

FINAL REGISTRATION REPORT

Part B

Section 3

Efficacy Data and Information

Concise summary

Product code: GLOB2007bF

Product name: Observer Pro

Chemical active substances:

Zoxamide, 67.5 g/L

Propamocarb-HCl, 450 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: Globachem NV

Submission date: November 2023

MS Finalisation date: 31/10/2024

Version history

When	What
November 2023	Initial dossier submission by applicant for approval of new product
March 2024	Dossier sent for evaluation
July 2024	zRMS finalised evaluation
October 2024	zRMS finalised evaluation after commenting period

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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:	The commenting boxes are filled-in by the zRMS. They are usually placed at the end of each chapter. Commenting boxes should be understandable alone and refer very precisely to the text commented. The main advantage of their use is to distinguish easily between the applicant and the zRMS text.
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3.2 Summary and conclusions of zRMS on Section 3: Efficacy (KCP 6)

Abstract

zRMS to provide main conclusions on each use. Indicate whether the overall assessment was performed according to the uniform principles. Overall summaries are not necessary here, as they will be provided at the end of each chapter of the dRR. Poland is zonal rapporteur member state, concern member states are Czech Republic, Germany, Slovakia, Hungary, Romania, Ireland.

Fungicide GLOB2007bF (Observer Pro 2.0l/ha) is a SC formulation containing a.s. propamocarb-HCL 450g/l and zoxamide 67.6g/l. It is proposed to be used in potato to control *Phytophthora infestans* as foliar spray in 1-3 application in vegetation season

Efficacy evaluation: In order to support the registration of GLOB2007bF (Observer Pro 2.0l/ha) for field uses, plot trials were conducted in countries belonging to Maritime EPPO climatic zone, South-East EPPO zone and North-East EPPO zone between 2021-2022 to demonstrate the effectiveness of tested product against *P. infestans* in potatoes.

Preliminary test to show the benefit of the tank mix of Zoxium + Sporax comparison of both solo preparation was done in 4 trials in potato, conducted in North- East and Maritime EPPO climatic zone. From the submitted results it is clear that effectiveness was higher when the combination of propamocarb and zoxamide was tested to compare with the effectiveness of used each individually (solo).

Minimum effective dose: Based on available results the proposed application rate 2.0l/ha of GLOB2007bF (Observer Pro) for *P. infestans* control in potato is justified as minimum effective dose

Effectiveness: To demonstrate efficacy of GLOB2007bF (Observer Pro 2l/ha) 8 experiments were selected with 1-3 applications to obtain clear effect.

The intended use of GLOB2007bF (Observer Pro 2.0l/ha) is 1-3 applications during the growing season to protect potatoes against *P. infestans*. Experiments from each zone were selected to analyse the effectiveness of 1-3 applications. The data of dRR complement the confirmation of the effectiveness of GLOB2007bF (Observer Pro 2.0l/ha) in combating *P. infestans* in potatoes.

In 8 experiments conducted in the North-East EPPO climate zone + CZ, in 2021- 2022, the tested GLOB2007bF (Observer Pro 2.0l/ha) agent showed an average effectiveness of 86.7% against *P. infestans* in potatoes. This is the average effectiveness obtained using 1-3 applications. In these selected experiments, the average occurrence of potato late blight amounted to 23% of the leaf area. The tested agent and reference standards showed an effect at the same level.

The presented results in dRR, based on assessment dates only can be considered as a protection program using the tested agent:” from first symptoms” to “harvest” for preventative application. The obtained results may allow for the assessment of trends in the protection of potatoes against *P. infestans*.

The data presented meet the criteria required for registration of the product in the North-East EPPO climate zone.

In the **Maritime** EPPO climatic zone, **3 relevant experiments in two** vegetation seasons are presented. The tested GLOB2007bF (Observer Pro 2.0l/ha) agent applied in 3 applications showed an average **effectiveness of 96.4%** against *P. infestans* in potatoes. The reference standards showed an effect at the similar level. In these experiments, the average occurrence of potato late blight amounted to 9.7% of the leaf area.

The presentation of results for 3 selected experiments using 3 applications indicates the high effectiveness of GLOB2007bF (Observer Pro 2.0l/ha) and the repeatability of the results.

The **dRR presents** the high effectiveness of the tested agent: **“first symptoms” - 97.1%, 7-10 “days after “ 96.8 %, 12-16 “days after” -92.1 %**. These data can complement the confirmation of the effectiveness of GLOB2007bF (Observer Pro 2.0l/ha) in combating *P. infestans* in potatoes. The tested product was active at the higher level of effectiveness of the standard product Revus 0.6l/ha (84.4-72.9%).

The presented data can be accepted as the basis for registering the GLOB2007bF (Observer Pro 2.0l/ha) agent to control *P. infestans* in 3 application in potatoes in the Maritime EPPO climatic zone.

The data provided is not sufficient for GLOB2007bF (Observer Pro 2.0l/ha) registration in the **South-East EPPO climatic zone**. **The decision on the possibility of authorization based on the data presented or the use of conditional registration after providing appropriate experiments may be accepted at the national level for each CMS.**

The anti-resistance strategy is well presented in the dRR and the label. The use of the tested GLOB2007bF (Observer Pro 2.0l/ha) agent had a beneficial effect on potato yield and did not cause any adverse effects on the plants. The tested measure had no negative impact on the transform processing.

The presented results of GLOB2007bF (Observer Pro 2.0l/ha) applied in 1-3 applications in potatoes for the control of *Phytophthora infestans* indicate compliance with the GAP table and with label of the measure tested and Uniform principles. It is justified to claim the registration of GLOB2007bF (Observer Pro) for 3 applications in dose 2,0 l/ha for the control of *Phytophthora infestans* in potatoes crop in the North-East (PL) and Maritime EPPO climate zone (CZ, IE, **DE, NL, BE, SK). The decision on the possibility of authorization based on the data presented or the use of conditional registration after providing appropriate experiments may be accepted at the national level for each CMS in Maritime and South –East EPPO climate zone (**SK, HU, RO**). (~~Southern~~ **Central** regulatory zone)**

Table 3.1-1: Acceptability of intended uses (and respective fall-back GAPs, if applicable)

GAP rev. 2.2 date: 2022-03-03

PPP (product name/code): GLOB2007bF

Formulation type: SC ^(a, b)

Active substance 1: zoxamide

Conc. of as 1: 67.5 g/L ^(c)

Active substance 2: propamocarb

Conc. of as 2: 450 g/L ^(c)

Applicant: Globachem NV

Professional use: ☒

Zone(s): Central

Non professional use: ☐

Verified by MS: **yes**/~~no~~

Field of use: Fungicide

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No. (e)	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn 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 (f)	zRMS Conclusion (efficacy)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between application s (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			

Zonal uses (field or outdoor uses, certain types of protected crops)														
1	CZ, HU, IE, PL, RO, SK	Potato	F	PHYTIN	Downwardspraying	BBCH 21-79	a) 3 b) 3	7	a) 2 b) 2	a) 135 Zoxamide + 900 Propamocarb-HCl b) 405 Zoxamide + 2700 Propamocarb-HCl	150-300	7	1) Alternative GAP with a slightly lower dose rate in order to maintain a mitigation of max.10mVFS only where necessary/1.9l/ha	A
2	CZ, SK, IE, BE, DE, NL	Potato	F	PHYTIN	Downwardspraying	BBCH 21-79	a) 3 b) 3	7	a) 2 b) 2	a) 135 Zoxamide + 900 Propamocarb-HCl b) 405 Zoxamide + 2700 Propamocarb-HCl	150-300	7	1) Alternative GAP with a slightly lower dose rate in order to maintain a mitigation of max.10mVFS only where necessary/1.9l/ha	C
3	HU, RO, SK	Potato	F	PHYTIN	Downwardspraying	BBCH 21-79	a) 3 b) 3	7	a) 2 b) 2	a) 135 Zoxamide + 900 Propamocarb-HCl b) 405 Zoxamide + 2700 Propamocarb-HCl	150-300	7	1) Alternative GAP with a slightly lower dose rate in order to maintain a mitigation of max.10mVFS only where necessary/1.9l/ha	C***

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

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

*** The qualification has been changed to: to be confirmed by CMS

1) Alternative GAP according to GAP B0.

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

Comments of zRMS. Notes on the GAP table: the experimental results allow for the acceptance of the use and registration of GLOB07bF(Observer Pro 2.0l/ha) agent in Poland and for the cMS to make a decision on the use and registration on nationale level of the tested agent Observer Pro in CZ, SK, IE, DE, NL, BE, HU, RO and for lack of acceptance for the HU and RO countries. The GAP table does not include countries from the EPPO Mediterranean climate zone.

zRMS introduced a dose of 1.9l/ha into the GAP table (as alternative GAP) in RR B3 and B0, A for cMS and allows for a decision at the national level on this rate of product Observer Pro (GLOB2007 bF). Alternative GAP with a slightly lower (5%) dose rate 1.9l/ha (1 application: 130g Zoxamide+855g Propamocarb; 3 applications: 390g Zoxamide + 2565g Propamocarb) in order to maintain a mitigation of maximum 10 m VFS only where necessary.

There is no comment on the label design.

Each cMS country should develop a label for Observer Pro (GLOB2007bF) at the national level. The label should clearly indicate the use of the product and the procedure in areas where there is a risk to aquatic organisms (adjacent to water bodies). For these areas, a slightly lower dose of 1.9 l/ha of Observer Pro has been established.

The maintenance of buffer zones can be emphasized and the negative impact on aquatic organisms can be emphasized in the label.

3.3 Efficacy data (KCP 6)

Introduction

This document summarises the information related to the efficacy of the plant protection product GLOB2007bF, containing the active substances propamocarb-HCl and zoxamide. GLOB2007bF is used against late blight (*Phytophthora infestans*) on potatoes.

It should be noted that all trials performed for this project are included in this submission, this includes trials performed in the Maritime, North-East, Mediterranean and South-East EPPO Zone. The applicant is aware that not all submitted data is accepted by the countries where registration is requested, however data from other EPPO Zones can be considered confirmatory data that demonstrates the performance of GLOB2007bF under a wide range of climatic and edaphic conditions.

For the implementation of the uniform principles of Annex VI, the conclusions of the review report on propamocarb-HCl and zoxamide, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health shall be taken into account.

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

Description of active substances

Propamocarb-HCl is a carbamate ester that is the propyl ester of 3-(dimethylamino)propylcarbamic acid. It is a systemic fungicide that affects cell membrane permeability and is used for the control of soil, root and leaf diseases caused by oomycetes, particularly *Phytophthora* and *Pythium* species. Zoxamide is a broad-spectrum contact fungicide that affects tubulin polymerization and is used to control various fungal diseases on potatoes, grapes and other fruits and vegetables.

Mode of action

Propamocarb-HCl belongs to the chemical group of the carbamates (group 28), which affect the cell membrane permeability (F4). It is a systemic compound with protective action against oomycetes that is used to control leaf diseases in vegetables and ornamental plants, it can also be used to combat soil borne diseases in some crops (applied directly to the soil). For the use against late blight on potatoes it is applied as a foliar spray.

Zoxamide belongs to the chemical group of the toluamides, which affect tubulin polymerization (B3). It is a contact compound that has protective as well as curative activity against oomycetes.

Table 3.2-1: Details of the active substance in GLOB2007cF

Active substance	Propamocarb-HCL	Zoxamide
Concentration	450 g/L (=378 g/L propamocarb)	67.5 g/L
Chemical group	Carbamates	Toluamides
Mode of action	Systemic fungicide (F4)	Contact fungicide (B3)
Biological action	Interference with oomycete membrane biosynthesis	Interference with oomycete nuclear division and microtubule cytoskeleton

Description of the plant protection product

Information on the detailed composition of GLOB2007bF can be found in the confidential dossier of this submission (Registration Report - Part C).

GLOB2007bF contains 450 g/L propamocarb-HCl and 67.5 g/L zoxamide and is formulated as a suspension concentrate (SC). It is used against *Phytophthora infestans* (late blight) on potato. Its technical characteristics are acceptable for a suspension concentration formulation, no particular problems are expected when GLOB2007bF is used as recommended.

More information can be found in Part B1, B2 and B4 of this submission.

The classification proposal for GLOB2007bF according to Regulation (EC) 1272/2008 (CLP Regulation) can be found in Part A of this submission.

Comments of zRMS:	The description of the active substances and the tested GLOB2007bF (Observer Pro) preparation is complete and appropriate and complies with the Uniform Principles .
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Table 3.2-2: Simplified table of requested uses for GLOB2007bF

Uses		Member State	Requested rate(s)	Comments / Other relevant details on GAPs
Crop(s)	Target(s)			
Potato	Late blight (<i>Phytophthora infestans</i>)	zRMS + all cMS	2 L/ha	1-3 applications 7 day interval 7 day PHI

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

Comments of zRMS:	Regarding Requested uses Tab.3.22: It should be emphasized that the Applicant requests the application of the GLOB2007bF(Observer Pro 2.0l/ha) agent 1-3 times during the growing season to control <i>P.infestans</i> in potato cultivation at 7-day intervals and this was not presented in the research.
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Description of the target pests

GLOB2007bF is used as a fungicide against *Phytophthora infestans* on potato.

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

EPPO code	Scientific name
PHYTIN	<i>Phytophthora infestans</i>

Comments of zRMS:	<p>The Applicant did not provide a description of the tested pathogen.</p> <p><i>Phytophthora infestans</i> is the pathogen that causes the potato late blight.</p> <p>The description of the controlled disease, which is potato late blight, does not contain some particularly important information. It should be emphasized that this pathogen is characterized by high pathogenicity and can potentially easily produce resistance to the plant protection products used.</p> <p>Protecting potatoes against late blight is difficult due to the ease and speed of its spread. The effectiveness of chemical protection is determined by properly selected dates of chemical treatments.</p>
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Level of control 3.2-1

Claim level	Level of control
Control (C)	> 80 %
Moderate control (MC)	60 - 80 %
Some control (SC)	40 - 60 %

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

Crop and/or situation	Crop status		Pests or group of pests controlled	Pest status	
	Major	minor		Major	minor
	zRMS + all cMS	-	Late blight (<i>Phytophthora infestans</i>)	zRMS + all cMS	-

Comments of zRMS:	The major status for the crop - potatoes, as well as the status for the pathogen <i>Phytophthora infestans</i> for the zRMS and cMS countries is appropriate.
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Compliance with the Uniform Principles

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

Information on trials submitted (3.1 Efficacy data)

The list of individual trials is presented under 3.2.3 Efficacy tests.

Table 3.2-5: Presentation of reference standards used in the efficacy trials

Crop(s)	Reference standard	Countries where the product is registered	Authorization number	Active substance(s)	Formulation		Registered application rate	Application rate in trials (per trt.)	Comments / Other relevant details on GAPs
					Type	Concentration of a.s.			
Potato	Revus	CZ	4608	Mandipropamid	SC	250 g/L	0.6 L/ha	0.6 L/ha	
		DE	026221-00	Mandipropamid	SC	250 g/L	0.6 L/ha	0.6 L/ha	
		DK	1-195	Mandipropamid	SC	250 g/L	0.6 L/ha	0.6 L/ha	
		ES	25186	Mandipropamid	SC	250 g/L	0.6 L/ha	0.6 L/ha	
		FR	2080098	Mandipropamid	SC	250 g/L	0.6 L/ha	0.6 L/ha	
		HU	02.5/2622	Mandipropamid	SC	250 g/L	0.6 L/ha	0.6 L/ha	
		NL	12969	Mandipropamid	SC	250 g/L	0.6 L/ha	0.6 L/ha	
		RO	2718/ 25.10.2007	Mandipropamid	SC	250 g/L	0.6 L/ha	0.6 L/ha	
		SE	4843	Mandipropamid	SC	250 g/L	0.6 L/ha	0.6 L/ha	
	Revus 250 SC	LV	0312	Mandipropamid	SC	250 g/L	0.6 L/ha	0.6 L/ha	
		PL	R-12/2009	Mandipropamid	SC	250 g/L	0.6 L/ha	0.6 L/ha	
	Pergado SC	IT	13382	Mandipropamid	SC	250 g/L	0.6 L/ha	0.6 L/ha	
	Revus Top	LV	0453	Mandipropamid Difenoconazole	SC	250 g/L 250 g/L	0.6 L/ha	0.6 L/ha	
	Shirlan	DE	034092-00	Fluazinam	SC	500 g/L	0.4 L/ha	0.4 L/ha	
	Shirlan Gold	NL	14744	Fluazinam	SC	500 g/L	0.4 L/ha	0.4 L/ha	
	Frownicide (=Shirlan)	FR	9100636	Fluazinam	SC	500 g/L	0.4 L/ha	0.4 L/ha	
	Winby (=Shirlan)	PL	R-134/2018	Fluazinam	SC	500 g/L	0.4 L/ha	0.4 L/ha	
	Ranman Top	CZ	4592-0	Cyazofamid	SC	160 g/L	0.5 L/ha	0.5 L/ha	
		DE	006860-00	Cyazofamid	SC	160 g/L	0.5 L/ha	0.5 L/ha	
		FR	2110012	Cyazofamid	SC	160 g/L	0.5 L/ha	0.5 L/ha	
		NL	13467	Cyazofamid	SC	160 g/L	0.5 L/ha	0.5 L/ha	

Crop(s)	Reference standard	Countries where the product is registered	Authorization number	Active substance(s)	Formulation		Registered application rate	Application rate in trials (per trt.)	Comments / Other relevant details on GAPs
					Type	Concentration of a.s.			
	Ranman Top 160 SC	SE	4995	Cyazofamid	SC	160 g/L	0.5 L/ha	0.5 L/ha	
		PL	R-12/2012 wu	Cyazofamid	SC	160 g/L	0.5 L/ha	0.5 L/ha	
	Infinito	CZ	4602-2	Fluopicolid Propamocarb	SC	62.5 g/L 625 g/L	1.6 L/ha	1.6 L/ha	
		DE	025876-00	Fluopicolid Propamocarb	SC	62.5 g/L 625 g/L	1.6 L/ha	1.6 L/ha	
		FR	2090136	Fluopicolid Propamocarb	SC	62.5 g/L 625 g/L	1.6 L/ha	1.6 L/ha	
		HU	04.2/3959	Fluopicolid Propamocarb	SC	62.5 g/L 625 g/L	1.6 L/ha	1.6 L/ha	
		LV	0302	Fluopicolid Propamocarb	SC	62.5 g/L 625 g/L	1.6 L/ha	1.6 L/ha	
		NL	12927	Fluopicolid Propamocarb	SC	62.5 g/L 625 g/L	1.6 L/ha	1.6 L/ha	
		SE	5072	Fluopicolid Propamocarb	SC	62.5 g/L 625 g/L	1.6 L/ha	1.6 L/ha	
		UK	16335	Fluopicolid Propamocarb	SC	62.5 g/L 625 g/L	1.6 L/ha	1.6 L/ha	
	Infinito 687.5 SC	PL	R-37/2011	Fluopicolid Propamocarb	SC	62.5 g/L 625 g/L	1.6 L/ha	1.6 L/ha	
	Volare	ES	25351	Fluopicolid Propamocarb	SC	62.5 g/L 625 g/L	1.6 L/ha	1.6 L/ha	
		IT	13592	Fluopicolide Propamocarb	SC	62.5 g/L 625 g/L	1.6 L/ha	1.6 L/ha	

Comments of zRMS:	Reference standards were appropriately selected to compare the performance of the tested agent GLOB2007bF (Observer Pro, 2l/ha) in controlling <i>P.infestans</i> in potato crops and complies with the Uniform Principles .
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Table 3.2-6: Presentation of efficacy trials

Crop	Target(s)	Country	Years	Type of trial**	Number of trials per EPPO Zone*				GEP, non-GEP, official***
					MAR	N-E	MED	S-E	

Potato	PHYTIN	CZ	2020	P	1				Prelim. trials
		DE	2020	P	1				
		SE	2020	P	1				
		PL	2020	P		1			
		TOTAL			3	1			4
		CZ	2021	E, MED	3				
			2022	E, MED	2				
		DE	2022	E, MED	1				
		FR	2021	E, MED	2				
		NL	2022	E, MED	2				
		SE	2022	E, MED	2				
		UK	2021	E, MED	1				
		PL	2021	E, MED		4			
			2022	E, MED		2			
		LV	2021	E, MED		3			
			2022	E, MED		2			
		IT	2021	E, MED			3		
			2022	E, MED			1		
		ES	2021	E, MED			1		
			2022	E, MED			1		
		HU	2021	E, MED				3	
			2022	E, MED				2	
		RO	2021	E, MED				1	
		TOTAL			13	11	6	6	36

* MAR: Maritime / N-E: North-East / MED: Mediterranean / S-E: South-East EPPO Zone

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

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

Comments of zRMS:	<p>In the presented dRR, 4+36 experiments are presented to confirm the effectiveness of the tested agent GLOB2007fB (Observer Pro) in controlling <i>P. infestans</i> in potatoes.</p> <p>Preliminary trials -4 -PL, SE, DE, CZ MAR – 13- CZ, DE, FR, NL, SE, UK N- E - 11-PL, LV MED - 6 -IT, ES S- E – 6- HU, RO</p> <p>No experiments has been demonstrated in SK and IE, these countries are listed in Table GAP. The applicant presented trials for the Mediterranean EPPO climatic zone, but the GAP table does not include countries from this zone.</p> <p>The number of experiments carried out for North-East, Maritime EPPO, South-East climate zone is in accordance with the requirements and complies with the Uniform Principles.</p>
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3.3.1 Preliminary tests (KCP 6.1)

To test the combination of the active substances propamocarb-HCl and zoxamide, a tank mix of Sporax / Propamocarb 722 SL (722 g/L propamocarb; owned by Globachem N.V.) and Zoxium (240 SC; 240 g/L zoxamide) was tested, applied at multiple dose rates.

The preliminary trial program (ref.

Table 3.2-6) consisted of 3 trials performed in the Maritime EPPO Zone (the Czech Republic, Germany and Sweden) and 1 trial performed in the North-East EPPO Zone (Poland).

All preliminary tests were performed by GEP certified research institutes in accordance with EPPO Guidelines. Detailed information on these trials is included in the tables describing the regular efficacy trials under section 3.2.3.1.

For individual trial data reference is made to Appendix 3 of the BAD – Preliminary trial data.

Pest severity (PESSEV) was assessed multiple times throughout the season. In all trials applications started preventatively, but depending on the specific weather conditions there is a lot of variation in the time between the start of the applications and the first observation of the disease between the trials. To demonstrate the impact of the tested treatments on disease development, all assessment data was grouped according to the number of days since the disease was first observed in each trial as follows:

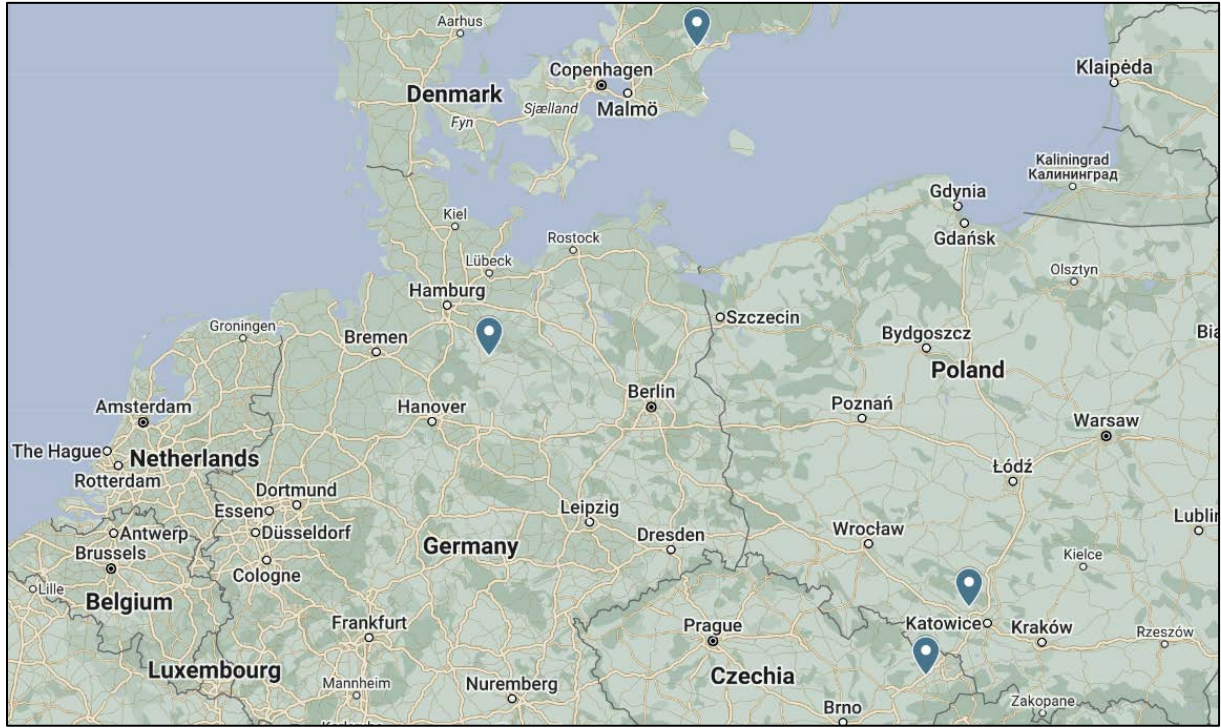
First symptoms (0 days, first symptoms)
1 week after symptoms (7-10 days after first symptoms)
2 weeks after symptoms (14 days after first symptoms)
3 weeks after symptoms (15-21 days after first symptoms)
4 weeks after symptoms (22-28 days after first symptoms)
5 weeks after symptoms (31-35 days after first symptoms)
6 weeks after symptoms (39-42 days after first symptoms)
7 weeks after symptoms (44-49 days after first symptoms)
8 weeks after symptoms (55-56 days after first symptoms)

The Area Under the Disease Progress Curve (AUDPC) is a summarizing value for the efficacy of the treatments across the season. Therefore all assessment data is presented together.

The geographical distribution of the preliminary trials (ref.

Table 3.2-6) is shown in Figure 3.2-1 below.
Because of the limited spread of the trials the applicant ought it acceptable to summarize all gathered data together to be able to draw stronger conclusions, as opposed to splitting the data set according to the EPPO Zone they are performed in.

Figure 3.2-1 Geographical distribution of preliminary trials



The table below summarizes the efficacy data found in Appendix 3 of the BAD – Preliminary trial data. It should be noted that in this summarizing table Sporax refers to Propamocarb 722 SL.

Table 3.2-7 Summary of preliminary efficacy trials performed with tank mix of Sporax and Zoxium

Assessment timing	At first symptoms			7-10 days after symptoms			15-21 days after symptoms		
Number of trials	2 trials			2 trials			3 trials		
	Mean	Min	Max	Mean	Min	Max	Mean	Min	Max

UNTREATED			8.3	8.3	8.3	40.8	23.3	58.3	54.2	13.3	92.5
Sporax	1	L/ha	88.1	84.4	91.7	79.7	77.2	82.2	68.4	55.1	82.4
Sporax	1.4	L/ha	86.0	80.2	91.7	76.4	70.6	82.2	76.1	55.1	91.8
Zoxium	0.4	L/ha	76.2	70.7	81.7	70.0	65.6	74.4	65.0	37.3	82.3
Zoxium	0.62	L/ha	83.4	70.7	96.0	80.6	75.6	85.6	73.0	59.5	84.0
Zoxium	0.75	L/ha	85.8	75.5	96.0	81.4	80.6	82.2	79.1	63.7	92.2
Zoxium + Sporax	0.4 + 1	L/ha	81.5	71.3	91.7	81.9	79.4	84.4	83.7	74.6	98.3
Zoxium + Sporax	0.4 + 1.4	L/ha	84.0	74.9	93.0	88.1	80.6	95.6	87.1	78.1	100.0
Zoxium + Sporax	0.62 + 1	L/ha	82.6	66.5	98.7	86.4	80.6	92.2	83.7	75.3	97.8
Zoxium + Sporax	0.62 + 1.4	L/ha	87.6	85.2	90.0	89.8	86.7	92.8	90.5	83.6	100.0
Zoxium + Sporax	0.75 + 1	L/ha	80.6	62.4	98.7	88.1	82.2	93.9	86.9	78.1	99.0
Zoxium + Sporax	0.75 + 1.4	L/ha	88.0	79.6	96.3	87.5	81.1	93.9	88.7	82.5	100.0
Ranman Top 160 SC	0.5	L/ha	74.1	71.5	76.7	54.2	28.9	79.4	59.6	7.7	94.3
Assessment timing	22-28 days after symptoms			31-35 days after symptoms			39-42 days after symptoms				
Number of trials	3 trials			3 trials			2 trials				
			Mean	Min	Max	Mean	Min	Max	Mean	Min	Max
UNTREATED			77.8	65.0	88.3	97.8	96.0	99.2	99.5	99.0	100.0
Sporax	1	L/ha	81.3	74.1	92.5	40.1	11.9	76.2	8.3	4.2	12.4
Sporax	1.4	L/ha	76.7	64.1	89.8	50.8	24.4	92.2	13.7	5.0	22.4
Zoxium	0.4	L/ha	74.6	69.6	79.2	42.2	4.2	78.0	11.9	3.3	20.4
Zoxium	0.62	L/ha	78.1	66.3	96.9	55.0	35.8	88.2	18.1	12.5	23.6
Zoxium	0.75	L/ha	80.6	79.9	81.2	57.1	41.0	89.2	24.1	12.5	35.7
Zoxium + Sporax	0.4 + 1	L/ha	80.2	66.3	98.9	63.2	41.1	90.5	23.3	15.0	31.5
Zoxium + Sporax	0.4 + 1.4	L/ha	88.2	82.0	99.6	65.1	44.5	92.9	36.3	20.0	52.5
Zoxium + Sporax	0.62 + 1	L/ha	86.7	72.5	96.2	66.9	47.9	94.9	44.0	25.0	62.9
Zoxium + Sporax	0.62 + 1.4	L/ha	87.1	80.7	96.2	66.8	46.2	96.2	34.6	20.0	49.2
Zoxium + Sporax	0.75 + 1	L/ha	88.2	80.8	96.3	66.6	48.1	93.9	37.2	32.7	41.7
Zoxium + Sporax	0.75 + 1.4	L/ha	86.7	79.7	97.4	66.5	44.3	97.3	44.9	33.3	56.4
Ranman Top 160 SC	0.5	L/ha	76.7	69.1	87.4	39.9	4.2	76.2	20.2	0.8	39.5
Assessment timing	44-49 days after symptoms			55-56 days after symptoms			AUDPC				
Number of trials	2 trials			2 trials			4 trials				
			Mean	Min	Max	Mean	Min	Max	Mean	Min	Max
UNTREATED			100.0	100.0	100.0	100.0	100.0	100.0	2726.8	1553.9	4662.5
Sporax	1	L/ha	31.3	0.8	61.7	30.0	0.0	60.0	54.6	27.7	71.9
Sporax	1.4	L/ha	45.9	1.7	90.0	43.4	0.0	86.7	59.2	30.7	90.1
Zoxium	0.4	L/ha	39.6	0.8	78.3	36.7	0.0	73.3	54.3	19.6	77.8
Zoxium	0.62	L/ha	46.0	4.2	87.7	42.7	0.0	85.3	60.4	37.5	89.2
Zoxium	0.75	L/ha	46.3	4.2	88.3	44.6	0.8	88.3	65.0	38.2	87.4
Zoxium + Sporax	0.4 + 1	L/ha	47.0	5.0	89.0	44.3	0.8	87.7	64.6	45.8	91.5
Zoxium + Sporax	0.4 + 1.4	L/ha	48.2	5.0	91.3	45.8	0.8	90.7	71.5	48.0	93.6
Zoxium + Sporax	0.62 + 1	L/ha	50.4	10.0	90.7	44.4	0.0	88.7	72.7	49.4	92.8
Zoxium + Sporax	0.62 + 1.4	L/ha	51.9	12.5	91.3	46.3	2.5	90.0	72.2	50.1	93.7
Zoxium + Sporax	0.75 + 1	L/ha	53.4	15.0	91.7	45.4	0.8	90.0	71.8	53.6	93.1
Zoxium + Sporax	0.75 + 1.4	L/ha	54.5	15.0	94.0	48.1	4.2	92.0	73.3	53.4	95.4
Ranman Top 160 SC	0.5	L/ha	33.4	0.0	66.7	31.7	0.0	63.3	53.8	8.8	71.2

Conclusion

The results obtained in the preliminary studies demonstrate a clear benefit in combining propamocarb-HCl and zoxamide. The benefit of combining these active substances becomes more apparent as more time passes after the initial symptoms and the disease pressure increases.

When comparing the amount of control obtained by using different ratios of the Zoxium (Zoxium 240 SC) and Sporax (Propamocarb 722 SL) it is clear that that 0.62 L/ha Zoxium + 1.4 L/ha provides good control (marked in green in Table 3.2-7 above). There is no clear benefit in further increasing the amount of zoxamide in the mixture.

For the development of GLOB2007bF the applicant continued working with the above ratio between both active substances, as can be seen in Table 3.2-8 below.

Table 3.2-8 Ratio between propamocarb-HCl and zoxamide in GLOB2007bF

	propamocarb-HCl	zoxamide	ratio
1.4 L/ha Sporax	1010.8 g/ha	-	6.8 : 1
0.62 L/ha Zoxium	-	148.8 g/ha	
2 L/ha GLOB2007bF	900 g/ha	135 g/ha	6.7 : 1

Further lowering of the amount of propamocarb-HCl in the formulation is not advisable, because according to the FRAC (Fungicide Resistance Action Committee), reduced rates of active substances can contribute to accelerate the shift to less sensitive populations.

Comments of zRMS:	<p>The Preliminary trials based on the use of combination of the active substances propamocarb-HCl and zoxamide, a tank mix of Sporax / Propamocarb 722 SL (722 g/L propamocarb) and Zoxium 240 SC (240 g/L zoxamide) was tested, applied at multiple dose rates. Both active substances, have been used as fungicide in potatoes in commercial practice for many years. To show the benefit of the combination of propamocarb and zoxamide a comparison of both solo active substances was done.</p> <p>The preliminary trial program consisted of 3 trials performed in the Maritime EPPO Zone (the Czech Republic, Germany and Sweden) and 1 trial performed in the North-East EPPO Zone (Poland).</p> <p>From the submitted trials it is clear that the effectiveness was higher when the combination of Sporax / Propamocarb 722 SL (722 g/L propamocarb) and Zoxium 240 SC (240 g/L zoxamide) was applied compared with the effectiveness of solo active substances used individually.</p> <p>Tank mix Sporax 1.4l/ha + Zoxium 0.62l/ha gave the appropriate effectiveness in controlling <i>P. infestans</i> in potato crop, and the proposed doses are consistent with the anti-resistance policy of using plant protection products and complies with the Uniform Principles.</p>
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3.3.2 Minimum effective dose (MED) tests (KCP 6.2)

In all trials presented in this dossier, a reduced dose rate of 1.2 L/ha GLOB2007bF was included to confirm 2 L/ha as the minimum effective dose. These trials were performed in the Maritime EPPO Zone, the North-East EPPO Zone, the Mediterranean EPPO Zone and the South-East EPPO Zone (Hungary). For a complete list of countries reference is made to

Sites and application details of these trials are presented in the tables under 3.2.3.1.

For individual trial data reference is made to Appendix 4 of the BAD – Efficacy data.

For more information on the presentation of the results in Appendix 4 of the BAD reference is made to section 3.2.3.2.

First, the minimum effective dose is demonstrated for all trials presented in this dossier, this demonstrates the minimum effective dose across a wide variety of conditions. Next it is demonstrated for each EPPO Zone separately. For Poland an additional summary is made for all trials performed in the North-East EPPO Zone combined with the trials performed in the Czech Republic and Germany.

Table 3.2-9 Minimum effective dose of GLOB2007bF across all EPPO Zones

Rating type	Part rated	Timing	n	Untreated control			% control GLOB2007bF									
							1.2 L/ha					2 L/ha				
				Mean	Min	Max	Mean	Min	Max	Med.	Stdev	Mean	Min	Max	Med.	Stdev
AUDPC	LEAF	season	35	1126.5	34.4	3698.5	67.7	16.7	100.0	67.7	22.6	73.8	18.9	100.0	76.1	22.6
PESINC	TUBER	harvest	10	11.9	5.0	30.0	74.8	27.7	100.0	86.2	25.6	79.8	28.6	100.0	87.8	22.4
PESSEV	LEAF	first symptoms	8	11.4	5.3	25.0	80.8	45.8	100.0	79.7	19.2	83.4	57.5	100.0	90.1	18.3
PESSEV	LEAF	5-10 days after symptoms	16	20.3	5.0	82.5	76.1	27.1	100.0	76.9	21.3	82.9	47.9	100.0	89.9	18.5
PESSEV	LEAF	12-16 days after symptoms	19	25.5	5.0	100.0	75.2	40.0	100.0	78.1	20.7	80.6	46.9	100.0	90.0	19.7
PESSEV	LEAF	17-21 days after symptoms	26	31.7	5.0	98.8	68.7	11.5	100.0	73.7	26.9	74.6	25.3	100.0	84.0	25.5
PESSEV	LEAF	23-28 days after symptoms	26	42.2	6.5	100.0	65.3	25.4	100.0	62.5	24.6	69.4	32.1	100.0	68.4	24.1
PESSEV	LEAF	29-36 days after symptoms	22	49.9	9.2	100.0	64.7	2.3	100.0	76.9	30.2	71.5	2.5	100.0	80.3	29.6
PESSEV	LEAF	37-45 days after symptoms	19	44.5	12.4	100.0	55.9	0.0	100.0	58.3	27.6	64.9	0.5	100.0	69.6	28.2
PESSEV	LEAF	46-52 days after symptoms	8	48.0	9.5	100.0	71.4	38.8	100.0	70.5	27.6	80.3	50.0	100.0	82.4	19.9

Table 3.2-10 Minimum effective dose of GLOB2007bF in the Maritime EPPO Zone

Rating type	Part rated	Timing	n	Untreated control			% control GLOB2007bF									
							1.2 L/ha					2 L/ha				
				Mean	Min	Max	Mean	Min	Max	Med.	Stdev	Mean	Min	Max	Med.	Stdev
AUDPC	LEAF	season	12	1112.7	104.4	3422.5	77.2	16.7	100.0	94.5	28.6	78.9	18.9	100.0	96.2	27.6
PESINC	TUBER	harvest	3	11.4	9.0	16.0	72.5	27.7	100.0	89.9	39.2	72.5	28.6	100.0	88.9	38.4
PESSEV	LEAF	first symptoms	2	19.7	14.3	25.0	92.1	84.2	100.0	92.1	11.2	97.1	94.2	100.0	97.1	4.1
PESSEV	LEAF	7-10 days after symptoms	4	41.4	8.0	82.5	84.2	52.9	100.0	91.9	21.7	86.5	55.7	100.0	95.2	20.8
PESSEV	LEAF	12-16 days after symptoms	5	43.3	5.0	100.0	89.8	68.8	100.0	95.5	13.2	93.7	84.5	100.0	94.1	6.6
PESSEV	LEAF	17-21 days after symptoms	7	34.9	5.0	98.8	82.7	32.5	100.0	99.8	27.2	85.1	49.3	100.0	99.9	23.5
PESSEV	LEAF	23-28 days after symptoms	9	40.0	6.5	100.0	70.4	35.0	100.0	77.5	30.4	72.6	37.5	100.0	70.8	28.0
PESSEV	LEAF	29-35 days after symptoms	8	52.4	9.2	100.0	66.7	2.3	100.0	91.5	42.9	69.9	12.5	100.0	95.1	39.7
PESSEV	LEAF	37-45 days after symptoms	6	50.6	13.3	100.0	60.3	0.0	100.0	74.9	45.1	63.0	0.5	100.0	84.8	47.1
PESSEV	LEAF	48-52 days after symptoms	3	21.7	9.5	35.5	99.8	99.5	100.0	99.9	0.3	99.9	99.7	100.0	99.9	0.2

Table 3.2-11 Minimum effective dose of GLOB2007bF in the North-East EPPO Zone

Rating type	Part rated	Timing	n	Untreated control			% control GLOB2007bF									
							1.2 L/ha					2 L/ha				
				Mean	Min	Max	Mean	Min	Max	Med.	Stdev	Mean	Min	Max	Med.	Stdev
AUDPC	LEAF	season	12	1513.7	383.9	3698.5	58.2	21.6	82.8	60.8	18.4	67.4	31.1	88.9	70.6	17.4
PESINC	TUBER	harvest	4	14.6	5.0	30.0	74.2	52.1	86.5	79.0	16.1	82.1	65.2	94.1	84.6	12.3
PESSEV	LEAF	first symptoms	3	8.5	5.3	13.8	73.7	45.8	100.0	75.2	27.1	73.0	57.5	100.0	61.6	23.4
PESSEV	LEAF	5-10 days after symptoms	6	15.3	6.4	30.0	71.0	27.1	100.0	76.6	28.5	80.8	47.9	100.0	91.7	22.7
PESSEV	LEAF	12-14 days after symptoms	5	23.8	10.0	42.5	66.0	40.0	100.0	52.5	27.3	76.0	49.3	100.0	75.4	22.9
PESSEV	LEAF	17-21 days after symptoms	10	27.4	5.6	90.0	60.7	11.5	97.2	62.3	26.4	68.3	25.8	98.4	71.7	23.9
PESSEV	LEAF	23-28 days after symptoms	9	40.6	11.2	100.0	60.7	25.4	90.6	58.3	21.8	66.5	32.1	95.9	61.8	20.2
PESSEV	LEAF	29-35 days after symptoms	11	41.5	10.3	100.0	61.2	5.0	82.7	63.4	23.7	68.6	2.5	90.0	76.3	25.0
PESSEV	LEAF	38-42 days after symptoms	10	40.2	16.6	100.0	58.6	28.1	79.0	60.6	16.5	68.8	36.3	86.4	71.6	16.0
PESSEV	LEAF	46-52 days after symptoms	5	63.9	28.0	100.0	54.4	38.8	86.1	52.3	19.1	68.5	50.0	91.3	65.3	15.3

Table 3.2-12 Minimum effective dose of GLOB2007bF in the North-East EPPO Zone + CZ/DE

Rating type	Part rated	Timing	n	Untreated control			% control GLOB2007bF									
							1.2 L/ha					2 L/ha				
				Mean	Min	Max	Mean	Min	Max	Med.	Stdev	Mean	Min	Max	Med.	Stdev
AUDPC	LEAF	season	17	1410.5	215.3	3698.5	60.8	16.7	100.0	61.6	23.1	68.0	18.9	100.0	70.8	21.9
PESINC	TUBER	harvest	6	13.9	5.0	30.0	69.0	27.7	89.9	79.0	24.6	76.2	28.6	100.0	84.6	26.2
PESSEV	LEAF	first symptoms	5	9.4	5.3	14.3	78.6	45.8	100.0	75.2	22.6	81.0	57.5	100.0	86.0	20.5
PESSEV	LEAF	5-10 days after symptoms	8	20.9	6.4	65.0	78.0	27.1	100.0	91.7	27.3	85.4	47.9	100.0	96.8	20.9
PESSEV	LEAF	12-15 days after symptoms	8	27.2	5.0	88.8	76.3	40.0	100.0	87.8	25.4	83.0	49.3	100.0	92.1	20.0
PESSEV	LEAF	17-21 days after symptoms	14	29.2	5.0	98.8	66.4	11.5	100.0	71.2	28.5	73.5	25.8	100.0	76.2	24.3
PESSEV	LEAF	23-28 days after symptoms	13	33.0	8.8	100.0	61.3	25.4	100.0	58.3	23.8	65.2	32.1	100.0	61.8	22.1
PESSEV	LEAF	29-35 days after symptoms	15	44.1	10.3	100.0	60.6	5.0	100.0	63.4	28.1	66.9	2.5	100.0	76.3	28.4
PESSEV	LEAF	38-45 days after symptoms	13	44.3	16.6	100.0	58.1	11.9	100.0	58.6	23.0	66.6	8.0	100.0	69.6	24.0
PESSEV	LEAF	46-52 days after symptoms	5	63.9	28.0	100.0	54.4	38.8	86.1	52.3	19.1	68.5	50.0	91.3	65.3	15.3

Table 3.2-13 Minimum effective dose of GLOB2007bF in the Mediterranean EPPO Zone

Rating type	Part rated	Timing	n	Untreated control			% control GLOB2007bF									
							1.2 L/ha					2 L/ha				
				Mean	Min	Max	Mean	Min	Max	Med.	Stdev	Mean	Min	Max	Med.	Stdev
AUDPC	LEAF	season	6	639.9	34.4	2753.9	68.3	47.9	78.5	71.4	11.5	74.4	43.0	98.5	79.4	24.6
PESINC	TUBER	harvest	2	10.3	5.0	15.5	96.2	92.3	100.0	96.2	5.4	96.0	92.0	100.0	96.0	5.7
PESSEV	LEAF	first symptoms	2	7.5	7.5	7.5	86.1	72.1	100.0	86.1	19.7	93.0	86.0	100.0	93.0	9.9
PESSEV	LEAF	7-10 days after symptoms	3	13.1	5.0	24.3	69.4	62.0	73.8	72.5	6.5	83.1	64.0	98.0	87.3	17.4
PESSEV	LEAF	13-13 days after symptoms	4	17.6	5.8	43.8	71.2	60.7	87.7	68.3	12.3	68.3	55.5	90.1	63.8	15.3
PESSEV	LEAF	18-20 days after symptoms	4	24.6	5.5	71.3	61.6	20.3	87.6	69.3	29.2	66.0	25.3	97.3	70.7	34.7
PESSEV	LEAF	25-28 days after symptoms	4	34.6	7.2	91.3	61.4	39.9	86.4	59.6	21.8	57.2	33.0	92.1	51.9	27.5
PESSEV	LEAF	35-35 days after symptoms	1	100.0	100.0	100.0	77.5	77.5	77.5	77.5		88.5	88.5	88.5	88.5	
PESSEV	LEAF	41-42 days after symptoms	2	56.2	12.4	100.0	40.4	38.3	42.5	40.4	3.0	55.6	39.8	71.3	55.6	22.3

Table 3.2-14 Minimum effective dose of GLOB2007bF in the South-East EPPO Zone

Rating type	Part rated	Timing	n	Untreated control			% control GLOB2007bF									
							1.2 L/ha					2 L/ha				
				Mean	Min	Max	Mean	Min	Max	Med.	Stdev	Mean	Min	Max	Med.	Stdev
AUDPC	LEAF	season	5	814.4	223.6	1652.5	66.7	40.9	90.3	63.1	20.9	76.4	48.2	99.4	79.2	21.0
PESINC	TUBER	harvest	1	6.0	6.0	6.0	41.7	41.7	41.7	41.7		60.4	60.4	60.4	60.4	
PESSEV	LEAF	first symptoms	1	11.3	11.3	11.3	69.2	69.2	69.2	69.2		67.5	67.5	67.5	67.5	
PESSEV	LEAF	7-7 days after symptoms	3	9.3	5.0	15.8	82.2	66.7	100.0	80.0	16.8	82.1	66.4	100.0	80.0	16.9
PESSEV	LEAF	14-15 days after symptoms	5	15.9	5.0	42.5	72.9	46.9	100.0	78.1	22.5	81.9	46.9	100.0	97.9	24.7
PESSEV	LEAF	21-21 days after symptoms	4	39.3	10.5	80.0	80.8	62.5	88.4	86.2	12.3	89.3	68.8	100.0	94.2	14.6
PESSEV	LEAF	28-28 days after symptoms	4	58.2	17.5	98.0	68.2	33.7	89.7	74.8	25.4	80.8	49.0	99.5	87.4	22.0
PESSEV	LEAF	35-36 days after symptoms	2	60.7	23.8	97.5	69.9	57.5	82.2	69.9	17.5	85.6	72.3	98.8	85.6	18.7
PESSEV	LEAF	42-42 days after symptoms	1	28.8	28.8	28.8	34.2	34.2	34.2	34.2		55.8	55.8	55.8	55.8	

Summary

The data presented above clearly demonstrates the benefit of using GLOB2007bF at the requested dose rate of 2 L/ha, with higher and most consistent levels of control compared to the lower dose rates. Additionally it should be noted that drastically lowering the amount of active substances applied compared to their currently registered dose rates (1000 g/ha propamocarb-HCl) is not advisable, because according to the FRAC (Fungicide Resistance Action Committee) reduced rates of active substances can contribute to accelerate the shift to less sensitive populations. This further supports the use of the 2 L/ha dose rate for GLOB2007bF.

Comments of zRMS:	The results obtained in experiments presented in dRR indicate that the GLOB2007bF (Observer Pro) dose of 2l/ha is the appropriate minimum dose for controlling <i>P. infestans</i> in potatoes. Overall 35 field trials to control <i>P. infestans</i> on potatoes were carried out across four climatic EPPO zones: MAR- 12 trials, N-E-12, N-E+ CZ, DE- 17, ME-6, S-E -5. GLOB2007bF (Observer Pro) was tested in dose 1.2 l/ha and 2.0 l/ha. The tested preparation at a dose of 2.0 l/ha gave clearly better effectiveness than when used at a dose of 1.2 l/ha. Therefore, the proposed application rate of 2.0 l/ha of GLOB2007bF (Observer Pro) for potato protection against <i>P. infestans</i> in the field is justified as minimum effective dose.
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3.3.3 Efficacy tests (KCP 6.2)

3.3.3.1 Use on potatoes

GLOB2007bF is used in potatoes for the control of a late blight (*Phytophthora infestans*) at a dose rate of 2 L/ha.

The trials presented in this dossier were conducted by contractor companies and official Research Institutes, all of which followed the EPPO standards and are officially recognized by the competent authorities to carry out field registration trials in accordance with the principles of Good Experimental Practice (GEP). Trials were conducted across a wide range of sites. The trials are therefore representative of a wide range of environmental conditions likely to be encountered in practice in the area of proposed use.

It should be noted that all trials performed for this project are included in this submission, this includes trials performed in the Maritime, North-East, Mediterranean and South-East EPPO Zone (ref.

Table 3.2-6). The applicant is aware that not all submitted data is accepted by the countries where registration is requested, however data from other EPPO Zones can be considered confirmatory data that demonstrates the performance of GLOB2007bF under a wide range of climatic and edaphic conditions.

The trials package of GLOB2007bF includes 13 trials performed in the Maritime EPPO Zone (the Czech Republic, Germany, France, the Netherlands, Sweden and the UK), 11 trials performed in the North-East EPPO Zone (Poland and Latvia), 6 trials performed in the Mediterranean EPPO Zone (Italy and Spain) and 6 trials performed in the South-East EPPO Zone (Hungary and Romania). All trials were performed in 2021 and 2022.

It is important to note that more than the requested 3 applications were performed in the submitted trials, applications were continued at a 5-10 day interval until harvest. Assessments were made before every new application to assess the efficacy of each application.

Table 3.2-16 below, the trial methodology and details of the individual trials is shown.

Table 3.2-15: Details on trial methodology

Guidelines	General guidelines	EPPO PP 1/152 (4), 1/135 (4), 1/181 (4)
	Specific guidelines	EPPO PP 1/2 (4)
Experimental design	Plot design	RCBD
	Plot size	18-30 m ²
	Number of replications	4
Crop	Trials per crop (varieties)	All submitted data: 36 trials (27 varieties) Maritime EPPO Zone → Czech/German trials 13 trials (12 varieties) 6 trials (6 varieties) North-East EPPO Zone

		11 trials (7 varieties) Mediterranean EPPO Zone: 6 trials (5 varieties) South-East EPPO Zone: 6 trials (5 varieties)
Application	Crop stage at first application	BBCH 13-70
	Pest stage at first application	First application was preventative or at the latest at the start of the disease.
	First application-Final application	Maritime EPPO Zone → Czech/German trials June 13 th – September 20 th June 21 st – September 9 th North-East EPPO Zone June 14 th – September 22 nd Mediterranean EPPO Zone March 29 th – November 20 th South-East EPPO Zone June 17 th – October 14 th
	Application interval	Applications were continued at 5-10 day interval until one week before harvest
	Spray volumes	150-300 L/ha
Assessment	Assessment types	Pest severity: from start of trial Phytotoxicity; from 7 DA-A Yield: total weight, weight per class, total number of tubers, number of tubers per class, starch concentration Pest incidence on tubers after 4-8 weeks in storage
	e.g. Field / Greenhouse...	Field trials

Table 3.2-16: Summary form of information concerning trial sites and application details of the efficacy trials

Type of trials

Crop

Harmful organism

Responsible body for reporting trial

Effectiveness

Potato

Phytophthora infestans

Reference is made to the BAD.

Trial reference		Trial location	Test method	Application details		Crop variety
		Soil type	Plot size	First applic. Final applic.	Applic. Amount (method)	
KCP 6.2-07 Preliminary trial		Kujavy (CZ) loam	PP 1/135(4) PP 1/152(4) PP 181(4) PP 1/2(2) 30 m ²	Jun-25-2020 Aug-17-2020	200 L/ha (Downward spraying)	Antonie
KCP 6.2-08 Preliminary trial		Oetzendorf (DE) loamy sand	PP 1/135(4) PP 1/152(4) PP 181(4) PP 1/2(2) 18 m ²	Jun-24-2020 Aug-13-2020	200 L/ha (Downward spraying)	Kuba
KCP 6.2-09 Preliminary trial		Kristianstad (SE) sand	PP 1/135(4) PP 1/152(4) PP 181(4) PP 1/2(2) 30 m ²	Jun-23-2020 Aug-27-2020	300 L/ha (Downward spraying)	Avenue
KCP 6.2-10 Preliminary trial		Księży Las (PL) sandy loam	PP 1/135(4) PP 1/152(4) PP 181(4) PP 1/2(2) 15 m ²	Jun-23-2020 Aug-14-2020	200 L/ha (Downward spraying)	Lord
KCP 6.2-21		Ligatne (LV) loamy sand	PP 1/135(4) PP 1/152(4) PP 181(4) PP 1/2(2) 24 m ²	Jul-7-2021 Aug-9-2021	250 L/ha (Downward spraying)	Lady Claire
KCP 6.2-22		Czarne Piątkowo (PL) loamy sand	PP 1/135(4) PP 1/152(4) PP 181(4) PP 1/2(2) 24 m ²	Jun-18-2021 Aug-20-2021	200 L/ha (Downward spraying)	Denar
KCP 6.2-23		Feliksów (PL) sandy clay loam	PP 1/135(4) PP 1/152(4) PP 181(4)	Jul-16-2021 Sep-3-2021	200 L/ha (Downward spraying)	Melody

Trial reference		Trial location Soil type	Test method Plot size	Application details		Crop variety
				First applic. Final applic.	Applic. Amount (method)	
			PP 1/2(2) 24 m ²			
KCP 6.2-24		Balastya (HU) sandy loam	PP 1/135(4) PP 1/152(4) PP 181(4) PP 1/2(2) 24 m ²	Aug-26-2021 Oct-14-2021	200 L/ha (Downward spraying)	Balatoni Rózsa
KCP 6.2-25		Krasne Udoli (CZ) sandy loam	PP 1/135(4) PP 1/152(4) PP 181(4) PP 1/2(2) 25.8 m ²	Jul-13-2021 Aug-10-2021	150 L/ha (Downward spraying)	Anuschka
KCP 6.2-27		Aumenancourt (FR) clay loam	PP 1/135(4) PP 1/152(4) PP 181(4) PP 1/2(2) 18.4 m ²	Jun-21-2021 Aug-11-2021	200 L/ha (Downward spraying)	Orchestra
KCP 6.2-28		Portas (ES) sandy clay loam	PP 1/135(4) PP 1/152(4) PP 181(4) PP 1/2(2) 24 m ²	Jul-22-2021 Aug-30-2021	200 L/ha (Downward spraying)	Kenebec
KCP 6.2-30		Zapponeta (IT) sand	PP 1/135(4) PP 1/152(4) PP 181(4) PP 1/2(2) 20 m ²	Sep-28-2021 Nov-10-2021	200 L/ha (Downward spraying)	Agata
KCP 6.2-32		Sinteu (RO) sandy clay loam	PP 1/135(4) PP 1/152(4) PP 181(4) PP 1/2(2) 24 m ²	Jun-17-2021 Aug-2-2021	200 L/ha (Downward spraying)	Margaret
KCP 6.2-33		Bystrice nad Pernštejnem (CZ) loamy sand	PP 1/135(4) PP 1/152(4) PP 181(4) PP 1/2(2) 24 m ²	Jul-13-2021 Sep-9-2021	200 L/ha (Downward spraying)	Vysocina
KCP 6.2-35		Zirc (HU) clay loam	PP 1/135(4) PP 1/152(4) PP 181(4) PP 1/2(2) 24 m ²	Jun-29-2021 Aug-12-2021	200 L/ha (Downward spraying)	Agria

Trial reference		Trial location Soil type	Test method Plot size	Application details		Crop variety
				First applic. Final applic.	Applic. Amount (method)	
KCP 6.2-36		San Benedetto dei Marsi (IT) clay loam	PP 1/135(4) PP 1/152(4) PP 181(4) PP 1/2(2) 24 m ²	Jun-16-2021 Aug-23-2021	200 L/ha (Downward spraying)	Agria
KCP 6.2-37		Renceles (LV) loamy sand	PP 1/135(4) PP 1/152(4) PP 181(4) PP 1/2(2) 24 m ²	Jul-5-2021 Aug-18-2021	250 L/ha (Downward spraying)	Alouette
KCP 6.2-39		Wielgie (PL) loamy sand	PP 1/135(4) PP 1/152(4) PP 181(4) PP 1/2(2) 20 m ²	Jul-1-2021 Aug-13-2021	200 L/ha (Downward spraying)	Denar
KCP 6.2-40		Olaszfału (HU) sandy clay	PP 1/135(4) PP 1/152(4) PP 181(4) PP 1/2(2) 28 m ²	Jul-22-2021 Sep-16-2021	200 L/ha (Downward spraying)	Delila
KCP 6.2-41		Kromeriz (CZ) silty clay loam	PP 1/135(4) PP 1/152(4) PP 181(4) PP 1/2(2) 24 m ²	Jun-25-2021 Aug-16-2021	200 L/ha (Downward spraying)	Marabel
KCP 6.2-42		Zapponeta (IT) sand	PP 1/135(4) PP 1/152(4) PP 181(4) PP 1/2(2) 20 m ²	Sep-24-2021 Nov-20-2021	200 L/ha (Downward spraying)	Spunta
KCP 6.2-43		Ligatne (LV) loamy sand	PP 1/135(4) PP 1/152(4) PP 181(4) PP 1/2(2) 24 m ²	Jul-5-2021 Aug-20-2021	250 L/ha (Downward spraying)	Sorentina
KCP 6.2-44		Liskeard (GB) clay	PP 1/135(4) PP 1/152(4) PP 181(4) PP 1/2(2) 18 m ²	Jun-15-2021 Aug-17-2021	150 L/ha (Downward spraying)	Sagitta
KCP 6.2-45		Pieruszyce (PL) sandy loam	PP 1/135(4) PP 1/152(4)	Jun-24-2021 Aug-12-2021	200 L/ha (Downward spraying)	Vineta

Trial reference		Trial location Soil type	Test method Plot size	Application details		Crop variety
				First applic. Final applic.	Applic. Amount (method)	
			PP 181(4) PP 1/2(2) 24 m ²			
KCP 6.2-46		Kristianstad (SE) sandy loam	PP 1/135(4) PP 1/152(4) PP 181(4) PP 1/2(2) 30 m ²	Jun-29-2022 Aug-16-2022	200 L/ha (Downward spraying)	Saprodi
KCP 6.2-47		Forráskút (HU) sandy loam	PP 1/135(4) PP 1/152(4) PP 181(4) PP 1/2(2) 24 m ²	Jul-28-2022 Sep-15-2022	200 L/ha (Downward spraying)	Bella Rosa
KCP 6.2-48		Csegele (HU) sandy clay loam	PP 1/135(4) PP 1/152(4) PP 181(4) PP 1/2(2) 24 m ²	Aug-23-2022 Oct-11-2022	200 L/ha (Downward spraying)	Balatoni Rózsa
KCP 6.2-49		Ligatne (LV) loamy clay sand	PP 1/135(4) PP 1/152(4) PP 181(4) PP 1/2(2) 27 m ²	Jul-1-2022 Aug-9-2022	200 L/ha (Downward spraying)	Lady Clair
KCP 6.2-50		Kristianstad (SE) sand	PP 1/135(4) PP 1/152(4) PP 181(4) PP 1/2(2) 30 m ²	Jun-21-2022 Aug-16-2022	200 L/ha (Downward spraying)	Kuras
KCP 6.2-51		Kujavy (CZ) loam	PP 1/135(4) PP 1/152(4) PP 181(4) PP 1/2(2) 30 m ²	Jun-29-2022 Aug-15-2022	200 L/ha (Downward spraying)	Antonie
KCP 6.2-52		Stachy-Chalupy (CZ) loamy sand	PP 1/135(4) PP 1/152(4) PP 181(4) PP 1/2(2) 25.2 m ²	Jun-27-2022 Aug-1-2022	150 L/ha (Downward spraying)	Red Sonia
KCP 6.2-53		Ilsfeld (DE) clay loam	PP 1/135(4) PP 1/152(4) PP 181(4)	Jun-21-2022 Aug-9-2022	200 L/ha (Downward spraying)	Antonia

Trial reference		Trial location Soil type	Test method Plot size	Application details		Crop variety
				First applic. Final applic.	Applic. Amount (method)	
			PP 1/2(2) 24 m ²			
KCP 6.2-54		Blairville (FR)	PP 1/135(4) PP 1/152(4) PP 181(4) PP 1/2(2) 18 m ²	Jul-21-2022 Sep-19-2022	200 L/ha (Downward spraying)	Kaptah
KCP 6.2-56		Hoogkarspel (NL) sandy clay	PP 1/135(4) PP 1/152(4) PP 181(4) PP 1/2(2) 24 m ²	Jun-22-2022 Sep-22-2022	200 L/ha (Downward spraying)	Bintje
KCP 6.2-57		Międzychód (PL) loamy sand	PP 1/135(4) PP 1/152(4) PP 181(4) PP 1/2(2) 24 m ²	Jun-14-2022 Aug-3-2022	200 L/ha (Downward spraying)	Bella Rosa
KCP 6.2-58		Jabłowo Pańuckie (PL) clay loam	PP 1/135(4) PP 1/152(4) PP 181(4) PP 1/2(2) 24 m ²	Jul-25-2022 Sep-22-2022	300 L/ha (Downward spraying)	Melody
KCP 6.2-59		Ligatne (LV) loamy clay sand	PP 1/135(4) PP 1/152(4) PP 181(4) PP 1/2(2) 27 m ²	Jul-1-2022 Aug-17-2022	200 L/ha (Downward spraying)	Sorentina
KCP 6.2-61		Los Palacios (ES) silt loam	PP 1/135(4) PP 1/152(4) PP 181(4) PP 1/2(2) 24 m ²	Mar-29-2022 May-4-2022	200 L/ha (Downward spraying)	Soprano
KCP 6.2-62		Hoogkarspel (NL) sandy clay	PP 1/135(4) PP 1/152(4) PP 181(4) PP 1/2(2) 24 m ²	Jun-22-2022 Sep-20-2022	200 L/ha (Downward spraying)	Bintje
KCP 6.2-63		Augusta (IT) sandy clay loam	PP 1/135(4) PP 1/152(4) PP 181(4) PP 1/2(2) 24 m ²	Apr-15-2022 May-9-2022	200 L/ha (Downward spraying)	Soprano

Details on the treatments included in each trial are provided in Table 3.2-17 and Table 3.2-18. It should be noted that the names of the reference products can differ (slightly) between the different countries. For country-specific information reference is made to Table 3.2-5. However, all identical reference products were summarized together.

Comments of zRMS:	<p>Trials methodology:</p> <p>The Specific guidelines EPPO PP 1/2 (4) is used in dRR but the current specific guidelines applicable from 2020 is EPPO PP1/002(5).</p> <p>Experiment – design is EPPO compliant, The countries where the experiments were located should be listed Crop - no indication of the crop on which the experiments were carried out, no pest name Application- no indication of the number of applications, Assessment types-no data on which plant organs the assessment was performed, and no units in which the assessment was performed. (this information is provided only in the text: Assessment methods).</p> <p>The applicant should complete the missing data. The Methodology presented in dRR will be appropriate after the Applicant completes the above-mentioned data.</p>
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Table 3.2-17: Formulations included in efficacy trials

Product	Active substance	Active substance content	Formulation type
GLOB2007bF	Zoxamide Propamocarb	67.5 g/L 450 g/L	SC
GLOB2106cF*	Reference is made to the BAD		
GLOB2106aF*			
GLOB2013F*			
GLOB178F*			
Propamocarb 722 SL / GLOB2008F	Propamocarb-HCl	722 g/L	SL
Revus (250 SC) / Pergado SC	Mandipropamid	250 g/L	SC
Revus Top	Mandipropamid Difenoconazole	250 g/L 250 g/L	SC
Ranman Top (160 SC)	Cyazofamid	160 g/L	SC
Shirlan (Gold) / Winby / Frowncide	Fluazinam	500 g/L	SC
Infinito (687.5 SC) / Volare	Fluopicolid Propamocarb	62.5 g/L 6.25 g/L	SC

*Not of importance for this dossier

Table 3.2-18: Treatments included in trials

Trial ref.	Product	Application details		
		g/ha	L/ha	interval
7-10	UNTREATED			
Prelim. trials	Propamocarb 722 SL	722	1	7-10 days
	Propamocarb 722 SL	1010.8	1.4	7-10 days
	Zoxium 240 SC	96	0.4	7-10 days
	Zoxium 240 SC + Propamocarb 722 SL	96 + 722	0.4 + 1	7-10 days
	Zoxium 240 SC + Propamocarb 722 SL	96 + 1010.8	0.4 + 1.4	7-10 days
	Zoxium 240 SC	148.8	0.62	7-10 days
	Zoxium 240 SC + Propamocarb 722 SL	148.8 + 722	0.62 + 1	7-10 days
	Zoxium 240 SC + Propamocarb 722 SL	148.8 + 1011	0.62 + 1.4	7-10 days
	Zoxium 240 SC	180	0.75	7-10 days
	Zoxium 240 SC + Propamocarb 722 SL	180 + 722	0.75 + 1	7-10 days
	Zoxium 240 SC + Propamocarb 722 SL	180 + 1011	0.75 + 1.4	7-10 days
	Ranman Top 160 SC		0.5	7-10 days

21-23	UNTREATED GLOB2013F GLOB2013F GLOB2013F GLOB2106aF GLOB2106aF GLOB2106cF GLOB2007bF GLOB2007bF Propamocarb 722 SL Revus 250 SC	81 135 149 690 1150 1050 620 1040 1010 150	0.18 0.3 0.33 1.2 2 2 1.2 2 1.4 0.6	5-7 days 5-7 days 5-7 days 5-7 days 5-7 days 5-7 days 5-7 days 5-7 days 5-7 days 5-7 days
24-32	UNTREATED GLOB2013F GLOB2013F GLOB2013F GLOB2106aF GLOB2106aF GLOB2106cF GLOB2007bF GLOB2007bF Revus 250 SC / Pergado SC (IT)	81 135 149 690 1150 1050 620 1040 150	0.18 0.3 0.33 1.2 2 2 1.2 2 0.6	5-7 days 5-7 days 5-7 days 5-7 days 5-7 days 5-7 days 5-7 days 5-7 days 5-7 days
33-39	UNTREATED GLOB2013F GLOB2013F GLOB2106aF GLOB2106cF GLOB2007bF GLOB2007bF Propamocarb 722 SL Revus 250 SC / Pergado SC Infinito / Volare	135 149 1150 1050 1040 620 1010 150 1100	0.3 0.33 2 2 2 1.2 1.4 0.6 1.6	5-10 days* 5-10 days* 5-10 days* 5-10 days* 5-10 days* 5-10 days* 5-10 days* 5-10 days* 5-10 days* *Low pressure: 8-10d. *High pressure: 5-7d.
40-45	UNTREATED GLOB2013F GLOB2013F GLOB2013F GLOB2106aF GLOB2106aF GLOB2106cF GLOB2007bF GLOB2007bF Infinito / Volare	81 135 149 690 1150 1040 1040 620 1100	0.18 0.3 0.33 1.2 2 2 2 1.2 1.6	5-10 days* 5-10 days* 5-10 days* 5-10 days* 5-10 days* 5-10 days* 5-10 days* 5-10 days* 5-10 days* *Low pressure: 8-10d. *High pressure: 5-7d.
46-50	UNTREATED GLOB2013F GLOB2013F GLOB2013F GLOB2106cF GLOB2106cF GLOB2007bF GLOB2007bF GLOB2008F Revus Infinito	81 135 149 630 998 621 1035 1010 150 1100	0.18 0.3 0.33 1.2 1.9 1.2 2 1.4 0.6 1.6	5-10 days* 5-10 days* 5-10 days* 5-10 days* 5-10 days* 5-10 days* 5-10 days* 5-10 days* 5-10 days* 5-10 days* *Low pressure: 8-10d. *High pressure: 5-7d.
51-58	UNTREATED GLOB2013F GLOB2013F GLOB2106cF GLOB2106cF GLOB2007bF GLOB2007bF	81 135 630 998 621 1035	0.18 0.3 1.2 1.9 1.2 2	5-10 days* 5-10 days* 5-10 days* 5-10 days* 5-10 days* 5-10 days*

	GLOB178F GLOB178F Revus Infinito	540 900 150 1100	1.2 2 0.6 1.6	5-10 days* 5-10 days* 5-10 days* 5-10 days* *Low pressure: 8-10d. *High pressure: 5-7d.
59	UNTREATED GLOB2013F GLOB2013F GLOB2106cF GLOB2106cF GLOB2007bF GLOB2007bF GLOB2008F GLOB178F GLOB178F Revus Top Infinito	81 135 630 998 / 1050 621 1035 1010 540 900 300 1100	0.18 0.3 1.2 1.9 / 2 1.2 2 1.4 1.2 2 0.6 1.6	5-10 days* 5-10 days* 5-10 days* 5-10 days* 5-10 days* 5-10 days* 5-10 days* 5-10 days* 5-10 days* 5-10 days* *Low pressure: 8-10d. *High pressure: 5-7d.
60-63	UNTREATED GLOB2013F GLOB2013F GLOB2013F GLOB2106cF GLOB2106cF GLOB2007bF GLOB2007bF Revus / Pergado SC Infinito / Volare	81 135 149 630 998 / 1050 621 1035 150 1100	0.18 0.3 0.33 1.2 1.9 / 2 1.2 2 0.6 1.6	5-10 days* 5-10 days* 5-10 days* 5-10 days* 5-10 days* 5-10 days* 5-10 days* 5-10 days* 5-10 days* *Low pressure: 8-10d. *High pressure: 5-7d.

Assessment methods

The following assessments were made in accordance with EPPO Guideline 1/2 (5):

- Phytotoxicity (and description of the symptoms) was assessed by visual estimation of the intensity on an overall plot basis on a percentage scale 0-100% (0% = no damage).
- The assessment of efficacy in the treated plots was made in relation to the untreated plot on an overall plot basis (scale 0-100%, 0% = no efficacy). Efficacy was recorded by estimation of the intensity (severity) of the disease on the leaves during the growing season and the frequency (incidence) of the disease on the tubers after harvest.

Area Under the Disease Progress Curve (AUDPC)

At the end of the growing season the AUDPC is calculated from the individual assessment data (pest severity at several time points). This value summarizes the plant disease infestation over the trials. Because of the discrete nature of assessments in an efficacy trial, the AUDPC is estimated using the trapezoidal method. In this method the total surface area under the curve between adjacent assessments is calculated.

Statistical analysis

Data were analysed using a two-way analysis of variance (ANOVA). The probability of no significant differences occurring between treatment means is calculated as the F probability value (Prob(F)). Student-Newman-Keuls test was then applied to separate any treatment differences that may be implied by the ANOVA TEST (Prob(F) < 0.05) and these are indicated by the LSD-value and by a letter-test. The ANOVA data and the plot data are included in the appendices of the study reports.

Comments of zRMS:	Appropriate methods of assessing plant damage and statistical analysis methods were used.
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3.3.3.2 Presentation of the results

For individual trial data reference is made to Appendix 4 of the BAD, more information on the presentation of individual assessment data can also be found in section 3.2.3.2 of the BAD.

Pest severity (PESSEV) was assessed multiple times throughout the season. Applications started preventatively, but depending on the specific weather conditions there is a lot of variation in the time between the start of the applications and the first observation of the disease between the trials.

In the efficacy trials presented in this dossier the days after first application at which the first symptoms were observed are shown below:

Maritime EPPO Zone:	7-57 DA-A	(average of 28 days, 19 days stdev.)
Czech/German trials:	7-24 DA-A	(average of 15 days, 8 days stdev.)
North-East EPPO Zone:	5-30 DA-A	(average of 13 days, 8 days stdev.)
Mediterranean EPPO Zone:	8-57 DA-A	(average of 30 days, 22 days stdev.)
South-East EPPO Zone:	18-35 DA-A	(average of 26 days, 8 days stdev.)

This means that if the assessment data were to be sorted by the number of days after first application this would result in highly variably results. Because of the different stages of disease development between the trials at a given time after trial initiation this would make it impossible to demonstrate the impact of the tested treatments on disease progression.

Therefore, in order to have the best presentation of the impact of tested treatments on the disease development, the moment of first observation was used as the reference point for the grouping of the data.

The individual assessment data (pest severity) for all trials was grouped by the number of days after the first symptoms of *Phytophthora infestans* infection were observed, indicated in the tables by 'Days after symptoms'. The following groupings were made based on the number days after the first observation of symptoms:

0 days		first observation of symptoms
5-10 days	~	1 week after symptoms
12-16 days	~	1-2 weeks after symptoms
17-21 days	~	2-3 weeks after symptoms
22-28 days	~	3-4 weeks after symptoms
29-36 days	~	4-5 weeks after symptoms
37-45 days	~	5-6 weeks after symptoms
46-52 days	~	6-7 weeks after symptoms

The tables below summarize the results obtained in the presented efficacy trials. First, summaries are provided for all EPPO Zones combined, followed by separate summaries per EPPO Zone.

All EPPO Zones

To provide an overview of all obtained efficacy data, Table 3.2-19 below summarizes the efficacy of GLOB2007bF at the 2 L/ha dose rate and allows comparison to the best performing reference product within each trial. This table is followed by an orthogonal comparison between GLOB2007bF at 2L/ha to the reference products Revus (Table 3.2-20) and Infinito/Volare (Table 3.2-21), separately.

Table 3.2-19 Efficacy of GLOB2007bF - All EPPO Zones

Rating type	Part rated	Timing	n	Infestation in the untreated			% control									
							GLOB2007bF 2 L/ha					Best reference				
				Mean	Min	Max	Mean	Min	Max	Med.	Stdev	Mean	Min	Max	Med.	Stdev
AUDPC	LEAF	season	35	1126.5	34.4	3698.5	73.8	18.9	100.0	76.1	22.6	77.7	36.7	100.0	77.6	19.7
PESINC	TUBER	harvest	10	11.9	5.0	30.0	79.8	28.6	100.0	87.8	22.4	79.6	32.4	100.0	87.6	21.2
PESSEV	LEAF	first symptoms	8	11.4	5.3	25.0	83.4	57.5	100.0	90.1	18.3	85.0	57.5	100.0	91.7	17.0
PESSEV	LEAF	5-10 days after symptoms	16	20.3	5.0	82.5	82.9	47.9	100.0	89.9	18.5	85.0	45.7	100.0	92.3	16.9
PESSEV	LEAF	12-16 days after symptoms	19	25.5	5.0	100.0	80.6	46.9	100.0	90.0	19.7	83.1	46.9	100.0	93.4	18.5
PESSEV	LEAF	17-21 days after symptoms	26	31.7	5.0	98.8	74.6	25.3	100.0	84.0	25.5	75.5	37.5	100.0	77.9	21.7
PESSEV	LEAF	23-28 days after symptoms	26	42.2	6.5	100.0	69.4	32.1	100.0	68.4	24.1	75.5	23.5	100.0	82.5	23.5
PESSEV	LEAF	29-36 days after symptoms	22	49.9	9.2	100.0	71.5	2.5	100.0	80.3	29.6	80.1	5.0	100.0	83.9	21.5
PESSEV	LEAF	37-45 days after symptoms	19	44.5	12.4	100.0	64.9	0.5	100.0	69.6	28.2	74.0	27.5	100.0	73.3	20.9
PESSEV	LEAF	46-52 days after symptoms	8	48.0	9.5	100.0	80.3	50.0	100.0	82.4	19.9	80.9	42.5	100.0	90.9	23.4

Table 3.2-20 Orthogonal comparison between GLOB2007bF and Revus - All EPPO Zones

Rating type	Part rated	Timing	n	Infestation in the untreated			% control									
							GLOB2007bF 2 L/ha					Revus 0.6 L/ha				
				Mean	Min	Max	Mean	Min	Max	Med.	Stdev	Mean	Min	Max	Med.	Stdev
AUDPC	LEAF	season	28	1279.9	59.3	3698.5	73.4	18.9	100.0	74.7	24.1	74.0	36.7	100.0	72.8	19.7
PESINC	TUBER	harvest	7	12.9	5.0	30.0	76.1	28.6	100.0	86.7	26.2	72.4	29.8	100.0	85.2	25.5
PESSEV	LEAF	first symptoms	8	11.4	5.3	25.0	83.4	57.5	100.0	90.1	18.3	83.5	45.8	100.0	91.7	20.0
PESSEV	LEAF	5-10 days after symptoms	14	22.3	5.0	82.5	83.8	47.9	100.0	89.9	17.9	85.2	55.0	100.0	88.1	14.6
PESSEV	LEAF	12-16 days after symptoms	18	26.7	5.0	100.0	79.5	46.9	100.0	87.3	19.7	78.4	41.0	100.0	87.1	20.3
PESSEV	LEAF	17-21 days after symptoms	22	34.2	5.5	98.8	75.3	25.3	100.0	90.1	26.3	74.9	37.5	100.0	79.2	22.3
PESSEV	LEAF	23-28 days after symptoms	22	43.4	6.5	100.0	70.8	32.1	100.0	70.5	25.1	76.8	13.3	100.0	88.4	25.3
PESSEV	LEAF	29-36 days after symptoms	18	56.7	9.2	100.0	69.9	2.5	100.0	81.9	32.6	79.3	2.5	100.0	85.2	24.8
PESSEV	LEAF	37-45 days after symptoms	14	51.4	12.4	100.0	61.0	0.5	100.0	61.7	32.0	73.9	27.5	100.0	78.6	24.0
PESSEV	LEAF	46-52 days after symptoms	6	49.2	9.5	100.0	79.6	50.0	100.0	82.5	22.8	63.4	40.1	89.5	67.5	19.0

Table 3.2-21 Orthogonal comparison between GLOB2007bF and Infinito/Volare - All EPPO Zones

Rating type	Part rated	Timing	n	Infestation in the untreated			% control									
							GLOB2007bF 2 L/ha					Infinito / Volare 1.6 L/ha				
				Mean	Min	Max	Mean	Min	Max	Med.	Stdev	Mean	Min	Max	Med.	Stdev
AUDPC	LEAF	season	26	840.4	34.4	2852.5	74.3	18.9	100.0	74.7	22.9	75.5	31.6	100.0	73.4	22.2
PESINC	TUBER	harvest	7	11.3	5.0	30.0	77.3	28.6	100.0	86.7	24.8	78.4	32.4	100.0	89.6	25.2
PESSEV	LEAF	first symptoms	4	9.7	6.3	13.8	81.3	57.5	100.0	83.8	22.0	82.5	57.5	100.0	86.3	21.1
PESSEV	LEAF	5-10 days after symptoms	9	81.7	45.7	100.0	80.6	47.9	100.0	96.7	21.6	81.7	45.7	100.0	92.9	20.4
PESSEV	LEAF	12-16 days after symptoms	11	16.6	5.0	42.5	80.2	49.3	100.0	90.0	20.6	81.8	50.4	100.0	90.9	20.4
PESSEV	LEAF	17-21 days after symptoms	18	27.8	5.0	90.0	71.8	25.3	100.0	76.2	26.6	72.1	35.5	100.0	71.7	23.4
PESSEV	LEAF	23-28 days after symptoms	20	37.5	6.5	100.0	67.6	32.1	100.0	68.4	25.8	69.4	23.5	100.0	69.9	26.8
PESSEV	LEAF	29-36 days after symptoms	15	39.8	9.2	100.0	72.9	2.5	100.0	82.3	31.2	76.5	5.0	100.0	78.6	26.3
PESSEV	LEAF	37-45 days after symptoms	14	35.3	12.4	93.8	69.4	8.0	100.0	72.2	26.8	70.1	21.0	100.0	72.2	23.7
PESSEV	LEAF	46-52 days after symptoms	6	42.4	9.5	100.0	85.7	50.0	100.0	95.5	20.3	79.8	37.5	100.0	96.1	28.7

Summary

The results shown in the tables above confirm the good efficacy of GLOB2007bF at the 2 L/ha dose rate.

Maritime EPPO Zone

Table 3.2-22 below summarizes the efficacy of GLOB2007bF at the 2 L/ha dose rate and allows comparison to the best performing reference product within each trial. This table is followed by an orthogonal comparison between GLOB2007bF at 2L/ha to the reference products Revus (Table 3.2-23) and Infinito/Volare (Table 3.2-24), separately.

Table 3.2-22 Efficacy of GLOB2007bF - Maritime EPPO Zone

Rating type	Part rated	Timing	n	Infestation in the untreated			% control									
							GLOB2007bF 2 L/ha					Best reference				
				Mean	Min	Max	Mean	Min	Max	Med.	Stdev	Mean	Min	Max	Med.	Stdev
AUDPC	LEAF	season	12	1112.7	104.4	3422.5	78.9	18.9	100.0	96.2	27.6	85.2	47.9	100.0	95.9	18.4
PESINC	TUBER	harvest	3	11.4	9.0	16.0	72.5	28.6	100.0	88.9	38.4	57.3	32.4	85.2	54.4	26.5
PESSEV	LEAF	first symptoms	2	19.7	14.3	25.0	97.1	94.2	100.0	97.1	4.1	95.0	90.0	100.0	95.0	7.1
PESSEV	LEAF	7-10 days after symptoms	4	41.4	8.0	82.5	86.5	55.7	100.0	95.2	20.8	85.4	45.7	100.0	97.9	26.5
PESSEV	LEAF	12-16 days after symptoms	5	43.3	5.0	100.0	93.7	84.5	100.0	94.1	6.6	96.7	94.0	100.0	95.0	3.0
PESSEV	LEAF	17-21 days after symptoms	7	34.9	5.0	98.8	85.1	49.3	100.0	99.9	23.5	84.7	50.1	100.0	100.0	23.1
PESSEV	LEAF	23-28 days after symptoms	9	40.0	6.5	100.0	72.6	37.5	100.0	70.8	28.0	82.4	42.5	100.0	90.0	21.9
PESSEV	LEAF	29-35 days after symptoms	8	52.4	9.2	100.0	69.9	12.5	100.0	95.1	39.7	84.9	60.0	100.0	92.5	17.7
PESSEV	LEAF	37-45 days after symptoms	6	50.6	13.3	100.0	63.0	0.5	100.0	84.8	47.1	73.9	27.5	100.0	81.2	30.8
PESSEV	LEAF	48-52 days after symptoms	3	21.7	9.5	35.5	99.9	99.7	100.0	99.9	0.2	100.0	99.9	100.0	100.0	0.1

Table 3.2-23 Orthogonal comparison between GLOB2007bF and Revus - Maritime EPPO Zone

Rating type	Part rated	Timing	n	Infestation in the untreated			% control									
							GLOB2007bF 2 L/ha					Revus 0.6 L/ha				
				Mean	Min	Max	Mean	Min	Max	Med.	Stdev	Mean	Min	Max	Med.	Stdev
AUDPC	LEAF	season	10	1193.1	104.4	3422.5	82.3	18.9	100.0	98.0	28.3	80.6	57.1	100.0	80.0	16.8
PESINC	TUBER	harvest	2	12.5	9.0	16.0	64.3	28.6	100.0	64.3	50.5	57.5	29.8	85.2	57.5	39.2
PESSEV	LEAF	first symptoms	2	19.7	14.3	25.0	97.1	94.2	100.0	97.1	4.1	95.0	90.0	100.0	95.0	7.1
PESSEV	LEAF	7-10 days after symptoms	3	52.5	10.0	82.5	96.8	92.5	100.0	97.8	3.9	98.6	97.6	100.0	98.1	1.3
PESSEV	LEAF	12-16 days after symptoms	4	52.8	5.0	100.0	92.1	84.5	99.8	92.1	6.5	94.6	90.0	99.8	94.2	4.0
PESSEV	LEAF	17-21 days after symptoms	5	36.8	6.3	98.8	89.3	52.5	100.0	99.9	20.7	88.5	52.5	100.0	100.0	20.6
PESSEV	LEAF	23-28 days after symptoms	7	34.7	6.5	100.0	77.6	37.5	100.0	99.1	29.0	89.2	47.5	100.0	99.5	19.1
PESSEV	LEAF	29-35 days after symptoms	8	52.4	9.2	100.0	69.9	12.5	100.0	95.1	39.7	83.9	52.5	100.0	92.4	19.4
PESSEV	LEAF	37-45 days after symptoms	5	54.7	13.3	100.0	61.7	0.5	100.0	100.0	52.5	76.2	27.5	100.0	99.8	33.8
PESSEV	LEAF	48-52 days after symptoms	3	21.7	9.5	35.5	99.9	99.7	100.0	99.9	0.2	58.3	40.1	69.3	65.6	15.9

Table 3.2-24 Orthogonal comparison between GLOB2007bF and Infinito/Volare - Maritime EPPO Zone

Rating type	Part rated	Timing	n	Infestation in the untreated			% control									
							GLOB2007bF 2 L/ha					Infinito / Volare 1.6 L/ha				
				Mean	Min	Max	Mean	Min	Max	Med.	Stdev	Mean	Min	Max	Med.	Stdev
AUDPC	LEAF	season	10	731.5	104.4	1440.8	79.5	18.9	100.0	98.0	29.1	81.8	31.6	100.0	99.8	25.7
PESINC	TUBER	harvest	2	9.2	9.0	9.3	58.8	28.6	88.9	58.8	42.6	43.4	32.4	54.4	43.4	15.6
PESSEV	LEAF	7-10 days after symptoms	2	72.9	45.7	100.0	77.9	55.7	100.0	77.9	31.3	72.9	45.7	100.0	72.9	38.4
PESSEV	LEAF	12-16 days after symptoms	3	9.2	5.0	17.5	96.6	90.0	100.0	99.8	5.7	98.3	95.0	100.0	99.9	2.9
PESSEV	LEAF	17-21 days after symptoms	6	24.2	5.0	55.0	83.6	49.3	100.0	100.0	25.4	82.5	45.0	100.0	100.0	27.1
PESSEV	LEAF	23-28 days after symptoms	8	32.5	6.5	100.0	73.6	37.5	100.0	85.0	29.8	74.6	32.5	100.0	82.2	28.7
PESSEV	LEAF	29-35 days after symptoms	6	36.6	9.2	95.3	75.8	16.7	100.0	99.1	37.5	83.0	38.3	100.0	99.8	27.1
PESSEV	LEAF	37-45 days after symptoms	5	40.7	13.3	93.8	75.5	8.0	100.0	100.0	40.0	76.7	21.0	100.0	100.0	35.1
PESSEV	LEAF	48-52 days after symptoms	3	21.7	9.5	35.5	99.9	99.7	100.0	99.9	0.2	100.0	99.9	100.0	100.0	0.1

Summary

The results shown in the tables above confirm the good efficacy of GLOB2007bF at the 2 L/ha dose rate.

North-East EPPO Zone

Table 3.2-25 and Table 3.2-26 below summarize the efficacy of GLOB2007bF at the 2 L/ha dose rate and allow comparison to the best performing reference product within each trial. This table is followed by an orthogonal comparison between GLOB2007bF at 2L/ha to the reference products Revus (Table 3.2-27 and Table 3.2-28) and Infinito/Volare (Table 3.2-29 and Table 3.2-30), separately.

Table 3.2-25 Efficacy of GLOB2007bF - North-East EPPO Zone

Rating type	Part rated	Timing	n	Infestation in the untreated			% control									
							GLOB2007bF 2 L/ha					Best reference				
				Mean	Min	Max	Mean	Min	Max	Med.	Stdev	Mean	Min	Max	Med.	Stdev
AUDPC	LEAF	season	12	1513.7	383.9	3698.5	67.4	31.1	88.9	70.6	17.4	68.3	36.7	94.6	69.9	16.4
PESINC	TUBER	harvest	4	14.6	5.0	30.0	82.1	65.2	94.1	84.6	12.3	85.2	71.0	94.1	87.9	10.0
PESSEV	LEAF	first symptoms	3	8.5	5.3	13.8	73.0	57.5	100.0	61.6	23.4	74.6	57.5	100.0	66.4	22.4
PESSEV	LEAF	5-10 days after symptoms	6	15.3	6.4	30.0	80.8	47.9	100.0	91.7	22.7	80.6	61.7	100.0	81.6	15.0
PESSEV	LEAF	12-14 days after symptoms	5	23.8	10.0	42.5	76.0	49.3	100.0	75.4	22.9	77.2	62.5	99.2	65.5	17.6
PESSEV	LEAF	17-21 days after symptoms	10	27.4	5.6	90.0	68.3	25.8	98.4	71.7	23.9	70.5	49.3	95.7	69.6	17.2
PESSEV	LEAF	23-28 days after symptoms	9	40.6	11.2	100.0	66.5	32.1	95.9	61.8	20.2	67.8	38.4	95.9	70.0	18.9
PESSEV	LEAF	29-35 days after symptoms	11	41.5	10.3	100.0	68.6	2.5	90.0	76.3	25.0	72.0	5.0	95.5	78.6	23.9
PESSEV	LEAF	38-42 days after symptoms	10	40.2	16.6	100.0	68.8	36.3	86.4	71.6	16.0	72.7	41.3	93.5	72.2	14.8
PESSEV	LEAF	46-52 days after symptoms	5	63.9	28.0	100.0	68.5	50.0	91.3	65.3	15.3	69.4	42.5	92.3	73.5	22.8

Table 3.2-26 Efficacy of GLOB2007bF - North-East EPPO Zone + CZ/DE

Rating type	Part rated	Timing	n	Infestation in the untreated			% control									
							GLOB2007bF 2 L/ha					Best reference				
				Mean	Min	Max	Mean	Min	Max	Med.	Stdev	Mean	Min	Max	Med.	Stdev
AUDPC	LEAF	season	17	1410.5	215.3	3698.5	68.0	18.9	100.0	70.8	21.9	71.5	36.7	100.0	70.5	16.6
PESINC	TUBER	harvest	6	13.9	5.0	30.0	76.2	28.6	100.0	84.6	26.2	65.5	0.0	94.1	85.2	35.7
PESSEV	LEAF	first symptoms	5	9.4	5.3	14.3	81.0	57.5	100.0	86.0	20.5	83.4	57.5	100.0	93.3	20.1
PESSEV	LEAF	5-10 days after symptoms	8	20.9	6.4	65.0	85.4	47.9	100.0	96.8	20.9	85.2	61.7	100.0	88.7	15.3
PESSEV	LEAF	12-15 days after symptoms	8	27.2	5.0	88.8	83.0	49.3	100.0	92.1	20.0	84.4	62.5	100.0	93.9	16.7
PESSEV	LEAF	17-21 days after symptoms	14	29.2	5.0	98.8	73.5	25.8	100.0	76.2	24.3	74.8	49.3	100.0	71.7	19.3
PESSEV	LEAF	23-28 days after symptoms	13	33.0	8.8	100.0	65.2	32.1	100.0	61.8	22.1	70.8	38.4	100.0	70.0	18.9
PESSEV	LEAF	29-35 days after symptoms	15	44.1	10.3	100.0	66.9	2.5	100.0	76.3	28.4	73.9	5.0	100.0	78.6	22.0
PESSEV	LEAF	38-45 days after symptoms	13	44.3	16.6	100.0	66.6	8.0	100.0	69.6	24.0	72.5	41.3	100.0	71.0	16.3
PESSEV	LEAF	46-52 days after symptoms	5	63.9	28.0	100.0	68.5	50.0	91.3	65.3	15.3	69.4	42.5	92.3	73.5	22.8

Table 3.2-27 Orthogonal comparison between GLOB2007bF and Revus - North-East EPPO Zone

Rating type	Part rated	Timing	n	Infestation in the untreated			% control									
							GLOB2007bF 2 L/ha					Revus 0.6 L/ha				
				Mean	Min	Max	Mean	Min	Max	Med.	Stdev	Mean	Min	Max	Med.	Stdev
AUDPC	LEAF	season	8	2003.5	434.7	3698.5	62.7	31.1	86.0	70.0	19.1	64.4	36.7	94.6	67.7	18.4
PESINC	TUBER	harvest	2	19.3	8.5	30.0	76.0	65.2	86.7	76.0	15.2	78.6	71.0	86.1	78.6	10.7
PESSEV	LEAF	first symptoms	3	8.5	5.3	13.8	73.0	57.5	100.0	61.6	23.4	70.7	45.8	100.0	66.4	27.4
PESSEV	LEAF	5-10 days after symptoms	6	15.3	6.4	30.0	80.8	47.9	100.0	91.7	22.7	79.5	55.0	100.0	81.6	16.8
PESSEV	LEAF	12-14 days after symptoms	5	23.8	10.0	42.5	76.0	49.3	100.0	75.4	22.9	75.3	56.3	99.2	65.2	19.5
PESSEV	LEAF	17-21 days after symptoms	8	32.7	9.6	90.0	68.6	25.8	98.4	71.7	26.3	69.9	44.3	95.7	66.7	18.4
PESSEV	LEAF	23-28 days after symptoms	7	48.9	11.2	100.0	66.2	32.1	95.9	61.8	21.7	68.2	31.7	95.9	70.0	21.7
PESSEV	LEAF	29-35 days after symptoms	7	54.2	16.1	100.0	62.6	2.5	90.0	74.6	30.2	66.3	2.5	95.5	70.5	30.2
PESSEV	LEAF	38-42 days after symptoms	6	50.7	22.5	100.0	63.0	36.3	84.6	61.7	18.1	69.9	41.3	93.5	70.8	18.4
PESSEV	LEAF	46-52 days after symptoms	3	76.7	30.0	100.0	59.3	50.0	65.3	62.5	8.1	68.5	42.5	89.5	73.5	23.9

Table 3.2-28 Orthogonal comparison between GLOB2007bF and Revus - North-East EPPO Zone + CZ/DE

Rating type	Part rated	Timing	n	Infestation in the untreated			% control									
							GLOB2007bF 2 L/ha					Revus 0.6 L/ha				
				Mean	Min	Max	Mean	Min	Max	Med.	Stdev	Mean	Min	Max	Med.	Stdev
AUDPC	LEAF	season	12	1778.1	215.3	3698.5	64.3	18.9	100.0	70.0	25.0	69.4	36.7	100.0	67.7	19.3
PESINC	TUBER	harvest	4	15.9	8.5	30.0	70.1	28.6	100.0	76.0	31.2	68.0	29.8	86.1	78.1	26.4
PESSEV	LEAF	first symptoms	5	9.4	5.3	14.3	81.0	57.5	100.0	86.0	20.5	81.1	45.8	100.0	93.3	24.1
PESSEV	LEAF	5-10 days after symptoms	8	20.9	6.4	65.0	85.4	47.9	100.0	96.8	20.9	84.4	55.0	100.0	88.7	16.9
PESSEV	LEAF	12-15 days after symptoms	7	30.4	5.0	88.8	80.6	49.3	100.0	90.0	20.3	80.1	56.3	99.2	90.0	18.0
PESSEV	LEAF	17-21 days after symptoms	11	35.6	6.3	98.8	72.3	25.8	100.0	73.2	25.6	72.9	44.3	100.0	69.1	19.7
PESSEV	LEAF	23-28 days after symptoms	10	38.8	8.8	100.0	64.2	32.1	100.0	60.5	24.5	71.2	31.7	100.0	72.4	22.5
PESSEV	LEAF	29-35 days after symptoms	11	53.1	16.1	100.0	62.5	2.5	100.0	74.6	32.2	70.3	2.5	100.0	71.7	26.4
PESSEV	LEAF	38-45 days after symptoms	8	56.0	22.5	100.0	60.8	8.0	100.0	61.7	29.2	71.6	41.3	100.0	70.8	20.2
PESSEV	LEAF	46-52 days after symptoms	3	76.7	30.0	100.0	59.3	50.0	65.3	62.5	8.1	68.5	42.5	89.5	73.5	23.9

Table 3.2-29 Orthogonal comparison between GLOB2007bF and Infinito/Volare - North-East EPPO Zone

Rating type	Part rated	Timing	n	Infestation in the untreated			% control									
							GLOB2007bF 2 L/ha					Infinito / Volare 1.6 L/ha				
				Mean	Min	Max	Mean	Min	Max	Med.	Stdev	Mean	Min	Max	Med.	Stdev
AUDPC	LEAF	season	9	1138.2	383.9	2852.5	69.2	39.0	88.9	70.8	14.3	68.6	43.4	89.4	69.2	12.6
PESINC	TUBER	harvest	3	16.7	5.0	30.0	87.8	82.5	94.1	86.7	5.9	89.4	84.4	94.1	89.6	4.9
PESSEV	LEAF	first symptoms	2	10.1	6.3	13.8	78.8	57.5	100.0	78.8	30.1	78.8	57.5	100.0	78.8	30.1
PESSEV	LEAF	5-10 days after symptoms	3	75.1	61.7	92.9	80.5	47.9	96.9	96.7	28.2	75.1	61.7	92.9	70.6	16.1
PESSEV	LEAF	12-14 days after symptoms	2	31.9	21.3	42.5	73.5	49.3	97.7	73.5	34.2	78.2	65.5	90.9	78.2	18.0
PESSEV	LEAF	17-21 days after symptoms	7	26.8	5.6	90.0	65.6	25.8	93.6	73.2	25.8	68.9	49.3	94.4	70.1	15.0
PESSEV	LEAF	23-28 days after symptoms	6	38.0	11.2	100.0	64.8	32.1	87.3	67.1	20.8	65.4	38.4	87.9	69.9	18.7
PESSEV	LEAF	29-35 days after symptoms	8	35.1	10.3	100.0	67.4	2.5	90.0	77.3	28.4	68.8	5.0	84.8	76.3	26.1
PESSEV	LEAF	38-42 days after symptoms	8	34.9	16.6	69.7	69.2	36.3	86.4	71.6	16.4	69.3	38.8	89.3	72.2	14.5
PESSEV	LEAF	46-52 days after symptoms	3	63.1	28.0	100.0	71.6	50.0	91.3	73.5	20.7	59.6	37.5	92.3	49.1	28.9

Table 3.2-30 Orthogonal comparison between GLOB2007bF and Infinito/Volare - North-East EPPO Zone + CZ/DE

Rating type	Part rated	Timing	n	Infestation in the untreated			% control									
							GLOB2007bF 2 L/ha					Infinito / Volare 1.6 L/ha				
				Mean	Min	Max	Mean	Min	Max	Med.	Stdev	Mean	Min	Max	Med.	Stdev
AUDPC	LEAF	season	13	1034.0	215.3	2852.5	67.4	18.9	100.0	70.8	21.0	68.3	31.6	100.0	69.2	17.4
PESINC	TUBER	harvest	4	14.8	5.0	30.0	73.0	28.6	94.1	84.6	30.0	75.1	32.4	94.1	87.0	28.8
PESSEV	LEAF	first symptoms	2	10.1	6.3	13.8	78.8	57.5	100.0	78.8	30.1	78.8	57.5	100.0	78.8	30.1
PESSEV	LEAF	5-10 days after symptoms	4	81.3	61.7	100.0	85.4	47.9	100.0	96.8	25.0	81.3	61.7	100.0	81.8	18.1
PESSEV	LEAF	12-15 days after symptoms	4	18.5	5.0	42.5	84.3	49.3	100.0	93.9	23.7	87.9	65.5	100.0	93.0	15.4
PESSEV	LEAF	17-21 days after symptoms	10	22.4	5.0	90.0	71.2	25.8	100.0	76.2	26.3	72.7	45.0	100.0	71.7	20.3
PESSEV	LEAF	23-28 days after symptoms	10	29.2	8.8	100.0	63.8	32.1	100.0	65.0	22.9	64.7	32.5	100.0	64.8	21.3
PESSEV	LEAF	29-35 days after symptoms	11	35.0	10.3	100.0	63.3	2.5	100.0	76.3	31.3	68.1	5.0	100.0	74.9	26.0
PESSEV	LEAF	38-45 days after symptoms	11	41.2	16.6	93.8	66.5	8.0	100.0	69.6	25.5	67.0	21.0	100.0	71.0	21.8
PESSEV	LEAF	46-52 days after symptoms	3	63.1	28.0	100.0	71.6	50.0	91.3	73.5	20.7	59.6	37.5	92.3	49.1	28.9

Summary

The results shown in the tables above confirm the good efficacy of GLOB2007bF at the 2 L/ha dose rate.

Mediterranean EPPO Zone

Table 3.2-31 below summarizes the efficacy of GLOB2007bF at the 2 L/ha dose rate and allows comparison to the best performing reference product within each trial. This table is followed by an orthogonal comparison between GLOB2007bF at 2L/ha to the reference products Revus (Table 3.2-32) and Infinito/Volare (Table 3.2-33), separately.

Table 3.2-31 Efficacy of GLOB2007bF - Mediterranean EPPO Zone

Rating type	Part rated	Timing	n	Infestation in the untreated			% control									
							GLOB2007bF 2 L/ha					Best reference				
				Mean	Min	Max	Mean	Min	Max	Med.	Stdev	Mean	Min	Max	Med.	Stdev
AUDPC	LEAF	season	6	639.9	34.4	2753.9	74.4	43.0	98.5	79.4	24.6	82.5	55.0	100.0	89.3	18.5
PESINC	TUBER	harvest	2	10.3	5.0	15.5	96.0	92.0	100.0	96.0	5.7	94.5	89.0	100.0	94.5	7.8
PESSEV	LEAF	first symptoms	2	7.5	7.5	7.5	93.0	86.0	100.0	93.0	9.9	96.7	93.3	100.0	96.7	4.7
PESSEV	LEAF	7-10 days after symptoms	3	13.1	5.0	24.3	83.1	64.0	98.0	87.3	17.4	95.9	91.7	100.0	96.0	4.2
PESSEV	LEAF	13-13 days after symptoms	4	17.6	5.8	43.8	68.3	55.5	90.1	63.8	15.3	81.2	60.2	100.0	82.3	18.3
PESSEV	LEAF	18-20 days after symptoms	4	24.6	5.5	71.3	66.0	25.3	97.3	70.7	34.7	72.2	40.3	94.4	77.1	23.2
PESSEV	LEAF	25-28 days after symptoms	4	34.6	7.2	91.3	57.2	33.0	92.1	51.9	27.5	74.7	48.4	100.0	75.2	25.9
PESSEV	LEAF	35-35 days after symptoms	1	100.0	100.0	100.0	88.5	88.5	88.5	88.5	-	92.3	92.3	92.3	92.3	-
PESSEV	LEAF	41-42 days after symptoms	2	56.2	12.4	100.0	55.6	39.8	71.3	55.6	22.3	71.1	51.8	90.3	71.1	27.2

Table 3.2-32 Orthogonal comparison between GLOB2007bF and Revus - Mediterranean EPPO Zone

Rating type	Part rated	Timing	n	Infestation in the untreated			% control									
							GLOB2007bF 2 L/ha					Revus 0.6 L/ha				
				Mean	Min	Max	Mean	Min	Max	Med.	Stdev	Mean	Min	Max	Med.	Stdev
AUDPC	LEAF	season	5	761.0	59.3	2753.9	69.5	43.0	97.9	70.5	24.1	77.1	55.0	92.8	85.8	16.4
PESINC	TUBER	harvest	2	10.3	5.0	15.5	96.0	92.0	100.0	96.0	5.7	94.5	89.0	100.0	94.5	7.8
PESSEV	LEAF	first symptoms	2	7.5	7.5	7.5	93.0	86.0	100.0	93.0	9.9	96.7	93.3	100.0	96.7	4.7
PESSEV	LEAF	7-10 days after symptoms	2	17.1	9.9	24.3	75.7	64.0	87.3	75.7	16.5	85.9	80.1	91.7	85.9	8.2
PESSEV	LEAF	13-13 days after symptoms	4	17.6	5.8	43.8	68.3	55.5	90.1	63.8	15.3	76.8	58.4	92.4	78.2	14.8
PESSEV	LEAF	18-20 days after symptoms	4	24.6	5.5	71.3	66.0	25.3	97.3	70.7	34.7	72.2	40.3	94.4	77.1	23.2
PESSEV	LEAF	25-28 days after symptoms	4	34.6	7.2	91.3	57.2	33.0	92.1	51.9	27.5	71.6	48.4	93.7	72.2	22.4
PESSEV	LEAF	35-35 days after symptoms	1	100.0	100.0	100.0	88.5	88.5	88.5	88.5	-	92.3	92.3	92.3	92.3	-
PESSEV	LEAF	41-42 days after symptoms	2	56.2	12.4	100.0	55.6	39.8	71.3	55.6	22.3	71.1	51.8	90.3	71.1	27.2

Table 3.2-33 Orthogonal comparison between GLOB2007bF and Infinito/Volare - Mediterranean EPPO Zone

Rating type	Part rated	Timing	n	Infestation in the untreated			% control									
							GLOB2007bF 2 L/ha					Infinito / Volare 1.6 L/ha				
				Mean	Min	Max	Mean	Min	Max	Med.	Stdev	Mean	Min	Max	Med.	Stdev
AUDPC	LEAF	season	4	256.6	34.4	367.0	65.0	43.0	98.5	59.2	25.4	72.7	44.4	100.0	73.3	29.9
PESINC	TUBER	harvest	1	5.0	5.0	5.0	100.0	100.0	100.0	100.0	-	100.0	100.0	100.0	100.0	-
PESSEV	LEAF	first symptoms	1	7.5	7.5	7.5	100.0	100.0	100.0	100.0	-	100.0	100.0	100.0	100.0	-
PESSEV	LEAF	7-10 days after symptoms	2	98.0	96.0	100.0	81.0	64.0	98.0	81.0	24.0	98.0	96.0	100.0	98.0	2.8
PESSEV	LEAF	13-13 days after symptoms	3	8.9	5.8	12.4	61.0	55.5	67.2	60.3	5.9	70.2	50.4	100.0	60.2	26.3
PESSEV	LEAF	18-20 days after symptoms	2	10.4	5.5	15.3	37.2	25.3	49.1	37.2	16.8	40.9	35.5	46.2	40.9	7.6
PESSEV	LEAF	25-28 days after symptoms	3	15.7	7.2	23.9	45.6	33.0	66.0	37.7	17.9	61.8	41.3	100.0	44.1	33.1
PESSEV	LEAF	41-42 days after symptoms	1	12.4	12.4	12.4	39.8	39.8	39.8	39.8	-	44.5	44.5	44.5	44.5	-

Summary

The results shown in the tables above confirm the good efficacy of GLOB2007bF at the 2 L/ha dose rate.

South-East EPPO Zone

Table 3.234 below summarizes the efficacy of GLOB2007bF at the 2 L/ha dose rate allows comparison to the best performing reference product within each trial. This table is followed by an orthogonal comparison between GLOB2007bF at 2L/ha to the reference products Revus (

Rating type	Part rated	Timing	n	Infestation in the untreated			% control									
							GLOB2007bF 2 L/ha					Best reference				
				Mean	Min	Max	Mean	Min	Max	Med.	Stdev	Mean	Min	Max	Med.	Stdev
AUDPC	LEAF	season	5	814.4	223.6	1652.5	76.4	48.2	99.4	79.2	21.0	76.4	46.7	99.6	90.1	27.3
PESINC	TUBER	harvest	1	6.0	6.0	6.0	60.4	60.4	60.4	60.4	-	93.8	93.8	93.8	93.8	-
PESSEV	LEAF	first symptoms	1	11.3	11.3	11.3	67.5	67.5	67.5	67.5	-	72.5	72.5	72.5	72.5	-
PESSEV	LEAF	7-7 days after symptoms	3	9.3	5.0	15.8	82.1	66.4	100.0	80.0	16.9	82.7	68.1	100.0	80.0	16.1
PESSEV	LEAF	14-15 days after symptoms	5	15.9	5.0	42.5	81.9	46.9	100.0	97.9	24.7	76.9	46.9	100.0	84.7	25.5
PESSEV	LEAF	21-21 days after symptoms	4	39.3	10.5	80.0	89.3	68.8	100.0	94.2	14.6	84.6	50.0	100.0	94.3	23.7
PESSEV	LEAF	28-28 days after symptoms	4	58.2	17.5	98.0	80.8	49.0	99.5	87.4	22.0	78.2	23.5	100.0	94.7	36.8
PESSEV	LEAF	35-36 days after symptoms	2	60.7	23.8	97.5	85.6	72.3	98.8	85.6	18.7	99.6	99.1	100.0	99.6	0.6
PESSEV	LEAF	42-42 days after symptoms	1	28.8	28.8	28.8	55.8	55.8	55.8	55.8	-	92.8	92.8	92.8	92.8	-

Table 3.2-35) and Infinito/Volare (Table 3.2-36), separately.

Table 3.2-34 Efficacy of GLOB2007bF - South-East EPPO Zone

Rating type	Part rated	Timing	n	Infestation in the untreated			% control									
							GLOB2007bF 2 L/ha					Best reference				
				Mean	Min	Max	Mean	Min	Max	Med.	Stdev	Mean	Min	Max	Med.	Stdev
AUDPC	LEAF	season	5	814.4	223.6	1652.5	76.4	48.2	99.4	79.2	21.0	76.4	46.7	99.6	90.1	27.3
PESINC	TUBER	harvest	1	6.0	6.0	6.0	60.4	60.4	60.4	60.4	-	93.8	93.8	93.8	93.8	-
PESSEV	LEAF	first symptoms	1	11.3	11.3	11.3	67.5	67.5	67.5	67.5	-	72.5	72.5	72.5	72.5	-
PESSEV	LEAF	7-7 days after symptoms	3	9.3	5.0	15.8	82.1	66.4	100.0	80.0	16.9	82.7	68.1	100.0	80.0	16.1
PESSEV	LEAF	14-15 days after symptoms	5	15.9	5.0	42.5	81.9	46.9	100.0	97.9	24.7	76.9	46.9	100.0	84.7	25.5
PESSEV	LEAF	21-21 days after symptoms	4	39.3	10.5	80.0	89.3	68.8	100.0	94.2	14.6	84.6	50.0	100.0	94.3	23.7
PESSEV	LEAF	28-28 days after symptoms	4	58.2	17.5	98.0	80.8	49.0	99.5	87.4	22.0	78.2	23.5	100.0	94.7	36.8
PESSEV	LEAF	35-36 days after symptoms	2	60.7	23.8	97.5	85.6	72.3	98.8	85.6	18.7	99.6	99.1	100.0	99.6	0.6
PESSEV	LEAF	42-42 days after symptoms	1	28.8	28.8	28.8	55.8	55.8	55.8	55.8	-	92.8	92.8	92.8	92.8	-

Table 3.2-35 Orthogonal comparison between GLOB2007bF and Revus - South-East EPPO Zone

Rating type	Part rated	Timing	n	Infestation in the untreated			% control									
							GLOB2007bF 2 L/ha					Revus 0.6 L/ha				
				Mean	Min	Max	Mean	Min	Max	Med.	Stdev	Mean	Min	Max	Med.	Stdev
AUDPC	LEAF	season	5	814.4	223.6	1652.5	76.4	48.2	99.4	79.2	21.0	73.2	39.3	99.5	82.1	28.6
PESINC	TUBER	harvest	1	6.0	6.0	6.0	60.4	60.4	60.4	60.4	-	45.8	45.8	45.8	45.8	-
PESSEV	LEAF	first symptoms	1	11.3	11.3	11.3	67.5	67.5	67.5	67.5	-	72.5	72.5	72.5	72.5	-
PESSEV	LEAF	7-7 days after symptoms	3	9.3	5.0	15.8	82.1	66.4	100.0	80.0	16.9	82.7	68.1	100.0	80.0	16.1
PESSEV	LEAF	14-15 days after symptoms	5	15.9	5.0	42.5	81.9	46.9	100.0	97.9	24.7	69.7	41.0	100.0	60.4	28.6
PESSEV	LEAF	21-21 days after symptoms	4	39.3	10.5	80.0	89.3	68.8	100.0	94.2	14.6	79.9	43.8	100.0	87.9	26.6
PESSEV	LEAF	28-28 days after symptoms	4	58.2	17.5	98.0	80.8	49.0	99.5	87.4	22.0	75.6	13.3	100.0	94.5	41.8
PESSEV	LEAF	35-36 days after symptoms	2	60.7	23.8	97.5	85.6	72.3	98.8	85.6	18.7	99.4	98.7	100.0	99.4	0.9
PESSEV	LEAF	42-42 days after symptoms	1	28.8	28.8	28.8	55.8	55.8	55.8	55.8	-	92.8	92.8	92.8	92.8	-

Table 3.2-36 Orthogonal comparison between GLOB2007bF and Infinito/Volare - South-East EPPO Zone

Rating type	Part rated	Timing	n	Infestation in the untreated			% control									
							GLOB2007bF 2 L/ha					Infinito / Volare 1.6 L/ha				
				Mean	Min	Max	Mean	Min	Max	Med.	Stdev	Mean	Min	Max	Med.	Stdev
AUDPC	LEAF	season	3	1088.5	223.6	1652.5	84.8	62.8	99.4	92.3	19.4	78.8	46.8	99.6	90.1	28.1
PESINC	TUBER	harvest	1	6.0	6.0	6.0	60.4	60.4	60.4	60.4	-	93.8	93.8	93.8	93.8	-
PESSEV	LEAF	first symptoms	1	11.3	11.3	11.3	67.5	67.5	67.5	67.5	-	72.5	72.5	72.5	72.5	-
PESSEV	LEAF	7-7 days after symptoms	2	84.1	68.1	100.0	83.2	66.4	100.0	83.2	23.8	84.1	68.1	100.0	84.1	22.6
PESSEV	LEAF	14-15 days after symptoms	3	21.6	5.3	42.5	87.5	64.6	99.9	97.9	19.8	79.1	52.8	99.9	84.7	24.0
PESSEV	LEAF	21-21 days after symptoms	3	48.9	10.5	80.0	85.7	68.8	99.6	88.8	15.6	79.5	50.0	99.9	88.6	26.2
PESSEV	LEAF	28-28 days after symptoms	3	71.7	24.6	98.0	79.4	49.0	99.5	89.7	26.8	71.0	23.5	99.6	89.8	41.4
PESSEV	LEAF	35-36 days after symptoms	1	97.5	97.5	97.5	98.8	98.8	98.8	98.8	-	99.1	99.1	99.1	99.1	-

Summary

The results shown in the tables above confirm the good efficacy of GLOB2007bF at the 2 L/ha dose rate.

Comments of zRMS:

Efficacy

According to Simplified table (3.2-2) of requested uses for GLOB2007bF (Observer Pro 2.0l/ha), table GAP and project of label the preparation is intended for use in one to three applications to protect potatoes against *P. infestans* during the growing season.

However, the Applicant presented results for the use of many applications of the tested product from first symptoms to harvest. Such a summary of results only allows for the assessment of the effectiveness of the entire protection program. Therefore, the evaluator prepared the **tables 1-3** of the obtained effectiveness of the tested agent for 1-3 number of treatments.

North-East

Table 1 : Efficacy - experiments for the EPPO climatic zone **North-East + CZ**

Trial No	Assessment data	Infestation in the untreated control (%)	% Efficacy				
			GLOB2007 bF - 1.2 l/ha	GLOB2007 bF - 2.0 l/ha	Propamocarb 722 SL - 1.4 l/ha REF. STD	Reyous 250 SC - 0.8 l/ha REF. STD	Infiniteo 1.6 l/ha REF. STD
KCP 6.2-22 FE-21-A- GLOB2013F- 2106F- 2007F-PL03	02.07.2021 (after 2 applications)	5.25	75.2	61.6	71.6	66.4	-
	09.07.2021 (after 3 applications)	9.25	51.8	56.8	67.9	65.7	-
KCP 6.2-23 FE-21-A- GLOB2013F- 2106F- 2007F-PL04	30.07.2021 (after 2 applications)	17.5	100.0	100.0	95.8	100.0	-
	06.08.2021 (after 3 applications)	30.0	100.0	100.0	75.4	99.2	-
KCP 6.2-25 FE-21-A- GLOB2013F- 2106F- 2007F-PL04	20.07.2021 (after 1 application)	14.0	100.0	100.0	-	100.0	-
	27.07.2021 (after 2 applications)	65.0	97.8	97.8	-	98.1	-
	03.08.2021 (after 3 applications)	89.0	95.5	95.5	-	94.4	-
KCP 6.2-33 FE-21-C- GLOB2013F- 2106F- 2007F-CZ01	12.08.2021 (after 3 applications)	10.0	100.0	100.0	100.0	-	100.0
KCP 6.2-39 FE-21-C- GLOB2013F- 2106F- 2007F-PL07	19.08.2021 (after 2 applications)	6.3	100.0	100.0	100.0	100.0	100.0
	26.08.2021 (after 3 applications)	30.0	96.7	94.0	91.7	92.9	92.9
KCP 6.2-45 FE-21-D- GLOB2013F- 2106F- 2007F-PL06	19.07.2021 (after 3 applications)	6.00	72.6	79.2	-	-	70.1
KCP 6.2-57 FE-22-B- GLOB2013F- 2106F- 2007F-PL08	06.07.2022 (after 3 applications)	13.75	52.5	47.5	-	45.83	57.50
Mean	-	23.2	87.1	86.7	86.1	86.6	85.9

In **8 experiments** conducted in the **North-East EPPO** climate zone + **CZ**, the tested GLOB2007bF (Observer Pro 2.0l/ha) agent showed an average **effectiveness of 86.7%** against *P. infestans* in potatoes. Tab.1. This is the average effectiveness obtained using **1-3 applications** of the tested preparation. Only experiments where disease infestation was more than 5% in the untreated control were selected for analysis. In these experiments, the average occurrence of potato late blight amounted to 23% of the leaf area.

The tested agent had an effectiveness level of 86.7% and reference standards showed an effect at the same level: for Propamocarb 722SL(1.4l/ha) - 86.1%, Revus 250SC (0.6l/ha) -86.6% and Infinito (1.6l/ha))- 85.9% in controlling *P. infestans*. Tab.1.

Effect: 1 application (1 experiment)- efficacy 100.0%
2 applications (2 experiments)- efficacy 89.85%
3 applications (8 experiments)- efficacy 83.50 %

The data presented meet the criteria required for registration of the product in the North-East EPPO climate zone.

The Applicant in dRR presented the effectiveness of the GLOB2007bF (Observer Pro 2.0l/ha) agent based on assessment dates only and not application dates. The term of use of GLOB2007bF (Observer Pro 2.0l/ha) and the number of applications are not given. The presented results can be considered as a protection program using the tested agent:" from first symptoms" to "harvest". The obtained results may allow for the assessment of trends in the protection of potatoes against *P. infestans*.

The effectiveness **86.7%** of GLOB2007bF (Observer Pro 2.0l/ha) action of 1-3 applications is confirmed by the results of the effectiveness of **programs presented** in the dRR: "first symptoms" to 5-10 "days after" is 81-85% and Revus 0,6l/ha-reference standard-81.1 % efficacy. The effectiveness of the tested agent is the highest in the first three assessments.

dRR -Table, 3.2-26- 30 Efficacy of GLOB2007bF - North-East EPPO Zone+CZ:
first symptoms: 81.0%

5-10 days after symptoms 85.4%

12-14 days after symptoms 83.0%

The tested preparation shows effectiveness that qualifies it to control *P. infestans* in potato crops in the 1- 3 applications in North-East climatic EPPO zone. The experiments are appropriately representative

Maritime

In the **Maritime EPPO** climatic zone, **3 relevant (selected) experiments in two** vegetation seasons are presented. Table 2. The tested GLOB2007bF (Observer Pro 2.0l/ha) agent applied in 3 applications showed an average **effectiveness of 96.4%** against *P. infestans* in potatoes. The reference standards showed an effect at the similar level: for Propamocarb 722 SL(1.4l/ha) – 100 %, Revus 250 SC (0.6l/ha) -90 % and Infinito (1.6l/ha))- 97.5% in controlling *P. infestans* in 3 applications. In these experiments, the average occurrence of potato late blight amounted to 9.7% of the leaf area. Only experiments where disease infestation was more than 5% in the untreated control were selected for analysis. In the Maritime climate zone, the criteria for presenting an appropriate number of 6 experiments for registration of the product are not met. However, the presentation of results for 3 experiments using 3 applications indicates the high effectiveness of GLOB2007bF (Observer Pro 2.0l/ha) and the repeatability of the results.

Table.2.: Efficacy - experiments for the **Maritime EPPO** climatic zone

Trial-No	Assessment- date	Infestation- in-the- untreated- control- (%)	%Efficacy				
			GLOB2007bF- -1,2 l/ha	GLOB2007bF- -2,0 l/ha	Propamocarb- 722-SL--1,4- l/ha REF, STD	Revus- 250-SC-- 0,6 l/ha REF, STD	Infinito-- 1,6 l/ha REF, STD
KCP-6,2-33 FE-21-C- GLOB2013F- 2106F- 2007F-CZ01	12.08.2021 (after 3- applications)	10.0	100.0	100.0	100.0	-	100.0
KCP-6,2-27 FE-21-A- GLOB2013F- 2106F- 2007F-PL04	12.07.2021 (after 3- applications)	14.0	84.2	94.2	-	90.0	-
KCP-6,2-52 FE-22-B- GLOB2013F- 2106F- 2007F-CZ02	18.07.2022 (after 3- applications)	5.00	90.0	95.0	-	90.0	95.0
Mean	-	9.7	91.4	96.4	100.0	90.0	97.5

Effect: 3 applications (3 experiments)- efficacy 96.4%

The dRR presents research results (Table, 3.2-22-24) in which the effectiveness of the agent is presented as the results of assessments without indicating the number and dates of application. However, the effectiveness of the tested agent is high, especially in the first three assessments and amounts to: “first symptoms” - 97.1%, 7-10 “days after” -96.8 %, 12-16 “days after” -92.1 %. These data can complement the confirmation of the effectiveness of GLOB2007bF (Observer Pro 2.0l/ha) in combating *P. infestans* in potatoes. The tested product was active at the higher level of effectiveness of the standard product Revus 0.6l/ha (84.4-72.9%). The justification for supplementing the data from dRR is in the North-East EPPO climatic zone, section.

In the opinion of the evaluator, the presented data can be accepted as the basis for registering the GLOB2007bF (Observer Pro 2.0l/ha) agent to control *P. infestans* in 3 application in potatoes in the Maritime EPPO climatic zone.

South-East

Experiments performed in the South-East EPPO climatic zone did not meet the requirements regarding the intensity of *P. infestans*. The first three applications of the tested product were made only as a preventive measure. The lack of plant infection by *P. infestans* did not provide grounds for assessing the effectiveness of the tested agent used in the first three applications. The South-East EPPO zone - lack of representative experiments to confirm performance using the three applications of GLOB2007bF (Observer Pro 2.0l/ha).

The data provided is not sufficient for GLOB2007bF (Observer Pro 2.0l/ha) registration in the South-East EPPO climatic zone.

In the dRR Table 3.2-34-36 to small a number of experiments (n) results were presented. The decision to authorise Observer Pro for the control of *Phytophthora infestans* on potatoes can be taken at the national level of each CMS. In order to conditionally authorise Observer Pro in the EPPO South-East climate zone, additional representative experiments are required.

Summary

	<p>The experiments conducted on the effectiveness of GLOB2007bF (Observer Pro 2.0l/ha) are representative and were carried out in various countries suitable for climatic zones and in various agrotechnical conditions, on many varieties. The development growth stages of potato plants during the first application were very diverse in the experiments but confirmed the date of application of the GLOB agent from the development growth stage of BBCH -21 to BBCH- 79 of plants. The amount of water used for spraying the plants, 150-300 l/ha, was also confirmed in the conducted research.</p> <p>The intended use of GLOB2007bF (Observer Pro 2.0l/ha) is 1-3 applications during the growing season to protect potatoes against <i>P.infestans</i>. Experiments from each zone were selected for analysis the effectiveness of 1-3 applications. The data of dRR complement the confirmation of the effectiveness of GLOB2007bF (Observer Pro 2.0l/ha) in combating <i>P.infestans</i> in potatoes. The tested GLOB2007bF (Observer Pro 2.0l/ha) agent showed an average effectiveness of 86.7% in the North-East and 96.4% in Maritime EPPO climatic zone applied against <i>P.infestans</i> in potatoes. This is the average effectiveness obtained using 1-3 applications of the tested preparation. The product tested performed at, or better than the standard preparations.</p> <p>The presented results of GLOB2007bF (Observer Pro 2.0l/ha) applied in 1-3 applications in potatoes for the control of <i>Phytophthora infestans</i> indicate compliance with the GAP table and with label of the measure tested and Uniform principles. It is justified to claim the registration of GLOB2007bF (Observer Pro) for <u>3 applications</u> in dose 2,0 l/ha for the control of <i>Phytophthora infestans</i> in potatoes crop in the North-East (PL) and Maritime EPPO climate zone (CZ, IE, DE, NL, BE, SK). In order to register or authorise Observer Pro in the South-East zone (SK, RO, HU), additional representative experience is required. The decision to register Observer Pro for the control of <i>Phytophthora infestans</i> can be taken at the national level of each cMS.</p>
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3.4 Information on the occurrence or possible occurrence of the development of resistance (KCP 6.3)

3.4.1 Inherent risk of active substance

Propamocarb belongs to the group of the carbamates, which target the cell membrane permeability and fatty acids (F4, FRAC Code 28). After exposure to propamocarb-HCl disruption of the cellular membrane and/or function can be observed.

According to the FRAC Fungicide Resistance Action Committee (FRAC), group 28 fungicides are considered low to medium risk.

Zoxamide is the only fungicide in the group of the benzamides, which inhibit tubulin polymerization (B3, FRAC Code 22) which destroys the microtubule cytoskeleton, thereby arresting nuclear division.

According to the FRAC, group 22 fungicides are considered low to medium risk.

3.4.2 Inherent risk of target pathogen

Phytophthora infestans was first considered a pathogen with a high risk of developing resistance, because it quickly developed resistance to phenylamide fungicides. However, although there is full cross-resistance among all members of the phenylamide (PA) fungicides there is no cross-resistance between PA fungicides and any of the other chemical classes, including carbamates. This resulted in a re-classification of *P. infestans*, making it a medium risk pathogen for all modes of action¹. This means it poses a much lower risk because resistance is not a major problem or has been slow to develop.

3.4.3 Evidence of resistance

There are no reported cases of propamocarb-HCl resistance of *Phytophthora* spp. according to the FRAC list² published in May 2020, there are no known resistance mechanisms.

Propamocarb-HCl has been used successfully to control potato late blight where metalaxyl-resistant populations presented an increasingly serious problem, which further underlines the need for propamocarb-HCl for the control of late blight.

Zoxamide-resistance has been observed in *Phytophthora capsica*, though it should be noted that these isolates' EC₅₀ values weren't dramatically higher than baseline sensitivity³.

¹ Pathogen Risk List, FRAC, September 2019

² List of first confirmed cases of plant pathogenic organisms resistant to disease control agents, FRAC, May 2020.

³ Bi Y, Chen L, Cai M, Zhu S, Pang Z, Liu X. Two non-target recessive genes confer resistance to the anti-oomycete microtubule inhibitor zoxamide in *Phytophthora capsici*. PLoS One. 2014 Feb 20;9(2):e89336. doi: 10.1371/journal.pone.0089336. PMID: 24586697; PMCID: PMC3930715.

3.4.4 Cross resistance

There are no reported cases of propamocarb-HCl -resistant isolates of *Phytophthora infestans* and there are no indications that cross-resistance between carbamates and other groups of fungicides is likely to occur.

It is very unlikely there's cross-resistance between zoxamide and other fungicides. It is the only member of toluamide fungicides and the only EU registered B3 fungicide. A 2016 study by Cai *et al.* confirmed that zoxamide resistant mutants (lab-created) of *Phytophthora sojae* show no cross-resistance to other fungicides⁴. It will therefore be essential to combine actives with different modes of action in order to fully control late blight⁵.

3.4.5 Sensitivity data

Propamocarb-HCl sensitivity has been assessed on a variety of *Phytophthora* species at several stages of their life cycles⁶. Oospore formation by *P. infestans* was found to be very sensitive to propamocarb, with complete inhibition at 100 µg/ml.

Another study tested the sensitivity to propamocarb-HCl (among other active substances) of 12 isolates of *Phytophthora infestans* collected on infected potato leaves.⁷ The EC₅₀ values for were between 12.1 and 31.1 µg/mL for propamocarb-HCl.

No information on baseline sensitivity of *Phytophthora infestans* to zoxamide is available to the applicant.

3.4.6 Use pattern

The use pattern is detailed in the GAP table.

3.4.7 Acceptability of the resistance risk

In an unrestricted use pattern, the resistance risk is unacceptable. However, if the resistance management strategy is respected, resistance can be kept under control as seen in the yearly reports of the FRAC.

⁴ Cai M, Miao J, Song X, Lin D, Bi Y, Chen L, Liu X and Tyler BM (2016) C239S Mutation in the β-Tubulin of *Phytophthora sojae* Confers Resistance to Zoxamide. *Front. Microbiol.* 7:762. doi: 10.3389/fmicb.2016.00762

⁵ <https://www.fwi.co.uk/arable/crop-management/disease-management/what-the-new-fungicide-resistant-blight-strain-means-for-uk-farmers>

⁶ Jiahuai Hu *et al.* (2007). Effects of Propamocarb Hydrochloride on Mycelial Growth, Sporulation, and Infection by *Phytophthora nicotianae* Isolates from Virginia Nurseries. *The American Phytopathological Society. Plant Disease* / Vol. 91 No. 4

⁷ Emil Rekanović *et al* (2011). Sensitivity of *Phytophthora infestans* (Mont.) de Bary Isolates to Fluazinam, Fosetyl-Al and Propamocarb-hydrochloride. *Pestic. Phytomed.* (Belgrade), 26(2), 2011, 111–116

3.4.8 Resistance management strategy

Any fungus population may contain individuals naturally less sensitive to propamocarb-HCl and zoxamide. Although resistance to both active substances is very unlikely to occur, resistant individuals can eventually dominate the fungus population if these fungicides are used repeatedly and exclusively in programs. To delay the onset (and spread) of fungicide resistance. It is in the best interest of all those involved in recommending and using these fungicides that they are utilised in such a way that their effectiveness is maintained.

The applicant suggests the following general guidelines;

- When multiple applications are required in a single growing season, use mixtures or alternate (in block sprays or in sequence) with effective non-cross-resistant fungicides.
- If performance of carbamates declines and less sensitive forms of the pathogen are detected, carbamates should only be used in mixture or alternated with effective non-cross-resistant fungicides.
- Avoid exclusive repeated use of fungicides from the same fungicide group code. Alternate with products from different fungicide group codes
- Complementary use of other fungicide classes with different modes of action should be maximised.
- Use as recommended on the label. Do not use reduced doses. This ensures good performance and reduces the risk of resistance development.
- Integrate other control methods (chemical, cultural, biological) into disease control programmes.
- Use other measures such as resistant varieties, good agronomic practice, plant hygiene.

Comments of zRMS:	<p><u>Resistance</u></p> <p>The GLOB2007bF (Obsever Pro 2.0l/ha) preparation contains two a.s. propamocarb and zoxamide.</p> <p>The active substance propamocarb is registered in Poland and Europe in many agents intended for application to control diseases in plants as a <i>Phytophthora infestans</i>, on potatoes, tomatoes and others, during the vegetation season.</p> <p>According to FRAC's information, fungus <i>Phytophthora infestans</i> developed resistance quite rapidly to phenylamide fungicides but not at all to CAA fungicides and Carbamates (propamocarb) and other.</p> <p>FRAC re-classified <i>P. infestans</i> as a medium risk pathogen for all modes of action. According to FRAC's code F 4: Chemical group carbamates, common name propamocarb is in group of low to medium risk of resistance. Resistance management is required.</p> <p>Currently, there is no risk of pathogens resistance to propamocarb, but with very frequent use this phenomenon may occur. Adequate policy should be followed and propamocarb should not be applied more than three times per season on one crop.</p> <p>According to FRAC's code B3: Chemical group benzamides, common name zoxamide is in group of low to medium risk of resistance. Resistance management is required.</p> <p>Currently, there is no risk of pathogens resistance to zoxamide, but with very frequent use this phenomenon may occur. Adequate policy should be followed and zoxamide should not be applied more than three times per season on one crop.</p> <p><u>Information from the FRAC</u></p> <p>Information is provided about the risk of pathogens to develop resistance to fungicides under specific agronomic conditions.</p>
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	<p>The risk increases when a pathogen undergoes many and short disease cycles per season.</p> <p>When the dispersal through spores over time and space is high.</p> <p>Furthermore, the risk is considered as high when resistance evolved already after few years of product use.</p> <p>Therefore, we consider the pathogen risk as medium to high only if resistance was reported in commercial situations for more than one fungicide class.</p> <p>The Applicant in section 3.3 has provided current data on pathogen resistance to a.s. propamocarb and zoxamide.</p> <p>An appropriate EPPO PP 1/213 guidelines (4)-compatible resistance policy should be presented.</p> <p>The Applicant included the appropriate indications in RR and on the label for the use of an anti-immune strategy for GLOB2007bF (Observer Pro 2.0l/ha) preparation.</p> <p>There should also be a wide information campaign among the producers of potatoes.</p>
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3.5 Adverse effects on treated crops (KCP 6.4)

3.5.1 Phytotoxicity to host crop (KCP 6.4.1)

Plant protection products containing propamocarb-HCl and zoxamide have been applied to a wide variety of vegetables in different countries for many years without any reports of damage symptoms to the crops. Both active substances are considered safe.

In accordance with EPPO PP 1/135 (4), crop safety assessments were made in the efficacy trials presented in this dossier (3.2.3). This guideline states that for fungicides it is considered sufficient to demonstrate the crop safety at the N dose rate when no phytotoxicity is expected. No significant adverse effects were recorded at the proposed dose rate.

Number of trials with...		Efficacy trials (36 trials)	
		GLOB2007bF	Reference products
		2 L/ha	N
Maximum of phytotoxicity recorded during the trials	0% to 5%	13 Maritime trial (6 CZ/DE) 11 North-East trials 6 Mediterranean trials 6 South-East trials	13 Maritime trial (6 CZ/DE) 11 North-East trials 6 Mediterranean trials 6 South-East trials
	>5% to 10%		
	>10% to 15%		
	>15 %		
Level of symptoms at the last assessments	0% to 5%	13 Maritime trial (6 CZ/DE) 11 North-East trials 6 Mediterranean trials 6 South-East trials	13 Maritime trial (6 CZ/DE) 11 North-East trials 6 Mediterranean trials 6 South-East trials
	>5% to 10%		
	>10% to 15%		
	>15 %		

Conclusion

No Phytotoxic effects were observed in any of the efficacy trials presented in this dossier.
Therefore GLOB2007bF can be considered safe for use on potatoes.

Comments of zRMS:	<p>The Applicant did not present separate experiments on phytotoxicity - in the case of fungicides, it is in accordance with EPPO guidelines. Phytotoxicity was assessed in all efficacy experiments (13 Maritime trial -6 CZ/DE, 11 North-East trials, 6 Mediterranean trials, 6 South-East trials).</p> <p>Observer Pro (GLOB2007bF) fungicide was used in 2021 and 2022 at a dose 1.2 and 2.0 l/ha. In only one experiment - KCP 6.2-21 (FE-21-A-GLOB2013F-2106F-2007F-LV02), Observer Pro (GLOB2007bF) was used only at a dose of 1.2 l/ha. The number of trials is sufficient and their location is appropriate for evaluation. The methods used in the presented experiments were appropriate, and the studies presented for evaluation are satisfactorily representative of the potato crop.</p> <p>In connection with the fact that no phytotoxic effects were observed in any of the efficacy trials presented in this dossier it can be concluded that fungicide Observer Pro (GLOB2007bF) is selective for potato crop.</p>
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3.5.2 Effect on the yield of treated plants or plant product (KCP 6.4.2)

Yield amount was assessed in all efficacy trials presented in section 3.2.3 except KCP 6.2-53 and 61, performed in Germany (Maritime EPPO Zone) and Spain (Mediterranean EPPO Zone), respectively.

Plots were harvested individually and the recorded yield was then converted to metric tons per ha. The number of tubers per plot was also recorded. The absolute yield amount (t/ha and number of tubers per plot) is given for the untreated control. The results for the different treatments are given as a percentage of the untreated control (%UNCK).

For individual trial data reference is made to Appendix 5 of the BAD – Crop safety data.

Comments of zRMS:	<p><u>Maritime EPPO Zone</u></p> <p>The results presented by the applicant indicate that the Observer Pro (GLOB2007bF) fungicide applied 5 to 13 times at a dose of 2.0 l/ha significantly increases yield, at least to the same level as standard products.</p> <p>The applicant requests three applications of the Observer Pro (GLOB2007bF) fungicide.</p> <p>The presented results do not allow the conclusion that this fungicide applied three times increases the yield. However, it can be stated that if the fungicide did not have a negative impact on yield after 5-13 applications, it will not have a negative impact on potato yield after three applications.</p> <p><u>North-East EPP Zone</u></p> <p>The results presented by the applicant indicate that the Observer Pro (GLOB2007bF) fungicide applied 6 to 10 times at a dose of 2.0 l/ha significantly increases yield, at least to the same level as standard products.</p> <p>The applicant requests three applications of the Observer Pro (GLOB2007bF) fungicide.</p> <p>The presented results do not allow the conclusion that this fungicide applied three times increases the yield. However, it can be stated that if the fungicide did not have a negative impact on yield after 6-10 applications, it will not have a negative impact on potato yield after three applications.</p> <p><u>North-East EPP Zone + Cz</u></p> <p>The results presented by the applicant indicate that the Observer Pro (GLOB2007bF) fungicide applied 5 to 10 times at a dose of 2.0 l/ha significantly increases yield, at least to the same level as standard products.</p> <p>The applicant requests three applications of the Observer Pro (GLOB2007bF) fungicide.</p> <p>The presented results do not allow the conclusion that this fungicide applied three times increases the yield. However, it can be stated that if the fungicide did not have a negative impact on yield after 5-10 applications, it will not have a negative impact on potato yield after three applications.</p> <p><u>South-East EPO Zone</u></p> <p>The results presented by the applicant indicate that the Observer Pro (GLOB2007bF) fungicide applied 7 to 8 times at a dose 2.0 l/ha significantly increases yield, at least to the same level as standard products.</p> <p>The applicant requests three applications of the Observer Pro (GLOB2007bF) fungicide.</p> <p>The presented results do not allow the conclusion that this fungicide applied three times increases the yield. However, it can be stated that if the fungicide did not have a negative impact on yield after 7-8 applications, it will not have a negative impact on potato yield after three applications.</p>
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Table 3.4-1 below summarizes the recorded yield amounts expressed in tons per hectare, gathered in the efficacy trials presented in section 3.2.3. For individual trial data reference is made to Appendix 5 of the BAD – Crop safety data.

The absolute yield amount (t/ha) is given for the untreated control. The results for the different treatments are given as a percentage of the untreated control.

Table 3.4-1 Summary of yield amount (tons per hectare)

		SUMMARY ALL						SUMMARY MARITIME						SUMMARY NORTH-EAST					
Rating Type	Rating Unit	YIELD (T-MET)						YIELD (T-MET)						YIELD (T-MET)					
		n	Mean	Min	Max	Med.	Stdev.	n	Mean	Min	Max	Med.	Stdev.	n	Mean	Min	Max	Med.	Stdev.
UNTREATED (t/ha)		34	29.1	6.3	72.0	28.1	13.6	12	36.9	6.8	72.0	35.5	15.1	11	28.5	16.9	42.4	26.8	9.6
GLOB2007bF	1.2 L/ha	34	124.2	93.6	251.0	116.3	32.9	12	129.3	99.8	238.4	121.8	36.6	11	118.1	103.4	139.5	115.2	10.8
GLOB2007bF	2 L/ha	34	134.6	101.2	313.3	126.9	42.8	12	135.1	101.7	271.9	123.7	45.8	11	126.5	111.8	151.6	126.9	12.3
Infinito	1.6 L/ha	22	121.2	99.9	151.9	116.3	14.6	10	118.8	106.1	147.4	112.6	14.5	8	124.8	107.5	151.9	121.1	15.1
Volare	1.6 L/ha	3	118.9	109.2	138.1	109.5	16.6												
Revus 250 SC	0.6 L/ha	24	135.9	99.5	325.4	125.5	53.1	10	132.7	99.5	273.8	120.0	51.2	8	127.8	103.8	156.6	130.4	17.9
Pergado SC	0.6 L/ha	3	126.2	113.6	135.4	129.6	11.3												
Revus Top	0.6 L/ha	1	125.7	125.7	125.7	125.7	-							1	125.7	125.7	125.7	125.7	-

		SUMMARY NORTH-EAST + CZ/DE						SUMMARY MEDITERRANEAN						SUMMARY SOUTH-EAST					
Rating Type	Rating Unit	YIELD (T-MET)						YIELD (T-MET)						YIELD (T-MET)					
		n	Mean	Min	Max	Med.	Stdev.	n	Mean	Min	Max	Med.	Stdev.	n	Mean	Min	Max	Med.	Stdev.
UNTREATED (t/ha)		16	31.0	16.9	42.4	30.2	9.2	5	23.2	6.3	43.0	24.2	13.5	6	19.8	10.9	38.8	16.9	10.2
GLOB2007bF	1.2 L/ha	16	117.1	99.8	142.0	115.1	12.4	5	139.5	102.5	251.0	110.1	63.3	6	112.5	93.6	130.6	110.5	14.6
GLOB2007bF	2 L/ha	16	124.1	102.5	151.6	123.4	13.8	5	162.6	110.9	313.3	125.7	85.2	6	125.1	101.2	148.4	122.0	18.8
Infinito	1.6 L/ha	12	119.5	106.1	151.9	113.7	14.4							4	120.1	99.9	135.9	122.4	16.4
Volare	1.6 L/ha							3	118.9	109.2	138.1	109.5	16.6						
Revus 250 SC	0.6 L/ha	12	124.0	103.8	156.6	123.5	17.7	1	325.4	325.4	325.4	325.4	-	5	117.3	99.5	132.7	114.9	14.3
Pergado SC	0.6 L/ha							3	126.2	113.6	135.4	129.6	11.3						
Revus Top	0.6 L/ha	1	125.7	125.7	125.7	125.7	-												

Table 3.42 below summarizes the recorded yield amounts expressed in number of tubers per plot, gathered in the efficacy trials presented in section 3.2.3. For individual trial data reference is made to Appendix 5 of the BAD – Crop safety data

The absolute yield amount (number of tubers per plot) is given for the untreated control. The results for the different treatments are given as a percentage of the untreated control.

Table 3.4-2 Summary of yield amount (number of tubers per plot)

		SUMMARY ALL						SUMMARY MARITIME						SUMMARY NORTH-EAST					
Rating Type	Rating Unit	YIELD (# TUBERS)						YIELD (# TUBERS)						YIELD (# TUBERS)					
		n	Mean	Min	Max	Med.	Stdev.	n	Mean	Min	Max	Med.	Stdev.	n	Mean	Min	Max	Med.	Stdev.
UNTREATED (#)		34	460.5	76.0	1101.3	375.4	257.6	12	591.5	216.3	1101.3	526.2	304.3	11	487.0	222.0	913.5	421.8	225.1
GLOB2007bF	1.2 L/ha	34	113.4	85.2	227.0	107.9	29.9	12	116.9	90.5	227.0	107.9	35.7	11	110.3	94.5	139.4	110.3	11.9
GLOB2007bF	2 L/ha	34	122.6	94.2	267.4	111.1	39.4	12	125.1	95.1	267.4	110.8	47.1	11	115.3	98.3	135.2	113.5	10.7
Infinito	1.6 L/ha	22	111.5	93.5	137.6	108.4	11.8	10	110.5	93.5	126.3	108.4	10.5	8	111.7	99.8	131.3	107.5	10.6
Volare	1.6 L/ha	3	119.5	98.4	131.9	128.1	18.3												
Revus 250 SC	0.6 L/ha	24	123.5	92.6	263.7	112.5	44.3	10	124.0	93.9	261.3	106.9	49.5	8	118.1	106.1	137.6	115.3	10.9
Pergado SC	0.6 L/ha	3	113.9	100.9	120.4	120.3	11.2												
Revus Top	0.6 L/ha	1	111.5	111.5	111.5	111.5	-							1	111.5	111.5	111.5	111.5	-

		SUMMARY NORTH-EAST + CZ/DE						SUMMARY MEDITERRANEAN						SUMMARY SOUTH-EAST					
Rating Type		YIELD (# TUBERS)						YIELD (# TUBERS)						YIELD (# TUBERS)					

Rating Unit		n	Mean	Min	Max	Med.	Stdev.	n	Mean	Min	Max	Med.	Stdev.	n	Mean	Min	Max	Med.	Stdev.
UNTREATED (#)		16	501.2	222.0	913.5	443.5	205.7	5	271.6	76.0	329.0	318.3	109.6	6	307.2	163.0	527.5	307.2	128.9
GLOB2007bF	1.2 L/ha	16	107.6	90.5	139.4	105.6	11.3	5	125.8	97.2	221.0	101.5	53.4	6	101.7	85.2	118.4	102.6	12.6
GLOB2007bF	2 L/ha	16	112.7	95.1	135.2	111.0	10.5	5	144.7	99.2	264.9	103.2	71.2	6	112.6	94.2	143.0	108.7	18.4
Infinito	1.6 L/ha	12	109.7	93.5	131.3	107.5	10.7							4	113.6	95.6	137.6	110.6	19.3
Volare	1.6 L/ha							3	119.5	98.4	131.9	128.1	18.3						
Revus 250 SC	0.6 L/ha	12	113.2	93.9	137.6	114.8	13.0	1	263.7	263.7	263.7	263.7	-	5	103.3	92.6	116.4	103.0	10.0
Pergado SC	0.6 L/ha							3	113.9	100.9	120.4	120.3	11.2						
Revus Top	0.6 L/ha	1	111.5	111.5	111.5	111.5	-												

Conclusion

From the results presented above, it can be concluded that GLOB2007bF has a positive effect on yield amount on potatoes compared to the untreated control. Furthermore, the results are highly comparable to the reference products. Overall these results fully support the authorization of GLOB2007bF at the requested dose rate.

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

Yield quality was assessed in all efficacy trials presented in section 3.2.3 except KCP 6.2-53 and 61, performed in Germany (Maritime EPPO Zone) and Spain (Mediterranean EPPO Zone), respectively.

In each trial the yield distribution was calculated as a % of total weight and as a percentage of total number of tubers.

The weight and amount of malformed tubers was also recorded.

For individual trial data reference is made to Appendix 5 of the BAD – Crop safety data.

Comments of zRMS:	<p><u>Maritime EPPO Zone</u> The results presented by the applicant indicate that the Observer Pro (GLOB2007bF) fungicide applied 5 to 13 times at a dose 2.0 l/ha did not show a negative effect on yield distribution, the number of malformed tubers and reduced the weight of deformed tubers. Based on this, it can be concluded that if we apply the Observer Pro (GLOB2007bF) fungicide three times at a dose of 2.0 l/ha, it will be safe for potato crop.</p> <p><u>North-East EPP Zone</u> The results presented by the applicant indicate that the Observer Pro (GLOB2007bF) fungicide applied 6 to 10 times at a dose of 2.0 l/ha did not show a negative effect on yield distribution, the number of malformed tubers and reduced the weight of deformed tubers. Based on this, it can be concluded that if we apply the Observer Pro (GLOB2007bF) fungicide three times at a dose of 2.0 l/ha, it will be safe for potato crop.</p> <p><u>North-East EPP Zone + Cz</u> The results presented by the applicant indicate that the Observer Pro (GLOB2007bF) fungicide applied 5 to 10 times at a dose of 2.0 l/ha did not show a negative effect on yield distribution, the number of malformed tubers and reduced the weight of deformed tubers. Based on this, it can be concluded that if we apply the Observer Pro (GLOB2007bF) fungicide three times at a dose of 2.0 l/ha, it will be safe for potato crop.</p> <p><u>South-East EPO Zone</u> The results presented by the applicant indicate that the Observer Pro (GLOB2007bF) fungicide applied 7 to 8 times at a dose of 2.0 l/ha did not show a negative effect on yield distribution, the number of malformed tubers and reduced the weight of deformed tubers. Based on this, it can be concluded that if we apply the Observer Pro (GLOB2007bF) fungicide three times at a dose of 2.0 l/ha, it will be safe for potato crop.</p>
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Because the sizing of potatoes is dependent on crop variety, no meaningful overall summary can be made from the percentages. However, the applicant calculated for each treatment the difference in percentage from the untreated. These ‘percent difference to untreated’ values were summarized in order to draw conclusions on possible shifts in yield distribution. For individual trial data (including the ‘percent difference to untreated’) reference is made to Appendix 5 of the BAD – Crop safety data.

[illegible]

				SUMMARY NORTH-EAST									SUMMARY NORTH-EAST + CZ/DE										
				Difference in yield distribution based on weight									Difference in yield distribution based on weight										
				COMPR1			COMPR2			COMPR3			COMPR1			COMPR2			COMPR3				
				n	Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	n	Mean	Min	Max	Mean	Min	Max	Mean	Min	Max
UNTREATED (%)				11	15.8	1.1	38.8	53.9	15.0	78.9	30.3	8.1	83.9	16	14.0	1.1	38.8	56.0	15.0	80.5	30.0	6.1	83.9
GLOB2007bF	1.2	l/ha		11	0.6	-7.0	13.9	-2.5	-11.2	5.5	1.9	-6.0	11.9	16	0.3	-7.0	13.9	-1.2	-11.2	5.5	1.0	-6.0	11.9
GLOB2007bF	2	l/ha		11	0.0	-8.5	13.2	-3.6	-11.3	5.3	3.6	-6.0	16.4	16	-0.3	-8.5	13.2	-2.0	-11.3	7.5	2.3	-6.0	16.4
Infinito	1.6	l/ha		8	-2.1	-9.4	6.0	-2.1	-9.3	9.1	4.2	-3.3	13.2	12	-1.6	-9.4	6.0	-0.5	-9.3	9.1	2.2	-7.9	13.2
Volare	1.6	l/ha																0.0			-	0.0	0.0
Revus 250 SC	0.6	l/ha		8	1.6	-5.1	10.2	-5.1	-11.7	4.5	3.5	-4.9	13.6	12	0.8	-5.1	10.2	-2.9	-11.7	4.5	2.2	-4.9	13.6
Pergado SC	0.6	l/ha																0.0			-	0.0	0.0
Revus Top	0.6	l/ha		1	-1.0	-1.0	-1.0	-7.9	-7.9	-7.9	8.9	8.9	8.9	1	-1.0	-1.0	-1.0	-7.9	-7.9	-7.9	8.9	8.9	8.9

[illegible]

Table 3.4-4 below summarizes the yield distribution data according to the number of tubers, gathered in the efficacy trials presented in section 3.2.3.

Because the sizing of potatoes is dependent on crop variety, no meaningful overall summary can be made from the percentages. However, the applicant calculated for each treatment the difference in percentage from the untreated. These ‘percent difference to untreated’ values were summarized in order to draw conclusions on possible shifts in yield distribution. For individual trial data (including the ‘percent difference to untreated’) reference is made to Appendix 5 of the BAD – Crop safety data.

Table 3.4-4 Summary of yield distribution differences (%) to untreated control based on number of tubers

		SUMMARY ALL									SUMMARY MARITIME										
		Difference in yield distribution based on number of tubers									Difference in yield distribution based on number of tubers										
		COMPR1			COMPR2			COMPR3			COMPR1			COMPR2			COMPR3				
		n	Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	n	Mean	Min	Max	Mean	Min	Max	Mean	Min	Max
UNTREATED (%)		33	23.8	0.0	68.0	50.2	0.0	79.3	26.0	0.0	100.0	12	21.8	0.0	54.7	53.2	0.0	79.3	24.9	0.0	100.0
GLOB2007bF	1.2 L/ha	33	-2.7	-12.7	9.8	0.9	-13.2	13.0	1.9	-11.2	21.0	12	-2.7	-10.7	0.5	2.0	-9.8	11.5	0.8	-11.2	13.0
GLOB2007bF	2 L/ha	33	-2.5	-13.9	9.2	0.4	-11.5	9.6	2.1	-9.6	22.3	12	-2.3	-12.7	0.9	1.9	-4.8	9.6	0.4	-8.6	10.0
Infinito	1.6 L/ha	21	-4.3	-13.5	2.2	2.1	-8.3	10.6	2.2	-9.2	13.9	10	-4.1	-13.5	0.8	3.3	-8.3	10.6	0.8	-9.2	12.5
Volare	1.6 L/ha	3	-5.0	-8.8	2.0	10.3	1.0	24.1	-5.3	-15.9	3.0										
Revus 250 SC	0.6 L/ha	23	-0.7	-10.8	9.8	-1.1	-10.5	7.0	1.9	-8.0	17.0	10	-1.1	-5.4	2.3	0.2	-5.0	5.8	0.9	-1.4	8.0
Pergado SC	0.6 L/ha	3	-5.4	-10.8	2.9	7.7	6.4	9.7	-2.3	-10.0	4.4										
Revus Top	0.6 L/ha	1	-0.5	-0.5	-0.5	-4.7	-4.7	-4.7	5.2	5.2	5.2										

			SUMMARY NORTH-EAST									SUMMARY NORTH-EAST + CZ/DE										
			Difference in yield distribution based on number of tubers									Difference in yield distribution based on number of tubers										
			n	COMPR1			COMPR2			COMPR3			n	COMPR1			COMPR2			COMPR3		
			Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	Mean	Min	Max		
UNTREATED (%)			10	27.4	6.5	68.0	51.8	23.6	68.3	20.9	3.0	57.0	15	23.5	0.5	68.0	53.3	23.6	79.3	23.1	1.1	64.9
GLOB2007bF	1.2	L/ha	10	-1.6	-10.5	9.8	0.3	-7.7	9.4	1.4	-7.3	10.2	15	-1.3	-10.5	9.8	1.2	-7.7	11.5	0.1	-11.2	10.2
GLOB2007bF	2	L/ha	10	-1.2	-9.0	8.3	-1.1	-10.1	7.3	2.3	-9.6	14.7	15	-1.3	-9.0	8.3	0.5	-10.1	9.4	0.9	-9.6	14.7
Infinito	1.6	L/ha	7	-4.5	-9.6	2.1	1.5	-5.1	7.2	3.0	-3.1	11.7	11	-3.4	-9.6	2.1	2.5	-5.1	9.5	1.0	-9.2	11.7
Volare	1.6	L/ha																0.0	-	0.0	0.0	
Revus 250 SC	0.6	L/ha	7	-0.7	-10.8	6.7	-1.3	-10.5	7.0	1.9	-8.0	12.2	11	-0.5	-10.8	6.7	-1.0	-10.5	7.0	1.5	-8.0	12.2
Pergado SC	0.6	L/ha																0.0	-	0.0	0.0	
Revus Top	0.6	L/ha	1	-0.5	-0.5	-0.5	-4.7	-4.7	-4.7	5.2	5.2	5.2	1	-0.5	-0.5	-0.5	-4.7	-4.7	-4.7	5.2	5.2	5.2

				SUMMARY MEDITERRANEAN									SUMMARY SOUTH-EAST									
				Difference in yield distribution based on number of tubers									Difference in yield distribution based on number of tubers									
				n	COMPR1			COMPR2			COMPR3			n	COMPR1			COMPR2			COMPR3	
				Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	
UNTREATED (%)			5	25.0	17.5	30.5	57.3	43.8	71.8	17.7	3.0	38.7	6	20.8	2.5	34.3	35.7	20.0	49.9	43.5	25.6	63.9
GLOB2007bF	1.2	L/ha	5	-3.1	-10.0	8.1	2.7	-4.1	13.0	0.3	-4.0	4.8	6	-4.2	-12.7	5.1	-2.0	-13.2	3.4	6.4	-2.2	21.0
GLOB2007bF	2	L/ha	5	-3.6	-11.7	1.9	2.3	0.7	6.0	1.3	-5.0	6.9	6	-3.8	-13.9	9.2	-1.7	-11.5	4.0	5.7	-3.7	22.3
Infinito	1.6	L/ha											4	-4.5	-9.2	2.2	0.3	-4.6	4.8	4.2	-2.6	13.9
Volare	1.6	L/ha	3	-5.0	-8.8	2.0	10.3	1.0	24.1	-5.3	-15.9	3.0										
Revus 250 SC	0.6	L/ha	1	1.6	1.6	1.6	-3.1	-3.1	-3.1	1.5	1.5	1.5	5	-0.6	-10.4	9.8	-3.1	-8.5	2.9	3.7	-7.3	17.0
Pergado SC	0.6	L/ha	3	-5.4	-10.8	2.9	7.7	6.4	9.7	-2.3	-10.0	4.4										
Revus Top	0.6	L/ha																				

Table 3.4-5 below summarizes the recorded amount of malformed tubers expressed in kg weight per plot, gathered in the efficacy trials presented in section 3.2.3. For individual trial data reference is made to Appendix 5 of the BAD – Crop safety data
The absolute yield amount (kg per plot) is given for the untreated control. The results for the different treatments are given as a percentage of the untreated control.

Table 3.4-5 Summary of amount of malformed tubers (weight per plot)

		SUMMARY ALL						SUMMARY MARITIME						SUMMARY NORTH-EAST					
		MAMDEF (kg)						MAMDEF (kg)						MAMDEF (kg)					
Rating Type	Rating Unit	n	Mean	Min	Max	Med.	Stdev.	n	Mean	Min	Max	Med.	Stdev.	n	Mean	Min	Max	Med.	Stdev.
UNTREATED (#)		34	2.1	0.0	29.9	0.9	5.1	12	1.6	0.0	6.5	0.8	2.1	11	0.7	0.0	1.9	0.8	0.5
GLOB2007bF	1.2 L/ha	34	57.0	0.0	183.3	47.0	59.0	12	47.4	0.0	183.3	2.4	70.6	11	82.2	0.0	170.0	88.9	59.7
GLOB2007bF	2 L/ha	34	58.4	0.0	222.7	44.5	63.6	12	49.9	0.0	222.7	6.2	76.9	11	76.2	0.0	166.7	87.5	58.7
Infinito	1.6 L/ha	22	62.8	0.0	259.1	32.4	75.9	10	67.5	0.0	259.1	7.4	91.9	8	72.3	0.0	200.0	72.5	63.4
Volare	1.6 L/ha	3	73.5	52.2	112.2	56.3	33.5												
Revus 250 SC	0.6 L/ha	24	47.5	0.0	288.9	23.6	66.9	10	27.3	0.0	133.3	1.5	44.2	8	94.0	0.0	288.9	83.9	88.2
Pergado SC	0.6 L/ha	3	95.6	49.2	143.9	93.8	47.4												
Revus Top	0.6 L/ha	1	200.0	200.0	200.0	200.0	-							1	200.0	200.0	200.0	200.0	-

		SUMMARY NORTH-EAST + CZ/DE						SUMMARY MEDITERRANEAN						SUMMARY SOUTH-EAST					
		MAMDEF (kg)						MAMDEF (kg)						MAMDEF (kg)					
Rating Type	Rating Unit	n	Mean	Min	Max	Med.	Stdev.	n	Mean	Min	Max	Med.	Stdev.	n	Mean	Min	Max	Med.	Stdev.
UNTREATED (#)		16	1.1	0.0	6.5	0.8	1.5	5	7.4	0.0	29.9	1.6	12.6	6	1.2	0.0	3.5	0.7	1.5

GLOB2007bF	1.2	L/ha	16	76.6	0.0	183.3	88.2	67.0	5	46.3	0.0	87.5	43.9	31.4	6	39.2	0.0	100.0	32.9	44.5
GLOB2007bF	2	L/ha	16	70.4	0.0	175.0	87.5	63.2	5	65.5	0.0	163.4	45.2	60.9	6	36.7	0.0	115.4	15.4	48.3
Infinito	1.6	L/ha	12	70.4	0.0	200.0	72.5	65.1							4	31.7	0.0	126.9	0.0	63.5
Volare	1.6	L/ha							3	73.5	52.2	112.2	56.3	33.5						
Revus 250 SC	0.6	L/ha	12	75.9	0.0	288.9	64.5	82.2	1	0.0	0.0	0.0	0.0	-	5	22.9	0.0	68.6	0.0	32.4
Pergado SC	0.6	L/ha							3	95.6	49.2	143.9	93.8	47.4						
Revus Top	0.6	L/ha	1	200.0	200.0	200.0	200.0	-							1	200.0	200.0	200.0	200.0	-

Table 3.4-6 below summarizes the recorded amount of malformed tubers expressed in number of tubers per plot, gathered in the efficacy trials presented in section 3.2.3. For individual trial data reference is made to Appendix 5 of the BAD – Crop safety data
The absolute yield amount (number of tubers per plot) is given for the untreated control. The results for the different treatments are given as a percentage of the untreated control.

Table 3.4-6 Summary of amount of malformed tubers (number of tubers per plot)

		SUMMARY ALL						SUMMARY MARITIME						SUMMARY NORTH-EAST					
Rating Type	Rating Unit	MAMDEF (#)						MAMDEF (#)						MAMDEF (#)					
		n	Mean	Min	Max	Med.	Stdev.	n	Mean	Min	Max	Med.	Stdev.	n	Mean	Min	Max	Med.	Stdev.
UNTREATED (#)		33	13.0	0.0	99.3	8.3	19.4	11	6.9	0.0	23.3	3.0	8.6	10	7.5	1.8	12.5	8.1	3.5
GLOB2007bF	1.2 L/ha	33	52.5	0.0	175.6	49.0	54.0	11	29.9	0.0	140.0	0.0	52.3	10	82.4	8.0	175.6	82.7	55.8
GLOB2007bF	2 L/ha	33	53.9	0.0	160.0	51.0	51.5	11	32.9	0.0	150.0	0.3	53.1	10	78.0	6.4	140.0	78.4	44.3
Infinito	1.6 L/ha	21	55.8	0.0	220.7	42.2	66.3	9	48.1	0.0	171.4	0.0	72.5	7	79.3	6.4	220.7	62.2	68.4
Volare	1.6 L/ha	3	73.6	46.6	118.8	55.4	39.4												
Revus 250 SC	0.6 L/ha	23	46.7	0.0	347.8	23.0	75.4	10	22.9	0.0	120.0	0.0	40.7	7	107.2	23.0	347.8	76.0	108.1
Pergado SC	0.6 L/ha	3	88.6	47.6	135.1	83.0	44.0												
Revus Top	0.6 L/ha	1	189.7	189.7	189.7	189.7	-							1	189.7	189.7	189.7	189.7	-

		SUMMARY NORTH-EAST + CZ/DE						SUMMARY MEDITERRANEAN						SUMMARY SOUTH-EAST					
Rating Type	Rating Unit	MAMDEF (#)						MAMDEF (#)						MAMDEF (#)					
		n	Mean	Min	Max	Med.	Stdev.	n	Mean	Min	Max	Med.	Stdev.	n	Mean	Min	Max	Med.	Stdev.
UNTREATED (#)		15	7.7	0.0	18.5	7.8	5.0	5	39.1	0.0	99.3	23.5	38.7	6	11.2	0.0	35.3	5.8	14.4
GLOB2007bF	1.2 L/ha	15	75.1	0.0	175.6	78.9	63.1	5	46.6	0.0	68.1	55.0	27.7	6	31.5	0.0	82.6	24.5	36.3
GLOB2007bF	2 L/ha	15	66.8	0.0	140.0	77.8	50.1	5	65.1	0.0	160.0	52.8	58.6	6	33.5	0.0	100.0	25.1	40.9
Infinito	1.6 L/ha	11	67.5	0.0	220.7	62.2	64.0							4	29.3	0.0	117.4	0.0	58.7
Volare	1.6 L/ha							3	73.6	46.6	118.8	55.4	39.4						
Revus 250 SC	0.6 L/ha	11	79.3	0.0	347.8	72.2	97.8	1	0.0	0.0	0.0	0.0	-	5	19.0	0.0	50.2	0.0	26.1
Pergado SC	0.6 L/ha							3	88.6	47.6	135.1	83.0	44.0						
Revus Top	0.6 L/ha	1	189.7	189.7	189.7	189.7	-												

Conclusion

The results summarized in above in Table 3.4-3 and Table 3.4-4 confirm GLOB2007bF has no impact on yield distribution.
Table 3.4-5 demonstrates that, based on weight, there is an overall trend towards lowered amounts of malformed tubers for all tested treatments.
The number of malformed tubers (Table 3.4-6) is very similar between all tested treatments, which on average all have a slight increase compared to the untreated control. However, the numbers of malformed tubers is less important than the weight of malformed tubers.
Taken together, all results presented above confirm that GLOB2007bF is safe at the requested dose rate.

3.5.4 Effects on transformation processes (KCP 6.4.4)

According to EPPO Guideline PP 1/243 (2) potato is not subjected to transformation processes, therefore no transformation studies were performed.

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

Propamocarb-HCl and zoxamide are well-known active substances.

Other products containing propamocarb-HCl (Edipro/Proplant/Rival) have been registered at application rates higher than the one requested for GLOB2007bF (900 g propamocarb/ha) and have been used for many years on potatoes (and a wide range of other crops). These have proven safe when applied as recommended.

Similarly, zoxamide has been used on potatoes in the following products:

Crop(s)	Reference standard	Countries where the product is registered	Active substance(s)	Formulation		Dose rate	Amount of zoxamide applied per application	Number of application per season	Amount of zoxamide applied per growing season
				Type	Concentration of a.s.				
Potato	Presidium	CZ, HU, RO, PL, UK, FR, IT	dimethomorph zoxamide	SC	180 g/L 180 g/L	1 L/ha	180 g/ha	5	900 g/ha
	Lieto, Carlito, Reboot	CZ, HU, RO, PL, SK, IE, UK, FR, IT	cymoxanil zoxamide	WG	330 g/kg 330 g/kg	0.45 kg/ha	148.5 g/ha	6	891 g/ha
	Zoxium 240 SC	IT	zoxamide	SC	240 g/L	0.625-0.75 L/ha	180 g/ha	5	900 g/ha

Products containing propamocarb-HCl and zoxamide have been used together in fungicide programs against *Phytophthora infestans* on potatoes for many years, which supports that the combination of these active substances is safe.

Comments of zRMS:	<p>The applicant did not submit additional studies aimed at transformation processes and determining the impact on treated plants or plant products to be used for propagation.</p> <p>Considering that the selectivity studies showed no negative effects on potato crop and the fact that propamocarb-HCl and zoxamide are a known active substances, it can be concluded that Observer Pro (GLOB2007bF) has no negative effect on parts of plants used for transformation processes and propagating purposes.</p>
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3.6 Observations on other undesirable or unintended side-effects (KCP 6.5)

Samples of two efficacy trials submitted in this dossier (FE-22-B-GLOB2013F-2106F-2007F-CZ02 and FE-22-B-GLOB2013F-2106F-2007F-DE04, KCP 6.2-52 and 53, respectively) were sent over to the National Institute of Horticultural Research (InHort) in Poland for organoleptic testing. It should be noted there was no infestation in trial KCP 6.2-53.

The evaluation was carried out for the quality parameters characterizing the smell, colour and texture of boiled and fried potatoes. The results of the evaluation can be found in KCP 6.5.1-01 and 02 respectively and are shown below.

Table 3.5-1 Results of sensory analysis of boiled potatoes

Trial	Treatment Dose rate		Odour of boiled potatoes	Off-odour	Colour	Consistency	Flavour of boiled potatoes	Sweet taste	Bitter taste	Off-flavour	Overall quality
			0-none 10-very intense	0-none 10-very intense	0-bright 10-yellow	0-loose 10-floury	0-none 10-very intense	0-none 10-very intense	0-none 10-very intense	0-none 10-very intense	0-low quality 10-high quality
FE-22-B-GLOB2013F-2106F-2007F-CZ02 Efficacy trial KCP 6.2-52 Variety: Red Sonia InHort Report 098/2022 KCP 6.5-01	Untreated		6.7	0	7.9	7.4	6.6	0.8	0	0.1	7.6
	GLOB2013F	0.3 L/ha	6.7	0.3	8.3	7.9	7.7	1.1	0.1	0	8.5
	GLOB2106cF	1.9 L/ha	6.4	0.1	7.8	7.3	6.9	0.9	0.1	0	7.3
	GLOB2007bF	2 L/ha	6.4	0.1	8.2	7.7	6.8	1.1	0.1	0.1	6.6
	GLOB178F	2 L/ha	6.2	0.2	8.4	7.8	7.4	1.2	0	0.1	8.1
	Revus 250 SC	0.6 L/ha	6.8	0.2	7.9	7.8	7.5	0.9	0.1	0.1	7.8
FE-22-B-GLOB2013F-2106F-2007F-DE04 Efficacy trial KCP 6.5-54 Variety: Antonia Inhort Report 099/2022 KCP 6.5-02	Untreated		7.1	0.5	6.9	6.1	7	0.9	0.3	0.3	6.8
	GLOB2013F	0.3 L/ha	7.6	0.2	7.3	6.8	7.5	2.7	0.1	0	7.1
	GLOB2106cF	1.9 L/ha	6.6	0.1	7.1	6.6	7.7	0.7	0.1	0.1	7.1
	GLOB2007bF	2 L/ha	7	0.4	7.6	6.2	7.5	1.5	0.3	0.2	7.2
	GLOB178F	2 L/ha	6.2	0.2	7.7	6.6	7	2.2	0.1	0.4	7.5
	Revus 250 SC	0.6 L/ha	7.1	0.1	7.8	6.5	6.9	1.3	0.2	0.1	7.4

Table 3.5-2 Results of sensory evaluation of fried potatoes

Trial	Treatment Dose rate		Odour of boiled potatoes	Off-odour	Colour	Crunchiness	Hardness	Flavour	Off-flavour	Overall quality
			0-none 10-very intense	0-none 10-very intense	0-light golden 10-dark brown	0-not crunchy 10-very crunchy	0-soft 10-hard	0-none 10-very intense	0-none 10-very intense	0-low quality 10-high quality
FE-22-B-GLOB2013F-2106F-2007F-CZ02 Efficacy trial KCP 6.2-52 Variety: Red Sonia InHort Report 098/2022 KCP 6.5-01	Untreated		7.1	0	4.9	6.2	4.8	7.3	0.1	7.1
	GLOB2013F	0.3 L/ha	7.4	0.4	3.5	4.9	3.5	6.9	0.3	7.8
	GLOB2106cF	1.9 L/ha	7.4	0	4.1	5.8	4.1	7.2	0	7.1
	GLOB2007bF	2 L/ha	7.2	0.1	4.1	5.9	4.4	7.2	0	7.6
	GLOB178F	2 L/ha	7.4	0	3.2	5.6	3.2	7.4	0.1	8.2
	Revus 250 SC	0.6 L/ha	7.6	0.2	3.2	6	3.4	7.3	0.1	7.7
FE-22-B-GLOB2013F-2106F-2007F-DE04 Efficacy trial KCP 6.5-54 Variety: Antonia Inhort Report 099/2022 KCP 6.5-02	Untreated		7.5	0	3.9	7.7	6.3	7.7	0.1	8.1
	GLOB2013F	0.3 L/ha	7.8	0.1	4.1	6.7	5.9	8.1	0.1	8.5
	GLOB2106cF	1.9 L/ha	7.4	0.1	3.6	5.4	5.6	8	0.1	7.9
	GLOB2007bF	2 L/ha	6.9	0.1	4	7.2	5.7	7.4	0.1	7.9
	GLOB178F	2 L/ha	7	0.1	4.2	6.8	6.1	7.4	0.1	7.4
	Revus 250 SC	0.6 L/ha	7.7	0.1	3.4	6.2	5.4	7.7	0.1	7.6

It's important to note that even though there is some variance in the scores for the different parameters when comparing different treatments, all scores were very similar. Overall only minor differences were observed between the tested samples.

Comments of zRMS:	The results of two sensory evaluation tests for evaluation of cooked potatoes and fried potatoes in the form of fries presented by the applicant show that the Observer Pro (GLOB2007bF) fungicide does not affect the taste attributes of boiled potatoes and fried potatoes.
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3.6.1 Impact on succeeding crops (KCP 6.5.1)

As mentioned in section 3.4.5, products containing propamocarb-HCl and zoxamide have been used together in fungicide programs against *Phytophthora infestans* on potatoes for many years at dose rates similar to the currently requested dose rate for GLOB2007bH, which supports that the combination of these active substances is safe.

The RAR of propamocarb-HCl of June 2017 states that propamocarb-HCl has very little effect on the seedling emergence of plants, the NOEC in the RAR data package was 9.18 kg propamocarb-HCl/ha.

The RAR of zoxamide of June 2016 includes a glasshouse screening study that tested the effects of zoxamide, applied at doses up to 500 g/ha, on broad-leaved weeds, grass weeds and crop plants. Applications were made pre- and post-emergence. No adverse effects were seen on any species at any dose, therefore no further studies on seedling emergence and vegetative vigour were required.

Table 3.5-3 below provides a simplified worst-case calculation of the amount of active substances that can be expected. This simplified approach can be considered worst-case as it assumes the following:

- All (3) requested applications are performed at once (not taking into account a.i. degradation)
- The full dose rate is applied to bare soil (not taking into account crop interception)

Table 3.5-3 Total dose of a.i. per season for GLOB2007bF – worst case approach

GLOB2007bF		Dose per application	Applications per season	Total dose per season
Propamocarb-HCl	450 g/L	2 L/ha	3	1350 g/ha
Zoxamide	67.5 g/L			202.5 g/ha

Conclusion

From the above worst-case calculations it can be concluded that the amount of active substances in the soil would still be below the safe concentrations mentioned in the RAR of both propamocarb-HCl (9180 g/ha) and zoxamide (500 g/ha).

It should be kept in mind that the above calculation is an absolute worst-case scenario, further refinements taking into account crop interception⁸ and the time between applications⁹ would drastically lower the amount of active substances in the soil even further.

Comments of zRMS:	The reasoning presented by the Applicants is correct and confirms that the Observer Pro (GLOB2007bF) fungicide is safe for successively cultivated plants.
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⁸ According to Generic Guidance for Tier 1 FOCUS Ground Water Assessments (May 2014), the crop interception of potato is never less than 15%.

⁹ Propamocarb-HCl and zoxamide have very short DT₅₀ values in field conditions: 23.7 days and 10 days, respectively.

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

As mentioned in section 3.4.5 products containing propamocarb-HCl and zoxamide have been used together in fungicide programs against *Phytophthora infestans* on potatoes for many years at dose rates similar to the currently requested dose rate for GLOB2007bH, which supports that the combination of these active substances is safe. Fungicides are generally considered safe to plants.

The RAR of propamocarb-HCl of June 2017 states that propamocarb-HCl only has very minor effects on the vegetative vigour of soybean and oats at an application rate of 9.18 kg propamocarb-HCl/ha. Other tested crops were unaffected.

The RAR of zoxamide of June 2016 includes a glasshouse screening study that tested the effects of zoxamide, applied at doses up to 500 g/ha, on broad-leaved weeds, grass weeds and crop plants. Applications were made pre- and post-emergence. No adverse effects were seen on any species at any dose, therefore no further studies on seedling emergence and vegetative vigour were required.

As the above-mentioned threshold values are identical to those used in section 3.5.1, reference is made to the worst-case approach used in section 3.5.1.

Table 3.5-4 Total dose of a.i. per season for GLOB2007bF – worst case approach

GLOB2007bF		Dose per application	Applications per season	Total dose per season
Propamocarb-HCl	450 g/L	2 L/ha	3	1350 g/ha
Zoxamide	67.5 g/L			202.5 g/ha

Conclusion

From the above worst-case calculations it can be concluded that the amount of active substances in the soil would still be below the safe concentrations mentioned in the RAR of both propamocarb-HCl (9180 g/ha) and zoxamide (500 g/ha).

Comments of zRMS:	Both active substances, propamocarb-HCl and zoxamide, included in the Observer Pro (GLOB2007bF) fungicide have been known for many years and are widely used without affecting adjacent crops. The reasoning presented by the applicant, combined with the commonly known effects of the active substances contained in Observer Pro (GLOB2007bF), allow us to conclude that there is no adverse risk of exposure to adjacent crops. According to the guidelines contained in EPPO PP 1/256(1) - no further tests need to be performed and registration should be without restrictions.
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3.6.3 Effects on beneficial and other non-target organisms (KCP 6.5.3)

There are no known effects of on non-target organisms.

3.7 Other/special studies

No other studies were carried out.

3.8 List of test facilities including the corresponding certificates

Table 3.7-1: List of test facilities

Test facility	Address	Certificate (Yes or No)
Reference is made to the Biological Assessment Dossier		

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. Company GLP or GEP status Published or not	Data protected (Y/N)	Owner
Reference is made to the Biological Assessment Dossier.					

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

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

The following tables are to be completed by MS

List of data submitted by the applicant and not relied on

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

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

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