FFA SC508.8.

General informations on efficacy trials submitted for USE004 are presented in the table below.

The following tables give an overview about different winter soft wheat and winter barley varieties which were tested in efficacy trials.

Table 3.4-30: List of varieties in winter soft wheat tested in Efficacy trials - USE004

Crop	Variety	Maritime EPPO climatic zone			North-East EPPO climatic zone	Sum
		CZE	GBR	FRA	POL	
Winter soft wheat (TRZAW)	ADVISOR			1		1
	APRILIO			2 1		2 1
	ATRIST				1	1
	AVENUE	2				2
	BELISSA				1	1
	CESARIO	-	-	4	-	4
	CHEVIGNON			2 1		2 1
	ELICIT		1			1
	FRUCTIDOR			1		1

	GALLANT		1			1
	GRAHAM		1			1
	KWS KERRIN		1			1
	LG AMSTRONG			1		1
	LINUS				2	2
	LUMINON			1		1
	LYRIK			1		1
	MACARON			1		1
	NEMO			1		1
	OSTROGA				1	1
	PASTORAL			1		1
	PATRAS				1	1
	RGT ILLUSTRIOUS		1			1
	RGT SACRAMENTO	-	-	±	-	±
	SISKIN		2			2
	SKYFALL		± 2			± 2
	SYLLON			± 2		± 2
	VELASKO			1		1
TOTAL sum TRZAW	27 25 varieties	2	10 9	18 13	6	36 30

Table 3.4- 31: List of varieties in winter barley tested in Efficacy trials - USE004

Crop	Variety	Maritime EPPO climatic zone			North-East EPPO climatic zone	South-East EP-PO climatic zone	Sum
		AUT	CZE	BEL	POL	SVK	
Winter barley (HORVW)	AZRAH	±	-	-	-	-	±
	FINOLA KWS	1					1
	KOSMOS	-	-	-	±	-	±
	LEOPARD		1				1
	TONIC			1			1
	WODAN			1			1
	ZENIEK	-	-	-	±	-	±
	ZOO					1	1
TOTAL sum HORVW	8 5 varieties	2 1	1	2	2	1	8 5

Summary of phytotoxicity in Efficacy trials

Data is presented by crop and EPPO climatic zone.

Table 3.4-32: Phytotoxicity of FFA SC508.8 in winter soft wheat, Maritime, North-East and South-East-EPPO climatic zone – Efficacy trials - USE004

Maritime EPPO climatic zone				
		Efficacy trials		
Number of trials with		FFA SC508.8	Standard*	
		N	N	
TRZAW		Efficacy trials		
		(30 24 trials)		
Maximum of phytotoxicity recorded during the trials	0% to 5%	26 20	25 19	
	>5% to 10%	1	2	
	>10% to 15%	3	3	
	>15 %	-	-	
Level of symptoms at the last assessments	0% to 5%	30 24	30 24	
	>5% to 10%	-	-	
	>10% to 15%	-	-	
	>15 %	-	-	
North-East EPPO climatic zone				
		Efficacy trials		
Number of trials with		FFA SC508.8	Standard*	
		N	N	

TRZAW		Efficacy trials	
		(6 trials)	
Maximum of phytotoxicity recorded during the trials	0% to 5%	6	6
	>5% to 10%	-	-
	>10% to 15%	-	-
	>15 %	-	-
Level of symptoms at the last assessments	0% to 5%	6	6
	>5% to 10%	-	-
	>10% to 15%	-	-
	>15 %	-	-

*Standard: Herold SC600 0.6 L/ha, STOMP 400 4.1 L/ha, BOXER 3 L/ha, Liberator 0.6 L/ha

Table 3.4-33: Phytotoxicity of FFA SC508.8 in winter barley, Maritime, North-East and South-East- EP-PO climatic zone – Efficacy trials - USE004

Maritime EPPO climatic zone			
		Efficacy trials	
Number of trials with		FFA SC508.8	Standard*
		N	N
HORVW		Efficacy trials	
		(= 4 trials)	
Maximum of phytotoxicity recorded during the trials	0% to 5%	≤ 4	≤ 4
	>5% to 10%	-	-
	>10% to 15%	-	-
	>15 %	-	-
Level of symptoms at the last assessments	0% to 5%	≤ 4	≤ 4
	>5% to 10%	-	-
	>10% to 15%	-	-
	>15 %	-	-
North-East EPPO climatic zone			
		Efficacy trials	
Number of trials with		FFA SC508.8	Standard*
		N	N
HORVW		Efficacy trials	
		(2 trials)	
Maximum of phytotoxicity recorded during the trials	0% to 5%	2	2
	>5% to 10%	-	-
	>10% to 15%	-	-
	>15 %	-	-
Level of symptoms at the last assessments	0% to 5%	2	2
	>5% to 10%	-	-
	>10% to 15%	-	-
	>15 %	-	-
South-East EPPO climatic zone			
		Efficacy trials	
Number of trials with		FFA SC508.8	Standard*
		N	N
HORVW		Efficacy trials	
		(1 trial)	
Maximum of phytotoxicity recorded during the trials	0% to 5%	1	1
	>5% to 10%	-	-
	>10% to 15%	-	-
	>15 %	-	-
Level of symptoms at the last assessments	0% to 5%	1	1
	>5% to 10%	-	-
	>10% to 15%	-	-
	>15 %	-	-

*Standard: Herold SC600 0.6 L/ha, STOMP 400 4.1 L/ha, BOXER 3 L/ha, Liberator 0.6 L/ha

Overall conclusion of phytotoxicity in Efficacy trials, USE004

It is concluded that application of FFA SC508.8 applied at 0.48 L/ha in winter soft wheat and winter barley as tested in a range of climatic and soil conditions, will not cause any significant adverse effects, when applied according to the recommendations for use at crop BBCH 10-13.

Comments of zRMS:

The Applicant has submitted results from 35 efficacy trials (30 trials in winter wheat and 5 in winter barley) for phytotoxicity assessment of FFA SC 508.8 G at dose rate of 0,48 l/ha in post-emergence application.

In the Maritime EPPPO climatic zone, the phytotoxicity on a level from 0% to 5% was noted in 20 out of 24 efficacy trials conducted in winter wheat. The maximum general phytotoxicity on a level >10% was observed in 3 efficacy trials, but these were transient symptoms. In one trial the general phytotoxicity was on a level of 6,3%, however the reference product caused the phytotoxicity on higher level. No crop effects were observed in all 4 trials conducted in winter barley after application at dose rate of 0,48 l/ha.

In the North-East EPPO climatic zone, no negative symptoms were noted in all 6 efficacy trials conducted in winter wheat, either during the trials and the last assessment.

In the South-East EPPO climatic zone, no negative impact was noted in 1 efficacy trial conducted in winter barley, either during the trials and the last assessment.

It can be concluded that FFA SC 508.8 G is safe for winter wheat and winter barley if it is applied at dose rate of 0,48 l/ha in post-emergence application.

USE003 and USE004: FFA SC508.8 applied at 0.48 L/ha (1N rate) and at 0.96 L/ha (2N rate); BBCH 10-13, Crop tolerance trials ([M-761954-01-1](#)).

Single trial reports (crop tolerance trials) are available in the document Compilation of trial reports.

Phytotoxicity of FFA SC508.8 applied post-emergence in winter cereals, Crop tolerance trials, USE004

Phytotoxicity to host crops was evaluated in all 71 crop tolerance trials in which any visual crop effects (e.g. colour change, stunting) was evaluated after application of 0.48 L/ha FFA SC508.8.

General informations on efficacy trials submitted for USE004 are presented in the table below.

Table 3.4-34: Presentation of crop safety trials – data points for selectivity - USE004

Crops	Country	Type of trial*	Trials (number of valid trials)			Years	GEP, non-GEP, official	Remarks
			North-East zone	South-East zone	Maritime zone			
TRZAW	DEU	S, Y, Q			4(4)	2003	GEP	
		S, Y, Q			2(2)	2004	GEP	
		S, Y			3(3)	2004	GEP	
		S			1(1)	2004	GEP	
	BEL	S, Y, Q			1(1)	2020	GEP	
	CZE	S, Y, Q			2(2)	2020	GEP	
	FRA	S, Y, Q			3(3)	2020	GEP	
	POL	S, Y, Q	4(4)			2020	GEP	
TOTAL			4(4)		16(16)	2003, 2004, 2020	GEP	
HORVW	DEU	S, Y, Q			5(5)	2003	GEP	
					2(2)	2004	GEP	

Crops	Country	Type of trial*	Trials (number of valid trials)			Years	GEP, non-GEP, official	Remarks
			North-East zone	South-East zone	Maritime zone			
		S,Y			3(3)		GEP	
		S			1(1)		GEP	
	BEL	S, Y, Q			1(1)	2020	GEP	
	CZE	S, Y, Q			1(1)	2020	GEP	
	FRA	S,Y, Q			3(3)	2020	GEP	
	POL	S, Y, Q	3(3)			2020	GEP	
TOTAL			3(3)		16(16)	2003, 2004, 2020	GEP	
SECCW	DEU	S,Y			3(3)	2003	GEP	
		S			1(1)	2003	GEP	
		S, Y, Q			2(2)	2004	GEP	
		S, Y			3(3)	2004	GEP	
TOTAL					9(9)	2003, 2004	GEP	
TTLWI	DEU	S, Y, Q			4(4)	2003	GEP	
					6(6)	2004	GEP	
TOTAL					10(10)	2003, 2004	GEP	
TRZDW	DEU	S, Y, Q			2(2)	2015	GEP	
					3(3)	2019	GEP	
TOTAL					5(5)	2015, 2019	GEP	
TRZSP	DEU	S, Y, Q			2(2)	2015	GEP	
		S, Y, Q			3(3)	2019	GEP	
		S			1(1)	2019	GEP	
TOTAL					6(6)	2015, 2019	GEP	
TOTAL			7(7)		62(62)	2003, 2004, 2015, 2019	GEP	69

Table 3.4- 4: Details on trial methodology in Crop tolerance trials, winter cereals conducted in 2003 and 2004 - USE003 and USE004

Guidelines	General guidelines	-
	Specific guidelines	-
Experimental design	Plot design	RCBD (41 40 trials)
	Plot size	15.75 – 25 m ² (39 38 trials), 48-78.75 m2 (2 variety trials)
	Number of replications	2 (2 variety trials) 3 (35 34 trials)

		4 (4 trials)
Crop	Trials per crop	TRZAW: 11 10 trials
		HORVW: 11 trials
		SECCW: 9 trials
		TTLWI: 10 trials
	Varieties per crop	TRZAW: Vivant (2), Aviso(1), Drifter (1), Aspirant (1), Ritmo (1), Biscay (1), TORONTO (1), Dekan (1), Cubus (1), Elvis (1)
		HORVW: Candessea (3), Franziska (1), Duett (2), THERESA (1), LOMMERIT (2), ELBANY (1), Camera (1)
		SECCW: Avanti (4), Picasso (5)
		TTLWI: Modus (2), Vitalis (1), Santop (1), Triamant (2), LAMBERTO (2), Kitaro (1), Mundo (1)
	Sowing period	TRZAW DEU: September (4), October (5), November (1)
		HORVW DEU: September (9), October (2)
		SECCW DEU: September (5), October (4)
		TTLWI DEU: September (5), October (5)
Application	Crop stage (BBCH) at application	TRZAW DEU: BBCH 10 to BBCH 13
		HORVW DEU: BBCH 11 to BBCH 13
		SECCW DEU: BBCH 11 to BBCH 13
		TTLWI DEU: BBCH 11
	Timing	
	Pest stage at application	Weed-free plots
	Number of applications	
Assessment	Intervals between applications	1 (41 40 trials)
	Spray volumes	200-400 L/ha
	Assessment types	% general phytotoxicity, yield and quality
	Assessment dates	Post-emergence applications
		A1: After crop emergence 8-74 DAA, crop BBCH 10-21
		A2: End of vegetation period 17-79 DDA, crop BBCH 12-27
		A3: Spring, 134-222 DAA, crop BBCH 21-83
Other relevant information	e.g. Soil type, pH (in case of soil active substance ...)	DEU: Clayey Silt (1), Fine Clay Loam (3), Fine Sand (1), Fine Sandy Loam (2 1), Humic Sand (5 4), Loamy Sand (6), Sand (2 3), Sandy Loam (19), Silty Sand (2)
	e.g. Natural / artificial inoculation...	weed-free
	e.g. Field / Greenhouse...	field

Table 3.4-36: Details on trial methodology in Crop tolerance trials, winter cereals conducted from 2015 to 2020- USE003 and USE004

Guidelines	General guidelines	EPPO PP1/135(3), PP1/135(4), PP1/152(4), PP1/181(3), PP1/181(4)
	Specific guidelines	EPPO PP1/093(3)
Experimental design	Plot design	RCBD (29 trials)
	Plot size	12 – 22 m ²
	Number of replications	4 (29 trials)
Crop	Trials per crop	TRZAW: 10 trials
		HORVW: 8 trials
		TRZDW: 5 trials
		TRZSP: 6 trials
	Varieties per crop	TRZAW: AIRBUS (1), APACHE (1), APRILIO (1), BERGHAMO (1), FRUCTIDOR (1), JULIE

		(1), KILIMANDYARO (1), OPAL (1), OSTROGA (1), ROTAX (1) HORVW: CARMINA (1), KOSMOS (1), KWS BORRELLY (1), KWS FARO (1), KWS MERIDIAN (1), ORBIT (1), VISUEL (1), ZENEK (1) TRZDW: ELSADUR (2), WINTERGOLD (3) TRZSP: FRANCKENKORN (2), ZOLLERNSELZ (4), n.a (1 trial)
	Sowing period	TRZAW BEL: October (1) CZE: October (2) FRA: October (3) POL: September (2), October (2) HORVW BEL: October (1) CZE: September (1) FRA: October (3) POL: September (3) TRZDW DEU: October (5) TRZSP DEU: September (1), October (4, 5), n.a (1)
Application	Crop stage (BBCH) at application	TRZAW BEL: BBCH 11 CZE: BBCH 12 FRA: BBCH 11 POL: BBCH 11 to BBCH 12 HORVW BEL: BBCH 11 CZE: BBCH 11 to BBCH 13 FRA: BBCH 11 POL: BBCH 11 to BBCH 12 TRZDW DEU: BBCH 11 to BBCH 12 TRZSP DEU: BBCH 10 to BBCH 17
		Timing
		Pest stage at application
		Weed-free plots
		Number of applications
		Intervals between applications
	Spray volumes	1 (29 trials)
Assessment	Assessment types	150 – 300 L/ha
	Assessment dates	% general phytotoxicity, yield and quality WINTER CEREALS/ Post-emergence applications Autumn application A0: At application: Assessment of crop stage only A1: 10-14 days after application - phytotox A2: BBCH 21-29 - phytotox A3: BBCH 37-39 - phytotox Additional assessments can be added if necessary, for example if one needs to distinguish vegetation stop (autumn) and vegetation start (spring).
Other relevant information	e.g. Soil type, pH (in case of soil active substance ...)	BEL: Loam (2) CZE: Loamy Sand (2), Sandy Loam (1) FRA: Calcareous Clay (1), Clayey Silt (1), Loam (1), Loamy Clay Sand (1), Silt (1), n.a (1) DEU: Clay Loam (1), Loamy Sand (2), Sandy Loam (6), Silt Loam (1), Sand (1) POL: Clay (1), Gravelly Clay Loam (1), Loamy Sand (4), n.a Loamy Fine Sand (1)
	e.g. Natural / artificial inoculation...	weed-free

	e.g. Field / Greenhouse...	field
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Reference products

In all crop tolerance trials conducted in the Maritime EPPO climatic zone, Herold SC600 0.6 L/ha (1N rate) and 1.2 L/ha (2N rate) was used as the reference standard. In all crop tolerance trials conducted in the North-East EPPO climatic zone, Boxer 3 L/ha (1N rate) and 6 L/ha (2N rate) was used as the reference standard.

Table 3.4- 5: List of varieties in TRZAW tested in Crop safety trials - USE004

Crop	Variety	Maritime zone				North-East zone	Sum
		BEL	FRA	CZE	DEU	POL	
Winter soft wheat- TRZAW	Vivant				2		2
	Drifter				2 1		2 1
	Ritmo				1		1
	Biscay				1		1
	TORONTO				1		1
	Dekan				1		1
	Cubus				1		1
	Elvis (Biscay, Charger, Drifter)				1		1
	Biscay				1	-	1
	Charger				1	-	1
	BERGHAMO	1					1
	AIRBUS			1			1
	JULIE			1			1
	APACHE		1				1
	APRILIO		1				1
	FRUCTIDOR		1				1
	OSTROGA					1	1
	OPAL					1	1
	ROTAX					1	1
	KILIMANDYARO					1	1
	N/A Aviso				1		1
Total Sum TRZAW	22 20 varieties	1	3	2	13 10	4	23 20

Table 3.4-38: List of varieties in HORVW tested in Crop safety trials - USE004

Crop	Variety	Maritime zone				North-East zone	Sum
		BEL	FRA	CZE	DEU	POL	
Winter barley'- HORVW	Candessa				3		3
	Franziska				1		1
	Duett				2		2
	THERESA				1		1
	LOMMERIT				2		2
	ELBANY				1		1
	Reni	-	-	-	1	-	1
	Tafeno	-	-	-	1	-	1
	Camera (Reni, Tafeno, Ludmila)				1		1
	Ludmila		-	-	1	-	1
	ORBIT	1					1
	KWS MERIDIAN			1			1
	KWS BORRELLY		1				1
	VISUEL		1				1
	KWS FARO		1				1
	CARMINA					1	1
	KOSMOS					1	1
	ZENEK					1	1
Total Sum HORVW	18 varieties	1	3	1	14 11	3	22 19

Table 3.4- 39: List of varieties in SECCW tested in Crop safety trials - USE004

Crop	Variety	Maritime zone				North-East zone	Sum
		BEL	FRA	CZE	DEU	POL	
Winter rye- SECCW	Avanti				4		4
	Picasso				5		5
Total Sum	2 varieties	0	0	0	9	0	9
SECCW							

Table 3.4-40: List of varieties in TTLWI tested in Crop safety trials - USE004

Crop	Variety	Maritime zone				North-East zone	Sum
		BEL	FRA	CZE	DEU	POL	
Winter triticales- TTLWI	Modus				2		2
	Vitalis				1		1
	Santop				1		1
	Mundo				1		1
	Triamant				2		2
	LAMBERTO				2		2
	Kitaro				1		1
Total Sum	7 varieties	0	0	0	10	0	10
TTLWI							

Table 3.4-41: List of varieties in TRZDW tested in Crop safety trials - USE004

Crop	Variety	Maritime zone				North-East zone	Sum
		BEL	FRA	CZE	DEU	POL	
Winter durum wheat- TRZDW	ELSADUR				2		2
	WINTERGOLD				3		3
Total Sum	2 varieties	0	0	0	5	0	5
TRZDW							

Table 3.4-42: List of varieties in TRZSP tested in Crop safety trials - USE004

Crop	Variety	Maritime zone				North-East zone	Sum
		BEL	FRA	CZE	DEU	POL	
Spelt- TRZSP	FRANCKENKORN				2		2
	ZOLLERNSELZ				4		4
Total Sum	2 varieties	0	0	0	6	0	6
TRZSP							

Summary of phytotoxicity in Crop tolerance trials

The maximum and the last general phytotoxicity observed in selectivity and efficacy trials after post-emergence application with FFA SC508.8 applied at 0.48 L/ha (1N rate) are presented below.

Table 3.4-43: Summary: Phytotoxicity of FFA SC508.8, Winter soft wheat - USE004

Maritime EPPO climatic zone							
Number of trials with		Selectivity trials				Efficacy trials	
		FFA SC508.8		Standard*		FFA SC508.8	Standard**
		N	2N	N	2N	N	N
TRZAW		Selectivity trials (16 trials)				Efficacy trials (30 trials)	
Maximum of phy- totoxicity recorded during the trials	0% to 5%	14	16	11	9	26	25
	>5% to 10%	2		1	2	1	2
	>10% to 15%					3	3
	>15 %			4	5		
Level of symptoms at the last assessments	0% to 5%	16	16	13	12	30	30
	>5% to 10%			1	2		
	>10% to 15%						
	>15 %			2	2		

North-East EPPO climatic zone							
Number of trials with		Selectivity trials				Efficacy trials	
		FFA SC508.8		Standard*		FFA SC508.8	Standard**
		N	2N	N	2N	N	N
TRZAW		Selectivity trials				Efficacy trials	
		(4 trials)				(6 trials)	
Maximum of phytotoxicity recorded during the trials	0% to 5%	4	3	3	3	6	6
	>5% to 10%	-	1	1	1	-	-
	>10% to 15%	-	-	-	-	-	-
	>15 %	-	-	-	-	-	-
Level of symptoms at the last assessments	0% to 5%	4	3	4	3	6	6
	>5% to 10%	-	1	-	1	-	-
	>10% to 15%	-	-	-	-	-	-
	>15 %	-	-	-	-	-	-

Test product = FFA SC508.8 0.48 L/ha (1N rate) and at 0.96 L/ha (2N rate)

*Standard products in Crop tolerance trials = Herold SC600 0.6 L/ha (N rate) and at 1.2 L/ha (2N rate) or Boxer 3 L/ha (N rate) and at 6 L/ha (2N rate), **Standard product in Efficacy trials = Herold SC600 0.6 L/ha, STOMP 400 4.1 L/ha, BOXER 3 L/ha, Liberator 0.6 L/ha

Table 3.4- 44: Summary: Phytotoxicity of FFA SC508.8, Winter barley - USE004

Maritime EPPO climatic zone							
Number of trials with		Selectivity trials				Efficacy trials	
		FFA SC508.8		Standard*		FFA SC508.8	Standard**
		N	2N	N	2N	N	N
HORVW		Selectivity trials				Efficacy trials	
		(16 trials)				(5 trials)	
Maximum of phytotoxicity Recorded during the trials	0% to 5%	12	11	12	10	5	5
	>5% to 10%	1	1	3	2	-	-
	>10% to 15%	2	-	1	-	-	-
	>15 %	1	4	-	4	-	-
Level of symptoms at the last assessments	0% to 5%	13	13	14	12	5	5
	>5% to 10%	1	-	1	1	-	-
	>10% to 15%	1	-	1	-	-	-
	>15 %	1	3	-	3	-	-
North-East EPPO climatic zone							
Number of trials with		Selectivity trials				Efficacy trials	
		FFA SC508.8		Standard*		FFA SC508.8	Standard**
		N	2N	N	2N	N	N
HORVW		Selectivity trials				Efficacy trials	
		(4 trials)				(2 trials)	
Maximum of phytotoxicity recorded during the trials	0% to 5%	3	3	3	2	2	2
	>5% to 10%	-	-	-	1	-	-
	>10% to 15%	-	-	-	-	-	-
	>15 %	-	-	-	-	-	-
Level of symptoms at the last assessments	0% to 5%	3	3	3	2	2	2
	>5% to 10%	-	-	-	1	-	-
	>10% to 15%	-	-	-	-	-	-
	>15 %	-	-	-	-	-	-
South-East EPPO climatic zone							
		Selectivity trials				Efficacy trials	

Number of trials with		FFA SC508.8		Standard*		FFA SC508.8	Standard**
		N	2N	N	2N	N	N
HORVW		Selectivity trials				Efficacy trials	
		(0 trials)				(1 trial)	
Maximum of phytotoxicity recorded during the trials	0% to 5%	-	-	-	-	1	1
	>5% to 10%	-	-	-	-	-	-
	>10% to 15%	-	-	-	-	-	-
	>15 %	-	-	-	-	-	-
Level of symptoms at the last assessments	0% to 5%	-	-	-	-	1	1
	>5% to 10%	-	-	-	-	-	-
	>10% to 15%	-	-	-	-	-	-
	>15 %	-	-	-	-	-	-

*Standard products in Crop tolerance trials = Herold SC600 0.6 L/ha (N rate) and at 1.2 L/ha (2N rate) or Boxer 3 L/ha (N rate) and at 6 L/ha (2N rate).

**Standard product in Efficacy trials = Herold SC600 0.6 L/ha, STOMP 400 4.1 L/ha, BOXER 3 L/ha, Liberator 0.6 L/ha

Table 3.4- 45: Summary: Phytotoxicity of FFA SC508.8, Winter rye - USE004

Maritime EPPO climatic zone					
Number of trials with		Selectivity trials			
		FFA SC508.8		Standard*	
		N	2N	N	2N
SECCW		Selectivity trials			
		(8 9 trials)			
Maximum of phytotoxicity recorded during the trials	0% to 5%	6	4	5	2
	>5% to 10%	-	1	2	1
	>10% to 15%	2	-	1	-
	>15 %	1	3 4	1	5 6
Level of symptoms at the last assessments	0% to 5%	6 7	6 7	6 7	4 5
	>5% to 10%	-	-	-	1
	>10% to 15%	2	-	2	-
	>15 %	-	2	-	3

*Standard products in Crop tolerance trials = Herold SC600 0.6 L/ha (N rate) and at 1.2 L/ha (2N rate) or Boxer 3 L/ha (N rate) and at 6 L/ha (2N rate).

Table 3.4-46: Summary: Phytotoxicity of FFA SC508.8, Winter tritcale - USE004

Maritime EPPO climatic zone					
Number of trials with		Selectivity trials			
		FFA SC508.8		Standard*	
		N	2N	N	2N
TTLWI		Selectivity trials			
		(10 trials)			
Maximum of phytotoxicity recorded during the trials	0% to 5%	7	2	7	1
	>5% to 10%	-	-	2	2
	>10% to 15%	1	-	-	-
	>15 %	2	8	1	7
Level of symptoms at the last assessments	0% to 5%	8	5	8	4
	>5% to 10%	-	-	1	1
	>10% to 15%	-	-	-	-
	>15 %	2	5	1	5

*Standard products in Crop tolerance trials = Herold SC600 0.6 L/ha (N rate) and at 1.2 L/ha (2N rate) or Boxer 3 L/ha (N rate) and at 6 L/ha (2N rate).

Table 3.4- 47: Summary: Phytotoxicity of FFA SC508.8, Winter durum wheat - USE004

Maritime EPPO climatic zone				
Number of trials with		Selectivity trials		
		FFA SC508.8		Standard*
		N	2N	N
TRZDW		Selectivity trials		
		(5 trials)		

Maximum of phytotoxicity recorded during the trials	0% to 5%	4	4	4	2
	>5% to 10%	-	-	1	1
	>10% to 15%	1	-	-	-
	>15 %	-	1	-	2
Level of symptoms at the last assessments	0% to 5%	5	4	5	3
	>5% to 10%	-	-	-	1
	>10% to 15%	-	-	-	-
	>15 %	-	1	-	1

*Standard products in Crop tolerance trials = Herold SC600 0.6 L/ha (N rate) and at 1.2 L/ha (2N rate) or Boxer 3 L/ha (N rate) and at 6 L/ha (2N rate).

Table 3.4- 48: Summary: Phytotoxicity of FFA SC508.8, spelt - USE004

Maritime EPPO climatic zone					
Number of trials with		Selectivity trials			
		FFA SC508.8		Standard*	
		N	2N	N	2N
TRZSP		Selectivity trials			
		(6 trials)			
Maximum of phytotoxicity recorded during the trials	0% to 5%	5	4	4	4
	>5% to 10%	-	-	1	-
	>10% to 15%	1	2	-	-
	>15 %	-	-	1	2
Level of symptoms at the last assessments	0% to 5%	6	6	6	6
	>5% to 10%	-	-	-	-
	>10% to 15%	-	-	-	-
	>15 %	-	-	-	-

*Standard products in Crop tolerance trials = Herold SC600 0.6 L/ha (N rate) and at 1.2 L/ha (2N rate) or Boxer 3 L/ha (N rate) and at 6 L/ha (2N rate).

Overall conclusion of phytotoxicity in Efficacy and Crop tolerance trials, USE003 and USE004

It is concluded that application of FFA SC508.8 applied at ~~0.48~~ 0.24 L/ha (USE003) in winter soft wheat, winter barley, rye, triticale, spelt and durum wheat, as tested in a range of climatic and soil conditions, will not cause any significant adverse effects, when applied according to the recommendations for use at crop BBCH 10-13. ~~Therefore, the use at the normal dose rate 0.24 L/ha FFA SC508.8, should also be considered crop safe in winter soft wheat, winter barley, rye, triticale, spelt and durum wheat.~~ The trial results present that application of FFA SC508.8 applied at 0.48 l/ha (USE004) can cause some unacceptable adverse effects which are not transient.

Comments of zRMS:

The Applicant has submitted results from 69 selectivity trials (40 trials conducted in 2003-2004 and 29 trials conducted in 2015-2020) for phytotoxicity assessment of FFA SC 508.8 G at dose rates of 0,48 l/ha and 0,96 l/ha (1N and 2N respectively) in post-emergence application. These trials were carried out in winter wheat, winter barley, winter triticale, winter rye, wheat durum and spelt in the two EPPO climatic zones: Maritime and North-East. Because no selectivity trials have been submitted from the South-East zone, the cMS is asked to consider the USE0023 and USE004 based on the results from other EPPO zones on the national level. Furthermore, it should be emphasized that the acceptance of trials conducted only in the years 2003-2004 is an exception due to the fact that the active substance flufenacet is known for winter triticale and winter rye. In the future, for the renewal of FFA SC 508.8 G, more recent selectivity trials would have to be submitted.

In the Maritime EPPO climatic zone, 16 selectivity trials were carried out in **winter wheat**. 10 crop tolerance trials were carried out in 2003-2004. The general phytotoxicity on a level >5% was noted in 1 trial at dose rate of 0,48 l/ha (1N) and in 2 trials at dose rate of 0,96 l/ha (2N). In 1 out of 6 trials from 2020, volume reduction was detected on a level 8% at dose rate 1N. The negative symptoms were on an acceptable level in the last assessment. The negative impacts on the plants were noted also in case of dose rate 2N in 4 trials (thinning, volume reduction, general phytotoxicity). 16 selectivity trials were carried out in **winter barley**. In 4 out of 11 trials from 2003-2004, the general phytotoxicity on a level >5% was noted at dose rate of 0,48 l/ha, either during trials and the last assessments. The general phytotoxicity and thinning on a level >10% were noted after application at dose rate of 0,96 l/ha. No negative impacts on the plants were observed in the trials conducted in the year 2020. 9 selectivity trials were carried out in **winter rye** in the years 2003-2004. The general phytotoxicity and thinning on a level >10% were observed in 2 trials and on a level >15% in one trial after application at dose rate rate of 0,48 l/ha. The negative symptoms on a level >15% were noted in 4 trials at dose rate of 0,96 l/ha. However, these symptoms were transient in the

most of trials. 10 selectivity trials were carried out in **winter triticale** in the years 2003-2004. The general phytotoxicity on a level >10% were noted in 3 trials at dose rate of 0,48 l/ha. The dose rate of 0,96 l/ha caused negative symptoms on a level >15% in most of selectivity trials. 6 crop tolerance trials were conducted in **spelt**. The general phytotoxicity and stunting on a level >10% were observed in one trial at dose rate 1N, however they were transient. Also general phytotoxicity, chlorosis and stunting on a level >10% were after application at dose rate of 2N in 2 trials. 5 selectivity trials were conducted in **durum wheat**. The test product at dose rate of 0,48 l/ha caused general phytotoxicity on a level >10% in one trial. Chlorosis, thinning and general phytotoxicity on a level >10% were noted at dose rate of 0,96 l/ha in 2 trials.

In the North-East EPPO climatic zone, 4 selectivity trials were carried out in **winter wheat**. The general phytotoxicity on an acceptable level was noted in all trials at dose rate of 0,48 l/ha. The general phytotoxicity and thinning on a level 8,75% were detected after application of test product at dose rate of 0,96 l/ha in one trial. 3 crop tolerance trials were conducted in **winter barley**. No phytotoxicity symptoms were noted in these trials in case of dose rate 0,48 l/ha. The general phytotoxicity, colour change and thinning on an acceptable level were observed after an application at dose rate of 0,96 l/ha. No selectivity trials have been conducted in winter rye, winter triticale, wheat durum and spelt in the North-East EPPO zone. Because flufenacet is a known active substance for winter cereals in Poland, the zRMS decided to use of the trials conducted in the neighbour countries (Czech Republic and Germany) for assessment. 9 selectivity trials were carried out in **winter rye** in the years 2003-2004 in Germany. The general phytotoxicity and thinning on a level >10% were observed in 2 trials and on a level >15% in one trial after application at dose rate rate of 0,48 l/ha. The negative symptoms on a level >15% were noted in 4 trials at dose rate of 0,96 l/ha. However, these symptoms were transient in the most trials. 10 selectivity trials were carried out in **winter triticale** in the years 2003-2004 in Germany. The general phytotoxicity on a level >10% were noted in 3 trials at dose rate of 0,48 l/ha. The dose rate of 0,96 l/ha caused negative symptoms on a level >15% in most of selectivity trials. 6 crop tolerance trials were conducted in **spelt** in Germany. The general phytotoxicity and stunting on a level >10% were observed in one trial at dose rate 1N, however they were transient. Also general phytotoxicity, chlorosis and stunting on a level >10% were after application at dose rate of 2N in 2 trials. 5 selectivity trials were conducted in **durum wheat** in Germany. The test product at dose rate of 0,48 l/ha caused general phytotoxicity on a level >10% in one trial. Chlorosis, thinning and general phytotoxicity on a level >10% were noted at dose rate of 0,96 l/ha in 2 trials.

It can be concluded that FFA SC 508.8 G at dose rate of 0,48 l/ha applied post-emergence can cause some transient phytotoxicity symptoms i.a. thinning, stunting or volume reduction on winter barley, triticale and rye. In the opinion of zRMS this warning should be included to the product label. The efficacy trial results show that the dose rate of 0,24 l/ha is safe for the winter cereals.

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

Trial grouping and USE evaluation

In the following section yield assessments from selectivity trials will be presented. Selectivity trials were conducted with the higher dose rates of 0.48 L/ha as 1 N for USE002 and USE004, respectively. Taking a risk envelope approach these results are deemed to be valid to cover the potential yield reduction for 0.24 L/ha as 1 N in USE001 and USE003, respectively. An overview of the subchapters is given below:

- “**USE001 and USE002**” where the recommended dose rate of FFA SC508.8 on winter wheat, winter barley, winter triticale, winter spelt and winter durum wheat is 0.24 L/ha (USE001) and 0.48 L/ha (USE002) at crop BBCH 00-09. Yield data in selectivity trials of USE002 covers USE001.
- “**USE003 and USE004**” where the recommended dose rate of FFA SC508.8 on winter wheat, winter barley, winter triticale, winter spelt and winter durum wheat is 0.24 L/ha (USE003) and 0.48 L/ha (USE004) at crop BBCH 10-13. Yield data in selectivity trials of USE004 covers USE003.

USE001 and USE002: Relationship between phytotoxicity and yield of FFA SC508.8 applied pre-emergence in winter soft wheat, Crop tolerance trials ([M-761947-01-1](#)).

Crop tolerance trials are presented in the document Compilation of trial reports.

All 68 crop tolerance trials (21 trials winter wheat, 18 trials winter barley, 8 trials in winter rye, 9 trials in winter triticale, 6 trials winter durum and 6 trials spelt) were used to evaluate any potential negative effect of the test product FFA SC508.8 on yield of winter cereals and were harvested.

For statistical analysis the untreated is included to determine if any yield increase/decrease following the application with FFA SC508.8 at 0.48 L/ha (1N rate USE002) and at 0.96 L/ha (2N rate) may significantly differ.

The evaluation of the product complies with the Uniform Principles.

In the following table, yield data per crop and zone are presented.

Table 3.4-49: Summary on yield after application of FFA SC508.8 at 0.48 L/ha (N rate USE002) and at 0.96 L/ha (2N rate USE002) in crop tolerance trials, USE002

Crop	Grouping (EPPO climat- ic zone)	Trials	% yield relative to the untreated											
			Test N			Standard N			Test 2N			Standard 2N		
			Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	Mean	Min	Max
TRZAW	Central Zone	21	99.0	88.8	108.8				95.9	75.7	109.1			
	Maritime	17	99.0	88.0	108.8	98.1	81.7	109.9	95.3	75.7	109.1	92.5	67.7	109.7
	North-East	4	99.0	97.6	100.4	99.9	98.6	101.2	98.6	97.4	99.5	99.8	98.6	100.5
HORVW	Central Zone	18	98.4	79.8	108.9				98.1	71.4	109.8			
	Maritime	15	97.5	79.8	106	99.8	85.2	106.4	97.3	71.4	109.8	94.1	57.3	113.7
	North-East	3	102.9	98.9	108.9	101.4	98.5	103.5	102.4	101.8	103	105.0	101.2	110.7
TTLWI	Central Zone	9	97.5	89.9	101.3	95.5	86.6	101.6	91.1	64.7	100.5	89.6	73.6	99.8
	Maritime	9	97.5	89.9	101.3	95.5	86.6	101.6	91.1	64.7	100.5	89.6	73.6	99.8
SECCW	Central Zone	8	98.4	94.7	101.9	97.8	94.2	104.7	94.3	82.5	105.1	92.8	81.5	104.3
	Maritime	8	98.4	94.7	101.9	97.8	94.2	104.7	94.3	82.5	105.1	92.8	81.5	104.3
TRZSP	Central Zone	6	98.8	96.8	103.3	99.2	95.1	103.7	95.9	84.6	103	92.3	73.0	103.4
	Maritime	6	98.8	96.8	103.3	99.2	95.1	103.7	95.9	84.6	103	92.3	73.0	103.4
TRZDW	Central Zone	6	96.7	90.9	101.8	98.1	89.9	102.8	95.3	86.2	102.8	94.3	79.4	103.8
	Maritime	6	96.7	90.9	101.8	98.1	89.9	102.8	95.3	86.2	102.8	94.3	79.4	103.8

Test product = FFA SC508.8 applied at 0.48 L/ha (N rate USE002) and at 0.96 L/ha (2N rate USE002)

Standard = Maritime EPPO climatic zone: Herold applied at 0.6 L/ha (N rate) and at 1.2 L/ha (2N rate), North East EPPO climatic zone: Boxer applied at 3 L/ha (N rate) and 6 L/ha (2N rate).

Conclusion on yield, USE001 and USE002

All 68 crop tolerance trials (21 trials winter wheat, 18 trials winter barley, 8 trials in winter rye, 9 trials in winter triticale, 6 trials winter durum and 6 trials spelt) were used to evaluate any potential negative effect of the test product FFA SC508.8 applied pre-emergence at 0.48 L/ha (N USE002) and 0.96 L/ha (2N USE002) to winter cereals were harvested.

Data shows, that FFA SC508.8 applied under weed free conditions at N rate and at 2N rate did not show any negative impact on yield of winter cereals (winter soft wheat, winter triticale, winter rye and winter durum wheat) in most of the situations, when applied under the recommendations for use at BBCH 00 - 09. The slight yield reduction caused by FFA SC508.8 at 2N rate (USE002) is on an acceptable level and on the same level as the standard reference products used in the trials.

USE003 and USE004: Relationship between phytotoxicity and yield of FFA SC508.8 applied post-emergence in winter soft wheat, Crop tolerance trials ([M-761954-01-1](#)).

Crop tolerance trials from USE004, also valid for USE003 are presented in the document Compilation of trial reports.

65 out of 69 crop tolerance trials (19 trials winter wheat, 18 trials winter rye, 8 trials winter rye trials, 10 trials winter triticale, 5 trials winter durum wheat and 5 trials spelt wheat) which were used to evaluate any potential negative effect of the test product FFA SC508.8 at a normal dose rate of 0.48 L/ha post-emergence (USE004) on yield, were harvested. 4 trials were not harvested.

For statistical analysis the untreated is included to determine if any yield increase/decrease following the application with FFA SC508.8 at 0.48 L/ha (N rate USE004) and at 0.96 L/ha (2N rate) may significantly differ.

The evaluation of the product complies with the Uniform Principles.

Table 3.4-50: Summary on yield after application of FFA SC508.8 0.48 L/ha (N rate) and at 0.96 L/ha (2N rate) in crop tolerance trials, USE003 and USE004

Crop	Grouping (EPPO climatic zone)	Trials	% yield relative to the untreated																	
			Test N			Standard* N			Standard** N			Test 2N			Standard* 2N			Standard** 2N		
			Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	Mean	Min	Max
TRZAW	Central European Regulatory Zone	19	101.3	94.9	124.3	102.1	95.4	125.2	98.5	93.4	101.4	100.0	92.0	121.0	100.5	85.0	127.9	99.7	98.3	100.7
	North-East	4	99.4	97.6	100.9	-	-	-	98.5	93.4	101.4	98.4	95.4	101.0	-	-	-	99.7	98.3	100.7
	Maritime	15	101.8	94.9	124.3	102.1	95.4	125.2	-	-	-	100.5	92.0	121.0	100.5	85.0	127.9	-	-	-
HORVW	Central European Regulatory Zone	18	101.9	83.5	127.5	101.8	79.3	121.7	102.1	101.2	102.9	98.3	68.5	128.6	97.8	52.2	120.5	98.6	91.1	102.8
	North-East	3	100.4	93.5	105.9	-	-	-	102.1	101.2	102.9	97.2	90.4	100.8	-	-	-	98.6	91.1	102.8
	Maritime	15	102.2	83.5	127.5	101.8	79.3	121.7	-	-	-	98.6	68.5	128.6	97.8	52.2	120.5	-	-	-
SECCW	Maritime	8	103.1	96.2	113.1	100.6	93.7	107.8	-	-	-	95.0	84.5	104.8	96.7	91.8	100.7	-	-	-
TTLWI	Maritime	10	97.3	88.5	101.7	97.5	92.7	104.3	-	-	-	90.8	81.0	99.8	90.4	81.8	99.6	-	-	-
TRZSP	Maritime	5	99.6	93.0	104.3	94.7	88.5	99.0	-	-	-	95.5	80.5	102.4	92.8	69.3	100.4	-	-	-
TRZDW	Maritime	5	94.7	90.9	98.1	96.2	90.1	100.4	-	-	-	94.4	86.4	101.5	93.5	79.3	102.0	-	-	-

Test product = FFA SC508.8 0.48 L/ha (N rate) and at 0.96 L/ha (2N rate)

Standard*= Herold SC600 0.6 L/ha (N rate) and at 1.2 L/ha (2N rate)

Standard** = Boxer 3 L/ha (N rate) and at 6 L/ha (2N rate)

Conclusion on yield, USE003 and USE004

66 crop tolerance trials (TRZAW - 20 trials, HORVW - 18 trials, SECCW - 8 trials, TTLWI - 10 trials, TRZDW – 5 trials, TRZSP - 5 trials) were performed in the EPPO climatic zone Maritime and North-East which were used to evaluate any potential negative effect on yield of the test product FFA SC508.8. The product was applied at 0.48 L/ha (1N rate) and at double dose rate to winter soft wheat, winter barley, winter rye, winter triticale, winter durum wheat and spelt. Data shows, that FFA SC508.8 applied under weed free conditions at 1N rate and at 2N rate did not show any negative impact on yield of these crops in most of the situations, when applied under the recommendations for use at BBCH 10-13.

It is assumed that the post-emergence application of FFA SC508.8 at the recommended dose rate of 0.48 L/ha gave no negative impact on yield on winter soft wheat, winter barley, winter triticale, winter rye, winter durum wheat and spelt. To compensate for any adverse effects on yield, spray overlaps should be avoided.

Comments of zRMS:

FFA SC 508.8 G applied at dose rate of 0,48 l/ha (either in pre- and post-emergence application) did not cause any negative impact on the yield of winter cereals. Moreover, the results from objects treated of reference product were similar and no significant differences have been detected.

Because no results from the South-East EPPO zone have been presented, the CMS is asked to decide whether to accept the assessment of the yield based on the trials from other zones at the national level.

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

Trials implemented to assess whether the test product has negative influence of treated crop yield were also valid to assess the impact of the product on quality.

Information on the trial methodology is reported in chapter 3.4.1 “Phytotoxicity to host crop”.

Following EPPO standard PP1/093(3) these quantitative and qualitative parameters of cereal yield were assessed:

- Grain weight per hectolitre (HLW);
- 1000-grain weight (TGW);
- Protein content (PROCON)

For these parameters, the comparison in percentage with the untreated control and the standard reference product is done. For the evaluation, the test product and reference product was applied at N rate and at 2N rate.

The evaluation of the product complies with the Uniform Principles.

Trial grouping and USE evaluation

Selectivity trials were conducted with the higher dose rates of 0.48 L/ha as 1N for USE002 and USE004, respectively. Taking a risk envelope approach these results are deemed to be valid to cover the potential impact on quality parameters for 0.24 L/ha as 1N in USE001 and USE003, respectively. An overview of the subchapters is given below:

- **“USE001 and USE002”** where the recommended dose rate of FFA SC508.8 on winter wheat, winter barley, winter triticale, winter spelt and winter durum wheat is 0.24 L/ha (USE001) and 0.48 L/ha (USE002) at crop BBCH 00-09. Quality data in selectivity trials of USE002 covers USE001.
- **“USE003 and USE004”** where the recommended dose rate of FFA SC508.8 on winter wheat, winter barley, winter triticale, winter spelt and winter durum wheat is 0.24 L/ha (USE003) and 0.48 L/ha (USE004) at crop BBCH 10-13. Quality data in selectivity trials of USE004 covers USE003.

Effects on quality of FFA SC508.8 applied pre-emergence in winter cereals, Crop tolerance trials, USE001 and USE002 (M-761947-01-1).

Single trial reports are given in the document Compilation of trial reports.

In the seasons 2003, 2004, 2015, 2019 and 2020, 21 trials in winter wheat, 18 trials in winter barley, 8 trials in winter rye, 9 trials in winter triticale, 6 trials in spelt and 6 trials in winter durum wheat were carried out to determine the quality parameter after applying the test product. Information on the number of trials conducted in each country and the quality parameter assessed are presented in the table below.

Table 3.4-51: Trials per country assessing the effect of FFA SC508.8 on the quality parameters

EPPO climatic zone	Country	Crop	HLW	TGW	PROCON
Central zone	all	TRZAW	11	20	7
North-East	POL		4	4	1
Maritime	BEL		1		
	CZE		2	2	2
	DEU			10	
	FRA		4	4	4
Central	all	HORVW	9	17	6
North-East	POL		3	3	2
Maritime	BEL		1		
	CZE		1	1	
	DEU			9	
	FRA		4	4	4
Central	all	TTLWI		9	
Maritime	DEU			9	
Central	all	SECCW		8	
Maritime	DEU			8	
Central	all	TRZSP	6	6	
	DEU		6	6	
Central	all	TRZDW	6	6	
Maritime	DEU		6	6	
Central zone		Winter cereals	32	66	13

Table 3.4-52: Summary: Effect of FFA SC508.8 on quality parameter thousand grain weight (TGW) in % relative to untreated, winter cereals, USE002

Crop	Parameter	Grouping	Trials	% quality parameter relative to the untreated											
		(EPPO zone)		Test N			Standard N			Test 2N			Standard 2N		
				Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	Mean	Min	Max
TRZAW	TGW	Central zone	17	101.4	96.9	105.2	-	-	-	101.3	94.7	105.2	-	-	-
		Maritime	13	101.5	96.9	105.2	101.3	97.2	105.6	101.8	94.7	105.2	101.6	93.4	107.7
		North-East	4	101	98.3	105	101.9	99.3	104.5	99.8	98.5	100.8	101.4	97.8	104.4
HORVW		Central zone	13	100.1	97.3	103.4				100.2	94.6	103.5			
		Maritime	10	100.1	97.3	103.4	100.4	97.7	1005.4	100.2	94.6	103.5	102.9	100.2	107.5
		North-East	3	100.1	97.9	101.7	101.2	99.1	102.9	100.3	98.1	102.2	101.2	99	103.3
SECCW		Central zone	6	100.6	99.2	102.6	101.6	100.3	105.3	100.7	96.3	104	102.3	100.2	105.1
		Maritime	6	100.6	99.2	102.6	101.6	100.3	105.3	100.7	96.3	104	102.3	100.2	105.1
TTLWI		Central zone	9	98.8	95.1	104.9	100.8	95.3	103.8	100.2	93.2	106	98.1	84.7	105.2
		Maritime	9	98.8	95.1	104.9	100.8	95.3	103.8	100.2	93.2	106	98.1	84.7	105.2
TRZSP		Central zone	6	100.9	97.1	106.2	98.7	94.6	104.1	101.1	96.3	105.5	100.7	97.4	108.4
		Maritime	6	100.9	97.1	106.2	98.7	94.6	104.1	101.1	96.3	105.5	100.7	97.4	108.4
TRZDW		Central zone	6	99.3	91.3	103.9	100.8	95.7	107.2	101.0	94.7	109.0	101.2	88.6	117.4
		Maritime	6	99.3	91.3	103.9	100.8	95.7	107.2	101.0	94.7	109.0	101.2	88.6	117.4

Test product = FFA SC508.8 applied at 0.48 L/ha (N rate USE002) and at 0.96 L/ha (2N rate USE002)

Standard = Maritime EPPO climatic zone: Herold applied at 0.6 L/ha (N rate) and at 1.2 L/ha (2N rate), North East EPPO climatic zone: Boxer applied at 3 L/ha (N rate) and 6 L/ha (2N rate).

Table 3.4-53: Summary: Effect of FFA SC508.8 on quality parameter hectolitre weight (HLW) in % relative to untreated, winter cereals, USE002

Crop	Parameter	Grouping	Trials	% quality parameter relative to the untreated											
		(EPPO zone)		Test N			Standard N			Test 2N			Standard 2N		
				Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	Mean	Min	Max
TRZAW	HLW	Central zone	11	99.9	95.5	103.2				98.8	93.5	102.1			
		Maritime	7	99.9	98.5	101.5	99.5	96.3	101.9	98.2	93.5	102.1	98.0	93.9	102.6
		North-East	4	99.9	95.5	103.2	100.2	97.7	102.7	100.1	98.6	101.1	100.2	98.7	103.4
HORVW		Central zone	10	100.4	98.4	104.9				99.4	96.8	103.1			
		Maritime	7	100.3	98.4	104.9	99.9	98	102.8	99.2	96.8	103.1	99.7	96.0	102.1
		North-East	3	100.7	99.4	102	101.0	100.4	102	99.8	98.8	100.9	102.1	100.6	104.1
TRZSP		Central zone	6	101.4	98.5	104.0	99.9	96.6	102.5	100.2	94.7	105.0	99.2	97.0	104.7
		Maritime	6	101.4	98.5	104.0	99.9	96.6	102.5	100.2	94.7	105.0	99.2	97.0	104.7
TRZDW		Central zone	6	96.9	82.1	102.2	100.6	99.3	103.6	101.0	99.4	103.1	99.0	96.6	101.0
		Maritime	6	96.9	82.1	102.2	100.6	99.3	103.6	101.0	99.4	103.1	99.0	96.6	101.0

Test product = FFA SC508.8 applied at 0.48 L/ha (N rate USE002) and at 0.96 L/ha (2N rate USE002)

Standard = Maritime EPPO climatic zone: Herold applied at 0.6 L/ha (N rate) and at 1.2 L/ha (2N rate), North East EPPO climatic zone: Boxer applied at 3 L/ha (N rate) and 6 L/ha (2N rate).

Table 3.4-54: Summary: Effect of FFA SC508.8 on quality parameter protein content (PROCON) in % relative to untreated, winter cereals, USE002

Crop	Parameter	Grouping	Trials	% quality parameter relative to the untreated											
		(EPPO zone)		Test N			Standard N			Test 2N			Standard 2N		
				Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	Mean	Min	Max
TRZAW	PROCON	Central zone	7	103.2	99.3	110.1				103.2	100.0	109.9			
		Maritime	6	103.9	101.1	110.1	102.8	98.2	108.8	103.7	100.0	109.9	106.4	100.9	115.2
		North-East	1	99.3			100.0			100.0			100.0		
HORVW		Central zone	6	98.9	91.8	103.5				101.7	97.7	108.5			
		Maritime	4	100.6	99.1	103.5	100.4	97.6	102.8	102.6	97.7	108.5	104.3	94.7	111.3
		North-East	2	95.5	91.8	99.2	95.6	90.3	100.8	100.0	100.0	100.0	94.0	91.8	96.2

Test product = FFA SC508.8 applied at 0.48 L/ha (N rate USE002) and at 0.96 L/ha (2N rate USE002)

Standard = Maritime EPPO climatic zone: Herold applied at 0.6 L/ha (N rate) and at 1.2 L/ha (2N rate), North East EPPO climatic zone: Boxer applied at 3 L/ha (N rate) and 6 L/ha (2N rate).

Conclusion, USE001 and USE002

In the seasons 2003, 2004, 2015, 2019 and 2020, hectolitre weight was measured in a total of 34 out of 68 trials assessing yield quality parameters: 11 out of 21 trials in winter wheat, 9 out of 18 trials in winter barley, no trials in winter rye, no trials in winter triticale, 6 trials in spelt and 6 trials in winter durum wheat. Thousand grain weight was measured in a total of 68 trials: 21 trials in winter wheat, 18 trials in winter barley, 8 trials in winter rye, 9 trials in winter triticale, 6 trials in spelt and 6 trials in winter durum wheat. Protein content was measured in a total of 13 out of 68 trials: 7 trials in winter soft wheat and 6 trials in winter barley.

Across all climatic zones it can be seen that overall mean of all quality parameters with the test and standard products at N and 2N doses stayed at a level of untreated check or slightly differed. Some reduction of the individual parameters (hectolitre weight or thousand grain weight) had no real detrimental effect on the quality of winter soft wheat, winter rye, winter triticale, spelt and winter durum wheat grain.

Effects on quality of FFA SC508.8 applied post-emergence in winter soft wheat, Crop tolerance trials, USE003 and USE004 ([M-761954-01-1](#)).

Single trial reports are given in the document Compilation of trial reports.

In season 2003 to 2004 and 2015 to 2020, 53 out of 69 crop tolerance trials in winter soft wheat, winter barley, winter rye, winter triticale, winter durum wheat and were carried out to determine the quality parameter after applying the test product. Information on the number of trials conducted in each country and the quality parameter assessed are presented in the table below.

Table 3.4-55: Trials per country assessing the effect of FFASC508.8 on the quality parameters

EPPO climatic zone	Country	Crop	HLW	TGW	PROCON
Central zone	all		10	17	6
North-East	POL		4	4	1
Maritime	BEL	TRZAW	1	1	
	CZE		2	2	2
	DEU			7	
	FRA		3	3	3
Central	all		8	18	5
North-East	POL		3	3	2
Maritime	BEL	HORVW	1	1	
	CZE		1	1	
	DEU			10	
	FRA		3	3	3
Central	all			9	
Maritime	DEU	TTLWI		9	
Central	all			10	
Maritime	DEU	SECCW		10	
Central	all		5	5	
Maritime	DEU	TRZSP	5	5	
Central	all		5	5	
Maritime	DEU	TRZDW	5	5	
Central zone		Winter cereals	28	64	11

Table 3.4-56: Summary: Effect of FFA SC508.8 on the quality parameter thousand grain weight (TGW) in % relative to untreated, winter cereals, USE003

Crop	Parameter	Grouping	Trials	% quality parameter relative to the untreated																	
		(EPPO zone)		Test N			Standard* N			Standard** N			Test 2N			Standard* 2N			Standard** 2N		
				Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	Mean	Min	Max
TRZAW	TGW	Central European Regulatory zone	14	99.9	93.5	104.5	100.2	97.0	105.2	100.7	97.3	104.2	100.2	96.5	104.2	99.8	94.5	105.6	101.3	100.0	102.9
		North-East	4	100.7	97.3	103.9	-	-	-	100.7	97.3	104.2	101.6	98.5	104.2	-	-	-	101.3	100.0	102.9
		Maritime	10	99.6	93.5	104.5	100.2	97.0	105.2	-	-	-	99.7	96.5	103.7	99.8	94.5	105.6	-	-	-
HORV W	TGW	Central European Regulatory zone	14	100.6	96.2	106.8	101.6	98.4	111.5	97.4	97.1	97.7	100.4	95.8	108.9	101.9	97.3	106.8	98.7	98.1	99.3
		North-East	3	97.8	96.2	98.9	-	-	-	97.4	97.1	97.7	98.4	96.2	101.2	-	-	-	98.7	98.1	99.3
		Maritime	11	101.3	98.1	106.8	101.6	98.4	111.5	-	-	-	101.0	95.8	108.9	101.9	97.3	106.8	-	-	-
SECCW	TGW	Maritime	2	104.2	102.6	105.7	103.3	102.4	104.1	-	-	-	106.0	102.6	109.3	105.7	101.8	109.5	-	-	-
TTLWI	TGW	Maritime	10	99.4	88.9	107.9	100.2	93.9	105.7	-	-	-	100.7	91.3	106.0	101.0	94.2	108.7	-	-	-
TRZSP	TGW	Maritime	5	100.3	98.8	101.7	101.2	99.4	103	-	-	-	104.1	99.7	108.5	101.5	99.9	103.1	-	-	-
TRZDW	TGW	Maritime	4	99.05	96.4	103	98.2	96.6	99.8	-	-	-	97.4	95.5	100	97.88	94.6	99.4	-	-	-

Test product = FFA SC508.8 0.48 L/ha (N rate) and at 0.96 L/ha (2N rate)

Standard*= Herold SC600 0.6 L/ha (N rate) and at 1.2 L/ha (2N rate)

Standard** = Boxer 3 L/ha (N rate) and at 6 L/ha (2N rate)

Table 3.4-57: Summary: Effect of FFA SC508.8 on quality parameter hectolitre weight (HLW) in % relative to untreated, winter cereals, USE003 and USE004

Crop	Parameter	Grouping	Trials	% quality parameter relative to the untreated																	
		(EPPO zone)		Test N			Standard* N			Standard** N			Test 2N			Standard* 2N			Standard** 2N		
				Mean	Min	Max	Mean	Min	Max				Mean	Min	Max	Mean	Min	Max			
TRZAW	HLW	Central European Regulatory zone	10	100.1	98.4	103.1	100.5	99.5	101.4	99.5	98.4	101.7	100.1	97.6	101.7	100.2	98.9	101.5	100.2	99.1	101.2
		North-East	4	99.2	98.4	99.6	-	-	-	99.5	98.4	101.7	100.3	97.6	101.7	-	-	-	100.2	99.1	101.2
		Maritime	6	100.7	99.4	103.1	100.5	99.5	101.4	-	-	-	99.9	98.8	101.3	100.2	98.9	101.5	-	-	-
HORV W	HLW	Central European Regulatory zone	8	99.6	97.4	102.4	100.2	99.5	101.2	100.5	100.4	100.6	100.1	98.0	103.2	99.4	97.4	101.0	101.2	98.8	103.2
		North-East	3	99.9	98.2	102.4	-	-	-	100.5	100.4	100.6	100.0	98.0	103.2	-	-	-	101.2	98.8	103.2
		Maritime	5	99.4	97.4	101.0	100.2	99.5	101.2	-	-	-	100.1	98.8	101.0	99.4	97.4	101.0	-	-	-
TRZSP	HLW	Maritime	5	97.1	89.3	101.7	97.3	95.5	98.5	-	-	-	96.7	90.3	101.2	97.7	94.2	101.4	-	-	-
TRZDW	HLW	Maritime	5	99.8	98.4	102.1	99.0	98.4	99.6	-	-	-	99.8	99.2	100.8	99.6	98.4	101.2	-	-	-

Test product = FFA SC508.8 0.48 L/ha (N rate) and at 0.96 L/ha (2N rate)

Standard*= Herold SC600 0.6 L/ha (N rate) and at 1.2 L/ha (2N rate)

Standard** = Boxer 3 L/ha (N rate) and at 6 L/ha (2N rate)

Table 3.4-58: Summary: Effect of FFA SC508.8 on quality parameter protein content (PROCON) in % relative to untreated, winter cereals, USE003 and USE004

Crop	Parameter	Grouping	Trials	% quality parameter relative to the untreated																	
		(EPPO zone)		Test N			Standard N*			Standard N**			Test 2N			Standard 2N*			Standard 2N**		
				Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	Mean	Min	Max
TRZAW	PROCON	Central zone	6	101.5	98.4	107.7	103.7	100.6	110.8	102.1	-	-	102.3	98.2	106.8	104.6	101.1	109.0	100.0	-	-
		North-East	1	102.1	-	-	-	-	-	102.1	-	-	100.7	-	-	-	-	-	100.0	-	-
		Maritime	5	101.4	98.4	107.7	103.7	100.6	110.8	-	-	-	102.6	98.2	106.8	104.6	101.1	109.0	-	-	-
HORV W	PROCON	Central zone	5	100.2	94.0	107.0	98.7	94.2	101.8	104.3	100.8	107.8	101.4	92.9	106.1	99.7	95.2	103.7	108.2	107.6	108.7
		North-East	2	103.9	100.8	107.0	-	-	-	104.3	100.8	107.8	105.2	104.2	106.1	-	-	-	108.2	107.6	108.7
		Maritime	3	97.7	94.0	99.8	98.7	94.2	101.8	-	-	-	99.0	92.9	103.3	99.7	95.2	103.7	-	-	-

Test product = FFA SC508.8 0.48 L/ha (N rate) and at 0.96 L/ha (2N rate)

Standard*= Herold SC600 0.6 L/ha (N rate) and at 1.2 L/ha (2N rate)

Standard** = Boxer 3 L/ha (N rate) and at 6 L/ha (2N rate)

Conclusion, USE003 and USE004

In season 2003 to 2004 and 2015 to 2020, 62 out of 69 crop tolerance trials in winter soft wheat, winter barley, winter rye, winter triticale, winter durum wheat and spelt performed in the EPPO climatic zone Maritime and North-East were carried out to determine the hectolitre weight, thousand grain weight and protein content after applying the test product. FFA SC508.8 was applied at 0.48 L/ha (1N rate) and at double dose rate at crop BBCH 10-13.

Across all climatic zones it can be seen that overall mean of all quality parameters of the test and standard products at 1N and 2N doses stayed at a level of untreated check or slightly differed. Some reduction of the individual parameters (hectolitre weight or thousand grain weight) had no real detrimental effect on the quality of winter soft wheat, winter barley, winter rye, winter triticale, winter durum wheat and spelt grain.

Comments of zRMS:

FFA SC 508.8 G applied at dose rate of 0,48 l/ha (either in pre- and post-emergence application) did not cause any negative impact on protein content of winter cereals. Wheares, some reduction of hectolitre weight or thousand grain weight had not significant impact on the quality of grain. Moreover, the results from objects treated of reference product were similar and no significant differences have been detected.

Because no results from the South-East EPPO zone have been presented, the cMS is asked to decide whether to accept the assessment of the yield parameters based on the trials from other zones at the national level.

3.4.4 Effects on transformation processes (KCP 6.4.4)

No data concerning effects on the processing procedure are presented according to the EPPO standard PP 1/243 *Effects of plant protection products on transformation processes*, which provides an indication of the circumstances under which data on transformation processes are required. This standard is stating there is no requirement to address the issue as there are no residues issues. Due to the early timing of the application at either crop BBCH 00-09 or crop BBCH 10-13 and the non-residue situation (residues are below LOD) no influence on the processing procedure is to be expected.

Therefore, it is concluded that applications of FFA SC508.8 following the use recommendation will not cause any adverse effect on the processing procedure of the harvested grains.

Comments of zRMS:

Accepted.

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

In accordance to EPPO guidance PP 1/135 (4) *Phytotoxicity assessment* no data are required for herbicide applications before crop BBCH 30. Due to the early timing of the application and the non-residue situation (residues are below LOD) no influence on propagation is to be expected.

Comments of zRMS:

Accepted.

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

3.5.1 Impact on succeeding crops (KCP 6.5.1)

[M-092929-01-1](#)

Following the EPPO standard PP1/207(2) 'Effects on succeeding crops', a stepwise approach was implemented to evaluate the risk of effects from FFA SC508.8 on succeeding crops:

Below the first step of conducting an EC10 greenhouse study on sensitivity of crop species including TER calculations is presented.

The results of these risk calculations are favourable for a number of potentially succeeding crops, no further results from field trials were necessary.

EC 10 - studies

Basis of the following discussion is the study on fate and behaviour in soil with the active ingredients flufenacet (EC₁₀-data and its estimation on recropping crops).

For this study, a standardised greenhouse trial with another formulation (FFA WG60) has been carried out (Report KIII A 6.2.6/01). 13 different crops were planted in a standard soil mixed with 10 concentrations of FFA WG60, this replicated 3 times. The highest concentration corresponds to the field application rate of 1.0 kg/ha or 600 g/ha (1.179 l/ha FFA SC508) active ingredient. Phytotoxicity was evaluated. For the calculation of the EC₁₀-data the evaluation at 29 days after application was used, Table below.

Table 3.5-1: EC10 values in µg a.s./kg FFA WG60 mixed in dry soil; 21 day after application

Crop	BEAVA	BRSNS	HELAN	HORVS	LIUT	LOLMU
µg/kg soil formulated product	36.10	79.60	11.90	4.60	94.10	10.80

Table 3.5-1: (cont.):

Crop	PHSVN	PIBST	SECCW	SINAL	TRZAS	TRZAW	ZEAMX
µg/kg soil formulated product	137.80	19.90	10.10	18.30	38.60	37.30	109.60

The following information is the basis for the evaluation of selectivity issues of FFA SC508.8 in the following crops:

- EC₁₀ data of the formulation FFA WG60.
- Late application of FFA SC508.8 at 1st of November.
- The ingredient of FFA SC508.8 with 254.4 g a.s. / ha with flufenacet at application rate with 0,5 l/ha (FFA WG60 with 0.424 kg/ha).
- The interception at crop stage BBCH 00 – 19 in cereals with 0%.
- The half-life period of diflufenican in soil with DT50 = 31,2 d.
- The calculation of ingredient concentration in soil depth of 10 and 20 cm was done with the following formula:

$$c(t) = c(0) * e^{-k * t}$$

$$c(t) = \text{concentration at time } t \text{ (in days), } c(0) = \text{initial concentration; } k = \text{degradation rate (with unit 1/d). The degradation rate is calculated from half-life period DT50 (in days) with:}$$

$$k = 0,693 / DT50$$
- TER-calculation: EC₁₀ / PEC_(t); Risk for recropping with TER > 1.

Based on these recropping scenarios the estimation of recropping issues with crop cultivation in autumn and spring in the following year is made and TER values are presented in the Table below.

Table 3.5-2: TER calculation for FFA WG60 based on EC10-data, recropping

Following crop	Sowing date	Days after application	PEC FFA µg/kg soil 10 cm	PEC FFA µg/kg soil 20 cm	EC10 value FFA WG60 sum of FFA µg/kg	TER EC10/PEC 10 cm	TER EC10/PEC 20 cm
BEAVA	15.03.	134	8.64	4.32	21.66	2.51	5.01
BRSNS	01.04.	151	5.92	2.96	47.76	8.06	16.13
HELAN	01.04.	151	5.92	2.96	7.14	1.21	2.41
HORVS	01.03.	120	11.79	5.90	2.76	0.23	0.47

LIUT	01.03.	120	11.79	5.90	56.46	4.79	9.58
LOLMU	15.04.	165	4.34	2.17	6.48	1.49	2.99
PHSVN	01.04.	151	5.92	2.96	82.68	13.96	27.92
PIBST	15.03.	134	8.64	4.32	11.94	1.38	2.76
SECCW	01.09.	304	0.20	0.10	6.06	30.63	61.26
SINAL	10.08.	282	0.32	0.16	10.98	34.04	68.09
TRZAS	01.03.	120	11.79	5.90	23.16	1.96	3.93
TRZAW	01.09.	304	0.20	0.10	22.38	113.12	226.24
ZEAMX	01.05.	181	3.04	1.52	65.76	21.63	43.26

Based on the above calculation most tested plants would be possible recropping crops including crops failure (bold crops) over winter time. Only spring barley as a recropping crop after application of FFA WG60 would not be safe.

Considering normal rotatory agricultural practice even for spring barley as recropping crop no negative impact could be shown.

Table 3.5-3: TER calculation for FFA WG60 based on EC10-data, succeeding crop

Following crop	Sowing date	Days after application	PEC FFA µg/kg soil 10 cm	PEC FFA µg/kg soil 20 cm	EC10 value FFA WG60 sum of FFA µg/kg	TER EC10/PEC 10 cm	TER EC10/PEC 20 cm
BEAVA	15.03.	134	8.64	4.32	21.66	2.51	5.01
BRNS	01.04.	151	5.92	2.96	47.76	8.06	16.13
HELAN	01.04.	151	5.92	2.96	7.14	1.21	2.41
HORVS	01.03.	485	0.00	0.00	2.76	777.96	1555.92
LIUT	01.03.	120	11.79	5.90	56.46	4.79	9.58
LOLMU	15.04.	165	4.34	2.17	6.48	1.49	2.99
PHSVN	01.04.	151	5.92	2.96	82.68	13.96	27.92
PIBST	15.03.	134	8.64	4.32	11.94	1.38	2.76
SECCW	01.09.	304	0.20	0.10	6.06	30.63	61.26
SINAL	10.08.	282	0.32	0.16	10.98	34.04	68.09
TRZAS	01.03.	120	11.79	5.90	23.16	1.96	3.93
TRZAW	01.09.	304	0.20	0.10	22.38	113.12	226.24
ZEAMX	01.05.	181	3.04	1.52	65.76	21.63	43.26

This positive test does not implement further investment on recropping according to EPPO PP01/207 (2) field trials to evaluate this risk on a higher tier approach.

Comments of zRMS:

Based on the trials results submitted by the applicant, it can be concluded that FFA SC 508.8 G has not impact on the succeeding crops. Moreover, in case of crop failure (as a result of damage to plants by frost, pests or diseases) on the same field can be grown: sugar beet, sunflower, spring oilseed rape, flax, Italian ryegrass, snap bean, winter rye, white mustard, spring wheat, winter wheat and maize. Wheares, TER calculation shows that spring barley should not be used as recropping crops after application of FFA SC 508.8 G.

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

[M-248250-01-1](#)

[M-248251-01-1](#)

The risk posed by the test product to adjacent crops has been evaluated according to the EPPO guideline PP 1/256 (1).

For the estimation of the risk of FFA SC508 to harm adjacent crops the lowest end point of tier 2 studies has been chosen. The most sensitive species was identified in the seedling emergence test as sorghum, having an ER₅₀value (ER₅₀ is exposure ratio which kills 50 % of the plants) of 10.5 g a.s./ha, please refer to study [M-248250-01-1](#).

Table 3.5-4: Survey of non-target plant tests performed with the formulated product

Test design	Test species	Lowest ecotoxicological endpoint ER ₅₀ [g a.s./ha]	Reference
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Flufenacet SC508				
Tier 2 test glasshouse Seedling emergence 10 species, 21 days	<i>Sorghum bicolor</i> (sorghum)	10,5	fresh weight	Friedrich 2005 M-248250-01-1
Tier 2 test glasshouse Vegetative vigour 10 species, 21 days	<i>Lolium perenne</i> (perennial ryegrass)	17	fresh weight	Friedrich 2005 M-248251-01-1

This data can now be used together with the estimated spray drift, to calculate the PEC (Predicted environmental concentration), which in turn gives an estimation of the potential risk to adjacent crops, following an application of the test product.

The calculation of the estimated drift is shown in the Table below.

Table 3.5-5: Predicted environmental concentration (PEC) at 1m and 5 m distances from the field edge for the max application rate of 0.5 l/ha product (254.4 a.s./ha)

Application rate [g a.s./ha]	Distance [m]	Drift* (%)	PEC no drift reduction [g/ha]
254.4	1	2.77	7.05
	5	0.57	1.45

* drift value (1 application, field crops)

The TER is calculated as follows: $TER = ER_{50} / \text{estimated drift}$. The risk is acceptable if a TER of 1 is achieved. These calculations are shown in the Table below.

Table 3.5-6: Deterministic risk assessment for non-target terrestrial plants based on the lowest ER_{50} of 10.5 g a.s./ha (seedling emergence)

Cereals, one application, 508.8 g a.s./ha; lowest ER_{50} = 10.5 g a.s./ha (sorghum)						
Distance [m]	Drift (%)	PEC no drift reduction [g/ha]	TER ^a			
			No drift reduction	50% drift reduction	75% drift reduction	90% drift reduction
1	2.77	7.05	1.5	3.0	6.0	14.9
5	0.57	1.45	7.2	14.5	29.0	72.4

^a TER values meeting the trigger are marked in bold

The TER trigger value of 1 is achieved for an application rate of 0.5 l product/ha without any restriction on buffer zones and usage of drift reducing nozzles.

Summary

Considering the aforementioned studies, the test product FFA SC508,8 does not pose any risk for adjacent crops. No risk mitigation measurements must be considered.

Comments of zRMS:

Based on the trial results with the most sensitive crop species (sorghum and perennial ryegrass), it can be concluded that FFA SC 508.8 G is safe for adjacent crops when it used at dose rate of 0,5 l/ha without any restriction on buffer zones and drift reducing nozzles.

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

Detailed studies on the potential adverse effects to beneficial organisms are submitted and summarised in Part B, Section 9 (Ecotoxicology).

Comments of zRMS:

Accepted.

3.6 Other/special studies

Tank cleaning ([M-357166-01-1](#))

In the year 2008 a report summarizing the results of trials on tank cleaning realized in the years 2000 - 2008 was written. These trials were carried out because registration of crop protection products requires specific information on the cleaning of sprayer tanks to avoid damages during subsequent treatments. During this period, 72 studies were conducted, in which a total of 60 active substances (16 fungicides, 33 herbicides, 3 safeners, 7 insecticides and 1 growth regulator) was tested. All tests were done with the same spraying equipment and under the same test protocol, thus the differences found in the results reflect the different behaviour of active substances and formulation systems.

Within this report it has been shown that cleaning efficacy does not depend on chemical or formulation related parameters and therefore a global statement on tank cleaning efficacy is justified. The results can be summarized as follows:

1. The established cleaning procedure, including two rinsing processes and the careful cleaning of all filters, is able to remove or reduce active substances leftover down to neglectable quantities.
2. By following the tank cleaning recommendation product groups (herbicides, fungicides, insecticides, and growth regulators), formulations and concentrations differ only quantitatively. The cleaning success follows an exponential function of the general formula $y = a e^{-bx}$. From one cleaning step to the next one, the initial concentration is reduced by at least one order of magnitude.
3. After filling the tank with fresh water, the active substance concentrations in all trials are either below the Limit of Quantification or are not relevant as far as biological effects during follow-up treatments are concerned.
4. According to the extensive number of results available, the recommendations on the product label regarding tank cleaning can apply equally to all products.

As a conclusion it can be proposed that no further studies for individual formulations need to be performed.

Comments of zRMS:

According to the trial results, it can be concluded that the below statement is justify:
“Two rinsing processes and the careful cleaning of all filters, is able to remove or reduce active substances leftover down to neglectable quantities”.

3.7 List of test facilities including the corresponding certificates

Table 3.7-1: List of test facilities

Organisation	Town	Country	Valid From	Valid To	Link
Bayer CropScience, Bayer Austria GmbH	Wien	Austria	24-nov-15	31-dec-19	1d68da7c755
Bayer CropScience NV	Diegem	Belgium	09-jan-20	09-jan-21	1d68da7c7e9
Bayer CropScience NV	Diegem	Belgium	04-sep-15	09-jan-20	1d68da7c4f7
INF Agro, s.r.o.	Uherske Hradiste	Czech Republic	01-sep-16	31-aug-21	1d68da7c587
InTec Agro Trials s.r.o.	Uhersky Ostroh	Czech Republic	07-feb-18	07-feb-23	1d68da7c688
Krasne Udoli, Ing. Jitka Mareckova	Touzim	Czech Republic	01-sep-16	31-aug-21	1d68da94ca9
OSEVA PRO s.r.o., odstepny zavod Vyzkumna stanice travinarska Roznov pod Radh. se sidlem v Zubri	Zubri	Czech Republic	01-sep-16	01-sep-21	1d68da94cc7

Organisation	Town	Country	Valid From	Valid To	Link
Zemservis zkusebni stanice Do-maninek, s.r.o.	Bystrice nad Pernštejnem	Czech Republic	01-sep-16	01-sep-21	1d68da7c5ac
Zkusebni Stanice Trutnov. s.r.o.	Trutnov	Czech Republic	01-sep-16	01-sep-21	1d68da7c5b6
Bayer CropScience France	Lyon	France	1-Oct-2018	30-sep-23	1d68da7c6c3
Agrartest GmbH	Aarbergen-Panrod	Germany	2-May-2016	2-May-2020	1d68da7c57d
Bayer CropScience Deutschland GmbH	Langenfeld	Germany	21-nov-18	10-dec-23	1d68da7c6f7
Bayer CropScience Deutschland GmbH, Entwicklung und Beratung	Langenfeld	Germany	28-jan-03	28-jan-08	1d68da7bfc
BioChem Agrar GmbH	Machern OT Gerichshain	Germany	21-mar-19	21-mar-24	1d68da94db2
BioChem Agrar GmbH	Uedem	Germany	11-nov-15	11-nov-20	1d68da94c2c
BioChem Agrar GmbH	Machern OT Gerichshain	Germany	24-mar-14	24-mar-19	1d68da94b2b
Eurofins Agrosience Services GmbH (Germany)	Stade	Germany	15-jan-16	15-jan-21	1d68da7c53c
Hetterich Fieldwork GbR	Schwarzach	Germany	20-jun-19	19-jun-24	1d68da7c7dc
Hetterich Fieldwork GbR	Schwarzach	Germany	20-jun-14	20-jun-19	1d68da7c3fe
Martin Feldversuchswesen Ing.-Büro zur Durchführung von Feldversuchen	Orsingen-Nenzingen	Germany	14-May-2017	31-dec-21	1d68da7c619
Martin Feldversuchswesen Ing.-Büro zur Durchführung von Feldversuchen	Orsingen-Nenzingen	Germany	04-jun-12	03-jun-17	1d68da7c263
Bayer Sp. z o. o.	Warszawa	Poland	16-jun-10	31-dec-00	1d68da7c385
Bayer Sp. z o. o.	Warszawa	Poland	16-jun-10	31-dec-00	1d68da94a25
Gemerprodukt Valice ovocinarsko-vinohradnicke druzstvo	Rimavska Sobota	Slovakia	12-apr-16	12-apr-21	1d68da7c54d
Ustredny kontrolny a skusobny ustav pol'nohospodarsky v Bratislave - Bratislave	Bratislava	Slovakia	15-feb-16	15-feb-21	1d68da94c0e
Bayer CropScience Limited (UK)	Cambridge	UK	01-jan-18	31-dec-22	1d68da7c656
FieldArm Limited	Maldon	UK	29-jan-14	31-jan-19	1d68da7c558
Bayer CropScience Deutschland GmbH, Entwicklung und Beratung	Langenfeld	Germany	17-sep-98	28-jan-03	-

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	Feuerhahn, I.; Nielsen, T.; Bartlett, M.	2021	Biological assessment dossier - Efficacy data and information - Detailed summary - FFA SC 508.8 - Flufenacet, 508.8 g/L - Central zone - Zonal rapporteur member state: Poland - Core assessment (authorization) Report No.: M-767892-01-1 Bayer S.A.S., Crop Science Division, Lyon, France GLP/GEP: n.a. unpublished	No	Bayer
KCP 6.2 / 01 ... also filed: KCP 6.4.1 / 01	Nielsen, T.	2021	Compilation of trial reports for FFA SC508.8 - Minimum effective dose and efficacy trials on grass and broadleaved weeds on winter cereals - USE001 and USE002 Report No.: M-761917-01-1 Bayer CropScience Division GLP/GEP: Yes unpublished	No	Bayer
KCP 6.2 / 02 ... also filed: KCP 6.4.1 / 03	Nielsen, T.	2021	Compilation of trial reports for FFA SC508.8 - Minimum effective dose and efficacy trials on grass weeds on winter cereals - USE003 and USE004 Report No.: M-761933-01-1 Bayer CropScience Division GLP/GEP: Yes unpublished	No	Bayer
KCP 6.2 / 03	Anon.	2016	Methodological instruction no. 2/2014 on submission of the number of biological effectiveness experiments for an applicant for authorisation, extension of an authorisation, change or amendment to an authorisation, or re-assessment of a plant protection products authorisation Report No.: M-630120-01-1 Central Controlling and Testing Institute in Agriculture, Bratislava, Slovakia GLP/GEP: n.a. unpublished	No	-public data-
KCP 6.3 / 01	Collavo, A.; Kaiser, J.	2020	Statement - Information on the occurrence or possible occurrence of the development of resistance of the plant protection product - Flufenacet (508.8 g/L) for use in cereals (for submission in Europe) Report No.: M-759325-01-1 Bayer AG GLP/GEP: n.a. 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 6.4.1 / 01 ... also filed: KCP 6.2 / 01	Nielsen, T.	2021	Compilation of trial reports for FFA SC508.8 - Minimum effective dose and efficacy trials on grass and broadleaved weeds on winter cereals - USE001 and USE002 Report No.: M-761917-01-1 Bayer CropScience Division GLP/GEP: Yes unpublished	No	Bayer
KCP 6.4.1 / 02 ... also filed: KCP 6.4.2 / 01 KCP 6.4.3 / 01	Nielsen, T.	2021	Compilation of trial reports for FFA SC508.8 - Selectivity trials on winter cereals - USE001 and USE002 Report No.: M-761947-01-1 Bayer CropScience Division GLP/GEP: Yes unpublished	No	Bayer
KCP 6.4.1 / 03 ... also filed: KCP 6.2 / 02	Nielsen, T.	2021	Compilation of trial reports for FFA SC508.8 - Minimum effective dose and efficacy trials on grass weeds on winter cereals - USE003 and USE004 Report No.: M-761933-01-1 Bayer CropScience Division GLP/GEP: Yes unpublished	No	Bayer
KCP 6.4.1 / 04 ... also filed: KCP 6.4.2 / 02 KCP 6.4.3 / 02	Nielsen, T.	2021	Compilation of trial reports for FFA SC508.8 - Selectivity trials on winter cereals - USE003 and USE004 Report No.: M-761954-01-1 Bayer CropScience Division GLP/GEP: Yes unpublished	No	Bayer
KCP 6.4.2 / 01 ... also filed: KCP 6.4.1 / 02 KCP 6.4.3 / 01	Nielsen, T.	2021	Compilation of trial reports for FFA SC508.8 - Selectivity trials on winter cereals - USE001 and USE002 Report No.: M-761947-01-1 Bayer CropScience Division GLP/GEP: Yes unpublished	No	Bayer
KCP 6.4.2 / 02 ... also filed: KCP 6.4.1 / 04 KCP 6.4.3 / 02	Nielsen, T.	2021	Compilation of trial reports for FFA SC508.8 - Selectivity trials on winter cereals - USE003 and USE004 Report No.: M-761954-01-1 Bayer CropScience Division GLP/GEP: Yes unpublished	No	Bayer
KCP 6.4.3 / 01 ... also filed: KCP 6.4.1 / 02 KCP 6.4.2 / 01	Nielsen, T.	2021	Compilation of trial reports for FFA SC508.8 - Selectivity trials on winter cereals - USE001 and USE002 Report No.: M-761947-01-1 Bayer CropScience Division 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 6.4.3 / 02 ... also filed: KCP 6.4.1 / 04 KCP 6.4.2 / 02	Nielsen, T.	2021	Compilation of trial reports for FFA SC508.8 - Selectivity trials on winter cereals - USE003 and USE004 Report No.: M-761954-01-1 Bayer CropScience Division GLP/GEP: Yes unpublished	No	Bayer
KCP 6.5.1 / 01	Slater, A. E.	2003	Soil mix crop screening tests - Cadou WG Report No.: MO-04-011245, Edition Number: M-092929-01-1 Bayer CropScience GmbH, Frankfurt am Main, Germany GLP/GEP: No unpublished	No	Bayer
KCP 6.5.2 / 01 ... also filed: KCP 10.6.2 / 01 KCP 5.1.2.6 / 10	Friedrich, S.	2005	Flufenacet SC 500: seedling emergence and seedling growth test on terrestrial non-target plants Report No.: 041048104, Edition Number: M-248250-01-1 BioChem agrar GmbH, Gerichshain, Germany GLP/GEP: Yes unpublished	No	Bayer
KCP 6.5.2 / 02 ... also filed: KCP 10.6.2 / 02 KCP 5.1.2.6 / 11	Friedrich, S.	2005	Flufenacet SC 500: vegetative vigour test on non-target terrestrial plants Report No.: 041048105, Edition Number: M-248251-01-1 BioChem agrar GmbH, Gerichshain, Germany GLP/GEP: Yes unpublished	No	Bayer
KCP 6.5.3 / 01	Friessleben, R.	2008	Summary and conclusive report of studies on spray tank cleaning realized in the years 2000 - 2008 Report No.: M-357166-01-1 Bayer CropScience AG, Monheim, Germany GLP/GEP: n.a. 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

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 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
-	-	-	-	-	-