REGISTRATION REPORT

Part B

Section 3

Efficacy Data and Information

Concise summary

Product code: GLOB1817H

Product Name: **Eledura**

Chemical active substances:

Prosulfocarb, 667 g/L

Diflufenican, 14 g/L

Halauxifen-methyl, 1.33 g/L

Cloquintocet-mexyl, 1.33 g/L (Safener)

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: Globachem N.V.

Submission date: May 2021

MS Finalisation date: January 2022

Revision date: April 2022

Version history

When	What
May 2021	Initial dossier submission by the applicant for approval of new product.
January 2022	Version evaluated by zRMS PL
April 2022	Version modified to take into account comments of cMS and the applicant

Table of Contents

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

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

The process chosen by the zRMS to transform the dRR into a RR should be explained. Options are to rewrite the document (with track change or not) or to use commenting boxes such as the following:

Comments of zRMS:	Comments of zRMS are presented in commenting boxes at the end of each chapter. The text of dRR was generally not changed or rewritten (small changes in the document are marked by grey colour).

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

Abstract

This document summarises the information related to the efficacy assessment of the plant protection product GLOB1817H, an emulsifiable concentrate formulation (EC) containing the active ingredients prosulfocarb (667 g/L), diflufenican (14 g/L) and halauxifen-methyl (1.33 g/L), they belong to different groups of HRAC and act by different modes of action. The target of GLOB1817H is early post-emergence weed control in winter wheat (TRZAW), winter barley (HORVW), winter rye (SECCW) and triticale (TTLWI), in combination with the safener cloquintocet-mexyl (1.33 g/L). The proposed use rate is 3,0 L/ha with a maximum of one application at growth stages ranging from BBCH 10-14. To support the proposed use of GLOB1817H data is presented from trials conducted between 2018 and 2019 in European countries of the maritime EPPO zone, and northeast EPPO zone.

Preliminary tests
The presented results, of three components in GLOB1817H prosulfocarb, diflufenican and halauxifen-methyl demonstrated activity against weed in cereals. GLOB1817H demonstrated at least comparable control and frequently superior control of weed compared to the standard product JURA. Therefore, the inclusion of proposed amount of prosulfocarb (667 g/L), diflufenican (14 g/L) and halauxifen-methyl (1.33 g/L) in the formulation GLOB1817H are fully justified.

Minimum effective dose tests
Maritime EPPO zone
To determine the minimum effective dose for the control of weed in winter cereals by GLOB1817H, the applicant presented data from 23 field trials. GLOB1817H was tested at doses 1,8 L/ha (60% of the target dose rate) was compared with the full recommended rate of 3.0 L/ha of GLOB1817H, under EPPO standard PP 1/225 'Minimum effective dose'. A clear dose-response was observed for almost all tested weeds, except *Geranium sp. Veronica sp, Thlaspi arvense* and , *Viola arvensis* where the weeds were controlled above 90% with two application rates, the full application rate 3.0 L/ha and reduced application rate 1,8 L/ha.
A very marked dosage-response was observed for grasses *Apera spica-venti*, *Poa annua* and broad-leaved *Centaurea cyanus*, *Galium aparine*, *Matricaria chamomilla*, *Matricaria inodora*, *Myosotis arvensis*, *Papaver rhoeas*, *Stellaria media*. For these weeds, the lower dose (1.8 l/ha) gave inferior but still good control, while increasing the dose to the full 3.0 l/ha led to very good control.
The justification of the proposed application rate of 3,0 L/ha will be accepted.

North East EPPO zone
To determine the minimum effective dose for the control of weed in winter cereals by GLOB1817H, the applicant presented data from 10 field trials. GLOB1817H was tested at doses 1,8 L/ha, 2,4 L/ha (60%, 80% of the target dose rate) was compared with the full recommended rate of 3.0 L/ha of GLOB1817H, under EPPO standard PP 1/225 'Minimum effective dose'. No clear dose-response was observed for all tested weeds, all application rates provided similar very good control of tested weed.
Since limited results were available for *Brassica napus, Capsella bursa-pastoris, Lamium purpureum, Matricaria inodora* these weed results may not be representative.
The justification of the proposed application rate of 3,0 L/ha will be accepted.

Efficacy tests
Maritime EPPO zone
Data are presented from 23 efficacy trials with GLOB1817H. The trials were conducted in the Maritime, EPPO zone between 2018 and 2019 by GEP certified research institutions in the Czech Republic, France, Germany, and the Netherlands. The crops that were used in these efficacy trials were winter wheat (19), winter rye (1), winter barley (1) and winter triticale (2).
The data show that a single application of 3 L/ha GLOB1817H in winter cereals gives very good (>85%) control of the majority of presented in the trials of annual broadleaved weeds *Galium aparine, Centaurea cyanus, Papaver rhoeas, Viola arvensis, Stellaria media, Matricaria inodora, Veronica persica, Geranium dissectum, Matricaria chamomilla, Thlaspi arvense, Myosotis arvensis, Descurainia Sophia, Fumaria officinalis* and annual grasses *Apera spica-venti and Poa annua*. The only weed partially controlled was *Senecio vulgaris*, where the average control was around 77,5%. 'GLOB1817H' demonstrated either comparable or higher control than the reference products.

North East EPPO zone
A total of 10 trials were carried out in the North-East EPPO Zone to evaluate the efficacy of GLOB1817H for the control of weeds on winter wheat (5), winter barley (1), winter triticale (4). Those trials have been conducted between 2018 and 2019 in Poland. Additionally, those trials were combined with the results of the German and Czech trials of winter wheat (18), winter barley (1) and winter rye (1).
In these trials GLOB1817H at the recommended application rate of 3 L/ha provided good control (>85%) of the annual broadleaved weeds *Centaurea cyanus, Viola arvensis, Papaver rhoeas, Tripleurospermum inodorum, Galium aparine, Stellaria media, Veronica persica, Matricaria chamomilla, Myosotis arvensis, Thlaspi arvense* and grass *Apera spica-venti*.
Based on efficacy results from efficacy field trials with GLOB1817H applied post emergence for weed control in winter cereals the intended application rate of 3 L/ha can be justified for registration.

Phytotoxicity to host crop
Maritime EPPO zone
The crops that were used in these selectivity trials were winter wheat (8), winter barley (7), winter rye (8) and winter triticale (8). As shown in the tables (Tables 3.4-6 to 3.4-12), the phytotoxicity observed at N and 2N only exceeded 15% in one trial. Overall, whilst there were some phytotoxicity symptoms, the majority were transient and disappeared over time and they did not appear to have a negative impact on the yield. Additionally, comparable symptoms were observed following treatment with the reference product. Therefore, it is considered that the proposed use of GLOB1817H is unlikely to cause any unacceptable levels of phytotoxicity.

North East EPPO zone
The crops that were used in these selectivity trials were winter wheat (5), winter barley (6), winter rye (6) and winter triticale (6). The results in this section show that GLOB1817H can be considered a herbicide with good crop safety when compared to a reference standard. As shown in the tables (Tables 3.4-6 to 3.4-12), the phytotoxicity observed at 2N only exceeded 15% in 1 trial. In all cases, the phytotoxicity symptoms caused by GLOB1817H were transient and did not affect the crop vigour, the growing and neither the grain yield. Additionally, comparable symptoms were observed following treatment with the reference product. Therefore, it is considered that the proposed use of GLOB1817H is unlikely to cause any unacceptable levels of phytotoxicity.

Yield and quality parameters
Maritime EPPO Zone
In the Maritime EPPO Zone, statistically lower yield was observed in two cases. In one trial on winter wheat, a lower yield was observed, but in the same trial with the 2N dose this effect was not observed. The second case was observed on winter barley at N and 2 N rates. A similar yield reduction was observed for the reference product, despite even lower levels of phytotoxicity effect.
Overall, the yield following treatments with 'GLOB1817H' and the reference products at both N and 2N were comparable to the untreated. The data indicate that at the proposed dose 3 l/ha of 'GLOB1817H' is unlikely to have a significant negative effect on the yield of winter cereals.

North east EPPO zone
In the North East EPPO zone, statistically lower yield was observed in two cases. Overall, the yield following treatments with 'GLOB1817H' and the reference products at both N and 2N were comparable to the untreated. The data indicate that at the proposed dose 3 l/ha of 'GLOB1817H' is unlikely to have a significant negative effect on the yield of winter cereals

Overall, the data have shown that neither the proposed dose of GLOB1817H nor 2N are likely to have a significant negative impact on the TGW, hectolitre weight of winter cereals. Therefore, it is considered that the proposed uses of GLOB1817H are unlikely to have a significant negative impact on quality of claimed crops.

Information on the occurrence or possible occurrence of the development of resistance
The applicant addresses all points of the EPPO Standard PP 1/213 to evaluate the possible actual resistance risk of GLOB1817H and claims that the active substances prosulfocarb, diflufenican and halauxifen-methyl which are combined in the product GLOB1817H act by different modes of action. Based on HRAC assessment the applicant stated due to this mixture with different modes of action, the risk for development of resistance is considered to be low.
Therefore, the risk of resistance development against GLOB1817H is considered to be low if the product is used in adherence with the proposed management strategy.
Based on submitted information it can be concluded to accept the data provided by the applicant.

Impact on other plants including adjacent crops
From the results presented, it can be concluded that a buffer zone of 1 m in combination with 90% drift reducing techniques, a buffer zone of 3 m in combination with 50% drift reducing techniques or a buffer zone of 10 m without drift reduction is needed to protect non-target plants after application of GLOB1817H according to the intended use.

Impact on succeeding crops
From the results presented and current knowledge, it can be concluded that there is a risk of adverse effects of GLOB1817H herbicide on succeeding crops. There is a particular risk if cereal crops have to be liquidated. In case of crop failure, for any reason, before sowing winter cereals, peas and sunflower and maize, the soil previously treated with GLOB1817H should be ploughed (ensure complete inversion of the furrow patch) or cultivated to a depth of 20 cm. Beans should not be sown within 12 months of product application. The recommendations proposed by the applicant are acceptable and should be included on the national label.

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: developmental 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)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	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)														
1	DE, CZ	Winter wheat (TRZAW), Winter barley (HORVW), Winter rye (SECCW), Triticale (TTLWI)	F	*Galium aparine, Centaurea cyanus, Papaver rhoeas, Viola arvensis, Stellaria media, Matricaria inodora, Veronica sp., Geranium sp., Matricaria chamomilla, Thlaspi arvense, Myosotis arvensis, Descurainia Sophia, Fumaria officinalis* and annual grasses *Apera spica-venti and Poa annua*.	Downward spraying	BBCH10-14, (sept)oct-dec	a) 1 b) 1	/	a) 3 b) 3	a) Prosulfocarb: 2.001 Diflufenican: 0.042 Halauxifen-methyl: 0.00399 b) Prosulfocarb: 2.001 Diflufenican: 0.042 Halauxifen-methyl: 0.00399	200-300	/	Cloquintocet-mexyl: 0.00399 kg/ha	C
2	PL	Winter wheat (TRZAW), Winter barley (HORVW), Winter rye (SECCW), Triticale (TTLWI)	F	*Centaurea cyanus, Viola arvensis, Papaver rhoeas, Tripleurospermum inodorum, Galium aparine, Stellaria media, Veronica persica, Matricaria chamomilla, Myosotis arvensis, Thlaspi arvense* and grass *Apera spica-venti*	Downward spraying	BBCH10-14, (sept)oct-dec	a) 1 b) 1	/	c) 3 d) 3	c) Prosulfocarb: 2.001 Diflufenican: 0.042 Halauxifen-methyl: 0.00399 d) Prosulfocarb: 2.001 Diflufenican: 0.042 e) Halauxifen-methyl: 0.00399	200-300	/	Cloquintocet-mexyl: 0.00399 kg/ha	A

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

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

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

This core assessment dossier summarises the information related to the efficacy of the plant protection product GLOB1817H, an emulsifiable concentrate formulation (EC) containing the active ingredients prosulfocarb (667 g/L), diflufenican (14 g/L) and halauxifen-methyl (1.33 g/L) for early post-emergence weed control in cereals, in combination with the safener cloquintocet-mexyl (1.33 g/L).

Poland is considered to be the zonal Rapporteur Member State (zRMS) of this submission for the Central zone, while France is considered to be the zRMS for the Southern zone according to the Regulation No. 1107/2009. At the time of submission, Czech Republic and Germany are also included as concerned Member States (cMS) for the Central zone and Italy and Spain are cMS for the Southern zone. Trials included in the BAD were therefore performed across the concerned climatic zones, including the Maritime, North-East and Mediterranean EPPO Zones according to the EPPO standard PP1/241. Only data from relevant climatic regions for the Central zone are summarized in this dRR, except for preliminary tests, where results are reported across all available EPPO zones.

The active ingredients were included into Annex I of Directive 91/414, repealed by Regulation (EC) No 1107/2009 (Directive 2007/76/EC for prosulfocarb, Directive 2008/66/EC for diflufenican and Directive 1165/2015/EC for halauxifen-methyl). The review reports for prosulfocarb (SANCO/2824/07 – 10/09/2007), for diflufenican (SANCO/3782/08 – 14/03/2008) and for halauxifen-methyl (SANTE/10406/2015 rev. 1 – 29/05/2015 [updated 26 January 2018]) are considered to provide the relevant review information or a reference to where such information can be found.

The Annex I Inclusion Directive for the active substances provides specific provisions under Part B which need to be considered by the applicant in the preparation of their submission and by the MS prior to granting an authorisation.

For the implementation of the uniform principles of Annex VI, the conclusions of the review report on the active substances, and in particular Appendices I and II thereof, as finalised in the corresponding Standing Committee on Plants, Animals, Food and Feed shall be taken into account.

In this overall assessment there are however no efficacy related concerns.

Description of active substances

The active substances prosulfocarb and diflufenican are old active substances registered in many EU countries and used for the weed control in cereals.

Prosulfocarb was first developed by Syngenta in the 1980s and commercialized in Europe in winter cereals in 1988. It is effective against a range of grass and broadleaf weeds, it can handle some difficult problems, (like herbicide-resistant weeds), it’s safe to the crop and it offers some residual activity for longer control. It is available either alone or in mixture with other herbicides.

Diflufenican was developed in 1979 by Bayer CropScience and has been widely used in agriculture since the mid-1980s, as both a pre- and early post-emergent herbicide for certain broadleaf weeds.The product originally became one of the leading cereal herbicides in Europe, where it is predominantly sold in mixtures with other herbicides such as flufenacet, aclonifen and pendimethalin.

On the contrary, halauxifen-methyl is a relatively new active substance, developed by Dow AgroSciences (now Corteva) and is only available in mixture with other herbicides (either florasulam

or aminopyralid). It is a post-emergence herbicide that can be used in winter and spring cereals against a range of broadleaf weeds.

The applicant considers that the mixture of prosulfocarb and diflufenican with halauxifen-methyl is not yet approved in any country.

Mode of action

Prosulfocarb

Prosulfocarb is a thiocarbamate, belonging to the HRAC/WSSA Group 15 (former N) (lipid inhibitors). Other herbicides belonging to Group 15 are the benzofuranes, chloro-carbonic-acids and phosphorodithioates like benfuresate and ethofumesate (both benzofuranes), TCA (chloro-carbonic-acid) and bensulide (phosphorodithioate).

It provides selective weed control in a range of crops, when applied either pre-emergence or post-emergence. Certain grass and broad-leaved weeds are controlled through inhibition of the process of lipid synthesis. Uptake of prosulfocarb into plants from pre-emergence application usually results in the death of weed seedlings prior to emergence. Those which do emerge die quickly. It is believed that the primary site of action is at the apical meristem which passes through the herbicide-containing soil layer before emergence at the soil surface. Where application is made at early (up to 2 leaf) post-emergent growth stages of weeds, prosulfocarb enters through the foliage and moves towards the growing points. The meristem is killed quickly, leading to death of the whole plant.
Typical symptoms of thiocarbamate injury in susceptible plants include dark greening, inhibition of shoot and root and failure of leaf emergence from coleoptiles of grass species. Application to larger plants results in severe necrosis of meristem and surrounding tissues.

Diflufenican

Diflufenican is an old member of the chemical group of the pyridinecarboxamides which inhibit the carotenoids biosynthesis at the phytoene desaturase step (PDS) thus acting as a bleacher and for which no resistance to diflufenican has ever been reported in Europe after many years of use although the target weeds of diflufenican are mainly annual ones. This is HRAC/WSSA group 12 (former F1). This group is devided in three subgroups:
Diphenyl heterocycles, N-Phenyl heterocycles and Phenyl ethers, this last one to which duflufenican belongs.

Diflufenican is a selective contact and residual herbicide, absorbed principally by the shoots of germinating seedlings, with limited translocation. When Diflufenican is applied in pre-emergence, it is strongly absorbed in the soil surface (2 cm deep) forming a continuous layer on the surface which is resistant to the runoff and persists during the plant cycle. Once it is absorbed, it is translocated towards the apical tissues where the carotenoid biosynthesis is avoided. This causes chlorosis in the new shoots followed by a pinkish mauve discoloration and finally the plantings dry up. When it is applied in post-emergence, it goes through the leaves and is translocated to the apical tissues. Diflufenican is applied in pre or early post-emergence on autumn-sown cereals to control grass and broad-leaved weeds.

Halauxifen-methyl

Halauxifen-methyl is a member of the arylpicolinates (Pyridine-carboxylic acids) group of herbicides whose mode of action is synthetic auxin, HRAC/WSSA group 4 (former Group O). Halauxifen-methyl acts by inducing characteristic auxin-type responses, e.g. leaf curling. These herbicides disrupt hormone balance and protein synthesis in plants, leading to a variety of plant growth abnormalities. It is

considered that the site(s) of action is unknown and halauxifen-methyl is believed to have multiple sites of action.

Used as a post-emergence herbicide on a variety of winter cereals (wheat, spelt, barley, rye and triticale) and spring cereals (wheat, durum wheat and barley) for the control of a range of broad leaved weeds, there are no cases of resistance to halauxifen-methyl worldwide.

Given the characteristics of the 3 active substances, GLOB1817H is to be used for post-emergence control of grass and broadleaved weeds in winter cereals.

Table 3.2-2: Details of the active substances in GLOB1817H

Active substance	Prosulfocarb	Diflufenican	Halauxifen-methyl
Concentration (Unit: g/kg or g/L...)	667 g/L	14 g/L	1.33 g/L
Chemical group	thiocarbamates	phenyl ethers	pyridine-carboxylates
Mode of action	lipid synthesis inhibitor	carotenoid biosynthesis inhibitors	synthetic auxin
Biological action	Pre and post-emergence control of grasses and broadleaved weeds	Pre and post-emergence control of grasses and broadleaved weeds	Post-emergence control of broadleaved weeds

Description of the plant protection product

The product GLOB1817H contains prosulfocarb (667 g/L), diflufenican (14 g/L) and halauxifen-methyl (1.33 g/L). The other ingredients are the safener cloquintocet-mexyl (1.33 g/L) and co-formulants. Information on the detailed composition can be found in the confidential dossier of this submission (Registration Report - Part C).

The appearance of the product is that of an emulsifiable concentrate formulation (EC). It is not explosive, has no oxidising properties. It does not self-ignite. The stability data indicate a shelf life of at least 2 years at ambient temperature.
Its technical characteristics are acceptable for an EC formulation and such that no particular problems are to be expected when GLOB1817H is used as recommended.

The classification proposal GLOB1817H according to Regulation (EC) 1272/2008 (CLP Regulation) can be found in Part A of this submission.

Table 3.2-3: Simplified table of currently registered uses and requested uses for GLOB1817H

Uses		Member State	Requested rate(s)	Comments / Other relevant details on GAPs
Crop(s)	Target(s)			
Winter wheat (TRZAW), Winter barley (HORVW), Winter rye (SECCW), Triticale (TTLWI)	Annual broad leaved weeds (BBBAN) & grasses (GGGAN)	PL, CZ, DE	0.3 L/ha	1 application post-emergence (BBCH10-14)

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

Description of the target weeds

Table 3.2-4: Glossary of pests mentioned in the dossier

Group	EPPO code		Scientific name	Common name
Broad leaf	ANGAR		*Anagallis arvensis*	Scarlet pimpernel
	BRSNW		*Brassica napus*	Winter rape
	CAPBP		*Capsella bursa-pastoris*	Shepherd's purse
	CENCY		*Centaurea cyanus*	Bachelor's- button, cornflower
	CENDL		*Centaurea diluta*	North African knapweed
	CHYSE		*Glebionis segetum*	Corn marigold
	CLDAR		*Calendula arvensis*	Field calendula
	DESSO		*Descurainia sophia*	Flixweed
	DIPMU		*Diplotaxis muralis*	Sand rocket
	FUMOF		*Fumaria officinalis*	Common fumitory
	GALAP		*Galium aparine*	Cleavers
	1GERG Geranium spp.	GERDI	*Geranium dissectum*	Cut-leaf geranium
		GERPU	*Geranium pusillum*	Small-flower geranium
		GERRT	*Geranium rotundifolium*	Round-leaved cranesbill
	1 LAMG Lamium spp.	LAMAM	*Lamium amplexicaule*	Henbit
		LAMPU	*Lamium purpureum*	Purple deadnettle
	MATCH		*Matricaria chamomilla*	Wild chamomile
	MATIN		*Tripleurospermum inodorum*	False chamomille, scentless mayweed
	MYOAR		*Myosotis arvensis*	Field forget-me-not
	PAPRH		*Papaver rhoeas*	Common poppy
	PAPRS		*Papaver rhoeas subsp. strigosum*	Papaver rhoeas subsp. strigosum
	SENVU		*Senecio vulgaris*	Common groundsel
	SINAR		*Sinapis arvensis*	Wild mustard
	SSYOF		*Sisymbrium officinale*	Hedge mustard
	STEME		*Stellaria media*	Common chickweed
	THLAR		*Thlaspi arvense*	Fanweed
	1VERG Veronica spp.	VERAG	*Veronica agrestis*	Field speedwell
		VERAR	*Veronica arvensis*	Corn speedwell
		VERHE	*Veronica hederifolia*	Ivy-leaved speedwell
		VERPE	*Veronica persica*	Bird's-eye speedwell
		VERSS	*Veronica sp.*	Speedwell
	VICCR		*Vicia cracca*	Bird vetch
	VIOAR		*Viola arvensis*	Field violet
Grasses	ALOMY		*Alopecurus myosuroides*	Blackgrass
	APESV		*Apera spica-venti*	Windgrass
	1AVEG Avena spp.	AVESA	*Avena sativa*	Common oat
		AVEST	*Avena sterilis*	Sterile oat
	LOLMU		*Lolium multiflorum*	Italian ryegrass
	LOLPE		*Lolium perenne*	Perennial ryegrass
	LOLRI		*Lolium rigidum*	Swiss ryegrass
	POAAN		*Poa annua*	Annual bluegrass
Rushes	IUNBU		*Juncus bufonius*	Toad rush

The weed susceptibility scale used in this BAD is shown in the table below.

Table 3.2-5: Susceptibility scale

Weed species susceptibility	Level of control
Highly Susceptible (HS)	95 - 100 %
Susceptible (S)	85 - 94.9 %
Moderately Susceptible (MS)	70 - 84.9%
Moderately Tolerant (MT)	50 - 69.9%
Tolerant (T)	0 - 49.9 %

Table 3.2-6: Major / minor status of intended uses (for all cMS and zRMS).

Crop and/or situation	Crop status		Pests or group of pests controlled	Pest status	
	Major	minor		Major	minor
Winter wheat (soft) (TRZAW)	PL, DE, CZ	-	Annual grassy weeds and Annual dicotyledonous weeds	PL, DE, CZ	-
Winter durum wheat (TRZDW)	-	PL, DE, CZ		-	-
Winter barley (HORVW)	PL, DE, CZ	-		PL, DE, CZ	
Winter rye (SECCW)	PL, DE, CZ	-		PL, DE, CZ	-
Winter triticale (TTLWI)	PL, DE, CZ	-		PL, DE, CZ	-

Compliance with the Uniform Principles

All data submitted in this dossier are in compliance with the Uniform Principles.

Information on trials submitted (3.2 Efficacy data)

The following table aims to give an overview of submitted trials.

Table 3.2-7: Presentation of trials (efficacy trials, preliminary trials...)

Target(s)	Crop	Country	Years	Type of trial**	Number of trials		GEP, non-GEP, official***	Comments (any other relevant information)
					Maritime zone	North-East zone		
Annual broad leaved weeds (BBBAN) & grasses (GGGAN)	HORVW	PL	2018	P+E+MED		1	GEP	-
	SECCW	DE	2018	P+E+MED	1		GEP	-
	TRZAW	CZ	2018	P+E+MED	4		GEP	-
			2019	E+MED	5		GEP	-
		DE	2018	P+E+MED	3		GEP	-
			2019	E+MED	2		GEP	-
		NL	2018-2019	E+MED	2		GEP	-
		FR	2018-2019	E+MED	4		GEP	-
		PL	2018	P+E+MED		2	GEP	-
			2019	E+MED		3	GEP	-
	TTLWI	DE	2018	P+E+MED	1		GEP	-
			2019	E+MED	1		GEP	-

		PL	2018	P+E+MED		2	GEP	-
			2019	E+MED		2	GEP	-
Total			**2018-2019**	**-**	**23**	**10**	**-**	**All zones: 33**

* 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).
** P = preliminary trial, MED = minimum effective dose, E = efficacy trial.
*** GEP: Good Experimental Practices. Official: carried out by a national official organisation.

Table 3.2-8: Presentation of trials used exclusively on preliminary section

Target(s)	Crop	Country	Years	Type of trial**	Number of trials			GEP, non-GEP, official***	Comments (any other relevant information)
					Marit. zone	North-East zone	Medit. zone		
Annual broad leaved weeds (BBBAN) & grasses (GGGAN)	HORVW	DE	2017	P	1			GEP	-
	TRZAW	CZ	2017	P	1			GEP	-
			2017	P	1			GEP	-
		DE	2017	P	2			GEP	-
		FR	2017	P			1	GEP	-
		HR	2017	P			1	GEP	-
	TTLWI	PL	2017	P		1		GEP	-
Total			**2017**	**-**	**5**	**1**	**2**	**-**	**All zones: 8**

* 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).
** P = preliminary trial, MED = minimum effective dose, E = efficacy trial.
*** GEP: Good Experimental Practices. Official: carried out by a national official organisation.

Table 3.2-9: Presentation of reference standards used in efficacy trials

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)	Remark(4)
					Type(2)	Concentr. of a.s.			
Cereals	Jura (=Jura EC)	PL	R -108/2017	Prosulfocarb + Diflufenican	EC	667 g/L + 14 g/L	4 L/ha	4 L/ha	
		DE	008324-00				Max. 4 L/ha	4 L/ha	
		CZ	5244-0				4 L/ha	4 L/ha	
		NL	-				-	3-4 L/ha	
		FR	-				-	4 L/ha	
	Roxy (=Roxy 800 EC)	DE	-	Prosulfocarb	EC	800 g/L	-	5 L/ha	
		CZ	5290-0				4 L/ha	4 L/ha	
		NL	13164 N				Max. 5 L/ha	5 L/ha	
		FR	2090186				Max. 5 L/ha	5 L/ha	
	Boxer (=Boxer 800 EC)	DE	033838-00				Max. 5 L/ha	N: 5 L/ha	
		PL	R- 88/2015				3 L/ha	N: 3 L/ha	

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

3.2.1 Preliminary tests (KCP 6.1)

Effects of prosulfocarb are well known, nevertheless, the amounts of a.s. required for effective control are quite high. About 5 years ago, Globachem introduced on the market Jura, a mixture of prosulfocarb (PRO) and diflufenican (DFF), which allowed to reduce the amount of prosulfocarb applied by about 30%, also demonstrated an enhanced and broader spectrum of control compared to straight formulations. Jura's full rate is 4 L/ha (PRO 2668g/ha + DFF 56g/ha). In some countries (e.g. Germany), recomended rates in practice may start already from 3 L/ha.

The product under submission, GLOB1817H, aimed to further reduce the needed amount of prosulfocarb by adding a relatively new compound, halauxifen-methyl (HXN), which also improves the control of broad leaved weeds.

Therefore, a total of 22 trials trials were carried out to evaluate the efficacy of different rates of Jura (known to be effective), tested in combination with different amounts of halauxifen-methyl for the control of dicotyledonous and grass weeds in winter cereals. Of those, 8 trials were performed early in 2017, by comparing formulations GLOB1316H and GLOB1317H and 14 trials were performed during 2018 by comparing the formulations GLOB1815H and GLOB1817H. In addition, during 2017 trials, a combination of only prosulfocarb and halauxifen-methyl (GLOB1315H) was tested.

14 trials were performed in the Maritime EPPO Zone, 6 trials were performed in the North-East EPPO Zone (Poland), while other 2 trials were performed in the Mediterranean EPPO zone. All trials from Maritime zone were conducted in DE or CZ and therefore are deemed to support also the authorization in Poland. Given the preliminary character of the analysis, results in this section are reported across the EPPO zones. Means are calculated among all cereals (EPPO code YCERE).

The formulations tested are presented in the table below:

a.s./L / PPP	PRO	DFF	HXN
Jura	667	14	-
GLOB1815H	667	14	1.1
GLOB1817H	**667**	**14**	**1.3**
GLOB1316H	667	14	1.4
GLOB1317H	667	14	2
GLOB1315H	800	-	1.7

Table 3.2-10 and Table 3.2-11 summarize the results of weed control at the assessment at the end of spring, from trials testing Jura at 3 and 4 L/ha, as well as different rates of the formulations GLOB1316H, GLOB1317H and GLOB1315H for 2017 trials and GLOB1815 and GLOB1817 for 2018 trials. Results are presented limited to weeds that occurred on at least 2 different trials.

A color grade scheme was used to highlight, for each weed, differences in efficacy among the formulations. The darker the green, the higher the efficacy.

On average, the rates of PRO 2001g/ha + DFF 42g/ha + HXN 3.3 to 4.2g/ha provided the best results with the minimun amount of a.s. needed. These rates were comparable or even superior to the efficacy provided by the reference product at its label rate, and the addition of HXN clearly increases the control broadly.

Although good results were achieved already at the rate of 3.3 g of halauxifen-methyl (HXN)/ha, in view of an anti-resistance strategy, it was decided not to go below 2/3 of the amount currently used in other herbicide mixtures containing halauxifen-methyl, wich is 6 g a.s./ha.

The rate of 3 L/ha of GLOB1817H was thus selected and included in large scale trial series and results are provided in the efficacy section (KCP 6.2). Lower rates were also tested in order to confirm the minimum effective dose.

Comments of zRMS:	The presented results, of three components in GLOB1817H prosulfocarb, diflufenican and halauxifen-methyl demonstrated activity against weed in cereals. GLOB1817H demonstrated at least comparable control and frequently superior control of weed compared to the standard product JURA. Therefore, the inclusion of proposed amount of prosulfocarb (667 g/L), diflufenican (14 g/L) and halauxifen-methyl (1.33 g/L) in the formulation GLOB1817H are fully justified.

Table 3.2-10: Justification to combine the active ingredients in GLOB1817H – 2017 trials

Target code	EPPO zone	Target group	Crop code	Grouping	Crop BBCH at appl.	Weed BBCH at appl.	Nb. trials	DA-A	Infestation in the untreated control (PLANT/M2)		Jura at 3 L/ha PRO 2000g/ha + DFF 42g/ha		Jura at 4 L/ha PRO 2670g/ha + DFF 56g/ha		GLOB1316H at 4 L/ha PRO 2668g/ha + DFF 56g/ha + HXN 5,6g/ha		GLOB1316H at 3 L/ha PRO 2001g/ha + DFF 42g/ha + HXN 4.2g/ha		GLOB1317H at 3 L/ha PRO 2001g/ha + DFF 42g/ha + HXN 6g/ha		GLOB1315H at 3..5 L/ha PRO 2800g/ha + HXN 5,95g/ha		GLOB1315H at 2.5 L/ha PRO 2000g/ha + HXN 4,25g/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	MAR+NE +MED	grasses	YCERE	All	12-13	0-12	5	156-202	18.0	5-44.5	93.1	82.5-100	95.7	86.3-100	95.8	87.5-100	95.4	88.8-100	96.8	92.5-100	97.2	93.8-100	93.9	87.5-100
CENCY	MAR+NE	broad leaved	YCERE	All	12-13	11-12	5	159-216	28.8	5-93.8	91.9	75.8-100	95.7	86.3-100	97.8	91.3-100	97.0	87.5-100	96.5	90-100	99.0	95-100	96.1	82.5-100
GALAP	MAR	broad leaved	YCERE	All	12-13	0-12	6	156-216	18.5	5-32	89.8	68.5-100	92.7	74.3-100	93.5	77.3-100	91.5	71.8-100	92.2	77.8-100	86.9	66.3-100	87.1	70-100
MATCH	MAR+NE	broad leaved	YCERE	All	12-13	14-14	2	134-202	16.6	12.2-21	85.6	71.3-100	86.9	73.8-100	96.8	93.5-100	96.3	92.5-100	96.1	92.3-100	91.3	82.5-100	82.5	65-100
MATIN	MAR	broad leaved	YCERE	All	12-12	11-11	2	159-190	113.5	40-187	86.9	73.8-100	93.4	86.8-100	99.1	98.3-100	99.0	98-100	100.0	100-100	96.3	92.5-100	93.4	87.3-99.5
PAPRH	MAR+NE	broad leaved	YCERE	All	12-13	11-14	4	134-202	13.3	5-22.5	92.3	78.8-100	91.3	75-100	96.5	91.3-100	95.6	91.3-100	95.0	88.8-100	89.1	63.8-100	87.2	62.5-100
1VERG	MAR+NE	broad leaved	YCERE	All	12-13	11-14	3	134-216	8.7	5-13	81.0	71.3-100	82.9	71.3-100	92.0	81-100	88.8	72.5-100	91.9	81-100	88.5	80-100	83.1	73-100
VIOAR	MAR+NE	broad leaved	YCERE	All	12-12	11-11	2	190-202	135.9	18.7-253	97.4	96.5-98.3	99.0	98-100	99.3	99-99.5	97.5	97-98	96.9	95-98.8	69.4	51.3-87.5	48.1	16.3-80

Table 3.2-11: Justification to combine the active ingredients in GLOB1817H – 2018 trials

Target code	EPPO zone	Target group	Crop code	Grouping	Crop BBCH at appl.	Weed BBCH at appl.	Nb. trials	DA-A	Infestation in the untreated control (plant/m^2)		Jura at 3 L/ha PRO 2000g/ha + DFF 42g/ha		Jura at 4 L/ha PRO 2670g/ha + DFF 56g/ha		GLOB1815H at 3.6 L/ha PRO 2400g/ha + DFF 50,4g/ha + HXN 3,96g/ha		GLOB1815H at 3 L/ha PRO 2000g/ha + DFF 42g/ha + HXN 3,3g/ha		GLOB1815H at 1.8 L/ha PRO 1200g/ha + DFF 25,2g/ha + HXN 1,98g/ha		GLOB1817H at 3 L/ha PRO 2000g/ha + DFF 42g/ha + HXN 4g/ha		GLOB1817H at 1.8 L/ha PRO 1200g/ha + DFF 25,2g/ha + HXN 2,4g/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	MAR+NE	grasses	YCERE	All	11-14	10-12	10	173-246	56.2	7-225	93.5	65-100	96.5	82.5-100	96.1	76.3-100	95.9	75-100	92.4	62.5-100	95.6	67.5-100	92.6	60-100
CENCY	MAR+NE	broad leaved	YCERE	All	11-14	10-19	9	176-246	11.9*	5-36	64.3	0-100	70.4	0-100	98.9	91.3-100	98.9	91.3-100	98.5	90-100	98.9	91.3-100	98.3	86.3-100
DESSO	MAR	broad leaved	TRZAW	All	11-12	0-10	2	207-224	5.0	5-5	99.5	99-100	99.5	99-100	99.5	99-100	99.5	99-100	99.5	99-100	99.5	99-100	99.4	99-99.8
GALAP	MAR+NE	broad leaved	YCERE	All	11-14	10-22	10	176-246	11*	5-21	96.2	78.8-100	95.9	82.5-100	98.7	88.8-100	98.5	90-100	98.1	91.3-100	98.0	87.5-100	97.9	90-100
1GERG	MAR+NE	broad leaved	YCERE	All	12-13	0-13	3	42-213	39.2	5.5-105	88.0	65-100	87.6	63.8-100	99.3	99-100	99.3	99-100	99.3	99-100	96.3	90-100	99.3	99-100
MATCH	MAR	broad leaved	YCERE	All	11-12	9-11	2	207-218	16.0	8.3-23.8	97.9	96.8-99	97.6	96.3-99	97.9	96.8-99	92.0	85-99	84.8	70.5-99	94.9	90.8-99	62.0	25-99

MATIN	MAR+NE	broad leaved	YCERE	All	11-14	10-14	5	176-246	9.4	5-19	77.3	25-100	80.9	50-100	95.5	87.5-100	95.7	88.8-100	88.4	60-100	90.5	70-100	86.5	50-100
PAPRH	MAR+NE	broad leaved	YCERE	All	11-13	0-14	5	207-224	10.5	5-25	99.0	96-100	99.1	96.3-100	99.0	95.8-100	99.0	96-100	93.8	70-100	99.3	97.3-100	99.0	96.3-100
STEME	MAR+NE	broad leaved	YCERE	All	11-14	10-16	5	216-246	15.1	5-42.5	98.3	91.5-100	98.6	93-100	98.6	93-100	98.0	89.8-100	86.5	32.5-100	99.1	95.5-100	95.3	76.3-100
1VERG	MAR+NE	broad leaved	YCERE	All	11-13	0-16	5	176-246	7.5*	5-13	97.5	87.5-100	98.3	91.3-100	98.0	90-100	98.3	91.3-100	97.8	88.8-100	97.5	87.5-100	97.5	87.5-100
VIOAR	MAR+NE	broad leaved	YCERE	All	11-14	10-13	10	185-246	24.4*	7-40	98.6	91.3-100	97.2	85-100	96.0	75-100	98.6	91.3-100	94.5	56.8-100	98.4	90-100	95.9	73.8-100

* in 1 trial, weed pressure expressed in terms of % of ground cover and thus not included in means. Cover above 10%.

3.2.2 Minimum effective dose tests (KCP 6.2)

Reference is made to the efficacy trials submitted under section KCP 6.2. In all trials the efficacy of a lower dose rate of GLOB1817H was tested and compared to the advised dose rate. Field trials were carried out across several countries of the Central Zone to fully reflect the range of climatic and agronomic conditions. Details on trial methodology are are reported here under section 3.2.3 and in Appendix 3 of the Biological Assessment Dossier.

In total, 33 efficacy trials evaluated a lower dose rate. These trials were carried out between 2018 and 2019 by GEP certified research institutions in the Czech Republic, France, Germany, and the Netherlands (23 trials belonging to the Maritime EPPO Zone), as well as in Poland (10 trials belonging to the North-East EPPO Zone).

A summary of the most representative results (weeds occurred in at least 3 trials) regarding the minimum effective dose, evaluated at 100% of the target dose rate (3 L/ha) as well as 60% of ther full rate (1.8 L/ha) on winter cereals are shown in the tables below.

As an intermediate lower rate of 2.4 L/ha was included in part of the trials conducted in the North-East EPPO zone only, detailed results at this rate are not presented in section 3.2.3. Those data are presented here instead, summarizing trials where the effective dose was thus evaluated at 100%, 80% as well as 60% of ther full rate.

The levels of weed control are displayed in summary tables reflecting the common EU scale as reported in the guidance SANCO/10055/2013 Rev. 4:

Weed species susceptibility	**Level of control**
Highly Susceptible (HS)	95 - 100 %
Susceptible (S)	85 - 94.9 %
Moderately Susceptible (MS)	70 - 84.9%
Moderately Tolerant (MT)	50 - 69.9%
Tolerant (T)	0 - 49.9 %

Key results are also represented graphically through box and whisker charts. The ends of the whisker are set at 1.5*IQR above the third quartile (Q3) and 1.5*IQR below the first quartile (Q1). Outliers are shown as an asterisk. Bar within the box represents the median.

Conclusion

The results show that the requested dose rate of 3 L/ha in winter cereals provide the best control against most weeds. Furthermore, for some weeds a clear dose response relationship can be observed, with the highest dose rate having not only the highest efficacy, but also offering a more stable control throughout a wide range of climatic conditions.

However, for some weeds a lower dose rate could be sufficient, depening on the weed species. In particular, in a limited set of trials in the North-East EPPO zone, in conditions of lower pressure compared to the whole set of trials, the dose rate of 2.4 L still provided good control but for a reliable broad spectrum control, 3 L/ha is required across all zones.

Maritime EPPO zone

Table 3.2-12: Summary of the minimum effective dose of GLOB1817H on winter cereals at 100 and 60% of the proposed label rate– Maritime EPPO zone

Target code		Crop BBCH at appl.	Weed BBCH at appl.	Nb. trials	DA-A	Infestation in the untreated control (PLANT/M2)			GLOB1817H at 1.8 L/ha			GLOB1817H at 3 L/ha		
						Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn
grasses	APESV	11-14	10-16	16	173-249	59.3	5-225	27.5	88.9	40-100	99.0	95.9	67.5-100	99.9
	POAAN	11-16	0-21	4	93-232	15.3	10-28	11.7	81.6	50-99	88.8	93.5	90-99	92.5
broad leaved	CENCY	11-22	10-19	14	80-249	16.9	5-71.5	9.0	93.6	40-100	99.1	98.1	87.5-100	99.9
	GALAP	11-16	0-22	14	14-249	13.0	6-30	12.0	93.3	55-100	99.0	98.6	90-100	100.0
	1GERG	12-13	0-13	4	42-245	39.1	5.5-105	23.0	97.5	95-99	98.0	96.6	90-100	98.3
	MATCH	11-12	9-11	3	207-245	24.7	8.3-42	23.8	71.9	25-99	91.8	96.4	90.8-99.5	99.0
	MATIN	11-14	0-14	9	176-239	25.6	5-96.5	15.0	78.5	18.8-100	92.0	87.1	61.3-100	98.3
	MYOAR	11-11	10-12	3	200-232	20.5	6-30	25.5	73.8	22.5-100	99.0	95.8	88.3-100	99.0
	PAPRH	11-14	0-14	13	170-249	26.3	6-99	10.3	88.2	45-100	96.3	95.0	75-100	98.0
	STEME	11-16	0-16	9	93-249	17.2	5-42.5	16.0	87.7	45-100	96.5	98.8	95.5-100	100.0
	THLAR	11-13	0-14	3	200-239	22.8	8-50	10.3	99.7	99-100	100.0	99.7	99-100	100.0
	1VERG	11-16	0-16	6	93-239	10.5	5-18	9.5	100.0	100-100	100.0	99.4	96.3-100	100.0
	VIOAR	11-22	0-13	10	80-239	19.0	5-44.5	17.4	95.6	73.8-100	99.0	98.1	93.8-100	99.0

Grasses

Figure 3.2-1: Minimum Effective dose of GLOB1817H for the control of APESV (last spring assessment, n=16) – Maritime EPPO zone

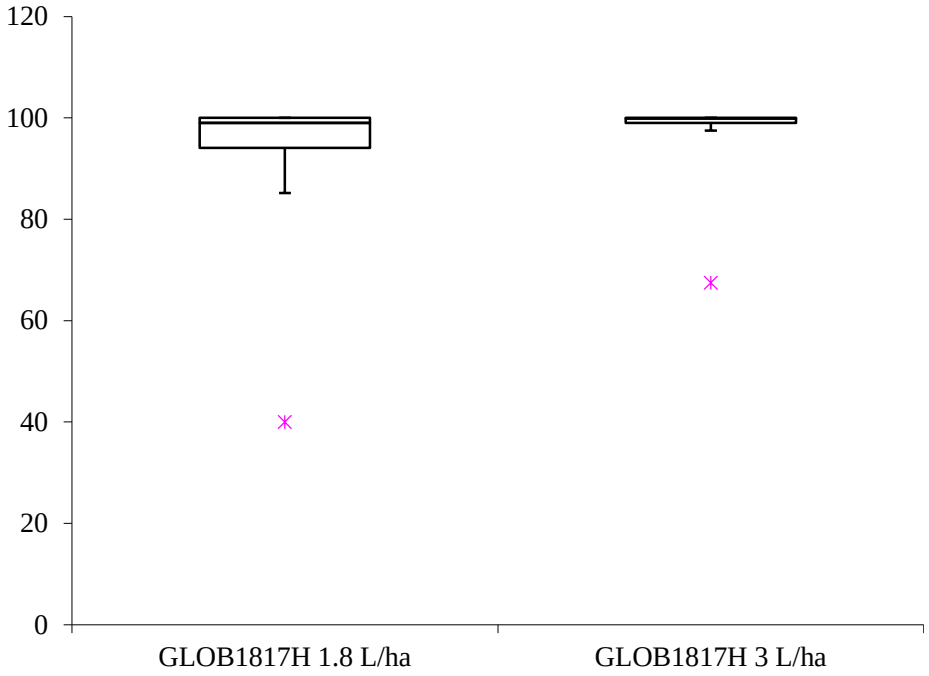


Figure 3.2-2: Minimum Effective dose of GLOB1817H for the control of POAAN (last spring assessment, n=4) – Maritime EPPO zone

Broad Leaved

Figure 3.2-3: Minimum Effective dose of GLOB1817H for the control of GALAP (last spring assessment, n=14) – Maritime EPPO zone

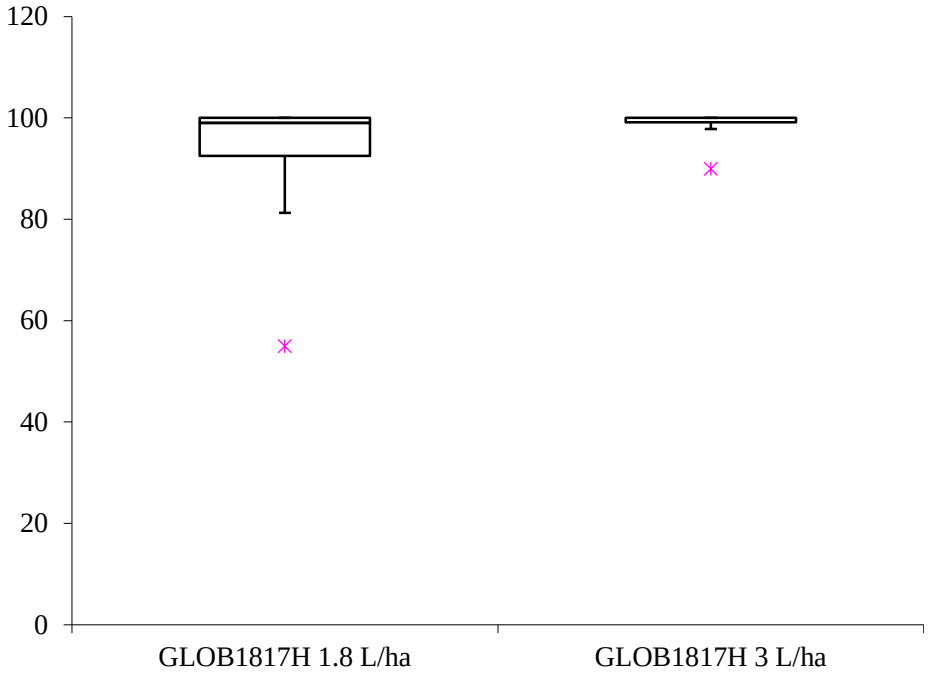


Figure 3.2-4: Minimum Effective dose of GLOB1817H for the control of MATCH (last spring assessment, n=3) – Maritime EPPO zone

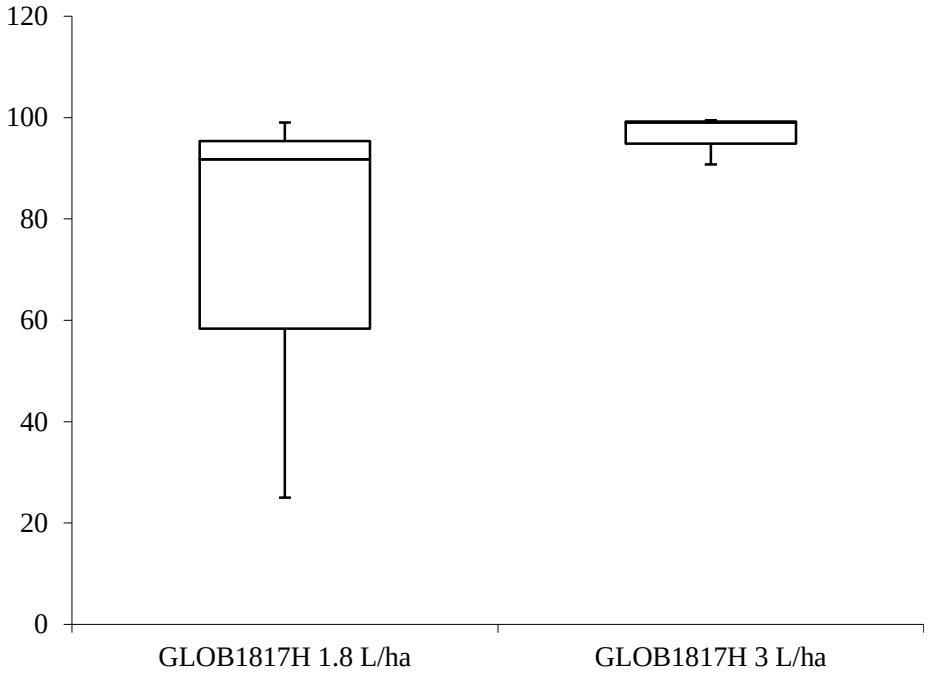


Figure 3.2-5: Minimum Effective dose of GLOB1817H for the control of MIOAR (last spring assessment, n=3) – Maritime EPPO zone

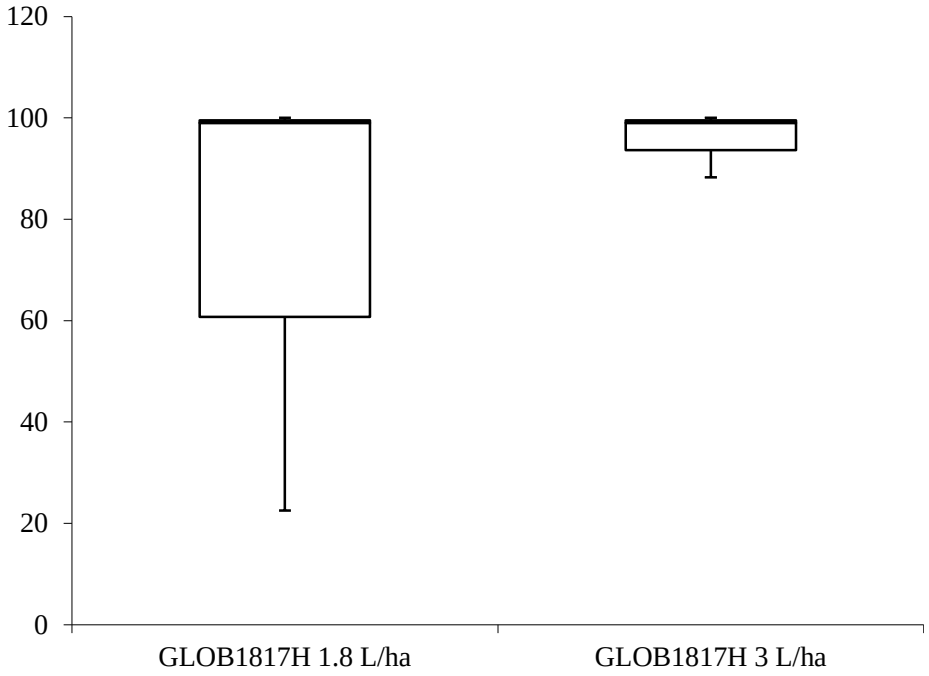


Figure 3.2-6: Minimum Effective dose of GLOB1817H for the control of STEME (last spring assessment, n=9) – Maritime EPPO zone

North-East EPPO zone

As an intermediate lower rate of 2.4 L/ha was included in half of the trials conducted in the North-East EPPO zone (5 out of 10 trials), detailed results of weed control at 100%, 80% as well as 60% of the full rate are presented here. Since this is a limited number of trials, also results for weeds that occurred in 1 or 2 trials are summarized. Detailed data are reported in

Table 3.2-13: Summary of the minimum effective dose of GLOB1817H on winter cereals at 100 and 60% of the proposed label rate– North-East EPPO zone

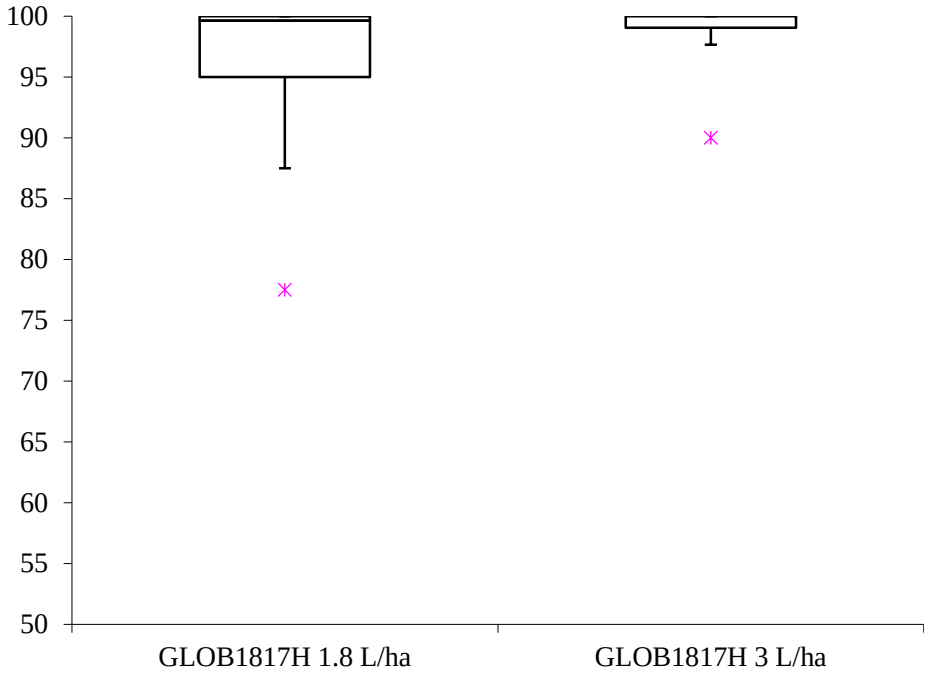
Target code		Crop BBCH at appl.	Weed BBCH at appl.	Nb. trials	DA-A	Infestation in the untreated control (PLANT/M2)			GLOB1817H at 1.8 L/ha (60% of full rate)			GLOB1817H at 3 L/ha (Full rate)		
						Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn
grasses	APESV	12-21	10-13	8	187-246	17.7	5-38	16.0	95.8	77.5-100	99.6	98.3	90-100	100.0
broad leaved	CENCY	12-14	10-13	8	187-246	12.9	6-36	9.0	97.8	86.3-100	100.0	98.6	91.3-100	100.0
	GALAP	11-13	0-12	8	156-246	7.9	5-21	5.0	98.4	90-100	100.0	98.4	87.5-100	100.0
	MATIN	13-14	10-13	3	220-246	12.0	7-19	10.0	99.2	97.5-100	100.0	99.2	97.5-100	100.0
	PAPRH	11-14	0-13	5	156-220	9.1	5-18	6.3	99.0	97.5-100	100.0	99.3	96.3-100	100.0
	STEME	12-21	10-13	5	192-246	8.1	5.3-12	7.0	98.0	93.8-100	100.0	98.6	96.3-100	100.0
	1VERG	12-13	0-11	3	216-246	9.0	5-13	9.0	95.8	87.5-100	100.0	95.8	87.5-100	100.0
	VIOAR	11-14	10-13	8	156-246	22.7	9-40	19.0	96.7	87.5-100	100.0	98.1	90-100	100.0

Table 3.2-14: Summary of the minimum effective dose of GLOB1817H on winter cereals at 100, 80% and 60% of the proposed label rate– North-East EPPO zone

Target code	Crop BBCH at appl.	Weed BBCH at appl.	Nb. trials	DA-A	Infestation in the untreated control (PLANT/M2)			GLOB1817H at 1.8 L/ha (60% of full rate)			GLOB1817H at 2.4 L/ha (80% of full rate)			GLOB1817H at 3 L/ha (Full rate)		
					Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn
APESV	12-21	10-13	4	187-220	12.6	5-17	14.3	98.8	95-100	100.0	99.1	96.3-100	100.0	99.1	96.3-100	100.0
BRSNW	12-12	11-11	1	187	14.0	14-14	14.0	100.0	100-100	100.0	100.0	100-100	100.0	100.0	100-100	100.0
CAPBP	21-21	11-11	1	218	8.0	8-8	8.0	98.8	98.8-98.8	98.8	90.0	90-90	90.0	100.0	100-100	100.0
CENCY	12-14	12-13	3	187-220	9.3	8-11	9.0	98.8	96.3-100	100.0	98.8	96.3-100	100.0	99.2	97.5-100	100.0
GALAP	11-12	0-12	3	156-192	5.3	5-6	5.0	99.2	97.5-100	100.0	100.0	100-100	100.0	100.0	100-100	100.0
LAMPU	21-21	13-13	1	218	10.0	10-10	10.0	100.0	100-100	100.0	93.8	93.8-93.8	93.8	100.0	100-100	100.0
MATIN	14-14	13-13	1	220	7.0	7-7	7.0	97.5	97.5-97.5	97.5	95.0	95-95	95.0	97.5	97.5-97.5	97.5
PAPRH	11-14	0-13	4	156-220	10.1	5.3-18	8.7	98.8	97.5-100	98.8	98.4	95-100	99.4	99.1	96.3-100	100.0
STEME	12-21	10-13	3	192-220	7.1	5.3-10	6.0	96.7	93.8-100	96.3	94.2	85-100	97.5	97.7	96.3-100	96.8
VIOAR	11-14	11-13	3	156-220	13.0	9-19	11.0	95.4	90-100	96.3	97.5	93.8-100	98.8	98.8	96.3-100	100.0

Grasses

Figure 3.2-7: Minimum Effective dose of GLOB1817H for the control of APESV (last spring assessment, n=8) – North-East EPPO zone



Broad Leaved

Figure 3.2-8: Minimum Effective dose of GLOB1817H for the control of PAPRH (last spring assessment, n=5) – North-East EPPO zone

Figure 3.2-9: Minimum Effective dose of GLOB1817H for the control of VIOAR (last spring assessment, n=8) – North-East EPPO zone

Comments of zRMS:	**Maritime EPPO zone** To determine the minimum effective dose for the control of weed in winter cereals by GLOB1817H, the applicant presented data from 23 field trials. GLOB1817H was tested at doses 1,8 L/ha (60% of the target dose rate) was compared with the full recommended rate of 3.0 L/ha of GLOB1817H, under EPPO standard PP 1/225 'Minimum effective dose'. A clear dose-response was observed for almost all tested weeds, except *Geranium sp. Veronica sp*, THLAR and VIOAR where the weeds were controlled above 90% with two application rates, the full application rate 3.0 L/ha and reduced application rate 1,8 L/ha. A very marked dosage-response was observed for grasses APESV, POAAN and broad-leaved CENCY, GALAP, MATCH, MATIN, MYOAR, PAPRH, STEME. For these weeds the lower dosage rate (1,8 L/ha) provided inferior but still good control and the increase of the dosage rate to the full application rate of 3,0 L/ha lead to very good control. The justification of the proposed application rate of 3,0 L/ha will be accepted. **North East EPPO zone** To determine the minimum effective dose for the control of weed in winter cereals by GLOB1817H, the applicant presented data from 10 field trials. GLOB1817H was tested at doses 1,8 L/ha, 2,4 L/ha (60%, 80% of the target dose rate) was compared with the full recommended rate of 3.0 L/ha of GLOB1817H, under EPPO standard PP 1/225 'Minimum effective dose'. No clear dose-response was observed for all tested weeds, all application rates provided similar very good control of tested weed. Since limited results were available for BRSNW, CAPBP, LAMPU, MATIN these weed results may not be representative. The justification of the proposed application rate of 3,0 L/ha will be accepted.

3.2.3 Efficacy tests (KCP 6.2)

In total, 33 efficacy trials were submitted to demonstrate the efficacy of GLOB1817H for the use on winter cereals. These trials were carried out between 2018 and 2019 by GEP certified research institutions in the Czech Republic, France, Germany, and the Netherlands (23 trials belonging to the Maritime EPPO Zone), as werll as in Poland (10 trials belonging to the North-East EPPO Zone).

Trial methodology

Information on trial methodology is summarized in Table 3.2-15 and Table 3.2-16. Trial site information and application details are presented in Appendix 3 of the Biological Assessment Dossier.

All trials were carried out by testing facilities, or organisations, officially recognised as competent to perform efficacy testing in accordance with the requirements of Directive 93/71/EEC, and with the principles of GEP. Copies of certificates can be found in the Biological Assessment dossier.

According to the EPPO reference standard PP 1/93 (3) Weeds in cereals, a preliminary assessment of the weed population in terms of plant counting as well as soil coverage was performed in all trials. Following assessments were in general at 2 weeks after the application, during tillering (BBCH 21-29), around flag leaf emergence (BBCH 37-39) and a last assessment from the end of flowering until shortly before harvest.

Data were subjected to analysis of variance (ANOVA) at the 95% confidence level. When significant differences were found a Student-Newman-Keuls (SNK) Post-Hoc test was applied to separate the means. Treatment means with no letters in common are significantly different according to SNK test. Where no letter is presented no difference was registered among treatments.

The percentage of visual control at the final spring assessment containing enough weeds per square meters were summarized below for each weed. The minimum population of 5 plants/m² was considered for validation of the trial and assessment timing. Other assessments not considered for means calculation are presented shaded in grey in the Biological Assessment dossier. The final spring assessment, besides having a higher weed pressure compared to earlier assessments, also provides a long term view of the effects of the herbicide applied just after emergence. In very few cases, when the above criteria could not be met, an earlier assessment was chosen. Whenever a given weed was present in trials on different crops, means were calculated among all cereals (EPPO code YCERE).

The number of trials where product is >, <, = compared to standards is provided orthogonally.

The levels of weed control are displayed in summary tables reflecting the common EU scale as reported in the guidance SANCO/10055/2013 Rev. 4:

Weed species susceptibility	Level of control
Highly Susceptible (HS)	95 - 100 %
Susceptible (S)	85 - 94.9 %
Moderately Susceptible (MS)	70 - 84.9%
Moderately Tolerant (MT)	50 - 69.9%
Tolerant (T)	0 - 49.9 %

Table 3.2-15: Details on trial methodology – Maritime EPPO zone

Guidelines	General guidelines	PP 1/135(4), EPPO PP 1/152 (4), PP 1/181(4)
	Specific guidelines	EPPO PP 1/93(3)
Experimental design	Plot design	RCBD (23)
	Plot size	12-24 m²
	Number of replications	4 (22), 3(1)
Crop	Trials per crop	Winter wheat (20) Winter triticale (2) Winter rye (1)
	Varieties per crop	Winter wheat: APRILIO Avenue Benchmark Dagmar Desamo Energo Euclide Frisky IG ABSALON KWS Talent LG Mocca LIPARIS+VELAZCO Nemo Opal RTG Reform Sandra SCENARIO Tobak Winter triticale: Lombardo Winter rye: KWS Gatano
	Sowing period	Winter wheat: 18/09-02/12 Winter triticale: 25/10-01/11 Winter rye: 28/09
Application	Crop stage majority (BBCH) at application	Winter wheat: 11-22 Winter triticale: 12 Winter rye: 14
	Timing	Post-emergence
	Pest stage majority (BBCH) at application	ALOMY(BBCH 11-21) APESV(BBCH 10-16) CAPBP(BBCH 0-10) CENCY(BBCH 10-19) DESSO(BBCH 0-10) FUMOF(BBCH 10-12) GALAP(BBCH 0-22) GERDI(BBCH 11-13) GERRT(BBCH 0-0) IUNBU(BBCH 11-11) LAMPU(BBCH 10-10) LOLPE(BBCH 0-0) MATCH(BBCH 9-11) MATIN(BBCH 0-14) MYOAR(BBCH 10-12) PAPRH(BBCH 0-14) POAAN(BBCH 0-21) SENVU(BBCH 0-11) SSYOF(BBCH 12-12) STEME(BBCH 0-16) THLAR(BBCH 0-14)

		VERAG(BBCH 0-0) VERHE(BBCH 16-16) VERPE(BBCH 10-14) VICCR(BBCH 12-12) VIOAR(BBCH 0-13)
	Number of applications	1
	Intervals between applications	-
	Spray volumes	150-300 L/ha
Assessment	Assessment types	% of weed coverage, number of weeds/m2, number of ears/m2, % control (on plant density), % phytotoxicity
	Assessment dates	First preliminary assessment at application timing. Depending on the trial, further assessments at: 2 weeks after the application, during tillering (BBCH 21-29), around flag leaf emergence (BBCH 37-39) from the end of flowering until shortly before harvest.
Other relevant information	Soil types	clay, clay loam, loamy sand, sandy clay, sandy clay loam, sandy loam, sandy silt, silt loam, silty clay, silty clay loam
	Natural / artificial innoculation	Natural infestation (18) Artificial weed sowing (5)
	Field / Greenhouse	Field conditions

Table 3.2-16: Details on trial methodology – North-East EPPO zone

Guidelines	General guidelines	PP 1/135(4), EPPO PP 1/152 (4), PP 1/181(4)
	Specific guidelines	EPPO PP 1/93(3)
Experimental design	Plot design	RCBD (10)
	Plot size	10.5-21 m²
	Number of replications	4 (22), 3(1)
Crop	Trials per crop	Winter wheat (5) Winter triticale (4) Winter barley (1)
	Varieties per crop	Winter wheat: Bogatka Patras Toras Arkadia Apostel Winter triticale: Trapero Grenado Toledo Borwo Winter barley: KWS Kosmos
	Sowing period	Winter wheat: 19/09-05/11 Winter triticale: 22/09-01/10 Winter barley: 25/09
Application	Crop stage majority (BBCH) at application	Winter wheat: 11-12 (4 trials), 21 (1 trial) Winter triticale: 12-14 Winter barley: 13
	Timing	Post-emergence
	Pest stage majority (BBCH) at application	APESV(BBCH 10-13) BRSNW(BBCH 11-12) CAPBP(BBCH 11-11) CENCY(BBCH 10-13) GALAP(BBCH 0-12)

		GERPU(BBCH 11-11) LAMPU(BBCH 13-13) MATIN(BBCH 10-13) PAPRH(BBCH 0-13) STEME(BBCH 10-13) VERPE(BBCH 0-11) VERSS(BBCH 10-10) VIOAR(BBCH 10-13)
	Number of applications	1
	Intervals between applications	-
	Spray volumes	150-300 L/ha
Assessment	Assessment types	% of weed coverage, number of weeds/m2, number of ears/m2, % control (on plant density), % phytotoxicity
	Assessment dates	First preliminary assessment at application timing. Depending on the trial, further assessments at: 2 weeks after the application, during tillering (BBCH 21-29), around flag leaf emergence (BBCH 37-39) from the end of flowering until shortly before harvest.
Other relevant information	Soil types	loam, loamy sand, sandy clay, sandy clay loam, sandy loam
	Natural / artificial innoculation	Natural infestation
	Field / Greenhouse	Field conditions

Maritime EPPO zone

A total of 23 trials were carried out in the Maritime EPPO Zone to evaluate the efficacy of GLOB1817H for the control of weeds on winter cereals (wheat, triticale and rye). Those trials have been conducted between 2018 and 2019 in the Czech Republic, France, Germany, and the Netherlands.

As a lower dose rate was included in all trials, these results are also presented in detail under point 3.2.3 Efficacy tests but summarized and discussed above under point 3.2.2 Minimum effective dose tests.

During the trials, a total of 4 different grass weed species and 21 different broad leaved weed species were assessed. Some species where grouped according to taxonomic and biological similarity (i.e. *Geranium* and *Veronica* species) and are listed below:

Group	**EPPO code**	**Scientific name**	**Common name**
Grasses	ALOMY	*Alopecurus myosuroides*	Blackgrass
	APESV	*Apera spica-venti*	Windgrass
	LOLPE	*Lolium perenne*	Perennial ryegrass
	POAAN	*Poa annua*	Annual bluegrass
Rushes	IUNBU	*Juncus bufonius*	Toad rush
Broad leaf	CAPBP	*Capsella bursa-pastoris*	Shepherd's purse
	CENCY	*Centaurea cyanus*	Bachelor's- button, cornflower
	DESSO	*Descurainia sophia*	Flixweed
	FUMOF	*Fumaria officinalis*	Common fumitory
	GALAP	*Galium aparine*	Cleavers
	GERDI	*Geranium dissectum*	Cut-leaf geranium
	GERRT	*Geranium rotundifolium*	Round-leaved cranesbill
	LAMPU	*Lamium purpureum*	Purple deadnettle
	MATCH	*Matricaria chamomilla*	Wild chamomile
	MATIN	*Tripleurospermum inodorum*	False chamomille, scentless mayweed
	MYOAR	*Myosotis arvensis*	Field forget-me-not
	PAPRH	*Papaver rhoeas*	Common poppy
	SENVU	*Senecio vulgaris*	Common groundsel
	SSYOF	*Sisymbrium officinale*	Hedge mustard
	STEME	*Stellaria media*	Common chickweed
	THLAR	*Thlaspi arvense*	Fanweed
	VERAG	*Veronica agrestis*	Field speedwell
	VERHE	*Veronica hederifolia*	Ivy-leaved speedwell
	VERPE	*Veronica persica*	Bird's-eye speedwell
	VICCR	*Vicia cracca*	Bird vetch
	VIOAR	*Viola arvensis*	Field violet

Jura (prosulfocarb 667 g/L + diflufenican 14 g/L) was included in all trials as a uniform reference, applied at authorized label rates. In most of the cases the maximum rate was applied (4L/ha with some exceptions where 3 L/ha was used instead, applying the same amount of diflufenican and prosulfocarb as GLOB1817H). In part of the trials, where Jura is not authorized at national level, in addition to Jura a prosulfocarb alone standard namely Roxy (=Roxy 800 EC) or Boxer (=Boxer 800 EC) was used at 5 L/ha providing a total amount of 4000 g of prosulfocarb/ha. Table headers report the most common product name/rate applied. Exceptions are specified in the detailed table.

Data were summarized by an orthogonal comparison of the control achieved by the tested dose rates of GLOB1817H to Jura across all trials (grouping “All”). An additional comparison is provided among only trials that also tested prosulfocarb alone standards (grouping “vs. Roxy). The number of trials where GLOB1817H is >, <, = compared to each standard is provided.

The color scheme used to classify the levels of weed control are described above in section 3.2.3 Efficacy tests (KCP 6.2).

Conclusion

A total of 23 trials were carried out in the Maritime EPPO Zone to evaluate the efficacy of GLOB1817H for the control of weeds on winter cereals (wheat, triticale and rye). Those trials have been conducted between 2018 and 2019 in the Czech Republic, France, Germany, and the Netherlands.

Data demonstrated that the efficacy of GLOB1817H at the proposed rate of 3 L/ha was as a rule equivalent to the efficacy of standard product Jura (applied at a higher amount per hectare of the actives prosulfocarb and diflufenican). In very few cases the control was lower. In particular, against some weeds as cornflower (CENCY) and scentless mayweed (MATIN), GLOB1817H performed even better than this reference product in terms of overall control.

In part of the trials where a prosulfocarb alone (Roxy/Boxer) was used in addition to Jura, providing the double amount of prosulfocarb per hectare, GLOB1817H was often superior to this reference product, especially against CENCY, MATIN, PAPRH and VIOAR.

Generally, these results also confirm the results obtained from the North-East EPPO climatic zone.

From the presented results it can be clearly concluded that most of the weeds commonly populating cereal fields are susceptible or highly susceptible to GLOB1817H applied at the proposed rate of 3 L/ha. As results are strongly linked to the weed species, reference is made to the tables below showing the susceptibility spectrum of the different weeds.

Table 3.2-17 and Table 3.2-18 show respectively the overall mean efficacy results of GLOB1817H in 1 application of 1.8 and 3 L/ha against grasses and broad leaved weeds compared to the reference standards. The number of trials on which each result is based is also shown. The overall susceptibility level of each weed at the maximum proposed rate of 3 L/ha is indicated.

Table 3.2-19 presents separately results from some grasses and broad leaved weed species that appeared in just one trial.

Table 3.2-17: Overall efficacy and susceptibility level to GLOB1817H at the target rate of 3 L/ha on winter cereals against grasses- Maritime EPPO zone

EPPO zone	Target code	Crop code	Grouping	Crop BBCH at appl.	Weed BBCH at appl.	Nb. trials	DA-A	Infestation in the untreated control (PLANT/M2)			GLOB1817H at 1.8 L/ha			GLOB1817H at 3 L/ha			Jura at 4 L/ha*			Roxy 800 EC at 5 L/ha			N° trials where product is >, <, = compared to standard [5% cutoff]	Suscept. Level**
								Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn		
MAR	APESV	YCERE	All	11-14	10-16	16	173-249	59.3	5-225	27.5	88.9	40-100	99.0	95.9	67.5-100	99.9	96.7	67.5-100	100.0	-	-	-	1x<,15x=	HS
			vs. Roxy	11-14	10-16	5	178-245	74.9	7-179	32.0	85.9	43.8-100	98.0	94.0	72.5-100	99.0	92.9	67.5-100	99.0	88.0	58.8-100	96.0	3x=,2x>	-
	POAAN	TRZAW	All	11-16	0-21	4	93-232	15.3	10-28	11.7	81.6	50-99	88.8	93.5	90-99	92.5	93.2	81.3-99	96.3	-	-	-	1<,2=,1>	S
			vs. Roxy	11-16	12-21	3	93-232	17.0	10-28	13.0	92.2	80-99	97.5	93.8	90-99	92.5	92.6	81.3-99	97.5	88.8	82.5-99	85.0	1<,1=,1>	-

*in 1 trial Jura tested at 3 L/ha
**T=Tolerant; MT=Moderately Tolerant; MS=Moderately Susceptible; S=Susceptible; HS=Highly Susceptible

Table 3.2-18: Overall efficacy and susceptibility level to GLOB1817H at the target rate of 3 L/ha on winter cereals against broad leaved weeds- Maritime EPPO zone

EPPO zone	Target code	Crop code	Grouping	Crop BBCH at appl.	Weed BBCH at appl.	Nb. trials	DA-A	Infestation in the untreated control (PLANT/M2)			GLOB1817H at 1.8 L/ha			GLOB1817H at 3 L/ha			Jura at 4 L/ha*			Roxy 800 EC at 5 L/ha			N° trials where product is >, <, = compared to standard [5% cutoff]	Suscept. Level**
								Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn		
MAR	CENCY	YCERE	All	11-22	10-19	14	80-249	16.9	5-71.5	9.0	93.6	40-100	99.1	98.1	87.5-100	99.9	64.7	0-100	81.9	-	-	-	5x=,9x>	HS
			vs. Roxy	11-22	12-15	5	80-245	27.7	10-71.5	17.0	94.7	85-100	98.0	95.3	87.5-100	96.7	68.5	16.7-98	80.0	21.1	0-37.5	18.8	5x>	-
	DESSO	TRZAW	All	11-12	0-10	2	207-224	5.0	5-5	5.0	99.4	99-99.8	99.4	99.5	99-100	99.5	99.5	99-100	99.5	-	-	-	2x=	HS
	FUMOF	TRZAW	All	13-14	10-12	2	220-239	12.0	9-15	12.0	100.0	100-100	100.0	100.0	100-100	100.0	100.0	100-100	100.0	-	-	-	2x=	HS
	GALAP	YCERE	All	11-16	0-22	14	14-249	13.0	6-30	12.0	93.3	55-100	99.0	98.6	90-100	100.0	92.0	13.8-100	99.8	-	-	-	12x=,2x>	HS
			vs. Roxy	12-16	0-12	4	93-245	17.0	6-30	16.0	95.8	90.8-100	96.3	99.4	97.5-100	100.0	99.4	97.5-100	100.0	70.0	0-100	90.0	2x=,2x>	-
	1GERG	YCERE	All	12-13	0-13	4	42-245	39.1	5.5-105	23.0	97.5	95-99	98.0	96.6	90-100	98.3	88.3	63.8-99	95.1	-	-	-	3x=,1x>	HS
			vs. Roxy	13	11	1	175	6.0	-	-	95.0	-	-	97.5	-	-	95.0	-	-	85.0	-	-	1x>	-
	MATCH	YCERE	All	11-12	9-11	3	207-245	24.7	8.3-42	23.8	71.9	25-99	91.8	96.4	90.8-99.5	99.0	98.2	96.3-99.3	99.0	-	-	-	2x=,1x<	HS

EPPO zone	Target code	Crop code	Grouping	Crop BBCH at appl.	Weed BBCH at appl.	Nb. trials	DA-A	Infestation in the untreated control (PLANT/M2)			GLOB1817H at 1.8 L/ha			GLOB1817H at 3 L/ha			Jura at 4 L/ha*			Roxy 800 EC at 5 L/ha			N° trials where product is >, <, = compared to standard [5% cutoff]	Suscept. Level**
								Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn		
	MATIN	YCERE	All	11-14	0-14	9	176-239	25.6	5-96.5	15.0	78.5	18.8-100	92.0	87.1	61.3-100	98.3	77.8	30-100	90.0	-	-	-	4x=, 5x>	S
			vs. Roxy	11-14	0-12	2	178-232	58.8	21-96.5	58.8	58.6	18.8-98.5	58.6	80.1	61.3-99	80.1	64.3	30-98.5	64.3	40.0	10-70	40.0	2x>	-
	MYOAR	TRZAW	All	11-11	10-12	3	200-232	20.5	6-30	25.5	73.8	22.5-100	99.0	95.8	88.3-100	99.0	95.8	88.3-100	99.0	-	-	-	3x=	HS
	PAPRH	YCERE	All	11-14	0-14	13	170-249	26.3	6-99	10.3	88.2	45-100	96.3	95.0	75-100	98.0	88.3	50-100	98.0	-	-	-	9x=,4x>	S
			vs. Roxy	11-14	0-12	4	170-232	45.5	8-99	37.5	92.2	85-97.3	93.3	92.4	85-99	92.9	74.5	50-98	75.0	41.2	0-98.5	33.1	1x=,3x>	-
	SENVU	TRZAW	All	13-14	0-11	2	118-175	16.5	5-28	16.5	90.0	80-100	90.0	77.5	55-100	77.5	87.5	75-100	87.5	66.3	32.5-100	66.3	1x=,1x<Jura 1x=,1x>Roxy	MS
	STEME	YCERE	All	11-16	0-16	9	93-249	17.2	5-42.5	16.0	87.7	45-100	96.5	98.8	95.5-100	100.0	98.6	93-100	100.0	-	-	-	9x=	HS
			vs. Roxy	13-16	0-12	3	93-178	20.2	18-22.5	20.0	91.8	78.8-100	96.5	97.8	95.8-100	97.5	98.1	96.3-100	98.0	81.3	43.8-100	100.0	2x=,1x>	-
	THLAR	TRZAW	All	11-13	0-14	3	200-239	22.8	8-50	10.3	99.7	99-100	100.0	99.7	99-100	100.0	99.7	99-100	100.0	-	-	-	3x=	HS
	1VERG	YCERE	All	11-16	0-16	6	93-239	10.5	5-18	9.5	100.0	100-100	100.0	99.4	96.3-100	100.0	98.5	91.3-100	100.0	-	-	-	6x=	HS
			vs. Roxy	14-16	0-12	2	93-178	11.0	8-14	11.0	100.0	100-100	100.0	98.1	96.3-100	98.1	95.6	91.3-100	95.6	98.8	97.5-100	98.8	2x=	-
	VIOAR	YCERE	All	11-22	0-13	10	80-239	19.0	5-44.5	17.4	95.6	73.8-100	99.0	98.1	93.8-100	99.0	97.7	83.3-100	99.5	-	-	-	1x<,8x=,1x>	HS
			vs. Roxy	12-22	0-12	3	80-195	18.8	5-44.5	7.0	97.2	95-100	96.7	97.2	95-100	96.7	93.5	83.3-100	97.3	48.1	10-96.7	37.5	1x=,2x>	-

* Except in 1 trial (MATIN, PAPRH, STEME, 1VERG, VIOAR) or 2 trials (CENCY, GALAP) Jura tested at 3 L/ha
**T=Tolerant; MT=Moderately Tolerant; MS=Moderately Susceptible; S=Susceptible; HS=Highly Susceptible

Table 3.2-19: Overall efficacy and susceptibility level to GLOB1817H at the target rate of 3 L/ha on winter cereals against grasses and broad leaved weeds which occurred in only one trial- Maritime EPPO zone

	EPPO zone	Target code	Crop code	Grouping	Crop BBCH at appl.	Weed BBCH at appl.	Nb. trials	DA-A	Infestation in the untreated control (PLANT/M2)			GLOB1817H at 1.8 L/ha			GLOB1817H at 3 L/ha			Jura at 4 L/ha*			Roxy 800 EC at 5 L/ha			N° trials where product is >, <, = compared to standard [5% cutoff]	Suscept. Level**
									Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn		
grasses	MAR	ALOMY	TRZAW	All	22	21	1	80	167.0	-	-	16.7	-	-	50.0	-	-	16.7	-	-	16.7	-	-	1x> Jura	MT
	MAR	LOLPE	TRZAW	All	14	0	1	178	29.0	-	-	87.5	-	-	90.0	-	-	93.8	-	-	93.8	-	-	1x= Jura	S
rushes, grass like	MAR	IUNBU	TRZAW	All	13	11	1	170	12.0	-	-	95.3	-	-	95.8	-	-	97.3	-	-	37.5	-	-	1x=Jura 1x>Roxy	HS

broad leaved	MAR	CAPBP	TRZAW	All	11-11	10-10	1	200	19.0	-	-	99.8	-	-	100.0	-	-	100.0	-	-	-	-	-	1x=	HS
	MAR	LAMPU	TRZAW	All	16-16	10-10	1	93	10.0	-	-	80.0	-	-	100.0	-	-	85.0	-	-	85.0	-	-	1x>Jura 1x>Roxy	HS
	MAR	SSYOF	SECCW	All	14	12	1	54	4.5	-	-	84.6	-	-	91.3	-	-	92.2	-	-	-	-	-	1x=	S
	MAR	VICCR	TRZAW	All	11	12	1	232	8.5	-	-	98.5	-	-	99.0	-	-	98.8	-	-	90.0	-	-	1x=Jura 1x>Roxy	HS

*ALOMY, LOLPE Jura tested at 3 L/ha
**T=Tolerant; MT=Moderately Tolerant; MS=Moderately Susceptible; S=Susceptible; HS=Highly Susceptible

North-East EPPO Zone

A total of 10 trials were carried out in the North-East EPPO Zone to evaluate the efficacy of GLOB1817H for the control of weeds on winter cereals (wheat, barley, triticale and rye). Those trials have been conducted between 2018 and 2019 in Poland. Those were combined with the results of the German and Czech trials (17 trials) since these are neighbouring countries and considered as valid to the cMS Poland. The combined results from 27 trials are thus shown in the tables below.

As a lower dose rate was included in all trials, these results are also presented in detail under point 3.2.3 Efficacy tests but summarized and discussed above in point 3.2.2 Minimum effective dose tests.

During the trials, a total of 2 different grass weed species and 22 different broad leaved weed species were assessed. Some species where grouped according to taxonomic and biological similarity (i.e. *Geranium* and *Veronica* species) and are listed below:

Group	EPPO code		Scientific name	Common name
Grasses	APESV		*Apera spica-venti*	Windgrass
	POAAN		*Poa annua*	Annual bluegrass
Broad leaf	BRSNW		*Brassica napus*	Winter rape
	CAPBP		*Capsella bursa-pastoris*	Shepherd's purse
	CENCY		*Centaurea cyanus*	Bachelor's- button, cornflower
	DESSO		*Descurainia sophia*	Flixweed
	FUMOF		*Fumaria officinalis*	Common fumitory
	GALAP		*Galium aparine*	Cleavers
	1GERG Geranium spp.	GERDI	*Geranium dissectum*	Cut-leaf geranium
		GERPU	*Geranium pusillum*	Small-flower geranium
		GERRT	*Geranium rotundifolium*	Round-leaved cranesbill
	LAMPU		*Lamium purpureum*	Purple deadnettle
	MATCH		*Matricaria chamomilla*	Wild chamomile
	MATIN		*Tripleurospermum inodorum*	False chamomille, scentless mayweed
	MYOAR		*Myosotis arvensis*	Field forget-me-not
	PAPRH		*Papaver rhoeas*	Common poppy
	SSYOF		*Sisymbrium officinale*	Hedge mustard
	STEME		*Stellaria media*	Common chickweed
	THLAR		*Thlaspi arvense*	Fanweed
	1VERG Veronica spp.	VERHE	*Veronica hederifolia*	Ivy-leaved speedwell
		VERPE	*Veronica persica*	Bird's-eye speedwell
		VERSS	*Veronica sp.*	Speedwell
	VICCR		*Vicia cracca*	Bird vetch
	VIOAR		*Viola arvensis*	Field violet

Jura (prosulfocarb 667 g/L + diflufenican 14 g/L) was included in all trials as a uniform reference, applied at authorized label rate of 4L/ha. In part of the trials, in addition to Jura, a prosulfocarb alone standard namely Roxy (=Roxy 800 EC) or Boxer (=Boxer 800 EC) was used at 5 L/ha providing a total amount of 4000 g of prosulfocarb/ha. Table headers report the most common product name applied. Exceptions are specified in the detailed table.

Data were summarized by an orthogonal comparison of the control achieved by the tested dose rates of GLOB1817H to Jura across all trials (grouping “All”). An additional comparison is provided among only trials that also tested prosulfocarb alone standards (grouping “vs. Roxy). The number of trials where GLOB1817H is >, <, = compared to each standard is provided.

The color scheme used to classify the levels of weed control are described above in section 3.2.3 Efficacy tests (KCP 6.2).

Conclusion

A total of 10 trials were carried out in the North-East EPPO Zone to evaluate the efficacy of GLOB1817H for the control of weeds on winter cereals (wheat, barley, triticale and rye). Those trials have been conducted between 2018 and 2019 in Poland. Those were combined with the results of the German and Czech trials (17 trials) since these are neighbouring countries and considered as valid to the cMS Poland. The combined results from 27 trials are thus shown.

Data demonstrated that the efficacy of GLOB1817H at the proposed rate of 3 L/ha was as a rule equivalent to the efficacy of standard product Jura (applied at a higher amount per hectare of the actives prosulfocarb and diflufenican). In very few cases the control was lower. In part of the trials where a prosulfocarb alone (Roxy/Boxer) was used in addition to Jura, providing the double amount of prosulfocarb per hectare, similar results were observed. In particular, against some weeds as cornflower (CENCY) and scentless mayweed (MATIN), GLOB1817H performed even better than the reference products in terms of overall control.

Generally, these results also confirm the results obtained from the Maritime EPPO climatic zone.

From the presented results it can be clearly concluded that most of the weeds commonly populating cereal fields are susceptible or highly susceptible to GLOB1817H applied at the proposed rate of 3 L/ha. As results are strongly linked to the weed species, reference is made to the tables below showing the susceptibility spectrum of the different weeds.

Table 3.2-20 and Table 3.2-21 show respectively the overall mean efficacy results of GLOB1817H in 1 application of 1.8 and 3 L/ha against grasses and broad leaved weeds compared to the reference standards. The number of trials on which each result is based is also shown. The overall susceptibility level of each weed at the maximum proposed rate of 3 L/ha is indicated.

Table 3.2-22 presents separately results from some grasses and broad leaved weed species that appeared in just one trial.

Table 3.2-20: Overall efficacy and susceptibility level to GLOB1817H at the target rate of 3 L/ha on winter cereals against grasses - North-East EPPO zone

EPPO zone/ Country	Target code	Crop code	Grouping	Crop BBCH at appl.	Weed BBCH at appl.	Nb. trials	DA-A	Infestation in the untreated control (PLANT/M2)			GLOB1817H at 1.8 L/ha			GLOB1817H at 3 L/ha			Jura at 4 L/ha			Roxy 800 EC at 5 L/ha			N° trials where product is >, <, = compared to standard [5% cutoff]	Suscept. Level**
								Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn		
NE+CZ,DE	APESV	YCERE	All	11-21	10-13	22	173-249	41.1	5-225	20.0	93.1	40-100	99.8	97.7	67.5-100	100.0	98.1	82.5-100	100.0	-	-	-	1x<,20x=,1x>	HS
CZ,DE	APESV	YCERE	vs. Roxy	11-12	10-12	3	197-245	62.8	7.3-149	32.0	95.8	89-100	98.5	99.4	99-100	99.3	99.7	99-100	100.0	98.3	96-100	99.0	3x=	-
DE	POAAN	TRZAW	All	11-11	0-12	2	218-232	19.2	10.3-28	19.2	74.5	50-99	74.5	95.8	92.5-99	95.8	97.0	95-99	97.0	-	-	-	2x=	HS
DE	POAAN	TRZAW	vs. Roxy	11-11	12-12	1	232	28.0	-	-	99.0	-	-	99.0	-	-	99.0	-	-	99.0	-	-	1x=	-

**T=Tolerant; MT=Moderately Tolerant; MS=Moderately Susceptible; S=Susceptible; HS=Highly Susceptible

Table 3.2-21: Overall efficacy and susceptibility level to GLOB1817H at the target rate of 3 L/ha on winter cereals against broad leaved weeds - North-East EPPO zone

EPPO zone/ Country	Target code	Crop code	Grouping	Crop BBCH at appl.	Weed BBCH at appl.	Nb. trials	DA-A	Infestation in the untreated control (PLANT/M2)			GLOB1817H at 1.8 L/ha			GLOB1817H at 3 L/ha			Jura at 4 L/ha			Roxy 800 EC at 5 L/ha			N° trials where product is >, <, = compared to standard [5% cutoff]	Suscept. Level**
								Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn		
NE	BRSNW	TRZAW	All	12-12	11-12	2	187-191	14.5	14-15	14.5	97.5	95-100	97.5	98.8	97.5-100	98.8	98.8	97.5-100	98.8	-	-	-	2x=	HS
NE+CZ	CAPBP	TRZAW	All	11-21	10-11	2	200-218	13.5	8-19	13.5	99.3	98.8-99.8	99.3	100.0	100-100	100.0	100.0	100-100	100.0	-	-	-	2x=	HS
NE+CZ,DE	CENCY	YCERE	All	11-14	10-19	19	176-249	15.3*	5-71.5	8.0	95.7	40-100	100.0	99.2	91.3-100	100.0	73.8	0-100	90.0	-	-	-	10x>	HS
DE	CENCY	YCERE	vs. Roxy	11-12	12-12	2	232-245	44.3	17-71.5	44.3	99.0	98-100	99.0	99.5	99-100	99.5	74.0	57.5-90.5	74.0	9.4	0-18.8	9.4	2x>	-
CZ,DE	DESSO	TRZAW	All	11-12	0-10	2	207-224	5.0	5-5	5.0	99.4	99-99.8	99.4	99.5	99-100	99.5	99.5	99-100	99.5	-	-	-	2x=	HS
CZ	FUMOF	TRZAW	All	13-14	10-12	2	220-239	12.0	9-15	12.0	100.0	100-100	100.0	100.0	100-100	100.0	100.0	100-100	100.0	-	-	-	2x=	HS

EPPO zone/ Country	Target code	Crop code	Grouping	Crop BBCH at appl.	Weed BBCH at appl.	Nb. trials	DA-A	Infestation in the untreated control (PLANT/M2)			GLOB1817H at 1.8 L/ha			GLOB1817H at 3 L/ha			Jura at 4 L/ha			Roxy 800 EC at 5 L/ha			N° trials where product is >, <, = compared to standard [5% cutoff]	Suscept. Level**
								Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn		
NE+CZ,DE	GALAP	YCERE	All	11-14	0-22	19	14-249	11.1*	5-30	8.0	94.8	55-100	99.8	98.4	87.5-100	100.0	93.2	13.8-100	100.0	-	-	-	16x=,3x>	HS
NE+DE	1GERG	YCERE	All	12-13	0-13	4	42-245	39.4	5.5-105	23.5	98.8	97-100	99.0	97.3	90-100	99.5	89.5	63.8-100	97.1	-	-	-	3x=,1x>	HS
DE	MATCH	YCERE	All	11-12	9-11	3	207-245	24.7	8.3-42	23.8	71.9	25-99	91.8	96.4	90.8-99.5	99.0	98.2	96.3-99.3	99.0	-	-	-	2x=,1x<	HS
NE+CZ,DE	MATIN	YCERE	All	11-14	10-14	11	176-246	22.3	5-96.5	10.0	89.6	50-100	97.5	92.8	70-100	98.3	85.2	50-100	90.0	-	-	-	5x=, 6x>	S
DE	MATIN	YCERE	vs. Roxy	11-11	12-12	1	232	96.5	-	-	98.5	-	-	99.0	-	-	98.5	-	-	70.0	-	-	1x>	-
CZ,DE	MYOAR	TRZAW	All	11-11	10-12	3	200-232	20.5	6-30	25.5	73.8	22.5-100	99.0	95.8	88.3-100	99.0	95.8	88.3-100	99.0	-	-	-	3x=	HS
NE+CZ,DE	PAPRH	YCERE	All	11-14	0-14	15	156-249	20.3	5-99	10.3	91.4	45-100	97.5	97.4	75-100	99.8	94.4	65-100	100.0	-	-	-	12x=,3x>	HS
DE	PAPRH	YCERE	vs. Roxy	11-11	12-12	1	232	99.0	-	-	97.3	-	-	99.0	-	-	97.5	-	-	98.5	-	-	1x=	-
NE+CZ,DE	STEME	YCERE	All	11-21	10-16	11	192-249	12.3	5-42.5	9.0	91.3	45-100	100.0	99.0	95.5-100	100.0	98.2	91.3-100	100.0	-	-	-	10x=,1x>	HS
CZ,DE	THLAR	TRZAW	All	11-13	0-14	3	200-239	22.8	8-50	10.3	99.7	99-100	100.0	99.7	99-100	100.0	99.7	99-100	100.0	-	-	-	3x=	HS
NE+CZ	1VERG	YCERE	All	11-13	0-16	7	176-246	9.8*	5-18	9.0	98.2	87.5-100	100.0	98.2	87.5-100	100.0	98.8	91.3-100	100.0	-	-	-	7x=	HS
NE+CZ,DE	VIOAR	YCERE	All	11-14	10-13	15	156-246	20.9*	7-40	18.4	95.9	73.8-100	100.0	98.3	90-100	100.0	97.2	85-100	100.0	-	-	-	1x<,12x=,2x>	HS

* in 1 trial, weed pressure expressed in terms of % of ground cover and thus not included in means. Cover above 10%.
**T=Tolerant; MT=Moderately Tolerant; MS=Moderately Susceptible; S=Susceptible; HS=Highly Susceptible

Table 3.2-22: Overall efficacy and susceptibility level to GLOB1817H at the target rate of 3 L/ha on winter cereals against grasses and broad leaved weeds which occurred in only one trial - North-East EPPO zone

EPPO zone/ Country	Target code	Crop code	Grouping	Crop BBCH at appl.	Weed BBCH at appl.	Nb. trials	DA-A	Infestation in the untreated control (PLANT/M2)			GLOB1817H at 1.8 L/ha			GLOB1817H at 3 L/ha			Jura at 4 L/ha			Roxy 800 EC at 5 L/ha			N° trials where product is >, <, = compared to standard [5% cutoff]	Suscept. Level**
								Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn		
NE	LAMPU	TRZAW	All	21-21	13-13	1	218	10.0	-	-	100.0	-	-	100.0	-	-	100.0	-	-	-	-	-	1x=	HS
DE	SSYOF	SECCW	All	14	12	1	54	4.5	-	-	84.6	-	-	91.3	-	-	92.2	-	-	-	-	-	1x=	S
DE	VICCR	TRZAW	All	11	12	1	232	8.5	-	-	98.5	-	-	99.0	-	-	98.8	-	-	90.0	-	-	1x=Jura 1x>Roxy	HS

**T=Tolerant; MT=Moderately Tolerant; MS=Moderately Susceptible; S=Susceptible; HS=Highly Susceptible

Comments of zRMS:

Maritime EPPO zone

Data are presented from 23 efficacy trials with GLOB1817H. The trials were conducted in the Maritime, EPPO zone between 2018 and 2019 by GEP certified research institutions in the Czech Republic, France, Germany, and the Netherlands. The crops that were used in these efficacy trials were winter wheat (19), winter rye (1), winter barley (1) and winter triticale (2).

Control was assessed visually where 0% = no control, 100% = complete control. Based on "National guidance" the susceptibility will be rated on the following scale:

% efficacy	Weed species susceptibility
at least a 85 %	Susceptible (S)
70 - 85 %	Moderately Susceptible (MS)
60% - 70%	Moderately Resistant (MR)

The following table show the levels of control provided by 3.0 l/ha GLOB1817H against each weed. It is expected that the relevance of each weed will vary across the countries of the Maritime zone and the zRMS cannot confirm how important each weed is in each cMS. Weeds that were observed in only one trial was not included in this assessment as this is insufficient to support a claim.

Target code	Crop BBCH at appl.	Weed BBCH at appl.	N trials	DA-A	Infestation in the untreated control (PLANT/m²)		GLOB1817H at 3 L/ha		Jura at 4 L/ha*		Roxy 800 EC at 5 L/ha	
					Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max
APESV *Apera spica-venti*	11-14	10-16	16	173-249	59.3	5-225	**95.9**	67.5-100	**96.7**	67.5-100	-	-
POAAN *Poa annua*	11-16	0-21	4	93-232	15.3	10-28	**93.5**	90-99	**93.2**	81.3-99	88.8	82.5-99
GALAP *Galium aparine*	11-16	0-22	14	14-249	13.0	6-30	**98.6**	90-100	**92.0**	13.8-100	70.0	0-100
CENCY *Centaurea cyanus*	11-22	10-19	14	80-249	16.9	5-71.5	**98.1**	87.5-100	**64.7**	0-100	21.1	0-37.5
PAPRH *Papaver rhoeas*	11-14	0-14	13	170-249	26.3	6-99	**95.0**	75-100	**88.3**	50-100	41.2	0-98.5
VIOAR *Viola arvensis*	11-22	0-13	10	80-239	19.0	5-44.5	**98.1**	93.8-100	**97.7**	83.3-100	48.1	10-96.7
STEME *Stellaria media*	11-16	0-16	9	93-249	17.2	5-42.5	**98.8**	95.5-100	**98.6**	93-100	81.3	43.8-100
MATIN *Matricaria inodora*	11-14	0-14	9	176-239	25.6	5-96.5	**87.1**	61.3-100	**77.8**	30-100	40.0	10-70
VERPE *Veronica persica*	11-16	0-16	4	93-239	10.5	5-18	**99,0**	96.3-100	**98.5**	91.3-100	98.8	97.5-100
GERDI *Geranium dissectum*	12-13	0-13	3	42-245	39.1	5.5-105	**95,8**	90-100	**88.3**	63.8-99	(1n) 85.0	-
MATCH *Matricaria chamomilla*	11-12	9-11	3	207-245	24.7	8.3-42	**96.4**	90.8-99.5	**98.2**	96.3-99.3	-	-
THLAR *Thlaspi arvense*	11-13	0-14	3	200-239	22.8	8-50	**99.7**	99-100	**99.7**	99-100	-	-
MYOAR *Myosotis arvensis*	11-11	10-12	3	200-232	20.5	6-30	**95.8**	88.3-100	**95.8**	88.3-100	-	-
SENVU *Senecio vulgaris*	13-14	0-11	2	118-175	16.5	5-28	**77.5**	55-100	**87.5**	75-100	66.3	32.5-100
DESSO *Descurainia sophia*	11-12	0-10	2	207-224	5.0	5-5	**99.5**	99-100	**99.5**	99-100	-	-
FUMOF *Fumaria officinalis*	13-14	10-12	2	220-239	12.0	9-15	**100.0**	100-100	**100.0**	100-100	-	-

The data show that a single application of 3 L/ha GLOB1817H in winter cereals gives very good (>85%) control of the majority of presented in the trials of annual broadleaved weeds *Galium aparine, Centaurea*

cyanus, Papaver rhoeas, Viola arvensis, Stellaria media, Matricaria inodora, Veronica persica, Geranium dissectum, Matricaria chamomilla, Thlaspi arvense, Myosotis arvensis, Descurainia Sophia, Fumaria officinalis and annual grasses *Apera spica-venti and Poa annua*. The only weed partially controlled was *Senecio vulgaris*, where the average control was around 77,5%. 'GLOB1817H' demonstrated either comparable or higher control than the reference products.

North EAST EPPO ZONE

A total of 10 trials were carried out in the North-East EPPO Zone to evaluate the efficacy of GLOB1817H for the control of weeds on winter wheat (5), winter barley (1), winter triticale (4). Those trials have been conducted between 2018 and 2019 in Poland. Additionally, those trials were combined with the results of the German and Czech trials of winter wheat (18), winter barley (1) and winter rye (1).
Control was assessed visually where 0% = no control, 100% = complete control. Based on "National guidance" the susceptibility will be rated on the following scale:

% efficacy	Weed species susceptibility
at least a 85 %	Susceptible (S)
70 - 85 %	Moderately Susceptible (MS)
60% - 70%	Moderately Resistant (MR)

Target code	Crop BBCH at appl.	Weed BBCH at appl.	N trials	DA-A	Infestation in the untreated control (PLANT/m^2)		GLOB1817H at 3 L/ha		Jura at 4 L/ha		Roxy 800 EC at 5 L/ha	
					Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max
Major weeds (at least 6 results are required)												
CENCY	11-14	10-19	19	176-249	15.3	5-71.5	99.2	91.3-100	73.8	0-100	9,4	-0,0-18,8
VIOAR	11-14	10-13	15	156-246	20.9	7-40	98.3	90-100	97.2	85-100	-	-
PAPRH	11-14	0-14	15	156-249	20.3	5-99	97.4	75-100	94.4	65-100	(1) 98.5	-
MATIN	11-14	10-14	11	176-246	22.3	5-96.5	92.8	70-100	85.2	50-100	70.0	-
APESV	11-21	10-13	22	173-249	41.1	5-225	97.7	67.5-100	98.1	82.5-100	-	-
GALAP	11-14	0-22	19	14-249	11.1	5-30	98.4	87.5-100	93.2	13.8-100	-	-
BRSNW*|	12-12	11-12	2	187-191	14.5	14-15	98.8	97.5-100	98.8	97.5-100	-	-
Minor weeds (at least 3 results are required)												
STEME	11-21	10-16	11	192-249	12.3	5-42.5	99.0	95.5-100	98.2	91.3-100	-	-
VERPE	12-13	0-10	5	200 - 246	10.8	5.0-18.0	100	100	100	100	-	-
MATCH	11-12	9-11	3	207-245	24.7	8.3-42	96.4	90.8-99.5	98.2	96.3-99.3	-	-
MYOAR	11-11	10-12	3	200-232	20.5	6-30	95.8	88.3-100	95.8	88.3-100	-	-
THLAR	11-13	0-14	3	200-239	22.8	8-50	99.7	99-100	99.7	99-100	-	-
CAPBP*	11-21	10-11	2	200-218	13.5	8-19	100.0	100-100	100.0	100-100		
DESSO*	11-12	0-10	2	207-224	5.0	5-5	99.5	99-100	99.5	99-100		

FUMOF*	13-14	10-12	2	220-239	12.0	9-15	100.0	100-100	100.0	100-100		
GERDI*	12-13	0-13	2	213-245	72,5	40-105	95,0	90,0-100	78,0	63,7-92,2		
VERHE*	12	10-16	2	176-234	7,5	5.0-10.0	93.7	87.5-100	95.6	91.2-100		
POAAN*	11-11	0-12	2	218-232	19.2	10.3-28	95.8	92.5-99	97.0	95-99	-	-

* GLOB1817H contains a new combination of active ingredients, therefore national guidelines require at least six results for major weeds and at least three results for minor weeds. As the submitted number of results for BRSNW, CAPBP, DESSO, FUMOF, GERDI, VERHE, POAAN is lower than required, these results are considered as not significant and have not been included in the effectiveness assessment.

In these trials GLOB1817H at the recommended application rate of 3 L/ha provided good control (>85%) of the annual broadleaved weeds CENCY, VIOAR, PAPRH, MATIN, GALAP, STEME, VERPE, MATCH, MYOAR, THLAR and grass APESV.
Based on efficacy results from efficacy field trials with GLOB1817H applied post emergence for weed control in winter cereals the intended application rate of 3 L/ha can be justified for registration.

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

GLOB1817H is an emulsifiable concentrate formulation (EC) containing the active ingredients prosulfocarb (667 g/L), diflufenican (14 g/L) and halauxifen-methyl (1.33 g/L) for early post-emergence weed control in cereals, in combination with the safener cloquintocet-mexyl (1.33 g/L). The proposed label rate is 3 L/ha in one early pre-emergence application.

A resistance risk analysis is carried out in accordance with the EPPO guideline 1/213 (4).

Mode of action

GLOB1817H has three different compounds (prosulfocarb, diflufenican and halauxifen-methyl). They belong to different groups of the Herbicide Resistance Action Comitee (HRAC) and act by different modes of action.

Prosulfocarb (HRAC/WSSA Group 15 - former N) inhibits fatty acid elongase enzymes, altering cell membranes and disrupting vital cell processes. Diflufenican HRAC/WSSA group 12 (former F1) inhibits the carotenoids biosynthesis at the phytoene desaturase step (PDS) thus acting as a bleacher. Halauxifen-methyl (HRAC/WSSA group 4 - former Group O) is a synthetic auxine, which disrupts hormone balance and protein synthesis in plants, leading to a variety of plant growth abnormalities.

Evidence of resistance

Resistance events have been reported in Europe for 2 of the MoA groups to which active substances present in GLOB1817H belong. These are group 15 (former N) and 4 (former O). The following table summarizes these reports[1]. Regarding the Moa group 12 (former F1), no resistance case was ever reported in Europe.

Table 3.3-1 Resistance events reported to MoA groups 15 (former N) and 4 (former O) in EU (+ UK) on arable crops

Year	Species	Country	MOAs	Actives	Crops
2011	*Alopecurus myosuroides*	Sweden	ACCase inhibitors (A/1), ALS inhibitors (B/2), Lipid Inhibitors (N/8)	fenoxaprop-P-ethyl, flupyrsulfuron-methyl-sodium, **prosulfocarb**, pyroxsulam	Wheat
2012	*Centaurea cyanus*	Poland	Auxin Mimics (O/4)	dicamba	Winter wheat
1993	*Papaver rhoeas*	Spain	ALS inhibitors (B/2), Auxin Mimics (O/4)	tribenuron-methyl, 2,4-D	Cereals, Wheat
1998		Italy	ALS inhibitors (B/2), Auxin Mimics (O/4)	tribenuron-methyl, 2,4-D, iodosulfuron-methyl-sodium	Wheat
2002		Greece	ALS inhibitors (B/2), Auxin Mimics (O/4)	2,4-D, iodosulfuron-methyl-sodium, mesosulfuron-methyl	Wheat
2016		France	ALS inhibitors (B/2), Auxin Mimics (O/4)	metsulfuron-methyl, MCPA, 2,4-D, iodosulfuron-methyl-sodium, mesosulfuron-methyl	Cereals
1985	*Stellaria media*	United Kingdom	Auxin Mimics (O/4)	mecoprop	Cereals, Wheat

[1] Heap, I. The International Herbicide-Resistant Weed Database. Online. Accessed on April, 2021. Available at www.weedscience.org

A total of 14 auxinic herbicides are currently registered in the European Union for the control of weeds species in a range of crops including cereals and grasslands. Many of these herbicides have been on the market for decades. For example, fluroxypyr was discovered in the early 1980s and has been sold in Europe since 1984. 2,4-D was one of the first herbicides discovered during the Second World War and has been in use for over fifty years.

Despite the length of time these herbicides have been on the EU market, resistance to this class of herbicide is still relatively low, especially when compared to high risk groups such as the ALS herbicides.

In Europe, three annual broad leaf weed species have developed resistance to auxinic herbicides: *Stellaria media* to mecoprop in the UK, *Papaver rhoeas* to 2,4-D (and MCPA) in Spain, France and Italy, and *Centaurea cyanus* to Dicamba in Poland

Considering the length of time these auxinic herbicides have been on the market, their wide geographic spread of use and a relatively low number of confirmed cases of resistance, this chemistry can be considered to be a low/medium risk in terms of resistance developing. As a member of the Group O herbicides halauxifen-methyl is considered to be a low/medium risk for developing herbicide resistance.

Resistance for compounds of the Lipid Inhibitors family excluding prosulfocarb are all reported outside Europe and are therefore considered as not relevant. Only one resistance case was detected in Sweden for Blackgrass (*Alopecurus myosuroides*), a monocot weed in the Poaceae family. *A. myosuroides*) is a monocot weed in the Poaceae family. It is one of the most important grass weeds on arable land and has developed herbicide-resistant populations from many years. ACCase- (Group A) and ALS-inhibiting herbicides (Group B), in particular, have lost significant efficacy.Blackgrass resistance to herbicides is especially a problem in Belgium and the UK.

Cross-resistance

According to HRAC, there have been few reports of target site resistance to herbicides with modes of action other than ALS, ACCase, or PS2. Where such reports are available, there are few cross resistance studies and relatively few studies with the target site *in vitro*. One of these cases where target site cross resistance is evident concerns synthetic auxines (group 4 - former Group O) and is briefly described below.

A biotype of *Sinapis arvensis* is resistant to a wide range of auxinic herbicides including dicamba, MCPA, mecoprop, 2,4-D, and picloram (outside EU). The mechanism of resistance to these herbicides in this population has not been firmly established, but is probably the result of a modification of the auxin receptors.

Resistance for compounds of the N family excluding prosulfocarb are all reported outside Europe (Canada, the United States, China, Australia and New Zealand) and are therefore considered as not relevant for Europe.

For diflufenican, only three cases of resistance have been detected so far against herbicides of this family. One of them relates to resistance detected in the United States for another compound of the F1 family (fluridone) for which cross resistance to diflufenican may be expected. However this compound is not approved in Europe.

The other cases were detected in Australia for the Wild Radish (*Raphanus raphanistrum*), a dicot weed in the Brassicaceae family and Sisymbrium orientale.

Based on this information, it is considered that the risk of resistance development is negligible.

Sensitivity data

No studies on baseline sensitivity data are available to the applicant

Use pattern

The use pattern is detailed in the GAP table: applications are made to winter cereals only with one applications per year. Application should be performed early pre-emergence (BBCH10-14).

Resistance risk assessment of unrestricted use pattern & Acceptability of the resistance risk

Cereal weeds typically produce only one generation per year and therefore development of resistance in general is a relatively slow process. A typical weed control scheme in cereals consists of a mixture of different active ingredients, applied all together. In GLOB1817H, 3 active substances are applied in mixture. Due to this mixture with different modes of action, the risk for development of resistance is considered to be low. Moreover, GLOB1817H is only applied once per year. Based on this information, it is considered that the risk of resistance development is negligible for all target weeds.

Management strategy

In view of the very low risk, it is considered that no specific resistance risk management should be followed for GLOB1817H. However, mixtures or sequences of herbicides with differing modes of action are important especially to prevent or overcome resistance based on target site differences. Crop rotations may allow different herbicides or cultivation techniques to be used and may also provide different competitive environments to shift the weed flora. As precautionary approach we advise to mention the following warning on the label:

As strains of some annual grasses (e.g. black-grass, wild-oats, and Italian rye-grass) have developed resistance to a range of herbicides which may lead to poor control from one or more products or mode of action, a general strategy for preventing and managing such resistance should be adopted, in accordance with HRAC.

Proposed resistance management strategy

The main resistance management strategies currently recommended are: monitoring the field regularly, follow the conditions indicated in the product label (do not apply at a rate higher or lower than the recommended rate or too early or too late), integrating chemical and agronomical methods, rotating crops with different cycles, selecting more competitive varieties, delaying the date of planting, conventional tillage, mechanical weeding. Wherever feasible, several strategies should be used together.
Thus the proposed resistance strategy should follow the general principles of weed resistance management: (source: HRAC website):

1. Apply integrated weed management practices. Use multiple herbicide modes-of-action with overlapping weed spectrums in rotation, sequences, or mixtures.
2. Use the full recommended herbicide rate and proper application timing for the hardest to control weed species present in the field.
3. Scout fields after herbicide application to ensure control has been achieved. Avoid allowing weeds to reproduce by seed or to proliferate vegetatively.
4. Monitor site and clean equipment between sites.

Comments of zRMS:	The applicant addresses all points of the EPPO Standard PP 1/213 to evaluate the possible actual resistance risk of GLOB1817H and claims that the active substances prosulfocarb, diflufenican and halauxifen-methyl which are combined in the product GLOB1817H act by different modes of action. Based on HRAC assessment the applicant stated due to this mixture with different modes of action, the risk for development of resistance is considered to be low. Therefore, the risk of resistance development against GLOB1817H is considered to be low if the product is used in adherence with the proposed management strategy. Based on submitted information it can be concluded to accept the data provided by the applicant. Considering the suggestions of cMS DE: The herbicide GLOB1817H is intended to control annual mono- and dicotyledonous weed species in winter cereals pre-emergence. Due to the increase in resistance to post-emergence herbicides such as ACCase and ALS inhibitors, the use of pre-emergence herbicides also increases. Winter cereals are commonly grown in narrow crop rotations in Europe. This can lead to consecutive uses of GLOB1817H and enhance the selection pressure – particularly for grass weed species since they are mainly controlled by only the active prosulfocarb. Therefore, the risk of resistance development against GLOB1817H is extended from low to medium.

3.4 Adverse effects on treated crops (KCP 6.4)

Adverse effects on the treated crops were assessed in separate selectivity trials. Phytotoxicity was also determined in the efficacy trials described above in 3.2.3 (KCP 6.2).

In support of authorizations in the Central zone, 54 specific selectivity trials covering the Maritime and North-East EPPO zones are presented.

The selectivity trials were carried out between 2018 and 2019 in the Czech Republic, Germany, northern part of France, the Netherlands and the United Kingdom (31 trials belonging to the Maritime EPPO zone), as well as in Poland (23 trials belonging to the North-East EPPO Zone).

Supporting data are provided from trials carried out with an analogous formulation named GLOB1815H. This is a very similar formulation to GLOB1817H, only differing in a slightly lower amount of halauxifen-methyl. The formulation GLOB1815H was tested at higher application rates and thus corresponds to a worst case situation.

	Formulation concentration			**Application rate (L/ha)**		**a.i. application rate (g a.i./ha)**					
						N			**2N**		
	PRO	**DFF**	**HXN**	**N**	**2N**	**PRO**	**DFF**	**HXN**	**PRO**	**DFF**	**HXN**
GLOB1817H	667	14	1.3	3	6	2001	42	3.9	4002	84	7.8
GLOB1815H	667	14	1.1	3.6	7.2	2401.2	50.4	3.96	4802.4	100.8	7.92

An overview of the selectivity trials is presented in the table below. The trials were carried out by officially recognised organisations in accordance with the principles of Good Experimental Practice.

Table 3.4-1 Presentation of selectivity trials

Crop	**Country**	**Years**	**Type of trial****	**Number of trials**			**GEP, non-GEP, official*****	**Tested formulation**
				Marit. zone	**North-East zone**	**Medit. zone**		
HORVW	**CZ**	2018	S+Y+Q	2			GEP	GLOB1815H
		2019	S+Y+Q	1			GEP	GLOB1817H
	DE	2018	S+Y+Q	2			GEP	GLOB1815H
	FR	2018	S+Y+Q	2			GEP	GLOB1815H
	PL	2018	S+Y+Q		4		GEP	GLOB1815H
		2019	S+Y+Q		2		GEP	GLOB1817H
HORVW Total				**7**	**6**	**-**		
SECCW	**CZ**	2018	S+Y+Q	2			GEP	GLOB1815H
		2019	S+Y+Q	1			GEP	GLOB1817H
	DE	2018	S+Y+Q	3			GEP	GLOB1815H
	FR	2018	S+Y+Q	2			GEP	GLOB1815H
	PL	2018	S+Y+Q		4		GEP	GLOB1815H
		2019	S+Y+Q		2		GEP	GLOB1817H
SECCW Total				**8**	**6**	**-**		
TRZAW	**CZ**	2018	S+Y+Q	3			GEP	GLOB1815H
		2019	S+Y+Q	1			GEP	GLOB1817H
	DE	2018	S+Y+Q	1			GEP	GLOB1815H
	NL	2019	S+Y+Q	1			GEP	GLOB1817H
	UK	2018	S+Y+Q	1			GEP	GLOB1815H
	FR	2018	S+Y+Q	1			GEP	GLOB1815H
	PL	2018	S+Y+Q		4		GEP	GLOB1815H
		2019	S+Y+Q		1		GEP	GLOB1817H

Crop	Country	Years	Type of trial**	Number of trials			GEP, non-GEP, official***	Tested formulation
				Marit. zone	North-East zone	Medit. zone		
TRZAW Total				**8**	**5**	**-**		
TTLWI	**CZ**	2018	S+Y+Q	1			GEP	GLOB1815H
	DE	2018	S+Y+Q	3			GEP	GLOB1815H
		2019	S+Y+Q	1			GEP	GLOB1817H
	FR	2018	S+Y+Q	3			GEP	GLOB1815H
	PL	2018	S+Y+Q		4		GEP	GLOB1815H
		2019	S+Y+Q		2		GEP	GLOB1817H
TTLWI Total				**8**	**6**	**-**		
Overall total		**2018-2019**	**-**	**31**	**23**	**-**	**-**	**54**

** S= selectivity trial, Y= trial with yield assessment, Q= trial with quality assessment

Information on trial methodology is summarized below for each EPPO climatic zone. Trial site information and application details are also presented in Appendix 3 of the Biological Assessment Dossier.

Both the highest target dose and the double dose rate of GLOB1817H were tested and compared to the standard treatment. Reference standards used in trials are presented in Table 3.4-2 below.

Table 3.4-2 Presentation of reference standards used in 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 rate in trials (per treatment)	Remark(4)
					Type(2)	Concentr. of a.s.			
Cereals	Jura (=Jura EC)	PL	R -108/2017	Prosulfocarb + Diflufenican	EC	667 g/L + 14 g/L	4 L/ha	N: 4 L/ha 2N: 8 L/ha	
	Roxy (=Roxy 800 EC)	CZ	5290-0	Prosulfocarb	EC	800 g/L	4 L/ha	N: 4 L/ha 2N: 8 L/ha	
		NL	13164 N	Prosulfocarb	EC	800 g/L	Max. 5 L/ha	N: 5 L/ha 2N: 10 L/ha	
		FR	2090186	Prosulfocarb	EC	800 g/L	Max. 5 L/ha	N: 5 L/ha 2N: 10 L/ha	
	Boxer (=Boxer 800 EC)	DE	033838-00	Prosulfocarb	EC	800 g/L	Max. 5 L/ha	N: 5 L/ha 2N: 10 L/ha	
		PL	R- 88/2015	Prosulfocarb	EC	800 g/L	3 L/ha	N: 3 L/ha 2N: 6 L/ha	
	Herold	PL	R - 792/2019d	Diflufenican + Flufenacet	SC	200 g/L + 400 g/L	Max. 0.35 L/ha	N: 0.35 L/ha 2N: 0.7 L/ha	
		DE	005878-00	Diflufenican + Flufenacet	SC	200 g/L + 400 g/L	Max. 0.6 L/ha	N: 0.5 - 0.6 L/ha 2N: 1 - 1.2 L/ha	Registered on Triticale at max. 0.5 L/ha
	Naceto	UK	18063	Diflufenican + Flufenacet	SC	200 g/L + 400 g/L	Max. 0.43 L/ha	N: 0.43 L/ha 2N: 0.86 L/ha	Registered at max. 0.43 L/ha in post-em
		CZ	5265-0	Diflufenican + Flufenacet	SC	200 g/L + 400 g/L	0.3-0.6 L/ha	N: 0.6 L/ha 2N: 1.2 L/ha	
	Fosburi	FR	2080145	Diflufenican + Flufenacet	SC	200 g/L + 400 g/L	Max. 0.6 L/ha	N: 0.6 L/ha 2N: 1.2 L/ha	

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

Table 3.4-3 Details on trial methodology from selectivity trials – Maritime EPPO zone

Guidelines	General guidelines	PP 1/135(4), EPPO PP 1/152 (4), PP 1/181(4)
	Specific guidelines	EPPO PP 1/93(3)
Experimental design	Plot design	RCBD (31)
	Plot size	12-30 m²
	Number of replications	4 (31)
Crop	Trials per crop	Winter wheat (8) Winter barley (7) Winter rye (8) Winter triticale (8)
	Varieties per crop	Winter wheat: Energo Fructidor Istabraq KWS Talent Tobak
		Winter barley: Etincel Fabian KWS Meridian Sandra Titus
		Winter rye: Conduct Daňkovské Nové Dankowskie Rubin Inspector Mephisto Performer
		Winter triticale: Barolo Bikini Cando Kauleos Lombardo Omeac
	Sowing period	Winter wheat: 23/09-28/10 Winter barley: 16/09-12/10 Winter rye: 19/09-06/10 Winter triticale: 22/09-02/11
Application	Crop stage majority (BBCH) at application	Winter wheat: 11-12 Winter barley: 11-13 Winter rye: 10-13 Winter triticale: 10-13
	Timing	Post-emergence
	Pest stage majority (BBCH) at application	-
	Number of applications	1
	Intervals between applications	-
	Spray volumes	150-300 L/ha
Assessment	Assessment types	Phytotoxicity: PHYGEN (general phyto), PHYBLE (% bleaching), PHYCHL (% chlorosis), PHYSTU (% stunting), PHYTHI (% thinnig), PHYNLB (necrosis, leaf blotch), PHYCOL (phytotoxicity - color change), PHYDEF (phyto deformation), PHYDIS (phytotoxicity - discoloration) Yield Quality (HLW)
	Assessment dates	3 assessments during the season for phytotoxicity After harvest for quality and yeild parameters
Other relevant information	Field / Greenhouse	Field conditions

Table 3.4-4 Details on trial methodology from selectivity trials – North-East EPPO zone

Guidelines	General guidelines	PP 1/135(4), EPPO PP 1/152 (4), PP 1/181(4)
	Specific guidelines	EPPO PP 1/93(3)
Experimental design	Plot design	RCBD (23)
	Plot size	12-30 m²
	Number of replications	4 (23)
Crop	Trials per crop	Winter wheat (5) Winter barley (6) Winter rye (6) Winter triticale (6)
	Varieties per crop	Winter wheat: Arkadia Bogatka Julius Kepler
		Winter barley: Gloria Idra Joy KWS Kosmos SY Tepee
		Winter rye: Dankowskie Diament Dańkowskie Złote KWS Binntto Hadron Serafino SU Nasri
		Winter triticale: Borwo Porto Securo Trapero Sekret
	Sowing period	Winter wheat: 19/09-09/10 Winter barley: 11/09-10/10 Winter rye: 20/09-11/10 Winter triticale: 03-12/10
Application	Crop stage majority (BBCH) at application	Winter wheat: 11-12 Winter barley: 11-13 Winter rye: 11-13 Winter triticale: 11-12
	Timing	Post-emergence
	Pest stage majority (BBCH) at application	-
	Number of applications	1
	Intervals between applications	-
	Spray volumes	150-200 L/ha
Assessment	Assessment types	Phytotoxicity: PHYGEN (general phyto), PHYBLE (% bleaching), PHYTHI (% thinnig), PHYDEF (phyto deformation), PHYDIS (phytotoxicity - discoloration), PHYSTU (% stunting) Yield Quality (HLW)
	Assessment dates	3 assessments during the season for phytotoxicity After harvest for quality and yeild parameters
Other relevant information	Field / Greenhouse	Field conditions

3.4.1 Phytotoxicity to host crop (KCP 6.4.1)

Phytotoxicity was evaluated in trials presented in this dossier including efficacy and weed free trials. Data from 87 field trials are presented for the phytotoxicity evaluation. Out of these, 33 trials are efficacy trials, while other 54 trials were specific selectivity trials (weed free).

The selectivity trials were carried out between 2018 and 2019 in the Czech Republic, Germany, northern part of France, the Netherlands and the United Kingdom (31 trials belonging to the Maritime EPPO zone), as well as in Poland (23 trials belonging to the North-East EPPO Zone).

Details from efficacy trials are reported under section 3.2.3.

The test formulation GLOB1817H and the analogous formulation GLOB1815H were used in order to demonstrate the crop safety as described above in point 3.4 Adverse effects on treated crops (KCP 6.4).

In all the selectivity trials GLOB1817H was applied once according to the GAP table (crop BBCH 10-14) at the rate of 3 L/ha (N) and 6 L/ha (2N), respectively representing the maximum target rate and the double target rate of application. GLOB1815H was applied at 3.6 L/ha (N) and 7.2 L/ha (2N), providing at higher amount of actives per hectare and thus corresponding to a worst case situation.

Commercial standards, were as well applied at N and 2N as comparison. Details of the reference standards used in trials and application rates are presented in Table 3.4-2.

In the efficacy trials, GLOB1817H was applied at the same timing up to the maximum dose rate of 3 L/ha (N). For the efficacy trials, results of only the highest dose rate tested (N) as well as the reference product(s) are shown.

Phytotoxicity was visually assessed in all trials in accordance with the EPPO guideline PP 1/135, as a numerical record (%) at various intervals after application starting from 13 days up to 246 days.

Details on trial methodology for selectivity trials is summarized in Table 3.4-3 and Table 3.4-4, split for each EPPO climatic zone.

Maritime EPPO Zone

Table 3.4-5 Phytotoxicity of GLOB1817H in winter wheat: highest phytotoxicity and phytotoxicity at final assessment - Maritime EPPO Zone

Number of trials with…		Selectivity trials (2)				Efficacy trials (20)		
		GLOB1817H		Reference 2		GLOB1817H	Reference 1	Reference 2
		N	2N	N	2N	N	N	N (n=8)
Highest phytotoxicity (bleaching)	0% to 5%	1	-	2	2	14	15	7
	>5% to 10%	-	1	-	-	5	3	1
	>10% to 15%	1	-	-	-	-	1	-
	>15 %	-	1	-	-	1	1	-
Phytotoxicity at final assessment (bleaching)	0% to 5%	2	2	2	2	20	20	8
	>5% to 10%	-	-	-	-	-	-	-
	>10% to 15%	-	-	-	-	-	-	-
	>15 %	-	-	-	-	-	-	-

Reference 1: Jura at 4 L/ha
Reference 2: Roxy/Boxer at 5L/ha (in selectivity trials, N: 4-5 L/ha , 2N 8-10 L/ha)

Supportive data from GLOB1815H formulation

Table 3.4-6 Phytotoxicity of GLOB1815H in winter wheat: highest phytotoxicity and phytotoxicity at final assessment - Maritime EPPO Zone

Number of trials with…		Selectivity trials (6)			
		GLOB1815H		Reference	
		N	2N	N	2N
Highest phytotoxicity (bleaching)	0% to 5%	4	2	5	5
	>5% to 10%	1	2	1	1
	>10% to 15%	1	1	-	-
	>15 %	-	1	-	-
Phytotoxicity at final assessment (bleaching)	0% to 5%	6	6	6	6
	>5% to 10%	-	-	-	-
	>10% to 15%	-	-	-	-
	>15 %	-	-	-	-

Reference: Herold/Naceto/Fosburi at N: 0.6 L/ha, 2N: 1.2 L/ha.
In trial KCP 6.4-63, the reference product was applied at N: 0.43 L/ha and 2N: 0.86 L/ha

In both efficacy and selectivity trials, some transient phytotoxic effects were observed, either at the N dose or the 2N dose, always reported as bleaching. Similar effects were observed for the reference product in the efficacy trials, reaching even higher levels of phytotoxicity.

In all cases, the effect observed for GLOB1817H disappeared at the end of the season, which is confirmed by the yield data obtained from selectivity trials (see section 3.4.2). Similar results were obtained with the formulation GLOB1815H, providing higher amounts of actives. It can be concluded there is no need to mention a warning on the label.

Table 3.4-7 Phytotoxicity of GLOB1817H in winter barley: highest phytotoxicity and phytotoxicity at final assessment - Maritime EPPO Zone

Number of trials with…		Selectivity trials (1)				Efficacy trials (1)		
		GLOB1817H		Reference 2		GLOB1817H	Reference 1	Reference 2
		N	2N	N	2N	N	N	N
Highest phytotoxicity (bleaching)	0% to 5%	-	-	-	-	-	-	1
	>5% to 10%	-	-	-	-	-	-	-
	>10% to 15%	-	-	-	-	1	1	-
	>15 %	1	1	1	1	-	-	-
Phytotoxicity at final assessment (bleaching)	0% to 5%	-	-	1	1	-	-	1
	>5% to 10%	-	-	-	-	-	-	-
	>10% to 15%	-	-	-	-	1	1	-
	>15 %	1	1	-	-	-	-	-

Reference 1: Jura at 4 L/ha
Reference 2: Roxy at 5L/ha (in selectivity trials, N: 4 L/ha, 2N 8 L/ha)

In both efficacy and selectivity trials performed with GLOB1817H, phytotoxic effects were observed, either at the N dose or the 2N dose, always reported as bleaching. Similar effects were observed for at least one of the reference products.

Supportive data from GLOB1815H formulation

Table 3.4-8 Phytotoxicity of GLOB1815H in winter barley: highest phytotoxicity and phytotoxicity at final assessment - Maritime EPPO Zone

Number of trials with…		Selectivity trials (6)			
		GLOB1815H		Reference	
		N	2N	N	2N
Highest phytotoxicity (bleaching)	0% to 5%	3		5	5
	>5% to 10%	1	1		
	>10% to 15%		2		
	>15 %	2	2		
Phytotoxicity at final assessment (bleaching)	0% to 5%	4	5	5	5
	>5% to 10%	1			
	>10% to 15%				
	>15 %				

Reference: Herold/Naceto/Fosburi at N: 0.6 L/ha, 2N: 1.2 L/ha.

In selectivity trials performed with GLOB1815H, some transient phytotoxic effects were observed, either at the N dose or the 2N dose, always reported as bleaching. No similar effect was observed for the reference product. The effect observed for GLOB1815H nearly disappeared at the end of the season.

In all cases, the effects observed tend to diminish at the end of the trial, not significantly affecting the yield, which is confirmed by the yield data (see section 3.4.2). It can be concluded there is no need to mention on the label a warning other than to avoid overlap of sprays.

Table 3.4-9 Phytotoxicity of GLOB1817H in winter rye: highest phytotoxicity and phytotoxicity at final assessment - Maritime EPPO Zone

Number of trials with…		Selectivity trials (1)				Efficacy trials (1)		
		GLOB1817H		Reference 2		GLOB1817H	Reference 1	Reference 2
		N	2N	N	2N	N	N	N
Highest phytotoxicity	0% to 5%	-	-	1	1	1	-	-
	>5% to 10%	-	-	-	-	-	-	-
	>10% to 15%	1	-	-	-	-	1	-
	>15 %		1	-	-	-	-	-
Phytotoxicity at final assessment	0% to 5%	1	1	1	1	1	1	-
	>5% to 10%	-	-	-	-	-	-	-
	>10% to 15%	-	-	-	-	-	-	-
	>15 %	-	-	-	-	-	-	-

Reference 1: Jura at 4 L/ha
Reference 2: Roxy at N 4 L/ha , 2N 8 L/ha)

In the selectivity trial, some transient phytotoxic effects were observed, either at the N dose or the 2N dose, always reported as thining. The same effect was not observed for the reference product Roxy applied in the selectivity trial. Still, in the efficacy trial, GLOB1817H at N did not cause any phytotoxicity, different from the reference product Jura which elicited some bleaching.

In all cases, the effect observed for GLOB1817H disappeared at the end of the season.

Supportive data from GLOB1815H formulation

Table 3.4-10 Phytotoxicity of GLOB1815H in winter rye: highest phytotoxicity and phytotoxicity at final assessment - Maritime EPPO Zone

Number of trials with…		Selectivity trials (7)					
		GLOB1815H		Reference 1		Reference 2	
		N	2N	N (n=4)	2N (n=4)	N (n=3)	2N (n=3)
Highest phytotoxicity	0% to 5%	3	1	3	2	1	-
	>5% to 10%	1	1	1	1	2	1
	>10% to 15%	2	-	-	-	-	-
	>15 %	1	5	-	1	-	2
Phytotoxicity at final assessment	0% to 5%	7	5	4	3	1	1
	>5% to 10%	-	-	-	1	2	-
	>10% to 15%	-	2	-	-	-	-
	>15 %	-	-	-	-	-	2

Reference 1: Roxy at N 4-5 L/ha , 2N 8-10 L/ha
Reference 2: Herold/Naceto/Fosburi at N: 0.6 L/ha, 2N: 1.2 L/ha.

Some transient phytotoxic effects were observed in part of the selectivity trials performed with GLOB1815H, either at the N dose or the 2N dose, usually reported as bleaching/chlorosis. Similar effects were observed for the reference products but at lowers levels in 5 out of 7 trials.

In all cases, the effect observed for GLOB1817H applied at the recommended N rate disappeared at the end of the season, which is confirmed by the yield data obtained from selectivity trials (see section 3.4.2).
I one particular trial (KCP 6.4-51, carried out in Germany on variety Conduct), a significant yield reduction at 2N was observed. In this case, a stronger reduction was observed for the reference standard. It can be concluded there is no need to mention on the label a warning other than to avoid overlap of sprays.

Table 3.4-11 Phytotoxicity of GLOB1817H in winter triticale: highest phytotoxicity and phytotoxicity at final assessment - Maritime EPPO Zone

Number of trials with…		Selectivity trials (1)				Efficacy trials (1)		
		GLOB1817H		Reference 2		GLOB1817H	Reference 1	Reference 2
		N	2N	N	2N	N	N	N
Highest phytotoxicity	0% to 5%	1	1	1	1	1	1	-
	>5% to 10%	-	-	-	-	-	-	-
	>10% to 15%	-	-	-	-	-	-	-
	>15 %	-	-	-	-	-	-	-
Phytotoxicity at final assessment	0% to 5%	1	1	1		1	1	-
	>5% to 10%	-	-	-	-	-	-	-
	>10% to 15%	-	-	-	-	-	-	-
	>15 %	-	-	-	-	-	-	-

Reference 1: Jura at 4 L/ha
Reference 2: Boxer at N 5L/ha, 2N 10 L/ha)

Supportive data from GLOB1815H formulation

Table 3.4-12 Phytotoxicity of GLOB1815H in winter triticale: highest phytotoxicity and phytotoxicity at final assessment - Maritime EPPO Zone

Number of trials with…		Selectivity trials (7)					
		GLOB1815H		Reference 1		Reference 2	
		N	2N	N (n=4)	2N (n=4)	N (n=3)	2N (n=3)
Highest phytotoxicity	0% to 5%	3	3	3	3	3	2
	>5% to 10%	1		1			1
	>10% to 15%	3	2		1		
	>15 %		2				
Phytotoxicity at final assessment	0% to 5%	6	5	4	4	3	2
	>5% to 10%	1					1
	>10% to 15%		2				
	>15 %						

Reference 1: Roxy at N 4-5 L/ha , 2N 8-10 L/ha
Reference 2: Herold at N: 0.5 L/ha, 2N: 1 L/ha

On winter triticale, phytotoxic effects were observed in part of the trials, being only light symptoms at the N dose. Similar effects were observed for the reference products but at lowers levels.

In the vast majority of cases, the effects observed tend to diminish at the end of the trial, not significantly affecting the yield, which is confirmed by the yield data (see section 3.4.2). It can be concluded there is no need to mention on the label a warning other than to avoid overlap of sprays.

North-East EPPO Zone

Table 3.4-13 Phytotoxicity of GLOB1817H in winter wheat: highest phytotoxicity and phytotoxicity at final assessment – North-East EPPO Zone

Number of trials with…		Selectivity trials (1)				Efficacy trials (5)		
		GLOB1817H		Reference 1		GLOB1817H	Reference 1	Reference 2
		N	2N	N	2N	N	N	N (n=3)
Highest phytotoxicity	0% to 5%	-	-	-	-	5	4	3
	>5% to 10%	-	-	1	-	-	-	-
	>10% to 15%	-	-	-	-	-	1	-
	>15 %	1	1	-	1	-	-	-
Phytotoxicity at final assessment	0% to 5%	1	1	1	1	5	5	3
	>5% to 10%	-	-	-	-	-	-	-
	>10% to 15%	-	-	-	-	-	-	-
	>15 %	-	-	-	-	-	-	-

Reference 1: Jura at N: 4 L/ha, 2N: 8 L/ha
Reference 2: Boxer at N: 3 L/ha, 2N: 6 L/ha

In the selectivity trial performed with GLOB1817H, some transient phytotoxic effects were observed, either at the N dose or the 2N dose, primarily due to bleaching. Similar effect was observed for the reference product Jura, especially at 2N rate. Still, in the efficacy trial, GLOB1817H at N did not cause any phytotoxicity, different from the reference product Jura which again elicited some bleaching.

Supportive data from GLOB1815H formulation

Table 3.4-14 Phytotoxicity of GLOB1815H in winter wheat: highest phytotoxicity and phytotoxicity at final assessment - North-East EPPO Zone

Number of trials with…		Selectivity trials (4)			
		GLOB1815H		Reference	
		N	2N	N	2N
Highest phytotoxicity	0% to 5%	2	2	4	4
	>5% to 10%	1			
	>10% to 15%				
	>15 %	1	2		
Phytotoxicity at final assessment	0% to 5%	4	4	4	4
	>5% to 10%				
	>10% to 15%				
	>15 %				

Reference: Herold at N: 0.35 L/ha, 2N: 0.7 L/ha

In selectivity trials performed with GLOB1815H, some transient phytotoxic effects were observed, either at the N dose or the 2N dose, reported as bleaching/discoloration. No similar effect was observed for the reference product. The effect observed for GLOB1815H nearly disappeared at the end of the season.

In all cases, the effect observed for GLOB1817H disappeared at the end of the season, which is confirmed by the yield data obtained from selectivity trials (see section 3.4.2).

I one particular trial (KCP 6.4-65, carried out in Poland on variety Arkadia), a numerical yield reduction was observed especially at 2N but not statistically different from untreated plots nor from the reference product. It can be concluded there is no need to mention on the label a warning other than to avoid overlap of sprays.

Reference is also made to the results of 5 selectivity trials presented above for the Maritime EPPO zone, conducted in Germany and Czech Republic, neighbouring countries and considered as valid to the cMS Poland.

Table 3.4-15 Phytotoxicity of GLOB1817H in winter barley: highest phytotoxicity and phytotoxicity at final assessment - North-East EPPO Zone

Number of trials with…		Selectivity trials (2)					
		GLOB1817H		Reference 1		Reference 2	
		N	2N	N (n=1)	2N (n=1)	N (n=1)	2N (n=1)
Highest phytotoxicity	0% to 5%	1	-	-	-	-	1
	>5% to 10%	-	1	1		1	-
	>10% to 15%	1	-	-	1	-	-
	>15 %	-	1	-	-	-	-
Phytotoxicity at final assessment	0% to 5%	2	2	1	1	1	1
	>5% to 10%	-	-	-	-	-	-
	>10% to 15%	-	-	-	-	-	-
	>15 %	-	-	-	-	-	-

Reference 1: Jura at N: 4 L/ha, 2N: 8 L/ha
Reference 2: Boxer at N: 3 L/ha, 2N: 6 L/ha

Supportive data from GLOB1815H formulation

Table 3.4-16 Phytotoxicity of GLOB1815H in winter barley: highest phytotoxicity and phytotoxicity at final assessment - North-East EPPO Zone

Number of trials with…		Selectivity trials (4)			
		GLOB1815H		Reference	
		N	2N	N	2N
Highest phytotoxicity	0% to 5%	1	1	3	3
	>5% to 10%	1			1
	>10% to 15%	1	1		
	>15 %	1	2	1	
Phytotoxicity at final assessment	0% to 5%	4	4	4	4
	>5% to 10%				
	>10% to 15%				
	>15 %				

Reference: Herold at N: 0.35 L/ha, 2N: 0.7 L/ha

Only selectivity trials were conducted on barley in the North-east EPPO zone. Some transient phytotoxic effects were observed, either at the N dose or the 2N dose, reported as bleaching/discoloration. Similar effects were observed for the reference products but at lowers levels.

In all cases, the effects observed disappeared at the end of the season, which is confirmed by the yield data obtained from selectivity trials (see section 3.4.2). Even for trials where yield at N or 2N was about 95-97% compared to untreated control set at 100%, these results were statistically comparable. It can be concluded there is no need to mention on the label a warning other than to avoid overlap of sprays.

Reference is also made to the results of 5 selectivity trials presented above for the Maritime EPPO zone, conducted in Germany and Czech Republic, neighbouring countries and considered as valid to the cMS Poland.

Table 3.4-17 Phytotoxicity of GLOB1817H in winter rye: highest phytotoxicity and phytotoxicity at final assessment - North-East EPPO Zone

Number of trials with…		Selectivity trials (2)					
		GLOB1817H		Reference 1		Reference 2	
		N	2N	N (n=1)	2N (n=1)	N (n=1)	2N (n=1)
Highest phytotoxicity	0% to 5%	2	2	1	-	1	1
	>5% to 10%	-	-	-	1	-	-
	>10% to 15%	-	-	-	-	-	-
	>15 %	-	-	-	-		
Phytotoxicity at final assessment	0% to 5%	2	2	1	-	1	1
	>5% to 10%	-	-	-	1	-	-
	>10% to 15%	-	-	-	-	-	-
	>15 %	-	-	-	-	-	-

Reference 1: Jura at N: 4 L/ha, 2N: 8 L/ha
Reference 2: Boxer at N: 3 L/ha, 2N: 6 L/ha

Only selectivity trials were conducted on rye in the North-east EPPO zone. In trials performed with GLOB1817H, no phytotoxic effects were observed either at the N dose or the 2N dose. For the referred trials, only a bit of discolouration in the 2N rate of the reference product Jura was observed.

Supportive data from GLOB1815H formulation

Table 3.4-18 Phytotoxicity of GLOB1815H in winter rye: highest phytotoxicity and phytotoxicity at final assessment - North-East EPPO Zone

Number of trials with…		Selectivity trials (4)			
		GLOB1815H		Reference	
		N	2N	N	2N
Highest phytotoxicity	0% to 5%			2	1
	>5% to 10%	2	1	1	1
	>10% to 15%		1	1	2
	>15 %	2	2		
Phytotoxicity at final assessment	0% to 5%	3	3	4	3
	>5% to 10%	1			1
	>10% to 15%				
	>15 %		1		

Reference: Herold at N: 0.35 L/ha, 2N: 0.7 L/ha

In selectivity trials performed with GLOB1815H, providing higher amounts of actives, some transient phytotoxic effects were observed, either at the N dose or the 2N dose, usually reported as bleaching. In one trial also thinning was observed.

In all but 1 trial, the effects observed disappeared at the end of the season. I one particular trial (KCP 6.4-42 carried out in Poland on variety Dańkowskie Złote), with high discoloration and thining, a numerical yield reduction was observed especially at 2N but not statistically different from untreated plots nor from the reference product. Detailed results from yield data obtained from selectivity trials are presented in section 3.4.2. It can be concluded there is no need to mention on the label a warning other than to avoid overlap of sprays.

Reference is also made to the results of 6 selectivity trials presented above for the Maritime EPPO zone, conducted in Germany and Czech Republic, neighbouring countries and considered as valid to the cMS Poland.

Table 3.4-19 Phytotoxicity of GLOB1817H in winter triticale: highest phytotoxicity and phytotoxicity at final assessment - North-East EPPO Zone

Number of trials with…		Selectivity trials (2)						Efficacy trials (4)		
		GLOB1817H		Reference 1		Reference 2		GLOB1817H	Reference 1	Reference 2
		N	2N	N (n=1)	2N (n=1)	N (n=1)	2N (n=1)	N	N	N (n=2)
Highest phytotoxicity	0% to 5%	1	1	1	-	1	1	2	2	2
	>5% to 10%	1	-	-	1	-	-	-	-	-
	>10% to 15%	-	-	-	-	-	-	1	1	-
	>15 %	-	1	-	-	-	-	1	1	-
Phytotoxicity at final assessment	0% to 5%	2	2	1	-	1	1	4	4	2
	>5% to 10%	-	-	-	1	-	-	-	-	-
	>10% to 15%	-	-	-	-	-	-	-	-	-
	>15 %	-	-	-	-	-	-	-	-	-

Reference 1: Jura at N: 4 L/ha, 2N: 8 L/ha
Reference 2: Boxer at N: 3 L/ha, 2N: 6 L/ha

In both efficacy and selectivity trials performed with GLOB1817H, some transient phytotoxic effects were observed, either at the N dose or the 2N dose, always reported as bleaching. Similar effects were observed for the reference product Jura.

Supportive data from GLOB1815H formulation

Table 3.4-20 Phytotoxicity of GLOB1815H in winter triticale: highest phytotoxicity and phytotoxicity at final assessment - North-East EPPO Zone

Number of trials with…		Selectivity trials (4)			
		GLOB1815H		Reference	
		N	2N	N	2N
Highest phytotoxicity	0% to 5%	1	1	3	3
	>5% to 10%	1	1	1	1
	>10% to 15%				
	>15 %	2	2		
Phytotoxicity at final assessment	0% to 5%	4	4	4	4
	>5% to 10%				
	>10% to 15%				
	>15 %				

Reference: Herold at N: 0.35 L/ha, 2N: 0.7 L/ha

In selectivity trials performed with GLOB1815H, providing higher amounts of actives, some transient phytotoxic effects were observed, either at the N dose or the 2N dose, usually reported as bleaching/discoloration. In one trial also thinning was observed.

In all cases, the effect observed for GLOB1817H disappeared at the end of the season, which is confirmed by the yield data obtained from selectivity trials (see section 3.4.2). Even for 1 trial (KCP 6.4-43 conduct in Poland on variety Securo) where yield at N or 2N was about 93-96% compared to untreated control set at 100%, these results were statistically comparable. Moreover, another trial on the same variety showed no negative effect. It can be concluded there is no need to mention on the label a warning other than to avoid overlap of sprays.

Reference is also made to the results of 5 selectivity trials presented above for the Maritime EPPO zone, conducted in Germany and Czech Republic, neighbouring countries and considered as valid to the cMS Poland.

Conclusion

In conclusion it can be observed that transient phytotoxic effects can be observed, in general as a form of bleaching, due to the mode of action of the active substances. These symptoms tend to disappears at the end of the season and, as will be shown further, this leads to no negative effect on the yield of the different winter cereals on the vast majority of varieties tested.

Comments of zRMS:	Phytotoxicity in cereals was assessed in 33 efficacy trials. In addition, it was assessed in 54 specific crop safety trials conducted between 2018 and 2019 in the Czech Republic, Germany, northern part of France, the Netherlands and the United Kingdom (31 trials belonging to the Maritime EPPO zone), in Poland (23 trials belonging to the North-East EPPO Zone). The applicant also provided supporting data from trials carried out with an analogous formulation GLOB1815H, only differing in a slightly lower amount of halauxifen-methyl. The formulation GLOB1815H was tested at higher application rates and thus corresponds to a worst-case situation. This approach is considered to be acceptable. In all the selectivity trials GLOB1817H was applied once according to the GAP table (crop BBCH 10-14) at the rate of 3 L/ha (N) and 6 L/ha (2N), respectively representing the maximum target rate and the double target rate of application. GLOB1815H was applied at 3.6 L/ha (N) and 7.2 L/ha (2N), providing at higher amount of actives per hectare and thus corresponding to a worst-case situation. **Maritime EPPO zone** The crops that were used in these efficacy trials were Winter wheat (8), Winter barley (7), Winter rye (8) and Winter triticale (8). As shown in the tables above (Tables 3.4-6 to 3.4-12), the phytotoxicity observed at N and 2N only exceeded 15% in one trial. Overall, whilst there were some phytotoxicity symptoms, the majority were transient and disappeared over time and they did not appear to have a negative impact on the yield. Additionally, comparable symptoms were observed following treatment with the reference product. Therefore, it is considered that the proposed use of GLOB1817H is unlikely to cause any unacceptable levels of phytotoxicity. **North east EPPO zone** The crops that were used in these efficacy trials were Winter wheat (5), Winter barley (6), Winter rye (6) and Winter triticale (6). The results in this section show that GLOB1817H can be considered a herbicide with good crop safety when compared to a reference standard. As shown in the tables above (Tables 3.4-13 to 3.4-20), the phytotoxicity observed at 2N only exceeded 15% in one trial. In all cases, the phytotoxicity symptoms caused by GLOB1817H were transient and did not affect the crop vigour, the growing and neither the grain yield. Additionally, comparable symptoms were observed following treatment with the reference product. Therefore, it is considered that the proposed use of GLOB1817H is unlikely to cause any unacceptable levels of phytotoxicity.

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

The effect on yield was determined in all the crop safey trials presented in section 3.4 in accordance with the EPPO standard PP 1/135 (4) requirements. Herbicides should be tested for phytotoxicity at both the single (N) and double (2N) dose in the absence of weeds and yield has to be determined.

Yield was evaluated in 54 specific selectivity trials (weed free) carried out between 2018 and 2019 in the Czech Republic, Germany, northern part of France, the Netherlands and the United Kingdom (31 trials belonging to the Maritime EPPO zone), as well as in Poland (23 trials belonging to the North-East EPPO Zone).

Results from trials conducted in Poland were combined with the results of the German and Czech trials (21 trials) since these are neighbouring countries and considered as valid to the cMS Poland. The combined results from 44 trials are thus shown in the tables below under the North-East EPPO zone section. The trials highlighted in yellow are those conducted in the North-East EPPO Zone (Poland), while blue one are those conducted in DE and CZ.

The test formulation GLOB1817H and the analogous formulation GLOB1815H were used in order to demonstrate the crop safety as described above in point 3.4 Adverse effects on treated crops (KCP 6.4).

In all the selectivity trials GLOB1817H was applied once according to the GAP table (crop BBCH 10-14) at the rate of 3 L/ha (N) and 6 L/ha (2N), respectively representing the maximum target rate and the double target rate of application. GLOB1815H was applied at 3.6 L/ha (N) and 7.2 L/ha (2N), providing at higher amount of actives per hectare and thus corresponding to a worst case situation.

Commercial standards, were as well applied at N and 2N as comparison. Details of the reference standards used in trials and application rates are presented in Table 3.4-2.

Plots were harvested individually to give results in kg per plot, and then converted to metric tons per ha. The percentage relative to the control is shown in the tables below and the absolute values assessed are reported for the untreated check.

Furthermore, a comparison of the phytotoxicity encountered in the weed free trials and the yield from those trials where a significant phytotoxicity was observed is presented below.

Statistical analysis was made as letter test based on Student-Newman-Keuls (P = 0.05). Where no letter is presented no difference was registered among treatments. Letters accompanying yield absolute values correspond to the post-hoc test result for the UTC value set at 100%.

Details on trial methodology for selectivity trials is summarized in Table 3.4-3 and Table 3.4-4 split for each EPPO climatic zone.

Maritime EPPO Zone

In the tables below, the phytotoxic effects observed in weed free trials are compared to the effects on the yield of those trials (only for trials where a significant phytotoxicity was observed). Slight differences observed could be attributed to natural variation and were not statistically significant in the vast majority of cases. Yield data from all trials are summarized from Table 3.4-28 to Table 3.4-35.

On winter wheat, in one trial on variety Tobak (KCP 6.4-33), a statistically lower yield was observed at N. Nevertheless, this result may be atributed to other reasons than the test product since in the same trial at 2N rate this effect was not observed, neither a reduction was obserevd in other two trial testing the same variety Tobak.

On winter barley, in one trial on variety Etincel (KCP 6.4-58), statistically lower yield was observed at N and 2N rates, despite low levels of phytotoxicity observed. Similar yield reduction was observed for the reference product, despite even lower levels of phytotoxicity (bleaching). Therefore, it is believed that those reductions are due to other reasons than the test products. Moreover, on another trial on the same variety Etincel, higher levels of phytotoxicity were observed and normal yield values were assessed, especially at 2N rate.

On winter rye, in one trial on variety Conduct (KCP 6.4-51), a yield reduction was observed at 2N rate of both GLOB1815H and the reference standard, with a stronger reduction for this last one.

On winter triticale, no statistically significant differences on yield were observed.

Table 3.4-21: Relationship between phytotoxicity and yield on winter wheat – Maritime EPPO zone

Test report	Variety	Maximum phyto. at 1N rate (%) (DAA)		Maximum phyto. at 2N (or other) rate (%) (DAA)		Yield in the untreated control Absolute figures (ton/ha)	Yield at 1N as % of untreated		Yield at 2N as % of untreated	
		GLOB1817H	Standard*	GLOB1817H	Standard*		GLOB1817H	Standard*	GLOB1817H	Standard*
Winter wheat										
KCP 6.4-2	Tobak	5 (14)	5 (14)	10 (14)	5 (14)	7.52	104.73	104.22	108	104.65
KCP 6.4-3	KWS Talent	18.75 (32)	0	37.5 (32)	0	10.35	101.35	101.54	102.72	101.65

*In trial KCP 6.4-3, the reference product Roxy was applied at 5 & 10 L/ha while in KCP 6.4-2 it was applied at 4 & 8 L/ha

Supportive data from GLOB1815H formulation

Table 3.4-22: Relationship between phytotoxicity and yield on winter wheat – GLOB1815H trials – Maritime EPPO zone

Test report	Variety	Maximum phyto. at 1N rate (%) (DAA)		Maximum phyto. at 2N (or other) rate (%) (DAA)		Yield in the untreated control Absolute figures (ton/ha)**	Yield at 1N as % of untreated		Yield at 2N rate as % of untreated	
		GLOB1815H	Standard*	GLOB1815H	Standard*		GLOB1815H	Standard*	GLOB1815H	Standard*
Winter wheat										
KCP 6.4-29	Tobak	17.5 (14)	3 (14)	25 (14)	3 (14)	9.61	100.13	98.61	99.41	101.01
KCP 6.4-61	Fructidor	10 (32)	8 (32)	12 (32)	8 (32)	9.98	110.17	105.55	101.42	100.15
KCP 6.4-33	Tobak	4 (14)	0 (14)	6 (14)	0 (14)	9.1a	94.18b	97.19ab	99.16ab	97.16ab
KCP 6.4-25	Energo	0 (14)	0 (14)	6.75 (14)	0 (14)	6	99.16	99.86	99.3	100.13

*Reference 1: Herold/Naceto/Fosburi at N: 0.6 L/ha, 2N: 1.2 L/ha.
**Letters correspond to the post-hoc test result for the UTC value set at 100%

Table 3.4-23: Relationship between phytotoxicity and yield on winter barley – Maritime EPPO zone

Test report	Variety	Maximum phyto. at 1N rate (%) (DAA)		Maximum phyto. at 2N (or other) rate (%) (DAA)		Yield in the untreated control Absolute figures (ton/ha)	Yield at 1N as % of untreated		Yield at 2N as % of untreated	
		GLOB1817H	Standard*	GLOB1817H	Standard*		GLOB1817H	Standard*	GLOB1817H	Standard*
Winter barley										
KCP 6.4-1	Fabian	80 (14)	57.5 (14)	85 (14)	77.5 (14)	7.71	101.77	106.77	102.89	92.73

Te reference product Roxy was applied at 4 & 8 L/ha

Supportive data from GLOB1815H formulation

Table 3.4-24: Relationship between phytotoxicity and yield on winter barley – GLOB1815H trials – Maritime EPPO zone

Test report	Variety	Maximum phyto. at 1N rate (%) (DAA)		Maximum phyto. at 2N (or other) rate (%) (DAA)		Yield in the untreated control Absolute figures (ton/ha)**	Yield at 1N as % of untreated		Yield at 2N rate as % of untreated	
		GLOB1815H	Standard*	GLOB1815H	Standard*		GLOB1815H	Standard*	GLOB1815H	Standard*
Winter barley										
KCP 6.4-28	Fabian	55 (14)	5 (14)	73.75 (14)	9.25 (14)	9.61	100.73	99.04	100.41	98.41
KCP 6.4-30	Titus	9.5 (14)	2.5 (14)	11 (14)	3 (14)	7.95b	107.54a	102.75b	103.95ab	107.51a
KCP 6.4-31	KWS Meridian	31.25 (14)	0 (14)	38.75 (14)	2.5 (14)	7.92	87.8	97.26	92.18	96.03
KCP 6.4-57	Sandra	4.25 (28)	0 (28)	6.5 (28)	0 (28)	9.91	96.83	97.11	97.31	96.44
KCP 6.4-58	Etincel	5 (15)	0 (15)	15 (15)	5 (106)	9.68a	96.59b	97.93ab	95.6b	94.9b
KCP 6.4-60	Etincel	18.75 (14)	5 (28)	52.5 (14)	8.75 (28)	7.47	92.39	100.74	102.95	96.43

*Reference 1: Herold/Naceto/Fosburi at N: 0.6 L/ha, 2N: 1.2 L/ha.
**Letters correspond to the post-hoc test result for the UTC value set at 100%

Table 3.4-25: Relationship between phytotoxicity and yield on winter rye – Maritime EPPO zone

Test report	Variety	Maximum phyto. at 1N rate (%) (DAA)		Maximum phyto. at 2N (or other) rate (%) (DAA)		Yield in the untreated control Absolute figures (ton/ha)	Yield at 1N as % of untreated		Yield at 2N as % of untreated	
		GLOB1817H	Standard*	GLOB1817H	Standard*		GLOB1817H	Standard*	GLOB1817H	Standard*
Winter rye										
KCP 6.4-4	Inspector	11.25 (14)	0 (14)	17.5 (14)	0 (14)	4.88	93.54	104.42	100.63	98.66

*In trial, the reference product Roxy was applied at 4 & 8 L/ha

Supportive data from GLOB1815H formulation

Table 3.4-26: Relationship between phytotoxicity and yield on winter rye – GLOB1815H trials – Maritime EPPO zone

Test report	Variety	Maximum phyto. at 1N rate (%) (DAA)		Maximum phyto. at 2N (or other) rate (%) (DAA)		Yield in the untreated control Absolute figures (ton/ha)**	Yield at 1N as % of untreated		Yield at 2N rate as % of untreated	
		GLOB1815H	Standard*	GLOB1815H	Standard*		GLOB1815H	Standard*	GLOB1815H	Standard*
Winter rye										
KCP 6.4-64	Daňkovské Nové	15 (14)	3 (14)	20 (14)	5 (14)	5.06c	113.09a	112.85a	114.39a	114.82a
KCP 6.4-34	Inspector	8 (15)	6 (15)	10 (15)	7 (15)	7.85	100.57	97.48	100.37	100.61
KCP 6.4-37	Mephisto	21.25 (14)	5 (14)	37.5 (14)	6.25 (14)	5	98.05	95.36	98.67	93.98
KCP 6.4-51	Conduct	4.25 (28)	7.5 (133)	27.5 (28)	47.5(133)	4.23a	99.4a	94.22ab	91.94b	84.09c
KCP 6.4-36	Performer	0 (179)	10 (179)	5 (179)	61.25 (179)	5.31ab	106.1a	98.4b	100.86ab	94.08b
KCP 6.4-56	Dankowskie Rubin	16.75 (28)	4 (14)	25 (28)	21.25 (14)	8.15ab	99.54ab	99.81ab	95.62b	104.52a
KCP 6.4-68	Dankowskie robin	0 (39)	0 (39)	18.75 (39)	0 (39)	8.99	98.45	103.97	98.22	99.1

*In trial KCP 6.4-64, KCP 6.4-34, the reference product Roxy was applied at 4 & 8 L/ha
In trial KCP 6.4-56, KCP 6.4-68, the reference product Roxy was applied at 5 & 10 L/ha
In trial KCP 6.4-37, KCP 6.4-51, KCP 6.4-36 the reference product Herold/Naceto/Fosburi was applied at N: 0.6 L/ha, 2N: 1.2 L/ha.
**Letters correspond to the post-hoc test result for the UTC value set at 100%

Winter triticale - Supportive data from GLOB1815H formulation

Table 3.4-27: Relationship between phytotoxicity and yield on winter triticale – GLOB1815H trials – Maritime EPPO zone

Test report	Variety	Maximum phyto. at 1N rate (%) (DAA)		Maximum phyto. at 2N (or other) rate (%) (DAA)		Yield in the untreated control Absolute figures (ton/ha)**	Yield at 1N as % of untreated		Yield at 2N rate as % of untreated	
		GLOB1815H	Standard*	GLOB1815H	Standard*		GLOB1815H	Standard*	GLOB1815H	Standard*
Winter triticale										
KCP 6.4-53	Lombardo	5.5 (185)	0 (185)	15 (185)	9.75 (133)	7.24	98.11	98.66	94.26	97.2
KCP 6.4-38	Lombardo	16.25 (14)	1 (14)	40 (14)	1.5 (14)	6.43	97.23	103.03	93.68	100.99
KCP 6.4-62	Kauleos	13 (151)	5.5 (151)	26.75 (151)	14.25 (151)	9.85	99.08	101.99	93.63	98.08
KCP 6.4-59	Omeac	12 (15)	0 (15)	15 (15)	0 (15)	7.68b	108.5a	100.74b	104.99ab	103.31ab

*In trial KCP 6.4-26, the reference product Roxy was applied at 4 & 8 L/ha
In trial KCP 6.4-69, KCP 6.4-62 and KCP 6.4-59, the reference product Roxy was applied at 5 & 10 L/ha
In trial KCP 6.4-53, KCP 6.4-52 and KCP 6.4-38 the reference product Herold was applied at N: 0.5 L/ha, 2N: 1 L/ha.
**Letters correspond to the post-hoc test result for the UTC value set at 100%

Summary of yield data - Maritime EPPO Zone

Table 3.4-28: Impact on yield from GLOB1817H on winter wheat under weed free conditions – Maritime EPPO zone

EPPO zone	Crop code	Nb. trials	Grouping	Assessment type (unit)	Absolut value in the untreated control			Yield at 1N as % of untreated						Yield at 2N as % of untreated					
								GLOB1817H at 3 L/ha (N)			Roxy at 4-5 L/ha (2N)			GLOB1817H at 6 L/ha (2N)			Roxy at 8-10 L/ha (2N)		
					Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn
MAR	TRZAW	2	All	Yield (t/ha)	8.9	7.5-10.4	8.9	103.0	101.4-104.7	103.0	102.9	101.5-104.2	102.9	105.4	102.7-108	105.4	103.2	101.7-104.7	103.2

Supportive data from GLOB1815H formulation

Table 3.4-29: Impact on yield from GLOB1815H on winter wheat under weed free conditions – Maritime EPPO zone

EPPO zone	Crop code	Nb. trials	Grouping	Assessment type (unit)	Absolut value in the untreated control			Yield at 1N as % of untreated									Yield at 2N as % of untreated								
								GLOB1815H at 3.6 L/ha (N)			Naceto at 0.43 L/ha (N)			Herold/Naceto/Fosburi at 0.6 L/ha (N)			GLOB1815H at 7.2 L/ha (2N)			Naceto at 0.86 L/ha (2N)			Herold/Naceto/Fosburi at 1.2 L/ha (2N)		
					Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn
MAR	TRZAW	6	All	Yield (t/ha)	8.2	5.8-10	8.9	100.9	94.2-110.2	100.2	-	-	-	-	-	-	100.3	99.2-102.2	99.7	-	-	-	-	-	-
		1	vs. Naceto at 0.43 L/ha	Yield (t/ha)	5.8	-	-	100.3	-	-	101.5	-	-	-	-	-	102.2	-	-	101.5	-	-	-	-	-
		5	vs. Herold/Naceto/ Fosburi at 0.6 L/ha	Yield (t/ha)	8.7	6-10	9.1	101.0	94.2-110.2	100.1	-	-	-	100.5	97.2-105.6	99.9	99.9	99.2-101.4	99.4	-	-	-	99.7	97.2-101	100.2

Table 3.4-30: Impact on yield from GLOB1817H on winter barley under weed free conditions – Maritime EPPO zone

EPPO zone	Crop code	Nb. trials	Grouping	Assessment type (unit)	Absolut value in the untreated control			Yield at 1N as % of untreated						Yield at 2N as % of untreated					
								GLOB1817H at 3 L/ha (N)			Roxy at 4 L/ha (N)			GLOB1817H at 6 L/ha (2N)			Roxy at 8 L/ha (2N)		
					Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn
MAR	HORVW	1	All	Yield (t/ha)	7.7	7.7-7.7	7.7	101.8	101.8-101.8	101.8	106.8	106.8-106.8	106.8	102.9	102.9-102.9	102.9	92.7	92.7-92.7	92.7

Supportive data from GLOB1815H formulation

Table 3.4-31: Impact on yield from GLOB1815H on winter barley under weed free conditions – Maritime EPPO zone

EPPO zone	Crop code	Nb. trials	Grouping	Assessment type (unit)	Absolut value in the untreated control			Yield at 1N as % of untreated						Yield at 2N as % of untreated					
								GLOB1815H at 3.6 L/ha (N)			Herold/Naceto/Fosburi at 0.6 L/ha (N)			GLOB1815H at 7.2 L/ha (2N)			Herold/Naceto/Fosburi at 1.2 L/ha (2N)		
					Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn
MAR	HORVW	6	All	Yield (t/ha)	8.8	7.5-9.9	8.0	97.0	87.8-107.5	96.8	99.1	97.1-102.8	99.0	98.7	92.2-104	100.4	98.3	94.9-107.5	96.4

Table 3.4-32: Impact on yield from GLOB1817H on winter rye under weed free conditions – Maritime EPPO zone

EPPO zone	Crop code	Nb. trials	Grouping	Assessment type (unit)	Absolut value in the untreated control			Yield at 1N as % of untreated						Yield at 2N as % of untreated					
								GLOB1817H at 3 L/ha (N)			Roxy at 4 L/ha (N)			GLOB1817H at 6 L/ha (2N)			Roxy at 8 L/ha (2N)		
					Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn
MAR	SECCW	1	All	Yield (t/ha)	5.2	5.2-5.2	5.2	93.5	93.5-93.5	93.5	104.4	104.4-104.4	104.4	100.6	100.6-100.6	100.6	98.7	98.7-98.7	98.7

Supportive data from GLOB1815H formulation

Table 3.4-33: Impact on yield from GLOB1815H on winter rye under weed free conditions – Maritime EPPO zone

EPPO zone	Crop code	Nb. trials	Grouping	Assessment type (unit)	Absolut value in the untreated control			Yield at 1N as % of untreated									Yield at 2N as % of untreated								
								GLOB1815H at 3.6 L/ha (N)			Roxy at 4-5 L/ha (N)			Herold at 0.6 L/ha (N)			GLOB1815H at 7.2 L/ha (2N)			Roxy at 8-10 L/ha (2N)			Herold at 1.2 L/ha (2N)		
					Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn
MAR	SECCW	7	All	Yield (t/ha)	6.4	4.2-9	5.3	102.2	98.1-113.1	99.5	-	-	-	-	-	-	100.0	91.9-114.4	98.7	-	-	-	-	-	-
		4	vs. Roxy at 4-5 L/ha	Yield (t/ha)	7.5	5.1-9	8.0	102.9	98.5-113.1	100.1	103.5	97.5-112.9	101.9	-	-	-	102.2	95.6-114.4	99.3	104.8	99.1-114.8	102.6	-	-	-
		3	vs. Herold at 0.6 L/ha	Yield (t/ha)	4.8	4.2-5.3	5.0	101.2	98.1-106.1	99.4	-	-	-	96.0	94.2-98.4	95.4	97.2	91.9-100.9	98.7	-	-	-	90.7	84.1-94.1	94.0

Table 3.4-34: Impact on yield from GLOB1817H on winter triticale under weed free conditions – Maritime EPPO zone

EPPO zone	Crop code	Nb. trials	Grouping	Assessment type (unit)	Absolut value in the untreated control			Yield at 1N as % of untreated						Yield at 2N as % of untreated					
								GLOB1817H at 3 L/ha (N)			Boxer at 5 L/ha (2N)			GLOB1817H at 6 L/ha (2N)			Boxer at 10 L/ha (2N)		
					Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn
MAR	SECCW	1	All	Yield (t/ha)	4.8	4.8-4.8	4.8	99.8	99.8-99.8	99.8	103.9	103.9-103.9	103.9	105.0	105-105	105.0	98.8	98.8-98.8	98.8

Supportive data from GLOB1815H formulation

Table 3.4-35: Impact on yield from GLOB1815H on winter triticale under weed free conditions – Maritime EPPO zone

EPPO zone	Crop code	Nb. trials	Grouping	Assessment type (unit)	Absolut value in the untreated control			Yield at 1N as % of untreated									Yield at 2N as % of untreated								
								GLOB1815H at 3.6 L/ha (N)			Roxy at 4-5 L/ha (N)			Herold at 0.5 L/ha (N)			GLOB1815H at 7.2 L/ha (2N)			Roxy at 8-10 L/ha (2N)			Herold at 1 L/ha (2N)		
					Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn
MAR	TTLWI	7	All	Yield (t/ha)	7.3	5.9-9.9	7.2	100.7	97.2-108.5	99.1	-	-	-	-	-	-	97.9	93.6-105	97.5	-	-	-	-	-	-
		4	vs. Roxy at 4-5 L/ha	Yield (t/ha)	7.8	5.9-9.9	7.7	101.4	97.8-108.5	99.7	100.7	99.6-102	100.7				99.0	93.6-105	98.7	100.8	98.1-103.3	101.0			
		3	vs. Herold/Naceto/Fosburi at 0.6 L/ha	Yield (t/ha)	6.7	6.4-7.2	6.4	99.7	97.2-103.9	98.1	-	-	-	101.3	98.7-103	102.3	96.4	93.7-101.3	94.3	-	-	-	99.6	97.2-101	100.5

North-East EPPO Zone

In the tables below, the phytotoxic effects observed in weed free trials are compared to the effects on the yield of those trials (only for trials where a significant phytotoxicity was observed carried out in the North-East EPPO Zone). Slight differences observed could be attributed to natural variation and were never statistically significant for GLOB1817H or GLOB1815H.

Yield data from all trials are summarized from trials conducted in Poland combined with the results of the German and Czech trials since these are neighbouring countries and considered as valid to the cMS Poland and presented from Table 3.4-43 to Table 3.4-50.

On winter wheat, in one trial on variety Arkadia (KCP 6.4-65), a numerical yield reduction was observed especially at 2N but not statistically different from untreated plots nor from the reference product.

On winter barley, no statistically significant differences on yield were observed.

On winter rye, in one trial on variety Dańkowskie Złote (KCP 6.4-42) with high discoloration and thining, a numerical yield reduction was observed especially at 2N but not statistically different from untreated plots nor from the reference product.

On winter triticale, no statistically significant differences on yield were observed. Even for 1 trial (KCP 6.4-43 conduct in Poland on variety Securo) where yield at N or 2N was about 93-96% compared to untreated control set at 100%, these results were statistically comparable. Moreover, another trial on the same variety showed no negative effect.

Table 3.4-36: Relationship between phytotoxicity and yield on winter wheat – North-East EPPO zone

Test report	Variety	Maximum phyto. at 1N rate (%) (DAA)		Maximum phyto. at 2N (or other) rate (%) (DAA)		Yield in the untreated control Absolute figures (ton/ha)	Yield at 1N as % of untreated		Yield at 2N rate as % of untreated	
		GLOB1817H	Standard 1*	GLOB1817H	Standard 1*		GLOB1817H	Standard 1*	GLOB1817H	Standard 1*
Winter wheat										
KCP 6.4-8	Julius	16.25 (14)	8.75 (14)	27.5 (14)	26.25 (14)	6.64	99.69	101.35	101.34	100.38

*In trial, the reference product Jura was applied at 4 & 8 L/ha

Supportive data from GLOB1815H formulation

Table 3.4-37: Relationship between phytotoxicity and yield on winter wheat – GLOB1815H trials – North-East EPPO zone

Test report	Variety	Maximum phyto. at 1N rate (%) (DAA)		Maximum phyto. at 2N (or other) rate (%) (DAA)		Yield in the untreated control Absolute figure (ton/ha)	Yield at 1N as % of untreated		Yield at 2N rate as % of untreated	
		GLOB1815H	Standard*	GLOB1815H	Standard*		GLOB1815H	Standard*	GLOB1815H	Standard*
Winter wheat										
KCP 6.4-39	Kepler	32.5 (28)	0 (28)	65 (28)	0 (28)	7.42	95.58	101.29	92.79	97.29
KCP 6.4-65	Arkadia	8.75 (28)	0 (28)	32.5 (28)	0 (28)	3.81	84.18	91.17	78.2	80.25

*Reference: Herold at N: 0.35 L/ha, 2N: 0.7 L/ha

Table 3.4-38: Relationship between phytotoxicity and yield on winter barley – North-East EPPO zone

Test report	Variety	Maximum phyto. at 1N rate (%) (DAA)			Maximum phyto. at 2N (or other) rate (%) (DAA)			Yield in the untreated control Absolute figures (ton/ha)	Yield at 1N as % of untreated			Yield at 2N rate as % of untreated		
		GLOB1817H	Standard 1*	Standard 2*	GLOB1817H	Standard 1*	Standard 2*		GLOB1817H	Standard 1*	Standard 2*	GLOB1817H	Standard 1*	Standard 2*
Winter barley														
KCP 6.4-6	Ida	12.5 (14)	-	6.25 (14)	16.25 (14)	-	2 (14)	5	112.09	-	100.23	107.14	-	115.55
KCP 6.4-7	KWS Kosmos	1.5 (28)	5.75 (28)	-	5.75 (28)	13.75 (28)	-	5.67	95.69	92.13	-	95.03	94.99	-

Reference 1: Jura at N: 4 L/ha, 2N: 8 L/ha
Reference 2: Boxer at N: 3 L/ha, 2N: 6 L/ha

Supportive data from GLOB1815H formulation

Table 3.4-39: Relationship between phytotoxicity and yield on winter barley – GLOB1815H trials – North-East EPPO zone

Test report	Variety	Maximum phyto. at 1N rate (%) (DAA)		Maximum phyto. at 2N (or other) rate (%) (DAA)		Yield in the untreated control Absolute figures (ton/ha)	Yield at 1N as % of untreated		Yield at 2N rate as % of untreated	
		GLOB1815H	Standard*	GLOB1815H	Standard*		GLOB1815H	Standard*	GLOB1815H	Standard*
Winter barley										
KCP 6.4-41	SY TEPEE	47.5 (14)	17.5 (14)	70 (14)	8.75 (28)	7.18	97.51	101.87	96.69	93.36
KCP 6.4-45	Gloria	6.5 (28)	0.5 (28)	13.75 (28)	3.25 (28)	7.42	103.49	102.7	104.18	105.75
KCP 6.4-66	Kosmos	11.25 (14)	0 (14)	26.25 (14)	0 (14)	6.34	100.02	100.49	99.45	101.09

*Reference: Herold at N: 0.35 L/ha, 2N: 0.7 L/ha

Table 3.4-40: Relationship between phytotoxicity and yield on winter triticale – North-East EPPO zone

Test report	Variety	Maximum phyto. at 1N rate (%) (DAA)			Maximum phyto. at 2N (or other) rate (%) (DAA)			Yield in the untreated control Absolute figures (ton/ha)	Yield at 1N as % of untreated			Yield at 2N rate as % of untreated		
		GLOB1817H	Standard 1*	Standard 2*	GLOB1817H	Standard 1*	Standard 2*		GLOB1817H	Standard 1*	Standard 2*	GLOB1817H	Standard 1*	Standard 2*
Winter triticale														
KCP 6.4-10	Porto	0	2.25 (14)	-	2.75 (14)	5.25 (28)	-	5.14	98.64	102.17		101.51	97.96	
KCP 6.4-12	Sekret	7.5 (14)	-	2 (14)	16.25 (14)	-	1.5 (14)	3.14	99.91		94.31	99.22		100

Supportive data from GLOB1815H formulation

Table 3.4-41: Relationship between phytotoxicity and yield on winter triticale – GLOB1815H trials – North-East EPPO zone

Test report	Variety	Maximum phyto. at 1N rate (%) (DAA)		Maximum phyto. at 2N (or other) rate (%) (DAA)		Yield in the untreated control Absolute figures (ton/ha)**	Yield at 1N as % of untreated		Yield at 2N rate as % of untreated	
		GLOB1815H	Standard*	GLOB1815H	Standard*		GLOB1815H	Standard*	GLOB1815H	Standard*
Winter triticale										
KCP 6.4-43	Securo	32.5 (25)	7.5 (25)	72.5 (25)	7.5 (25)	6.04	96.41	100.8	93.54	99.25
KCP 6.4-48	Securo	5.75 (14)	0 (14)	9 (14)	2 (14)	6.42	101.76	103.27	103.37	101.35
KCP 6.4-67	Borwo	20 (14)	0 (14)	30 (14)	0 (14)	3.62ab	110.82ab	114.58a	100.08ab	92.45b

*Reference: Herold at N: 0.35 L/ha, 2N: 0.7 L/ha
**Letters correspond to the post-hoc test result for the UTC value set at 100%

Winter rye
Supportive data from GLOB1815H formulation

Table 3.4-42: Relationship between phytotoxicity and yield on winter rye – GLOB1815H trials – North-East EPPO zone

Test report	Variety	Maximum phyto. at 1N rate (%) (DAA)		Maximum phyto. at 2N (or other) rate (%) (DAA)		Yield in the untreated control Absolute figures (ton/ha)**	Yield at 1N as % of untreated		Yield at 2N rate as % of untreated	
		GLOB1815H	Standard*	GLOB1815H	Standard*		GLOB1815H	Standard*	GLOB1815H	Standard*
Winter rye										
KCP 6.4-44	KWS Binntto	5.75 (28)	1 (14)	9.5 (14)	9 (14)	7.46	101	104.38	102.25	102.53
KCP 6.4-42	Dańkowskie Złote	47.5 (28)	6.25 (28)	88.75 (138)	11.25 (28)	4.37	89.29	89.02	79.8	96.56
KCP 6.4-47	SU Nasri	8.5 (14)	0 (14)	11.25 (14)	1.75 (14)	5.19b	104.95ab	104.4ab	110.98a	110.4a
KCP 6.4-46	Dankowskie Diament	25 (28)	12.5 (28)	31.25 (28)	15 (28)	5.14	94.99	94.93	94.35	89.09

*Reference: Herold at N: 0.35 L/ha, 2N: 0.7 L/ha
**Letters correspond to the post-hoc test result for the UTC value set at 100%

Summary of yield data - North-East EPPO Zone

Table 3.4-43: Impact on yield from GLOB1817H on winter wheat under weed free conditions – North-East EPPO zone

EPPO zone	Crop code	Nb. trials	Grouping	Assessment type (unit)	Absolut value in the untreated control			Yield at 1N as % of untreated									Yield at 2N as % of untreated								
								GLOB1817H at 3 L/ha (N)			Jura at 4 L/ha (N)			Roxy at 4 L/ha (N)			GLOB1817H at 6 L/ha (2N)			Jura at 8 L/ha (2N)			Roxy at 8 L/ha (2N)		
					Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn
NE (+CZ)	TRZAW	2	All	Yield (t/ha)	7.1	6.6-7.5	7.1	102.2	99.7-104.7	102.2	-	-	-	-	-	-	104.7	101.3-108	104.7	-	-	-	-	-	-
		1	vs. Jura	Yield (t/ha)	6.6	-	-	99.7	-	-	101.4	-	-	-	-	-	101.3	-	-	100.4	-	-	-	-	-
		1	vs. Roxy	Yield (t/ha)	7.5	-	-	104.7	-	-	-	-	-	104.2	-	-	108.0	-	-	-	-	-	104.7	-	-

Supportive data from GLOB1815H formulation

Table 3.4-44: Impact on yield from GLOB1815H on winter wheat under weed free conditions – North-East EPPO zone

EPPO zone	Crop code	Nb. trials	Grouping	Assessment type (unit)	Absolut value in the untreated control			Yield at 1N as % of untreated									Yield at 2N as % of untreated								
								GLOB1815H at 3.6 L/ha (N)			Herold at 0.35 L/ha (N)			Herold/Naceto at 0.6 L/ha (N)			GLOB1815H at 7.2 L/ha (2N)			Herold at 0.7 L/ha (2N)			Herold/Naceto at 1.2 L/ha (2N)		
					Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn
NE (+CZ,DE)	TRZAW	8	All	Yield (t/ha)	7.2	3.8-9.6	7.1	96.9	84.2-101.5	99.5	-	-	-	-	-	-	96.1	78.2-101.2	99.2	-	-	-	-	-	-
		4	vs. Herold at 0.35 L/ha	Yield (t/ha)	6.0	3.8-7.4	6.5	95.0	84.2-100.4	97.7	98.3	91.2-101.3	100.3	-	-	-	92.7	78.2-101.2	95.8	94.8	80.3-101.4	98.8	-	-	-
		4	vs. Herold/Naceto at 0.6 L/ha	Yield (t/ha)	8.3	6-9.6	8.9	98.7	94.2-101.5	99.6	-	-	-	99.2	97.2-101.3	99.2	99.5	99.2-100	99.4	-	-	-	99.6	97.2-101	100.2

Table 3.4-45: Impact on yield from GLOB1817H on winter barley under weed free conditions – North-East EPPO zone

EPPO zone	Crop code	Nb. trials	Grouping	Assessment type (unit)	Absolut value in the untreated control			Yield at 1N as % of untreated									Yield at 2N as % of untreated								
								GLOB1817H at 3 L/ha (N)			Jura at 4 L/ha (N)			Roxy/Boxer at 3-4 L/ha (2N)			GLOB1817H at 6 L/ha (2N)			Jura at 8 L/ha (2N)			Roxy/Boxer at 6-8 L/ha (2N)		
					Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn
NE (+CZ)	HORVW	3	All	Yield (t/ha)	6.1	5-7.7	5.7	103.2	95.7-112.1	101.8	-	-	-	-	-	-	101.7	95-107.1	102.9	-	-	-	-	-	-
		1	vs. Jura	Yield (t/ha)	5.7	-	-	95.7	-	-	92.1	-	-	-	-	-	95.0	-	-	95.0	-	-	-	-	-
		2	vs. Roxy	Yield (t/ha)	6.4	5-7.7	6.4	106.9	101.8-112.1	106.9	-	-	-	103.5	100.2-106.8	103.5	105.0	102.9-107.1	105.0	-	-	-	104.1	92.7-115.6	104.1

Supportive data from GLOB1815H formulation

Table 3.4-46: Impact on yield from GLOB1815H on winter barley under weed free conditions – North-East EPPO zone

EPPO zone	Crop code	Nb. trials	Grouping	Assessment type (unit)	Absolut value in the untreated control			Yield at 1N as % of untreated									Yield at 2N as % of untreated								
								GLOB1815H at 3.6 L/ha (N)			Herold at 0.35 L/ha (N)			Herold/Naceto at 0.6 L/ha (N)			GLOB1815H at 7.2 L/ha (2N)			Herold at 0.7 L/ha (2N)			Herold/Naceto at 1.2 L/ha (2N)		
					Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn
NE(+CZ,DE)	HORVW	8	All	Yield (t/ha)	7.8	6-9.9	7.7	99.5	87.8-107.5	100.4	-	-	-	-	-	-	99.8	92.2-104.2	99.9	-	-	-	-	-	-
		4	vs. Herold at 0.35 L/ha	Yield (t/ha)	6.7	6-7.4	6.8	100.8	97.5-103.5	101.0	101.0	98.9-102.7	101.2	-	-	-	101.1	96.7-104.2	101.8	100.3	93.4-105.8	101.0	-	-	-
		4	vs. Herold/Naceto at 0.6 L/ha	Yield (t/ha)	8.8	7.9-9.9	8.8	98.2	87.8-107.5	98.8	-	-	-	99.0	97.1-102.8	98.2	98.5	92.2-104	98.9	-	-	-	99.6	96-107.5	97.4

Table 3.4-47: Impact on yield from GLOB1817H on winter rye under weed free conditions – North-East EPPO zone

EPPO zone	Crop code	Nb. trials	Grouping	Assessment type (unit)	Absolut value in the untreated control			Yield at 1N as % of untreated									Yield at 2N as % of untreated								
								GLOB1817H at 3 L/ha (N)			Jura at 4 L/ha (N)			Roxy/Boxer at 3-4 L/ha (2N)			GLOB1817H at 6 L/ha (2N)			Jura at 8 L/ha (2N)			Roxy/Boxer at 6-8 L/ha (2N)		
					Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn
NE (+CZ)	SECCW	3	All	Yield (t/ha)	5.6	5.2-6	5.5	98.9	93.5-104.1	99.1	-	-	-	-	-	-	100.3	99.9-100.6	100.3	-	-	-	-	-	-
NE (+CZ)	SECCW	1	vs. Jura	Yield (t/ha)	5.5	-	-	104.1	104.1-104.1	104.1	99.4	-	-	-	-	-	100.3	100.3-100.3	100.3	101.9	-	-	-	-	-
NE (+CZ)	SECCW	2	vs. Roxy	Yield (t/ha)	5.6	5.2-6	5.6	96.3	93.5-99.1	96.3	-	-	-	102.4	100.4-104.4	102.4	100.2	99.9-100.6	100.2	-	-	-	99.4	98.7-100.2	99.4

Supportive data from GLOB1815H formulation

Table 3.4-48: Impact on yield from GLOB1815H on winter rye under weed free conditions – North-East EPPO zone

EPPO zone	Crop code	Nb. trials	Grouping	Assessment type (unit)	Absolut value in the untreated control			Yield at 1N as % of untreated												Yield at 2N as % of untreated								
								GLOB1815H at 3.6 L/ha (N)			Roxy at 4 L/ha (N)			Herold at 0.35 L/ha (N)			Herold at 0.6 L/ha (N)			GLOB1815H at 7.2 L/ha (2N)			Roxy at 8 L/ha (2N)			Herold at 0.7 L/ha (2N)			Herold at 1.2 L/ha (2N)		
					Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn
NE (+CZ,DE)	SECCW	9	All	Yield (t/ha)	5.5	4.2-7.9	5.1	100.8	89.3-113.1	100.6	-	-	-	-	-	-	-	-	-	99.3	79.8-114.4	100.4	-	-	-	-	-	-	-	-	-
		4	vs. Herold at 0.35 L/ha	Yield (t/ha)	5.5	4.4-7.5	5.2	97.6	89.3-105	98.0	-	-	-	98.2	89-104.4	99.7	-	-	-	96.8	79.8-111	98.3	-	-	-	99.6	89.1-110.4	99.5	-	-	-
		2	vs. Roxy at 4-5 L/ha	Yield (t/ha)	6.5	5.1-7.9	6.5	106.8	100.6-113.1	106.8	105.2	97.5-112.9	105.2	-	-	-	-	-	-	107.4	100.4-114.4	107.4	107.7	100.6-114.8	107.7	-	-	-	-	-	-
		3	vs. Herold at 0.6 L/ha	Yield (t/ha)	4.8	4.2-5.3	5.0	101.2	98.1-106.1	99.4	-	-	-	-	-	-	96.0	94.2-98.4	95.4	97.2	91.9-100.9	98.7	-	-	-	-	-	-	90.7	84.1-94.1	94.0

Table 3.4-49: Impact on yield from GLOB1817H on winter triticale under weed free conditions – North-East EPPO zone

EPPO zone	Crop code	Nb. trials	Grouping	Assessment type (unit)	Absolut value in the untreated control			Yield at 1N as % of untreated									Yield at 2N as % of untreated								
								GLOB1817H at 3 L/ha (N)			Jura at 4 L/ha (N)			Roxy/Boxer at 3-4 L/ha (2N)			GLOB1817H at 6 L/ha (2N)			Jura at 8 L/ha (2N)			Roxy/Boxer at 6-8 L/ha (2N)		
					Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn
NE (+DE)	TTLWI	3	All	Yield (t/ha)	4.4	3.1-5.1	4.8	99.4	98.6-99.9	99.8	-	-	-	-	-	-	101.9	99.2-105	101.5	-	-	-	-	-	-
NE (+DE)	TTLWI	1	vs. Jura	Yield (t/ha)	5.1	-	-	98.6	98.6-98.6	98.6	102.2	-	-	-	-	-	101.5	101.5-101.5	101.5	98.0	-	-	-	-	-
NE (+DE)	TTLWI	2	vs. Roxy	Yield (t/ha)	4.0	3.1-4.8	4.0	99.8	99.8-99.9	99.8	-	-	-	99.1	94.3-103.9	99.1	102.1	99.2-105	102.1	-	-	-	99.4	98.8-100	99.4

Supportive data from GLOB1815H formulation

Table 3.4-50: Impact on yield from GLOB1815H on winter triticale under weed free conditions – North-East EPPO zone

EPPO zone	Crop code	Nb. trials	Grouping	Assessment type (unit)	Absolut value in the untreated control			Yield at 1N as % of untreated										Yield at 2N as % of untreated											
								GLOB1815H at 3.6 L/ha (N)			Roxy at 4 L/ha (N)			Herold at 0.35 L/ha (N)			Herold at 0.5 L/ha (N)			GLOB1815H at 7.2 L/ha (2N)			Roxy at 8 L/ha (2N)			Herold at 0.7 L/ha (2N)			Herold at 1 L/ha (2N)		
					Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn
NE (+CZ,DE)	TTLWI	8	All	Yield (t/ha)	5.9	3.6-7.7	6.4	100.7	96.4-110.8	99.2	-	-	-	-	-	-	-	-	-	98.2	93.5-103.4	99.9	-	-	-	-	-	-	-	-	-
		4	vs. Herold at 0.35 L/ha	Yield (t/ha)	5.0	3.6-6.4	4.9	101.6	96.4-110.8	99.5	-	-	-	105.1	100.8-114.6	102.6	-	-	-	99.2	93.5-103.4	100.0	-	-	-	98.7	92.5-101.6	100.3	-	-	-
		1	vs. Roxy at 4 L/ha	Yield (t/ha)	7.7	-	-	100.4	-	-	99.6	-	-	-	-	-	-	-	-	99.9	-	-	99.6	-	-	-	-	-	-	-	-
		3	vs. Herold at 0.5 L/ha	Yield (t/ha)	6.7	6.4-7.2	6.4	99.7	97.2-103.9	98.1	-	-	-	-	-	-	101.3	98.7-103	102.3	96.4	93.7-101.3	94.3	-	-	-	-	-	-	99.6	97.2-101	100.5

Conclusion

A total of 54 specific selectivity trials (weed free) carried out between 2018 and 2019 in the Czech Republic, Germany, northern part of France, the Netherlands and the United Kingdom (31 trials belonging to the Maritime EPPO zone), as well as in Poland (23 trials belonging to the North-East EPPO Zone) on the target crops wheat, barley, rye and triticale. Table 3.4-51 shows the overall yield results obtained from all weed free trials.

In the vast majority of the trials, GLOB1817H at the proposed label rate of 3 L/ha (N) or GLOB1815H at the rate of 3.6 L/ha (providing higher amounts of actives), did not have any statistically significant effect on the yield of the target crops in the absence of weed compared to the untreated plots. Slight differences observed could be usually attributed to natural variation and were not observed in the same variety in different trials.

The differences in yield between test product and untreated plots were significant and could not be linked to other sources of variation in only 1 out of 8 trials on winter rye in the Maritime zone. Nevertheless, the detrimental effect on yield was higher for the reference products.

Overall, these results confirm that there is no risk for negative side effects on yield of the treated winter cereals when overlap of sprays is avoided. Moreover, even when some transient phytotoxic symptoms were observed as presented in 3.4.1 (KCP 6.4.1), the global plant health status was normally able to recover and no significant effects on final yield were observed.

Table 3.4-51: Overall yield results from GLOB1817H and GLOB1815H on cereals under weed free conditions across EPPO zones

EPPO zone	Crop code	Nb. trials	Absolut value in the untreated control			Yield at 1N as % of untreated						Yield at 2N as % of untreated					
						GLOB1817H / GLOB1815H at 3 / 3.6 L/ha (N)			Standards			GLOB1817H / GLOB1815H at 6 / 7.2 L/ha (2N)			Standards		
			Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn
MAR	TRZAW	8	8.4	5.8-10.4	8.9	101.4	94.2-110.2	100.8	101.2	97.2-105.6	101.4	101.5	99.2-108	100.7	100.8	97.2-104.7	100.7
	HORVW	7	8.6	7.5-9.9	8.0	97.7	87.8-107.5	96.8	100.2	97.1-106.8	99.0	99.3	92.2-104	100.4	97.5	92.7-107.5	96.4
	SECCW	8	6.2	4.2-9	5.3	101.1	93.5-113.1	99.5	100.8	94.2-112.9	99.1	100.1	91.9-114.4	99.5	98.7	84.1-114.8	98.9
	TTLWI	8	7.0	4.8-9.9	6.8	100.6	97.2-108.5	99.4	101.3	98.7-103.9	101.4	98.8	93.6-105	98.7	100.1	97.2-103.3	100.1
NE (+CZ, DE)	TRZAW	10	7.2	3.8-9.6	7.1	97.9	84.2-104.7	99.7	99.6	91.2-104.2	100.3	97.8	78.2-108	99.4	95.9	80.3-101.4	100.3
	HORVW	11	7.3	5-9.9	7.4	100.5	87.8-112.1	100.7	99.9	92.1-106.8	100.2	100.3	92.2-107.1	100.4	99.2	93.4-105.8	100.9
	SECCW	12	5.5	4.2-7.9	5.2	100.3	89.3-113.1	100.0	99.6	89-112.9	98.9	99.5	79.8-114.4	100.3	98.9	84.1-114.8	99.4
	TTLWI	11	5.5	3.1-7.7	6.0	100.4	96.4-110.8	99.8	102.2	94.3-114.6	102.2	99.2	93.5-105	99.9	99.1	92.5-101.6	99.6

Comments of zRMS:	54 selectivity trials were conducted and taken to harvest between 2018 and 2019 to assess the potential impact of 'GLOB1817H' on the yield of winter cereals. The design and analysis of the trials was in accordance with the relevant EPPO standards. The trials were conducted in the Czech Republic, Germany, northern part of France, the Netherlands and the United Kingdom (31 trials belonging to the Maritime EPPO zone), as well as in Poland (23 trials belonging to the North-East EPPO Zone). **Maritime EPPO Zone** In the Maritime EPPO Zone, a statistically lower yield was observed in two cases. In one trial on winter wheat, a lower yield was observed, but in the same trial with the 2N dose this effect was not observed. The second case of yield reduction was observed on winter barley at N and 2 N rates. A similar yield reduction was observed for the reference product, despite even lower levels of phytotoxicity effect. Overall, the yield following treatments with 'GLOB1817H' and the reference products at both N and 2N was comparable to the untreated. The data indicate that at the proposed dose 3 l/ha of 'GLOB1817H' is unlikely to have a significant negative effect on the yield of winter cereals. **North east EPPO zone** In the North East EPPO zone, statistically lower yield was observed in two cases. Overall, the yield following treatments with 'GLOB1817H' and the reference products at both N and 2N were comparable to the untreated. The data indicate that at the proposed dose 3 l/ha of 'GLOB1817H' is unlikely to have a significant negative effect on the yield of winter cereals.

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

The effect on the quality was determined in all the crop safey trials presented in section 3.4 in accordance with the EPPO standard PP 1/135 (4) requirements.

The hectoliter weight (HLW) was evaluated in 54 specific selectivity trials (weed free) carried out between 2018 and 2019 in the Czech Republic, Germany, northern part of France, the Netherlands and the United Kingdom (31 trials belonging to the Maritime EPPO zone), as well as in Poland (23 trials belonging to the North-East EPPO Zone).

Results from trials conducted in Poland were combined with the results of the German and Czech trials (21 trials) since these are neighbouring countries and considered as valid to the cMS Poland. The combined results from 44 trials are thus shown in the tables below under the North-East EPPO zone section.

The test formulation GLOB1817H and the analogous formulation GLOB1815H were used in order to demonstrate the crop safety as described above in point 3.4 Adverse effects on treated crops (KCP 6.4).

In all the selectivity trials GLOB1817H was applied once according to the GAP table (crop BBCH 10-14) at the rate of 3 L/ha (N) and 6 L/ha (2N), respectively representing the maximum target rate and the double target rate of application. GLOB1815H was applied at 3.6 L/ha (N) and 7.2 L/ha (2N), providing at higher amount of actives per hectare and thus corresponding to a worst case situation.

Commercial standards, were as well applied at N and 2N as comparison. Details of the reference standards used in trials and application rates are presented in Table 3.4-2.

Plots were harvested individually to give results in kg per volume (100 L). The percentage relative to the control is shown in the tables below and the absolute values assessed are reported for the untreated check.

Statistical analysis was made as letter test based on Student-Newman-Keuls (P = 0.05). Where no letter is presented no difference was registered among treatments. Letters accompanying HLW absolute values correspond to the post-hoc test result for the UTC value set at 100%.

Details on trial methodology for selectivity trials is summarized in Table 3.4-3 and Table 3.4-4, split for each EPPO climatic zone.

Maritime EPPO Zone

Summary of quality data - Maritime EPPO Zone

Table 3.4-52: Impact on the quality (HLW) from GLOB1817H on winter wheat under weed free conditions – Maritime EPPO zone

EPPO zone	Crop code	Nb. trials	Grouping	Assessment type (unit)	Absolut value in the untreated control			% of untreated at 1N						% of untreated at 2N					
								GLOB1817H at 3 L/ha (N)			Roxy at 4-5 L/ha (2N)			GLOB1817H at 6 L/ha (2N)			Roxy at 8-10 L/ha (2N)		
					Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn
MAR	TRZAW	2	All	HLW (kg/100L)	59.4	52.1-66.8	59.4	98.9	97.7-100.1	98.9	104.4	102.7-106.1	104.4	99.7	98.9-100.4	99.7	99.6	97.7-101.5	99.6

Supportive data from GLOB1815H formulation

Table 3.4-53: Impact on the quality (HLW) from GLOB1815H on winter wheat under weed free conditions – Maritime EPPO zone

EPPO zone	Crop code	Nb. trials	Grouping	Assessment type (unit)	Absolut value in the untreated control			Yield at 1N as % of untreated									Yield at 2N as % of untreated								
								GLOB1815H at 3.6 L/ha (N)			Naceto at 0.43 L/ha (N)			Herold/Naceto/Fosburi at 0.6 L/ha (N)			GLOB1815H at 7.2 L/ha (2N)			Naceto at 0.86 L/ha (2N)			Herold/Naceto/Fosburi at 1.2 L/ha (2N)		
					Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn
MAR	TRZAW	6	All	HLW (kg/100L)	76.9	69.2-83.4	77.3	100.8	99.9-103.6	100.3	-	-	-	-	-	-	100.4	98.4-102.5	100.3	-	-	-	-	-	-
		1	vs. Naceto at 0.43 L/ha	HLW (kg/100L)	69.2	-	-	100.7	-	-	100.5	-	-	-	-	-	101.1	-	-	100.8	-	-	-	-	-
		5	vs. Herold/Naceto/ Fosburi at 0.6 L/ha	HLW (kg/100L)	78.4	73.5-83.4	80.1	100.8	99.9-103.6	100.3	-	-	-	100.4	99.6-103	99.7	100.2	98.4-102.5	99.9	-	-	-	100.6	99.2-103.8	100.0

Table 3.4-54: Impact on quality (HLW) from GLOB1817H on winter barley under weed free conditions – Maritime EPPO zone

EPPO zone	Crop code	Nb. trials	Grouping	Assessment type (unit)	Absolut value in the untreated control			% of untreated at 1N						% of untreated at 2N					
								GLOB1817H at 3 L/ha (N)			Roxy at 4 L/ha (N)			GLOB1817H at 6 L/ha (2N)			Roxy at 8 L/ha (2N)		
					Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn
MAR	HORVW	1	All	HLW (kg/100L)	53.2	53.2-53.2	53.2	99.5	99.5-99.5	99.5	100.5	100.5-100.5	100.5	100.1	100.1-100.1	100.1	100.2	100.2-100.2	100.2

Supportive data from GLOB1815H formulation

Table 3.4-55: Impact on the quality (HLW) from GLOB1815H on winter barley under weed free conditions – Maritime EPPO zone

EPPO zone	Crop code	Nb. trials	Grouping	Assessment type (unit)	Absolut value in the untreated control			Yield at 1N as % of untreated						Yield at 2N as % of untreated					
								GLOB1815H at 3.6 L/ha (N)			Herold/Naceto/Fosburi at 0.6 L/ha (N)			GLOB1815H at 7.2 L/ha (2N)			Herold/Naceto/Fosburi at 1.2 L/ha (2N)		
					Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn
MAR	HORVW	6	All	HLW (kg/100L)	63.8	56.3-69.2	65.4	100.9	98.3-103.8	101.4	100.8	97.8-105.7	99.5	101.8	100.2-103	102.5	101.6	98.7-105.3	102.4

Table 3.4-56: Impact on quality (HLW) from GLOB1817H on winter rye under weed free conditions – Maritime EPPO zone

EPPO zone	Crop code	Nb. trials	Grouping	Assessment type (unit)	Absolut value in the untreated control			% of untreated at 1N						% of untreated at 2N					
								GLOB1817H at 3 L/ha (N)			Roxy at 4 L/ha (N)			GLOB1817H at 6 L/ha (2N)			Roxy at 8 L/ha (2N)		
					Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn
MAR	SECCW	1	All	HLW (kg/100L)	70.3	70.3-70.3	70.3	97.5	97.5-97.5	97.5	100.2	100.2-100.2	100.2	97.5	97.5-97.5	97.5	100.4	100.4-100.4	100.4

Supportive data from GLOB1815H formulation

Table 3.4-57: Impact on the quality (HLW) from GLOB1815H on winter rye under weed free conditions – Maritime EPPO zone

EPPO zone	Crop code	Nb. trials	Grouping	Assessment type (unit)	Absolut value in the untreated control			Yield at 1N as % of untreated									Yield at 2N as % of untreated								
								GLOB1815H at 3.6 L/ha (N)			Roxy at 4-5 L/ha (N)			Herold at 0.6 L/ha (N)			GLOB1815H at 7.2 L/ha (2N)			Roxy at 8-10 L/ha (2N)			Herold at 1.2 L/ha (2N)		
					Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn
MAR	SECCW	7	All	HLW (kg/100L)	72.1	69.9-76.5	70.8	101.0	99.4-106	100.0	-	-	-	-	-	-	101.0	99.7-106.1	100.2	-	-	-	-	-	-
		4	vs. Roxy at 4-5 L/ha	HLW (kg/100L)	72.1	70.5-76.5	70.7	101.4	99.4-106	100.1	101.3	99.7-105.9	99.9	-	-	-	101.5	99.8-106.1	100.1	101.2	99.4-106	99.8	-	-	-
		3	vs. Herold at 0.6 L/ha	HLW (kg/100L)	72.1	69.9-74	72.3	100.5	99.6-101.8	100.0	-	-	-	100.6	99.8-101.8	100.2	100.3	99.7-101	100.2	-	-	-	99.9	99-100.7	100.0

Table 3.4-58: Impact on quality (HLW) from GLOB1817H on winter triticale under weed free conditions – Maritime EPPO zone

EPPO zone	Crop code	Nb. trials	Grouping	Assessment type (unit)	Absolut value in the untreated control			% of untreated at 1N						% of untreated at 2N					
								GLOB1817H at 3 L/ha (N)			Boxer at 5 L/ha (2N)			GLOB1817H at 6 L/ha (2N)			Boxer at 10 L/ha (2N)		
					Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn
MAR	SECCW	1	All	HLW (kg/100L)	75.6	75.6-75.6	75.6	98.2	98.2-98.2	98.2	99.7	99.7-99.7	99.7	99.8	99.8-99.8	99.8	97.5	97.5-97.5	97.5

Supportive data from GLOB1815H formulation

Table 3.4-59: Impact on the quality (HLW) from GLOB1815H on winter triticale under weed free conditions – Maritime EPPO zone

EPPO zone	Crop code	Nb. trials	Grouping	Assessment type (unit)	Absolut value in the untreated control			Yield at 1N as % of untreated									Yield at 2N as % of untreated								
								GLOB1815H at 3.6 L/ha (N)			Roxy at 4-5 L/ha (N)			Herold at 0.5 L/ha (N)			GLOB1815H at 7.2 L/ha (2N)			Roxy at 8-10 L/ha (2N)			Herold at 1 L/ha (2N)		
					Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn
MAR	TTLWI	7	All	HLW (kg/100L)	69.7	64.3-75.4	68.8	100.3	99.3-101.7	100.1	-	-	-	-	-	-	101.1	98.7-104.4	100.6	-	-	-	-	-	-
		4	vs. Roxy at 4-5 L/ha	HLW (kg/100L)	71.2	66.3-75.4	71.6	99.9	99.3-100.7	99.7	99.8	98.5-101.2	99.8				99.7	98.7-100.6	99.9	99.8	99.2-100.6	99.6			
		3	vs. Herold/Naceto/ Fosburi at 0.6 L/ha	HLW (kg/100L)	67.7	64.3-70	68.8	101.0	100.1-101.7	101.1	-	-	-	101.0	99.9-103.1	100.0	103.0	100.7-104.4	103.9	-	-	-	101.7	100.7-103	101.5

North-East EPPO Zone

Summary of quality data - North-East EPPO Zone

Table 3.4-60: Impact on quality (HLW) from GLOB1817H on winter wheat under weed free conditions – North-East EPPO zone

EPPO zone	Crop code	Nb. trials	Grouping	Assessment type (unit)	Absolut value in the untreated control			% of untreated at 1N									% of untreated at 2N								
								GLOB1817H at 3 L/ha (N)			Jura at 4 L/ha (N)			Roxy at 4 L/ha (N)			GLOB1817H at 6 L/ha (2N)			Jura at 8 L/ha (2N)			Roxy at 8 L/ha (2N)		
					Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn
NE (+CZ)	TRZAW	2	All	HLW (kg/100L)	73.2	66.8-79.6	73.2	100.1	100.1-100.1	100.1	-	-	-	-	-	-	100.3	100.2-100.4	100.3	-	-	-	-	-	-
		1	vs. Jura	HLW (kg/100L)	79.55	-	-	100.14	-	-	99.88	-	-	-	-	-	100.19	-	-	99.94	-	-	-	-	-
		1	vs. Roxy	HLW (kg/100L)	66.75	-	-	100.05	-	-	-	-	-	102.66	-	-	100.41	-	-	-	-	-	101.53	-	-

Supportive data from GLOB1815H formulation

Table 3.4-61: Impact on the quality (HLW) from GLOB1815H on winter wheat under weed free conditions – North-East EPPO zone

EPPO zone	Crop code	Nb. trials	Grouping	Assessment type (unit)	Absolut value in the untreated control			Yield at 1N as % of untreated									Yield at 2N as % of untreated								
								GLOB1815H at 3.6 L/ha (N)			Herold at 0.35 L/ha (N)			Herold/Naceto at 0.6 L/ha (N)			GLOB1815H at 7.2 L/ha (2N)			Herold at 0.7 L/ha (2N)			Herold/Naceto at 1.2 L/ha (2N)		
					Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn
NE (+CZ,DE)	TRZAW	8	All	HLW (kg/100L)	75.7	67.2-83.4	75.7	100.3	98-103.6	100.1	-	-	-	-	-	-	99.5	95.6-102.5	99.9	-	-	-	-	-	-
		4	vs. Herold at 0.35 L/ha	HLW (kg/100L)	71.8	67.2-77	71.5	99.6	98-100.4	100.1	99.3	98.4-100.2	99.3	-	-	-	99.0	95.6-100.2	100.0	98.7	96.6-100	99.0	-	-	-
		4	vs. Herold/ Naceto at 0.6 L/ha	HLW (kg/100L)	79.6	74.5-83.4	80.3	100.9	99.9-103.6	100.1	-	-	-	100.6	99.6-103	99.9	100.1	98.4-102.5	99.8	-	-	-	100.7	99.2-103.8	99.9

Table 3.4-62: Impact on quality (HLW) from GLOB1817H on winter barley under weed free conditions – North-East EPPO zone

EPPO zone	Crop code	Nb. trials	Grouping	Assessment type (unit)	Absolut value in the untreated control			% of untreated at 1N									% of untreated at 2N								
								GLOB1817H at 3 L/ha (N)			Jura at 4 L/ha (N)			Roxy/Boxer at 3-4 L/ha (2N)			GLOB1817H at 6 L/ha (2N)			Jura at 8 L/ha (2N)			Roxy/Boxer at 6-8 L/ha (2N)		
					Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn
NE (+CZ)	HORVW	3	All	HLW (kg/100L)	55.7	53.2-59	55.0	100.6	99.5-101.7	100.6	-	-	-	-	-	-	101.1	100.1-102.9	100.4	-	-	-	-	-	-
		1	vs. Jura	HLW (kg/100L)	55.0	-	-	100.6	-	-	101.0	-	-	-	-	-	102.9	-	-	99.9	-	-	-	-	-
		2	vs. Roxy	HLW (kg/100L)	56.1	53.2-59	56.1	100.6	99.5-101.7	100.6	-	-	-	101.3	100.5-102.1	101.3	100.3	100.1-100.4	100.3	-	-	-	100.6	100.2-100.9	100.6

Supportive data from GLOB1815H formulation

Table 3.4-63: Impact on the quality (HLW) from GLOB1815H on winter barley under weed free conditions – North-East EPPO zone

EPPO zone	Crop code	Nb. trials	Grouping	Assessment type (unit)	Absolut value in the untreated control			Yield at 1N as % of untreated									Yield at 2N as % of untreated								
								GLOB1815H at 3.6 L/ha (N)			Herold at 0.35 L/ha (N)			Herold/Naceto at 0.6 L/ha (N)			GLOB1815H at 7.2 L/ha (2N)			Herold at 0.7 L/ha (2N)			Herold/Naceto at 1.2 L/ha (2N)		
					Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn
NE(+CZ,DE)	HORVW	8	All	HLW (kg/100L)	64.8	58.8-69.2	65.9	100.3	95.2-103.8	100.4	-	-	-	-	-	-	100.4	91.2-103	101.8	-	-	-	-	-	-
		4	vs. Herold at 0.35 L/ha	HLW (kg/100L)	64.6	60.1-68.7	64.7	99.6	95.2-102.4	100.4	100.3	99.7-101.2	100.1	-	-	-	99.0	91.2-101.9	101.4	99.4	96.4-101.2	100.0	-	-	-
		4	vs. Herold/Naceto at 0.6 L/ha	HLW (kg/100L)	65.0	58.8-69.2	65.9	101.0	98.3-103.8	101.0	-	-	-	101.7	98-105.7	101.5	101.9	100.2-103	102.3	-	-	-	102.7	99.7-105.3	102.8

Table 3.4-64: Impact on quality (HLW) from GLOB1817H on winter rye under weed free conditions – North-East EPPO zone

EPPO zone	Crop code	Nb. trials	Grouping	Assessment type (unit)	Absolut value in the untreated control			% of untreated at 1N									% of untreated at 2N								
								GLOB1817H at 3 L/ha (N)			Jura at 4 L/ha (N)			Roxy/Boxer at 3-4 L/ha (2N)			GLOB1817H at 6 L/ha (2N)			Jura at 8 L/ha (2N)			Roxy/Boxer at 6-8 L/ha (2N)		
					Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn
NE (+CZ)	SECCW	3	All	HLW (kg/100L)	71.2	70.3-72.6	70.8	99.2	97.5-100.2	100.0	-	-	-	-	-	-	99.3	97.5-100.3	100.2	-	-	-	-	-	-
NE (+CZ)	SECCW	1	vs. Jura	HLW (kg/100L)	70.8	-	-	100.2	100.2-100.2	100.2	100.5	-	-	-	-	-	100.2	100.2-100.2	100.2	102.0	-	-	-	-	-
NE (+CZ)	SECCW	2	vs. Roxy	HLW (kg/100L)	71.4	70.3-72.6	71.4	98.8	97.5-100	98.8	-	-	-	100.1	99.9-100.2	100.1	98.9	97.5-100.3	98.9	-	-	-	100.3	100.2-100.4	100.3

Supportive data from GLOB1815H formulation

Table 3.4-65: Impact on the quality (HLW) from GLOB1815H on winter rye under weed free conditions – North-East EPPO zone

EPPO zone	Crop code	Nb. trials	Grouping	Assessment type (unit)	Absolut value in the untreated control			Yield at 1N as % of untreated												Yield at 2N as % of untreated								
								GLOB1815H at 3.6 L/ha (N)			Roxy at 4 L/ha (N)			Herold at 0.35 L/ha (N)			Herold at 0.6 L/ha (N)			GLOB1815H at 7.2 L/ha (2N)			Roxy at 8 L/ha (2N)			Herold at 0.7 L/ha (2N)			Herold at 1.2 L/ha (2N)		
					Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn
NE (+CZ,DE)	SECCW	9	All	HLW (kg/100L)	71.2	67.6-76.5	70.8	100.5	96.9-106	100.0	-	-	-	-	-	-	-	-	-	100.6	97.9-106.1	100.2	-	-	-	-	-	-	-	-	-
		4	vs. Herold at 0.35 L/ha	HLW (kg/100L)	69.3	67.6-72.7	68.4	99.4	96.9-100.3	100.1	-	-	-	99.5	98.1-101.2	99.4	-	-	-	99.6	97.9-101.2	99.5	-	-	-	100.1	98.6-101.6	100.2	-	-	-
		2	vs. Roxy at 4-5 L/ha	HLW (kg/100L)	73.7	70.8-76.5	73.7	103.0	100-106	103.0	102.8	99.7-105.9	102.8	-	-	-	-	-	-	103.0	100-106.1	103.0	102.9	99.7-106	102.9	-	-	-	-	-	-
		3	vs. Herold at 0.6 L/ha	HLW (kg/100L)	72.1	69.9-74	72.3	100.5	99.6-101.8	100.0	-	-	-	-	-	-	100.6	99.8-101.8	100.2	100.3	99.7-101	100.2	-	-	-	-	-	-	99.9	99-100.7	100.0

Table 3.4-66: Impact on quality (HLW) from GLOB1817H on winter triticale under weed free conditions – North-East EPPO zone

EPPO zone	Crop code	Nb. trials	Grouping	Assessment type (unit)	Absolut value in the untreated control			% of untreated at 1N									% of untreated at 2N								
								GLOB1817H at 3 L/ha (N)			Jura at 4 L/ha (N)			Roxy/Boxer at 3-4 L/ha (2N)			GLOB1817H at 6 L/ha (2N)			Jura at 8 L/ha (2N)			Roxy/Boxer at 6-8 L/ha (2N)		
					Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn
NE (+DE)	TTLWI	3	All	HLW (kg/100L)	70.0	61-75.6	73.5	99.6	98.2-101.2	99.5	-	-	-	-	-	-	100.9	99.8-102.9	100.0	-	-	-	-	-	-
NE (+DE)	TTLWI	1	vs. Jura	HLW (kg/100L)	73.5	-	-	99.5	99.5-99.5	99.5	99.8	-	-	-	-	-	100.0	100-100	100.0	100.9	-	-	-	-	-
NE (+DE)	TTLWI	2	vs. Roxy	HLW (kg/100L)	68.3	61-75.6	68.3	99.7	98.2-101.2	99.7	-	-	-	99.1	98.5-99.7	99.1	101.3	99.8-102.9	101.3	-	-	-	98.6	97.5-99.8	98.6

Supportive data from GLOB1815H formulation

Table 3.4-67: Impact on the quality (HLW) from GLOB1815H on winter triticale under weed free conditions – North-East EPPO zone

EPPO zone	Crop code	Nb. trials	Grouping	Assessment type (unit)	Absolut value in the untreated control			Yield at 1N as % of untreated												Yield at 2N as % of untreated											
								GLOB1815H at 3.6 L/ha (N)			Roxy at 4 L/ha (N)			Herold at 0.35 L/ha (N)			Herold at 0.5 L/ha (N)			GLOB1815H at 7.2 L/ha (2N)			Roxy at 8 L/ha (2N)			Herold at 0.7 L/ha (2N)			Herold at 1 L/ha (2N)		
					Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn	Mean	Min & Max	Mdn
NE (+CZ,DE)	TTLWI	8	All	HLW (kg/100L)	67.7	60.6-74.5	68.5	100.6	97.1-104.1	100.6	-	-	-	-	-	-	-	-	-	101.2	98.4-104.4	100.5	-	-	-	-	-	-	-	-	-	-	-
		4	vs. Herold at 0.35 L/ha	HLW (kg/100L)	66.1	60.6-69.3	67.2	100.6	97.1-104.1	100.6	-	-	-	101.0	100.2-102.5	100.6	-	-	-	100.3	98.4-102.4	100.1	-	-	-	100.8	99.4-102.9	100.4	-	-	-	-	-
		1	vs. Roxy at 4 L/ha	HLW (kg/100L)	74.5	-	-	99.3	-	-	99.6	-	-	-	-	-	-	-	-	99.8	-	-	99.3	-	-	-	-	-	-	-	-	-	-
		3	vs. Herold at 0.5 L/ha	HLW (kg/100L)	67.7	64.3-70	68.8	101.0	100.1-101.7	101.1	-	-	-	-	-	-	101.0	99.9-103.1	100.0	103.0	100.7-104.4	103.9	-	-	-	-	-	-	101.7	100.7-103	101.5	-	-

Conclusion

A total of 54 specific selectivity trials (weed free) carried out between 2018 and 2019 in the Czech Republic, Germany, northern part of France, the Netherlands and the United Kingdom (31 trials belonging to the Maritime EPPO zone), as well as in Poland (23 trials belonging to the North-East EPPO Zone) on the target crops wheat, barley, rye and triticale.

In the vast majority of the trials GLOB1817H at the proposed label rate of 3 L/ha (N) or GLOB1815H at the rate of 3.6 L/ha (providing higher amounts of actives) did not reveal any negative impact on quality of the grains and no significant differences were identified between GLOB1817H, the reference products and the untreated control, even at a double dose rate in all winter cereals tested cereals. Slight differences observed could be usually attributed to natural variation and were not observed in the same variety in different trials.

Overall, these results confirms that there is no risk for negative side effects on the quality parameters of the treated winter cereals after treatment with GLOB1817H.

Comments of zRMS:	Overall, the data have shown that neither the proposed dose of GLOB1817H nor 2N are likely to have a significant negative impact on the TGW, hectolitre weight of winter cereals. Therefore, it is considered that the proposed uses of GLOB1817H are unlikely to have a significant negative impact on quality of claimed crops.

3.4.4 Effects on transformation processes (KCP 6.4.4)

According to EPPO PP1/243 "*Effects of plant protection products on transformation processes*", wheat and barley are crops used for industrial processes (such as bread making or brewing).

GLOB1817H is a formulated product based on active substances already used in straight formulations and/or in mixtures with other a.s. and authorised in EU, with no negative effects known on transformation processes on the target crops. Additionally, no significant residues of any of the active ingredients are found at harvest (<0.05 mg/kg). Therefore, according to EPPO guideline PP 1/243, no further data is deemed to be necessary. A safe use of GLOB1817H can be considered for crops involved on transformation processes.

Comments of zRMS:	Despite the absence of specific data on GLOB1817H it may be considered that the proposed uses of GLOB1817H are unlikely to have a negative impact on the transformation processes.

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

According to EPPO guideline PP 1/135 "*Phytotoxicity assessment*", trials on plants or plant products to be used for propagation would be required in case of post-emergence of the crop when application is made at or after inflorescence initiation e.g. for cereals when the first node is detectable (BBCH 30) or where detectable residues occur in harvested seed.

Taking into account that the mixture represented by GLOB1817H is applied in early stages of the crop (significantly before tillering) and its selectivity towards target cereal crops demonstrated in this dossier, no negative effects on seed germination is to be expected. A safe use of GLOB1817H can be considered for plant products to be used for propagation with no further data.

Comments of zRMS:	The early application timing of the product and its selectivity towards target cereal crops demonstrated suggest that the risk of GLOB1817H to plant products used for propagating purposes is minimal.

Summary and conclusion

GLOB1817H is a formulated product based on active substances already used in straight formulations and/or in mixtures with other a.s. and authorised in EU, with no negative effects known. Enough data to study the adverse effects on treated crops of GLOB1817H has been submitted.

In support of authorizations in the Central zone, 33 efficacy trials and 54 specific selectivity trials (Maritime and North-East EPPO zones) demonstrate the safe use of GLOB1817H at target rates on winter cereals, with the absence of negative effects on treated crops.

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

3.5.1 Impact on succeeding crops (KCP 6.5.1)

The impact on succeeding crops is calculated in accordance with the EPPO 1/217(2) - Effects on succeeding crops by comparing the PECsoil values to the ER10 values from the seedling emergence study (KCP 6.5.1-1).

The seedling emergence study was performed with GLOB1817H in a worst-case scenario. In this seedling emergence study of non-target plants 6 different crops are tested. The following results were obtained:

Table 3.5-1: Results of the study based on shoot fresh weight reduction

Species	ER_{10}# (mg product /kg of soil)	ER_{25} (mg product /kg of soil)	ER_{50} (mg product /kg of soil)	R-Sq.	Statistical Model Function	NOEC (mg product /kg of soil)
Wheat	0.77	3.61	>4.1	0.32	Linear	2.05
Corn	0.49	>4.1	>4.1	0.04	Linear	4.1
Pea	0.35	1.08	2.29	0.76	Linear	1.025
Sunflower	1.39	3.76	>4.1	0.70	Linear	1.025
Dwarf French bean	0.55	0.86	1.35	0.96	Rodbard	0.513
Oilseed rape	0.19	1.08	2.57	0.76	Linear	0.513

ER_{10} values should be treated with caution due to natural plant to plant variability.

Table 3.5-2: Results of the study based on percentage visual injury assessment at harvest

Species	ER_{10}# (mg product /kg of soil)	ER_{25} (mg product /kg of soil)	ER_{50} (mg product /kg of soil)	R-Sq.	Statistical Model Function	NOEC (mg product /kg of soil)
Wheat	2.05	>4.1	>4.1	0.95	Rodbard	1.025
Corn	>4.1	>4.1	>4.1	N/A	N/A	4.1
Pea	1.3685	2.2109	3.1781	0.96	Rodbard	1.025
Sunflower	>4.1	>4.1	>4.1	0.76	Linear	2.05
Dwarf French bean	0.7917	1.1341	1.6163	0.99	Rodbard	0.513
Oilseed rape	0.7505	0.8143	0.9052	0.94	Rodbard	0.513

ER_{10} values should be treated with caution due to natural plant to plant variability.

The most sensitive species was oilseed rape with ER_{10} value of 0.19 mg product/kg soil and a NOEC value of 0.513 mg product/kg soil based on shoot weight.

Calculation of the PEC_{soil} for the intended use of GLOB1817H

The initial and actual PEC_{soil} are calculated with equation 1 and 2 respectively:

PEC initial

$$PEC_{ini} = \frac{A \cdot (1 - f_{int})}{100 \cdot d \cdot bd} \qquad (1)$$

where
A = application rate [g/ha]
f_{int} = fraction intercepted by plant cover
d = depth of the soil layer [cm]
bd = bulk soil density [g/cm³]

PEC actual

$$PEC_{act}(t) = PEC_{ini} \cdot e^{-kt} = PEC_{ini} \cdot e^{\frac{t \cdot \ln 2}{DT50}} \qquad (2)$$

PEC_{ini} was calculated for a dose rate of 3 L/ha of GLOB1817H (considering the sum of all a.s., for a total amount of 2050.98 g a.s./ha) and considering a crop interception of 25% in accordance with the GAP. The soil bulk density was set to 1.5 g/cm³. The depth of soil layer used was the standard 5 cm but also 20 cm in order to account for a tillage depth of 20 cm before planting the succeeding crop in accordance with the cultivation methods.

For the calculation of the PEC_{act}, the maximum field DT50 (worst-case) was used. The worst-case DT_{50} for prosulfocarb, diflufenican and halauxifen-methyl under field conditions are respectively 13, 621 and 43 days. The DT50 of the safener cloquintocet-mexyl is 16 days. Therefore, the DT_{50} of diflufenican (621 days) was used.

The PEC_{soil} values over time for a post-emergence application of GLOB1817H are shown in

Table 3.5-3: PECsoil calculations for 3 L/ha of GLOB1817H

Days after application	GLOB1817H (mg ai/kg soil)	
	PEC_{soil} 5 cm	PEC_{soil} 20 cm
0 (initial)	2.0510	0.5127
1	2.0487	0.5122
2	2.0464	0.5116
4	2.0418	0.5105
7	2.0350	0.5088
14	2.0192	0.5048
21	2.0035	0.5009
28	1.9879	0.4970
50	1.9397	0.4849
60	1.9181	0.4795
70	1.8968	0.4742
80	1.8758	0.4689
90	1.8550	0.4637
100	1.8344	0.4586
365 (1 yr)	1.3647	0.3412
1095 (3 yrs)	0.6042	0.1510

Calculation of the TER for the intended use of GLOB1817H

The ER_{10} is divided by the PEC_{soil} at different timings for each possible following crop. The TER should be equal or higher as 1 in order to show an acceptable risk. The ER_{10} values of the seedling emergence study are presented above in Table 3.5-1 based on shoot fresh weight reduction. Several species were tested and most of them are likely to be sown in case of crop failure. The TER calculations are presented in the table below.

Table 3.5-4: PEC-values and TER-calculation of GLOB1817H based on EC10-values.

Days after application	GLOB1817H		Succeeding crop[1] TER[4] ER10/PEC product 5 cm						Succeeding crop[1] TER[5] ER10/PEC product 20 cm					
	PEC[2]	PEC[3]												
	mg ai/kg soil 5 cm	mg ai/kg soil 20 cm	Wheat	Corn	Pea	Sunflower	Dwarf French bean	Oilseed rape	Wheat	Corn	Pea	Sunflower	Dwarf French bean	Oilseed rape
0 (initial)	2.0510	0.5127	0.2545	0.1620	0.1157	0.4594	0.1818	0.0628	1.0180	0.6478	0.4627	1.8377	0.7272	0.2512
1	2.0487	0.5122	0.2548	0.1621	0.1158	0.4599	0.1820	0.0629	1.0192	0.6486	0.4633	1.8398	0.7280	0.2515
2	2.0464	0.5116	0.2551	0.1623	0.1159	0.4605	0.1822	0.0629	1.0203	0.6493	0.4638	1.8418	0.7288	0.2518
4	2.0418	0.5105	0.2556	0.1627	0.1162	0.4615	0.1826	0.0631	1.0226	0.6507	0.4648	1.8459	0.7304	0.2523
7	2.0350	0.5088	0.2565	0.1632	0.1166	0.4630	0.1832	0.0633	1.0260	0.6529	0.4664	1.8521	0.7329	0.2532
14	2.0192	0.5048	0.2585	0.1645	0.1175	0.4667	0.1847	0.0638	1.0340	0.6580	0.4700	1.8667	0.7386	0.2552
21	2.0035	0.5009	0.2605	0.1658	0.1184	0.4703	0.1861	0.0643	1.0422	0.6632	0.4737	1.8813	0.7444	0.2572
28	1.9879	0.4970	0.2626	0.1671	0.1194	0.4740	0.1876	0.0648	1.0503	0.6684	0.4774	1.8961	0.7502	0.2592
50	1.9397	0.4849	0.2691	0.1713	0.1223	0.4858	0.1922	0.0664	1.0764	0.6850	0.4893	1.9432	0.7689	0.2656
60	1.9181	0.4795	0.2721	0.1732	0.1237	0.4913	0.1944	0.0671	1.0885	0.6927	0.4948	1.9650	0.7775	0.2686
70	1.8968	0.4742	0.2752	0.1751	0.1251	0.4968	0.1966	0.0679	1.1007	0.7005	0.5003	1.9871	0.7862	0.2716
80	1.8758	0.4689	0.2783	0.1771	0.1265	0.5023	0.1988	0.0687	1.1131	0.7083	0.5060	2.0094	0.7951	0.2747
90	1.8550	0.4637	0.2814	0.1791	0.1279	0.5080	0.2010	0.0694	1.1256	0.7163	0.5116	2.0319	0.8040	0.2777
100	1.8344	0.4586	0.2846	0.1811	0.1293	0.5137	0.2033	0.0702	1.1382	0.7243	0.5174	2.0547	0.8130	0.2809
365 (1 yr)	1.3647	0.3412	0.3825	0.2434	0.1739	0.6905	0.2732	0.0944	1.5300	0.9736	0.6954	2.7619	1.0928	0.3775
1095 (3 yrs)	0.6042	0.1510	0.8640	0.5498	0.3927	1.5596	0.6171	0.2132	3.4559	2.1992	1.5708	6.2385	2.4685	0.8527

[1] possible following crops in a regular crop rotation
[2] PEC (soil depth 5 cm)
[3] PEC (soil depth 20 cm)
[4] TER (soil depth 5 cm)
[5] TER (soil depth 20 cm)

It can be seen from the above table that without ploughing, a period longer than 1 year would be necessary for all crops. In the event of crop failure, re-drilling may take place with winter wheat and sunflower only after ploughing. Even if not tested, it is reasonable to consider that other winter cereals may also be re-drilled after ploughing since all active substances are registered on cereals, even at higher rates.

Nevertheless, as mentioned in the seedling emergence study with soil incorporation, the ER_{10} values should be treated with caution due to the nature of plant to plant variability. High variability of the results obtained in the study might result in ER_{10} values (based on a regression model that provided the estimated concentration that causes 10% effect) that are (much) lower than the real NOEC (No Observed Effect Concentration). For the ER_{10} values based on fresh shoot weight the calculated ER_{10} values of 4 out of 6 tested crops resulted lower than the observed NOEC values (i.e. wheat, corn, pea and oilseed rape).

The discrepancy between the calculated ER_{10} values and the NOEC values is also clear when comparing the NOEC values obtained for fresh shoot weight and the NOEC values based on visual injury. Even though the NOEC values are generally similar for both assessments, the ER_{10} values calculated for fresh weight reduction are much lower than those calculated for the visual injury. For instance for oilseed rape (the most sensitive crop in the study), the ER_{10} based on fresh weight reduction is only 25% of the ER_{10} based visual injury even with the same NOEC. Because the NOEC is no calculated value, but is actually observed in the study, the applicant believes that the lowest obtained NOEC should be used to calculate the waiting periods for the tested crops under these circumnstances.

Therefore, in order to determine the minimum timing that should elapse between the application and sowing or planting, a refinement of the TER calculations taking into account the real NOEC are presented in Table 3.5-5 below.

Moreover, examples of other plant protection products currently on the market and containing the same active ingredients as GLOB1817H and used in higher amount is provided with their major label limitations on following crops.

Proposed rate for the active ingredients of GLOB1817H:
2001 g a.i./ha prosulfocarb, 42 g a.i./ha diflufenican, 3.99 g a.i./ha of halauxifen-methyl, 3.99 g/ha of cloquintocet-mexyl (safener).

Product name	**Rate**	**Max application amount (a.i. rate)**	**Example of label limitations**
Jura EC	4 L/ha	*2668 g a.i./ha prosulfocarb* *56 g a.i./ha diflufenican*	No field or broad beans should be sown within 12 months of treatment
Herold SC	0.6 L/ha	*120 g a.i./ha diflufenican* *240 g a.i./ha flufenacet*	Damage to dicotyledonous catch crops and winter rape is possible.
Pixxaro EC	0.5 L/ha	*6 g a.i./ha of halauxifen-methyl* 140 g a.i./ha fluroxypyr meptyl *6 g/ha of cloquintocet-mexyl (safener).*	Ploughing is recommended prior to drilling lucerne, field bean, soybean, clover, maize and broad bean.
Diflanil 500 SC	0.25 L/ha	*125 ga.i/ha of diflufenican*	Plough to 150 mm and thoroughly mix the soil before drilling or planting any following crops (either after crop failure or normal harvest). CROP FAILIURE: In the event of crop failure, for any reason, only re-drill soil treated with DIFLANIL 500 SC with winter wheat or winter barley after ploughing. A period of 12 weeks must lapse after ploughing before spring crops of wheat, barley, oilseed rape, peas, field beans, sugar beet, potatoes, carrots, edible brassicas or onions may be drilled. NORMAL HARVEST: In the autumn following normal harvest, only drill wintercereals, oilseed rape, field beans, leaf brassicas, sugar beet seed crops and winter onions. In the spring following normal harvest, only the crops listed above (CROP FAILURE) can be drilled.

Table 3.5-5: PEC-values and TER-calculation of GLOB1817H based on NOEC values.

Days after application	GLOB1817H		Succeeding crop(1) TER(4) NOEC/PEC product 5 cm						Succeeding crop(1) TER(5) NOEC/PEC product 20 cm					
	PEC(2) mg ai/kg soil 5 cm	PEC(3) mg ai/kg soil 20 cm	Wheat	Corn	Pea	Sunflower	Dwarf French bean	Oilseed rape	Wheat	Corn	Pea	Sunflower	Dwarf French bean	Oilseed rape
0 (initial)	2.0510	0.5127	0.6776	1.3551	0.3388	0.3388	0.1696	0.1696	2.7103	5.4206	1.3551	1.3551	0.6782	0.6782
1	2.0487	0.5122	0.6783	1.3567	0.3392	0.3392	0.1697	0.1697	2.7133	5.4266	1.3567	1.3567	0.6790	0.6790
2	2.0464	0.5116	0.6791	1.3582	0.3395	0.3395	0.1699	0.1699	2.7164	5.4327	1.3582	1.3582	0.6798	0.6798
4	2.0418	0.5105	0.6806	1.3612	0.3403	0.3403	0.1703	0.1703	2.7224	5.4448	1.3612	1.3612	0.6813	0.6813
7	2.0350	0.5088	0.6829	1.3658	0.3414	0.3414	0.1709	0.1709	2.7316	5.4631	1.3658	1.3658	0.6836	0.6836
14	2.0192	0.5048	0.6882	1.3765	0.3441	0.3441	0.1722	0.1722	2.7530	5.5060	1.3765	1.3765	0.6889	0.6889
21	2.0035	0.5009	0.6936	1.3873	0.3468	0.3468	0.1736	0.1736	2.7746	5.5491	1.3873	1.3873	0.6943	0.6943
28	1.9879	0.4970	0.6991	1.3982	0.3495	0.3495	0.1749	0.1749	2.7963	5.5927	1.3982	1.3982	0.6998	0.6998
50	1.9397	0.4849	0.7165	1.4329	0.3582	0.3582	0.1793	0.1793	2.8659	5.7317	1.4329	1.4329	0.7172	0.7172
60	1.9181	0.4795	0.7245	1.4490	0.3623	0.3623	0.1813	0.1813	2.8980	5.7960	1.4490	1.4490	0.7252	0.7252
70	1.8968	0.4742	0.7326	1.4653	0.3663	0.3663	0.1833	0.1833	2.9306	5.8611	1.4653	1.4653	0.7334	0.7334
80	1.8758	0.4689	0.7409	1.4817	0.3704	0.3704	0.1854	0.1854	2.9634	5.9269	1.4817	1.4817	0.7416	0.7416
90	1.8550	0.4637	0.7492	1.4984	0.3746	0.3746	0.1875	0.1875	2.9967	5.9934	1.4984	1.4984	0.7499	0.7499
100	1.8344	0.4586	0.7576	1.5152	0.3788	0.3788	0.1896	0.1896	3.0303	6.0607	1.5152	1.5152	0.7583	0.7583
365 (1 yr)	1.3647	0.3412	1.0183	2.0367	0.5092	0.5092	0.2548	0.2548	4.0733	8.1467	2.0367	2.0367	1.0193	1.0193
1095 (3 yrs)	0.6042	0.1510	2.3002	4.6003	1.1501	1.1501	0.5756	0.5756	9.2006	18.4013	4.6003	4.6003	2.3024	2.3024

1 possible following crops in a regular crop rotation
2 PEC (soil depth 5 cm)
3 PEC (soil depth 20 cm)
4 TER (soil depth 5 cm)
5 TER (soil depth 20 cm)

Wheat, pea and sunflower can be immediately drilled after application of GLOB1817H, given that the soil is ploughed (ensure complete inversion of the furrow slice) or cultivated to a depth of 20 cm before sowing. Corn can be immediately drilled even without ploughing.

Even if not tested, it is reasonable to consider that other winter cereals may also be re-drilled after ploughing since all active substances are registered on cereals, even at higher rates, and given the absence of adverse effects in selectivity trials submitted.

RECROP[2] study (2021)
The Belgian institute 'Centre for Weed Research' has performed field trials to assess the effects of different herbicides on following crops. The Centre for Weed Research is affiliated with the Faculty of Agronomy and Applied Biological Sciences of Ghent University and is committed to develop the knowledge regarding the reasoned use of herbicides. They provide empirical data from multiple trial years, which increases the reliability of the results.

A study performed with diflufenican at a dose rate of 120 g of active substance per ha (about 3 times higher rate than requested for GLOB1817H) is presented on page 13. For their trial, the herbicide under study was applied to the soil in the autumn of 1997 with sowing of replacement crops in the spring of 1998. 21 replacement crops were sown on treated and non-treated plots after a superficial soil cultivation of 15 cm. The observed effects on replacement crops are ultimately described as follows:

A = safe, normal yield
B = temporary slight impact of growth (10%) or reduction of yield (10%), without thinning and/or growth inhibition
C = slight but permanent damage (10-15%) during the growth period and 10-20% yield reduction
D = clear damage on growth (15-35%) and 20-40% yield loss
E = severe damage on growth (35-80%) and 40-85% yield loss
F = very severe growth damage (> 80% thinning and inhibition), >85% yield loss

The results of the study on diflufenican at 120 g/ha are summarized below:

A: field bean, pea, Italian rye grass, maize, turnip, clover, savoy cabbage, salsify, lettuce, spinach, French bean, flax, chicory, carrot, onion, spring barley, spring oat, spring wheat
B: sugarbeet
C: kidney bean

These results from the RECROP study, simulating practical situation confirm our findings regarding the safety on a variety of succeeding crops. Beans should not be sown within 12 months of application.

The most critical active substance present in GLOB1817H concerning effects on succeeding crops is diflufenican due to its high DT_{50}. As mentioned earlier, TER calculations based on the seedling emergence study were based on a worst case scenario, considering the DT50 of diflufenican for the total load of active substances present on GLOB1817H and thus in practice, the residual amount on diflufenican in the soil will be much lower.

This is an active substance that has been widely used in agriculture since the mid-1980s, and is currently a component of several formulations with application rates much higher than that for GLOB1817H. Practical experience with JURA (similar formulation to GLOB1817H but without the addition of halauxifen-methyl and a safener) and with other diflufenican containing products (at field rates up to 120 g of diflufenican/ha

[2] Eelen, H., Bulcke, R., & Cools, K. (n.d.). Recrop 2001. Een gegevensbank over de werkingsduur van (bodem)herbiciden ten aanzien van vervanggewassen. Resultaten over de periode 1997-2000 Brussel: Ministerie van Middenstand en Landbouw. Bestuur voor Onderzoek en Ontwikkeling, 2001, 46 pp.

as e.g. for the Herold SC), has proven that there are no particular issues for oilseed rape, especially at the low rate applied with GLOB1817H (42 g/ha).

Summary and conclusion on the Impact on succeeding crops

Components of GLOB1817H are known active ingredients already authorised for cereal production. Restrictions on rotational crops are also well-known. Soils previously treated with GLOB1817H should be ploughed (ensure complete inversion of the furrow slice) or cultivated to a depth of 20 cm before sowing wheat, pea and sunflower. Corn can be immediately drilled even without ploughing. Even if not tested, it is reasonable to consider that other winter cereals may also be re-drilled after ploughing since all active substances are registered on cereals, even at higher rates, and given the absence of adverse effects in selectivity trials submitted. Practical experience with other diflufenican containing products has proven that there are no particular issues for oilseed rape, especially at the low rate applied with GLOB1817H. Beans should not be sown within 12 months of application.

Comments of zRMS:	From the results presented and current knowledge, it can be concluded that there is a risk of adverse effects of GLOB1817H herbicide on succeeding crops. There is a particular risk if cereal crops have to be liquidated. In case of crop failure, for any reason, before sowing winter cereals, peas and sunflower and maize, the soil previously treated with GLOB1817H should be ploughed (ensure complete inversion of the furrow patch) or cultivated to a depth of 20 cm. Beans should not be sown within 12 months of product application. The recommendations proposed by the applicant and described above are acceptable and should be included on the national label.

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

The impact on adjacent crops is calculated in accordance with the EPPO 1/256(1) – Effects on adjacent crops by comparing the drift rates to the lowest EC_{50} from the vegetative vigour study (KCP 10.6), discussed in Section B9 Ecotoxicology.

In the mentioned study, the test species consisted of two monocotyledon species (oat and onion) and four dicotyledon species (oilseed rape, tomato, carrot and soybean). Species tested represented the plant families of Poaceae, Liliaceae, Brassicaceae, Solanaceae, Apiaceae and Fabaceae.

The drift rates are calculated for the target rate of 3L/ha using the 90th percentile estimates derived by the BBA (2000) from the spray-drift predictions of Ganzelmeier & Rautmann (2000).

Distance to adjacent crop (m)	% drift	Drift test product (mL/ha)
1	2.77	83.1

Based on shoot fresh weight, the most sensitive monocotyledon species was oat, with an ER_{25} value of 400.69 mL GLOB1817H/ha and an ER_{50} value of 962.19 mL GLOB1817H/ha. The most sensitive dicotyledon species was tomato, with an ER_{25} value of 21.32 mL GLOB1817H/ha and an ER_{50} value of 75.93 mL GLOB1817H/ha. This last value was then taken into account for the TER calculations.

Table 3.5-6: TER calculations for each species based on the vegetative-vigour-test

Test species	ER_{50} (mL/ha)	PEC (g/ha)	TER at 1 m	
Oat	962.19	83.1	11.58	> 1

Onion	>1662	83.1	>20	> 1
Oilseed rape	>1662	83.1	>20	> 1
Tomato	**75.93**	**83.1**	**0.91**	**< 1**
Carrot	>1662	83.1	>20	> 1
Soybean	>1662	83.1	>20	> 1

It can be seen from the above table that the trigger value of 1 for the TER was exceed in one of the cros tested (tomato) and is considered as a worst case (the lowest ER_{50} value)

In order to reduce the off-field exposure, a following step was undertaken in the risk assessment. The results of the risk assessment using typical mitigation measures (no-spray buffer zones of 5 or 10m; drift-reducing nozzles with reduction by 50%, 75%, or 90%) are summarised in the following table.

Table 3.5-7: Risk assessment for non-target terrestrial plants due to the use of GLOB1817H in winter cereals considering risk mitigation (in-field no-spray buffer zones, and drift-reducing nozzles)

Intended use		Winter cereals			
Active substance/product		GLOB1817H			
Application rate (mL/ha)		1 × 3000			
MAF		-			
Buffer strip (m)	**Drift rate (%)**	**$PER_{off-field}$ (mL/ha)**	**$PER_{off-field}$ 50 % drift red. (mL /ha)**	**$PER_{off-field}$ 75 % drift red. (mL /ha)**	**$PER_{off-field}$ 90 % drift red. (mL /ha)**
3	1	30.22	15.11	7.55	3.022
5	0.57	17.28	8.64	4.32	1.728
10	0.29	8.8	4.4	2.2	0.88
Toxicity value		**TER**			
ER_{50} = 75.93 mL/ha		**criterion: TER ≥ 5**			
3		**2.51**	5.02	-	-
5		**4.39**	8.79	-	-
10		8.63	-	-	-

MAF: Multiple application factor; PER: Predicted environmental rates; TER: toxicity to exposure ratio. Criteria values shown in bold breach the relevant trigger.

Summary and conclusion on the Impact on other plants including adjacent crops

A buffer zone of 3 m in combination with 50% drift reducing techniques or a buffer zone of 10 m without drift reduction is needed to protect non-target plants after application of GLOB1817H according to the intended use.

Comments of zRMS:	From the results presented, it can be concluded that a buffer zone of 1 m in combination with 90% drift reducing techniques, a buffer zone of 3 m in combination with 50% drift reducing techniques or a buffer zone of 10 m without drift reduction is needed to protect non-target plants after application of GLOB1817H according to the intended use.

Tank cleaning

To confirm the safe use of GLOB1817H on the following applications, a tank cleaning tests has been performed. Detailed results are provided in Section B4 Further information on the plant protection product (study DNA5653, KCP 4.2).

A summary of the methodology and results is provided below:

The effectiveness of cleaning procedures was assessed in the storage stability study of GLOB1817H (Pomeroy D., 2020). The procedure is summarized below.
1. A 8 L garden sprayer is filled up to top with GLOB1817H and water at the concentration of 3 L/100L. The sprayer is shaken well.
2. The content is then sprayed using a normal spraying action to simulate that used in the field until the sprayer is empty.
3. 400 mL tap water is then poured into the sprayer. The sprayer is then shaken several times before spraying the contents to waste.
4. The step 3 is repeated twice so that the sprayer has been rinsed three times.
5. 20 mL acetonitrile is added to the sprayer which is then agitated to collect any remaining residue. The collected residue us assayed by LC-QQQ.

After three tank washes with 400 mL water 0.000086% prosulfocarb, 0.00011% diflufenican, 0.00023% halauxifen-methyl and 0.00011% cloquintocet-mexyl residue remained in the tank. This demonstrates that only a very limited amount of residue remains in the spray tank after cleaning.

As worst case approach, the calculation will be conducted using the highest value of 0.00023%. Based on the studies on non-target plants discussed in Section B9 of the Registration Report and in point 3.5.2 (KCP 6.5.2) above, it can be seen from the study on vegetative vigour, that the worst case (lowest) cut-off value can be found in tomato, namely a NOEC below the minimum amount of 13 ml GLOB1817H per ha tested.

Suppose a sprayer has a tank of 1000 L spray volume. The worst case dose rate is 3 L GLOB1817H per ha. If applied in 200L, the tank can be filled to spray 5 ha and thus will contain 15 L of GLOB1817H.
After water rinsing, the highest residue remaining residue was 0.00023% or 0.0345 ml GLOB1817H in the sprayer. Suppose, again as worst case approach, that after rinsing, an application is made to a new crop using the total capacity of 1000L per ha on the new crop, then 0.0345 ml of GLOB1817H would be applied to one ha of that new crop.

This is much lower than the EC_{50} value of the most sensitive crop (tomato) 75.93 mL of GLOB1817H and than the EC50 values of all other crops tested and thus it is clear that standard cleaning procedures are sufficient for GLOB1817H.

Comments of zRMS:	It can be seen from the above table that a standard cleaning procedure is sufficient for GLOB1817H.

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

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

Compatibility with current management practices including IPM

No trials were carried out.

3.6 Other/special studies

No other studies were carried out.

3.7 List of test facilities including the corresponding certificates

Table 3.7-1: List of test facilities

Test facility	Address	Certificate (Yes or No)
AGRECO Sp. z o.o.	Gać 64A, 55-200 Oława, Poland	Yes
Agro Research Consulting	ul. Nadbzurzańska 32 99-400 Łowicz, Poland	Yes
Fertico Sp. z o.o.	Goliany 43 05-620 Błędów, Poland	Yes
Field Research Support	Ul Dworcowa 2, Kościan-64-000, Poland	Yes
Proeftuin Zwaagdijk	Tolweg 13 1681 ND Zwaagdijk-Oost, the Netherlands	Yes
Staphyt Poland	Ziębicka 2, Poznań-60-164	Yes
SynTech Research Poland Sp. z o.o.	ul. Jagiellonska 69/1, 85-027 Bydgoszcz, Poland	Yes
Agrartest	Palmbachstrasse 37 65326 Aarbergen-Panrod, Germany	Yes
Anadiag France	13, rue de la Bourbre 38300 RUY – France	Yes
Agricultural Research Institute Kromeriz (Zemedelsky vyzkumny ustav Kromeriz, s. r. o.)	Havlíčkova 2787/121 Kroměříž-767 01, Czech Republic	Yes
Field Research Support Germany	Max-Planck-Straße 5 D-31515 Wunstorf, Germany	Yes
Ing. Jitka Mareckova	Krasné Udoli 141, Touzim-364 01, Czech Republic	Yes
InTec Agro Trials, s.r.o.	Blatnická 179, 687 24 Uherský Ostroh (CZ)	Yes
Oxford Agricultural Trials Ltd.	West Farm Barn, Launton Rd, Stratton Audley, Bicester OX27 9AS, UK	Yes
Quintus GmbH	Liepen 7 Hohen Wangelin OT Liepen-17194, Germany	Yes
Staphyt France	23 route de Moeuvres Inchy en Artois - 62860, France	Yes
Staphyt Germany	Langenburger Str. 35 74572 Blaufelden, Germany	Yes
Zemservis Domaninek, zk. st. s.r.o.	K Zámečku 1231, Bystřice nad Pernštejnem-593 01, Czech Republic	Yes
Zkusebni Stanice Kluky, spol. S R.o.	Boys 201 Boys at Písek-398 19, Czech Republic	Yes
Zkusebni stanice Rymarov, s.r.o.	8.května 61 795 01 Rýmařov, Czech Republic	Yes
Zkusebni Stanice Trutnov s.r.o.	Volanovska 409, Trutnov-541 01, Czech Republic	Yes

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 (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 6.2	XXXX	2021	Biological Assessment Dossier: GLOB1817H Globachem NV	N	Y