

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

Product code: SAP50SCF

Product name(s): FOLPEC

Chemical active substances:  
Folpet 500 g/L

Central Zone  
Zonal Rapporteur Member State: Poland

**CORE ASSESSMENT**  
(authorization)

Applicant: Selectis Produtos para a Agricultura, S.A.  
Submission date: December 202, April 2024  
MS Finalisation date: June 2024 (initial Core Assessment)  
August 2024 (final Core Assessment)

### Version history

When	What
December 2023	V0 - Initial version submitted by the Selectis Productos para a Agricultura, S.A. for submission to Poland in the frame of new PPP registration (According Art. 33 of Regulation EC No 1107/2009)
April 2024	V1 - Updated version submitted by the Selectis Productos para a Agricultura, S.A. to comply with Poland Data Gaps requests in the frame of new PPP registration (According Art. 33 of Regulation EC No 1107/2009). The changes include: 1) removing, from the GAP table, the MSs other than Poland 2) corrections to the parts concerned with succeeding crops, adjacent crops and tank cleaning, as well as 3) inserting the list of submitted trials, initially absent from the Appendix 1.
April 2024	V2 – Revised version submitted by the Selectis Productos para a Agricultura, S.A. for submission to Poland to address the data gaps received. All changes are highlighted in yellow. The changes include 1) Inserting, following Table 3.2-5., the applicant's statement concerned with and explaining the reasons for the reduced data package for barley, 2) Replacing, in the Resistance chapter, the irrelevant paragraph on Phenylamide fungicides with the appropriate text on Phthalimide fungicides.
June 2024	Initial zRMS assessment  The report in the dRR format has been prepared by the Applicant, therefore all comments, additional evaluations and conclusions of the zRMS are presented in grey commenting boxes. Minor changes are introduced directly in the text and <b>highlighted in grey</b> . Not agreed or not relevant information are <del>struck through</del> and <del>shaded</del> for transparency.  Following the evaluation and before sending the document for commenting, all coloured highlighting was removed from the parts updated by the Applicant, and all the text fragments struck through by the applicant as the result of the updates have been removed completely from the document, for better legibility.
August 2024	Final report (Core Assessment updated following the commenting period).  No additional information or assessments after the commenting period.


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

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

##### Comments of zRMS:

Conclusions from the assessment were prepared using grey commenting boxes placed at the end of each chapter. Textual changes were done using grey highlights in the text. The parts of the text amended or added by the zRMS evaluator are highlighted in grey, whereas the parts struck off are visibly marked with the grey font. As an exception, the coloured background  has been retained by zRMS in *Preliminary tests* chapter, where it is used by the applicant to highlight resistance issue, while reporting results of the respective trial. Any other coloured or grey background has been removed from all the tables, as its use is always restricted to places where zRMS actions must be marked visibly.

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

##### Abstract by zRMS

###### Introduction

The **SAP50SCF** (FOLPEC) is a fungicide containing 500 g/L folpet, the active of the FRAC group M04 (Phthalimides). The submission aims at authorization of the use in soft and in durum wheat in control of *Zymoseptoria tritici* (SEPTTR) and in barley, in control of *Pyrenophora teres* (PYRNTE). Contrary to SEPTTR, the use of the active folpet against PYRNTE is currently not authorized in Poland.

###### Data submitted

The main body of the submitted data includes **54 efficacy trials** and **no dedicated selectivity trials**, as these are not required for fungicide products, provided no phytotoxicity symptoms have been observed directly in efficacy trials (EPPO PP 1/135 (4) guideline: *Phytotoxicity assessment*) (which is indeed the case in the present submission).

Next to efficacy data, the dossier also contains **14** other trial reports: from 9 trials and from 1 set of laboratory analyses, all concerned with transformation processes (**4** trials in bread making and **5** in beer brewing plus **1** laboratory report), **2** studies on the effect on the non-target plants (seedling emergence test and vegetative vigour test), a **tank-cleaning** study and **one** preliminary glasshouse efficacy test, presented as evidence of efficacy of the active substance folpet in control of the prothioconazole-resistant strains of SEPTTR.

Of all the **54 efficacy trials** presented, 22 have been carried out in Maritime EPPO zone and 8 – in each one of the the NE and the SE zones. The dossier also includes 16 efficacy trials from the Mediterranean EPPO zone (ES, FR, IT).

The applicant **has excluded 8 trials** from the efficacy data set, based on the absence of the target pathogens SEPTTR or PYRNTE in them ( DE (4), FR (1), PL(1) ), or on the too low level of infestation by the target pathogens (PL(1), UK(1)). One of these trials (06-F-2021-HU01) has been used as selectivity trial only. **Seven other trials** (3 from the Maritime zone , 3 from Mediterranean zone and 1 from the SE zone), although originally intended to be used for their efficacy data, have been relied on only in terms of yield assessment.

Please note: as explained by the applicant in the update no. 3 out of 4, in April 2024, the “*cMS were included in the dossier by mistake, the submission intends only the registration of the PPP in Poland*”. Nevertheless, as the dossier includes data from other MSs and the authorization in Poland is inevitably based on some of them, making inspection of the data of other zones necessary, the zRMS PL has included comments issued initially / before the GAP update on authorization options in the other EPPO zones (within the Central zone). However, these comments do not affect the authorization in Poland.

###### Minimum Effective Dose

###### **SEPTTR in wheat**

The zRMS confirms that merging the **Maritime** and the **North-East** zone data from neighbouring MSs, either

for the estimation of the MED or for the proper efficacy assessment, as developed further in this document, is acceptable. On the contrary, neither the summarizing of the combined data sets from the **South-East** and the Maritime zone, nor the “extrapolating” from one zone to another can be accepted, since the data sets proposed as mutually supportive come from the MSs not neighboring one another. Therefore the 3 trials available from the **SE EPPO zone** should be treated as self-standing data set.

#### **PYRNTE in barley**

Since there is considerable a distance between the trial locations and the respective MSs do not neighbor one another, the data sets presented for each EPPO zone should be considered separately from one another rather than merged in order to draw any profound conclusions.

#### **MED assessed**

In light of the 15 trials in SEPTTR control and 12 trials in PYRNTE control, summarized for the MED assessment, the **1.2 L/ha** is the minimum effective dose rate of SAP50SCF to control each one of the pathogens in wheat and barley respectively, in the Maritime, in the North East and, **most probably**, in the South East zone (comments on the trial count that may allow or preclude authorization in particular zones are placed in the other commenting box, the one following the Efficacy chapter).

For more details and justification of the zRMS opinion see the: [zRMS comments on the MED](#)

#### **Efficacy**

#### **SEPTTR in wheat**

##### **The North-East zone**

The combined data set of the NE and the Maritime zones (PL (4) + DE (4) ) allows for authorization of the use in Poland, although the label note should be issued, informing of the moderate level of control. Since folpet is a known active and there has been one SEPTTR trial submitted in spring wheat (17-F-2020-DE01), the use in spring wheat can be authorized either, next to the winter form.

##### **The Maritime zone**

There are 8 valid trials submitted from the Maritime EPPO zone (DE(4), FR(3) and UK(1)). The use could possibly be authorized but the mediocre level of control should be stressed, in the prospective product label.

##### **The South-East zone**

There are 3 valid trials submitted from the South-East EPPO zone (BG(2), RO(1)). The number is too low for authorization of the use in the SE zone.

##### **The durum wheat**

In the absence of data (zero trials) in winter and spring durum wheat (TRZDW and TRZDS), the use in control of SEPTTR in that crop in Poland can be authorized only following article 51, as the crop is minor in the zRMS country. The status of durum wheat in the other MSs is unknown to zRMS and has not been reported by the applicant, making any future prospects for authorization, based on the present dossier, always dependent on consideration by the relevant MSs`.

#### **PYRNTE in barley**

##### **The North-East zone**

Only 2 trials in barley in control of PYRNTE have been submitted from Poland. The authorization of the use in barley in Poland is not possible.

##### **The Maritime zone**

The number of trials in the Maritime zone is 5. With the single trial missing to the number of 6, the data set would be insufficient to authorize SAP50SCF in control of PYRNTE in barley in the Maritime zone.

##### **The South-East zone**

The SE zone data set includes only 3 trials in winter barley alone. Therefore any future possibility of authorization should be necessarily confirmed by the cMSs of the SE zone.

For more extensive and detailed comments see: zRMS [commenting box following Efficacy chapter](#).

#### **Yield and its quality from the efficacy trials**

According to EPPO PP 1/135 (4) guideline: *Phytotoxicity assessment*, submission of the yield data is non-obligatory either, for the fungicide products. Notwithstanding, the applicant has submitted yield data from [11 efficacy trials](#). See also the zRMS comments on [yield quality](#).

#### **Phytotoxicity and other adverse effects on the crop**

No negative effects are expected.

#### **The effect on transformation processes**

No negative effect is concluded, based on 4 bread baking and 4 beer brewing tests plus the respective sensory analyses. For details see the zRMS [final comments](#) to that chapter, as well as the preceding, unlinked comments to particular trials.

#### **Succeeding crops**

#### **Adjacent crops**

#### **Tank cleaning**

#### **Resistance Risk**

### **Abstract**

**SAP50SCF** is a Suspension Concentrate (SC) containing 500 g of Folpet/L for use as a protectant fungicide for control of *Septoria* (*Zimoseptoria tritici*) in Wheat and *Helminthosporium* (*Pyrenophora teres*) in Barley, in Central European Union zone.

A total of 38 (30 of them valid) efficacy trials have been presented in wheat and barley. All trials included multiple rates of **SAP50SCF** in order to justify the minimum effective dose. Data have showed that the proposed dose of 0.9 L/ha ~~in have~~ **has** achieved better and more consistent control than lower application rates, ~~being the dose of 1.2 L/ha necessary~~ **the dose of 1.2 L/ha being necessary** to control the diseases in more difficult conditions.

Furthermore, another 2 trials have been performed and are on-going, in Maritime EPPO zone, in Barley against *Helminthosporium*.

The requested doses (0.9 L/ha and 1.2 L/ha) have been compared to reference authorized products. Average efficacy values reported of trials conducted showed a robust control of the diseases, similar to reference products which were tested.

These data are enough to confirm the effectiveness of **SAP50SCF** against *Septoria* (*Zimoseptoria tritici*) in Wheat and *Helminthosporium* (*Pyrenophora teres*) in Barley at 0.9 L/ha and 1.2 L/ha.

Requested GAP of **SAP50SCF** complies with specific recommendations of FRAC to the management the phthalimide fungicides. In addition, resistance management strategy has been proposed.

In resume, **SAP50SCF** is a product which complies with recommendations of FRAC to avoid occurrence of the development of resistance, as Folpet is a multi-site contact activity, demonstrating to be a tool for a good resistance management.

Phytotoxicity has been evaluated in all the efficacy trials and in other two selectivity trials, as well as in 9 other transformation trials, with no phytotoxicity symptoms **observed**.

Besides, 4 bread-making trials in wheat and 5 brewing trials in barley were conducted in order to analyze other undesirable effects on transformation processes.

Trials which were done to evaluate the effects of **SAP50SCF** at 1.5 l/ha (1.25N dose) on barley for brewing and on wheat for bread-making, showed consistent results to demonstrate the absence of non-intentional effects, even if some French trials are still on-going for brewing.

According to data submitted, the risk of impact of **SAP50SCF** ~~on the impact~~ on other plants including succeeding plants and adjacent crops can be considered like acceptable when it is applied following the corresponding GAP.

In conclusion, it has been proved that **SAP50SCF** provided satisfying efficacy to control *Septoria* (*Zimoseptoria tritici*) in Wheat and *Helminthosporium* (*Pyrenophora teres*) in Barley from 0.9 L/ha to 1.2 L/ha.

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

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No. *	Member state(s)	Crop and/ or situation  (crop destination / purpose of crop)	F, Fn, Fn G, Gn, Gnp or I **	Pests or Group of pests controlled  (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks:  e.g. g safener/ synergist per ha, other dose rate expression, dose range (min-max)	zRMS Conclusion (efficacy)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	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	PL	Soft wheat (spring) (TRZAS); Soft wheat (winter) (TRZAW); Durum wheat (spring) (TRZDS); Durum wheat (winter) (TRZDW)	F	Septoria (Zymoseptoria tritici, SEPTTR)	Tractor mounted spray	BBCH 30-59	a) 2 b) 2	14	a) 1,2 L/ha b) 2,4 L/ha	a) 600 g ai/ha b) 1200 g ai/ha	150- 400	42	Range: 0.9—1.2 L/ha	A TRZAW TRZAS
														N TRZDW TRZDS (possible registration on the grounds of article 51)
2	PL	Barley (spring) (HORVS); Barley (winter) (HORVW)	F	Helminthosporium (Pyrenophora teres, PYRNTE)	Tractor mounted spray	BBCH 30-59	a) 2 b) 2	14	a) 1,2 L/ha b) 2,4 L/ha	a) 600 g ai/ha b) 1200 g ai/ha	150- 400	42	Range: 0.9—1.2 L/ha	N

## **3.2 Efficacy data (KCP 6)**

### **Introduction**

This document summarises the information related to the efficacy of the plant protection product **SAP50SCF** with Concentrated Suspension (SC) formulation containing 500 g/l of Folpet, active ingredient that is included into Regulation (EC) N° 1107/2009, Regulation (EU) N° 540/2011, Regulation (EU) 2020/869).

The SANCO report for Folpet (SANCO/10032/2006 - rev. 5- 11 July 2008) is considered to provide the relevant review information or a reference to where such information can be found.

The purpose of this document is to provide data in support of an application for the national registration of SAP50SCF as a fungicide product to be used on wheat and barley in Poland.

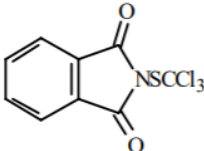
### **Description of active substances**

Folpet belongs to the chemical group of the phthalimide fungicides and, according to FRAC (Fungicide Resistance Action Committee) it is included in the group M4, substances with a multi-site contact activity. This substance acts by inhibiting many oxidative enzymes, carboxylases and enzymes involved with phosphate metabolism and citrate synthesis. Folpet reacts with the sulfhydryl groups of nuclear proteins, leading to an inhibition of the cell division.



## Mode of action

**Table 3.2-2: Description Folpet**

<b>Common name (ISO)</b>	Folpet
<b>Chemical name (IUPAC)</b>	<i>N</i> -(trichloromethylthio) phthalimide
<b>Chemical name (CA)</b>	2-[(trichloromethyl)thio]-1 <i>H</i> -isoindole-1,3(2 <i>H</i> )-dione
<b>CIPAC No</b>	75
<b>CAS No</b>	133-07-3
<b>EEC No</b>	205-088-6
<b>Minimum purity</b>	940 g/kg
<b>Identity of relevant impurities (of toxicological, environmental and/or other significance) in the active substance as manufactured (g/kg)</b>	Perchloromethylmercaptan (R005406) maximum level 3.5 g/kg carbon tetrachloride maximum level 4 g/kg
<b>Molecular formula</b>	C <sub>9</sub> H <sub>4</sub> Cl <sub>3</sub> NO <sub>2</sub> S
<b>Molecular mass</b>	296.6
<b>Structural formula</b>	

## Description of the plant protection product

SAP50SCF is a Suspension Concentrate (SC) containing 500 g of Folpet/L. It is a contact fungicide that has a protective effect against *Septoria* in Wheat and *Helminthosporium* in Barley.

## Description of the target pests

**Table 3.2-1: Glossary of pests mentioned in the dossier.**

EPPO code	Scientific name	Common name*
PYRNTE	<i>Pyrenophora teres</i>	Helminthosporium. Net blotch of barley
SEPTTR	<i>Zymoseptoria tritici</i>	Septoria leaf blotch/ speckled leaf blotch

\* optional

**Table 3.2-2: 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
Wheat	PL	-	SEPTTR	PL	-
Barley	PL	-	PYRNTE	PL	-

Regarding crop status: according to the lists of major and minor crops, wheat and barley are major

crops in Poland.

Regarding pest status: according to the lists of major and minor pests, the pests which are mentioned above are major ~~crops~~ pests in Poland.

### **Compliance with the Uniform Principles**

Data to support the registration of SAP50SCF has been generated by GEP companies and following EPPO/CEB guidelines. No deviations to these EPPO/CEB guidelines have been observed on the performance of the trials. Therefore, it can be concluded that the overall assessment can be performed according to the uniform principles.

### **Information on trials submitted (3.1 Efficacy data)**

An overview of submitted trials can be consulted on the following pages on tabular form. The list of all individual trials is detailed in the table 3.2.3.-1: “List of efficacy trials carried out on SAP50SCF” (see point 3.2.3 “Efficacy tests”).

**Table 3.2-3: Presentation of trials (efficacy trials, MED trials...)**

Crop(s) *	Target(s) *	Country	Years	Type of trial **	Number of trials (number of valid trials)			GEP, non-GEP, official ***	Comments (any other relevant information)
					Maritime zone	South-East zone	North-East zone		
Wheat	SEPTTR	FR	2020	MED+E	3 (2)			GEP	
			2021	MED+E	2 (2)			GEP	
		RO	2021	MED+E		1(1)		GEP	
		BG	2021	MED+E		2(2)		GEP	
		PL	2021	MED+E			4 (4)	GEP	
		HU	2021	MED+E		1 (1)		GEP	
		DE	2020	MED+E	2 (2)			GEP	
			2021	MED+E	2 (2)			GEP	
		UK	2020	MED+E	1 (1)			GEP	
			2021	MED+E	1 (1)			GEP	
Barley	PYRNTE	FR	2020	MED+E	3(3)			GEP	
			2021	MED+E	3(3)			GEP	
			2022	MED+E	2			GEP	Trials on-going
		BG	2021	MED+E		2(2)		GEP	
		PL	2021	MED+E			4(3)	GEP	
		RO	2021	MED+E		1(1)		GEP	
		HU	2021	MED+E		1(0)		GEP	
		UK	2021	MED+E	1(0)				
		DE	2020	MED+E	2(0)			GEP	
			2021	MED+E	2(0)			GEP	
	Total	-	2020-2021	P	-	-	-	GEP	

Crop(s) *	Target(s) *	Country	Years	Type of trial **	Number of trials (number of valid trials)			GEP, non-GEP, official ***	Comments (any other relevant information)
					Maritime zone	South-East zone	North-East zone		
	Total	-	2020-2021	MED	22 (16)	8 (7)	8 (7)	GEP	2 other trials on-going
	Total	-	2020-2021	E	22 (16)	8 (7)	8 (7)	GEP	2 other trials on-going
	Total	-	2020-2021	WHEAT	11 (10)	4 (4)	4 (4)	GEP	
	Total	-	2020-2021	BARLEY	11 (6)	4 (3)	4 (3)	GEP	2 other trials on-going
	<b>TOTAL</b>	-	<b>2020-2021</b>	-	<b>22 (16)</b>	<b>8 (7)</b>	<b>8 (7)</b>	<b>GEP</b>	2 other trials on-going

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

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

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

A reduced data package on Barley under North-Eastern conditions is submitted. However, submitted data package was prepared to cover a wide range of agroclimatological conditions across EU. Although presented as a dossier for a National registration in Poland, data from other EPPO climatic conditions should be considered as relevant for PL registration based on:

- Barley (and wheat) crops are grown under very similar conditions across EU (showing rate, growing dates, varieties, cultivation equipment...).
- According to EUROSTAT database (data from 2023), trials were distributed on main countries for Barley cropping (France and Germany as main countries for Barley cultivated area in EU, representing 18-15.6% of Barley cultivated area respectively, while Poland representing the 6%)
- In addition, trials were distributed mainly in areas where the disease was expected as most damaging (with more common periods of rainfall and leaf wetness, such as North-France).

Presented data package can support the authorization of SAP50SCF on Barley on Poland. Applicant approach is based on the EPPO guideline PP 1/226 (3) Number of efficacy trials, which states a possible reduction in the number of trials to be done based on the supporting evidence of the use of the product and on the similarity of the pests and crop. Reported data on Barley shows a similar disease pressure on the different trials across EU regardless of the climatic EPPO zone (please refer to data reported on Table 3.2.3.2 b on page 59): 13.9%-15.8%-12.5% average disease severity under Maritime, NE and SE conditions respectively; Reported data also shows a similar product behavior, showing 74.2-82.9-81.9% efficacy at 0.9 l/ha and 81.9-85.5-84.2% at 1.2 l/ha.

Therefore, based on the EPPO guideline PP1/226 (3), on the similarity of agronomical conditions across EU and on the demonstrated similar disease development and product behavior across EPPO climatic conditions, submitted data package is considered as enough to support the use of SAP50SCF on Barley in Poland.

#### Comments of zRMS:

The zRMS standpoint on the above statement of the applicant, inserted as part of the update (starting: “A reduced data package on Barley [...]”), has been explained in the [commenting box](#) following the *Efficacy tests* chapters.

A total of 38 trials on wheat and barley are submitted (22 in Maritime EPPO climatic zone, 8 in North-East EPPO climatic zone, 8 in South-East EPPO climatic zone).

Besides, another 2 trials performed in 2022 in France in Maritime EPPO zone, in Barley against *Helminthosporium*, are on-going and will be submitted once finished.

Trials considered as not valid when no disease have appeared (so they are used as selectivity trials), showed infestation on secondary diseases or the infestation on the main disease was too low to calculate any efficacy value.

**Table 3.2-4: Presentation of reference standards used in trials (efficacy trials, preliminary trials...)**

Crop(s)	Reference standard	Country(ies) where the product is registered <sup>(1)</sup>	Authorization number	Active substance(s)	Formulation		Registered application rate <sup>(3)</sup>	Application rate in trials (per treatment)	Remark <sup>(4)</sup>
					Type <sup>(2)</sup>	Concentration of a.s.			
Wheat	FOLPAN 500 SC	Germany	024256-00	Folpet	SC	500 g/L	1.5 L/ha	1.5 L/ha	
	Dithane Neotec	Germany	033924-00	Mancozeb	WG	750 g/kg	2.13 kg/ha	2.13 kg/ha	
	Torero	Germany	008235-00	Azoxystrobin	SC	250 g/L	1 L/ha	1 L/ha	
	SESTO	France	2190321	Folpet	SC	500 g/L	1.5 L/ha	1.5 L/ha	
	ACTIOL Phyteurop	France	8300063	Sulphur	SC	800 g/L	10 l/ha	10 l/ha	
	MANITOBA	United Kingdom	16539	Epoxiconazole + Folpet	SC	50 g/L + 375 g/L	2 L/ha	2 L/ha	
	Microthiol Special	United Kingdom	19419	Sulphur	WG	800 g/kg	10 kg/ha	10 kg/ha	
	AMISTAR 25 SC	Bulgaria	RD 11-2606	Azoxystrobin	SC	250 g/L	0.6 L/ha -0.8 L/ha	0.6 L/ha -0.8 L/ha	
	AMISTAR 25 SC	Hungary	35042/2001	Azoxystrobin	SC	250 g/L	0.75-1 L/ha	1 L/ha	
	TAZER 250 SC	Poland	410/2016	Azoxystrobin	SC	250 g/L	1 L/ha	1 L/ha	
	TAZER 250 SC	Romania	110PC	Azoxystrobin	SC	250 g/L	1 L/ha	1 L/ha	
	Arizona	United Kingdom	15318	Folpet	SC	500 g/L	1.5 L/ha	1.5 L/ha	
	Thiopron	United Kingdom	19147	Sulphur	SC	825 g/L	9.7 L/ha	9.7 L/ha	
Barley	Melucine 25 SC	France	2160839	Azoxystrobin	SC	250 g/L	1 L/ha	1 L/ha	
	AMISTAR	France	9600093	Azoxystrobin	SC	250 g/L	1 L/ha	1 L/ha	
	AMISTAR 25 SC	Bulgaria	RD 11-2606	Azoxystrobin	SC	250 g/L	0.6 L/ha -0.8 L/ha	0.6 L/ha	
	TAZER 250 SC	Poland	410/2016	Azoxystrobin	SC	250 g/L	1 L/ha	1 L/ha	
	TAZER 250 SC	Romania	110PC	Azoxystrobin	SC	250 g/L	1 L/ha	1 L/ha	
	Arizona	United Kingdom	15318	Folpet	SC	500 g/L	1.5 L/ha	1.5 L/ha	
	AMISTAR 25 SC	Hungary	35042/2001	Azoxystrobin	SC	250 g/L	0.75-1 L/ha	0.75 L/ha	
	Torero	Germany	008235-00	Azoxystrobin	SC	250 g/L	1 L/ha	1 L/ha	

### 3.2.1 Preliminary tests (KCP 6.1)

Folpet is an old active substance well known under several commercial formulations and which has been used for over a decade across Europe, such as SESTO (France, 2190321). SAP50SCF is targeting similar formulations and consequently no preliminary trials were considered to be necessary.

However, one laboratory trial has been performed, in order to demonstrate the benefit of Folpet against resistances.

To be able to compare and prove this benefit against resistances, a different product with known-resistance problems have been chosen: Prothioconazole.

Prothioconazole is a Triazole, which is one of the best solutions against *Septoria* in Wheat. However, lately, the more and more resistant strains to triazoles are found, what decrease or suppress the efficacy of those products.

That is why Folpet, which is has multisite contact activity and for instance do not create resistance, is a perfect solution to fight against this important problem.

In the following trial, it was evaluated the efficacy of SAP50SCF (Folpet) at the requested doses (0,9 L/ha and 1,2 L/ha) in wheat against two strains of Septoria leaf blotch (*Zemoseptoria tritici*): one resistant and one not resistant to Prothioconazole.

Results are presented hereafter:

Pest Type	D; Disease	D; Disease	D; Disease	D; Disease	D; Disease	D; Disease	Comments
Pest Code	SEPTTR	SEPTTR	SEPTTR	SEPTTR	SEPTTR	SEPTTR	
Crop Type, Code	C; TRZAW	C; TRZAW	C; TRZAW	C; TRZAW	C; TRZAW	C; TRZAW	
Crop Name	Winter wheat	Winter wheat	Winter wheat	Winter wheat	Winter wheat	Winter wheat	
Crop Variety	Palesio	Palesio	Palesio	Palesio	Palesio	Palesio	
Rating Date	12/7/2021	19/7/2021	26/7/2021	12/7/2021	19/7/2021	26/7/2021	
Part Rated	LEAF; P	LEAF; P	LEAF; P	LEAF; P	LEAF; P	LEAF; P	
Rating Type	PESSEV	PESSEV	PESSEV	PESSEV	PESSEV	PESSEV	
Rating Unit/Min/Max	%; 0; 100	%; 0; 100	%; 0; 100	%UNCK; -; -	%UNCK; -; -	%UNCK; -; -	
Sample Size	20 LEAF	20 LEAF	20 LEAF	20 LEAF	20 LEAF	20 LEAF	
Collection Basis	1 PLOT	1 PLOT	1 PLOT	1 PLOT	1 PLOT	1 PLOT	
Reporting Basis	1 PLOT	1 PLOT	1 PLOT	1 PLOT	1 PLOT	1 PLOT	
Crop Stage Scale	BBCH	BBCH	BBCH	BBCH	BBCH	BBCH	
Crop Stage Majority/Min/Max	14; 14; 15	15; 14; 16	15; 14; 16	14; 14; 15	15; 14; 16	15; 14; 16	
Days After First/Last Applic.	14; 14	21; 21	28; 28	14; 14	21; 21	28; 28	
Trt-Eval Interval	14 DA-A	21 DA-A	28 DA-A	14 DA-A	21 DA-A	28 DA-A	
Plant-Eval Interval	35 DP-1	42 DP-1	49 DP-1	35 DP-1	42 DP-1	49 DP-1	
ARM Action Codes	S05	S05	S05	@UTAB[5]	@UTAB[9]	@UTAB[13]	
Column n°	5	9	13	7	11	15	
Untreated and non inoculated	0,0 d	0,0 e	0,0 f	100,0	100,0	100,0	Sensible Sensitive to Prothioconazole
Untreated Check Z1	11,0 a	20,6 a	38,2 a	9,4	12,2	9,2	
SAP50SCF – 0.9 L/ha	0,3 d	0,9 e	6,7 cde	97,6	95,3	82,1	
SAP50SCF – 1.2 L/ha	0,1 d	0,6 e	3,5 ef	99,2	96,9	90,4	
Prothioconazole – 0.48 L/ha	3,3 bcd	6,0 b-e	13,7 bc	66,9	70,8	65,2	Resistant to Prothioconazole
Untreated Check Z2	10,1 a	20,4 a	39,3 a	8,8	3,0	2,2	
SAP50SCF – 0.9 L/ha	1,0 d	2,6 cde	9,4 cde	89,3	87	76,1	
SAP50SCF – 1.2 L/ha	0,8 d	2,2 de	5,4 de	91,5	88,9	86,2	
Prothioconazole – 0.48 L/ha	9,6 a	18,9 a	36,2 a	6,6	7,5	8,1	

As it is observable, efficacy of the products SAP50SCF (Folpet) and Prothioconazole is very similar in the strain which is sensible to the Prothioconazole. For that reason, both products have a good control in *Septoria* when there are applied in a sensible strain of wheat.

However, if results in the resistant strain are analysed, it is clearly demonstrable that Prothioconazole loses its control against *Septoria* while Folpet keep a similar control of the disease than in the sensible strain of wheat.

#### Comments of zRMS:

The data presented above are consistent with the trial report `KCP 3.2.1 (1) 63-F-2020-FR01.pdf`. The results have been accepted as supporting the sensitivity to folpet, of the tested prothioconazole-resistant strains of *Z. tritici*.

**To conclude, it has been demonstrated that Folpet do not lose its efficacy in resistant strains, what make it an excellent tool to fight against resistances.**

Besides, according to several organisations, hereafter are some recommendations for fungicides in cereals.

#### **FRAG (Fungicide Resistance Management in Cereals) (UK)**

*“The majority of modern fungicides have single-site modes of action, acting on specific biochemical pathways in the target fungal pathogen. Once a fungicide is used on a pathogen population, individual isolates of the fungal population that have a reduced sensitivity to the fungicide will be selected by repeated use of fungicides with the same mode of action. Multi-site fungicides are less prone to the development of resistance in the target pathogen and these older fungicides still have a very important role in the resistance strategy for the more modern fungicides.”*

#### **AHDB – “Wheat and barley disease management guide” (UK)**

*“Fungicides with multisite modes of action are much less prone to resistance. The process of mutation and selection, leading to resistance, is rarely seen with multisites outside the laboratory.”*

*“Fungicide resistance management strategies should:*

- Exploit all practical, non-chemical control options*

*...*

- Include a multisite fungicide, where available, in both the early and late-season sprays”*

#### **Resistance to fungicides – Cereals**

**Note commune 2022; INRAE, Anses, ARVALIS - Institut du Végétal (FR)**

#### **“RECOMMANDATIONS GENERALES POUR 2022**

- Recourir lorsque cela est possible et utile aux fongicides multisites, moins susceptibles de sélectionner des populations résistantes, en particulier sur septoriose.”*

Translated, that would be:

#### **GENERAL RECOMMENDATIONS IN 2022**

- Apply, when possible and useful, multi-site fungicides, which are less susceptible to select resistant populations, especially in *Septoria*.

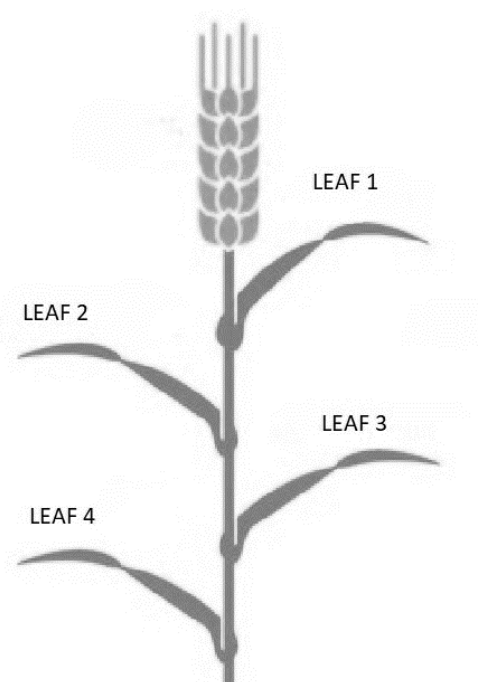
**Therefore, all these organisations recommend a multi-site fungicide in order to fight against resistances.**

**For all these reasons, SAP50SCF, based on Folpet, is considered to be a good tool against *Septoria* in Wheat and *Helminthosporium* in Barley, not only because of its efficacy, but to prevent resistant strains.**



### 3.2.2 Minimum effective dose tests (KCP 6.2)

In order to explain how the leaf levels have been evaluated, the following scheme is presented:



To determine the minimum effective dose of **SAP50SCF** against *Septoria* in Wheat and *Helminthosporium* in Barley, different rates (0.6, 0.9, 1.2 and 1.5 L/ha) were tested in the performed trials (for further details, please refer to BAD).

In order to establish the minimum effective dose rate, a study of the ~~rate~~ dose response of **SAP50SCF** is presented below, comparing the achieved control in the requested uses. Data is summarised numerically using tables and graphically in box whisker plots showing maximum, minimum, median, 25 and 75% quartiles. The results have been reported separately according the different EPPO climatic zones. However, to reinforce the results they have been presented together as well.

### 3.2.2.1 Wheat - *Septoria*

19 field trials were established in order to determine the minimum effective dose for the control of *Septoria* in Wheat, in 2020 and 2021, in countries belonging to 3 three EPPO climatic zones: Maritime, North-East and South-East. SAP50SCF was tested from 0,6 L/ha to 1.5 L/ha (500 g Folpet/L). Those rates reflect the requested label rates (0.9 – 1.2 L/ha), 60%\* of the requested rates (0.6 L/ha), in accordance with the EPPO standard PP 1/225 '*Minimum effective dose*', and an extra rate which is higher than the requested doses (1.5 L/ha).  
For each trial, the most representative leaf level and evaluation have been analyzed.

#### Comments of zRMS:

\*the dose rate of 0.6 L/ha represents 66.7 – 50.0% of the dose rates within the (proposed) dose range of 0.9-1.2 L/ha.

**Table 3.2.2.1- a: Minimum effective dose – Control of *Septoria* in Wheat (LEAF1-4) achieved by SAP50SCF at most representative evaluation (28 DA-A – 39 DA-B) – Detailed table (with individual trials` datapoints)** Refer to BAD.

To compare the effectiveness of the fungicide at the different doses, as a dose range is requested, both doses (0.9 and 1.2 L/ha) are compared with all the tested rates.

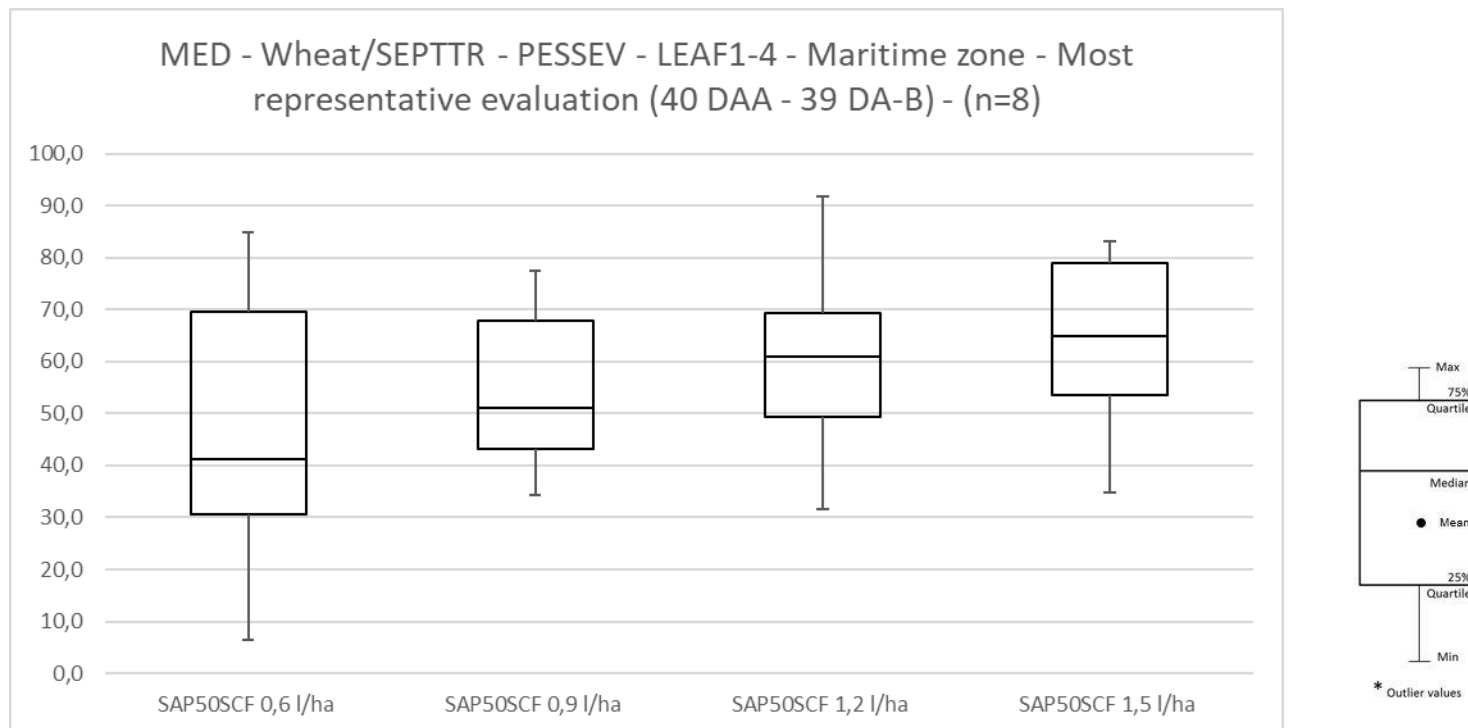
**Table 3.2.2.1- b: Minimum effective dose – Control of Septoria in Wheat (LEAF 1-4) achieved by SAP50SCF at most representative evaluation (~~28-DA-A-39-DA-B~~) (22-82 DAA; 0-55 DAB) – Dose 0.9 L/ha**

Target	Nb of trials	Untreated plot	% control				Nb of trials where SAP50SCF 0,9 l/ha is >, < or =	Nb of trials where SAP50SCF 0,9 l/ha is >, < or =	Nb of trials where SAP50SCF 0,9 l/ha is >, < or =
			SAP50SCF 0,6 l/ha	SAP50SCF 0.9 l/ha	SAP50SCF 1,2 l/ha	SAP50SCF 1,5 l/ha			
		Mean Max Min	Mean Max Min	Mean Max Min	Mean Max Min	Mean Max Min	SAP50SCF 0,6 L/ha	SAP50SCF 1,2 L/ha	SAP50SCF 1,5 L/ha
% CONTROL (28 DAA - 39 DAB) Global average	15	15,2	52,5	64,4	69,9	73,0	> 7 = 8 < 0	> 0 = 12 < 3	> 0 = 12 < 3
		43,2	85,0	85,7	91,8	95,4			
		5,2	6,3	34,4	31,5	34,9			
% CONTROL (28 DAA - 39 DAB) Maritime EPPO zone	8	18,5	47,4	54,4	60,2	63,8	> 3 = 5 < 0	> 0 = 7 < 1	> 0 = 7 < 1
		43,2	85,0	77,5	91,8	83,2			
		6,2	6,3	34,4	31,5	34,9			
% CONTROL (21-34 DAB) North-East EPPO zone	4	11,2	63,0	75,3 72,3	84,3	86,2	> 1 = 3 < 0	> 0 = 2 < 2	> 0 = 2 < 2
		16,6	78,8	83,3	91,7	95,4			
		5,2	52,4	65,8	75,5	75,1			
% CONTROL (11-27 DA-B) South-East EPPO zone	3	11,8	52,0	76,8	76,4	79,9	> 3 = 0 < 0	> 0 = 3 < 0	> 0 = 3 < 0
		13,2	73,8	85,7	87,4	92,0			
		10,9	36,9	65,0	65,0	70,0			

**Table 3.2.2.1- c: Minimum effective dose – Control of Septoria in Wheat (LEAF 1-4) achieved by SAP50SCF at most representative evaluation (~~30 DAA - 39 DAB~~) (22-82 DAA; 0-55 DAB) – Dose 1.2 L/ha**

Target	Nb of trials	Untreated plot	% control				Nb of trials where SAP50SCF 1,2 l/ha is >, < or =	Nb of trials where SAP50SCF 1,2 l/ha is >, < or =	Nb of trials where SAP50SCF 1,2 l/ha is >, < or =
			SAP50SCF 0,6 l/ha	SAP50SCF 0.9 l/ha	SAP50SCF 1,2 l/ha	SAP50SCF 1,5 l/ha			
		Mean Max Min	Mean Max Min	Mean Max Min	Mean Max Min	Mean Max Min	SAP50SCF 0,6 L/ha	SAP50SCF 0,9 L/ha	SAP50SCF 1,5 L/ha
% CONTROL (28 DAA - 39 DAB) Global average	15	15,2	52,5	64,4	69,9	73,0	> 9	> 3	> 0
		43,2	85,0	85,7	91,8	95,4	= 6	= 12	= 14
		5,2	6,3	34,4	31,5	34,9	< 0	< 0	< 1
% CONTROL (28 DAA - 39 DAB) Maritime EPPO zone	8	18,5	47,4	54,4	60,2	63,8	> 2	> 1	> 0
		43,2	85,0	77,5	91,8	83,2	= 6	= 7	= 7
		6,2	6,3	34,4	31,5	34,9	< 0	< 0	< 1
% CONTROL (21-34 DAB) North-East EPPO zone	4	11,2	63,0	75,3 72,3	84,3	86,2	> 4	> 2	> 0
		16,6	78,8	83,3	91,7	95,4	= 0	= 2	= 4
		5,2	52,4	65,8	75,5	75,1	< 0	< 0	< 0
% CONTROL (11-27 DA-B) South-East EPPO zone	3	11,8	52,0	76,8	76,4	79,9	> 3	> 0	> 0
		13,2	73,8	85,7	87,4	92,0	= 0	= 3	= 3
		10,9	36,9	65,0	65,0	70,0	< 0	< 0	< 0

**Figure 3.2.2.1- a: Minimum effective dose – Control of Septoria in Wheat (LEAF1-4) achieved by SAP50SCF at most representative evaluation (40 DA-A – 39 DA-B) – Maritime zone**



For Maritime EPPO climatic zone, according to the results reported in the Tables and Figure shown above, % severity of the untreated plots in the different leaf levels with *Septoria* in the 8 assessments had an average of 18.5%.

Tables and figures displayed above show that the lower rate of **SAP50SCF** (0.6 l/ha) presented a lower average control against *Septoria* in the different leaf levels on wheat than the requested application rates 0.9 and 1.2 l/ha.

To analyse data a comparative comparison between all rates have been done:

– comparative comparison with 0.9 l/ha dose

The lower rate of 0.6 l/ha reached an average control of 47.4%, while 0.9, 1.2 and 1.5 l/ha rates reached a 54.4%, 60.2% and 63.8% of control.

In 3 trials out of 8 significant differences have been found between the lower dose (0.6 l/ha) and the minimum requested dose (0.9 l/ha), proving a better control of the disease of this last one rate.

Between 0.9 l/ha and 1.2 l/ha, even if just in one trial significant differences have been found, a numerical difference is observable, proving a better control of 1.2 l/ha dose. This can be as well observed in the figure above, where the median of the box whisker plot at 1.2 l/ha is higher than at 0.9 l/ha.

Finally, between 0.9 l/ha and 1.5 l/ha, just one trial has shown significant differences. Besides, taking into account that 1.5 l/ha contains a 67% more Folpet than 0.9 l/ha, it has been considered that this high rate does not provide an efficacy sufficient in proportion.

– comparative comparison with 1.2 l/ha dose

The lower rate of 0.6 l/ha reached an average control of 47.4%, while 0.9, 1.2 and 1.5 l/ha rates reached a 54.4%, 60.2% and 63.8% of control.

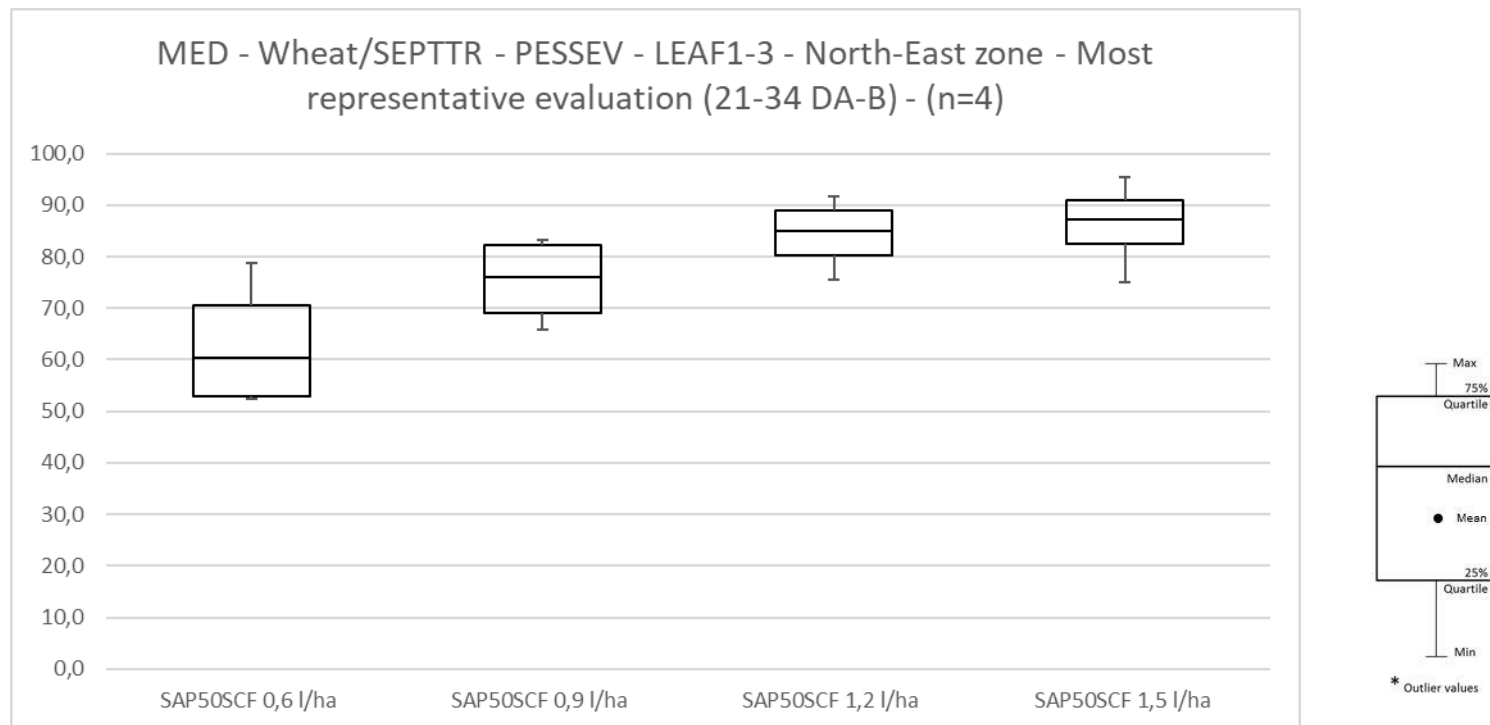
In 2 trials out of 8 significant differences have been found between the lower dose (0.6 l/ha) and the requested dose of 1.2 l/ha, proving a better control of the disease of this last one rate.

Between 1.2 l/ha and 0.9 l/ha, even if just in one trial significant differences have been found, a numerical difference is observable, proving a better control of 1.2 l/ha dose. This can be as well observed in the figure above, where the median of the box whisker plot at 1.2 l/ha is higher than at 0.9 l/ha.

Finally, between 1.2 l/ha and 1.5 l/ha, just one trial has shown significant differences. Besides, the numerical differences show a slightly better control of the higher dose (1.5 l/ha), proving a similar control than 1.2 l/ha dose.

In conclusion, all the reported data have shown that the 0.6 L/ha dose of SAP50SCF is non-effective, a rate of 0.9 L/ha being necessary to control *Septoria* in wheat, for Maritime EPPO climatic zone. Besides, the dose of 1.2 L/ha is considered as well necessary to achieve a more consistent and better control of the disease. The highest dose of 1.5 L/ha, showing similar results than 1.2 L/ha, has not been requested.

**Figure 3.2.2.1- b: Minimum effective dose – Control of Septoria in Wheat (LEAF1-4) achieved by SAP50SCF at most representative evaluation (30 DA-A – 36 DA-B) – North-East zone**



For North-East EPPO climatic zone, according to the results reported in the Table and Figure shown above, % severity of the untreated plots in the different leaf levels with *Septoria* in the 4 assessments had an average of 11.2%.

Tables and figures displayed above show that the lower rate of **SAP50SCF** (0.6 l/ha) presented a lower average control against *Septoria* in the different leaf levels on wheat than the requested application rates 0.9 and 1.2 l/ha.

To analyse data a comparative comparison between all rates have been done:

– comparative comparison with 0.9 l/ha dose

The lower rate of 0.6 l/ha reached an average control of 63%, while 0.9, 1.2 and 1.5 l/ha rates reached a 75.3%, 84.3% and 86.2% of control.

Even if just in 1 trial out of 4 significant differences have been found between the lower dose (0.6 l/ha) and the minimum requested dose (0.9 l/ha), there is an observable numerical difference, proving a better control of the disease of this last one rate. This can be as well observed in the figure above, where the median of the box whisker plot at 0.9 l/ha is clearly higher than at 0.6 l/ha.

Between 0.9 l/ha and 1.2 l/ha, 2 trials out of 4 have shown significant differences, proving a better control of by the 1.2 l/ha dose.

Finally, between 0.9 l/ha and 1.5 l/ha, two trials out of 4 have shown significant differences, the same number of differences than when compared to 1.2 l/ha. For that reason, it has been concluded that 1.5 l/ha does not provide an extra efficacy sufficient to be requested.

Nevertheless, only 4 trials have been performed in this EPPO climatic zone as it has been considered that data coming from Maritime zone can be extrapolated to the North-East zone, according to EPPO Guideline PP1/226(3) – ‘Number of efficacy trials’, which states that “*In some situations there may be the opportunity to reduce the number of trials done, and a case may be made for this as follows.*

- *Where there is a large amount of supporting evidence from use of the product, or of similar products with the same active substance, on closely related pests or against the same pests on different crops, the number of trials necessary will be determined by the amount of supporting evidence and the similarity of the pests and crops sought [...] Extrapolations from more challenging control situations to ones that pose a lower challenge to the active substance are more readily justifiable than extrapolations from less challenging to more challenging situations.*”

Trials performed in Maritime EPPO climatic zone have more favourable climatic conditions to develop the disease than other zones and have as well a bigger wheat production than other climatic zones, according to EUROSTAT database.

For that, reason it has been considered that Maritime EPPO zone is a more challenging zone for the requested diseases and crops, than the other EPPO zones.

Therefore, data coming from Maritime EPPO zone can be extrapolated to the other zones.

– comparative comparison with 1.2 l/ha dose

The lower rate of 0.6 l/ha reached an average control of 63%, while 0.9, 1.2 and 1.5 l/ha rates reached a 75.3%, 84.3% and 86.2% of control.

In all 4 trials significant differences have been found between the lower dose (0.6 l/ha) and the requested dose of 1.2 l/ha, proving a better control of the disease of this last one rate.

Between 1.2 l/ha and 0.9 l/ha, 2 trials out of 4 have shown significant differences, proving a better control of 1.2 l/ha dose.

Finally, between 1.2 l/ha and 1.5 l/ha, any of the 4 trials have shown significant differences, proving a similar control of both rates. For that reason, it has been Nevertheless, only 4 trials have been performed in this EPPO climatic zone as it has been considered that data coming from Maritime zone can be extrapolated to the North-East zone, according to EPPO Guideline PP1/226(3) – ‘Number of efficacy trials’, which states that “*In some situations there may be the opportunity to reduce the number of trials done, and a case may be made for this as follows.*

- *Where there is a large amount of supporting evidence from use of the product, or of similar products with the same active substance, on closely related pests or against the same pests on different crops,*



*the number of trials necessary will be determined by the amount of supporting evidence and the similarity of the pests and crops sought [...] Extrapolations from more challenging control situations to ones that pose a lower challenge to the active substance are more readily justifiable than extrapolations from less challenging to more challenging situations.”*

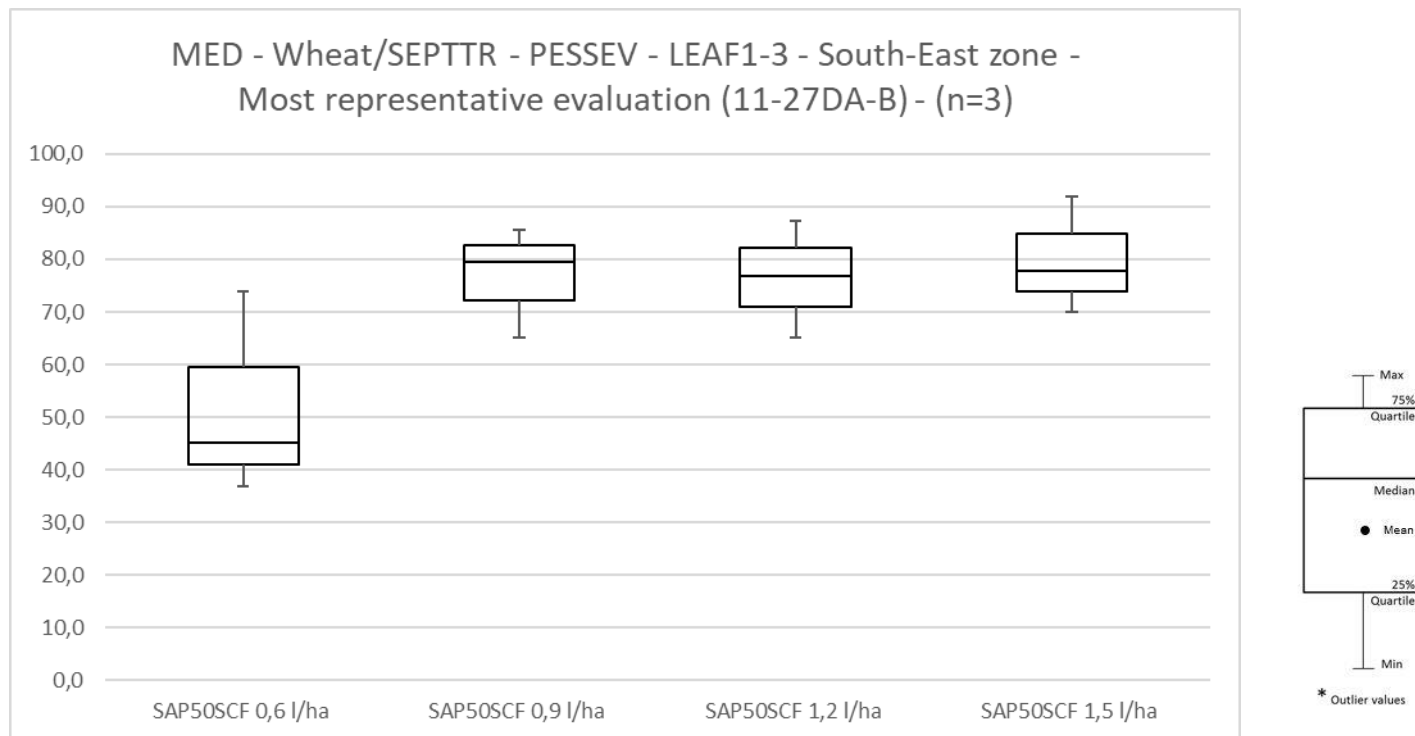
Trials performed in Maritime EPPO climatic zone have more favourable climatic conditions to develop the disease than other zones and have as well a bigger wheat production than other climatic zones, according to EUROSTAT database.

For that, reason it has been considered that Maritime EPPO zone is a more challenging zone for the requested diseases and crops, than the other EPPO zones.

Therefore, data coming from Maritime EPPO zone can be extrapolated to the other zones.

In conclusion, all the reported data have shown that the 0.6 L/ha of SAP50SCF dose is non-effective, a rate of 0.9 L/ha being necessary to control *Septoria* in wheat, for North-East EPPO climatic zone. Besides, the dose of 1.2 L/ha is considered as well necessary to achieve a more consistent and better control of the disease. The highest dose of 1.5 L/ha, showing similar results in terms of efficacy than 1.2 L/ha, has not been requested.

**Figure 3.2.2.1- c: Minimum effective dose – Control of Septoria in Wheat (LEAF1-3) achieved by SAP50SCF at most representative evaluation (11-27 DA-B) – South-East zone**



For South-East EPPO climatic zone, according to the results reported in the Table and Figure shown above, % severity of the untreated plots in the different leaf levels with *Septoria* in the 3 assessments had an average of 11.8%.

Tables and figures displayed above show that the lower rate of **SAP50SCF** (0.6 l/ha) presented a lower average control against *Septoria* in the different leaf levels on wheat than the requested application rates 0.9 and 1.2l/ha.

To analyse data a comparative comparison between all rates have been done:

– comparative comparison with 0.9 l/ha dose

The lower rate of 0.6 l/ha reached an average control of 52%, while 0.9, 1.2 and 1.5 l/ha rates reached a 76.8%, 76.4% and 79.9% of control.

In all 3 trials significant differences have been found between the lower dose (0.6 l/ha) and the minimum requested dose (0.9 l/ha), proving a better control of the disease of this last one rate.

Between 0.9 l/ha and 1.2 l/ha or 1.5 l/ha, ~~any~~ **no** trial has shown significant differences. However, just 3 trials have been analysed for this EPPO Climatic zone.

Nevertheless, only 4 trials have been performed in this EPPO climatic zone (and 3 trials have been analysed due to the disease level) as it has been considered that data coming from Maritime zone can be extrapolated to the South-East zone, according to EPPO Guideline PP1/226(3) – ‘Number of efficacy trials’, which states that “*In some situations there may be the opportunity to reduce the number of trials done, and a case may be made for this as follows.*

- *Where there is a large amount of supporting evidence from use of the product, or of similar products with the same active substance, on closely related pests or against the same pests on different crops, the number of trials necessary will be determined by the amount of supporting evidence and the similarity of the pests and crops sought [...] Extrapolations from more challenging control situations to ones that pose a lower challenge to the active substance are more readily justifiable than extrapolations from less challenging to more challenging situations.*”

Trials performed in Maritime EPPO climatic zone have more favourable climatic conditions to develop the disease than other zones and have as well a bigger wheat production than other climatic zones, according to EUROSTAT database.

For that, reason it has been considered that Maritime EPPO zone is a more challenging zone for the requested diseases and crops, than the other EPPO zones.

Therefore, data coming from Maritime EPPO zone can be extrapolated to the other zones.

– comparative comparison with 1.2 l/ha dose

The lower rate of 0.6 l/ha reached an average control of 52%, while 0.9, 1.2 and 1.5 l/ha rates reached a 76.8%, 76.4% and 79.9% of control.

In all 3 trials significant differences have been found between the lower dose (0.6 l/ha) and the requested dose of 1.2 l/ha, proving a better control of the disease of this last one rate.

Between 1.2 l/ha and 0.9 l/ha or 1.5 l/ha, any trial has shown significant differences. However, just 3 trials have been analysed for this EPPO Climatic zone.

Nevertheless, only 4 trials have been performed in this EPPO climatic zone (and 3 trials have been analysed due to the disease level) as it has been considered that data coming from Maritime zone can be extrapolated to the South-East zone, according to EPPO Guideline PP1/226(3) – ‘Number of efficacy trials’, which states that “*In some situations there may be the opportunity to reduce the number of trials done, and a case may be made for this as follows.*

- *Where there is a large amount of supporting evidence from use of the product, or of similar products with the same active substance, on closely related pests or against the same pests on different crops, the number of trials necessary will be determined by the amount of supporting evidence and the similarity of the pests and crops sought [...] Extrapolations from more challenging control situations to ones that pose a lower challenge to the active substance are more readily justifiable than extrapolations from less challenging to more challenging situations.*”

Trials performed in Maritime EPPO climatic zone have more favourable climatic conditions to develop the disease than other zones and have as well a bigger wheat production than other climatic zones, according to EUROSTAT database.

For that, reason it has been considered that Maritime EPPO zone is a more challenging zone for the requested diseases and crops, than the other EPPO zones.

Therefore, data coming from Maritime EPPO zone can be extrapolated to the other zones.

In conclusion, all the reported data, from trials performed in South-East and Maritime zones (as previously explained), have shown that the non-effective dose is 0.6 L/ha of SAP50SCF, being necessary a rate of 0.9 L/ha to control *Septoria* in wheat, for South-East EPPO climatic zone. Besides, the dose of 1.2 L/ha is considered as well necessary to achieve a more consistent and better control of the disease. The highest dose of 1.5 L/ha, showing similar results than 1.2 L/ha, has not been requested.

### **Conclusion Minimum Effective Dose – Wheat/*Septoria***

According to the reported data, 0.6 l/ha showed consistently worst efficacy results than the other tested rates, showing a global average efficacy close to 50%. Instead of that, from 0.9 l/ha the efficacy significantly increases to about 65%. 1.2 l/ha rate also increases the efficacy to almost 70%, with some significant differences with previous rate. Despite 1.5 l/ha still provide a better control than 1.2 l/ha, (around 73%), it is not significantly different.

Therefore, 0.6 l/ha is considered as non-effective dose rate for *Septoria* control. Effective rates range from 0.9 to 1.2 l/ha. Top target rate (1.2 l/ha) showed consistently higher efficacy values, regardless of the disease pressure. Therefore, it is ASCENZA recommendation that low rate (0.9 l/ha) should be used under low disease pressure conditions, using the top ones when moderate/high attacks are expected, in order to minimize the impact on crop production.

### 3.2.2.2 Barley – *Helminthosporium*

A total of 19 trials were carried out to evaluate the efficacy of **SAP50SCF** for the control of *Helminthosporium* in barley.

Besides, another 2 trials are still on-going and will be submitted once finished.

However, for different reasons, 7 trials have not been taken into account for this section:

- In 06-F-2021-HU01 trial, any diseases have appeared, so this trial has been used as selectivity trials.
- In 06-F-2021-UK01, 06-F-2021-DE01, 06-F-2021-DE02, 18-F-2020-DE01, 18-F-2020-DE02 and 06-F-2021-PL05 trials, other diseases were present in the trial but not *Helminthosporium*.

**Table 3.2.2.- a: Minimum effective dose – Control of *Helminthosporium* in Barley (LEAF 1-4) achieved by SAP50SCF at most representative evaluation (24 DA-A- 35 DA-B) – Detailed table (with individual trials` datapoints)** Refer to BAD.

To compare the effectiveness of the fungicide at the different doses, as a range is requested, both doses (0.9 and 1.2 L/ha) are compared with all the tested rates.

~~Table 3.2.2.1- b~~

**Table 3.2.2.2- b: Minimum effective dose – Control of *Helminthosporium* in Barley (LEAF 1-4 ~~3~~) achieved by SAP50SCF at most representative evaluation (~~24 DA- A – 35 DA-B~~) (33-56 DAA; 11-28 DAB) – Dose 0.9 L/ha**

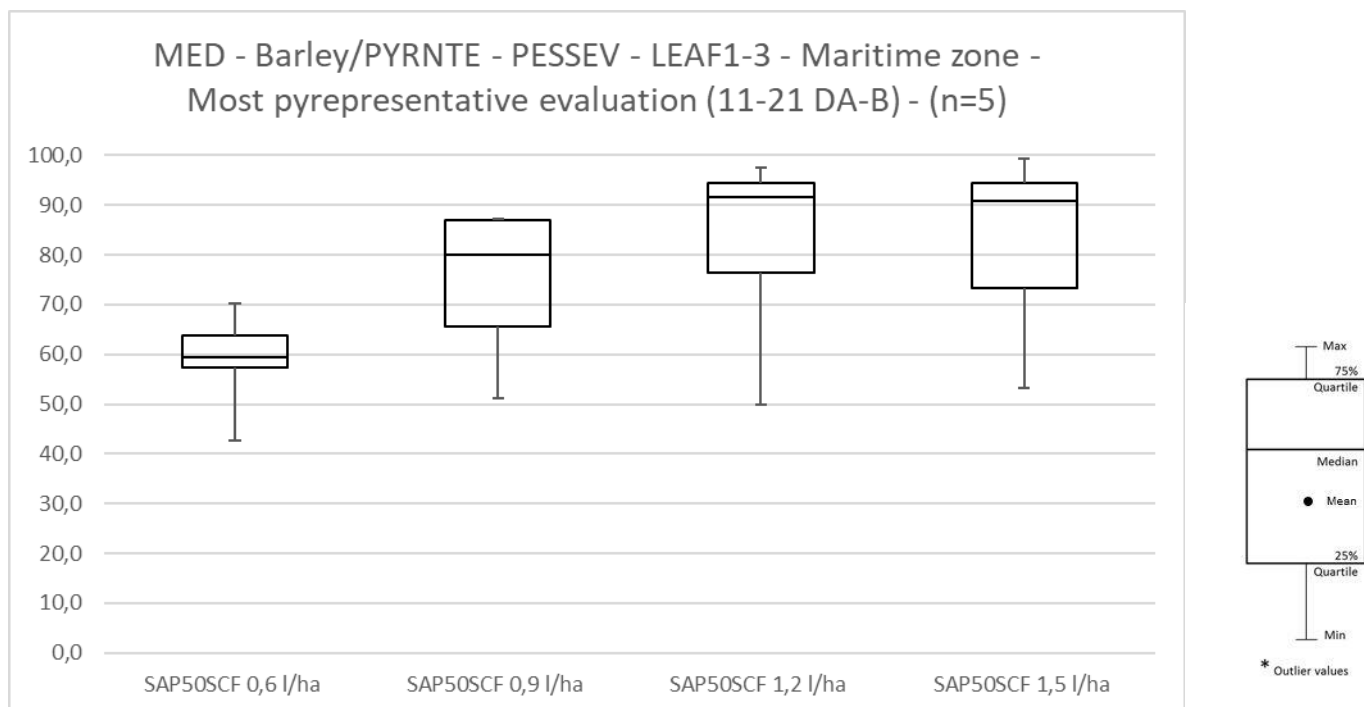
Target	Nb of trials	Untreated plot	% control				Nb of trials where SAP50SCF 0,9 l/ha is >, < or =	Nb of trials where SAP50SCF 0,9 l/ha is >, < or =	Nb of trials where SAP50SCF 0,9 l/ha is >, < or =
			SAP50SCF 0,6 l/ha	SAP50SCF 0.9 l/ha	SAP50SCF 1,2 l/ha	SAP50SCF 1,5 l/ha			
		Mean Max Min	Mean Max Min	Mean Max Min	Mean Max Min	Mean Max Min	SAP50SCF 0,6 L/ha	SAP50SCF 1,2 L/ha	SAP50SCF 1,5 L/ha
% CONTROL (24 DAA - 35 DAB) Global average	11 10	16,1	<del>57,1</del> 61,3	<del>73,5</del> 78,3	<del>76,7</del> 83,3	<del>78,3</del> 83,8	> 4 3 = 7 < 0	> 0 = 9 < 2	> 0 = 9 < 2
		49,9 41,2	70,2 79,5	94,3	97,5	99,3			
		6,3	42,7	<del>49,3</del> 51,2	<del>42,8</del> 50,0	<del>48,4</del> 53,3			
% CONTROL (11 - 21 DAB) Maritime EPPO zone	5	13,9	58,7	74,2	81,9	82,3	> 0 = 5 < 0	> 0 = 5 < 0	> 0 = 5 < 0
		41,2	70,2	87,2	97,5	99,3			
		6,3	42,7	51,2	50,0	53,3			
% CONTROL (14-28 DAB) North-East EPPO zone	2	15,8	77,1	82,9	85,5	86,4	> 0 = 2 < 0	> 0 = 1 < 1	> 0 = 1 < 1
		17,8	79,5	86,8	86,4	86,8			
		13,8	74,6	78,9	84,5	85,9			
% CONTROL (21-28 DA-B) South-East EPPO zone	3	12,5	55,2	81,9	84,2	84,7	> 3 = 0 < 0	> 0 = 2 < 1	> 0 = 2 < 1
		21,0	64,0	94,3	94,3	94,3			
		7,1	47,0	72,0	78,8	79,5			

Table 3.2.2.1-e

**Table 3.2.2.2- c: Minimum effective dose – Control of *Helminthosporium* in Barley (LEAF 1-4 3) achieved by SAP50SCF at most representative evaluation (24 DA- A – 35 DA-B) (33-56 DAA; 11-28 DAB) – Dose 1.2 L/ha**

Target	Nb of trials	Untreated plot	% control				Nb of trials where SAP50SCF 1,2 l/ha is >, < or =	Nb of trials where SAP50SCF 1,2 l/ha is >, < or =	Nb of trials where SAP50SCF 1,2 l/ha is >, < or =
			SAP50SCF 0,6 l/ha	SAP50SCF 0,9 l/ha	SAP50SCF 1,2 l/ha	SAP50SCF 1,5 l/ha			
		Mean Max Min	Mean Max Min	Mean Max Min	Mean Max Min	Mean Max Min	SAP50SCF 0,6 L/ha	SAP50SCF 0,9 L/ha	SAP50SCF 1,5 L/ha
% CONTROL (24 DAA - 35 DAB) Global average	11 10	16,1	57,1 61,3	73,5 78,3	76,7 83,3	78,3 83,8	> 6 = 5 4 < 0	> 2 = 9 < 0	> 0 = 11 < 0
		49,9 41,2	70,2 79,5	94,3	97,5	99,3			
		6,3	42,7	49,3 51,2	42,8 50,0	48,4 53,3			
% CONTROL (11 - 21 DAB) Maritime EPPO zone	5	13,9	58,7	74,2	81,9	82,3	> 2 = 3 < 0	> 0 = 5 < 0	> 0 = 5 < 0
		41,2	70,2	87,2	97,5	99,3			
		6,3	42,7	51,2	50,0	53,3			
% CONTROL (14-28 DAB) North-East EPPO zone	2	15,8	77,1	82,9	85,5	86,4	> 1 = 1 < 0	> 1 = 1 < 0	> 0 = 2 < 0
		17,8	79,5	86,8	86,4	86,8			
		13,8	74,6	78,9	84,5	85,9			
% CONTROL (21-28 DA-B) South-East EPPO zone	3	12,5	55,2	81,9	84,2	84,7	> 3 = 0 < 0	> 1 = 2 < 0	> 0 = 3 < 0
		21,0	64,0	94,3	94,3	94,3			
		7,1	47,0	72,0	78,8	79,5			

**Figure 3.2.2.1- a: Minimum effective dose – Control of *Helminthosporium* in Barley (LEAF 1-4) achieved by SAP50SCF at most representative evaluation – Maritime zone**





For Maritime EPPO climatic zone, according to the results reported in the Table and Figure shown above, % severity of the untreated plots in the different leaf levels with *Helminthosporium* in the 5 assessments had an average of 13.9%.

Tables and figures displayed above show that the lower rate of SAP50SCF (0.6 l/ha) presented a lower average control against *Helminthosporium* in the different leaf levels on barley than the requested application rates 0.9 and 1.2 l/ha.

To analyse data a comparative comparison between all rates have been done:

– comparative comparison with 0.9 l/ha dose

The lower rate of 0.6 l/ha reached an average control of 58.7%, while 0.9, 1.2 and 1.5 l/ha rates reached a 74.2%, 81.9% and 82.3% of control.

Even if any trial has shown 8 significant differences between the lower dose (0.6 l/ha) and the minimum requested dose (0.9 l/ha), an important numerical difference is observable, proving a better control of the disease of this last one rate. Besides, this is as well remarkable in the figure above, where the median of the 0.9 L/ha rate (around 80% of efficacy) is clearly higher than the median of 0.6 L/ha (around 60% of efficacy).

Between 0.9 l/ha and 1.2 l/ha, even in any trial significant differences have been found neither, a numerical difference is also observable, proving a better control of 1.2 l/ha dose. This can be as well observed in the figure above, where the median of the box whisker plot at 1.2 l/ha (around 92% of efficacy) is higher than at 0.9 l/ha (around 80% of efficacy).

Finally, between 0.9 l/ha and 1.5 l/ha, any trial has shown significant differences. Taking into account that the efficacy achieved by 1.2 L/ha and 1.5 L/ha are very similar and that 0.9 l/ha contains a 67% less Folpet than 1.5 l/ha, it has been considered that this high rate does not provide an efficacy sufficient in proportion.

– comparative comparison with 1.2 l/ha dose

The lower rate of 0.6 l/ha reached an average control of 58.7%, while 0.9, 1.2 and 1.5 l/ha rates reached a 74.2%, 81.9% and 82.3% of control.

In 2 trials out of 5 significant differences have been found between the lower dose (0.6 l/ha) and the requested dose of 1.2 l/ha, proving a better control of the disease of this last one rate. Besides, this difference is as well observed in the figure above, where the median of 1.2 L/ha reached a median of 92% while the median of 0.6 L/ha was 60%.

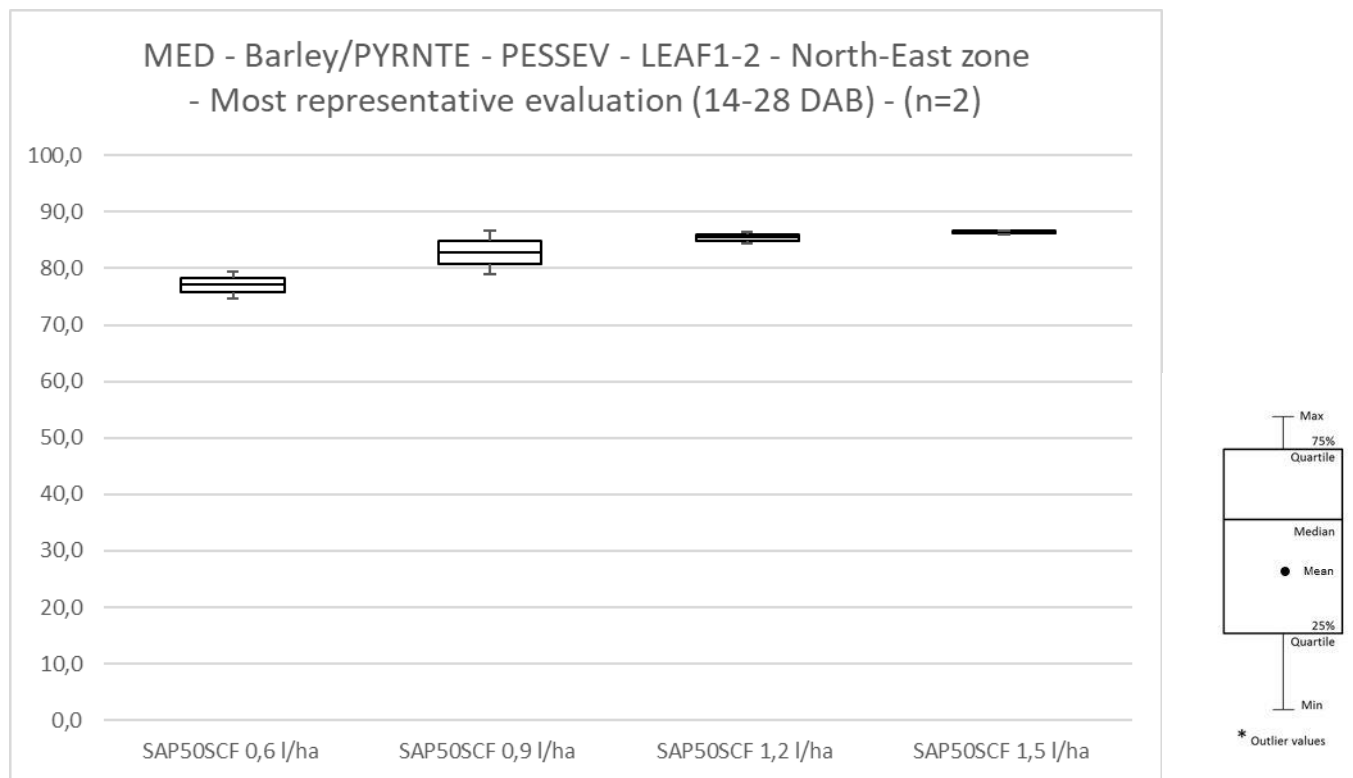
Between 1.2 l/ha and 0.9 l/ha, even if in any trial significant differences have been found, a numerical difference is observable, proving a better control of 1.2 l/ha dose. This can be as well observed in the figure above, where the median of the box whisker plot at 1.2 l/ha (around 92% of control) is higher than at 0.9 l/ha (around 80% of control).

Finally, between 1.2 l/ha and 1.5 l/ha, any trial has shown significant differences. What is more, the numerical differences show a slightly better control of the higher dose (1.5 l/ha), proving a similar control than 1.2 l/ha dose.

In conclusion, all the reported data have shown that the non-effective dose is 0.6 L/ha of SAP50SCF, being necessary a rate of 0.9 L/ha to control *Helminthosporium* in barley, for Maritime EPPO climatic zone. Besides, the dose of 1.2 L/ha is considered as well necessary to achieve a more consistent and better control of the disease. The highest dose of 1.5 L/ha, showing similar results than 1.2 L/ha, has not been requested.

Besides, in order to confirm the Minimum efficacy dose, another 2 trials are still on-going and will be submitted once finished.

**Figure 3.2.2.1- b: Minimum effective dose – Control of Helminthosporium in Barley (LEAF 1-2) achieved by SAP50SCF at most representative evaluation (14-28 DA-B) – North-East zone**



For North-East EPPO climatic zone, according to the results reported in the Table and Figure shown above, % severity of the untreated plots in the different leaf levels with *Helminthosporium* in the 2 assessments had an average of 15.8%.

Tables and figures displayed above show that the lower rate of **SAP50SCF** (0.6 l/ha) presented a lower average control against *Helminthosporium* in the different leaf levels on wheat than the requested application rates 0.9 and 1.2l/ha.

To analyse data a comparative comparison between all rates have been done:

– comparative comparison with 0.9 l/ha dose

The lower rate of 0.6 l/ha reached an average control of 77.1%, while 0.9, 1.2 and 1.5 l/ha rates reached an 82.9%, 85.5% and 86.4% of control.

Even if in any of the 2 trials significant differences have been found between the lower dose (0.6 l/ha) and the minimum requested dose (0.9 l/ha), a numerical difference is observable, showing 0.9 l/ha a better control.

Between 0.9 l/ha and 1.2 l/ha, 1 out of 2 trials have shown significant differences, demonstrating a better control at 1.2 L/ha rate.

Then, between 0.9 l/ha and 1.5 l/ha, 1 out of 2 trials have shown significant differences too, demonstrating a better control at 1.5 L/ha rate. However, taking into account that the efficacy achieved by 1.2 L/ha and 1.5 L/ha are very similar and that 1.5 l/ha contains a 67% more Folpet than 0.9 l/ha, it has been considered that this high rate does not provide an efficacy sufficient in proportion.

However, just 4 trials have been performed in this EPPO climatic zone, and 2 valid trials have been analysed, as it has been considered that data coming from Maritime zone can be extrapolated to the North-East zone, according to EPPO Guideline PP1/226(3) – ‘Number of efficacy trials’, which states that “*In some situations there may be the opportunity to reduce the number of trials done, and a case may be made for this as follows.*

- *Where there is a large amount of supporting evidence from use of the product, or of similar products with the same active substance, on closely related pests or against the same pests on different crops, the number of trials necessary will be determined by the amount of supporting evidence and the similarity of the pests and crops sought [...] Extrapolations from more challenging control situations to ones that pose a lower challenge to the active substance are more readily justifiable than extrapolations from less challenging to more challenging situations.*”

Trials performed in Maritime EPPO climatic zone have more favourable climatic conditions to develop the disease than other zones and have as well a bigger barley production than other climatic zones, according to EUROSTAT database.

For that, reason it has been considered that Maritime EPPO zone is a more challenging zone for the requested diseases and crops, than the other EPPO zones.

Therefore, data coming from Maritime EPPO zone can be extrapolated to the other zones.

– comparative comparison with 1.2 l/ha dose

The lower rate of 0.6 l/ha reached an average control of 77.1%, while 0.9, 1.2 and 1.5 l/ha rates reached an 82.9%, 85.5% and 86.4% of control.

In 1 out of 2 trials significant differences have been found between the lower dose (0.6 l/ha) and the requested dose of 1.2 l/ha, proving a better control of the disease of this last one rate.

Between 1.2 l/ha and 0.9 l/ha, significant differences have been found in 1 trial out of 2, demonstrating a better control of 1.2 l/ha rate.

Then, between 1.2 l/ha and 1.5 l/ha, any trial has shown significant differences, proving a similar control of both rates.

However, just 4 trials have been performed in this EPPO climatic zone, and 2 valid trials have been analysed, as it has been considered that data coming from Maritime zone can be extrapolated to the North-East zone, according to EPPO Guideline PP1/226(3) – ‘Number of efficacy trials’, which states

that “*In some situations there may be the opportunity to reduce the number of trials done, and a case may be made for this as follows.*

- *Where there is a large amount of supporting evidence from use of the product, or of similar products with the same active substance, on closely related pests or against the same pests on different crops, the number of trials necessary will be determined by the amount of supporting evidence and the similarity of the pests and crops sought [...] Extrapolations from more challenging control situations to ones that pose a lower challenge to the active substance are more readily justifiable than extrapolations from less challenging to more challenging situations.”*

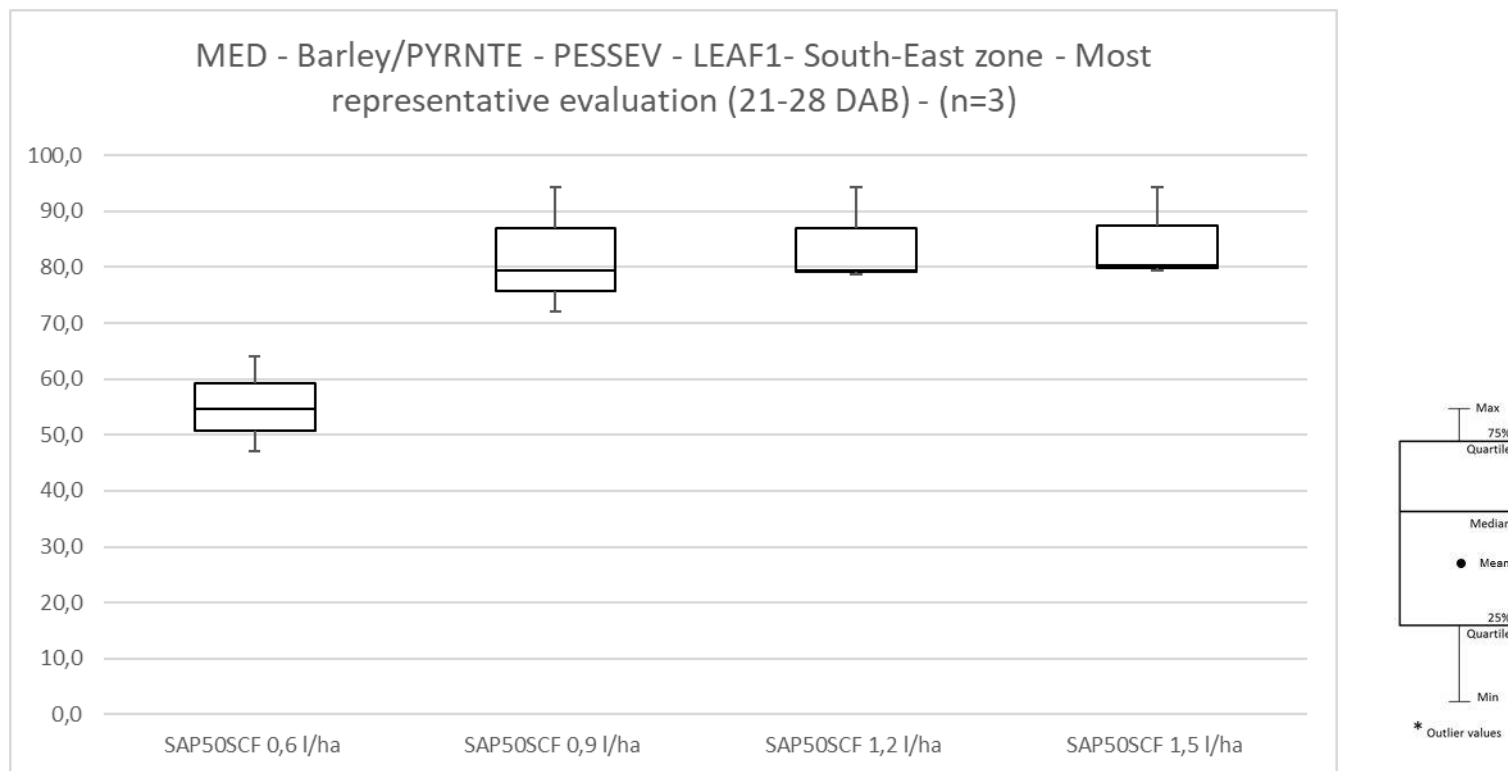
Trials performed in Maritime EPPO climatic zone have more favourable climatic conditions to develop the disease than other zones and have as well a bigger barley production than other climatic zones, according to EUROSTAT database.

For that, reason it has been considered that Maritime EPPO zone is a more challenging zone for the requested diseases and crops, than the other EPPO zones.

Therefore, data coming from Maritime EPPO zone can be extrapolated to the other zones.

In conclusion, all the reported data, from trials performed in North-East and Maritime zones (as previously explained), have shown that the non-effective dose is 0.6 L/ha of SAP50SCF, being necessary a rate of 0.9 L/ha to control *Helminthosporium* in barley. Besides, the dose of 1.2 L/ha is considered as well necessary to achieve a more robust control of the disease. The highest dose of 1.5 L/ha, showing similar results than 1.2 L/ha, has not been requested.

**Figure 3.2.2.1- c: Minimum effective dose – Control of *Helminthosporium* in Barley (LEAF 1-4) achieved by SAP50SCF at most representative evaluation – South-East zone**



For South-East EPPO climatic zone, according to the results reported in the Table and Figure shown above, % severity of the untreated plots in the different leaf levels with *Helminthosporium* in the 3 assessments had an average of 12.5%.

Tables and figures displayed above show that the lower rate of **SAP50SCF** (0.6 l/ha) presented a lower average control against *Helminthosporium* in the different leaf levels on wheat than the requested application rates 0.9 and 1.2l/ha.

To analyse data a **comparative comparison** between all rates have been done:

– **comparative comparison** with 0.9 l/ha dose

The lower rate of 0.6 l/ha reached an average control of 55.2%, while 0.9, 1.2 and 1.5 l/ha rates reached an 81.9%, 84.2% and 84.7% of control.

In all 3 trials significant differences have been found between the lower dose (0.6 l/ha) and the minimum requested dose (0.9 l/ha), proving a better control of the disease of this last one rate.

Between 0.9 l/ha and 1.2 l/ha, 1 out of 3 trials have shown significant differences, demonstrating a better control at 1.2 L/ha rate.

Then, between 0.9 l/ha and 1.5 l/ha, 1 out of 3 trials have shown significant differences too, demonstrating a better control at 1.5 L/ha rate. However, taking into account that the efficacy achieved by 1.2 L/ha and 1.5 L/ha are very similar and that 1.5 l/ha contains a 67% more Folpet than 0.9 l/ha, it has been considered that this high rate does not provide an efficacy sufficient in proportion.

However, just 4 trials have been performed in this EPPO climatic zone, and 3 valid trials have been analysed, as it has been considered that data coming from Maritime zone can be extrapolated to the South-East zone, according to EPPO Guideline PP1/226(3) – ‘Number of efficacy trials’, which states that “*In some situations there may be the opportunity to reduce the number of trials done, and a case may be made for this as follows.*”

• *Where there is a large amount of supporting evidence from use of the product, or of similar products with the same active substance, on closely related pests or against the same pests on different crops, the number of trials necessary will be determined by the amount of supporting evidence and the similarity of the pests and crops sought [...] Extrapolations from more challenging control situations to ones that pose a lower challenge to the active substance are more readily justifiable than extrapolations from less challenging to more challenging situations.*”

Trials performed in Maritime EPPO climatic zone have more favourable climatic conditions to develop the disease than other zones and have as well a bigger barley production than other climatic zones, according to EUROSTAT database.

For that, reason it has been considered that Maritime EPPO zone is a more challenging zone for the requested diseases and crops, than the other EPPO zones.

Therefore, data coming from Maritime EPPO zone can be extrapolated to the other zones.

– **comparative comparison** with 1.2 l/ha dose

The lower rate of 0.6 l/ha reached an average control of 55.2%, while 0.9, 1.2 and 1.5 l/ha rates reached an 81.9%, 84.2% and 84.7% of control.

In all 3 trials significant differences have been found between the lower dose (0.6 l/ha) and the requested dose of 1.2 l/ha, proving a better control of the disease of this last one rate.

Between 1.2 l/ha and 0.9 l/ha, significant differences have been found in 1 trial out of 3, demonstrating a better control of 1.2 l/ha rate.

Then, between 1.2 l/ha and 1.5 l/ha, any trial has shown significant differences, proving a similar control of both rates.

However, just 4 trials have been performed in this EPPO climatic zone, and 3 valid trials have been analysed, as it has been considered that data coming from Maritime zone can be extrapolated to the South-East zone, according to EPPO Guideline PP1/226(3) – ‘Number of efficacy trials’, which states

that “*In some situations there may be the opportunity to reduce the number of trials done, and a case may be made for this as follows.*

- *Where there is a large amount of supporting evidence from use of the product, or of similar products with the same active substance, on closely related pests or against the same pests on different crops, the number of trials necessary will be determined by the amount of supporting evidence and the similarity of the pests and crops sought [...] Extrapolations from more challenging control situations to ones that pose a lower challenge to the active substance are more readily justifiable than extrapolations from less challenging to more challenging situations.”*

Trials performed in Maritime EPPO climatic zone have more favourable climatic conditions to develop the disease than other zones and have as well a bigger barley production than other climatic zones, according to EUROSTAT database.

For that, reason it has been considered that Maritime EPPO zone is a more challenging zone for the requested diseases and crops, than the other EPPO zones.

Therefore, data coming from Maritime EPPO zone can be extrapolated to the other zones.

In conclusion, all the reported data, from trials performed in South-East and Maritime zones (as previously explained), have shown that the non-effective dose is 0.6 L/ha of SAP50SCF, being necessary a rate of 0.9 L/ha to control *Helminthosporium* in barley. Besides, the dose of 1.2 L/ha is considered as well necessary to achieve a more robust control of the disease. The highest dose of 1.5 L/ha, showing similar results than 1.2 L/ha, has not been requested.

### **Conclusion Minimum Effective Dose – Barley/*Helminthosporium***

According to the reported data, 0.6 l/ha showed consistently worst efficacy results than the other tested rates (specially in Maritime EPPO climatic zone), showing a global average efficacy close to 57% ~~%~~. Instead of that, from 0.9 l/ha the efficacy significantly increases to about 73%. 1.2 l/ha rate also increases the efficacy to almost 78%, with some significant differences with previous rate. ~~Despite~~ **In spite of** the 1.5 l/ha ~~provide~~ **providing** still better control than 1.2 l/ha, (around 78%), it is not significantly different **from the lower dose rate**.

Therefore, 0.6 l/ha is considered as non-effective dose rate for *Helminthosporium* control. Effective rates range from 0.9 to 1.2 l/ha. Top target rate (1.2 l/ha) showed consistently higher efficacy values, regardless of the disease pressure. Therefore, it is ASCENZA recommendation that low rate (0.9 l/ha) should be used under low disease pressure conditions, using the top ones when moderate/high attacks are expected, in order to minimize the impact on crop production.

#### **Comments of zRMS on the MED:**

The information that the present submission was intended for Poland alone had been revealed by the applicant already in the course of the evaluation. That is why the zRMS comments reflect the initial, Central Zone – oriented approach to dossier assessment. However, since the EPPO zones are discussed separately nevertheless, to the opinion of zRMS there is no reason to alter the approach: the comments concerning other zones may simply be disregarded by the reader.

#### **SEPTTR in wheat**

##### **1) Data summaries**

###### **The Maritime zone and the North-East zone**

The zRMS confirms that merging the Maritime and the North-East zone data from neighbouring MSs, either for the estimation of the MED or for the proper efficacy assessment, as developed further in this document, is acceptable.

###### **The South-East zone**

On the contrary, neither the summarizing of the combined data sets from the South-East and the Maritime zone, nor the “extrapolating” from one zone to another can be accepted, since the data sets proposed as mutually supportive come from the MSs not neighboring one another (DE, FR and UK *vs* RO+BG). Therefore the 3 trials available from the SE EPPO zone should be treated as self-standing data set.

##### **2) The MED values**

In light of all the 15 trials summarized for the MED assessment (Table 3.2.2.1-b and Table 3.2.2.1-c), the **1.2 L/ha** is the minimum effective dose rate of SAP50SCF to control SEPTTR in wheat in the Maritime, in the North East and, most probably, in the South East zone.

It should be noted that the efficacy of the 1.2 L/ha dose rate does exceed 80% only in the NE zone trials, and that the “global average” (n=15) efficacy of the 1.2 L/ha is hardly 70%. The same is essentially valid even for the 1.5 L/ha (the dose rate not requested), at which the dose rate **only the global average** efficacy is >70%, and **only the NE zone efficacy** is >80% (Table 3.2.2.1-b and Table 3.2.2.1-c).

Please also note, that in the set of 8 Maritime trials the min-max **efficacy range** is ca. 34-78% at 0.9L/ha and ca. 32-**92%** (*sic!*) at 1.2 L/ha. Likewise, in the NE zone the maxima of the efficacy range differ widely between the 0.9 and the 1.2 L/ha (83% *vs* 92% respectively). In contrast to the Mar and the NE zones, in the SE zone the difference between the efficacy of the 0.9 and 1.2 L/ha is negligible, both in the average and in the range of min-max values, making any considerations on the dose range – irrelevant.

Taken all the above into account, the recommending of the dose **range** of 0.9-1.2 L/ha, instead of the fixed 1.2 L/ha dose rate, in any EPPO zone indeed is, to the opinion of zRMS, unwise, even if the multi-site MoA character of the active folpet is considered, making the resistance issues of no concern. All the products currently authorized in Poland, of the identical folpet solo content of the active as the proposed SAP50SCF (500 g/L), are used against SEPTTR at the fixed dose rate of **1.5 L/ha**, thus delivering 750 g/ha a.s. Therefore proposing 450-600 g/ha a.s. **in a new product** is incomprehensible (unless triggered by restrictions from other sections of the



dossier). Instead, setting the highest dose proposed by the applicant as the fixed dose rate of 1.2 L/ha represents, to the opinion of zRMS, more robust and more sustainable a solution. The **1.2L /ha is definitely the Minimum Effective dose rate** for the control of SEPTTR in wheat.

### **PYRNTE in barley**

#### **1) Data summaries**

Since there is considerable a distance between the trial locations (FR, PL, BG+RO) and the respective MSs do not neighbor one another, the data sets presented for each EPPO zone (n=5, n=2, n=3, Mar, NE, SE respectively) should be considered separately from one another rather than merged in order to draw any profound conclusions.

#### **2) The MED values**

Contrary to the control of SEPTTR in wheat, the efficacy of the test item against PYRNTE at the 1.2 L/ha dose rate exceeds 80% in each EPPO zone. However, proposing dose **range** would be justified only in the Maritime zone, where the efficacy of the lower dose, 0.9 L/ha, is lower by nearly 8% compared to that of 1.2 L/ha, and where the data set of 5 trials justifies more robust conclusions. Conversely, the data for the NE (n=2) and the SE (n=3) EPPO zones are inconclusive, and implementing dose range in these zones is justified neither by the trial count nor by the negligible dose response observed (2.6% and 2.3% respectively).

Consequently, in light of all the 10 valid trials summarized for the MED assessment (Table 3.2.2.2-b and Table 3.2.2.2-c), the **1.2 L/ha** is definitely the only common MED of SAP50SCF to control PYRNTE in barley. Please note that all the products currently authorized in Poland, of the identical folpet solo content of the active as the proposed SAP50SCF (500 g/L), are used in barley only against RHYNSE, at the fixed dose rate of **1.5** L/ha, delivering 750 g/ha a.s. Bearing that in mind, the proposing of 450-600 g/ha a.s. (0.9-1.2 L/ha f.p.) **in a new product** and for the same crop is challenging from the efficacy perspective, since it means exposing the other pathogen present in the crop next to PYRNTE (i.e. RHYNSE) and already controlled by this active, to its lower dose compared to the dose used hitherto.

Given these circumstances, the setting of the highest proposed dose **of 1.2 L/ha** as the **fixed** minimum effective dose rate represents, to the opinion of zRMS, more robust and more sustainable a solution.

[To the zRMS comments on efficacy](#)

[To the zRMS abstract](#)

### 3.2.3 Efficacy tests (KCP 6.2)

A total of 38 field trials have been performed in France, Germany, United Kingdom, Hungary, Bulgaria, Romania and Poland under Maritime, North-East and South-East EPPO climatic conditions, from 2020 to 2021, in wheat and barley to evaluate the effectiveness of **SAP50SCF** (500 g Folpet/L) at the proposed range dose of 0.9-1.2 L/ha.

Besides, another 2 trials are still on-going and will be submitted once finished.

However, one trial has been used as selectivity trial and not taken into account for this section, due the non-appearance of disease (06-F-2021-HU01) and other trials were not considered due to the low infestation or the appearance of another disease.

**Table 3.2.3-1: Details on trial methodology**

#### WHEAT

<b>Guidelines</b>	General guidelines	EPPO PP 1/152(2), PP 1/181 (2), PP 1/135(2)
	Specific guidelines	EPPO PP 1/26(4), 1/242(2), 1/243(2), CEB 218
<b>Experimental design</b>	Plot design	RCBD
	Plot size	15-20 – 30 m <sup>2</sup>
	Number of replications	4
<b>Crop</b>	Trials per crop	Wheat (19-18)
	Varieties per crop	Arkadia, Barrel, Basmati, Bataja, RGT Bilanz, Creek (2), Euforia, Filon, Glosa, Gravity, Inspiration, Oregrain, Patras, GK Pilis, Porthus, Sadovo, Tobak, Trapez
<b>Application</b>	Crop stage (BBCH)* at application	Application A: BBCH 30-47 30-59 Application B: BBCH 37-69
	Timing Pest stage at application (1)	Application at first apparition of symptoms
	Number of applications Intervals between applications	2 applications -Application A: beginning of disease on leaf 3 -Application B: A1 + 3/4 weeks
	Spray volumes	150 – 300 L/ha
<b>Assessment</b>	Assessment types	PESINC (% incidence) PESSEV (% severity) GRNARE (% Green leaf area) YIELD (T/ha - harvest) PHYGEN (% phytotoxicity)
	Assessment dates	Pre-spray assessment: 0 (-1) DA-A Further assessments: - 0 DA-B; - 1-2 weeks after application B; - 3 weeks after application B.
<b>Other relevant information</b>	e.g. Natural / artificial inoculation...	Natural
	e.g. Field / Greenhouse...	Field

#### BARLEY

<b>Guidelines</b>	General guidelines	EPPO PP 1/152(2), PP 1/181 (2), PP 1/135(2)
	Specific guidelines	EPPO PP 1/26(4)

<b>Experimental design</b>	Plot design	RCBD
	Plot size	15 –24 m <sup>2</sup>
	Number of replications	4
<b>Crop</b>	Trials per crop	Barley ( <del>18</del> 10)
	Varieties per crop	Akkord, <del>Cervoise</del> , KWS Dementiel, Etincel (2), KWS Faro, Funky, <del>Galation</del> , <del>Kosmos</del> , Metaksa, <del>Oberek</del> , Obzor, <del>KWS Orbit</del> , Padura, Propino, Quadriga, <del>Saphira</del> Saphira.
<b>Application</b>	Crop stage (BBCH)* at application	Application A: BBCH <del>30-34</del> 31-33 Application B: BBCH <del>43-69</del> 41-59
	Timing Pest stage at application (1)	Application at first apparition of symptoms
	Number of applications Intervals between applications	2 applications -Application A: beginning of disease on leaf 3 -Application B: A1 + 3/4 weeks
	Spray volumes	200 – 300 L/ha
<b>Assessment</b>	Assessment types	PESINC (% incidence) PESSEV (% severity) GRNARE (% Green leaf area) YIELD (T/ha - harvest) PHYGEN (% phytotoxicity)
	Assessment dates	Pre-spray assessment: 0 (-1) DA-A Further assessments: - 0 DA-B; - 1-2 weeks after application B; - 3 weeks after application B.
<b>Other relevant information</b>	e.g. Natural / artificial inoculation...	Natural
	e.g. Field / Greenhouse...	Field

## Numerical and statistical analysis

Data were subjected to analysis of variance (ANOVA) at the 95% confidence level. When significant differences were found a Student-Newman-Keuls (SNK) Post-Hoc test were applied to separate the means.

Treatment means with no letters in common are significantly different according to SNK test. Bartlett's test was applied to study the assumption of ANOVA of homogeneity of variances. When it was necessary in order to improve the statistical analysis, raw data were transformed according to the appropriated transformation to increase homogeneity. In those cases, depending of the trial, means have been reported as de-transformed averages, as transformed averages or as raw averages with the statistical analysis of the transformed data.

### 3.2.3.1 Wheat/*Septoria*

A total of 19 trials were carried out to evaluate the efficacy of **SAP50SCF** for the control of *Septoria* in wheat.

Only data on SEPTTR (*Zymoseptoria tritici*) is reported. Data on other diseases appearing sporadically in some trials are not reported as being not relevant for the requested authorisations.

However, due to the ~~apparition~~ occurrence of another disease (PUCCST) and the absence of SEPTTR, 1 trial has not been taken into account for this section (17-F-2020-FR06).

**Table 3.2.3.1 a. Total *Septoria* of Wheat disease control (%) of PESSEV, achieved by SAP50SCF and the reference products at most representative evaluation – Detailed table (with individual trials` datapoints)** Refer to BAD.

Different reference products have been applied (different active ingredients), due to the different authorized products of each country. For that reason, in order to do an orthogonal comparison, four tables are presented here below with all the results.

**Table 3.2.3.1 b. Total *Septoria* of Wheat disease control (%) of PESSEV, achieved by SAP50SCF and the reference products – Reference 1**

Target	Nb of trials	Untreated plot	% control			Nb of trials where SAP50SCF 0,9 l/ha is >, < or =	Nb of trials where SAP50SCF 1,2 l/ha is >, < or =
			SAP50SCF 0.9 l/ha	SAP50SCF 1,2 l/ha	REF 1		
		Mean Max Min	Mean Max Min	Mean Max Min	Mean Max Min	REF 1	REF 1
% CONTROL (28 DAA - 39 DAB) Global average	9	12,8	68,2	74,9	68,0	> 2 = 4 < 3	> 3 = 5 < 1
		20,0	85,7	91,7	95,7		
		5,2	34,4	51,7	9,4		
% CONTROL (28 DAA - 39 DAB) 42-56 DAA; 20-30 DAB Maritime EPPO zone	2	17,5	41,4	54,0	33,1	> 1 = 1 < 0	> 1 = 1 < 0
		20,0	48,3	56,3	56,7		
		15,0	34,4	51,7	9,4		
% CONTROL (21-34 DAB) 42-55 DAA; 21-34 DAB North-East EPPO zone	4	11,2	75,3	84,3	78,3	> 1 = 1 < 2	> 2 = 2 < 0
		16,6	83,3	91,7	95,7		
		5,2	65,8	75,5	65,2		
% CONTROL (11-27 DAB) 35-52 DAA; 11-27 DAB South-East EPPO zone	3	11,8	76,8	76,4	77,5	> 0 = 2 < 1	> 0 = 2 < 1
		13,2	85,7	87,4	94,0		
		10,9	65,0	65,0	68,9		

**Note:**

- REF 1 (Azoxystrobin 250 g/L): AMISTAR at 1 L/ha (except in Bulgaria, where it is applied at 0,6\*\* and 0,8\* L/ha); Torero at 1 L/ha; Tazer at 1 L/ha;

The table above shows a summary of the control of **SAP50SCF** at 0.9 L/ha (450 g Folpet/ha) and 1.2 L/ha (600 g Folpet/ha) against *Septoria* on wheat, compared to **Reference 1** at 1 L/ha (250 g Azoxystrobin /ha), except in Bulgaria, which is applied at 0.6 and 0.8 L/ha (150 and 200 g of Azoxystrobin/ha).

The commercial names of the products belonging to Reference 1 group are the following ones: AMISTAR at 1 L/ha (except in Bulgaria, where it is applied at 0,6 and 0,8 L/ha); Torero at 1 L/ha; Tazer at 1 L/ha.

It was considered only the most representative evaluation timing and the most representative variable as the % severity (PESSEV) in Leaf 1, Leaf 2, Leaf 3 or Leaf 4 reached by the disease. According to the results, % severity in trials conducted ranged from 5.2 to 20 % in Maritime, North-East and South-East EPPO zones, where this reference product has been applied.

In the Maritime EPPO zone, the % severity in the untreated plots in all conducted trials ranged from 15 to 20%.

The efficacy average value obtained by **SAP50SCF** at 0.9 l/ha is 41.4 % and at 1.2 L/ha is 54% according to the assessments performed, and the one obtained by the Reference 1 is 33.1%.

In 1 out of 2 trials no significant differences were found between SAP50SCF at any requested dose and the references products belonging to Reference 1 group, showing a similar control than the authorized products. The other trial showed SAP50SCF at 0.9 L/ha and 1.2 L/ha to be significantly better than the reference product.

However, only two trials were performed with this reference product in the Maritime zone, so those results have to be taken carefully.

In the North-East EPPO zone, the % severity in the untreated plots in all conducted trials ranged from 5.2 to 16.6%.

The efficacy average value obtained by **SAP50SCF** at 0.9 l/ha is 75.3% and at 1.2 L/ha is 84.3% according to the assessments performed, and the one obtained by the Reference 1 is 78.3%.

Between SAP50SCF at 0.9 L/ha and the references products belonging to Reference 1 group (250 g Azoxystrobin /ha), in 1 out of 4 trials no significant differences have been found, being the control of SAP50SCF higher in 1 trial and lower in the 2 other trials. So, in general, results are showing a similar control of SAP50SCF than the authorized products.

Besides, SAP50CF at 1.2 L/ha, in comparison with the reference product (250 g Azoxystrobin /ha), has showed a similar control as in 2 out of 4 trials no significant differences have been found. Then, for the other 2 trials, SAP50SCf at 1.2 L/ha has proved to be statistically better than Reference 1.

In the South-East EPPO zone, the % severity in the untreated plots in all conducted trials ranged from 10.9 to 13.2%.

The efficacy average value obtained by **SAP50SCF** at 0.9 l/ha is 76.8% and at 1.2 L/ha is 76.4% according to the assessments performed, and the one obtained by the Reference 1 is 77.5%.

Furthermore, no significant differences were found between SAP50SCF at both requested doses and the references products belonging to Reference 1 group in 2 of the 3 trials, showing a similar control than the authorized products.

In resume, those facts indicate a similar behaviour in the control of *Septoria* in wheat achieved by **SAP50SCF** at requested doses (0.9 and 1.2 L/ha) and references tested products.

**Table 3.2.3.1 c. Total *Septoria* of Wheat disease control (%) of PESSEV, achieved by SAP50SCF and the reference products – Reference 2**

Target	Nb of trials	Untreated plot	% control			Nb of trials where SAP50SCF 0,9 l/ha is >, < or =	Nb of trials where SAP50SCF 1,2 l/ha is >, < or =
			SAP50SCF 0.9 l/ha	SAP50SCF 1,2 l/ha	REF 2		
		Mean Max Min	Mean Max Min	Mean Max Min	Mean Max Min	REF 2	REF 2
% CONTROL (28 DAA- 39 DAB) Global average	8	18,5	54,4	60,2	59,4	> 0 = 7 < 1	> 0 = 7 < 1
		43,2	77,5	91,8	87,5		
		6,2	34,4	31,5	34,0		
% CONTROL (28 DAA- 39 DAB) Maritime EPPO zone	8	18,5	54,4	60,2	59,4	> 0 = 7 < 1	> 0 = 7 < 1
		43,2	77,5	91,8	87,5		
		6,2	34,4	31,5	34,0		
% CONTROL North-East EPPO zone	0	-	-	-	-	-	-
		-	-	-	-		
		-	-	-	-		
% CONTROL South-East EPPO zone	0	-	-	-	-	-	-
		-	-	-	-		
		-	-	-	-		

**Note:**

- REF 2 (Folpet 500 g/L): Arizona at 1.5 L/ha; SESTO at 1.5 L/ha; FOLPAN 500 at 1.5 L/ha.

The table above shows a summary of the control of **SAP50SCF** at 0.9 L/ha (450 g Folpet/ha) and 1.2 L/ha (600 g Folpet/ha) against *Septoria* on wheat, compared to **Reference 2** at 1.5 L/ha (750 g Folpet/ha).

The commercial names of the products belonging to Reference 2 group are the following ones: Arizona at 1.5 L/ha; SESTO at 1.5 L/ha; FOLPAN 500 at 1.5 L/ha.

It was considered only the most representative evaluation timing and the most representative variable as the % severity (PESSEV) in Leaf 1, Leaf 2, Leaf 3 or Leaf 4 reached by the disease. According to the results, % severity in trials conducted ranged from 6.2 to 43.2 % in Maritime EPPO zones, where this reference product has been applied.

In the Maritime EPPO zone, the % severity in the untreated plots in all conducted trials ranged from 6.2 to 43.2%.

The efficacy average value obtained by **SAP50SCF** at 0.9 l/ha is 54.4 % and at 1.2 L/ha is 60.2% according to the assessments performed, and the one obtained by the Reference 2 is 59.4%.

In 7 out of 8 trials no significant differences were found between SAP50SCF at any requested dose and the references products belonging to Reference 2 group, proving a similar control than the authorized products.

In resume, those facts indicate a similar behaviour in the control of *Septoria* in wheat achieved by **SAP50SCF** at requested doses (0.9 and 1.2 L/ha) and references tested products.



**Table 3.2.3.1 d. Total *Septoria* of Wheat disease control (%) of PESSEV, achieved by SAP50SCF and the reference products – ~~Reference 2~~ and Reference 3**

Target	Nb of trials	Untreated plot	% control				Nb of trials where SAP50SCF 0,9 l/ha is >, < or =		Nb of trials where SAP50SCF 1,2 l/ha is >, < or =	
			SAP50SCF 0,9 l/ha	SAP50SCF 1,2 l/ha	REF 2	REF 3				
		Mean Max Min	Mean Max Min	Mean Max Min	Mean Max Min	Mean Max Min	REF 2	REF 3	REF 2	REF 3
% CONTROL (28 DAA - 39 DAB) Global average	4	14,4	62,7	66,9	61,2	70,6	≥0	> 0	≥0	> 0
		27,1	77,5	91,8	75,5	87,0	=4	= 4	=4	= 3
		6,2	45,8	42,5	34,0	37,2	≤0	< 0	≤0	< 1
% CONTROL (28 DAA - 39 DAB) Maritime EPPO zone	4	14,4	62,7	66,9	61,2	70,6	≥0	> 0	≥0	> 0
		27,1	77,5	91,8	75,5	87,0	=4	= 4	=4	= 3
		6,2	45,8	42,5	34,0	37,2	≤0	< 0	≤0	< 1
% CONTROL North-East EPPO zone	0	-	-	-	-	-	-	-	-	-
		-	-	-	-	-				
		-	-	-	-	-				
% CONTROL South-East EPPO zone	0	-	-	-	-	-	-	-	-	-
		-	-	-	-	-				
		-	-	-	-	-				

**Note:**

~~REF 2 (Folpet 500 g/L): Arizona at 1.5 L/ha; SESTO at 1.5 L/ha; FOLPAN 500 at 1.5 L/ha.~~

- REF 3 (Sulphur 800 g/L): Actiol Phytoeurop at 10 L/ha; Thiopron at 9.7 L/ha (but contains 825 g/L); Microthiol Special at 10 kg/ha (800 g/kg).

The table above shows a summary of the control of **SAP50SCF** at 0.9 and 1.2 L/ha (450 g Folpet /ha and 600 g Folpet/ha) against *Septoria* on wheat, compared to **Reference 2** applied at 1.5 L/ha (equivalent to 750 g of Folpet/ha) and **Reference 3** (applying the equivalent to 8 kg of Sulphur/ha).

The commercial names of the products belonging to Reference 2 are the following ones: Arizona at 1.5 L/ha; SESTO at 1.5 L/ha; FOLPAN 500 at 1.5 L/ha.

The commercial name of the product belonging to Reference 3 is the following ones: Actiol Phytoeurop at 10 L/ha; Thiopron at 9.7 L/ha (but contains 825 g/L); Microthiol Special at 10 kg/ha (800 g/kg).

It was considered only the most representative evaluation timing and the most representative variable as the % severity (PESSEV) in Leaf 1, Leaf 2, Leaf 3 or Leaf 4 reached by the disease. According to the results, % severity in trials conducted ranged from 6.2 to 27.1% in Maritime EPPO zone, where those reference products have been applied.

In the Maritime EPPO zone, the % severity in the untreated plots in all conducted trials ranged from 6.2 to 27.1%.

The efficacy average value obtained by **SAP50SCF** at 0.9 l/ha is 62.7% and at 1.2 L/ha is 66.9% according to the assessments performed, the one obtained by the Reference 2 is 61.2% and the one obtained by the Reference 3 is 70.6%.

Furthermore, no significant differences were found between SAP50SCF at lowest requested dose (0.9 L/ha) and the references products belonging to Reference 2 and Reference 3, in any of the 4 trials, showing a similar control than the authorized products.

Then, between SAP50SCF at 1.2 L/ha and the Reference 2, no significant differences have been found in any of the 4 trials. In 3 trials out of 4, no significant differences have been found between SAP50SCF at 1.2 L/ha and the Reference3, proving a similar behaviour of the products.

In resume, those facts indicate the similar behaviour in the control of *Septoria* on wheat achieved by **SAP50SCF** at the requested dose range and references tested products.

**Table 3.2.3.1 e. Total *Septoria* of Wheat disease control (%) of PESSEV, achieved by SAP50SCF and the reference products – ~~Reference 2~~ and Reference 4**

Target	Nb of trials	Untreated plot	% control				Nb of trials where SAP50SCF 0,9 l/ha is >, < or =		Nb of trials where SAP50SCF 1,2 l/ha is >, < or =	
			SAP50SCF 0,9 l/ha	SAP50SCF 1,2 l/ha	REF 2	REF 4				
		Mean Max Min	Mean Max Min	Mean Max Min	Mean Max Min	Mean Max Min	REF 2	REF 4	REF 2	REF 4
% CONTROL (18-31 DAB) Global average	2	27,8	50,8	53,1	52,1	44,3	> 0 = 2 < 0	> 0 = 2 < 0	> 0 = 2 < 0	> 1 = 1 < 0
		43,2	66,0	74,6	69,5	54,3				
		12,3	35,6	31,5	34,6	34,2				
% CONTROL (18-31 DAB) Maritime EPPO zone	2	27,8	50,8	53,1	52,1	44,3	> 0 = 2 < 0	> 0 = 2 < 0	> 0 = 2 < 0	> 1 = 1 < 0
		43,2	66,0	74,6	69,5	54,3				
		12,3	35,6	31,5	34,6	34,2				
% CONTROL Mediterranean EPPO zone	0	-	-	-	-	-	-	-	-	-
		-	-	-	-	-				
		-	-	-	-	-				
% CONTROL South-East EPPO zone	0	-	-	-	-	-	-	-	-	-
		-	-	-	-	-				
		-	-	-	-	-				

**Note:**

~~- REF 2 (Folpet 500 g/L): Arizona at 1.5 L/ha; SESTO at 1.5 L/ha; FOLPAN 500 at 1.5 L/ha.~~

- REF 4 (Mancozeb 750 g/L): Dithane Neotec at 2.13 kg/ha.

The table above shows a summary of the control of **SAP50SCF** at 0.9 and 1.2 L/ha (450 g Folpet /ha and 600 g Folpet/ha) against *Septoria* on wheat, compared to **Reference 2** applied at 1.5 L/ha (equivalent to 750 g of Folpet/ha) and **Reference 4** (750 g Mancozeb/L).

The commercial names of the products belonging to Reference 2 are the following ones: Arizona at 1.5 L/ha; SESTO at 1.5 L/ha; FOLPAN 500 at 1.5 L/ha.

The commercial name of the product belonging to Reference 4 is the following one: Dithane Neotec at 2.13 kg/ha.

It was considered only the most representative evaluation timing and the most representative variable as the % severity (PESSEV) in Leaf 1, Leaf 2, Leaf 3 or Leaf 4 reached by the disease. According to the results, % severity in trials conducted ranged from 12.3 to 43.2% in Maritime EPPO zone, where those reference products have been applied.

In the Maritime EPPO zone, the % severity in the untreated plots in all conducted trials ranged from 12.3 to 43.2%.

The efficacy average value obtained by **SAP50SCF** at 0.9 l/ha is 50.8% and at 1.2 L/ha is 53.1% according to the assessments performed, the one obtained by the Reference 2 is 52.1% and the one obtained by the Reference 4 is 44.3%.

Furthermore, no significant differences were found between SAP50SCF at lowest requested dose (0.9 L/ha) and the references products belonging to Reference 2 and Reference 3, in any of the 2 trials, showing a similar control than the authorized products.

Then, between SAP50SCF at 1.2 L/ha and the Reference 2, no significant differences have been found in any of the 2 trials. In 1 trial out of 2, no significant differences have been found between SAP50SCF at 1.2 L/ha and the Reference 4, proving a similar behaviour of the products.

However, those results have to be taken carefully as only two trials are being analysed.

In resume, those facts indicate the similar behaviour in the control of *Septoria* on wheat achieved by **SAP50SCF** at the requested dose range and references tested products.

## **Summary and Conclusions of Efficacy of SAP50SCF in wheat against *Septoria***

A total of 15 reliable trials (>5% severity of the disease in the untreated plots) were run in France, United Kingdom, Bulgaria, Romania, Germany and Poland in wheat where control of severity of **SAP50SCF** against *Septoria* on different leaf levels were assessed.

Average efficacy of SAP50SCF values reported of trials conducted against *Septoria* in wheat at the most representative variable and timing is 64.4% at 0.9 L/ha and 69.9% at 1.2 L/ha, taking into account the different EPPO climatic zones, showing a good control of the disease, similar to reference products used on these trials.

These data are enough to confirm the effectiveness of **SAP50SCF** against the mentioned target disease in wheat at the requested dose range (0.9 – 1.2 L/ha), being important to highlight the fact that SAP50SCF is a product which importance is not only because of its efficacy itself but also for being a key tool in the resistance management, as detailed in point 3.2.1.

### 3.2.3.2 Barley/*Helminthosporium*

A total of 19 trials were carried out to evaluate the efficacy of **SAP50SCF** for the control of *Helminthosporium* in barley.

Besides, another 2 trials are still on-going and will be submitted once finished.

However, for different reasons, 7 trials have not been taken into account for this section:

- In 06-F-2021-HU01 (South-East EPPO zone) trial, any diseases have appeared, so this trial has been used as selectivity trial.

- In 06-F-2021-UK01, 06-F-2021-DE01, 06-F-2021-DE02, 18-F-2021-DE01, 18-F-2021-DE02 (Maritime EPPO zone) and 06-F-2021-PL05 (North-East EPPO zone) trials, other diseases were present in the trials but not *Helminthosporium*.

**Table 3.2.3.2 a. Total *Helminthosporium* of Barley disease control (%) of PESSEV, achieved by SAP50SCF and the reference products – Detailed table** (with individual trials` datapoints)

Refer to BAD.

For all trials in barley the same reference product has been used: Azoxystrobin 250 g/l applied at 1 L/ha (except in Bulgaria, where it is applied at 0.6 L/ha and 0.8 L/ha). So, an orthogonal comparison has been made comparing the tested product SAP50SCF at each requested rate (0.9 L/ha and 1.2 L/ha) with the reference product.

**Table 3.2.3.2 b. Total *Helminthosporium* of Barley disease control (%) of PESSEV, achieved by SAP50SCF and the reference product – Reference product Azoxystrobin**

Target	Nb of trials	Untreated plot	% control			Nb of trials where SAP50SCF 0,9 l/ha is >, < or =	Nb of trials where SAP50SCF 1,2 l/ha is >, < or =
			SAP50SCF 0,9 l/ha	SAP50SCF 1,2 l/ha	Reference Product (Azoxystrobin 250 g/L)		
		Mean Max Min	Mean Max Min	Mean Max Min	Mean Max Min	Reference Product (Azoxystrobin 250 g/L)	Reference Product (Azoxystrobin 250 g/L)
% CONTROL (11 - 28 DAB) Global average	10	13,9	78,3	83,3	79,1	> 0 = 10 < 0	> 1 = 9 < 0
		41,2	94,3	97,5	100,0		
		6,3	51,2	50,0	39,6		
% CONTROL (11 - 21 DAB) Maritime EPPO zone	5	13,9	74,2	81,9	74,9	> 0 = 5 < 0	> 1 = 4 < 0
		41,2	87,2	97,5	100,0		
		6,3	51,2	50,0	39,6		
% CONTROL (14-28 DAB) North-East EPPO zone	2	15,8	82,9	85,5	83,9	> 0 = 2 < 1	> 0 = 2 < 0
		17,8	86,8	86,4	84,5		
		13,8	78,9	84,5	83,2		
% CONTROL (21-28 DA-B) South-East EPPO zone	3	12,5	81,9	84,2	82,8	> 0 = 3 < 0	> 0 = 3 < 0
		21,0	94,3	94,3	95,0		
		7,1	72,0	78,8	75,0		

**Note:**

- REF 1 (Azoxystrobin 250 g/L): Torero at 1L/ha; Amistar at 1 L/ha (except in Bulgaria, where it is applied at 0.6 L/ha\*\* and 0.8 L/ha\*); Tazer 250 SCat 1 L/ha; Melucine 25 SC at 1 L/ha.

The table above shows a summary of the control of **SAP50SCF** at 0.9 L/ha (450 g Folpet/ha) and 1.2 L/ha (600 g Folpet/ha) against *Helminthosporium* on barley, compared to **Reference product Azoxystrobin 250 g/L** at 1 L/ha (250 g Azoxystrobin /ha), except in Bulgaria, which is applied at 0.6 and 0.8 L/ha (150 and 200 g of Azoxystrobin/ha).

The commercial names of the products belonging to Reference 1 group are the following ones: Amistar at 1 L/ha (except in Bulgaria, where it is applied at 0,6 and 0,8 L/ha); Torero at 1 L/ha; Tazer 250 SC at 1 L/ha; Melucine 25 SC at 1 L/ha.

It was considered only the most representative evaluation timing and the most representative variable as the % severity (PESSEV) in Leaf 1, Leaf 2, Leaf 3 or Leaf 4 reached by the disease. According to the results, % severity in trials conducted ranged from 6.3 to 41.2 % in Maritime, North-East and South-East EPPO zones, where this reference product has been applied.

In the Maritime EPPO zone, the % severity in the untreated plots in all conducted trials ranged from 6.3 to 41.2%.

The efficacy average value obtained by **SAP50SCF** at 0.9 l/ha is 74.2 % and at 1.2 L/ha is 81.9% according to the assessments performed, and the one obtained by the Reference 1 is 74.9%.

In any of 5 trials significant differences were found between SAP50SCF at 0.9 L/ha and the references product Azoxystrobin at 1 L/ha, proving a similar control.

Besides, in 4 out of 5 trials, no significant differences were found between SAP50SCF at 1.2 L/ha and the references product Azoxystrobin at 1 L/ha, demonstrating a similar control. The other trial showed SAP50SCF at 1.2 L/ha to be significantly better than the reference product.

Besides, in order to confirm the efficacy, another 2 trials are still on-going and will be submitted once finished.

In the North-East EPPO zone, the % severity in the untreated plots in all conducted trials ranged from 13.8 to 17.8%.

The efficacy average value obtained by **SAP50SCF** at 0.9 l/ha is 82.9% and at 1.2 L/ha is 85.5% according to the assessments performed, and the one obtained by the Reference Azoxystrobin is 83.9%.

In the 2 trials no significant differences were found between SAP50SCF at any requested dose and the reference product Azoxystrobin, showing a similar control than the authorized products.

However, just 4 trials have been performed in this EPPO climatic zone, and 2 valid trials have been analysed, as it has been considered that data coming from Maritime zone can be extrapolated to the North-East zone, according to EPPO Guideline PP1/226(3) – ‘Number of efficacy trials’, which states that *“In some situations there may be the opportunity to reduce the number of trials done, and a case may be made for this as follows.*

- *Where there is a large amount of supporting evidence from use of the product, or of similar products with the same active substance, on closely related pests or against the same pests on different crops, the number of trials necessary will be determined by the amount of supporting evidence and the similarity of the pests and crops sought [...] Extrapolations from more challenging control situations to ones that pose a lower challenge to the active substance are more readily justifiable than extrapolations from less challenging to more challenging situations.”*

Trials performed in Maritime EPPO climatic zone have more favourable climatic conditions to develop the disease than other zones and have as well a bigger barley production than other climatic zones, according to EUROSTAT database.

For that, reason it has been considered that Maritime EPPO zone is a more challenging zone for the requested diseases and crops, than the other EPPO zones.

Therefore, data coming from Maritime EPPO zone can be extrapolated to the other zones.

In the South-East EPPO zone, the % severity in the untreated plots in all conducted trials ranged from 7.1 to 21%.



The efficacy average value obtained by **SAP50SCF** at 0.9 l/ha is 81.9% and at 1.2 L/ha is 84.2% according to the assessments performed, and the one obtained by the Reference Azoxystrobin is 82.8%.

Furthermore, no significant differences were found between SAP50SCF at any of requested doses and the references products, showing a similar control than the authorized products.

However, just 4 trials have been performed in this EPPO climatic zone, and 3 valid trials have been analysed, as it has been considered that data coming from Maritime zone can be extrapolated to the South-East zone, according to EPPO Guideline PP1/226(3) – ‘Number of efficacy trials’, which states that *“In some situations there may be the opportunity to reduce the number of trials done, and a case may be made for this as follows.*

- *Where there is a large amount of supporting evidence from use of the product, or of similar products with the same active substance, on closely related pests or against the same pests on different crops, the number of trials necessary will be determined by the amount of supporting evidence and the similarity of the pests and crops sought [...] Extrapolations from more challenging control situations to ones that pose a lower challenge to the active substance are more readily justifiable than extrapolations from less challenging to more challenging situations.”*

Trials performed in Maritime EPPO climatic zone have more favourable climatic conditions to develop the disease than other zones and have as well a bigger barley production than other climatic zones, according to EUROSTAT database.

For that, reason it has been considered that Maritime EPPO zone is a more challenging zone for the requested diseases and crops, than the other EPPO zones.

Therefore, data coming from Maritime EPPO zone can be extrapolated to the other zones.

In resume, those facts indicate a similar behaviour in the control of *Septoria* in wheat achieved by **SAP50SCF** at requested doses (0.9 and 1.2 L/ha) and references tested products.

## Summary and Conclusions of Efficacy of SAP50SCF in barley against *Helminthosporium*

A total of 10 reliable trials (>5% severity of the disease in the untreated plots) were run in France, Poland, Bulgaria and Romania in barley where control of severity of **SAP50SCF** against *Helminthosporium* on different leaf levels were assessed.

It has been considered that data coming from Maritime zone can be extrapolated to the North-East and South-East zone, according to EPPO Guideline PP1/226(3) – ‘Number of efficacy trials’, which states that *“In some situations there may be the opportunity to reduce the number of trials done, and a case may be made for this as follows.*

- *Where there is a large amount of supporting evidence from use of the product, or of similar products with the same active substance, on closely related pests or against the same pests on different crops, the number of trials necessary will be determined by the amount of supporting evidence and the similarity of the pests and crops sought [...] Extrapolations from more challenging control situations to ones that pose a lower challenge to the active substance are more readily justifiable than extrapolations from less challenging to more challenging situations.”*

Trials performed in Maritime EPPO climatic zone have more favourable climatic conditions to develop the disease than other zones and have as well a bigger barley production than other climatic zones, according to EUROSTAT database.

For that, reason it has been considered that Maritime EPPO zone is a more challenging zone for the requested diseases and crops, than the other EPPO zones.

Therefore, data coming from Maritime EPPO zone can be extrapolated to the other zones.

Average efficacy value reported of trials conducted against *Helminthosporium* in barley at the most representative variable and timing is 78.3% for SAP50SCF at 0.9 L/ha and 83.3% at SAP50SCF at 1.2 L/ha, taking into account the different EPPO climatic zones, showing a robust control of the disease, similar to reference product Azoxystrobin used on these trials, which is 79.1%.

These data are enough to confirm the effectiveness of **SAP50SCF** against the mentioned target disease in barley at the requested range (0.9-1.2 L/ha), being important to highlight the fact that SAP50SCF is a product which importance is not only because of its efficacy itself but also for being a key tool in the resistance management, as detailed in point 3.2.1.

## Comments of zRMS on Efficacy:

The information that the present submission was intended for Poland alone had been revealed by the applicant already in the course of the evaluation. That is why the zRMS comments reflect the initial, Central Zone – oriented approach to dossier assessment, *i.e.* discussing options for the EPPO zones separately from one another. To the opinion of zRMS there is no reason to alter the approach and amend the evaluation layout: the comments concerning other zones may simply be disregarded, by the reader.

### SEPTTR in wheat

#### The North-East zone

There are only 4 valid trials in the North East EPPO zone (PL(4)), therefore trials from the neighboring Germany are considered as supporting data. To the opinion of zRMS PL, the combined data set of the NE and the Maritime zones (PL (4) + DE (4) ) allows for authorization of this use in Poland, although the label note should be issued, informing of the moderate level of control by the 1.2 L/ha dose rate:

The zRMS efficacy summary of the merged NE and Maritime zone data  
on the control of SEPTTR in wheat (TRZAX); L1-L4, 42-56 DAA, 18-34 DAB

product	active substance	dose rate	dose rate (g a.s./ha)	Efficacy (%)			n
				mean	min	max	
SAP50SCF	folpet	0,9 L/ha	450	60,7	34,4	83,3	8
SAP50SCF	folpet	1,2 L/ha	600	68,9	31,5	91,7	8
Ref 1	azoxystrobin	1,0 L/ha	250	63,2	9,4	95,7	6
Ref 2	folpet	1,5 L/ha	750	57,5	38,3	87,5	5
Ref 4	mancozeb	2,13 kg/ha	1597,5	44,3	34,2	54,3	2
Ref 1,2, 4				58,1	9,4	95,7	12

Since folpet is known an active and there has been one valid SEPTTR trial submitted in spring wheat (17-F-2020-DE01), the use in spring wheat can be authorized either, next to the winter form.

#### The Maritime zone

There are 8 valid trials submitted from the Maritime EPPO zone (DE(4), FR(3) and UK(1)). Efficacy has been summarized by the applicant standard-wise, resulting in 4 different summaries (Table 3.3.3-1b – 3.2.3.1e). The following level of efficacy of SAP50SCF at 0.9 - 1.2L/ha is concluded in summaries b – e respectively: 41.4 - 54.0% (n=2); **54.4 - 60.2% (n=8)**; 62.7 - 66.9 (n=4) and 50.8 - 53.1 (n=2). Consequently, while the number of trials should enable authorization in the Maritime zone, based on the local, zonal data set alone, the efficacy levels reported deserve even more emphasis on the mediocre level of control, in the prospective label, than do the combined Mar + NE zone data, where the summary figures have been substantially enhanced by the NE zone efficacy exceeding 80% for most of the time, at least at the 1.2 L/ha dose rate.

#### The South-East zone

There are 3 valid trials submitted from the South-East EPPO zone (BG(2), RO(1)). The efficacy of the SAP50SCF has been compared to azoxystrobin alone, and it was on average (n=3) the level of the standard (Table 3.2.3.1 b), with a single trial demonstrating performance of the SAP50SCF (significantly) lower than that of standard, and two trials showing its efficacy as statistically equivalent to azoxystrobin.

The number of 3 trials is itself too low for authorization of the use in the SE zone. To the opinion of the zRMS, merging Bulgarian and Romanian data with data from Spain, Italy and from the Mediterranean part of France would be inappropriate either, taken the distance between these MSs. Therefore, as already commented by zRMS in the MED commenting box, the 3 trials available from the SE zone must be treated as self-standing data set, not supported by any other of the submitted data.

#### The durum wheat issue

In the absence of data (zero trials) in winter and spring durum wheat (TRZDW and TRZDS), the use in control of SEPTTR in that crop can be authorized in Poland only following article 51, as the crop is minor in the zRMS country.

The status of durum wheat in the other MSs is unknown to zRMS and has not been reported separately by the applicant in Table 3.2-4, making any future prospects for authorization based on the present dossier always

dependent on consideration by the relevant MSs`.

### **PYRNTE in barley**

Based on the presented trial data, the efficacy of SAP50SCF in control of PYRNTE in barley is >80%, except for the 0.9L/ha dose rate in the Maritime zone, which the dose performed the level of standard (74.2% vs 74.9% with the standard), while the 1.2L/ha dose outperformed the standard by 7.0% on average (n=5). Otherwise the test item had shown the efficacy equivalent to standard reference product (Ref. 1 based on azoxystrobin).

#### **The North-East zone**

Only 2 trials in barley in control of PYRNTE have been submitted from Poland (and from the North-East zone overall). Even though the average efficacy in these two trials is >80%, in such instances the MS PL usually also relies on supporting data from trials carried out in the neighboring DE, CZ or SK. Unfortunately, and contrary to the applicant`s claim of the “*similar disease pressure on the different trials across EU regardless of the climatic EPPO zone*” \*, all the four German trials intended to test efficacy in control of PYRNTE, including the single trial in HORVS, have been excluded (by the applicant), since the pathogen in question did not occur in them neither in 2020 nor in 2021. As the result, the Maritime data referred to in the Table 3.2.3.2 b come **exclusively** from France. On the other hand, the SE zone data presented in the same table come from Bulgaria and Romania. None of the three MSs is close enough to the NE zone to be included in any common summary of efficacy, along with the NE zone (PL) data.

While the EPPO 1/226 (3) guidance, referred to by the applicant, speaks of “*a large amount of supporting evidence from use of the product or of similar products with the same active*”, the EPPO 1/241(2) *Guidance on comparable climates* has it that “*Climate is only one factor in establishing the relevance of data from one region to another.*”, and that “[...] *other conditions [...] may be considered.*” The 7 trials from the countries distant to Poland may represent a large amount of data, but the differences in agronomy may be considerable even between the Maritime France and the parts of Germany close to Poland. These differences may include different routine of chemical control and the resultant variation in the pathogen pressure, which can be also concluded indirectly from the pathogen`s absence in the German trials of 2020 and 2021. Thus, with no data from Germany - one of the two main barley-producing countries in Europe and the neighbour to Poland, or at least some data from CZ or SK, which might link the SE zone to the NE zone - the claim of “across EU similarity” is in fact void. This claim cannot make the basis for authorization in lieu of the adequate data set, the more that the use of the active folpet in control of PYRNTE in barley is currently not authorized in Poland. All this makes proper, regional data more than welcome. Therefore, and without any supporting data from either the CZ, DE or SK, the authorization of the use in barley in PL is not possible.

\*The applicant`s [statement](#) on the barley data set, following Table 3.2-5.

#### **The Maritime zone**

The separate summaries of efficacy against PYRNTE between the zones reveal that the efficacy of the 0.9L/ha and 1.2 L/ha dose rates is indeed comparable between the EPPO zones of the Central EU zone, except for the NE zone vs Maritime zone comparison at 0.9L/ha, where the Maritime zone efficacy is **by 8,7% lower** compared to that reported from the NE zone (FR - n=5; PL - n=2) (Table 3.2.3.2 b).

The number of trials in the Maritime zone is 5 (only winter barley), and the efficacy is on average 74.2-81.9%, 0.9-1.2L/ha respectively, compared to 74.9% obtained with the standard reference based on azoxystrobin. Yet, with the single trial missing to the number of 6, the data set is, in principle, insufficient to authorize SAP50SCF in control of PYRNTE in barley in the Maritime zone.

#### **The South-East zone**

The efficacy of the 0.9 and 1.2 L/ha dose rates of SAP50SCF in the SE EPPO zone is comparable, and, at the same time, it is equivalent to that of the standard reference. However, the data set includes only 3 trials in winter barley alone. The situation is similar to that of SEPTTR control in wheat: the 3 barley trials must be treated as self-standing dat set, not supported by any other of the submitted data, and any possibility of authorization in the SE zone should be confirmed by the cMSs based on some supplementary data to be possibly delivered in the future.

[To the zRMS comments on the MED](#)

[To zRMS abstract](#)

### 3.2.3.3 Yield from efficacy trials

- **WHEAT**

A total of 4 trials were carried out in 2021 in France, Poland and Romania with the objective of confirming the yield response of SAP50SCF in wheat in presence of challenging pest populations, in this case in presence of *Septoria*.

Trials from other EPPO climatic zone (Mediterranean) has been included in order to have a bigger consistence in the results.

**Table 3.2.3.3-a Yield effect of SAP50SCF in efficacy trials on wheat / SEPTTR**

Refer to BAD.

**Table 3.2.3.3-b Yield effect of SA50SCF at 0.9 L/ha in efficacy trials on wheat / SEPTTR**

Grouping	N° of trials	Untreated YIELD (T/ha)		% yield relative to the untreated								No of trials where SAP50SCF at 0.9 L/ha is >, <, = compared to UTC	No of trials where SAP50SCF at 0.9 L/ha is >, <, = compared to REF 1	No of trials where SAP50SCF at 0.9 L/ha is >, <, = compared to REF 2	No of trials where SAP50SCF at 0.9 L/ha is >, <, = compared to REF 3
				SAP50SCF 0.9 L/ha		REF 1 1 L/ha		REF 2 1.5 L/ha		REF 3 10 L/ha					
		Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max				
Wheat - SEPTTR	3	6.5	4 – 8.5	111	107.4 – 116.7	112.4	107.3 – 120.3	-	-	-	-	< 0 = 1 > 2	< 0 = 3 > 0	-	-
Wheat - SEPTTR	1	6.4	6.4	109	109	-	-	113.5	113.5	106.7	106.7	< 0 = 1 > 0	-	< 0 = 1 > 0	< 0 = 1 > 0

**Note:**

- REF 1 (Azoxystrobin 250 g/L): Tazer at 1 L/ha
- REF 2 (Folpet 500 g/L): SESTO at 1.5 L/ha
- REF 3 (Sulphur 800 g/L): Actiol Phytoeurop at 10 L/ha

In all 4 trials the average total yield of the tested product SAP50SCF applied at 0.9 L/ha was higher than the average total yield of the untreated check (about 10% more than the UTC), showing significant differences in 2 out of 4 trials.

Besides, yield obtained with SAP50SCF, compared with all the standard products, was statistically identical and numerically similar.

All these facts prove a benefit of the product SAP50SCF in terms of wheat production.

**Table 3.2.3.3-c Yield effect of SA50SCF at 1.2 L/ha in efficacy trials on wheat / SEPTTR**

Grouping	N° of trials	Untreated YIELD (T/ha)		% yield relative to the untreated								No of trials where SAP50SCF at 0.9 L/ha is >, <, = compared to UTC	No of trials where SAP50SCF at 1.2 L/ha is >, <, = compared to REF 1	No of trials where SAP50SCF at 1.2 L/ha is >, <, = compared to REF 2	No of trials where SAP50SCF at 1.2 L/ha is >, <, = compared to REF 3
				SAP50SCF 1.2 L/ha		REF 1 1 L/ha		REF 2 1.5 L/ha		REF 3 10 L/ha					
		Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max				
Wheat - SEPTTR	3	6.5	4 – 8.5	109.8	106.6 – 115.3	112.4	107.3 – 120.3	-	-	-	-	< 0 = 1 > 2	< 0 = 3 > 0	-	-

Grouping	N° of trials	Untreated YIELD (T/ha)		% yield relative to the untreated								No of trials where SAP50SCF at 0.9 L/ha  is >, <, = compared to UTC	No of trials where SAP50SCF at 1.2 L/ha  is >, <, = compared to REF 1	No of trials where SAP50SCF at 1.2 L/ha  is >, <, = compared to REF 2	No of trials where SAP50SCF at 1.2 L/ha  is >, <, = compared to REF 3
				SAP50SCF 1.2 L/ha		REF 1 1 L/ha		REF 2 1.5 L/ha		REF 3 10 L/ha					
		Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max				
Wheat - SEPTTR	1	6.4	6.4	117.3	117.3	-	-	113.5	113.5	106.7	106.7	< 0 = 1 > 0	-	< 0 = 1 > 0	< 0 = 1 > 0

**Note:**

- REF 1 (Azoxystrobin 250 g/L): Tazer at 1 L/ha
- REF 2 (Folpet 500 g/L): SESTO at 1.5 L/ha
- REF 3 (Sulphur 800 g/L): Actiol Phytoeurop at 10 L/ha

In all 4 trials the average total yield of the tested product SAP50SCF applied at 1.2 L/ha was higher than the average total yield of the untreated check (about 11% more than the UTC), showing significant differences in 2 out of 4 trials.

Besides, yield obtained with SAP50SCF, compared with all the standard products, was statistically identical and numerically similar.

All these facts prove a benefit of the product SAP50SCF in terms of wheat production.

- **BARLEY**

A total of 7 trials were carried out in 2021 in France, Spain, Poland, Bulgaria and Romania with the objective was of confirming the yield response of SAP50SCF in barley in presence of challenging pest populations, in this case in presence of *Helminthosporium*, *Puccinia hordei*, *Blumeria graminis* and *Rhynchosporium secalis*.

Trials from other EPPO climatic zone (Mediterranean) has been included in order to have a bigger consistence in the results.

**Table 3.2.3.3-d      Yield effect of SAP50SCF in efficacy trials on barley / PYRNTE**

Refer to BAD.



**Table 3.2.3.3-e Yield effect of SAP50SCF in efficacy trials on barley / PYRNTE**

Grouping	N° of trials	Untreated YIELD (T/ha)		% yield relative to the untreated						No of trials where SAP50SCF at 0,9 L/ha is >, <, = compared to UTC	No of trials where SAP50SCF at 0,9 L/ha is >, <, = compared to REF 1	No of trials where SAP50SCF at 1,2 L/ha is >, <, = compared to UTC	No of trials where SAP50SCF at 1,2 L/ha is >, <, = compared to REF 1
				SAP50SCF 0,9 L/ha		SAP50SCF 1,2 L/ha		REF (Azoxystrobin)					
		Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max				
Barley / PYRNTE	7	5.3	2.3 – 8.7	106.6	100.4 – 121.5	109.7	103.4 – 124.7	110.8	102.5 – 122.8	< 0 = 3 > 4	< 1 = 6 > 0	< 0 = 3 > 4	< 0 = 6 > 1
Barley/ PUCCHD	1	6.7	6.7	104.4	104.4	107	107	110.5	110.5	< 0 = 3 > 4	< 1 = 6 > 0	< 0 = 3 > 4	< 0 = 6 > 1
Barley/ ERYSGH	1	6.1	6.1	104.5	104.5	107.1	107.1	102.5	102.5	< 0 = 3 > 4	< 1 = 6 > 0	< 0 = 3 > 4	< 0 = 6 > 1
Barley/ RHYNSE	1	3.4	3.4	100.4	100.4	105.5	105.5	113.5	113.5	< 0 = 3 > 4	< 1 = 6 > 0	< 0 = 3 > 4	< 0 = 6 > 1

**Note:**

- REF 1 (Azoxystrobin 250 g/L): Amistar at 0,8 L/ha (in Bulgaria); Mirador SC at 1 L/ha; Tazer 250 SC at 1 L/ha; Placaje 25 SC at 1 L/ha; Melucine 25 SC at 1 L/ha.

In all 7 trials the average total yield of the tested product SAP50SCF applied at 0.9 and 1.2 L/ha was higher than the average total yield of the untreated check (about 7% and 10% more than the UTC, respectively), showing significant differences in 4 out of 7 trials.

Besides, in 6 out 7 trials, no significant differences were found in yield obtained with SAP50SCF at 0.9 L/ha and 1.2 L/ha compared with all the standard products (Azoxystrobin 250 g/L).

All these facts prove a benefit of the product SAP50SCF in terms of barley production.

### **Summary of Yield from efficacy trials**

**In a total of 11 efficacy trials on wheat and barley, performed in different EPPO climatic zones and countries in 2021, in presence of challenging diseases, yield has been analysed.**

**Results have demonstrated that SAP50SCF applied at the requested range (0.9 and 1.2 L/ha) increase the production of wheat and barley about 10%, in comparison with the non-treated plot.**

**Besides, results are similar to the ones achieved by the reference products.**

**All these facts prove the benefit of SAP50SCF in yield.**

#### **Comments of zRMS on yield quantity from efficacy trials:**

According to EPPO PP 1/135 (4) guideline: *Phytotoxicity assessment*, submission of the yield data is non-obligatory for the fungicide products. Nevertheless the applicant has submitted yield data from 11 trials.

The data demonstrate no negative effect on the yield amount, of the test item SAP50SCF used at the dose rate of 1.2 L/ha against SEPTTR in wheat and against PYRNTE in barley.

Yield data concerning PUCCHD, ERYSGH and RHYNSE (barley), as much as the yield results demonstrated for the 0.9 L/ha dose rate in both the crops have been ignored in evaluation, as they are irrelevant for the present submission (SEPTTR and PYRNTE), or meaningless from the efficacy perspective (see the [MED comments](#)).

It should be noted that the data summarized by the applicant for (winter) wheat are from PL (2 trials), RO (1 trial) and from the Mediterranean FR (1 trial).

The data for (winter) barley come from PL (2 trials), BG (2 trials), Maritime FR (1 trial) and from IT (1 trial) and ES (1 trial).

[To zRMS abstract](#)

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

Following EPPO Standard PP 1/213 'Resistance risk analysis', ~~it is reported the information relevant information to the assessment of resistance risk~~ risk of resistance assessment is reported.

#### Mode of action

- Folpet belongs to the chemical group of the phthalimide fungicides and, according to FRAC (Fungicide Resistance Action Committee) it is included in the group M4, substances with a multi-site contact activity. This substance acts by inhibiting many oxidative enzymes, carboxylases and enzymes involved with phosphate metabolism and citrate synthesis. Folpet reacts with the sulfhydryl groups of nuclear proteins, leading to an inhibition of the cell division. It is considered as a low risk ~~group~~ active, without any signs of resistance developing to the fungicides.

#### Importance of multisite fungicides in managing pathogen resistance

One of the key recommendations is to make use of multisite fungicides (see FRAC Group M) in spray programs, especially in crops with multiple sprays such as fruits and vegetables, or certain arable crops. Due to their mode of action, multisite fungicides are considered as a low resistance risk group. Therefore, they offer the possibility for use as mixing partners or alternating with single site and other medium to high resistance risk fungicides. Over the past decades, no cases of field resistance against multisites have been reported.

There are clear benefits to recommending multi-site fungicides in spray programs:

- Multisite fungicides display a low risk to develop resistance and are effective mixing/alternating partners for medium to high risk fungicides.
- Beyond protecting and prolonging the lifespan of highly effective medium to high resistance risk fungicides, multisite fungicides provide added levels and spectrum of disease control. With this they can also support the single sites to be even more efficient.
- Multisite fungicides are considered a valuable tool to manage resistance, by preventing or delaying its development to many pathogens in many crops.
- In some crops, multisites play an increasing role in spray programs to sustain effective disease control and resistance management, e.g. for *Zymoseptoria tritici* in wheat, *Ramularia collo-cygni* in barley and for *Phakopsora pachyrhizi* in soybeans.

Restricting the use of multisite fungicides from use in important crops could result in faster development of resistance to single site mode of action fungicides. This in turn could lead to epidemic disease development, serious crop losses, and finally the loss of highly effective fungicides for a sustainable disease management.

#### General Use Recommendations

According to the information provided before, considering that multisite fungicides display a low risk to develop resistance and that ~~they~~ are effective mixing/alternating partners for medium to high risk fungicides, no use restrictions are considered to SAP50SCF regarding Resistance management issues. Indeed, SAP50SCF should be used in mixtures or application programs to avoid resistance issues on other fungicides.

#### Conclusions about the occurrence or possible occurrence of the development of resistance

Requested GAP of **SAP50SCF** complies with specific recommendations of FRAC to the management of fungicide resistance (number of applications, interval between applications etc.,). ~~In addition, resistance management strategy has been proposed.~~

In resume, **SAP50SCF** is a product which complies with recommendations of FRAC to avoid occurrence of the development of resistance and it has been demonstrated that achieves good control against *Septoria* and *Helminthosporium* on the different target crops. Demonstrating as a tool for a good resistance management.

#### Comments of zRMS on the risk of resistance development:

The applicant is quoting FRAC leaflet “Importance of multisite fungicides [...]” (2018) *verbatim*, thereby seemingly leaving little to be added to the resistance risk issue.

Nonetheless, please note that the same FRAC website has also made available another leaflet: “*Guidelines for Multi-Site Fungicides, Biological Control Agents and Plant Defence Inducers*”, reading, among others: “*Multi-site fungicides belonging to FRAC classes with code M1-M12 can be used solo or in mixtures with partners at manufacturer’s recommended effective rates<sup>1</sup>*” and: “*For a mixture of non-cross-resistant partners to be effective in a resistance management strategy the rate of each component must be sufficient to provide satisfactory control<sup>2</sup> when used alone at the same rate*”. Otherwise, the FRAC states that “*There are no limitations or restrictions concerning the number of applications, the timing, or the sequence as long as they are within the limits of the manufacturer’s labels and local regulatory requirements*” (bolding by zRMS).

The zRMS shares the view of the FRAC that the multi-site acting fungicides have unique a trait of not inducing resistance development, and to the knowledge of zRMS there is no reason to impose any “risk mitigating measures” on the use of the SAP50SCF containing the active folpet. The active itself is, to a considerable degree, an anti-resistance measure as mixture partner with other fungicides (although this is out of scope of the present submission). Consequently, no resistance strategy has been proposed by the applicant, which, to the opinion of zRMS, is acceptable. The authorization of the maximum of 2 applications *per* crop and *per* season is single and sufficient resistance risk-mitigating measure needed; although other limitations may possibly be imposed only by environmental factors.

However, the FRAC statements quoted above confirm and emphasize **the need to restrict the mode of application to the fixed 1.2 L/ha dose rate**, as the MED results clearly indicate that the efficacy of the lower dose rate (0.9) is inadequate (ineffective). Insisting on the dose range proposed by the applicant would be therefore in disagreement with the FRAC recommendations on the effective rates<sup>1</sup> and on the satisfactory control<sup>2</sup> that must both be provided by the mixture partner, in case the SAP50SCF is used in tank mixtures.

[To zRMS abstract](#)

### 3.4 Effects on treated crops (KCP 6.4)

Folpet is an active substance with fungicide activity that have been registered from more than 20 years ago in several European countries and extensively used during this period, with not known event of reducing yield in any of the authorised crops related to the use of these products.

38 efficacy trials were performed on wheat and barley in three EPPO Climatic zones (Maritime, South-East and North-East), however, in 1 of them any diseases have appeared, so it was used as selectivity trial\*.

Besides, 8 efficacy trials in wheat and 8 efficacy trials in barley, performed in the Mediterranean zone, have been included in order to add consistency (see table below). However, one of them performed in barley has been used as selectivity trial as well.

Indeed, in all these 54 trials, in addition to the efficacy, evaluations on any adverse phototoxicity symptoms were conducted.

Then, another 2 efficacy trials in Maritime EPPO zone and 3 others in Mediterranean EPPO zone are still on-going and will be submitted once finished.

Moreover, 9 transformation trials were performed and exposed hereunder.

<b>Trial</b>	<b>Country</b>	<b>Climate zone</b>	<b>Testing facility</b>	<b>Year</b>	<b>Crop type</b>	<b>Trial type</b>
17-F-2020-FR01	France	Mediterranean	QUALIPHYT	2021	Wheat	Efficacy trial
17-F-2020-SP01	Spain	Mediterranean	Agroensayos, Ensayos y Técnicas Agrícolas	2021	Wheat	Efficacy trial
05-F-2021-FR01	France	Mediterranean	QUALIPHYT	2021	Wheat	Efficacy trial
05-F-2021-FR02	France	Mediterranean	QUALIPHYT	2021	Wheat	Efficacy trial
05-F-2021-IT01	Italy	Mediterranean	Sagea Centro di Saggio	2021	Wheat	Efficacy trial
05-F-2021-IT02	Italy	Mediterranean	Sagea Centro di Saggio	2021	Wheat	Efficacy trial
05-F-2021-SP01	Spain	Mediterranean	Agroensayos, Ensayos y Técnicas Agrícolas	2021	Wheat	Efficacy trial
05-F-2021-SP02	Spain	Mediterranean	Agroensayos, Ensayos y Técnicas Agrícolas	2021	Wheat	Efficacy trial
06-F-2021-FR04	France	Mediterranean	QUALIPHYT	2021	Barley	Efficacy trial
06-F-2021-FR05	France	Mediterranean	QUALIPHYT	2021	Barley	Efficacy trial
06-F-2021-FR06	France	Mediterranean	QUALIPHYT	2021	Barley	Selectivity trial
06-F-2021-FR07	France	Mediterranean	QUALIPHYT	2021	Barley	Efficacy trial
06-F-2021-IT01	Italy	Mediterranean	Sagea Centro di Saggio	2021	Barley	Efficacy trial
06-F-2021-IT02	Italy	Mediterranean	Sagea Centro di Saggio	2021	Barley	Efficacy trial
06-F-2021-SP01	Spain	Mediterranean	Agroensayos, Ensayos y Técnicas Agrícolas	2021	Barley	Efficacy trial
06-F-2021-SP02	Spain	Mediterranean	Agroensayos, Ensayos y Técnicas Agrícolas	2021	Barley	Efficacy trial

<b>Trial</b>	<b>Country</b>	<b>Climate zone</b>	<b>Testing facility</b>	<b>Year</b>	<b>Crop type</b>	<b>Trial type</b>
25-TT-BM- 2021-FR01	France	Maritime	STAPHYT	2021	Wheat	Bread-making
25-TT-BM- 2021-FR02	France	Maritime	STAPHYT	2021	Wheat	Bread-making
25-TT-BM- 2021-IT01	Italy	Mediterranean	SAGEA	2021	Wheat	Bread-making
25-TT-BM- 2021-IT02	Italy	Mediterranean	SAGEA	2021	Wheat	Bread-making
26-TT-BW- 2021-FR01	France	Maritime	STAPHYT + iFBM	2021	Barley	Brewing
26-TT-BW- 2021-FR02	France	Maritime	STAPHYT + iFBM	2021	Barley	Brewing
26-TT-BW- 2021-FR03	France	Maritime	STAPHYT + iFBM	2021	Barley	Brewing
26-TT-BW- 2021-IT01	Italy	Mediterranean	SAGEA	2021	Barley	Brewing
26-TT-BW- 2021-IT02	Italy	Mediterranean	SAGEA	2021	Barley	Brewing

Information on trials submitted (3.4: Adverse effects on treated crops)

**Table 3.4-a Presentation of trials (selectivity trials, transformation trials...)**

Crop*	Country	Type of trial**	Number of trials			Years	GEP, non-GEP, official***	Comments (any other relevant information)
			Maritime EPPO zone	Mediterranean EPPO zone	South -East EPPO zone			
Wheat	FR	S+Y+TF+Q	2			2021	GEP	Bread-making trials
	IT	S+Y+TF+Q		2		2021	GEP	Bread-making trials
	FR	E		2		2021	GEP	Efficacy trials belonging to Mediterranean EPPO zone where phytotoxicity has been assessed
	IT	E		2		2021	GEP	
	SP	E		3		2021	GEP	
Barley	FR	S+Y+TF+Q	3			2021	GEP	Brewing trials
	IT	S+Y+TF+Q		2		2021	GEP	Brewing trials
	FR	S		1		2021	GEP	Selectivity trial (efficacy trial where any disease appeared)
	HU	S			1	2021	GEP	
	FR	E		4		2021	GEP	Efficacy trials belonging to Mediterranean EPPO zone where phytotoxicity has been assessed
	IT	E		2		2021	GEP	
	SP	E		2		2021	GEP	
TOTAL	-	Wheat	2	9	0	-	GEP	-
TOTAL	-	Barley	3	11	1	-	GEP	-
<b>TOTAL</b>	-	-	<b>5</b>	<b>20</b>	<b>1</b>	-	<b>GEP</b>	-

\* According to the GAP table

\*\* S = selectivity trial, Y = trial with yield assessment, Q = trial with quality assessment, T = trial on the basis of the study of impact on transformation process (TP: Physical transformation, TF: transformation involving microbial fermentation), P = trial with assessment of impact on propagation

\*\*\* Official: carried out by a national official organisation

### 3.1.1 Phytotoxicity to host crop (KCP 6.4.1)

~~Prothioconazole and Folpet are two active substances, with fungicide activity, that have been~~ Folpet has been registered from more than 20 years ago in several European countries and extensively used during this period in several crops such as cereals, with not known event of phytotoxicity or reducing yield in any of the authorised crops related to the use of these products.

Furthermore, according to EPPO PP1 /135 (4) “Phytotoxicity assessment” specific selectivity trials (in absence of pest/weeds/disease) including 2N dose are not necessary for fungicides, insecticides and plant growth regulators, because, for these types of plant protection products, phytotoxic effects will be less frequent. Therefore, assessment for phytotoxicity symptoms in efficacy trials are enough to support the registration of these type of products. Only, if phytotoxicity symptoms are recorded in efficacy trials, specific selectivity trials should be performed.

A total of 52 efficacy trials (37 in Maritime, South-East and North-East EPPO zones and 15 in Mediterranean EPPO zone) on wheat and barley, on a wide range of commercially grown varieties, have been conducted in France, Germany, United Kingdom, Italy, Spain, Bulgaria, Romania and Poland from 2020 to 2021.

No phytotoxicity symptoms caused by SAP50SCF at the proposed range of doses from 0.9 to 1.2 L/ha in wheat and barley ~~was~~ were recorded in any of the trials (For SAP50SCF, N=1.2 L/ha) nor at 1.5 L/ha (1.25N), as this dose was tested as well.

Besides, 2 other selectivity trials showed no phytotoxicity in barley (in France and Hungary).

Furthermore, in 9 other transformation trials, any phytotoxicity has been recorded neither, being applied 1.25 N dose (1.5 L/ha) (in France and Italy).

#### WHEAT

Number of trials with...		Efficacy trials (27 trials)		Bread-making trials (4 trials)	
		Test product	Standards	Test product	Standards
		N and 1.25N	N	1.25N	N
Maximum of phytotoxicity recorded during the trials	0% to 5%	27	27	4	4
	>5% to 10%	0	0	0	0
	>10% to 15%	0	0	0	0
	>15 %	0	0	0	0
Level of symptoms at the last assessments	0% to 5%	27	27	4	4
	>5% to 10%	0	0	0	0
	>10% to 15%	0	0	0	0
	>15 %	0	0	0	0

## **BARLEY**

Number of trials with...		Efficacy trials (25 trials)		Selectivity trails (2 trials)		Brewing trials (5 trials)	
		Test product	Standards	Test product	Standards	Test product	Standards
		N and 1.25N	N	N and 1.25N	N	1.25N	N
<b>Maximum of phytotoxicity recorded during the trials</b>	0% to 5%	25	25	2	2	5	5
	>5% to 10%	0	0	0	0	0	0
	>10% to 15%	0	0	0	0	0	0
	>15 %	0	0	0	0	0	0
<b>Level of symptoms at the last assessments</b>	0% to 5%	25	25	2	2	5	5
	>5% to 10%	0	0	0	0	0	0
	>10% to 15%	0	0	0	0	0	0
	>15 %	0	0	0	0	0	0

To conclude, no phytotoxic symptoms have been caused at the proposed maximum rate of SAP50SCF (1.2 L/ha) was recorded in any of the 54 efficacy/selectivity trials conducted nor in the 9 transformations trials conducted.

### **Comments of zRMS:**

The absence of phytotoxicity symptoms in efficacy trials, as much as in the transformation trials (field phase) has been confirmed. To the [zRMS abstract](#)

### **3.4.1 Effect on the yield of treated plants or plant product (KCP 6.4.2)**

According to EPPO PP1/135 (4) ‘*Phytotoxicity assessment*’, specific selectivity trials (in absence of pest/weeds/disease) including 2N dose are not necessary for fungicides, insecticides and plant growth regulators, because, for these types of plant protection phytotoxicity symptoms are less frequent.

Only if phytotoxicity symptoms appear in trials at N dose, this type of trials should be conducted.

As previously ~~it has been~~ noticed, phytotoxicity symptoms ~~have~~ **did** not appear in any of the 54 total trials carried out, **and** for that reason specific selectivity trials testing 2N dose have not been performed.

Nevertheless, in absence of any disease, 9 transformations trials have been performed, where yield at N dose was evaluated and SAP50SCF ~~did not had any~~ **had no** negative effect on yield, compared with the untreated plot or the plots treated with reference products.

### **Summary and conclusion on effect on the yield of treated plants or plant product.**

According to data submitted, the risk of impact of SAP50SCF on the yield of treated plants can be considered like acceptable when it is applied following the corresponding GAP.



#### Comments of zRMS:

The non-submission of dedicated selectivity trials has been accepted by the zRMS based on the EPPO PP1/135 (4) guidance. On the other hand, the 9 efficacy trials, producing wheat and barley grain for “the effect on transformation processes” tests, had shown no negative effect of the test item on the yield amount.

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

A total of 8 trials on wheat and 12 trials on barley allow to study the quality of plants or plants products after SAP50SCF application.

Two submitted trials on Wheat and three on Barley are presented as supportive data, because being performed on a different climatic zone (Mediterranean, Italy).

Data on wheat was generated on 4 trials to study any unintentional effect on Baking and 4 efficacy trials where yield and quality parameters were recorded.

Data on Barley was generated on 5 trials to study any unintentional effect on Brewing and 7 efficacy trials where yield and quality parameters were recorded.

In addition to the effect on Baking and Brewing quality parameters, other variables such as %Moisture content (evaluated in all trials), TKW (3 trials in Wheat and 4 trials in Barley) and HLW (5 trials in Wheat and 9 trials in Barley) were recorded.

According to the submitted data, just few differences were observed on quality parameters, namely:

- Slightly higher HLW on wheat than the untreated in 1 up to 4 trials (05-F-2021-RO01). Similar to the reference.
- Slightly higher TKW on wheat than the untreated in 1 up to 3 trials (25-TT-BM-2021-IT01)
- No differences at all on moisture content on wheat on 4 trials
- No differences on HLW on barley in 9 trials
- Slightly higher TKW than the untreated in 1 up to 3 trials (04B-F-2020-RO01)
- Slightly higher Moisture content than the untreated and reference in 2 up to 12 trials in Barley (06-F-2021-PL02 and 06-F-2021-RO01)

Folpet is an active ingredient used for long ago in cereals to control diseases, with no reported negative effect on quality of plants products. In fact, reported results demonstrate the absence of relevant negative effects on treated plots with SAP50SCF, or even better-quality parameters on efficacy trials (higher TKW and HLW for some trials), with a similar performance to the references.

According to the reported data, it can be concluded that the use of SAP50SCF is safe for cereals when applied according to the GAP.

#### Comments of zRMS:

Variation in quality parameters listed by the applicant is negligible and of no practical relevance. In none of the 9 “transformation” trials nor in the 11 remaining trials in which yield quality was characterized, were the differences between the treatments statistically significant, in the quality parameters observed. Moreover, in the 9 transformation trials the product was always applied only at 1.5 L/ha dose rate, the one exceeding the target rate. It may therefore be concluded that no negative effect on yield quality should be expected following the application of SAP50SCF at the recommended **1.2 L/ha** dose rate.

To the [zRMS abstract](#).

### 3.1.3 Effects on transformation processes (KCP 6.4.4)

According to EPPO guideline PP 1/243 (2) “*Effects of plant protection products on transformation processes*”:

## **Effects on the processing procedure: BAKING**

Four trials (25-TT-BM-2021-FR01, 25-TT-BM-2021-FR02, 25-TT-BM-2021-IT01 and 25-TT-BM-2021-IT02) were performed to study the unintentional effects of the product on quality of wheat on baking were done in France and Italy in 2021, in Maritime and Mediterranean EPPO zones.

SAP50SCF at 1.5 L/ha (1.25N) and two reference products PROSARO 250 EC (1 l/ha) and SESTO (1.5 l/ha) were tested for quality.

For detailed information on trials site and application details refer to Appendixes.

Hereafter, the conclusion of each trial is detailed.

- **25-TT-BM-2021-IT01**

Considering chemical analysis results, it could be stated:

- no significant differences on most of the main qualitative parameters were assessed in wheat grain samples;

- no differences occurred on the parameters between Treatment 3 (SAP50SCF) and Treatment 4 (PROSARO 250)

After the Processing Phase, the product obtained (fresh bread) was used for the Taint test session performed on December 17th, 2021.

During this session, the assessors were not able to differentiate one sample from the other.

The comparison between processed product (bread) obtained from field specimens did not show any significant difference on the organoleptic parameters (smell, taste, odour, texture and colour).

### **Comments of zRMS:**

Final conclusion on comparability of bread has been confirmed based on the inspection the 25-TT-BM-2021-IT01 trial report, with no additional remarks.

- **25-TT-BM-2021-IT02**

Considering chemical analysis results, it could be stated:

- no significant differences on most of the main qualitative parameters were assessed in wheat grain samples;

- no differences occurred on the parameters between Treatment 3 (SAP50SCF) and Treatment 4 (PROSARO 250)

After the Processing Phase, the product obtained (fresh bread) was used for the Taint test session performed on December 17th, 2021.

During this session, the assessors were not able to differentiate one sample from the other.

The comparison between processed product (bread) obtained from field specimens did not show any significant difference on the organoleptic parameters (smell, taste, odour, texture and colour).

### **Comments of zRMS:**

Final conclusion on comparability of bread has been confirmed based on the inspection the 25-TT-BM-2021-IT02 trial report, although it has been noticed that Zeleny index was **well below the critical 22 ml** in all treatments in that trial (16 ml with the UNCK and 10 ml to 13 ml with the test item and both standards), thus testifying of the low baking quality (poor protein complex) of the flour from that trial overall.

However, since the results of other parameters are comparable between the test and the standard items, as much as are the Zeleny results, the trial has been considered as valid.

- **25-TT-BM-2021-FR01**

Regarding the treatment SAP50SCF, no significant differences were found for these analyses, Hagberg and thousand grains, between the reference or the untreated modality and the experimental treatment.

Regarding Zeleny index, there was no significant difference between the different modalities.

Regarding the alveogram indexes, experimental product SAP50SCF obtained better result than reference SESTO.

Regarding the baking test, dough, bread and crumb marks were good for all the modalities but as the alveogram analysis higher for the experimental product SAP50SCF and the reference SESTO.

Consequently, under these trial conditions and according to physicochemical results and the baking test the experimental product SAP50SCF applied twice at 1.5 L/ha doesn't seem to have negative impact on the physicochemical parameters

Concerning the sensorial analysis results, no significant difference was found between breads stemming from untreated wheat and those from reference wheat treated with SESTO applied twice at 1.5 l/ha.

But significant difference was found between breads stemming from reference wheat treated with SESTO applied twice at 1.5 l/ha and those from experimental product SAP50SCF applied twice at 1.5 L/ha.

However, looking into taster's comments, it was established that this difference was linked to texture or taste of bread. It seems that bread from experimental treatment SAP50SCF were preferred to the reference SESTO. Moreover, no chemical taste, odor, unpleasant taste was highlighted. Therefore, the difference did not seem to be associated with the applications of SAP50SCF applied twice at 1.5 L/ha.

Consequently, under these trial conditions and according the sensorial analysis results, we can conclude that, experimental treatment SAP50SCF applied twice at 1.5 L/ha, obtained significant higher results on wheat criteria, bread processing and organoleptic qualities compared with reference SESTO at twice at 1.5 L/ha.

**Comments of zRMS:**

Final conclusion on bread comparability has been confirmed based on the inspection the 25-TT-BM-2021-FR01 trial report; the applicant's summary of this trial is correct. No additional remarks.

- 25-TT-BM-2021-FR02

Considering the physicochemical analysis, no significant differences were found between the grain from the untreated and the reference SESTO also between the experimental treatment SAP50SCF and the grain from the reference SESTO.

Regarding Zeleny index, there was no significant difference between the different modalities.

Regarding the alveogram indexes, no significant differences were found between the grain from the untreated and the reference SESTO also between the experimental treatment SAP50SCF and the grain from the reference SESTO.

Regarding the baking test, dough, bread and crumb marks were good for all the modalities but lower for the experimental product SAP50SCF and the reference SESTO\*.

Consequently, under these trial conditions and according to physicochemical results and the baking test the experimental products SAP50SCF applied twice at 1.5 L/ha don't seem to have negative impact on the physicochemical properties .

Concerning the sensorial analysis results, no significant difference was found between breads stemming from untreated wheat and those from reference wheat treated with SESTO applied twice at 1.5 l/ha.

No significant difference was found between breads stemming from reference wheat treated with SESTO applied twice at 1.5 l/ha and those from experimental product SAP50SCF applied twice at 1.5 L/ha.

Consequently, under these trial conditions and according the sensorial analysis results, we can conclude that, experimental treatments SAP50SCF applied twice at 1.5 L/ha, did not lead to any significant modifications on organoleptic qualities compared with reference SESTO applied twice at 1.5 l/ha.

**Comments of zRMS:**

Final conclusion on bread comparability has been confirmed based on the inspection the 25-TT-BM-2021-FR02

trial report; the applicant`s summary of this trial is correct. \*The difference in marks received in baking test, mentioned by the applicant, is negligible. No additional remarks.

Therefore, results from these 4 performed trials in Maritime and Mediterranean EPPO climatic zone, it can be concluded that SAP50SCF do not have any negative impact on baking quality or bread testing.

**Comments of zRMS:**

Final conclusion on the effect on bread making process has been confirmed based on the inspection of the 4 trial reports summarized above. No negative effect is concluded. No additional remarks.

## **Effects on the processing procedure: BREWING**

To evaluate the effect of the formulated product SAP50SCF (1.5 l/ha) when applied to barley for beer production, 5 trials were conducted in Italy and France, in Mediterranean and Maritime EPPO zones. From the 3 trials conducted in France (26-TT-BW-2021-FR01, 26-TT-BW-2021-FR02 and 26-TT-BW-2021-FR03) only 2 were selected to continue the analysis. Hereafter, the conclusion of each trial is detailed.

- **26-TT-BW-2021-IT01**

Generally, it could be stated that no undesired and unpleasant smells or tastes have been detected in all the analyzed samples. About 15 kg field specimen amount was obtained from each treatment to be subjected to the Processing Phases. After the Processing Phases (malting and brewing), the processed product (beer) was used for the Taint test session performed on January 17<sup>th</sup>, 2022.

All the obtained samples (barley, malt, wort, beer) showed good qualitative characteristics, typical of the commercial products obtained with common industrial processing. Considering chemical analysis results, it was possible to notice some light differences about the assessed qualitative parameters among the samples. Apart from the TKW differences on barley from the field (where Treatment 2 SAP50SCF was significantly higher than the other treatments), it is reasonable to state that the other differences were not due to the application of the test and reference products in field, but they emerged during the processing operations.

According to the Taint test results on Beer, no significant differences on smell and taste nor taints, due the application of the products were noticed by the assessors.

**Comments of zRMS:**

Conclusion on the final product (beer) comparability has been confirmed based on the inspection the 26-TT-BW-2021-IT01 trial report. No additional remarks.

- **26-TT-BW-2021-IT02**

Generally, it could be stated that no undesired and unpleasant smells or tastes have been detected in all the analyzed samples. About 15 kg field specimen amount was obtained from each treatment to be subjected to the Processing Phases. After the Processing Phases (malting and brewing), the processed product (beer) was used for the Taint test session performed on January 17<sup>th</sup>, 2022.

All the obtained samples (barley, malt, wort, beer) showed good qualitative characteristics, typical of the commercial products obtained with common industrial processing. Considering chemical analysis results, it was possible to notice some light differences about the assessed qualitative parameters among the samples. Anyway, it is reasonable to state that these differences were not due to the application of the test and reference products in field, but they emerged during the processing operations.

According to the Taint test results on Beer, no significant differences on smell and taste nor taints, due the application of the products were noticed by the assessors.

**Comments of zRMS:**

Conclusion on the final product (beer) comparability has been confirmed based on the inspection the 26-TT-BW-2021-IT02 trial report. No additional remarks.

- **26-TT-BW-FR01, 26-TT-BW-FR02 and 26-TT-BW-FR03 (field phase); RAF-1173 (processing phase)**

- CONTROL OF BARLEY SPECIMENS ON RECEIPT

CEB method n° 185 dedicated to brewing barley mentions the following rules to initiate the brewing process study:

- Protein content: between 9 and 12% of dry matter
- Germination after 3 days > 95%
- Kernel size of barley (>2.5 mm)  $\geq$  60%
- Barley infested by mould < 2%
- Moisture content  $\leq$  15%.

\*“The barley specimens from the trial 26B-TT-BW-2021-FR03 conform to the brewing criteria. Most of the barley specimens from the trial 26B-TT-BW-2021-FR01 have a protein content <9%. One barley specimen (E1173/007, plot 102 treatment SAP50SCF) from the trial 26B-TT-BW-2021-FR02 has a protein content <9%, but the fourth repetition (plot 402) for this treatment conform to the brewing criteria.

For the subsequent stages of the study we propose the trials 26B-TT-BW-2021-FR03 and 26B-TTBW-2021-FR02.

Germinative energies  $\leq$  95% will be redone on the specimens from the trials 26B-TT-BW-2021-FR03 and 26B-TT-BW-2021-FR02.

The specimens from the trial 26B-TT-BW-2021-FR01 will be destroyed.

The sponsor agreed.”

#### Comments of zRMS on the processing of the French barley grain:

Unlike the Italian trials, the French reports 26-TT-BW-2021-FR01, 26-TT-BW-2021-FR2 and 26-TT-BW-2021-FR01 03 contain the details and results of only the field phase, while the processing of the grain obtained from these trials is reported jointly in the document **RAF-1173**.

The (applicant`s) text directly above, marked \* “ “ by the zRMS, is *verbatim* quotation from the report: RAF-1173 (laboratory / processing phase), explaining the reasons for exclusion of material from the 26-TT-BW-2021-FR01 field trial, from the processing / brewing study. Therefore finally the processing study reported in **RAF-1173** is based on material from 2 trials instead of 3: the 26-TT-BW-2021-FR02 and the 26-TT-BW-2021-FR03.

The properties of grain and malt are similar in reference and the test item material, and differences between them are safely within the tolerance limits imposed by the respective guidelines (except for lower  $\beta$ -glucans in malt from the SAP50SCF-treated barley, which is positive a result, since for their ability to impair wort filtration  $\beta$ -glucans are generally perceived as detrimental to beer brewing process). The same is true for functional analysis of malt and wort in the course of filtration and fermentation, and for the properties of the produced beer. Sensory analysis had not detected any gustatory variation between the two batches of beer either.

The **above has been concluded** by zRMS **based on** the review of the **raw data** in the original the RAF-1173 document. On the contrary, the graphical diagrams, copy-pasted below by the applicant from the RAF-1173 and followed by the baffling “legend” named, by the report author, an “Identity card of the speciality” is only a summary of the same data, rather confusing a device once applied without connection to the original figures.

#### - MALTING STUDY

The malting experiments were carried out, according to the ISO/MPFE/001 procedure, in the IFBM micro-malting plant on 2 x 2.2 kg of calibrated barley (>2.5 mm), for each specimen.

JOAO (reference) – SAP50SCF (treated 2)

	<i>BARLEY</i>									
>Significance reference										
> No significance reference										
= Reference	■		■		■		■		■	
< No significance reference										
< Significance reference										
■: Winter barley	Protein content	Germination index		Kernel size		DON		Ergosterol		

	PHYSICO-CHEMICAL & FUNCTIONAL ANALYSES OF MALT															
>Significance reference			■													
> No significance reference					■											
= Reference	■						■		■		■		■		■	
< No significance reference																
< Significance reference																
■: Winter barley	Fine grind extract	β-glucans		Viscosity		Friability		Calcofluor (modification)		Filtration rate		Attenuation limit		Apparent gravity (8 <sup>th</sup> day)		

	<i>BREWERY</i>											
> Significance reference												
> No significance reference									■			
= Reference	■		■		■		■				■	
< No significance reference												
< Significance reference												
■: Winter barley	Maïsche filtration	Free amino nitrogen		Time to ferment 5°Plato		Apparent attenuation		Head retention		Sensory analyses		

## IDENTITY CARD OF THE SPECIALITY

= **Reference:** the difference between the mean of « treated samples » and the mean of « reference samples » of 2 spots is between  $-\frac{1}{2}$  and  $+\frac{1}{2}$  of the significance difference.

< **No significance reference:** the difference between the mean of « treated samples » and the mean of « reference samples » of 2 spots is between  $-1$  and  $-\frac{1}{2}$  of the significance difference.

> **No significance reference:** the difference between the mean of « treated samples » and the mean of « reference samples » of 2 spots is between  $+\frac{1}{2}$  and  $+1$  of the significance difference.

< **Significance reference:** the difference between the mean of « treated samples » and the mean of « reference samples » of 2 spots is lower than the significance difference.

> **Significance reference:** the difference between the mean of « treated samples » and the mean of « reference samples » of 2 spots is upper than the significance difference.

These parameters are represented by their opposite: DON, ergosterol,  $\beta$ -glucans, viscosity, apparent gravity (8<sup>th</sup> day).

Beta-glucans level is lower in the treated samples, but it is a positive effect.

All the other results are similar between the reference and the treated samples.

### Conclusion

To conclude, according to EPPO guideline PP 1/243 (2) “*Effects of plant protection products on transformation processes*” trials which were done to evaluate the effects of SAP50SCF at 1.5 l/ha (1.25N dose) on barley for brewing and on wheat for bread-making, showed consistent results to demonstrate the absence of non-intentional effects.

#### **Comments of zRMS on the effect on transformation processes:**

Final conclusions of the applicant on the effect on bread making and beer brewing processes have been confirmed, based on the inspection of the 4 reports of baking tests and 4 other – reporting beer brewing tests. No negative effects have been concluded on either of these processes.

To zRMS abstract

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

Based on EPPO PP 1/135(4) ‘*Phytotoxicity assessment*’ and PP 1/226(3) ‘*Number of efficacy trials*’, for fungicides, data on plant parts for propagation are only required when some phytotoxic effects are seen on some crops. As mentioned before, no phytotoxicity symptoms were observed on any of the 64 performed trials across wheat and barley. Therefore, additional evidence or justification for effects on parts of plants used for propagation should not be required.

### **Summary and conclusion on treated plants or plants products to be used for propagation**



Based on EPPO PP 1/135(4) ‘*Phytotoxicity assessment*’ the use of SAP50SCF can be considered as safe for plant products to be used for propagation when applied following the corresponding GAP conditions.

**Comments of zRMS on 3.1.4:**

The applicant's conclusion accepted, based on the absence of phytotoxic effects in the submitted efficacy trials.

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

#### **3.5.1 Impact on succeeding crops (KCP 6.5.1)**

According to EPPO guideline PP1/207(2) “*Effects on succeeding crops*”: “*If the TER (Toxicity-Exposure Ratio) values are >1 (or the specific national level, if higher), then no further testing is necessary.*”

$$TER = EC_{10} / PEC_{soil} > 1$$

Based on the historical use of the active ingredient of SAP50SCF (Folpet), no negative impact on succeeding crops are likely to be observed. Folpet is an old active ingredient authorised on a wide range of crops across EU for decades with no related negative impact on succeeding crops.

However, in order to ensure the safe use of SAP50SCF according to the GAP conditions regarding to any impact on succeeding crops, data to study the biological activity of the SAP50SCF are presented. Two trials are submitted. One Seedling Emergence tests (SE) and one Vegetative Vigour test (VV) coded as KCP 6.5 (2) - ACE-08-259 and KCP 6.5 (3) - ACE-08-260 respectively.

The objective of these tests was to determine the EC50 for ecotox purposes (VV) and discard any negative effect on SE, but no EC10 or NOER values were calculated. However, obtained results can be considered as valid to determine the biological activity of SAP50SCF on different plant species. A brief summary of the results is presented below for each test:

- Results on Vegetative Vigour test:
  - o ER50 was determined to be higher than the higher tested rate (3.2 kg a.s./ha).
  - o No significant reduction on the Foliar Fresh weight was observed on any of the tested species (Corn (*Zea mays*), Raygrass (*Lolium perenne*), Wheat (*Triticum aestivum*), Cucumber (*Cucumis sativus*), Rape (*Brassica napus*), Sugar beet (*Beta vulgaris*) and Tomato (*Lycopersicon esculentum*), at any of the tested rates (0.8, 1.6 and 3.2 kg as/ha)
  - o No dead plants were observed at any of the tested rates on any crop.
  - o No phytotoxicity symptoms were observed on any of the tested crops at any rate.
- Results on Seedling Emergence tests are as follows:
  - o Tests were performed comparing just one single rate (1.6 kg as/ha) with the untreated.
  - o An erratic nascence was observed on two of the crops both on untreated and treated plots. Three attempts were needed to reach at least the 70% of emergence on *Brassica napus*, while nascence on *Cucumis sativus* was just 70%. In fact, report concludes that the low emergence observed on untreated plots may have influenced the obtained results on final fresh weight. Therefore, conclusions on all crops (except Rape and Cucumber, which were not considered as relevant) were under normal values.
  - o No negative effects were observed on final foliar fresh weight on any crop (except on Cucumber, but as mentioned before, results on this crop were not considered as relevant because of the erratic nascence).
  - o No dead plants were observed at any of the tested crops.
  - o No phytotoxicity symptoms were observed on any of the tested crops.

According to the mentioned results, it can be concluded that no negative effect was observed on Foliar fresh weight, dead plants or phytotoxicity symptoms on seedling emergence test at 1.6 kg ai/ha on any crop, and that no negative effect on vegetative vigour test was observed at 3.2 kg ai/ha on foliar fresh weight, dead plants or phytotoxicity symptoms. It can be assumed then that 1.6 kg/ha ai and 3.2 kg/ha

ai are NOER values with respect to emergence and plant vigor.

Considering also, not the PECsoil, but the maximum requested rate on SAP50 SCF rate (0.6 kg ai/ha per application or 1.2 kg ai/ha if considered the accumulated rate after two applications), a safe use can be concluded for SAP50SCF for succeeding crops:

$$TER = 1.6 / 1.2 = 1.33$$

Therefore, a safe use of SAP50SCF can be concluded for the impact on succeeding crops.

#### Comments of zRMS on 3.5.1 Impact on succeeding crops:

The applicant's conclusion has been accepted, based on the Emergence and Vegetative Vigor tests reported after Ecotoxicology section. The test item applied at the recommended dose rate of **1.2 L/ha** is safe for the succeeding crops.

To the [zRMS abstract](#)

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

According to EPPO Guideline PP1/256(1) – “Effects on adjacent crops”, “If the TER-value of the most sensitive crop is greater than 1 (or the specific national level, if higher), no further testing is necessary.”

The TER-value is calculated by comparing the biological activity (ED50-value for each plant species) to the estimated drift values in order to predict the likelihood of effects on adjacent crops at different distances from the treated crop.

$$TER = \frac{ED_{50}}{\text{drift (estimated)}}$$

According to the results on VV and SE tests discussed at 3.5.1 point (Impact on succeeding crops (KCP 6.5.1)), 3.2 kg ai/ha and 1.6 kg ai/ha are considered as NOER rates for VV and SE tests respectively. Considering 1.6 kg ai/ha as worst case for calculations (1.6 kg ai/ha = 3.2 L/ha of SAP50SCF), and maximum requested rate for SAP50SCF on the GAP (1.2 l/ha), TER values are calculated as follows:

**Table 3.5.2-1: TER-values**

Distance to adjacent crop (m)	Drift (%)	Drift test product 1.2 L/ha of SAP50SCF	TER for ER <sub>50</sub> (3,2 L/ha of SAP50SCF)
1	2.77	0,033	96,3
3	0.95	0,011	280,7
5	0.57	0,007	467,8
10	0.29	0,003	919,5
15	0.20	0,002	1333,3

TER values are > 1 in all cases. Consequently, no negative impact on succeeding crops is expected so no restrictions on adjacent crops according to SAP50SCF application are needed.

#### Comments of zRMS on 3.5.2 Impact on other plants including adjacent crops:

The applicant's conclusion has been accepted, based on the Emergence and Vegetative Vigor tests reported after Ecotoxicology section and the respective TER calculation taking into account the drift values, after Rautmann et al. 2001.

The test item applied at the recommended dose rate of **1.2 L/ha** is safe for the adjacent crops.

To the [zRMS abstract](#)

Rautmann, D., Strelake, M., Winkler, R. 2001 (1999). New basic drift values in the authorization procedure for plant protection products. Workshop on Risk assessment and Risk Mitigation Measures (WORMM), 27.-29. September 1999

### **Tank cleaning**

An insufficient tank cleaning can cause adverse effects on other plants (following crops treated by using the same tank).

According to PP 1/292 (1) “Cleaning pesticide application equipment (PAE) – efficacy aspects”, a risk assessment evaluation is provided to ensure there is no unacceptable risk to subsequently treated crops. A tiered approach described on the mentioned EPPO guideline is followed:

Tier 0: Do not apply, as application equipment used to spray SAP50SCF requires of a cleaning procedure

Tier 1: “If application equipment is used for subsequent treatments with other plant protection products (e.g. field sprayers) the phytotoxic properties of the plant protection product should be assessed using single-dose phytotoxicity screening data for crop plants. Testing should be at the maximum application rate on a range of representative species.”

“If the plant protection product causes no symptoms of phytotoxicity on the plant species tested, no further testing is necessary”

Folpet is an old active ingredient used for decades in EU across a wide range of crops, with no related phytotoxicity issues on any crop. In addition, the SE and ~~VE~~ **VV** ~~and SE~~ tests mentioned on previous paragraphs (3.5.1, “Impact on succeeding crops (KCP 6.5.1)” and 3.5.2, “Impact on other plants including adjacent crops (KCP 6.5.2)”), conclude that the rates higher (1.6 kg ai/ha for SE test and 3.2 kg ai/ha for VV) ~~rates~~ than the one requested for SAP50SCF authorisation (0.6 kg ai/ha) are considered as safe, not causing any negative effect on foliar fresh weight, dead plants or phytotoxicity symptoms.

Therefore, according to the mentioned results and in accordance with EPPO guideline 1/292 (1), no further testing is necessary.

However, a Tier 2 approach is also calculated.

Tier 2a: Calculation of residues left in the PAE according to appendix 4 of EPPO guideline 1/292 (1). Considering the maximum requested dose for SAP50SCF on the GAP (0.6 kg ai/ha), at maximum possible concentration (corresponding to 150 l/ha application volume):

- the amount of ai in a 1000L sprayer is 4000 g ai:  
 $1000/150 = 6.6667 \times 600 \text{ g ai/ha} = 4000 \text{ g ai}$
- Amount left after spraying (2.6%) is 104 g as:  
 $4000 \times 2.6\% = 104 \text{ g as.}$
- Amount left after 1st stage of washout procedure (2.6%) is 2.70 g as:  
 $104 \times 2.6\% = 2.704 \text{ g as}$
- Amount left after 2nd stage of washout procedure (2.6%) is 0.07 g as:  
 $2.704 \times 2.6\% = 0.070304 \text{ g as}$
- Amount after re-filling sprayer (1000 L) is 0.07 g as.
- Dose applied (at 400 L/ha) to 2.5 ha is 0.028122 g as/ha

$$0.070304 / 2.5 = 0.028122 \text{ g as/ha}$$

According to the reported results on SE and VV tests which concludes that 1.6 kg as/ha = 1600 g ai/ha (SE) and 3.2 kg as/ha = 3200 g ai/ha (VV) are considered as rates that causes no negative effects on any crop, and according to previous calculations on theoretical rate/ha on remaining Folpet active ingredient (0.028122 g as/ha), clearly shows a safe use of equipment used to apply SAP50SCF for following crops treated by using the same tank:

$$\text{TER} = 1600/0.028122 = 56895.77$$

#### Tier 2b: Small-scale/large-scale tests

A GLP study to determine the effectiveness of tank cleaning procedure for SAP50SCF is submitted (KCP 6.5 (1) - EF/376/21), to demonstrate that residues of the plant protection product do not remain in the application equipment after cleaning, and that there is no risk to subsequently treated crops.

The study was conducted following PSD Efficacy Guideline 302, September 2005 and PSD Efficacy Guideline 305, December 2004.

The residue level of Folpet in the effectiveness of cleaning procedure performed using water D found is 0.0064%.

Considering the maximum requested dose for SAP50SCF on the GAP (0.6 kg ai/ha), at maximum possible concentration (corresponding to 150 l/ha application volume):

- the amount of ai in a 1000L sprayer is 4000 g ai:  
 $1000/150 = 6.6667 \times 600 \text{ g ai/ha} = 4000 \text{ g ai}$
- Amount left tank cleaning (0.0064%) is 0.256 g as:  
 $4000 \times 0.0064\% = 0.256 \text{ g as.}$
- Amount after re-filling sprayer (1000 L) is 0.256 g as.
- Dose applied (at 400 L/ha) to 2.5 ha is 0.1024 g as/ha  
 $0.256 / 2.5 = 0.1024 \text{ g as/ha}$

According to the reported results on SE and VV tests which concludes that 1.6 kg as/ha = 1600 g ai/ha (SE) and 3.2 kg as/ha = 3200 g ai/ha (VV) are considered as rates that causes no negative effects on any crop, and according to previous calculations on theoretical rate/ha on remaining Folpet active ingredient according to the presented tank cleaning test (0.1024 g as/ha), clearly shows a safe use of equipment used to apply SAP50SCF for following crops treated by using the same tank:

$$\text{TER} = 1600/0.1024 = 15625$$

#### Comments of zRMS on Tank cleaning:

The reasoning of the applicant is consistent with the decision scheme presented in Appendix 1 of the EPPO PP 1/292 (1) guidance *Cleaning pesticide application equipment (PAE) – efficacy aspects*: in the absence of phytotoxicity symptoms at the TIER 1 tests (here the SE and VV tests presented in the preceding chapters) the TIER 2 data should not be required.

The additional TER calculation presented by the applicant notwithstanding is correct, and it confirms the safety of any subsequent treatments with the equipment used previously for application of SAP50SCF.

To [zRMS abstract](#)

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

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

**Comments of zRMS:** Noted.

### 3.6 Other/special studies

No other special studies are submitted.

### 3.7 List of test facilities including the corresponding certificates

**Table 3.7-1: List of test facilities**

Test facility	Address	Certificate (Yes or No)
<b>Agroensayos, Ensayos y Técnicas Agrícolas S.L.</b>	Calle Esparragal, 4 Pol. Ind. El Esparragal, Santovenia de Pisuerga, 47155 Spain	Yes
<b>AGROFIL</b>	9235 Püski, Petőfi Sándor utca 7 Hungary	Yes
<b>AgroProspect SRL</b>	Fantana 1 Brasov 507099 Romania	Yes
<b>ESSAIS +</b>	1 rue du 8 mai Boyelles, 62128 France	Yes
<b>Fertico Sp. z o.o.</b>	Goliany 43 Błędów, 05-620 Poland	Yes
<b>Field Research Support</b>	Potts Kamp 8 31515 Wunstorf Germany	Yes
<b>i2LResearch</b>	Shotley Bridge - Consett – County Durham, DH8 6SB United Kingdom	Yes
<b>OAT (Central)</b>	Stratton Audley Oxfordshire OX27 9AS United Kingdom	Yes
<b>Oxford Agricultural Trials</b>	West Farm Barn, Launton Road, Stratton Audley Oxfordshire OX27 9AS United Kingdom	Yes
<b>QUALIPHYT</b>	80, chemin de Riboulin, Loriol-sur-Drôme, 26270 France	Yes
<b>SAGEA Centro di Saggio S.r.l.</b>	Via San Sudario, 15, Castagnito d'Alba (CN), 12050 Italy	Yes
<b>Sagea OOD</b>	Akchelar 522 Varna, 9000 Italy	Yes
<b>STAPHYT</b>	La Paluzette Route des Mas,	Yes

Test facility	Address	Certificate (Yes or No)
	Marsillargues, 34590 France	

## Appendix 1 Lists of data considered in support of the evaluation

### List of data submitted by the applicant and relied on

Annex point	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Vertebrate study Y/N	Data protect claimed Y/N
KCP 6.0 (1)	ASCENZA	2022	Biological Assessment Dossier of SAP50SCF	N	YES
KCP 6.0 (2)	ASCENZA	2022	Biological Assessment Dossier of SAP50SCF (appendix)	N	YES
KCP 6.1 (1)	Castella, G.	2020	Study the benefit of SAP50SCF in the preventions on resistances in Wheat against Zimoseptoria tritici under controled conditions. Italy 2021 Sagea Centro di Saggio s.r.l; 63-F-2020-FR01 GEP Unpublished	N	YES
KCP 6.2 (1)	Zöllner, H.	2020	Field study to evaluate the efficacy and crop selectivity of SAP50SCF against Septoria on Wheat Field Research Support; 17-F-2020-DE01 GEP Unpublished	N	YES
KCP 6.2 (2)	Herrera, D.	2020	Evaluate the efficacy of SAP50SCF against Septoria on Wheat STAPHYT; 17-F-2020-DE02 GEP Unpublished	N	YES
KCP 6.2 (3)	Biaunier, M.	2020	Evaluate the efficacy of SAP50SCF against Septoria on Wheat QUALIPHYT; 17-F-2020-FR01 GEP Unpublished	N	YES
KCP 6.2 (4)	Biaunier, M.	2020	Evaluate the efficacy of SAP50SCF against Septoria on Wheat QUALIPHYT; 17-F-2020-FR04 GEP Unpublished	N	YES
KCP 6.2 (5)	Biaunier, M.	2020	Evaluate the efficacy of SAP50SCF against Septoria on Wheat QUALIPHYT; 17-F-2020-FR05 GEP Unpublished	N	YES

Annex point	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Vertebrate study Y/N	Data protect claimed Y/N
KCP 6.2 (6)	Crepin, D.	2020	Evaluate the efficacy of SAP50SCF against Puccinia striiformis on Wheat ESSAIS+; 17-F-2020-FR06 GEP Unpublished	N	YES
KCP 6.2 (7)	Hernández, J.M.	2020	Evaluate the efficacy of SAP50SCF against Septoria on Wheat Agroensayos; 17-F-2020-SP01 GEP Unpublished	N	YES
KCP 6.2 (8)	Ord, S.	2020	Field study to evaluate the efficacy and crop selectivity Of SAP50SCF against Septoria on Wheat i2L Research; 17-F-2020-UK01 GEP Unpublished	N	YES
KCP 6.2 (9)	Desogus, S.	2021	Evaluate the efficacy of SAP50SCF against Septoria tritici and Puccinia recondita on Wheat. Bulgaria 2021 (EPPOSE). SAGEA OOD; 05-F-2021-BG01 GEP Unpublished	N	YES
KCP 6.2 (10)	Desogus, S.	2021	Evaluate the efficacy of SAP50SCF against Septoria tritici and Puccinia recondita on Wheat. Bulgaria 2021 (EPPOSE). SAGEA OOD; 05-F-2021-BG02 GEP Unpublished	N	YES
KCP 6.2 (11)	Zöllner, H.	2021	Field study to evaluate the efficacy of SAP50SCF against Septoria on Wheat (Germany) Field Research Support; 05-F-2021-DE01 GEP Unpublished	N	YES
KCP 6.2 (12)	Zöllner, H.	2021	Field study to evaluate the efficacy of SAP50SCF against Septoria on Wheat (Germany) Field Research Support; 05-F-2021-DE02 GEP Unpublished	N	YES



Annex point	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Vertebrate study Y/N	Data protect claimed Y/N
KCP 6.2 (13)	Biaunier, M.	2021	Evaluate the efficacy of SAP50SCF against Septoria on Wheat QUALIPHYT; 05-F-2021-FR01 GEP Unpublished	N	YES
KCP 6.2 (14)	Biaunier, M.	2021	Evaluate the efficacy of SAP50SCF against Septoria on Wheat QUALIPHYT; 05-F-2021-FR02 GEP Unpublished	N	YES
KCP 6.2 (15)	Biaunier, M.	2021	Evaluate the efficacy of SAP50SCF against Septoria on Wheat QUALIPHYT; 05-F-2021-FR03 GEP Unpublished	N	YES
KCP 6.2 (16)	Biaunier, M.	2021	Evaluate the efficacy of SAP50SCF against Septoria on Wheat QUALIPHYT; 05-F-2021-FR04 GEP Unpublished	N	YES
KCP 6.2 (17)	Szénási, Z.R.	2021	Evaluate the efficacy of SAP50SCF against Septoria on Wheat Agrofil SZMI Kft.; 05-F-2021-HU01 GEP Unpublished	N	YES
KCP 6.2 (18)	Desogus, S.	2021	Evaluate the efficacy of SAP50SCF against Zymoseptoria tritici on Wheat. Italy 2021 SAGEA Centro di Saggio s.r.l.; 05-F-2021-IT01 GEP Unpublished	N	YES
KCP 6.2 (19)	Desogus, S.	2021	Evaluate the efficacy of SAP50SCF against Zymoseptoria tritici on Wheat. Italy 2021 SAGEA Centro di Saggio s.r.l.; 05-F-2021-IT02 GEP Unpublished	N	YES
KCP 6.2 (20)	Zöllner, H.	2021	Field study to evaluate the efficacy of SAP50SCF against Septoria on Wheat (Poland) FIELD RESEARCH SUPPORT; 05-F-2021-PL01 GEP Unpublished	N	YES

Annex point	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Vertebrate study Y/N	Data protect claimed Y/N
KCP 6.2 (21)	Rusek, K.	2021	Evaluate the efficacy of mixtures based on SAP50SCF against Septoria on Winter Wheat, Poland Fertico Sp. z.o.o.; 05-F-2021-PL02 GEP Unpublished	N	YES
KCP 6.2 (22)	Herrera, D.	2021	Evaluate the efficacy of SAP50SCF against Septoria on Wheat STAPHYT; 05-F-2021-PL04 GEP Unpublished	N	YES
KCP 6.2 (23)	Herrera, D.	2021	Evaluate the efficacy of SAP50SCF against Septoria on Wheat STAPHYT; 05-F-2021-PL05 GEP Unpublished	N	YES
KCP 6.2 (24)	Botoman, G.	2021	Evaluate the efficacy of SAP50SCF against Septoria on Wheat AgroProspect SRL; 05-F-2021-RO01 GEP Unpublished	N	YES
KCP 6.2 (25)	Zöllner, H.	2021	Field study to evaluate the efficacy of SAP50SCF against Septoria on Wheat (United Kingdom) Field Research Support: 05-F-2021-UK01 GEP Unpublished	N	YES
KCP 6.2 (26)	Hernández, J.M.	2021	Evaluate the efficacy of SAP50SCF against Septoria on Wheat AGROENSAYOS, ENSAYOS Y TÉCNICAS AGRÍCOLAS S.L.; 05-F-2021-SP01 GEP Unpublished	N	YES
KCP 6.2 (27)	Hernández, J.M.	2021	Evaluate the efficacy of SAP50SCF against Septoria on Wheat AGROENSAYOS, ENSAYOS Y TÉCNICAS AGRÍCOLAS S.L.; 05-F-2021-SP02 GEP Unpublished	N	YES
KCP 6.2 (28)	Zöllner, H.	2020	Evaluate the efficacy of SAP50SCF against Helminthosporium on Barley Field Research Support; 18-F-2020-DE01 GEP Unpublished	N	YES

Annex point	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Vertebrate study Y/N	Data protect claimed Y/N
KCP 6.2 (29)	Zöllner, H.	2020	Evaluate the efficacy of SAP50SCF against Helminthosporium on Barley Field Research Support; 18-F-2020-DE02 GEP Unpublished	N	YES
KCP 6.2 (30)	Biaunier, M.	2020	Evaluate the efficacy of SAP50SCF against Helminthosporium on Barley QUALIPHYT; 18-F-2020-FR01 GEP Unpublished	N	YES
KCP 6.2 (31)	Biaunier, M.	2020	Evaluate the efficacy of SAP50SCF against Helminthosporium on Barley QUALIPHYT; 18-F-2020-FR02 GEP Unpublished	N	YES
KCP 6.2 (32)	Rivet, J.	2020	Evaluate the efficacy of SAP50SCF against Helminthosporium on Barley ESSAIS+; 18-F-2020-FR03 GEP Unpublished	N	YES
KCP 6.2 (33)	Desogus, S.	2021	Evaluate the efficacy of SAP50SCF against Pyrenophora teres on Barley. Bulgaria 2021 (EPPOSE). SAGEA OOD; 06-F-2021-BG01 GEP Unpublished	N	YES
KCP 6.2 (34)	Desogus, S.	2021	Evaluate the efficacy of SAP50SCF against Pyrenophora teres on Barley. Bulgaria 2021 (EPPOSE). SAGEA OOD; 06-F-2021-BG02 GEP Unpublished	N	YES
KCP 6.2 (35)	Zöllner, H.	2021	Field study to evaluate the efficacy of SAP50SCF against Helminthosporium on Barley (Germany) Field Research Support; 06-F-2021-DE01 GEP Unpublished	N	YES
KCP 6.2 (36)	Zöllner, H.	2021	Field study to evaluate the efficacy of SAP50SCF against Helminthosporium on Barley (Germany) Field Research Support; 06-F-2021-DE02 GEP Unpublished	N	YES

Annex point	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Vertebrate study Y/N	Data protect claimed Y/N
KCP 6.2 (37)	Crepin, D.	2021	Evaluate the efficacy of SAP50SCF against Helmintosporium on Barley ESSAIS+; 06-F-2021-FR01 GEP Unpublished	N	YES
KCP 6.2 (38)	Crepin, D.	2021	Evaluate the efficacy of SAP50SCF against Helmintosporium on Barley ESSAIS+; 06-F-2021-FR02 GEP Unpublished	N	YES
KCP 6.2 (39)	Crepin, D.	2021	Evaluate the efficacy of SAP50SCF against Helmintosporium on Barley ESSAIS+; 06-F-2021-FR03 GEP Unpublished	N	YES
KCP 6.2 (40)	Biaunier, M.	2021	Evaluate the efficacy of SAP50SCF against Helminthosporium on Barley QUALIPHYT; 06-F-2021-FR04 GEP Unpublished	N	YES
KCP 6.2 (41)	Biaunier, M.	2021	Evaluate the efficacy of SAP50SCF against Helminthosporium on Barley QUALIPHYT; 06-F-2021-FR05 GEP Unpublished	N	YES
KCP 6.2 (42)	Herrera, D.	2021	Evaluate the efficacy of SAP50SCF against Helminthosporium on Barley, GEP Trial, FRANCE, 2021 STAPHYT; 06-F-2021-FR07 GEP Unpublished	N	YES
KCP 6.2 (43)	Desogus, S.	2021	Evaluate the efficacy of SAP50SCF against Ramularia collo-cygni on Barley. Italy 2021 SAGEA Centro di Saggio s.r.l.; 06-F-2021-IT01 GEP Unpublished	N	YES
KCP 6.2 (44)	Desogus, S.	2021	Evaluate the efficacy of SAP50SCF against Ramularia collo-cygni on Barley. Italy 2021 SAGEA Centro di Saggio s.r.l.; 06-F-2021-IT02 GEP Unpublished	N	YES

Annex point	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Vertebrate study Y/N	Data protect claimed Y/N
KCP 6.2 (45)	Zöllner, H.	2021	Field study to evaluate the efficacy of SAP50SCF against Helminthosporium on Barley (Poland) Field Research Support; 06-F-2021-PL01 GEP Unpublished	N	YES
KCP 6.2 (46)	Rusek, K.	2021	Evaluate the efficacy of mixtures based on SAP50SCF against Helminthosporium on winter barley, Poland 2020/2021 Fertico Sp. z.o.o.; 06-F-2021-PL02 GEP Unpublished	N	YES
KCP 6.2 (47)	Herrera, D.	2021	Evaluate the efficacy of SAP50SCF against Helminthosporium on Barley GEP Trial, POLAND, 2021 STAPHYT; 06-F-2021-PL04 GEP Unpublished	N	YES
KCP 6.2 (48)	Herrera, D.	2021	Evaluate the efficacy of SAP50SCF against Helminthosporium on Barley GEP Trial, POLAND, 2021 STAPHYT; 06-F-2021-PL05 GEP Unpublished	N	YES
KCP 6.2 (49)	Botoman, G.	2021	Evaluate the efficacy of SAP50SCF against Helminthosporium on Barley GEP Trial, ROMANIA, 2021 AgroProspect; 06-F-2021-RO01 GEP Unpublished	N	YES
KCP 6.2 (50)	Zöllner, H.	2021	Field study to evaluate the efficacy of SAP50SCF against Helminthosporium on Barley (United Kingdom) Field Research Support; 06-F-2021-UK01 GEP Unpublished	N	YES
KCP 6.2 (51)	Hernández, J.M.	2021	Evaluate the efficacy of SAP50SCF against Helminthosporium on Barley AGROENSAYOS, ENSAYOS Y TÉCNICAS AGRÍCOLAS S.L.; 06-F-2021-SP01 GEP Unpublished	N	YES

<b>Annex point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished</b>	<b>Vertebrate study Y/N</b>	<b>Data protect claimed Y/N</b>
KCP 6.2 (52)	Hernández, J.M.	2021	Evaluate the efficacy of SAP50SCF against Helminthosporium on Barley AGROENSAYOS, ENSAYOS Y TÉCNICAS AGRÍCOLAS S.L.; 06-F-2021-SP02 GEP Unpublished	N	YES
KCP 6.2 (53)	Herrera, D.	2021	Evaluate the efficacy of SAP50SCF against Helminthosporium on Barley, GEP Trial, FRANCE, 2021 STAPHYT; 06-F-2021-FR06 GEP Unpublished	N	YES
KCP 6.2 (54)	Kasztner, G.	2021	Evaluate the efficacy of SAP50SCF against Helminthosporium on Barley Agrofil-SZMI Kft.; 06-F-2021-HU01 GEP Unpublished	N	YES
KCP 6.4 (1)	Gaia, U.	2021	EVALUATION OF NON-INTENTIONAL EFFECTS OF SAP2101F AND SAP50SCF ON TRANSFORMATION PROCESS (BREADMAKING) ON WHEAT– ITALY (2021) SAGEA Centro di Saggio s.r.l.; 25-TT-BM-2021-IT01 GEP Unpublished	N	YES
KCP 6.4 (2)	Gaia, U.	2021	EVALUATION OF NON-INTENTIONAL EFFECTS OF SAP2101F AND SAP50SCF ON TRANSFORMATION PROCESS (BREADMAKING) ON WHEAT– ITALY (2021) SAGEA Centro di Saggio s.r.l.; 25-TT-BM-2021-IT02 GEP Unpublished	N	YES
KCP 6.4 (3)	Milhan, C.	2021	Unintentional effects of SAP2101F and SAP50SCF on transformation process (bread making) on wheat - 2021 STAPHYT; 25-TT-BM-2021-FR01 GEP Unpublished	N	YES
KCP 6.4 (4)	Milhan, C.	2021	Unintentional effects of SAP2101F and SAP50SCF on transformation process (bread making) on wheat - 2021 STAPHYT; 25-TT-BM-2021-FR02 GEP Unpublished	N	YES

<b>Annex point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished</b>	<b>Vertebrate study Y/N</b>	<b>Data protect claimed Y/N</b>
KCP 6.4 (5)	Herrera, D.	2021	Non-intentional effects of SAP2101F and SAP50SCF on transformation process (brewing) on barley, GEP Trial, FRANCE, 2021 STAPHYT; 26-TT-BW-2021-FR01 GEP Unpublished	N	YES
KCP 6.4 (6)	Herrera, D.	2021	Non-intentional effects of SAP2101F and SAP50SCF on transformation process (brewing) on barley, GEP Trial, FRANCE, 2021 STAPHYT; 26-TT-BW-2021-FR02 GEP Unpublished	N	YES
KCP 6.4 (7)	Herrera, D.	2021	Non-intentional effects of SAP2101F and SAP50SCF on transformation process (brewing) on barley, GEP Trial, FRANCE, 2021 STAPHYT; 26-TT-BW-2021-FR03 GEP Unpublished	N	YES
KCP 6.4 (8)	Gless, A.E.	2021	INTERMEDIARY STUDY REPORT N°2: MALTING STUDY STUDY OF UNINTENTIONAL EFFECTS OF SAP2101F AND SAP50SCF PRODUCTS APPLIED ON WINTER BARLEY, HARVEST 2021, ON MALT AND BEER QUALITY AND PROCESS I.F.B.M.; R-A-I-1173 GLP Unpublished	N	YES
KCP 6.4 (9)	Gaia, U.	2021	EVALUATION OF NON-INTENTIONAL EFFECTS OF SAP2101F AND SAP50SCF ON TRANSFORMATION PROCESS (BREWING) ON BARLEY – ITALY (2021) SAGEA Centro di Saggio s.r.l.; 26-TT-BW-2021-IT01 GEP Unpublished	N	YES
KCP 6.4 (10)	Gaia, U.	2021	EVALUATION OF NON-INTENTIONAL EFFECTS OF SAP2101F AND SAP50SCF ON TRANSFORMATION PROCESS (BREWING) ON BARLEY – ITALY (2021) SAGEA Centro di Saggio s.r.l.; 26-TT-BW-2021-IT02 GEP Unpublished	N	YES

<b>Annex point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished</b>	<b>Vertebrate study Y/N</b>	<b>Data protect claimed Y/N</b>
KCP 6.5 (1)	Morais, F.	2022	FOLPET 500 g/L SC (SAP50SCF) Effectiveness of Cleaning Procedure ASCENZA Agro, S.A.; Study EF/376/21 GLP Unpublished	N	YES
KCP 6.5 (2)	Eley, R.	2008	Evaluation of the Phytotoxicity of Folpet 80% WG Non Target Terrestrial Plant Seedling Emergence and Growth Test AgroChemex Ltd.; ACE-08-259 GLP Unpublished	N	YES
KCP 6.5 (3)	Gless, A.E.	2021	INTERMEDIARY STUDY REPORT N°2: MALTING STUDY STUDY OF UNINTENTIONAL EFFECTS OF SAP2101F AND SAP50SCF PRODUCTS APPLIED ON WINTER BARLEY, HARVEST 2021, ON MALT AND BEER QUALITY AND PROCESS I.F.B.M.; R-A-I-1173 GLP Unpublished	N	YES
KCP 6.5 (3)	Eley, R.	2008	Evaluation of the Phytotoxicity of Folpet 80% WG Non Target Terrestrial Plant Vegetative Vigour Test AgroChemex Ltd.; ACE-08-260 GLP Unpublished	N	YES

**List of data submitted by the applicant and not relied on**

<b>Annex point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished</b>	<b>Vertebrate study Y/N</b>	<b>Data protect claimed Y/N</b>
KCP 6.2 (5)	Biaunier, M.	2020	Evaluate the efficacy of SAP50SCF against Septoria on Wheat QUALIPHYT; 17-F-2020-FR05 GEP Unpublished	N	YES
KCP 6.2 (6)	Crepin, D.	2020	Evaluate the efficacy of SAP50SCF against Puccinia striiformis on Wheat ESSAIS+; 17-F-2020-FR06 GEP Unpublished	N	YES



Annex point	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Vertebrate study Y/N	Data protect claimed Y/N
KCP 6.2 (8)	Ord, S.	2020	Field study to evaluate the efficacy and crop selectivity Of SAP50SCF against Septoria on Wheat i2LResearch; 17-F-2020-UK01 GEP Unpublished	N	YES
KCP 6.2 (13)	Biaunier, M.	2021	Evaluate the efficacy of SAP50SCF against Septoria on Wheat QUALIPHYT; 05-F-2021-FR01 GEP Unpublished	N	YES
KCP 6.2 (17)	Szénási, Z.R.	2021	Evaluate the efficacy of SAP50SCF against Septoria on Wheat Agrofil-SZMI Kft.; 05-F-2021-HU01 GEP Unpublished	N	YES
KCP 6.2 (28)	Zöllner, H.	2020	Evaluate the efficacy of SAP50SCF against Helminthosporium on Barley Field Research Support; 18-F-2020-DE01 GEP Unpublished	N	YES
KCP 6.2 (29)	Zöllner, H.	2020	Evaluate the efficacy of SAP50SCF against Helminthosporium on Barley Field Research Support; 18-F-2020-DE02 GEP Unpublished	N	YES
KCP 6.2 (30)	Biaunier, M.	2020	Evaluate the efficacy of SAP50SCF against Helminthosporium on Barley QUALIPHYT; 18-F-2020-FR01 GEP Unpublished	N	YES
KCP 6.2 (35)	Zöllner, H.	2021	Field study to evaluate the efficacy of SAP50SCF against Helminthosporium on Barley (Germany) Field Research Support; 06-F-2021-DE01 GEP Unpublished	N	YES
KCP 6.2 (36)	Zöllner, H.	2021	Field study to evaluate the efficacy of SAP50SCF against Helminthosporium on Barley (Germany) Field Research Support; 06-F-2021-DE02 GEP Unpublished	N	YES

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KCP 6.2 (44)	Desogus, S.	2021	Evaluate the efficacy of SAP50SCF against Ramularia collo-cygni on Barley. Italy 2021 SAGEA Centro di Saggio s.r.l.; 06-F-2021-IT02 GEP Unpublished	N	YES
KCP 6.2 (47)	Herrera, D.	2021	Evaluate the efficacy of SAP50SCF against Helminthosporium on Barley GEP Trial, POLAND, 2021 STAPHYT; 06-F-2021-PL04 GEP Unpublished	N	YES
KCP 6.2 (48)	Herrera, D.	2021	Evaluate the efficacy of SAP50SCF against Helminthosporium on Barley GEP Trial, POLAND, 2021 STAPHYT; 06-F-2021-PL05 GEP Unpublished	N	YES
KCP 6.2 (50)	Zöllner, H.	2021	Field study to evaluate the efficacy of SAP50SCF against Helminthosporium on Barley (United Kingdom) Field Research Support; 06-F-2021-UK01 GEP Unpublished	N	YES
KCP 6.2 (51)	Hernández, J.M.	2021	Evaluate the efficacy of SAP50SCF against Helminthosporium on Barley AGROENSAYOS, ENSAYOS Y TÉCNICAS AGRÍCOLAS S.L.; 06-F-2021-SP01 GEP Unpublished	N	YES