REGISTRATION REPORT

Part B

Section 3

Efficacy Data and Information

Concise summary

Product code: FHO04

Product name(s): Prothioconazole/Sulphur (50+625) SC, /Patton Supra

Chemical active substance(s):

Prothioconazole 50 g/L,

Sulphur 625 g/L

Central registration zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: UPL Holdings Coöperatief U.A.

Submission date: May 2024, update: October 2024

MS Finalisation date: November 2024 (initial Core Assessment)

February 2025 (final Core Assessment)

Version history

When	What
May 2024	Initial dRR - UPL Holdings Coöperatief U.A.
October 2024	Update dRR - UPL Holdings Coöperatief U.A. Changes made to address PL evaluator preliminary comments. These include summaries of efficacy for each crop species, clarification of the active substances of products tested in the preliminary trials, and further discussion of the processing assessments. All changes are highlighted yellow by the Applicant.
November 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 highlighted in grey. Not agreed or not relevant information are ~~struck through~~ and shaded for transparency. Following the evaluation and before sending the document for commenting, all coloured highlighting was removed by zRMS from the parts updated by the Applicant, for better legibility.
February 2025	Final report (Core Assessment updated following the commenting period) Additional information/assessments included by the zRMS in the report in response to comments received from the cMS and the Applicant are highlighted in yellow : (3.2.3.7, 3.5.2). Not agreed or not relevant information are ~~struck through~~ and shaded for transparency.

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

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~~.

In order to avoid ambiguity in marking, any grey highlighting used by the applicant in the cells of tables **has been removed by the zRMS**.

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

Abstract by zRMS

Introduction
FHO04 is a suspension concentrate co-formulating 50 g/L prothioconazole and 625 g/L sulphur, intended for the control of *Septoria* and *Puccinia* pathogens in cereals. The applicant, UPL Holdings Coöperatief U.A., is seeking full authorization of the fungicide FHO04 according to the article 33 of the Regulation (EU) No 1107/2009.

The Data Submitted
The dossier includes **63** valid preliminary, MED and efficacy trials: **43 in winter wheat** (including one in durum wheat), 36 of them addressing SEPTTR, 11 addressing PUCCRE or PUCCRT, 10 addressing PUCCST, or PUCCSI (3 trials), **6 trials in triticale** (2 addressing SEPTTR, 1 addressing PUCCRT and 3 addressing PUCCST) and **10 trials in rye** (all addressing PUCCRE or PUCCRT). (In addition, 4 trials in rye addressed RHYNSE and 7 trials in winter wheat, including durum wheat, addressed ERYSGT. None of these pathogens is, however subject to claim in the present submission.)
The winter wheat trials have been carried out in the Czech Republic (1), Germany (14), France (Maritime) (1), UK (3), Lithuania (4), Latvia (6) and Poland (18). The French and British trials are only used in Preliminary Tests chapter, they address co-formulation and the ratio of the actives in FHO04.
Triticale trials, as well as rye trials have been carried out in Germany (2 and 4, respectively) and in Poland (4 and 6 respectively).
Moreover, 3 French, winter wheat trials (field phase, 1 Mediterranean location and 2 Maritime locations) produced grain material for bread making test, reported in a separate, fourth document (lab phase).

Preliminary trials
Both the advantage of co-formulation of prothioconazole and sulphur as well as their ratio in the FHO04: **50/625** g/L, have been considered as demonstrated and justified effectively. For more detailed comments see the 4 consecutive commenting boxes in the pages 29-37.

MED - Minimum Effective Dose
The target dose rate of **4.0 L/ha** of the test item FHO04 has been effectively demonstrated and justified, as the minimum effective dose in control of pathogen complex (PUCCRE, PUCCST and SEPTTR) in winter wheat and in winter rye. For more detailed comments see the 4 consecutive commenting boxes in the pages 43-56.

EFFICACY
General remarks
1.The aim of the present submission is clearly to obtain authorization for 2 applications per use and per crop. Consequently, all the assessments present efficacy following the second application and data analysis apparently confirms that **it is only double application** that provides satisfactory efficacy in control of the pathogens in question. The applicant`s awarness of the situation is also evident from the label project wherein the respective phrase reads briefly: "Number of applications: 2", and from the data classification: a single trial reported in UPL Report No. F21EU-009-011-003 has been excluded, by the applicant, as inconsistent with efficacy and even with the yield assessment, based on its including only a single application of the FHO04.
Hence, the original entry in the column 8 GAP table, reading: "a) 1, b) 2)" was incoherent with efficacy dossier and had been as such considered incorrect. The zRMS has therefore replaced the entry with "a) 2, b) 2)", so it is now in line with the data set submitted.

2.Based on **the application timing** in trials, as reported by the applicant and as corrected by zRMS according to individual trial reports (both in Table 3.2-19), the entry in the column 7 GAP table, reading: BBCH 27-69, has been amended and it now reads: BBCH 30-69.
3.For most of the time, including when referred to triticale crop, the applicant is using the EPPO code PUCCSI, standing for *Puccinia striiformis* f. sp. *tritici*, which can be only found on wheat. In the complete data set only 3 trials explicitly describe the pathogen assessed as PUCCSI: this is on winter soft wheat crop. Otherwise, and **including all the other instances** when winter wheat is meant, the testing units always code the assessed pathogen as PUCCST. The zRMS therefore can see no reason to discuss the efficacy of the test item in control of the very specific pathogen: PUCCSI, while majority of the data submitted plainly testify of another: PUCCST. The zRMS conclusions are thus concerned only with PUCCST.

Control levels
In winter wheat, the efficacy of FHO04 in control of **SEPTTR**, after double applications at 4.0 L/ha, had reached the **moderate** level of 77-84%, depending on the assessment date and leaf stratum L1, L2 or L3, but it has been considered equivalent to standard reference products in 31 wheat trials, carried out in the North-Eastern and the Maritime EPPO zones. The efficacy of FHO04 against **PUCCRE** and **PUCCST** was clearly **higher** compared to that against SEPTTR: the level >90% and often exceeding 95%, particularly within the assessments 2-3 weeks following the 2nd application. At the last valid assessment efficacy declined to the levels < 90% and sometimes <80% in control of PUCCRE, but not so in control of PUCCST, where it remained the level of 90-97% in the NE zone and 62-99% in Maritime zone.
In winter rye the efficacy in control of SEPTTR was not assessed. The efficacy against **PUCCRE** was high in the NE zone trials, similar to that observed in wheat (95-100% 2-3 weeks after 2nd application and until the last valid assessment), although it was apparently lower in Maritime zone / in German trials (80-82%). To the opinion of zRMS in both cases the performance of the test item is comparable to standards.
In winter triticale only 2 trials tested for efficacy against **SEPTTR**, and a single trial – for efficacy against **PUCCRE**. These data proved the efficacy of the FHO04 equivalent to standards, with the efficacy figures between 90-100% (SEPTTR and PUCCRE). The control of **PUCCST** on triticale was visibly lower compared to that on wheat: 90-93% in the NE zone (n=2) and 52-78% in the Maritime zone (n=1), but in both cases efficacy of the test item was equivalent to that of averaged standards.

Green Leaf Area
The average *per cent* increase in the GLA, across the North-Eastern and Maritime zone data **in winter wheat** was the level of 35%, compared to 34% achieved by the averaged standard reference products. The increase **on triticale** and **on rye** respectively was, on average, 34 vs 38% and 36 vs 36% (test vs standard) (Table 3.2-37).

Trial count and authorization options
Testing for the use against SEPTTR has been addressed by 31 trials in wheat. Testing for the use against PUCCRE has been addressed by 10 trials in wheat, by 10 trials in rye and by one trial in each triticale and durum wheat. Testing for the use against PUCCST has been addressed by 9 valid trials in soft winter wheat, by one trial in durum wheat and by 3 trials in triticale. All trials have been carried out in at least 2 growth seasons, mostly between 2020 and 2023.
Based on the data submitted and considering the minimum requirements set by the EPPO PP 1/226 (3) *Number of efficacy trials,* it is possible to authorize FHO04 for double application at 4.0 L/ha at BBCH 30-69 in control of SEPTTR, PUCCRT and PUCCST in soft winter wheat (**TRZAW**) and in control of PUCCRR in winter rye (**SECCW**). Based on extrapolation of data from wheat and rye the authorization may also be granted for the use, at the same dose rate and growth stage, in winter triticale (**TTLWI**), in control of SEPTTR, PUCCRE and PUCCST.
For more details concerning control levels see the specific commenting boxes following respective sections of the efficacy chapter: SEPTTR, PUCCRE, PUCCST. For **justification of data extrapolation** to winter triticale crop also see the final efficacy comments.

Spring forms of cereals
Extrapolation from winter forms of wheat and triticale to spring forms, as suggested by the applicant in the GAP table, is **not** possible based on the present data set. The reason for that is the complete absence (n=0) of trials in spring forms, while the submission of 1-2 trials in the crop to which one extrapolates is, according to national requirements, the *sine qua non* condition making extrapolation possible. Moreover, in case of new products, including new actives or **new mixtures**, or in case of new uses, the required number of these trials is **no less than 2** for each use, with the "use" defined as each one of the combinations: *crop x pathogen*.

Durum wheat, Spelt wheat

Both species are minor crops in Poland, and since the applicant is seeking authorization in these crops according to Article 51 of the Regulation (EC) No 1107/2009, the efficacy data are not required for them.
Irrespectively, the pathogen nomenclature and codes have been corrected for these entries in the GAP table, as was the number of applications, for there is no good justification to have them *in*coherent with conditions defined for the other, major crops. On the contrary, the BBCH growth stages for these minor crops have been retained unaltered, since except the 2 trials in durum wheat there is hardly any data available for these species which could support any such amendments.

Information for potential authorizations based on mutual recognition
The dossiers includes only data from the North-Eastern zone and Maritime zone. No data from the South-Eastern zone have been submitted, and the single trial from Mediterranean zone (FR) has only produced material for baking tests; it has delivered **no efficacy data**.
To the opinion of zRMS PL, the German and Czech efficacy data from **winter wheat** may be useful and sufficient for authorization in the Maritime zone, but triticale and rye data are too scarce for authorization, since FHO04 is a new product.

PHYTOTOXICITY, YIELD, propagation material, transformation processes, succeeding crops, adjacent crops
Phytotoxicity and adverse effects on the yield, propagation material, transformation processes, succeeding crops and adjacent crops are not expected after application of FHO04, when used according to label recommendations.
Yield from efficacy trials
Phytotoxicity in Efficacy trials
Phytotoxicitty in disease-free and low-pressure trials
Effects on the quality of plants or plant products
Effects on transformation processes
Impact on treated plants or plant products to be used for propagation
Succeeding crops
Adjacent crops

RESISTANCE RISK
Based on the submitted data and in order to avoid possible development of resistance, the following **standard** resistance management tools are recommended to be included in the label of FHO04:

- *Use FHO04 in accordance with label recommendations, i.e. observing the maximum number applications per growth season, and the recommended dose rate,*
- *Include, in the adopted plant protection program, fungicides containing active substances from other groups according to the FRAC classification, with different modes of action (use the products alternately or in a tank mixture),*
- *Use FHO04 mainly preventively i.e. at the beginning of primary or secondary infection periods,*
- *Include, in the adopted disease plant protection program, control methods other than chemical, in accordance with the principles of integrated plant protection, e.g. cultivation of resistant varieties and the appropriate crop rotation.*

For the broader information on resistance risk follow the link Resistance.

This draft Registration Report supports an Article 33 submission for the authorisation of a new fungicide, FHO04. This product contains the active substances prothioconazole (50 g/L) and, sulphur (625 g/L), formulated as a Suspension concentrate (SC). Its intended use is as a fungicide for the control of foliar diseases of cereals in Poland.
Preliminary tests
Leaf spot (*Zymoseptoria tritici* - SEPTTR) is the major problematic disease in cereals. Therefore, the objective of this preliminary part is to justify the interest to associate sulphur with prothioconazole to control leaf spot (*Zymoseptoria tritici* - SEPTTR).
In 5 trials carried out in Maritime EPPO climatic zone and provided as supportive data, FHO04 applied at 4.0 L/ha (200 g a.s./ha prothioconazole + 2500 g a.s./ha sulphur) was compared to Prothioconazole based products applied straight at 200 g a.s./ha, Sulphur based products applied straight at 2475 g a.s./ha and the extemporaneous tank-mix prothioconazole + sulphur.
In these 5 trials, different ratios of prothioconazole and sulphur was also tested to determine the best ratio between both active substances.

In 28 trials, FHO04 applied at 4.0 L/ha (200 g a.s./ha prothioconazole + 2500 g a.s./ha sulphur) was compared only to Prothioconazole based products applied straight at 200 g a.s./ha. According to the trial, Prothioconazole based product used in the trials was an internal preparation (code name FGR06, Prothioconazole, 250 g/L) applied at 0.8 L/ha or Proline also applied at 0.8 L/ha.
Based on the benefits with respect to resistance prevention, the knowledge of each active substances, and technical possibilities on formulation, the combination of the active substances prothioconazole + sulphur in FHO04 and their rate ratio can be considered as justified.

Minimum effective dose tests

The confirmation of required doses of FHO04, was supported by the data from 58 valid efficacy trials carried out from 2020 to 2023 in the Northeast EPPO climatic zone (28 trials in Poland, 6 trials in Latvia and 4 trials in Lithuania) and Poland border countries (1 trial in Czech Republic, and 19 trials in Germany) in winter wheat (41 trials), durum wheat (1 trial) or winter triticale (6 trials) or winter rye (10 trials) against SEPTTR (33 trials) , PUCCRE (22 trials) and/or PUCCSI (13 trials). Some trials contained more than one target disease, therefore the total number of trials for all diseases exceeds 58 valid trials.
The mean efficacy increases in function of the dose rate of FHO04. FHO04 at 4.0 L/ha reached efficacy superior to ~~a superior efficacy than~~ the lower rates and a good efficacy to control the disease complex on cereals confirming the selection of 4.0 L/ha as maximum registered dose.

Efficacy tests

A total of 59 valid efficacy trials carried out from 2019 to 2023 are provided to confirm the efficacy of FHO04 at 4.0 L/ha in Poland in winter cereals.
In accordance with EPPO guideline PP1/257, all data against cereals disease complex (SEPTTR, PUCCRE, and/or PUCCSI) in winter and spring wheat, durum wheat, spelt, rye, and triticale can be considered as comparable and merged* in this section. The efficacy of FHO04 was good against cereals disease complex (SEPTTR, PUCCRE, and/or PUCCSI). Therefore, provided data are sufficient to justify the efficacy of FHO04 at 4.0 L/ha to control cereals disease complex.

Comments of zRMS:
*On request of the zRMS the applicant had updated the BAD and dRR in October 2024, providing, in the updated document, separate summaries of efficacy for each cereal species.

Information on the occurrence or possible occurrence of the development of resistance

The possibility of development of resistance or cross-resistance to the active substances contained in FHO04 is discussed thereafter based on the requirements detailed in EPPO standard PP1/213(4) '*Resistance risk analysis*'.
As a summary, the risk of resistance to low to medium is considered acceptable when the product is used according to the GAPs and taking into account the proposed management strategies.

Adverse effects on treated crops

The crop sensitivity was assessed in 59 efficacy trials in winter soft wheat, 2 efficacy trials in durum wheat, 10 efficacy trials in winter triticale and 12 efficacy trials in winter rye. No phytotoxicity symptoms caused by FHO04 at the proposed dose of 4.0 L/ha were recorded in any of the ~~all~~ efficacy trials. No effect is expected in cereals if FHO04 is applied at the maximum requested rate of 4.0 L/ha according to the Good Agricultural Practices and label recommendations.
Concerning the effect on the yield and the quality of harvested grains, sulphur and prothioconazole are existing active substances and no effect on the yield is known. In addition, no adverse effect and no difference with the reference standards was noted in valid efficacy trials harvested. No adverse effect on the yield and on the quality of cereals is expected if FHO04 is applied at the maximum requested rate of 4.0 L/ha according to the Good Agricultural Practices and label recommendations.
The possible effect of FHO04 on the transformation processes was studied from a set of 3 confirmatory processing trials implemented in 2022 in France in the Maritime (2 trials) and the Mediterranean EPPO climatic zone. No adverse influence on the transformation processes is expected if FHO04 is used in accordance with good agricultural practices, including label instructions.
A summary of the range of varieties tested and the extent of crop damage observed is provided to support the use of FHO04 on plants used for propagation purposes. It is concluded that no negative impact on plant propagation will occur to these crops. Therefore, no effect on parts of plant used for propagating

purposes is expected if FHO04 is applied in accordance with the Good Agricultural Practices and label recommendations.

Observations on other undesirable or unintended side - effects

Fungicides usually do not exhibit herbicidal activity. Phytotoxicity was considered as acceptable on cereals (wheat, rye and triticale) in all ~~any~~ of the 83 efficacy trials where FHO04 was applied as a straight product up to 4.0 L/ha.

In addition, any potential impact of FHO04 on succeeding and adjacent crops would principally be related to the active substances. Sulphur and prothioconazole are used in Europe for many years and no side-effect is known in Europe.

No side-effect on beneficial and other non - target organisms were observed in the 83 efficacy trials carried out in on cereals (wheat, rye and triticale) where FHO04 was applied as a straight product up to 4.0 L/ha.

Therefore, no side-effect is expected if FHO04 is used according to the Good Agricultural Practices and label recommendations.

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

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use - No. *	**Member state(s)**	**Crop and/ or situation** (crop destination / purpose of crop)	**F, Fn, Fnp G, Gn, Gnp or I ****	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application dose**			**PHI** (days)	**Remarks:** e.g. g safener/ synergist per ha, other dose 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. dose per appl. b) max. total dose per crop/season	g or kg a.s./ha a) max. dose per appl. b) max. total dose per crop/season	Water L/ha min / max			
1	PL	Winter wheat (TRZAW)	F	Septoria (*Zymoseptoria tritici*) SEPTTR Yellow rust (*Puccinia striiformis*) PUCCST Brown rust (*Puccinia triticina*) PUCCRT	Foliar spraying	BBCH 30-69	a) 2 b) 2	14	a) 4 b) 8	a) 0.2 + 2.5 b) 0.4 + 5.0	100-400	35		A
2	PL	Spring wheat (TRZAS)	F	Septoria (*Zymoseptoria tritici*) SEPTTR Yellow rust (*Puccinia striiformis*) PUCCST Brown rust (*Puccinia triticina*) PUCCRT	Foliar spraying	BBCH 30-69	a) 2 b) 2	14	a) 4 b) 8	a) 0.2 + 2.5 b) 0.4 + 5.0	100-400	35		N
3	PL	Winter triticale (TTLWI)	F	Septoria (*Zymoseptoria tritici*) SEPTTR Yellow rust (*Puccinia striiformis*) PUCCST Brown rust (*Puccinia triticina*) PUCCRT	Foliar spraying	BBCH 30-69	a) 2 b) 2	14	a) 4 b) 8	a) 0.2 + 2.5 b) 0.4 + 5.0	100-400	35		A
4	PL	Spring triticale (TTLSO)	F	Septoria (*Zymoseptoria tritici*) SEPTTR Yellow rust (*Puccinia striiformis*) PUCCST Brown rust (*Puccinia triticina*) PUCCRT	Foliar spraying	BBCH 30-69	a) 2 b) 2	14	a) 4 b) 8	a) 0.2 + 2.5 b) 0.4 + 5.0	100-400	35		N
5	PL	Winter rye (SECCW)	F	Brown rust (*Puccinia recondita f. sp. recondita*) PUCCRR	Foliar spraying	BBCH 30-69	a) 2 b) 2	14	a) 4 b) 8	a) 0.2 + 2.5 b) 0.4 + 5.0	100-400	35		A
Minor uses according to Article 51 (field uses)														
6	PL	Durum wheat (TRZDU)	F	Septoria (*Zymoseptoria tritici*) SEPTTR Yellow rust (*Puccinia striiformis*) PUCCST Brown rust (*Puccinia triticina*) PUCCRT	Foliar spraying	BBCH 27-69	a) 2 b) 2	14	a) 4 b) 8	a) 0.2 + 2.5 b) 0.4 + 5.0	100-400	35		n.r.
7	PL	Spelt (TRZSP)	F	Septoria (*Zymoseptoria tritici*) SEPTTR Yellow rust (*Puccinia striiformis*) PUCCST Brown rust (*Puccinia triticina*) PUCCRT	Foliar spraying	BBCH 27-69	a) 2 b) 2	14	a) 4 b) 8	a) 0.2 + 2.5 b) 0.4 + 5.0	100-400	35		n.r.
8	PL	Spring rye (SECCS)	F	Brown rust (*Puccinia recondita f. sp. recondita*) PUCCRR	Foliar spraying	BBCH 27-69	a) 2 b) 2	14	a) 4 b) 8	a) 0.2 + 2.5 b) 0.4 + 5.0	100-400	35		n.r.

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

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

Column 15: zRMS conclusion:

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

3.2 Efficacy data (KCP 6)

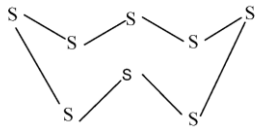
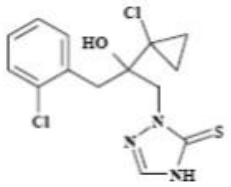
Introduction

This draft Registration Report supports an Article 33 submission for the authorisation of a new fungicide, FHO04. This product contains the active substances prothioconazole (50 g/L) and, sulphur (625 g/L), formulated as a Suspension concentrate (SC). Its intended use is as a fungicide for the control of foliar diseases of cereals in Poland.
Both actives are included into Regulation (EC) No 1107/2009 (Commission Implementing Regulation (EU) 2023/918 of 4 May 2023 and 2023/2595 of 21 November 2023, respectively). The SANCO report for prothioconazole: SANCO/3923/07 final 10 December 2007 and updated 26 January 2021) and for sulphur: SANCO/2676/08 – final (22 October 2009 and updated 13 July 2012) are considered to provide the relevant review information or a reference to where such information can be found.
zRMS in charge of the evaluation of this preparation is Poland. Only Poland is concerned by this submission.

Description of active substances

Active substances properties are summarised in Table 3.2-1.

Table 3.2-1: Details of the active substances

Active substance	Sulphur	Prothioconazole
Concentration	625 g/L	50 g/L
Chemical name (IUPAC)	Sulphur	(RS)-2-[2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)- 2-hydroxypropyl]-2,4-dihydro-1,2,4-triazole-3- thione
Chemical name (CA)	Sulphur	2-[2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2- hydroxypropyl]-1,2-dihydro-3H-1,2,4-triazole-3- thione
CAS No	7704-34-9	178928-70-6
Molecular formula	S_8	$C_{14}H_{15}Cl_2N_3OS$
Molecular mass	32.064 g/mol	344.26 g/mol
Structural formula		
Chemical group	Inorganic	Triazole
Group name	Sulphur	DMI-fungicides (DeMethylation Inhibitors) (SBI: Class I)
Mode of action	Multi-site FRAC Code M02	Sterol biosynthesis in membranes FRAC Code G1 New FRAC group : Group 3
Biological action	Multi-site contact activity	Curative and Protectant foliar fungicide, contact/residual with translaminar properties

Mode of action

Sulphur is a non-systemic multisite inorganic fungicide with a secondary biological activity against mites. It exerts its biological activity by contact. Sulphur inhibits the development and growth of diseases caused by fungal pathogens. Sulphur present on the leaves of treated plants acts as elemental sulphur. It could penetrate the fungal cells or mite cells due to its liposolubility and can break the cell membrane resulting in cell death due to dehydratation. It also acts at the respiratory chain level (on cytochrome C) by disrupting electron transport and therefore preventing the ATP formation. The particle size of sulphur influences anti-fungal activity. Chemicals with multi-site activity like sulphur are generally considered as a low risk group without any signs of resistance developing to the fungicides.

Prothioconazole is a broad-spectrum synthetic fungicide of the triazolinthione family of compounds with curative, preventive ~~preventative~~ and eradicative action (FRAC Group 3). It can be used as both a seed treatment and a foliar treatment. After absorption, it moves into cells of the target organisms, effecting sterol biosynthesis and thereby disrupting membrane structure. This ultimately effects hyphal growth and germ tube elongation. Fungi susceptible to prothioconazole include diseases caused by Ascomycetes, Basidiomycetes and Deuteromycetes. Prothioconazole is approved for use on barley, wheat (winter soft wheat, spring soft wheat, durum wheat), oats, rice, rye and triticale. Prothioconazole is sold in combination with numerous other fungicides, including bixafen, spiroxamine, tebuconazole, fluoxastrobin, trifloxystrobin and fluopyram.

Description of the plant protection product

FHO04 is a Suspension concentrate (SC) preparation containing 50 g/L prothioconazole and 625 g/L sulphur intended ~~addressed~~ to control foliar diseases of cereals by foliar application method. The trade name of FHO04 is PATTON SUPRA.
FHO04 is a new co-formulated product containing prothioconazole and sulphur. In Poland, several preparations containing prothioconazole are currently registered on cereals. On the other hand, no preparation containing sulphur is currently registered on cereals (Table 3.2-2).

Table 3.2-2: Products containing prothioconazole or sulphur - List of authorizations granted in Poland - Cereals

Active substance	Rate of active substance	Formulation	Authorisation Holder	Product Name	Registration No.	Registered Maximum single dose rate	Maximum rate of active substance
Prothioconazole	250 g/L	EC	ADAMA	SORATEL 250 EC	R-156/2023	0.8 L/ha	200 g a.s./ha
			INNVIGO	PROTIKON 250 EC	R-127/2021		
				VIRID 250 EC	R-128/2021		
			FINCHIMICA	PROTIOSTAR	R-77/2021		
			NUFARM	JOUST 250 EC	R-119/2023		
			ROTAM AGROCHEMICAL	EUSKATEL 250 EC	R-175/2022		
				SKELDON	R-8/2023		
			SHARDA	EXACTRIS	R-30/2020wu		
				PRAKTIS	R-222/2019		
	300 g/L	EC	GLOBACHEM	PROTENDO 300 EC	R-224/2019	0.3-0.6 L/ha	90-180 g a.s./ha
				PABI 300 EC	R-27/2020		
				PECARI 300 EC	R-28/2020		
				POLEPOSITION 300 EC	R-29/2020		
				PRO-PROTIO	R-62/2022 h.r.		
				PROVISO 300 EC	R-74/2021 h.r.		
			CAC Chemical	ERA	R-189/2019	0.6 L/ha	180 g a.s./ha
				BASIOR 300 EC	R-213/2019		
				CACTAI	R-171/2022		
				JUDYM 300 EC	R-209/2019		
				KANONIK 300 EC	R-210/2019		
				PODSTAWA 300 EC	R-212/2019		
				PROCER 300 EC	R-208/2019		
				PROMINO 300 EC	R-211/2019		
				TARTAROS 300 EC	R-167/2022		
				WADERA 300 EC	R-214/2019		
Sulphur	Not registered on cereals						

Comments of zRMS:
To be precise: on October 16th 2024 there are 236 fungicides authorized in cereals containing prothioconazole as single active ingredient, and **523** fungicides (authorized in cereals) including prothioconazole in manufacturer`s mixtures with other actives, representing modes of action such as C2, C3, C4, E1, E2 and G2.
Therefore it seems that the potential value of FHO04 lies mainly in its incorporating sulphur, the elemental active of multi-site MoA, working on contact as preventive fungicide on pathogens such as powdery mildews and some rusts.

The data presented in this dRR showed that this combination of active substances allowed increased efficacy against the target diseases. Moreover, the association of these two active substances (single site + multisite) is interesting for the resistance management on many pathogens, with two different mode of action without cross-resistance (see section 0). Overall, DMI-fungicide resistance management recommendations include to use in tank mix with a fungicide of a different mode of action in accordance with FRAC guidance. The simplified recommendations proposed for FHO04 are presented in Table 3.2-3. Further details are in the table "All intended uses" in Part B - Section 0.

Table 3.2-3: Simplified table of requested uses for FHO04

Uses		Member State	Maximum requested rate(s)	Comments / Other relevant details on GAPs
Crop(s)	**Target(s)**			
Winter wheat (TRZAW) Spring wheat (TRZAS) Durum wheat (TRZDU)	Leaf spot of wheat (*Zymoseptoria tritici*) SEPTTR Brown rust of wheat (*Puccinia recondita*) PUCCRT Yellow rust of wheat (*Puccinia striiformis*) PUCCSI	PL	4.0 L/ha	2 applications BBCH 27-69 100 to 400 L/ha
Winter rye (SECCW) Spring rye (SECCS)	Brown rust of rye (*Puccinia recondita f. sp. recondita*) PUCCRR	PL	4.0 L/ha	2 applications BBCH 27-69 100 to 400 L/ha
Triticale (TTLSS) Spelt (TRZSP)	Brown rust of triticale (*Puccinia recondita*) PUCCRE Yellow rust of wheat (*Puccinia striiformis*) ~~PUCCSI~~ PUCCST Leaf spot of triticale (*Zymoseptoria tritici*) SEPTTR	PL	4.0 L/ha	2 applications BBCH 27-69 100 to 400 L/ha

Description of the target diseases

The list of target diseases (EPPO code and scientific name) presented in this Section 6 is available in Table 3.2-4.

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

EPPO code	Scientific name	Common name
Cereals' diseases		
PUCCRE	*Puccinia recondita*	Brown rust of cereals
PUCCRR	*Puccinia recondita f. sp. recondita*	Brown rust of rye
PUCCRT	*Puccinia recondita* f. sp. *triticina*	Brown rust of wheat
~~PUCCSI~~ PUCCST	*Puccinia striiformis*	Yellow rust of cereals
PUCCSI	*Puccinia striiformis* f. sp. *tritici*	Yellow rust of wheat
SEPTTR	*Zymoseptoria tritici*	Leaf spot of wheat

PUCCRE (*Puccinia recondita*)

Brown rust is most common in temperate climates and is encouraged by warm temperatures (15-22 C) combined with periods of extreme (100%) humidity. As with yellow rust, the disease can develop rapidly with a latent period of just six days in ideal conditions. The need for warmer temperatures means that the disease tends to occur in mid to late summer in most of Central Europe, so yield losses are usually less than for yellow rust. *Puccinia recondita* can affect wheat (*Puccinia recondita f. sp. triticina*), rye (*Puccinia recondita f .sp. recondita*) and triticale (hybrid of wheat and rye). These subspecies are very close and, thus can be extrapolated between each other.

PUCCST (*Puccinia striiformis*)

Yellow rust is an important pathogen of wheat, particularly in cool, maritime regions where favourable conditions are prevalent (10-15°C and high humidity)**.** The disease is characterised by its explosive development (latent period of seven days in optimal conditions), often starting from foci of infection and then dispersing throughout the crop. Epidemics are associated with the growing of susceptible varieties coinciding with favourable weather conditions. Yield losses can exceed 40%.

SEPTTR (Zymoseptoria tritici)

Leaf spot is a major pathogen of wheat crops throughout the world but is most prevalent in regions with wet summers such as Northern Europe**.** Initial infection is via wind-dispersed ascospores, though rainfall plays a critical role in subsequent development of the disease by facilitating transmission within the crop as splash-dispersed pycnospores. The disease is characterised by a protracted latent period (21-28 days under ideal conditions). Severe infections can cause a significant reduction in yield, typically of 50%.

Description of crops

Table 3.2-5 presents the details of the surface area used for each crop in the concerned Member States.

Table 3.2-5: Surface area used for each crop for Poland in 2023(1).

Crop	Surface area (1000 ha)	Production (1000 t)
Winter wheat* (TRZAW)	2285.98	12284.57
Spring wheat* (TRZAS)	163.35	647.82
Durum wheat (TRZDU)	0.00	0.00
Triticale (TTLSS)	1201.18	5282.39
Rye (SECSS)	727.99	2533.22

* Spelt is a very minor crop, and so is grouped with winter and spring wheat

Table 3.2-6 presents the status of each crop and each use in the concerned Member States.

Table 3.2-6: Major / minor status of intended uses for Poland

Crop and/or situation	Crop status		Pests or group of pests controlled	Pest status	
	Major	Minor		Major	Minor
Winter wheat (TRZAW) Spring wheat (TRZAS)	X	-	*Zymoseptoria tritici* (SEPTTR)	X	-
			Puccinia recondita (PUCCRT)	X	-
			Puccinia striiformis (PUCCSI)	X	-
Durum wheat (TRZDU) Spelt (TRZSP)	-	X	*Zymoseptoria tritici* (SEPTTR)	-	X
			Puccinia recondita (PUCCRT)	-	X
			Puccinia striiformis (PUCCSI)	-	X
Triticale (TTLSS)	X	-	*Zymoseptoria tritici* (SEPTTR)	X	-
			Puccinia recondita (PUCCRE)		
Winter rye (SECCW)	X	-	*Puccinia recondita* (PUCCRR)	X	-
Spring rye (SECCS)	-	X	*Puccinia recondita* (PUCCRR)	-	X*

***Comments of zRMS:**
Neither SEPTTR, nor PUCCRT, PUCCSI and PUCCRR are considered minor pests *per se*. It is the fact that they infect crops considered as minor which makes uses against them minor uses.

The major/minor crop status of the different cereal crops and uses in Poland is based upon the information summarised in the EUMUDA database2.
According to the EPPO guideline PP1/257, about fungicides, an extrapolation can be considered as valid if:

- The crop, botanical family, cropping system, growth pattern can be considered as comparable. All cereals (winter and spring wheat, durum wheat, spelt, triticale and winter and spring rye) can be considered as comparable crops.

[1] Source: http://ec.europa.eu/eurostat/data/database
[2] Source: https://www.eumuda.eu/#PL

- The taxonomic relationship, biology, life cycle, behaviour, plant parts attacked, damage caused by diseases can be considered as comparable. Leaf spot, *Zymoseptoria tritici* (SEPTTR), brown rust, *Puccinia recondita* (PUCCRE) or yellow rust, *Puccinia striiformis* (PUCCSI) can be considered as comparable whatever the cereal crops.
- The growing conditions (field or protected) and cultivation techniques, growing systems, soil type can be considered as comparable. All cereals (winter and spring wheat, durum wheat, spelt, triticale and winter and spring rye) can be considered as agronomic comparable.

All data against *Zymoseptoria tritici* (SEPTTR) in winter and spring wheat, durum wheat, spelt, and triticale can be considered as comparable and merged in efficacy section.

~~All data against *Puccinia striiformis* (PUCCSI) in winter and spring wheat, durum wheat, spelt, and triticale can be considered as comparable and merged in efficacy section.~~

All data against *Puccinia recondita* (PUCCRE) in winter and spring wheat, durum wheat, spelt, rye and triticale can be considered as comparable and merged in efficacy section.

These extrapolations are confirmed by Dutch authorities document[3]. Polish national extrapolation guidance[4] also confirms that data generated on winter wheat and/or triticale can be extrapolated to spring wheat, durum wheat, spelt and rye.

Extrapolation between different cereal crop species, and winter and spring variants for the same or comparable disease species is also supported by the proposed new EPPO guideline for major use to major use extrapolations, which is expected to be published later this year (draft version is document number 23-28136). Nevertheless, the Applicant is planning to perform additional trials on spring cereals in 2025 to further demonstrate the comparable efficacy of FHO04 between winter and spring cereals; in the current absence of this data, the Applicant requests that it is set as a post-registration data requirement*.

Comments of zRMS:

*Data extrapolation does not justify data merging between crop species. Moreover, extrapolation has been admitted as procedure for **targets** on crops, and not – for crops and between the crops alone. Consequently, some data on efficacy against particular **targets** are necessary, **from the species to which one extrapolates**, and these must be summarized separately, in order to validate and justify extrapolation.
That is why the zRMS had requested the applicant to present data separately for each one of the cereal species for which the GAP claim has been made. The applicant has presented data separately as requested, in the updated (present) version of the document.

Compliance with the Uniform Principles

The overall assessment was performed according to the uniform principles. This dossier supplied is in accordance with the requirements of the Annex to Commission Regulation (EU) No 545/2011, at the latest at the time of finalization of the evaluation for the purpose of decision-making, without prejudice, where relevant, to the provisions of Articles 33, 34 and 59 of Regulation (EC) No 1107/209. The data submitted are acceptable in terms of quantity, quality, consistency and reliability and sufficient to permit a proper evaluation of the dossier. All field trials presented in this dossier to demonstrate the interest of the association, the minimum effective dose, the efficacy at the proposed label rate, trials to evaluate crop selectivity and the impact on yield and yield quality were carried out by GEP certified testing organisations according to the relevant EPPO guidelines.

The trials were carried out under a range of agricultural and environmental conditions across the EU, in areas or regions where the cereal crop species and varieties are commercially grown and where the diseases under investigation are abundant. The primary guidelines used were the following:

- PP1/26 Foliar and ear diseases on cereals
- PP 1/225 Minimum effective dose
- PP 1/135 Phytotoxicity
- PP 1/152 trial design

[3] Appendices Dutch extrapolation document in English EM v2.1
[4] Skuteczność działania środków ochrony roślin - Tabela ekstrapolacji dla sekcji skuteczność PL (aktualizacja 15.09.2023)

- PP 1/181 Conduct efficacy trial
- PP 1/278 Principles of Zonal Data Production and Evaluation
- PP 1/226 Number of Efficacy trials
- PP 1/241 Guidance on Comparable Climates
- PP 1/214 Principles of Acceptable Efficacy
- PP 1/213 Resistance Risk Analysis
- PP 1/207 Effects of Succeeding Crops

Information on trials submitted (3.1 Efficacy data)

Data to confirm efficacy claims for applications of FHO04 were taken from a set of **83 efficacy trials** carried out **from 2019 to 2023** in Poland (28 trials), Latvia (9 trials), and Lithuania (16 trials) for the Northeast EPPO climatic zone and in Germany (29 trials), and Czech Republic (1 trial) for the border countries of Poland. The trials were undertaken by contractors' test facilities, all of which follow the EPPO guidelines and have Official Recognition status for undertaking efficacy trials in accordance with the principles of Good Experimental Practice (GEP). Table 3.2-7 presents a summary of all efficacy trials provided in the dRR.

Table 3.2-7: Efficacy trials - Repartition of trials (valid trials number per use)

Crop	EPPO Climatic zone	Country	Year					Total
			2019	2020	2021	2022	2023	
Winter wheat TRZAW	Northeast	Poland	-	1 (1)	6 (6)	5 (5)	6 (6)	**18 (18)**
		Latvia	-	2 (1)	-	4 (3)	3 (2)	**9 (6)**
		Lithuania	-	2 (2)	5 (2)	4 (0)	5 (0 ~~1~~)	**16 (4 ~~5~~)**
	Maritime	Germany	2 (1)	2 (2)	3 (2)	5 (5)	3 (3)	**15 (13)**
		Czech Republic	-	-	-	-	1 (1)	**1 (1)**
Total			**2 (1)**	**7 (6)**	**14 (10)**	**18 (13)**	**18 (12 ~~13~~)**	**59 (42 ~~43~~)**
Winter durum wheat TRZDW	Maritime	Germany	-	-	-	1 (0)	1 (1)	**2 (1)**
Total			**-**	**-**	**-**	**1 (0)**	**1 (1)**	**2 (1)**
Winter triticale TTLWI	Northeast	Poland	-	-	3 (3)	-	1 (1)	**4 (4)**
	Maritime	Germany	-	-	3 (2)	2 (0)	1 (0)	**6 (2)**
Total			**-**	**-**	**6 (5)**	**2 (0)**	**2 (1)**	**10 (6)**
Winter rye SECCW	Maritime	Germany	-	-	1 (1)	4 (2)	1 (1)	**6 (4)**
	Northeast	Poland	-	-	2 (2)	4 (4)	-	**6 (6)**
Total			**-**	**-**	**3 (3)**	**8 (6)**	**1 (1)**	**12 (10)**
Number of trials provided in this dRR			**2 (1)**	**7 (6)**	~~26 (21)~~ **23 (18)**	**29 (19)**	**22 (15)** ~~22 (16)~~	**83 (59)** ~~83 (60)~~

An overview of available trials is provided in Table 3.2-8.

Table 3.2-8: Efficacy trials - Winter cereals - Presentation of trials

Crop(s)[1]	Target(s) assessed	EPPO climatic zone[2]	Country	Year	Number of trials	Type of trial[3]	GEP, non-GEP, official[4]
Winter soft wheat	Foliar diseases	Northeast	Poland	2020-2023	8	MED + E + S	GEP
				2021-2023	10	P + MED + E + S	GEP
			Latvia	2020-2023	2	MED + E + S	GEP
				2022-2023	4	P + MED + E + S	GEP
				2020-2023	3	S	GEP
			Lithuania	2020-2023	2	MED + E + S	GEP
				2021	2	P + MED + E + S	GEP
				2021-2023	12	S	GEP
		Maritime	Czech Republic	2023	1	MED + E + S	GEP
			Germany	2021-2023	8	P + MED + E + S	GEP
				2019	1	P + E + S	GEP
				2020-2022	4	MED + E + S	GEP
				2019-2021	2	S	GEP
Winter durum wheat	Foliar diseases	Maritime	Germany	2023	1	P + MED + E + S	GEP
				2022	1	S	GEP
Winter triticale	Foliar diseases	Northeast	Poland	2021	1	P + MED + E + S	GEP
				2021-2023	3	MED + E + S	GEP
		Maritime	Germany	2021	1	P + MED + E + S	GEP
				2021	1	MED + E + S	GEP
				2021-2023	4	S	GEP
Winter rye	Foliar diseases	Northeast	Poland	2021-2022	6	MED + E + S	GEP
		Maritime	Germany	2021-2023	4	MED + E + S	GEP
				2022	2	S	GEP

[1] According to the GAP table.
[2] According to EPPO guideline PP 1/241(1) "Guidance on comparable climates".
[3] P = preliminary trial, MED = minimum effective dose, E = efficacy trial, S = Phytotoxicity assessment, Y: Harvested trial, Q: Quality parameters measures (moist content, specific weight and/or Thousand grain weight).
[4] GEP: Good Experimental Practices. Official: carried out by a national official organisation.

To cover the largest spectrum of climatic and soil conditions and crop varieties, the efficacy trials were located in the Northeast EPPO climatic zone and border countries of Poland on the main area of the crops` production in Poland, Latvia, Lithuania, Czech Republic, and Germany. This repartition in Europe of efficacy trials is presented Figure 3.2-1.

Figure 3.2-1 Efficacy trials - Winter cereals - Location of the trial sites

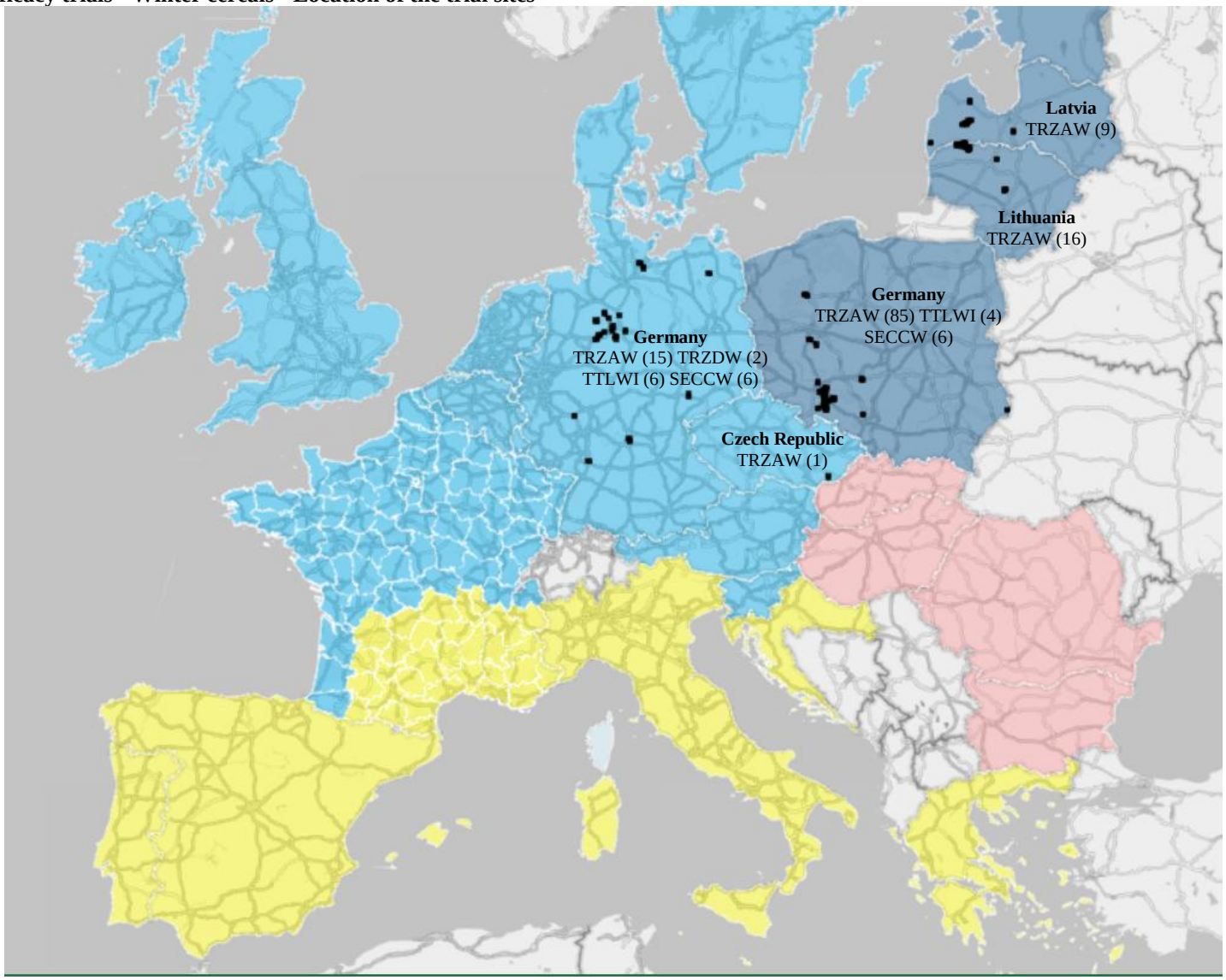


Table 3.2-9 presents the plant protection products used as reference standard and the dose rates applied in the efficacy trials.
In some efficacy trials, the efficacy of FHO04 was compared to the efficacy of reference standards containing only prothioconazole at 195-200 g a.s./ha, to understand the benefit of combining prothioconazole 200 g a.s./ha with sulphur 2475 g a.s./ha in the co-formulated product, FHO04
The various products used in trials containing these two rates of prothioconazole are grouped under a single tradename: Proline.
In 5 efficacy trials, the efficacy of FHO04 was also compared to the efficacy of the reference standard containing only sulphur at 2475 g a.s./ha, to understand the benefit of combining prothioconazole 200 g a.s./ha with sulphur 2475 g a.s./ha in the co-formulated product, FHO04.

Table 3.2-9: Efficacy trials - Presentation of reference standards

Crop(s) [1]	Target(s) [1]	Reference standard	Country(ies) where the product is used [1]	Authorization number	Active substance(s)	Formulation		Registered application rate [3]	Dose rate in trials (per treatment)	Rate of active substance per ha	Remark [4]
						Type [2]	Concentration of a.s.				
Cereals	All diseases	Microthiol Special Liquide	France	7700216	Sulphur	SC	825 g/L	7.28 L/ha	3.0 L/ha	2475 g a.s./ha	Named Microthiol in this dRR
		Microthiol	Germany	247152*				-			
		Thiopron	United Kingdom	20671				9.7 L/ha			
		Proline	Poland	R - 6/2023b 23.02.2023	Prothioconazole	EC	250 g/L	0.8 L/ha	0.8 L/ha	200 g a.s./ha	Named Proline in this dRR
		Proline	Latvia	*							
		Proline	Lithuania	*							
		Proline 250 EC	Czech Republic	4523-1							
		Proline	Germany	025287-00							
		Protendo 300 EC	Poland	R- 224/2019 -10.12.2019	Prothioconazole	EC	300 g/L	0.65 L/ha	0.65 L/ha	195 g a.s./ha	
		Prosaro	Latvia	0276	Tebuconazole Prothioconazole	SC	125 g/L 125 g/L	1.0 L/ha	1.0 L/ha	125 g a.s./ha 125 g a.s./ha	-
		Blizzard Xtra	Poland	R- 12/2013 21.01.2013	Cyproconazole + Azoxystrobin	SC	80 g/L 200 g/L	1.14 L/ha	1.14 L/ha	200+80 g a.s./ha	-
		Makler 250 SE	Poland	R - 207/2017 02.11.2017	Azoxystrobin	SE	250 g/L	1.0 L/ha	1.0 L/ha	250 g a.s./ha	Named Amistar in this dRR
		Amistar	Germany	008235-00 025315-							
		Adexar	Lithuania	AS2-28F(2019)	Epoxiconazole Fluxapyroxad	SE	62.5 g/L 62.5 g/L	1.0 L/ha	1.0 L/ha	62.5+62.5 g a.s./ha	-
		Opera N	Latvia	0281	Epoxiconazole Pyraclostrobin	SE	62.5 g/L 85 g/L		1.0 L/ha	62.5+85.0 g a.s./ha	-

Justification for the use of data from other countries/zones

Data from Latvia and Lithuania (representation from Northern registration zone) in cereal crops have been used in this dRR for FHO04.
This use has been considered possible by the division of biological data into three regions i.e. North, Central and South Europe based on data comparability between Member states as it is indicated in the Annex III of Directive 93/71/EEC. The following justifications are presented:
Disease presented are common throughout Europe. Although trials were performed in different countries, sites were selected with known pest populations in order to exert maximum control pressure and to exacerbate treatment differences. No difference in disease susceptibility is apparent from the control levels achieved between the efficacy data presented for each country within the zonal regions presented.
Similar trial methodology was used in all countries. trials were undertaken by official or officially recognized testing facilities in accordance with the relevant EPPO guidelines. Furthermore, identical methods of assessment for efficacy (disease severity, disease incidence) and crop tolerance (visual injury) were employed.
Trials were performed in the major growing areas in each respective country. These areas have been found to be particularly suitable for cereals production due to their innate similarity in terms of soil type and climate.
Data presented in this dRR shows that soil type has no effect on the level of diseases control achieved with FHO04 trials were carried out on different soil types and consistency of control was unaffected.
Data for FHO04 is summarised by EPPO PP 1/241(1) defined zones. The zones have been defined on the basis of comparable climates in the form of a 'Climatic Justification' paper as approved by EPPO and found within the standard PP 1/241(1), thus the issue of climatic differences need not be addressed within this dossier.
EPPO PP 1/24(1) zones:

- Mediterranean EPPO climatic zone includes the countries or parts of countries around the Mediterranean Sea, together with Jordan, Macedonia and Portugal.
- Maritime EPPO climatic zone is the zone north of the line from the coastal zone of south-west France, through Lyon (France), to the south border of Switzerland and Austria, west of the border between Austria and Hungary, west of the border between Czech Republic and Slovakia, west of the river Oder (between Poland and Germany). This zone also includes Ireland, Sweden and the United Kingdom.
- Northeast EPPO climatic zone is the zone in North-eastern part of Europe: the countries and the regions east of the river Oder (between Poland and Germany), north of the border between Czech Republic and Poland, west of the border between Poland and Ukraine, north of the border between Ukraine and Belarus, Russia north of 50° latitude.
- Southeast EPPO climatic zone includes Bosnia-Herzegovina, Bulgaria, Croatia, Hungary, Moldova, Romania, Russia south of 50° latitude, Slovakia, Slovenia, Serbia and Montenegro, Turkey, Ukraine, except the Mediterranean coastal zones.

In this dRR additional data from 25 trials conducted in Latvia (9 trials) and Lithuania (16 trials), countries ~~country~~ of the Northeast EPPO climatic zone, are presented to support efficacy claims for FHO04 against diseases in cereal crops.
Additional data from 30 trials conducted in border countries of Poland (29 trials in Germany and 1 trial in Czech Republic), countries ~~country~~ of Maritime EPPO climatic zone, are also presented to support efficacy claims for FHO04. Data from border countries to Poland is considered supportive, based upon national Polish guidance[5].
Due to comparable agronomic and climatic conditions within the EPPO climatic zone, the presented data is considered to be fully supportive of the label claim of FHO04 in Poland for the Central registration zone.

[5] Skuteczność działania środków ochrony roślin (aktualizacja 15.09.2023)

3.2.1 Preliminary tests (KCP 6.2)

Leaf spot (*Zymoseptoria tritici* - SEPTTR) is the major problematic disease in cereals. Therefore, the objective of this preliminary part is to justify the interest to associate sulphur with prothioconazole to control leaf spot (*Zymoseptoria tritici* - SEPTTR).

3.2.1.1 Material and Methods

In 5 trials carried out in Maritime EPPO climatic zone and provided as supportive data, FHO04 applied at 4.0 L/ha (200 g a.s./ha prothioconazole + 2500 g a.s./ha sulphur) was compared to Prothioconazole based products applied straight at 200 g a.s./ha, Sulphur based products applied straight at 2475 g a.s./ha and the extemporaneous tank-mix prothioconazole + sulphur.
In these 5 trials, different ratios of prothioconazole and sulphur was also tested to determine the best ratio between both active substances.
In 28 trials, FHO04 applied at 4.0 L/ha (200 g a.s./ha prothioconazole + 2500 g a.s./ha sulphur) was compared only to Prothioconazole based products applied straight at 200 g a.s./ha. According to the trial, Prothioconazole based product used in the trials was an internal preparation (code name FGR06, Prothioconazole, 250 g/L) applied at 0.8 L/ha or Proline also applied at 0.8 L/ha.
Material and Methods used in these efficacy trials are given within Section 3.2.3.1.
Only the trials and assessments with a sufficient infestation level in the untreated plot (thresholds of 5% coverage of foliar or ears area by the disease) and where the level of efficacy of the reference standards were as expected are considered in this synthesis. In practice, assessments from 4.5% were selected in the available data package notably to be able to select same number of assessments per trial.

3.2.1.2 Results on the benefit of the association: comparison with prothioconazole-based products and sulphur-based products applied straight

A total of **5 valid efficacy trials** were carried out to show the interest of the association Prothioconazole + Sulphur formulated in FHO04 compared to prothioconazole based product and sulphur based products applied straight. These trials were carried out **in 2019** in the Maritime EPPO climatic zone (1 trial in France, 1 trial in Germany and 3 trials in the United Kingdom) in winter soft wheat crop.
Table 3.2-10 summarises all observations for each disease (efficacy) and, so, synthetises the benefit of the association of sulphur and prothioconazole contained in FHO04 in cereal crops.

Table 3.2-10: Justification of the formulation FHO04 - Wheat - SEPTTR - Disease severity on leaves (Leaf 1, Leaf 2, Leaf 3) - Last valid assessment after application A or B

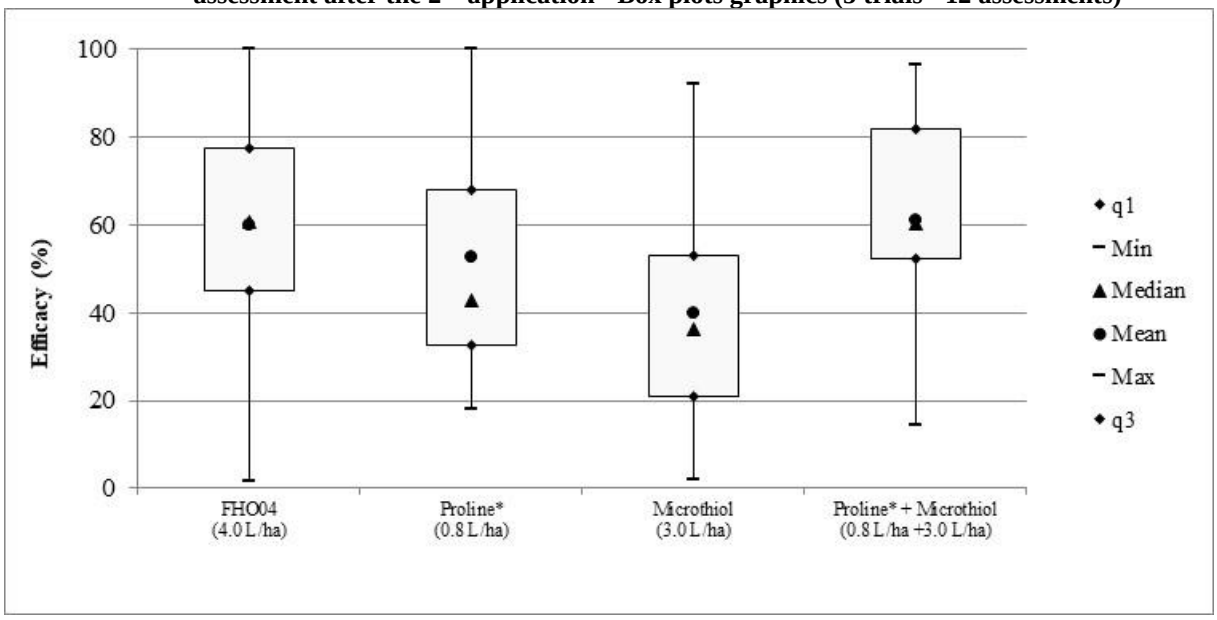
EPPO climatic zone	Parts	No. of trials	*Untreated*			Percentage of efficacy (%)														No. of assessments where FHO04 (4.0 L/ha) is significantly[(1)] >;=;< to		
						FHO04 4.0 L/ha				**Proline* 0.8 L/ha**				**Microthiol 3.0 L/ha**				**Proline* + Microthiol 0.8 L/ha +3.0 L/ha**						
						Prothioconazole + Sulphur				Prothioconazole				Sulphur				Prothioconazole + Sulphur						
						200+2500 g a.s./ha				200 g a.s./ha				2475 g a.s./ha				200+2475 g a.s./ha						
			Mean	*Min*	*Max*	**Mean**	Min	Max	*S.D.*	**Mean**	Min	Max	*S.D.*	**Mean**	Min	Max	*S.D.*	**Mean**	Min	Max	*S.D.*	**Proline***	**Microthiol**	**Proline* + Microthiol**
Maritime	Leaf 1	2	***16.4***	*7.1*	*25.8*	~~60.5~~ **62.1**	46.0	75.0	*14.5*	~~36.4~~ **43.9**	33.6	~~39.1~~ 54.3	*2.8*	~~36.3~~ **39.5**	32.1	~~40.5~~ 46.9	*4.2*	~~68.9~~ **73.2**	~~57.2~~ 65.9	80.6	*11.7*	0> ; 2= ; 0<	0> ; 2= ; 0<	0> ; 2= ; 0<
	Leaf 2	5	***24.3***	*6.0*	*80.8*	**57.4**	1.5	100.0	*34.4*	**55.1**	17.9	100.0	*32.5*	**41.6**	3.2	92.3	*35.0*	**63.7**	14.3	96.7	*28.5*	1> ; 4= ; 0<	1> ; 4= ; 0<	0> ; 5= ; 0<
	Leaf 3	5	***32.2***	*8.0*	*67.1*	~~62.8~~ **62.2**	25.8	100.0	*23.9*	~~57.2~~ **57.8**	29.6	100.0	*24.9*	~~39.7~~ **41.5**	~~1.8~~ 11.2	84.7	*27.5*	~~55.1~~ **56.2**	24.9	94.4	*23.7*	0> ; 5= ; 0<	1> ; 4= ; 0<	0> ; 5= ; 0<

(1) Comparison based on statistics carried out in each trial report.

* In British trials, Proline 275 at 0.72 L/ha (200 g a.s./ha) was applied.

At the last valid assessment after one or two applications, FHO04 applied at 4.0 L/ha delivered 61% on Leaf 1, 57% on Leaf 2 and 63% on Leaf 3 when prothioconazole based product applied straight at 200 g a.s./ha delivered 36% on Leaf 1, 55% on Leaf 2 and 57% on Leaf 3 and sulphur based product applied straight at 2475 g a.s./ha delivered 36% on Leaf 1, 42% on Leaf 2 and 40% on Leaf 3.
FHO04 at 4.0 L/ha was significantly superior to prothioconazole based product applied straight at 200 g a.s./ha in 1 out of 5 trials on Leaf 2. FHO04 at 4.0 L/ha was significantly superior to sulphur based product applied straight at 200 g a.s./ha in 1 out of 5 trials on Leaf 2 and Leaf 3.
No significant difference was noted between FHO04 applied at 4.0 L/ha and the tank-mix prothioconazole+sulphur bringing the same rate of each active substance per hectare.
The interest to add sulphur with prothioconazole can be illustrated by box plot graphics (Figure 3.2-2). Overall, box plot graphics clearly show a better control and homogeneity for FHO04 than prothioconazole or sulphur applied straight. Indeed, according to the box plots graphics, the efficacy level and the dispersion between efficacies is less important for FHO04 than prothioconazole or sulphur applied straight.
In addition, no difference was noted between FHO04 at 4.0 L/ha and the tank-mix prothioconazole + sulphur at the same rate per hectare. However, as FHO04 is a co-formulated product, it is considered easier to use and manage logistically than a tank-mixture of two products.

Figure 3.2-2 Benefit of the association of sulphur and prothioconazole - Wheat - SEPTTR Last valid assessment after the 2nd application - Box plots graphics (5 trials - 12 assessments)



To conclude, the benefit of the formulated product FHO04 over sulphur or prothioconazole applied straight against leaf spot (SEPTTR) can be considered as justified.

Comments of zRMS:
In spite of some differences found between the mean efficacy values assumed by the applicant in Table 3.2-10 and the means calculated by zRMS based on the original trial reports, the message in principle remains the same: co-formulation of the two actives results in enhanced the efficacy against SEPTTR, compared to prothioconazole and sulphur when applied separately at similar dose rates.
zRMS Abstract

3.2.1.3 Results on the benefit of the association prothioconazole and sulphur: comparison with prothioconazole based product applied straight

A total of **28 valid efficacy trials** were carried out to show the interest of the association Prothioconazole + Sulphur formulated in FHO04 compared to prothioconazole based product applied straight against SEPTTR in winter soft wheat (25 trials), winter durum wheat (1 trial) or winter triticale (2 trials). These

trials were carried out **from 2019 to 2023** in the Northeast EPPO climatic zone (11 trials in Poland, 4 trials in Latvia and 2 trials in Lithuania) and Poland border countries (11 trials in Germany).
In accordance with EPPO guideline PP1/257, all data against *Zymoseptoria tritici* (SEPTTR) in winter and spring wheat, durum wheat, spelt, and triticale can be considered as comparable and merged in this section. However, an analysis by crop is also provided hereafter.
Table 3.2-11 summarises all observations.

Table 3.2-11: Benefit of the association of sulphur and prothioconazole - Winter cereals – SEPTTR

Parameters	Assessment date	EPPO climatic zone	Parts	No. of trials	*Untreated*			Percentage of efficacy (%)								No. of assessments where FHO04 (4.0 L/ha) is significantly[(1)] >;=;< to Prothioconazole based product (200 g a.s./ha)
								FHO04 (4.0 L/ha) Prothioconazole + Sulphur 200+2500 g a.s./ha				Prothioconazole based product Prothioconazole 200 g a.s./ha				
					Mean	*Min*	*Max*	**Mean**	Min	Max	*S.D.*	**Mean**	Min	Max	*S.D.*	
Disease severity on winter wheat	2-3 weeks after the second application 13-40 DAB	Northeast	Leaf 1	3	***5.1***	*5.1*	*5.3*	**91.5**	87.2	94.6	*3.1*	**89.8**	87.2	91.2	*1.9*	0> ; 3= ; 0<
			Leaf 2	8	***6.9***	*5.0*	*9.7*	**88.8**	68.5	97.9	*8.4*	**90.6**	85.8	98.8	*3.8*	0> ; 7= ; 1<
			Leaf 3	14	***8.4***	*5.3*	*17.6*	**82.7**	46.5	95.9	*13.9*	**80.8**	40.8	96.6	*16.8*	1> ; 12= ; 1<
		Border countries of Poland (Germany)	Leaf 1	1	***5.9***	-	-	**100.0**	-	-	-	**100.0**	-	-	-	0> ; 1= ; 0<
			Leaf 2	4	***9.4***	*6.7*	*14.8*	**84.7**	62.8	100.0	*13.8*	**70.5**	28.7	100.0	*26.7*	0> ; 4= ; 0<
			Leaf 3	5	***23.8***	*5.0*	*67.1*	**72.4**	41.9	100.0	*24.3*	**64.4**	25.0	100.0	*30.2*	0> ; 5= ; 0<
		All EPPO climatic zones	Leaf 1	4	***5.3***	*5.1*	*5.9*	**93.6**	87.2	100.0	*4.6*	**92.4**	87.2	100.0	*4.7*	0> ; 4= ; 0<
			Leaf 2	12	***7.7***	*5.0*	*14.8*	**87.5**	62.8	100.0	*10.7*	**83.9**	28.7	100.0	*18.4*	0> ; 11= ; 1<
			Leaf 3	19	***12.4***	*5.0*	*67.1*	**80.0**	41.9	100.0	*17.8*	**76.5**	25.0	100.0	*22.3*	1> ; 17= ; 1<
	Last valid assessment after the 2nd application (13-49 DAB)	Northeast	Leaf 1	8	***12.1***	*4.5*	*37.8*	**77.1**	47.8	94.6	*15.5*	**77.6**	45.9	91.2	*14.4*	0> ; 7= ; 1<
			Leaf 2	13	***8.2***	*5.0*	*19.3*	**86.4**	57.4	97.9	*10.8*	**86.7**	71.1	98.8	*8.3*	0> ; 12= ; 1<
			Leaf 3	14	***8.4***	*5.3*	*17.6*	**82.7**	46.5	95.9	*13.9*	**80.8**	40.8	96.6	*16.8*	1> ; 12= ; 1<
		Border countries of Poland (Germany)	Leaf 1	2	***12.7***	*5.9*	*19.5*	**96.9**	93.8	100.0	*3.1*	**92.4**	84.9	100.0	*7.6*	1> ; 1= ; 0<
			Leaf 2	8	***12.9***	*6.7*	*20.9*	**84.0**	47.3	100.0	*18.0*	**73.5**	19.8	100.0	*30.1*	0> ; 8= ; 0<
			Leaf 3	6	***37.8***	*8.0*	*67.1*	**71.8**	41.9	100.0	*21.6*	**68.2**	25.0	100.0	*25.7*	0> ; 6= ; 0<
		All EPPO climatic zones	Leaf 1	10	***12.2***	*4.5*	*37.8*	**81.0**	47.8	100.0	*16.0*	**80.5**	45.9	100.0	*14.6*	1> ; 8= ; 1<
			Leaf 2	21	***10.0***	*5.0*	*20.9*	**85.5**	47.3	100.0	*14.1*	**81.6**	19.8	100.0	*20.7*	0> ; 20= ; 1<
			Leaf 3	20	***17.2***	*5.3*	*67.1*	**79.4**	41.9	100.0	*17.3*	**77.0**	25.0	100.0	*20.7*	1> ; 18= ; 1<
Disease severity on winter triticale	2-3 weeks after the second application 13-40 DAB	Northeast	Leaf 3	1	***7.3***	-	-	**89.1**	-	-	-	**88.1**	-	-	-	0> ; 1= ; 0<
	Last valid assessment after the 2nd application (23 DAB (NE zone), 36 DAB (Maritime zone))	Northeast	Leaf 3	1	***7.3***	-	-	**89.1**	-	-	-	**88.1**	-	-	-	0> ; 1= ; 0<
		Border countries of Poland (Germany)	Leaf 2	1	*11.9*	-	-	**100.0**	-	-	-	**100.0**	-	-	-	0> ; 1= ; 0<
			Leaf 3	1	*16.0*	-	-	**96.2**	-	-	-	**99.5**	-	-	-	0> ; 1= ; 0<
		All EPPO climatic zones	Leaf 2	1	*11.9*	-	-	**100.0**	-	-	-	**100.0**	-	-	-	0> ; 1= ; 0<
			Leaf 3	2	***11.7***	*7.3*	*16.0*	**92.7**	89.1	96.2	*3.6*	**93.8**	88.1	99.5	*5.7*	0> ; 2= ; 0<
Disease severity on winter durum wheat	2-3 weeks after the second application 13-40 DAB	Border countries of Poland (Germany)	Leaf 1	1	***8.4***	-	-	**33.3**	-	-	-	**54.4**	-	-	-	0> ; 0= ; 1<
			Leaf 2	1	***12.1***	-	-	**21.6**	-	-	-	**29.9**	-	-	-	0> ; 1= ; 0<
			Leaf 3	1	***18.5***	-	-	**14.8**	-	-	-	**7.6**	-	-	-	0> ; 1= ; 0<
	Last valid assessment after the 2nd application (45 DAB, Maritime zone)	Border countries of Poland (Germany)	Leaf 1	1	***17.7***	-	-	**24.8**	-	-	-	**39.6**	-	-	-	0> ; 0= ; 1<
			Leaf 2	1	***21.7***	-	-	**19.8**	-	-	-	**27.3**	-	-	-	0> ; 1= ; 0<
			Leaf 3	1	***33.4***	-	-	**12.7**	-	-	-	**6.6**	-	-	-	0> ; 1= ; 0<

Parameters	Assessment date	EPPO climatic zone	Parts	No. of trials	*Untreated*			Percentage of efficacy (%)								No. of assessments where FHO04 (4.0 L/ha) is significantly[(1)] >;=;< to Prothioconazole based product (200 g a.s./ha)
								FHO04 (4.0 L/ha)				Prothioconazole based product				
								Prothioconazole + Sulphur				Prothioconazole				
								200+2500 g a.s./ha				200 g a.s./ha				
					Mean	*Min*	*Max*	**Mean**	Min	Max	*S.D.*	**Mean**	Min	Max	*S.D.*	
Disease severity on winter cereals	2-3 weeks after the second application (13-40 DAB)	Northeast	Leaf 1	3	***5.1***	*5.1*	*5.3*	**91.5**	87.2	94.6	*3.1*	**89.8**	87.2	91.2	*1.9*	0> ; 3= ; 0<
			Leaf 2	8	***6.9***	*5.0*	*9.7*	**88.8**	68.5	97.9	*8.4*	**90.6**	85.8	98.8	*3.8*	0> ; 7= ; 1<
			Leaf 3	14	***8.4***	*5.3*	*17.6*	**82.7**	46.5	95.9	*13.9*	**80.8**	40.8	96.6	*16.8*	1> ; 12= ; 1<
		Border countries of Poland (Germany)	Leaf 1	2	***7.2***	*5.9*	*8.4*	**66.6**	33.3	100.0	*33.4*	**77.2**	54.4	100.0	*22.8*	0> ; 1= ; 1<
			Leaf 2	5	***9.9***	*6.7*	*14.8*	**72.1**	21.6	100.0	*28.1*	**62.4**	28.7	100.0	*28.9*	0> ; 5= ; 0<
			Leaf 3	6	***22.9***	*5.0*	*67.1*	**62.8**	14.8	100.0	*30.9*	**54.9**	7.6	100.0	*34.7*	0> ; 6= ; 0<
		All EPPO climatic zones	Leaf 1	5	***6.0***	*5.1*	*8.4*	**81.5**	33.3	100.0	*24.5*	**84.8**	54.4	100.0	*15.8*	0> ; 4= ; 1<
			Leaf 2	13	***8.1***	*5.0*	*14.8*	**82.4**	21.6	100.0	*20.3*	**79.7**	28.7	100.0	*22.8*	0> ; 12= ; 1<
			Leaf 3	20	***12.7***	*5.0*	*67.1*	**76.7**	14.8	100.0	*22.4*	**73.0**	7.6	100.0	*26.4*	1> ; 18= ; 1<
	Last valid assessment after the 2nd application (13-49 DAB)	Northeast	Leaf 1	8	***12.1***	*4.5*	*37.8*	**77.1**	47.8	94.6	*15.5*	**77.6**	45.9	91.2	*14.4*	0> ; 7= ; 1<
			Leaf 2	13	***8.2***	*5.0*	*19.3*	**86.4**	57.4	97.9	*10.8*	**86.7**	71.1	98.8	*8.3*	0> ; 12= ; 1<
			Leaf 3	14	***8.4***	*5.3*	*17.6*	**82.7**	46.5	95.9	*13.9*	**80.8**	40.8	96.6	*16.8*	1> ; 12= ; 1<
		Border countries of Poland (Germany)	Leaf 1	3	***14.4***	*5.9*	*19.5*	**72.9**	24.8	100.0	*34.1*	**74.8**	39.6	100.0	*25.7*	1> ; 1= ; 1<
			Leaf 2	10	***13.7***	*6.7*	*21.7*	**79.2**	19.8	100.0	*26.0*	**71.5**	19.8	100.0	*31.7*	0> ; 10= ; 0<
			Leaf 3	8	***34.6***	*8.0*	*67.1*	**67.5**	12.7	100.0	*29.0*	**64.5**	6.6	100.0	*32.8*	0> ; 8= ; 0<
		All EPPO climatic zones	Leaf 1	11	***12.7***	*4.5*	*37.8*	**75.9**	24.8	100.0	*22.3*	**76.8**	39.6	100.0	*18.2*	1> ; 8= ; 2<
			Leaf 2	23	***10.6***	*5.0*	*21.7*	**83.3**	19.8	100.0	*19.3*	**80.1**	19.8	100.0	*23.1*	0> ; 22= ; 1<
			Leaf 3	22	***17.9***	*5.3*	*67.1*	**77.1**	12.7	100.0	*22.0*	**74.9**	6.6	100.0	*25.1*	1> ; 20= ; 1<

(1) Comparison based on statistics carried out in each trial report.

The results are summarized by EPPO climatic zone in the summary table. Only results for all valid efficacy trials (all EPPO climatic zones presented Table 3.2-11) are discussed hereafter to justify the benefit of the association sulphur with prothioconazole formulated in FHO04

On winter wheat, 2-3 weeks after the second application, FHO04 at 4.0 L/ha provided a good level of efficacy similar to prothioconazole based product applied straight at 200 g a.s./ha on Leaf 1 (94% *vs.* 92% in 4 trials), but slightly better on Leaf 2 (88% *vs.* 84% in 12 trials) and Leaf 3 (80% *vs.* 77% in 19 trials). FHO04 at 4.0 L/ha was significantly superior to prothioconazole based product applied straight at 200 g a.s./ha in 1 out of 19 trials on Leaf 3.

At the last valid assessment after the second application, FHO04 at 4.0 L/ha provided a good level of efficacy similar to prothioconazole based product applied straight at 200 g a.s./ha on Leaf 1 (81% *vs.* 81% in 10 trials), but slightly better on Leaf 2 (86% *vs.* 82% in 21 trials) and Leaf 3 (79% *vs.* 77% in 20 trials). FHO04 at 4.0 L/ha was significantly superior to prothioconazole based product applied straight at 200 g a.s./ha in 1 out of 10 trials on Leaf 1, and in 1 out of 20 trials on Leaf 3.

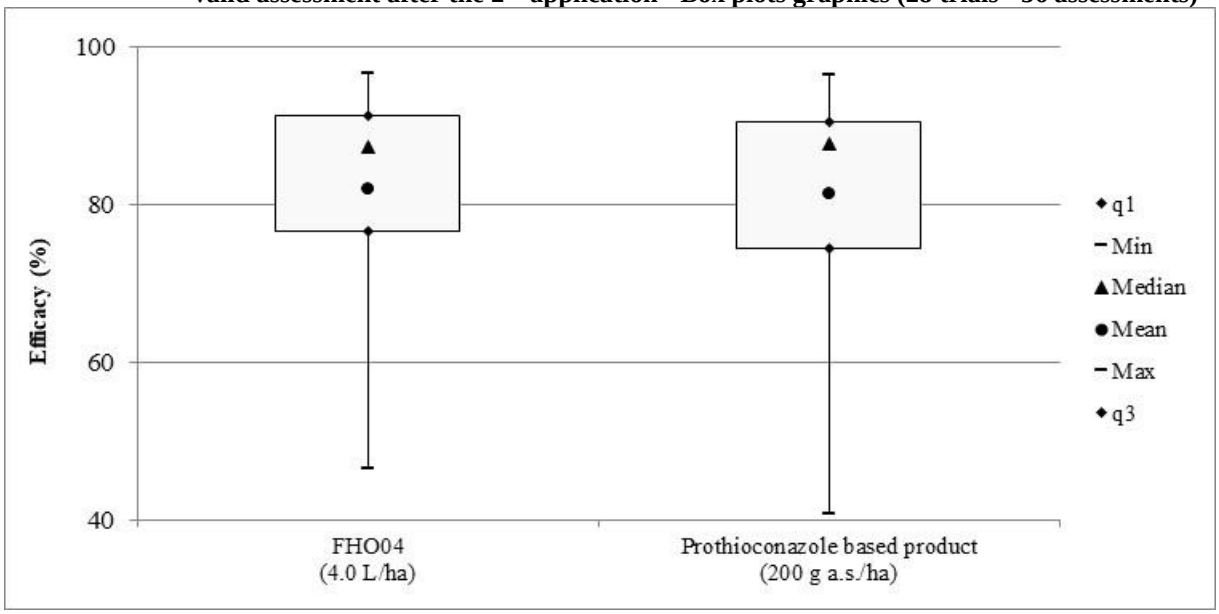
On other cereal crops (1 trial on triticale and 1 trial on durum wheat), the difference between FHO04 at 4.0 L/ha and prothioconazole based product applied straight at 200 g a.s./ha is less marked due to a high level of efficacy in trial carried out in winter triticale or no efficacy in trial carried out in durum wheat.

Finally, on winter cereals, 2-3 weeks after the second application, FHO04 at 4.0 L/ha provided a medium level of efficacy similar to prothioconazole based product applied straight at 200 g a.s./ha on Leaf 1 (82% *vs.* 85% in 5 trials), and Leaf 2 (82% *vs.* 80% in 13 trials) but slightly better on Leaf 3 (77% *vs.* 73% in 20 trials). FHO04 at 4.0 L/ha was significantly superior to prothioconazole based product applied straight at 200 g a.s./ha in 1 out of 22 trials on Leaf 3.

At the last valid assessment after the second application, FHO04 at 4.0 L/ha provided a medium level of efficacy similar to prothioconazole based product applied straight at 200 g a.s./ha on Leaf 1 (76% *vs.* 77% in 11 trials), but slightly better on Leaf 2 (83% *vs.* 80% in 23 trials) and Leaf 3 (77% *vs.* 75% in 22 trials). FHO04 at 4.0 L/ha was significantly superior to prothioconazole based product applied straight at 200 g a.s./ha in 1 out of 11 trials on Leaf 1, and in 1 out of 22 trials on Leaf 3.

The interest of the association of sulphur with prothioconazole can be illustrated by box plot graphics (Figure 3.2-3). Overall, box plot graphics show a better control and homogeneity for FHO04 than Prothioconazole based products. Indeed, the efficacy level and the dispersion between efficacies is less important for FHO04 than Prothioconazole based products.

Figure 3.2-3 Benefit of the association of sulphur and prothioconazole - Winter cereals - SEPTTR - Last valid assessment after the 2nd application - Box plots graphics (28 trials - 56 assessments)



To conclude, the benefit of the formulated product FHO04 over prothioconazole applied straight against leaf spot of wheat (*Zymoseptoria tritici* - SEPTTR)) can be considered as demonstrated.

Comments of zRMS:

Comparison of the FHO04 to prothioconazole-based products mostly highlights the fact that the efficacy advantage of the test item in wheat against SEPTTR is pronounced the most in German trials, and only at the second (last valid) assessment (96.9% vs 92.4%, test vs reference). Otherwise the differences between products are negligible. The trial count for triticale and for the durum wheat is too low to allow for definitive conclusions.

3.2.1.4 Results on the justification of the ratio of the active substances for the control of cereals diseases

A total of **5 valid efficacy trials** were carried out to justify the choice of ratio between active substance containing in FHO04. These trials were carried out **in 2019** in the Maritime EPPO climatic zone (1 trial in France, 1 trial in Germany and 3 trials in the United Kingdom) in winter soft wheat crop.
In these trials, several products were tested and presented Table 3.2-12.

Table 3.2-12: Presentation of products used in trials - Efficacy trials - Cereals

Reference standard	Active substance(s)	Formulation		Application rate in trials (per treatment)	Rate of active substance per ha
		Type	Concentration of a.s.		
Proline	**Prothioconazole**	EC	250 g/L	0.4 L/ha 0.8 L/ha	100 g a.s./ha 200 g a.s./ha
FCG08 [Microthiol]	**Sulphur**	EC	825 g/L	1.5 L/ha 3.0 L/ha 6.0 L/ha	1238 g a.s./ha 2475 g a.s./ha 4950 g a.s./ha
FHO04	**Prothioconazole** **Sulphur**	SC	50 g/L 625 g/L	4.0 L/ha	200+2500 g a.s./ha
FHO01	**Prothioconazole** **Sulphur**	SC	50 g/L 625 g/L	4.0 L/ha	200+2500 g a.s./ha
FHO02	**Prothioconazole** **Sulphur**	SC	50 g/L 625 g/L	4.0 L/ha	200+2500 g a.s./ha
FHO03	**Prothioconazole** **Sulphur**	SC	50 g/L 625 g/L	4.0 L/ha	200+2500 g a.s./ha
Bravo	Chlorothalonil	SC	500 g/L	1.0 L/ha	500 g a.s./ha
Ascra Xpro	Bixafen Flupyram **Prothioconazole**	EC	65 g/L 65 g/L 130 g/L	1.5 L/ha	97.5+97.5+195.0 g a.s./ha

Table 3.2-13 (Justification of prothioconazole ratio against SEPTTR), Table 3.2-14 (Justification of sulphur ratio against SEPTTR) summarise all observations for each disease (efficacy).

Table 3.2-13: Justification of the ratio of Prothioconazole - Wheat - SEPTTR - Disease severity on leaves (Leaf 1, Leaf 2, Leaf 3) -Last valid assessment after application A or B

EPPO climatic zone	Parts	No. of trials	*Untreated*			Percentage of efficacy (%)								No. of assessments where Prothioconazole+Sulphur (200 + 2475 g a.s./ha) is significantly[(1)] >;=;< to Prothioconazole+Sulphur (100 + 2475 g a.s./ha)
						Prothioconazole + Sulphur				Prothioconazole + Sulphur				
						200+2475 g a.s./ha				100+2475 g a.s./ha				
			Mean	*Min*	*Max*	**Mean**	Min	Max	*S.D.*	**Mean**	Min	Max	*S.D.*	
Maritime	Leaf 1	2	***16.4***	*7.1*	*25.8*	**68.9**	57.2	80.6	*11.7*	**37.5**	30.7	44.3	*6.8*	0> ; 2= ; 0<
	Leaf 2	5	***24.3***	*6.0*	*80.8*	**63.7**	14.3	96.7	*28.5*	**49.8**	4.7	94.4	*34.1*	0> ; 5= ; 0<
	Leaf 3	5	***32.2***	*8.0*	*67.1*	**55.1**	24.9	94.4	*23.7*	**46.8**	23.1	91.7	*24.4*	0> ; 5= ; 0<

(1) Comparison based on statistics carried out in each trial report.
* In British trials, Proline 275 at 0.72 L/ha (200 g a.s./ha) was applied.

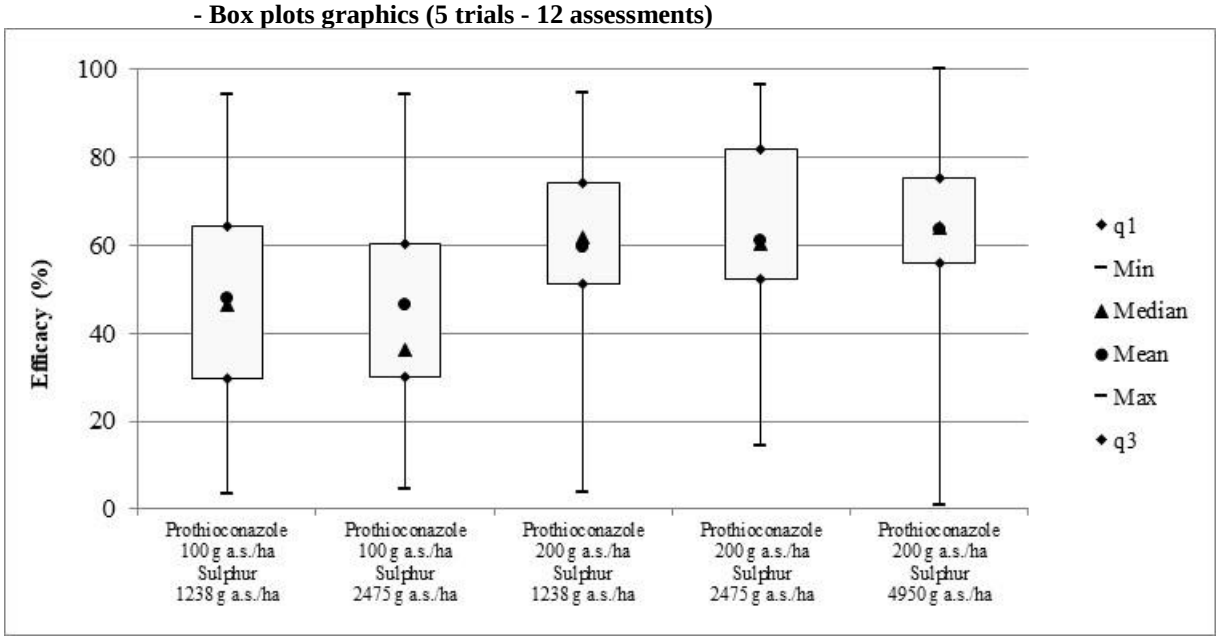
Table 3.2-14: Justification of the ratio of Sulphur - Wheat - SEPTTR - Disease severity on leaves (Leaf 1, Leaf 2, Leaf 3) -Last valid assessment after application A or B

EPPO climatic zone	Parts	No. of trials	*Untreated*			Percentage of efficacy (%)												No. of assessments where Prothioconazole+Sulphur (200 + 2475 g a.s./ha) is significantly[(1)] >;=;< to	
						Prothioconazole + Sulphur				Prothioconazole + Sulphur				Prothioconazole + Sulphur				**Prothioconazole + Sulphur**	**Prothioconazole + Sulphur**
						200+2475 g a.s./ha				200+1238 g a.s./ha				200+4950 g a.s./ha				**(200 + 1238 g a.s./ha)**	**(200 + 4950 g a.s./ha)**
			Mean	*Min*	*Max*	**Mean**	Min	Max	*S.D.*	**Mean**	Min	Max	*S.D.*	**Mean**	Min	Max	*S.D.*		
Maritime	Leaf 1	2	***16.4***	*7.1*	*25.8*	**68.9**	57.2	80.6	*11.7*	**67.0**	63.5	70.5	*3.5*	**69.5**	68.4	70.5	*1.1*	0> ; 2= ; 0<	0> ; 2= ; 0<
	Leaf 2	5	***24.3***	*6.0*	*80.8*	**63.7**	14.3	96.7	*28.5*	**60.6**	3.7	94.6	*31.8*	**62.5**	0.9	100.0	*34.7*	1> ; 4= ; 0<	1> ; 4= ; 0<
	Leaf 3	5	***32.2***	*8.0*	*67.1*	**55.1**	24.9	94.4	*23.7*	**56.1**	32.4	93.1	*21.7*	**62.2**	32.1	100.0	*21.9*	0> ; 5= ; 0<	1> ; 4= ; 0<

(1) Comparison based on statistics carried out in each trial report.

At the last valid assessment after one or two applications, if the ratio of sulphur is fixed at 2475 g a.s./ha, the tank mix with the same rate of prothioconazole (200 g a.s./ha) than FHO04 applied at 4.0 L/ha delivered 69% on Leaf 1, 64% on Leaf 2 and 55% on Leaf 3 when the tank mix with only 100 g a.s./ha of prothioconazole delivered 38% on Leaf 1, 50% on Leaf 2 and 47% on Leaf 3. Therefore, 200 g a.s./ha of prothioconazole is necessary to control leaf spot even if no significant difference was noted in these 5 trials.
If the ratio of prothioconazole is fixed at 200 g a.s./ha, the tank mix with the same rate of sulphur (2475 g a.s./ha) than FHO04 applied at 4.0 L/ha delivered 69% on Leaf 1, 64% on Leaf 2 and 55% on Leaf 3 when the tank mix with only 1238 g a.s./ha of sulphur delivered 67% on Leaf 1, 61% on Leaf 2 and 56% on Leaf 3 and the tank mix with 4950 g a.s./ha of sulphur delivered 70% on Leaf 1, 63% on Leaf 2 and 62% on Leaf 3. Therefore, there is no difference whatever the rate of sulphur applied even if the tank-mix with 2475 g a.s./ha was slightly superior to the tank mix with only 1238 g a.s./ha of sulphur, notably on Leaf 2 (significant in 1 out of 5 trials).
The justification of the ratio of each active substance (prothioconazole + sulphur) contained in FHO04 can be illustrated by box plot graphics (Figure 3.2-4). Overall, box plot graphics show a better control and homogeneity for the tank-mix prothioconazole (200 g a.s./ha) + sulphur (2475 g a.s./ha) compared to other tested tank-mix except prothioconazole (200 g a.s./ha) + sulphur (4950 g a.s./ha).

Figure 3.2-4 Justification of the ratio - Wheat - SEPTTR - Last valid assessment after the 2nd application - Box plots graphics (5 trials - 12 assessments)



To conclude, the ratio prothioconazole/sulphur contained in the product FHO04 can be considered as justified.

Comments of zRMS:

The tables 3.2-13 and 3.2-14 both clearly support the view that it is prothioconazole that is the efficacy driver of the FHO04, and not sulphur. Then, even though the Figure 3.2-4 may seem inappropriate in its showing of the averaged data from the leaf strata L1-L3, it nevertheless shows more convincingly than the tables do, that increasing the content of sulphur beyond the 625 g/L, in the FHO04, makes little sense from efficacy perspective. Therefore the ratio prothioconazole/sulphur in the FHO04: **50/625** g/L has been considered justified, and properly demonstrated by the applicant.

3.2.1.5 Summary and conclusion of the interest of the association

Leaf spot (*Zymoseptoria tritici* - SEPTTR) is the major problematic disease in cereals. Therefore, the objective of this preliminary part is to justify the interest to associate sulphur with prothioconazole to control leaf spot (*Zymoseptoria tritici* - SEPTTR).
In 5 trials carried out in Maritime EPPO climatic zone and provided as supportive data, FHO04 applied at 4.0 L/ha (200 g a.s./ha prothioconazole + 2500 g a.s./ha sulphur) was compared to Prothioconazole based products applied straight at 200 g a.s./ha, Sulphur based products applied straight at 2475 g a.s./ha and the extemporaneous tank-mix prothioconazole + sulphur.
In these 5 trials, different ratios of prothioconazole and sulphur was also tested to determine the best ratio between both active substances.
In 28 trials, FHO04 applied at 4.0 L/ha (200 g a.s./ha prothioconazole + 2500 g a.s./ha sulphur) was compared only to Prothioconazole based products applied straight at 200 g a.s./ha. According to the trial, Prothioconazole based product used in the trials was an internal preparation (code name FGR06, Prothioconazole, 250 g/L) applied at 0.8 L/ha or Proline also applied at 0.8 L/ha.
Based on the benefits with respect to resistance prevention, the knowledge of each active substances, and technical possibilities on formulation, the combination of the active substances prothioconazole + sulphur in FHO04 and their rate ratio can be considered as justified.

Comments of zRMS on active co-formulation in FHO04:

The advantage of co-formulation of the actives prothioconazole and sulphur as well as their intended ratio in the FHO04 have been considered justified and demonstrated effectively.

zRMS Abstract

3.2.2 Minimum effective dose tests (KCP 6.2)

The confirmation of required doses of FHO04, presented in the GAP table in Table 3.2-3, was supported by the data from **58 valid efficacy trials** carried out **from 2020 to 2023** in the Northeast EPPO climatic zone (28 trials in Poland, 6 trials in Latvia and 4 trials in Lithuania) and Poland border countries (1 trial in Czech Republic, and 19 trials in Germany) in winter wheat (41 trials), durum wheat (1 trial) or winter triticale (6 trials) or winter rye (10 trials) against SEPTTR (33 trials) , PUCCRE (22 trials), PUCCST (10 trials) and/or PUCCSI (13 trials). Some trials contained more than one target disease, therefore the total number of trials for all diseases exceeds 58 valid trials.

3.2.2.1 Material and methods

FHO04 was tested at 2.0, 3.0 and 4.0 L/ha. These rates reflect 50%, 75% and 100% (4.0 L/ha, the maximum recommended dose of FHO04) in accordance with the EPPO guideline PP 1/225(1) "Minimum effective rate". Material and Methods used in these efficacy trials are given within Section 3.2.3.1.
Only the trials and assessments with a sufficient infestation level in the untreated plot (thresholds of 5% coverage of foliar or ears area by the disease) and where the level of efficacy of the reference standards were as expected are considered in this synthesis. In practice, assessments from 4.5% were selected in the available data package notably to be able to select same number of assessments per trial.

3.2.2.2 Results of minimum effective dose tests to control leaf spot (*Zymoseptoria tritici* - SEPTTR)

A total of **33 valid efficacy trials** were carried out to justify the minimum effective dose of FHO04. against SEPTTR in winter wheat (30 trials), durum wheat (1 trial) or triticale (2 trials). These trials were carried out **from 2020 to 2023** in the Northeast EPPO climatic zone (12 trials in Poland, 5 trials in Latvia and 4 trials in Lithuania) and Poland border countries (12 trials in Germany).
In accordance with EPPO guideline PP1/257, all data against *Zymoseptoria tritici* (SEPTTR) in winter and spring wheat, durum wheat, spelt, and triticale can be considered as comparable and merged in this section. However, an analysis by crop is also provided hereafter.
Table 3.2-15 summarises all observations.

Table 3.2-15: Minimum effective dose of FHO04 - Winter cereals – SEPTTR (single trial data in Table 6.2-2 – 6.2-3 BAD)

Parameters	Assessment date	EPPO climatic zone	Parts	No. of trials	*Untreated*			Percentage of efficacy (%)												No. of assessments where FHO04 (4.0 L/ha) is significantly[(1)] >;=;< to	
								FHO04 2.0 L/ha				FHO04 3.0 L/ha				FHO04 4.0 L/ha					
								Prothioconazole + Sulphur				Prothioconazole + Sulphur				Prothioconazole + Sulphur					
								100+1250 g a.s./ha				150+1875 g a.s./ha				200+2500 g a.s./ha				FHO04	
					Mean	*Min*	*Max*	**Mean**	Min	Max	*S.D.*	**Mean**	Min	Max	*S.D.*	**Mean**	Min	Max	*S.D.*	**2.0 L/ha**	**3.0 L/ha**
Disease severity on winter wheat	~~2-3 weeks~~ 13-27 days after the second application	Northeast	Leaf 1	1	***5.3***	-	-	**86.2**	-	-	-	**85.7**	-	-	-	**87.2**	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<
				3	***5.1***	*5.1*	*5.3*	**-**	-	-	-	**87.0**	85.7	88.1	*1.0*	**91.5**	87.2	94.6	*3.1*	-	1> ; 2= ; 0<
			Leaf 2	3	***8.6***	*6.8*	*9.7*	**83.9**	74.7	93.9	*7.9*	**89.4**	83.9	96.1	*5.1*	**91.1**	85.3	97.9	*5.2*	0> ; 3= ; 0<	0> ; 3= ; 0<
				9	***6.7***	*5.0*	*9.7*	**-**	-	-	-	**84.8**	61.5	96.1	*8.9*	**89.2**	68.5	97.9	*8.0*	-	3> ; 6= ; 0<
			Leaf 3	6	***9.8***	*6.2*	*17.6*	**54.4**	26.6	75.9	*16.0*	**68.6**	46.8	77.7	*10.9*	**74.7**	46.5	90.7	*15.8*	3> ; 3= ; 0<	0> ; 6= ; 0<
				4	***8.4***	*5.3*	*17.6*	**-**	-	-	-	**75.8**	46.8	88.8	*12.0*	**82.9**	46.5	95.9	*14.0*	-	4> ; 10= ; 0<
		Border countries of Poland (Germany)	Leaf 1	1	***5.9***	-	-	**60.0**	-	-	-	**100.0**	-	-	-	**100.0**	-	-	-	1> ; 0= ; 0<	0> ; 1= ; 0<
			Leaf 2	2	***8.0***	*6.9*	*9.1*	**46.1**	22.9	69.3	*23.2*	**70.0**	39.9	100.0	*30.0*	**81.4**	62.8	100.0	*18.6*	1> ; 1= ; 0<	0> ; 2= ; 0<
				3	***7.6***	*6.7*	*9.1*	**-**	-	-	-	**74.5**	39.9	100.0	*25.4*	**84.7**	62.8	100.0	*15.9*	-	0> ; 3= ; 0<
			Leaf 3	2	***19.4***	*14.4*	*24.5*	**60.4**	43.5	77.3	*16.9*	**68.6**	47.0	90.1	*21.6*	**75.3**	50.5	100.0	*24.7*	1> ; 1= ; 0<	0> ; 2= ; 0<
				5	***12.5***	*5.0*	*24.5*	**-**	-	-	-	**71.9**	47.0	97.8	*20.6*	**74.6**	41.9	100.0	*24.4*	-	0> ; 5= ; 0<
		All EPPO climatic zones	Leaf 1	2	***5.6***	*5.3*	*5.9*	**73.1**	60.0	86.2	*13.1*	**92.8**	85.7	100.0	*7.2*	**93.6**	87.2	100.0	*6.4*	1> ; 1= ; 0<	0> ; 2= ; 0<
				4	***5.3***	*5.1*	*5.9*	**-**	-	-	-	**90.3**	85.7	100.0	*5.7*	**93.6**	87.2	100.0	*4.6*	-	1> ; 3= ; 0<
			Leaf 2	5	***8.4***	*6.8*	*9.7*	**68.8**	22.9	93.9	*24.4*	**81.6**	39.9	100.0	*21.6*	**87.3**	62.8	100.0	*13.3*	1> ; 4= ; 0<	0> ; 5= ; 0<
				12	***7.0***	*5.0*	*9.7*	**-**	-	-	-	**82.2**	39.9	100.0	*15.5*	**88.1**	62.8	100.0	*10.7*	-	3> ; 9= ; 0<
			Leaf 3	8	***12.2***	*6.2*	*24.5*	**55.9**	26.6	77.3	*16.4*	**68.6**	46.8	90.1	*14.4*	**74.8**	46.5	100.0	*18.5*	4> ; 4= ; 0<	0> ; 8= ; 0<
				19	***9.4***	*5.0*	*24.5*	**-**	-	-	-	**74.8**	46.8	97.8	*14.9*	**80.7**	41.9	100.0	*17.7*	-	4> ; 15= ; 0<

Parameters	Assessment date	EPPO climatic zone	Parts	No. of trials	*Untreated*			Percentage of efficacy (%)												No. of assessments where FHO04 (4.0 L/ha) is significantly[(1)] >;=;< to	
								FHO04 2.0 L/ha				FHO04 3.0 L/ha				FHO04 4.0 L/ha					
								Prothioconazole + Sulphur				Prothioconazole + Sulphur				Prothioconazole + Sulphur					
								100+1250 g a.s./ha				150+1875 g a.s./ha				200+2500 g a.s./ha				FHO04	
					Mean	*Min*	*Max*	**Mean**	Min	Max	*S.D.*	**Mean**	Min	Max	*S.D.*	**Mean**	Min	Max	*S.D.*	**2.0 L/ha**	**3.0 L/ha**
Disease severity on winter wheat	Last valid assessment after the 2nd application (13-50 DAB)	Northeast	Leaf 1	4	***19.0***	*5.0*	*37.8*	**50.4**	20.2	84.0	*25.4*	**65.5**	46.4	85.6	*14.3*	**71.5**	47.8	85.5	*14.2*	1> ; 3= ; 0<	1> ; 3= ; 0<
				11	***12.4***	*4.5*	*37.8*	-	-	-	-	**71.3**	46.4	88.1	*15.2*	**75.6**	47.8	94.6	*14.7*	-	4> ; 7= ; 0<
			Leaf 2	6	***10.1***	*5.0*	*19.3*	**79.3**	58.7	93.9	*11.8*	**82.4**	67.6	96.1	*11.2*	**86.1**	76.1	97.9	*9.2*	1> ; 5= ; 0<	0> ; 6= ; 0<
				16	***9.6***	*5.0*	*27.4*	-	-	-	-	**80.1**	47.6	96.1	*13.7*	**85.5**	57.4	97.9	*11.6*	-	5> ; 11= ; 0<
			Leaf 3	6	***9.8***	*6.2*	*17.6*	**54.4**	26.6	75.9	*16.0*	**68.6**	46.8	77.7	*10.9*	**74.7**	46.5	90.7	*15.8*	3> ; 3= ; 0<	0> ; 6= ; 0<
				14	***8.4***	*5.3*	*17.6*	-	-	-	-	**75.7**	46.8	88.8	*11.9*	**82.9**	46.5	95.9	*14.0*	-	4> ; 10= ; 0<
		Border countries of Poland (Germany)	Leaf 1	1	***5.9***	-	-	**60.0**	-	-	-	**100.0**	-	-	-	**100.0**	-	-	-	1> ; 0= ; 0<	0> ; 1= ; 0<
				4	***13.0***	*5.4*	*21.3*	-	-	-	-	**87.2**	77.8	100.0	*8.1*	**92.2**	83.9	100.0	*5.8*	-	1> ; 3= ; 0<
			Leaf 2	2	***10.6***	*9.1*	*12.0*	**49.8**	22.9	76.7	*26.9*	**64.7**	39.9	89.5	*24.8*	**81.4**	62.8	100.0	*18.6*	0> ; 2= ; 0<	0> ; 2= ; 0<
				8	***11.7***	*5.2*	*20.9*	-	-	-	-	**72.9**	15.4	98.6	*28.8*	**85.9**	47.3	100.0	*18.8*	-	1> ; 7= ; 0<
			Leaf 3	2	***21.2***	*17.6*	*24.8*	**54.7**	43.2	66.2	*11.5*	**65.5**	48.1	82.9	*17.4*	**75.6**	51.1	100.0	*24.5*	1> ; 1= ; 0<	1> ; 1= ; 0<
				7	***26.7***	*8.0*	*59.9*	-	-	-	-	**71.6**	48.1	94.2	*18.2*	**77.0**	41.9	100.0	*21.8*	-	2> ; 5= ; 0<
		All EPPO climatic zones	Leaf 1	5	***16.4***	*5.0*	*37.8*	**52.3**	20.2	84.0	*23.1*	**72.4**	46.4	100.0	*18.8*	**77.2**	47.8	100.0	*17.1*	2> ; 3= ; 0<	1> ; 4= ; 0<
				15	***12.6***	*4.5*	*37.8*	-	-	-	-	**75.5**	46.4	100.0	*15.4*	**80.0**	47.8	100.0	*14.9*	-	5> ; 10= ; 0<
			Leaf 2	8	***10.3***	*5.0*	*19.3*	**71.9**	22.9	93.9	*21.2*	**78.0**	39.9	96.1	*17.5*	**84.9**	62.8	100.0	*12.4*	1> ; 7= ; 0<	0> ; 8= ; 0<
				24	***10.3***	*5.0*	*27.4*	-	-	-	-	**77.7**	15.4	98.6	*20.3*	**85.6**	47.3	100.0	*14.4*	-	6> ; 18= ; 0<
			Leaf 3	8	***12.6***	*6.2*	*24.8*	**54.5**	26.6	75.9	*15.0*	**67.8**	46.8	82.9	*12.9*	**74.9**	46.5	100.0	*18.4*	4> ; 4= ; 0<	1> ; 7= ; 0<
				21	***14.5***	*5.3*	*59.9*	-	-	-	-	**74.3**	46.8	94.2	*14.5*	**80.9**	41.9	100.0	*17.2*	-	6> ; 15= ; 0<
Disease severity on winter triticale	~~2-3 weeks~~ 13-27 days after the second application	Northeast	Leaf 3	1	***7.3***	-	-	-	-	-	-	**85.1**	-	-	-	**89.1**	-	-	-	-	0> ; 1= ; 0<
	Last valid assessment after the 2nd application (13-50 DAB)	Northeast	Leaf 2	1	***11.9***	-	-	-	-	-	-	**94.3**	-	-	-	**100.0**	-	-	-	-	0> ; 1= ; 0<
			Leaf 3	2	***11.7***	*7.3*	*16.0*	-	-	-	-	**84.0**	82.8	85.1	*1.2*	**92.7**	89.1	96.2	*3.6*	-	1> ; 1= ; 0<
Disease severity on winter durum wheat	~~2-3 weeks~~ 13-27 days after the second application	Border countries of Poland (Germany) ~~Northeast~~	Leaf 1	1	*8.4*	-	-	-	-	-	-	**6.8**	-	-	-	**33.3**	-	-	-	-	0> ; 1= ; 0<
			Leaf 2	1	*12.1*	-	-	-	-	-	-	**11.3**	-	-	-	**21.6**	-	-	-	-	0> ; 1= ; 0<
			Leaf 3	1	*18.5*	-	-	-	-	-	-	**4.3**	-	-	-	**14.8**	-	-	-	-	0> ; 1= ; 0<
	Last valid assessment after the 2nd application (13-50 DAB)		Leaf 1	1	***17.7***	-	-	-	-	-	-	**5.2**	-	-	-	**24.8**	-	-	-	-	0> ; 1= ; 0<
			Leaf 2	1	***21.7***	-	-	-	-	-	-	**10.6**	-	-	-	**19.8**	-	-	-	-	0> ; 1= ; 0<
			Leaf 3	1	***33.4***	-	-	-	-	-	-	**3.9**	-	-	-	**12.7**	-	-	-	-	0> ; 1= ; 0<
Disease severity on winter cereals	~~2-3 weeks~~ 13-27 days after the second application	Northeast	Leaf 1	1	***5.3***	-	-	**86.2**	-	-	-	**85.7**	-	-	-	**87.2**	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<
				3	***5.1***	*5.1*	*5.3*	-	-	-	-	**87.0**	85.7	88.1	*1.0*	**91.5**	87.2	94.6	*3.1*	-	1> ; 2= ; 0<
			Leaf 2	3	***8.6***	*6.8*	*9.7*	**83.9**	74.7	93.9	*7.9*	**89.4**	83.9	96.1	*5.1*	**91.1**	85.3	97.9	*5.2*	0> ; 3= ; 0<	0> ; 3= ; 0<
				9	***6.7***	*5.0*	*9.7*	-	-	-	-	**84.8**	61.5	96.1	*8.9*	**89.2**	68.5	97.9	*8.0*	-	3> ; 6= ; 0<
			Leaf 3	6	***9.8***	*6.2*	*17.6*	**54.4**	26.6	75.9	*16.0*	**68.6**	46.8	77.7	*10.9*	**74.7**	46.5	90.7	*15.8*	3> ; 3= ; 0<	0> ; 6= ; 0<
				15	***8.3***	*5.3*	*17.6*	-	-	-	-	**76.4**	46.8	88.8	*11.9*	**83.3**	46.5	95.9	*13.6*	-	4> ; 11= ; 0<
		Border countries of Poland (Germany)	Leaf 1	1	***5.9***	-	-	**60.0**	-	-	-	**100.0**	-	-	-	**100.0**	-	-	-	1> ; 0= ; 0<	0> ; 1= ; 0<
				2	***7.2***	*5.9*	*8.4*	-	-	-	-	**53.4**	6.8	100.0	*46.6*	**66.6**	33.3	100.0	*33.4*	-	0> ; 2= ; 0<
			Leaf 2	2	***8.0***	*6.9*	*9.1*	**46.1**	22.9	69.3	*23.2*	**70.0**	39.9	100.0	*30.0*	**81.4**	62.8	100.0	*18.6*	1> ; 1= ; 0<	0> ; 2= ; 0<

Parameters	Assessment date	EPPO climatic zone	Parts	No. of trials	*Untreated*			Percentage of efficacy (%)												No. of assessments where FHO04 (4.0 L/ha) is significantly[(1)] >;=;< to	
								FHO04 2.0 L/ha				FHO04 3.0 L/ha				FHO04 4.0 L/ha					
								Prothioconazole + Sulphur				Prothioconazole + Sulphur				Prothioconazole + Sulphur					
								100+1250 g a.s./ha				150+1875 g a.s./ha				200+2500 g a.s./ha				FHO04	
					Mean	*Min*	*Max*	**Mean**	Min	Max	*S.D.*	**Mean**	Min	Max	*S.D.*	**Mean**	Min	Max	*S.D.*	**2.0 L/ha**	**3.0 L/ha**
				4	***8.7***	*6.7*	*12.1*	-	-	-	-	**58.7**	11.3	100.0	*35.1*	**68.9**	21.6	100.0	*30.6*	-	0> ; 4= ; 0<
			Leaf 3	2	***19.4***	*14.4*	*24.5*	**60.4**	43.5	77.3	*16.9*	**68.6**	47.0	90.1	*21.6*	**75.3**	50.5	100.0	*24.7*	1> ; 1= ; 0<	0> ; 2= ; 0<
				6	***13.5***	*5.0*	*24.5*	-	-	-	-	**60.6**	4.3	97.8	*31.4*	**64.6**	14.8	100.0	*31.5*	-	0> ; 6= ; 0<
		All EPPO climatic zones	Leaf 1	2	***5.6***	*5.3*	*5.9*	**73.1**	60.0	86.2	*13.1*	**92.8**	85.7	100.0	*7.2*	**93.6**	87.2	100.0	*6.4*	1> ; 1= ; 0<	0> ; 2= ; 0<
				5	***6.0***	*5.1*	*8.4*	-	-	-	-	**73.6**	6.8	100.0	*33.8*	**81.5**	33.3	100.0	*24.5*	-	1> ; 4= ; 0<
			Leaf 2	5	***8.4***	*6.8*	*9.7*	**68.8**	22.9	93.9	*24.4*	**81.6**	39.9	100.0	*21.6*	**87.3**	62.8	100.0	*13.3*	1> ; 4= ; 0<	0> ; 5= ; 0<
				13	***7.4***	*5.0*	*12.1*	-	-	-	-	**76.8**	11.3	100.0	*24.1*	**83.0**	21.6	100.0	*20.5*	-	3> ; 10= ; 0<
			Leaf 3	8	***12.2***	*6.2*	*24.5*	**55.9**	26.6	77.3	*16.4*	**68.6**	46.8	90.1	*14.4*	**74.8**	46.5	100.0	*18.5*	4> ; 4= ; 0<	0> ; 8= ; 0<
				21	***9.8***	*5.0*	*24.5*	-	-	-	-	**71.9**	4.3	97.8	*20.8*	**78.0**	14.8	100.0	*22.1*	-	4> ; 17= ; 0<
Disease severity on winter cereals	Last valid assessment after the 2nd application (13-50 DAB)	Northeast	Leaf 1	4	***19.0***	*5.0*	*37.8*	**50.4**	20.2	84.0	*25.4*	**65.5**	46.4	85.6	*14.3*	**71.5**	47.8	85.5	*14.2*	1> ; 3= ; 0<	1> ; 3= ; 0<
				11	***12.4***	*4.5*	*37.8*	-	-	-	-	**71.3**	46.4	88.1	*15.2*	**75.6**	47.8	94.6	*14.7*	-	4> ; 7= ; 0<
			Leaf 2	6	***10.1***	*5.0*	*19.3*	**79.3**	58.7	93.9	*11.8*	**82.4**	67.6	96.1	*11.2*	**86.1**	76.1	97.9	*9.2*	1> ; 5= ; 0<	0> ; 6= ; 0<
				16	***9.6***	*5.0*	*27.4*	-	-	-	-	**80.1**	47.6	96.1	*13.7*	**85.5**	57.4	97.9	*11.6*	-	5> ; 11= ; 0<
			Leaf 3	6	***9.8***	*6.2*	*17.6*	**54.4**	26.6	75.9	*16.0*	**68.6**	46.8	77.7	*10.9*	**74.7**	46.5	90.7	*15.8*	3> ; 3= ; 0<	0> ; 6= ; 0<
				15	***8.3***	*5.3*	*17.6*	-	-	-	-	**76.3**	46.8	88.8	*11.8*	**83.3**	46.5	95.9	*13.6*	-	4> ; 11= ; 0<
		Border countries of Poland (Germany)	Leaf 1	1	***5.9***	-	-	**60.0**	-	-	-	**100.0**	-	-	-	**100.0**	-	-	-	1> ; 0= ; 0<	0> ; 1= ; 0<
				5	***14.0***	*5.4*	*21.3*	-	-	-	-	**70.8**	5.2	100.0	*33.6*	**78.7**	24.8	100.0	*27.4*	-	1> ; 4= ; 0<
			Leaf 2	2	***10.6***	*9.1*	*12.0*	**49.8**	22.9	76.7	*26.9*	**64.7**	39.9	89.5	*24.8*	**81.4**	62.8	100.0	*18.6*	0> ; 2= ; 0<	0> ; 2= ; 0<
				10	***12.7***	*5.2*	*21.7*	-	-	-	-	**68.8**	10.6	98.6	*32.9*	**80.7**	19.8	100.0	*26.7*	-	1> ; 9= ; 0<
			Leaf 3	2	***21.2***	*17.6*	*24.8*	**54.7**	43.2	66.2	*11.5*	**65.5**	48.1	82.9	*17.4*	**75.6**	51.1	100.0	*24.5*	1> ; 1= ; 0<	1> ; 1= ; 0<
				9	***26.3***	*8.0*	*59.9*	-	-	-	-	**65.3**	3.9	94.2	*27.3*	**72.0**	12.7	100.0	*29.1*	-	3> ; 6= ; 0<
		All EPPO climatic zones	Leaf 1	5	***16.4***	*5.0*	*37.8*	**52.3**	20.2	84.0	*23.1*	**72.4**	46.4	100.0	*18.8*	**77.2**	47.8	100.0	*17.1*	2> ; 3= ; 0<	1> ; 4= ; 0<
				16	***12.9***	*4.5*	*37.8*	-	-	-	-	**71.1**	5.2	100.0	*22.6*	**76.6**	24.8	100.0	*19.6*	-	5> ; 11= ; 0<
			Leaf 2	8	***10.3***	*5.0*	*19.3*	**71.9**	22.9	93.9	*21.2*	**78.0**	39.9	96.1	*17.5*	**84.9**	62.8	100.0	*12.4*	1> ; 7= ; 0<	0> ; 8= ; 0<
				26	***10.8***	*5.0*	*27.4*	-	-	-	-	**75.8**	10.6	98.6	*23.7*	**83.7**	19.8	100.0	*19.0*	-	6> ; 20= ; 0<
			Leaf 3	8	***12.6***	*6.2*	*24.8*	**54.5**	26.6	75.9	*15.0*	**67.8**	46.8	82.9	*12.9*	**74.9**	46.5	100.0	*18.4*	4> ; 4= ; 0<	1> ; 7= ; 0<
				24	***15.1***	*5.3*	*59.9*	-	-	-	-	**72.2**	3.9	94.2	*19.8*	**79.0**	12.7	100.0	*21.5*	-	7> ; 17= ; 0<

(1) Comparison based on statistics carried out in each trial report.

The results are summarized by EPPO climatic zone in each summary table by disease. Only results for all valid efficacy trials (all EPPO climatic zones presented Table 3.2-15) are discussed hereafter to justify the minimum effective dose of FHO04 against SEPTTR.

Across 33 efficacy trials, FHO04, applied at the proposed label rate of 4.0 L/ha, was compared to FHO04 at 2.0 L/ha (50% of maximum recommended dose) and 3.0 L/ha (75% of maximum recommended dose).

Across 30 efficacy trials carried out in winter wheat in the Northeast EPPO climatic zone and Polish border countries, 2-3 weeks after the second application, FHO04 at 4.0 L/ha delivered 94% on Leaf 1 (in 4 trials), 88% on Leaf 2 (in 12 trials) and 81% on Leaf 3 (in 19 trials), when FHO04 at 3.0 L/ha provided 90% on Leaf 1, 82% on Leaf 2 and 75% on Leaf 3. FHO04 at 4.0 L/ha was significantly superior to FHO04 at 3.0 L/ha in 1 out of 4 trials on Leaf 1, 3 out of 12 trials on Leaf 2 and 4 out of 19 trials on Leaf 3.

FHO04 at 4.0 L/ha delivered 94% on Leaf 1 (in 2 trials), 87% on Leaf 2 (in 5 trials) and 75% on Leaf 3 (in 8 trials), when FHO04 at 2.0 L/ha provided only 73% on Leaf 1, 69% on Leaf 2 and 66% on Leaf 3. FHO04 at 4.0 L/ha was significantly superior to FHO04 at 2.0 L/ha in 1 out of 2 trials on Leaf 1, 1 out of 5 trials on Leaf 2 and 4 out of 8 trials on Leaf 3. In these trials, FHO04 at 3.0 L/ha provided 93% on Leaf 1, 82% on Leaf 2 and 69% on Leaf 3.

At the last valid assessment after the second application, FHO04 at 4.0 L/ha delivered 80% on Leaf 1 (in 15 trials), 86% on Leaf 2 (in 24 trials) and 81% on Leaf 3 (in 21 trials), when FHO04 at 3.0 L/ha provided 76% on Leaf 1, 78% on Leaf 2 and 74% on Leaf 3. FHO04 at 4.0 L/ha was significantly superior to FHO04 at 3.0 L/ha in 5 out of 15 trials on Leaf 1, 6 out of 24 trials on Leaf 2 and 6 out of 21 trials on Leaf 3.

FHO04 at 4.0 L/ha delivered 77% on Leaf 1 (in 5 trials), 85% on Leaf 2 (in 8 trials) and 75% on Leaf 3 (in 8 trials), when FHO04 at 2.0 L/ha provided only 52% on Leaf 1, 72% on Leaf 2 and 55% on Leaf 3. FHO04 at 4.0 L/ha was significantly superior to FHO04 at 2.0 L/ha in 2 out of 5 trials on Leaf 1, 1 out of 8 trials on Leaf 2 and 4 out of 8 trials on Leaf 3. In these trials, FHO04 at 3.0 L/ha provided 72% on Leaf 1, 78% on Leaf 2 and 68% on Leaf 3.

On other cereal crops (1 trial on triticale and 1 trial on durum wheat), few data are available. However, the efficacy of FHO04 at 4.0 L/ha was overall superior to the efficacy of FHO04 at 3.0 L/ha.

Finally, across 33 efficacy trials carried out in winter cereals, 2-3 weeks after the second application, FHO04 at 4.0 L/ha delivered 82% on Leaf 1 (in 5 trials), 83% on Leaf 2 (in 13 trials) and 78% on Leaf 3 (in 21 trials), when FHO04 at 3.0 L/ha provided 74% on Leaf 1, 77% on Leaf 2 and 72% on Leaf 3. FHO04 at 4.0 L/ha was significantly superior to FHO04 at 3.0 L/ha in 1 out of 5 trials on Leaf 1, 3 out of 13 trials on Leaf 2 and 4 out of 21 trials on Leaf 3.

FHO04 at 4.0 L/ha delivered 94% on Leaf 1 (in 2 trials), 87% on Leaf 2 (in 5 trials) and 75% on Leaf 3 (in 8 trials), when FHO04 at 2.0 L/ha provided only 73% on Leaf 1, 69% on Leaf 2 and 66% on Leaf 3. FHO04 at 4.0 L/ha was significantly superior to FHO04 at 2.0 L/ha in 1 out of 2 trials on Leaf 1, 1 out of 5 trials on Leaf 2 and 4 out of 8 trials on Leaf 3. In these trials, FHO04 at 3.0 L/ha provided 93% on Leaf 1, 82% on Leaf 2 and 69% on Leaf 3.

At the last valid assessment after the second application, FHO04 at 4.0 L/ha delivered 77% on Leaf 1 (in 16 trials), 84% on Leaf 2 (in 26 trials) and 79% on Leaf 3 (in 24 trials), when FHO04 at 3.0 L/ha provided 71% on Leaf 1, 76% on Leaf 2 and 72% on Leaf 3. FHO04 at 4.0 L/ha was significantly superior to FHO04 at 3.0 L/ha in 5 out of 16 trials on Leaf 1, 6 out of 26 trials on Leaf 2 and 7 out of 24 trials on Leaf 3.

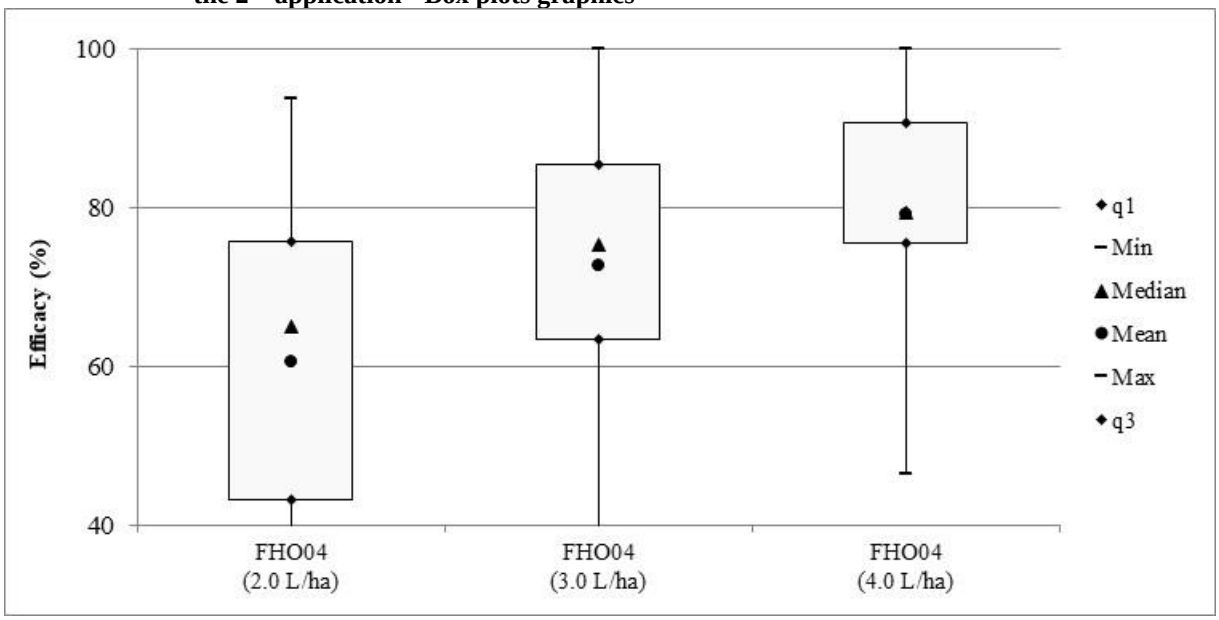
FHO04 at 4.0 L/ha delivered 77% on Leaf 1 (in 5 trials), 85% on Leaf 2 (in 8 trials) and 75% on Leaf 3 (in 8 trials), when FHO04 at 2.0 L/ha provided only 52% on Leaf 1, 72% on Leaf 2 and 55% on Leaf 3. FHO04 at 4.0 L/ha was significantly superior to FHO04 at 2.0 L/ha in 2 out of 5 trials on Leaf 1, 1 out of 8 trials on Leaf 2 and 4 out of 8 trials on Leaf 3. In these trials, FHO04 at 3.0 L/ha provided 72% on Leaf 1, 78% on Leaf 2 and 68% on Leaf 3.

It can be considered that the choice of 4.0 L/ha as maximum recommended dose rate of FHO04 is justified against leaf spot of cereals (SEPTTR). Indeed, the dose effect is clearly illustrated by box plot graphics (The mean **efficacy increases in function of the dose rate of FHO04. FHO04 at 4.0 L/ha reached ~~a superior~~ efficacy superior to ~~than~~ the lower dose rates and good efficacy to control leaf spot of cereals (SEPTTR) confirming the selection of 4.0 L/ha as maximum registered dose.**

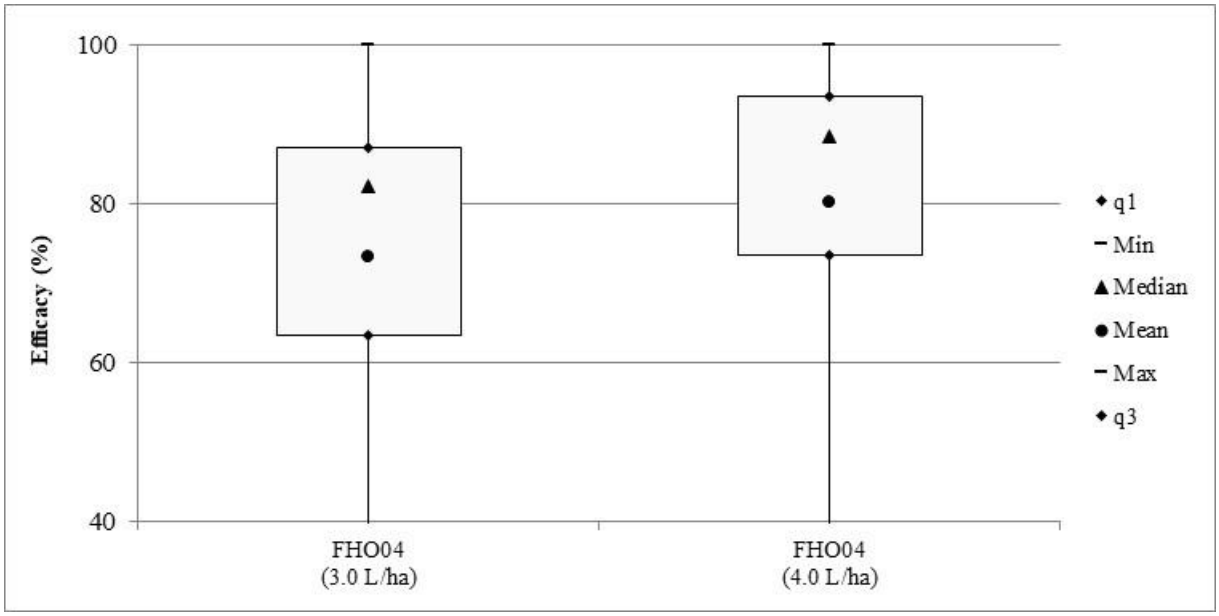
Figure 3.2-5). According to the box plot graphics, the higher the dose of FHO04, the lower the dispersion and variation between means.

The mean efficacy increases in function of the dose rate of FHO04. FHO04 at 4.0 L/ha reached ~~a superior~~ efficacy superior to ~~than~~ the lower dose rates and good efficacy to control leaf spot of cereals (SEPTTR) confirming the selection of 4.0 L/ha as maximum registered dose.

Figure 3.2-5 Minimum effective dose of FHO04 - Winter cereals - SEPTTR - Last valid assessment after the 2nd application - Box plots graphics



(11 trials - 21 assessments)



(33 trials - 66 assessments)

Comments of zRMS:

Altogether 33 efficacy trials, 21 in the North Eastern zone and 12 in the Maritime zone, had tested minimum effective dose of FHO04 in control of SEPTTR. Comparing the target dose rate of 4.0 L/ha to 3.0 l/ha and, where available, to 2.0 L/ha, demonstrates the sturdy dose response although it has been more pronounced on older leaves than on the leaf no. 1, most likely for their higher surface area allowing to conduct more precise visual assessment. The above conclusions refer only to winter soft wheat.
Data for durum wheat and triticale are too scarce to draw reliable conclusions for these crops separately. The triticale results may only suggest that the situation is likely similar to that on wheat, whereas the single durum trial considered valid by the applicant demonstrates extremely low efficacy even at the target dose rate of 4.0 L/ha (12.7 – 33.3 % n=6 across the 3 leaf strata and 2 assessment terms) thus making any considerations about dose response irrelevant.
The second durum wheat trial has not been included in the MED section but is considered useful only for selectivity data, despite its PESSEV in the UNCK reaching 46% on 0 DAB. Likely reason is that this trial is missing assessment on SEPTTR beyond that date. This other trial shows even lower efficacy and moreover the inversed dose response was observed in it (efficacy 17% at 3.0 L/ha and 7.0% at 4.0 L/ha, 0 DAB). Unfortunaely, no word of explanation is offered by the testing unit (Eurofins in both cases), nor by the applicant.

zRMS Abstract

3.2.2.3 Results of minimum effective dose tests to control brown rust (*Puccinia recondita* - PUCCRE)

A total of **22 valid efficacy trials** were carried out to justify the minimum effective dose of FHO04. against PUCCRE in winter wheat (10 trials), durum wheat (1 trial), winter triticale (1 trial) or winter rye (10 trials). These trials were carried out **from 2021 to 2023** in the Northeast EPPO climatic zone (12 trials in Poland), and Poland border countries (1 trial in Czech Republic and 9 trials in Germany).
In accordance with EPPO guideline PP1/257, all data against *Puccinia recondita* (PUCCRE) in winter and spring wheat, durum wheat, spelt, and triticale can be considered as comparable and merged in this section. However, an analysis by crop is also provided hereafter.
Table 3.2-16 summarises all observations.

Table 3.2-16: Minimum effective dose of FHO04 - Cereals – PUCCRE

Parameters	Assessment date	EPPO climatic zone	Parts	No. of trials	*Untreated*			Percentage of efficacy (%)												No. of assessments where FHO04 (4.0 L/ha) is significantly[(1)] >;=;< to	
								FHO04 2.0 L/ha				FHO04 3.0 L/ha				FHO04 4.0 L/ha					
								Prothioconazole + Sulphur				Prothioconazole + Sulphur				Prothioconazole + Sulphur					
								100+1250 g a.s./ha				150+1875 g a.s./ha				200+2500 g a.s./ha				FHO04	
					Mean	*Min*	*Max*	**Mean**	Min	Max	*S.D.*	**Mean**	Min	Max	*S.D.*	**Mean**	Min	Max	*S.D.*	**2.0 L/ha**	**3.0 L/ha**
Disease severity on winter wheat	2-3 weeks after the second application	Northeast	Leaf 1	2	***5.3***	*5.3*	*5.4*	-	-	-	-	**93.2**	91.9	94.4	*1.2*	**97.1**	95.7	98.6	*1.4*	-	0> ; 2= ; 0<
			Leaf 2	2	***5.1***	*5.1*	*5.2*	-	-	-	-	**94.8**	94.7	94.9	*0.1*	**100.0**	100.0	100.0	*0.0*	-	1> ; 1= ; 0<
			Leaf 3	4	***5.8***	*5.1*	*6.5*	-	-	-	-	**94.2**	90.2	96.5	*2.5*	**97.7**	96.0	100.0	*1.6*	-	0> ; 4= ; 0<
	Last valid assessment after the 2nd application	Northeast	Leaf 1	1	***7.9***	-	-	**61.1**	-	-	-	**62.1**	-	-	-	**68.8**	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<
				5	***6.2***	*5.3*	*7.9*	-	-	-	-	**83.5**	62.1	94.9	*13.2*	**89.7**	68.8	98.6	*11.3*	-	1> ; 4= ; 0<
			Leaf 2	1	***4.7***	-	-	**48.9**	-	-	-	**49.3**	-	-	-	**58.4**	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<
				3	***8.3***	*4.7*	*11.7*	-	-	-	-	**72.8**	49.3	94.7	*18.6*	**80.8**	58.4	98.8	*16.8*	-	1> ; 2= ; 0<
			Leaf 3	2	***6.2***	*5.9*	*6.5*	-	-	-	-	**96.2**	95.8	96.5	*0.4*	**99.2**	98.3	100.0	*0.9*	-	0> ; 2= ; 0<
		Border countries of Poland (Czech Republic, Germany)	Leaf 1	3	***19.3***	*8.2*	*29.4*	**46.4**	13.2	65.7	*23.6*	**67.1**	33.8	100.0	*27.0*	**79.0**	68.3	100.0	*14.9*	2> ; 1= ; 0<	1> ; 2= ; 0<
				5	***28.7***	*8.2*	*54.3*	-	-	-	-	**76.5**	33.8	100.0	*24.1*	**85.2**	68.3	100.0	*13.9*	-	1> ; 4= ; 0<
			Leaf 2	1	***16.0***	-	-	**49.7**	-	-	-	**60.2**	-	-	-	**57.8**	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<
				2	***17.1***	*16.0*	*18.1*	-	-	-	-	**75.8**	60.2	91.3	*15.6*	**75.6**	57.8	93.4	*17.8*	-	0> ; 2= ; 0<
		All EPPO climatic zones	Leaf 1	4	***16.4***	*7.9*	*29.4*	**50.1**	13.2	65.7	*21.4*	**65.9**	33.8	100.0	*23.5*	**76.4**	68.3	100.0	*13.6*	2> ; 2= ; 0<	1> ; 3= ; 0<
				10	***17.5***	*5.3*	*54.3*	-	-	-	-	**80.0**	33.8	100.0	*19.7*	**87.5**	68.3	100.0	*12.9*	-	2> ; 8= ; 0<
			Leaf 2	2	***10.4***	*4.7*	*16.0*	**49.3**	48.9	49.7	*0.4*	**54.8**	49.3	60.2	*5.5*	**58.1**	57.8	58.4	*0.3*	0> ; 2= ; 0<	0> ; 2= ; 0<
				5	***11.8***	*4.7*	*18.1*	-	-	-	-	**74.0**	49.3	94.7	*17.5*	**78.7**	57.8	98.8	*17.4*	-	1> ; 4= ; 0<
Disease severity on winter triticale	2-3 weeks after the second application	Northeast	Leaf 3	1	***5.2***	-	-	-	-	-	-	**90.5**	-	-	-	**94.4**	-	-	-	-	0> ; 1= ; 0<
	Last valid assessment after the 2nd application	Northeast	Leaf 1	1	***5.4***	-	-	-	-	-	-	**96.1**	-	-	-	**100.0**	-	-	-	-	0> ; 1= ; 0<
			Leaf 2	1	***6.0***	-	-	-	-	-	-	**92.9**	-	-	-	**95.6**	-	-	-	-	0> ; 1= ; 0<
			Leaf 3	1	***7.9***	-	-	-	-	-	-	**86.6**	-	-	-	**90.7**	-	-	-	-	0> ; 1= ; 0<
Disease severity on winter durum wheat	Last valid assessment after the 2nd application	Border countries of Poland (Czech Republic, Germany)	Leaf 1	1	***9.4***	-	-	-	-	-	-	**2.9**	-	-	-	**6.5**	-	-	-	-	1> ; 0= ; 0<
			Leaf 2	1	***4.7***	-	-	-	-	-	-	**5.6**	-	-	-	**13.5**	-	-	-	-	0> ; 1= ; 0<

Parameters	Assessment date	EPPO climatic zone	Parts	No. of trials	*Untreated*			Percentage of efficacy (%)												No. of assessments where FHO04 (4.0 L/ha) is significantly[(1)] >;=;< to	
								FHO04 2.0 L/ha				FHO04 3.0 L/ha				FHO04 4.0 L/ha					
								Prothioconazole + Sulphur				Prothioconazole + Sulphur				Prothioconazole + Sulphur					
								100+1250 g a.s./ha				150+1875 g a.s./ha				200+2500 g a.s./ha				FHO04	
					Mean	*Min*	*Max*	**Mean**	Min	Max	*S.D.*	**Mean**	Min	Max	*S.D.*	**Mean**	Min	Max	*S.D.*	**2.0 L/ha**	**3.0 L/ha**
Disease severity on winter rye	2-3 weeks after the second application	Northeast	Leaf 1	2	***6.6***	*5.9*	*7.3*	-	-	-	-	**98.0**	95.9	100.0	*2.0*	**100.0**	100.0	100.0	*0.0*	-	0> ; 2= ; 0<
			Leaf 2	5	***6.3***	*5.2*	*7.9*	-	-	-	-	**94.7**	87.9	99.5	*4.5*	**97.4**	92.5	100.0	*3.3*	-	1> ; 4= ; 0<
			Leaf 3	6	***6.1***	*5.2*	*6.5*	-	-	-	-	**92.6**	91.9	93.1	*0.5*	**95.1**	93.0	97.0	*1.2*	-	0> ; 6= ; 0<
	Last valid assessment after the 2nd application	Northeast	Leaf 1	6	***7.1***	*5.9*	*7.7*	-	-	-	-	**98.4**	95.9	100.0	*1.6*	**99.8**	98.6	100.0	*0.5*	-	0> ; 6= ; 0<
			Leaf 2	6	***7.7***	*7.5*	*8.1*	-	-	-	-	**86.4**	79.1	91.4	*3.7*	**91.2**	86.7	94.5	*2.4*	-	4> ; 2= ; 0<
			Leaf 3	6	***7.8***	*6.7*	*9.9*	-	-	-	-	**86.8**	83.7	89.1	*1.8*	**91.7**	88.1	93.9	*2.0*	-	3> ; 3= ; 0<
		Border countries of Poland (~~Czech Republic~~, Germany)	Leaf 1	3	***11.9***	*5.2*	*24.3*	-	-	-	-	**66.7**	36.0	91.7	*23.1*	**80.2**	55.6	98.8	*18.1*	-	1> ; 2= ; 0<
			Leaf 2	4	***16.9***	*5.1*	*41.5*	-	-	-	-	**73.3**	50.8	97.5	*19.8*	**81.6**	54.0	100.0	*17.2*	-	1> ; 3= ; 0<
		All EPPO climatic zones	Leaf 1	9	***8.7***	*5.2*	*24.3*	-	-	-	-	**87.8**	36.0	100.0	*20.1*	**93.3**	55.6	100.0	*14.0*	-	1> ; 8= ; 0<
			Leaf 2	10	***11.4***	*5.1*	*41.5*	-	-	-	-	**81.2**	50.8	97.5	*14.3*	**87.4**	54.0	100.0	*12.0*	-	5> ; 5= ; 0<
Disease severity on winter cereals	2-3 weeks after the second application	Northeast	Leaf 1	4	***6.0***	*5.3*	*7.3*	-	-	-	-	**95.6**	91.9	100.0	*2.9*	**98.6**	95.7	100.0	*1.8*	-	0> ; 4= ; 0<
			Leaf 2	7	***6.0***	*5.1*	*7.9*	-	-	-	-	**94.7**	87.9	99.5	*3.8*	**98.2**	92.5	100.0	*3.0*	-	2> ; 5= ; 0<
			Leaf 3	11	***5.9***	*5.1*	*6.5*	-	-	-	-	**93.0**	90.2	96.5	*1.9*	**96.0**	93.0	100.0	*1.9*	-	0> ; 11= ; 0<
	Last valid assessment after the 2nd application	Northeast	Leaf 1	1	***7.9***	-	-	**61.1**	-	-	-	**62.1**	-	-	-	**68.8**	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<
				12	***6.6***	*5.3*	*7.9*	-	-	-	-	**92.0**	62.1	100.0	*11.2*	**95.6**	68.8	100.0	*8.8*	-	1> ; 11= ; 0<
			Leaf 2	1	***4.7***	-	-	**48.9**	-	-	-	**49.3**	-	-	-	**58.4**	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<
				12	***7.7***	*4.7*	*11.7*	-	-	-	-	**84.4**	49.3	94.7	*12.0*	**89.6**	58.4	98.8	*10.1*	-	6> ; 6= ; 0<
			Leaf 3	11	***7.5***	*5.9*	*9.9*	-	-	-	-	**89.0**	83.7	96.5	*3.8*	**93.1**	88.1	100.0	*3.3*	-	3> ; 8= ; 0<
		Border countries of Poland (Czech Republic, Germany)	Leaf 1	3	***19.3***	*8.2*	*29.4*	**46.4**	13.2	65.7	*23.6*	**67.1**	33.8	100.0	*27.0*	**79.0**	68.3	100.0	*14.9*	2> ; 1= ; 0<	1> ; 2= ; 0<
				9	***21.0***	*5.2*	*54.3*	-	-	-	-	**65.0**	2.9	100.0	*31.7*	**74.8**	6.5	100.0	*28.4*	-	3> ; 6= ; 0<
			Leaf 2	1	***16.0***	-	-	**49.7**	-	-	-	**60.2**	-	-	-	**57.8**	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<
				7	***15.2***	*4.7*	*41.5*	-	-	-	-	**64.4**	5.6	97.5	*29.5*	**70.1**	13.5	100.0	*28.3*	-	1> ; 6= ; 0<
		All EPPO climatic zones	Leaf 1	4	***16.4***	*7.9*	*29.4*	**50.1**	13.2	65.7	*21.4*	**65.9**	33.8	100.0	*23.5*	**76.4**	68.3	100.0	*13.6*	2> ; 2= ; 0<	1> ; 3= ; 0<
				21	***12.8***	*5.2*	*54.3*	-	-	-	-	**80.4**	2.9	100.0	*26.1*	**86.7**	6.5	100.0	*22.3*	-	4> ; 17= ; 0<
			Leaf 2	2	***10.4***	*4.7*	*16.0*	**49.3**	48.9	49.7	*0.4*	**54.8**	49.3	60.2	*5.5*	**58.1**	57.8	58.4	*0.3*	0> ; 2= ; 0<	0> ; 2= ; 0<
				19	***10.5***	*4.7*	*41.5*	-	-	-	-	**77.0**	5.6	97.5	*22.5*	**82.5**	13.5	100.0	*21.2*	-	7> ; 12= ; 0<

(1) Comparison based on statistics carried out in each trial report.

The results are summarized by EPPO climatic zone in each summary table by disease. Only results for all valid efficacy trials (all EPPO climatic zones presented Table 3.2-16) are discussed hereafter to justify the minimum effective dose of FHO04 against PUCCRE.

Across 22 efficacy trials, FHO04, applied at the proposed label rate of 4.0 L/ha, was compared to FHO04 at 2.0 L/ha (50% of maximum recommended dose) and 3.0 L/ha (75% of maximum recommended dose).

Across 10 efficacy trials carried out in winter wheat in the Northeast EPPO climatic zone and Polish border countries, 2-3 weeks after the second application, FHO04 at 4.0 L/ha delivered 97% on Leaf 1 (in 2 trials), 100% on Leaf 2 (in 2 trials) and 98% on Leaf 3 (in 4 trials), when FHO04 at 3.0 L/ha provided 93% on Leaf 1, 95% on Leaf 2 and 94% on Leaf 3. FHO04 at 4.0 L/ha was significantly superior to FHO04 at 3.0 L/ha in 1 out of 2 trials on Leaf 2.

At the last valid assessment after the second application, FHO04 at 4.0 L/ha delivered 88% on Leaf 1 (in 10 trials), 79% on Leaf 2 (in 5 trials) and 99% on Leaf 3 (in 2 trials), when FHO04 at 3.0 L/ha provided 80% on Leaf 1, 74% on Leaf 2 and 96% on Leaf 3. FHO04 at 4.0 L/ha was significantly superior to FHO04 at 3.0 L/ha in 2 out of 10 trials on Leaf 1, and in 1 out of 5 trials on Leaf 2.

FHO04 at 4.0 L/ha delivered 76% on Leaf 1 (in 4 trials), 58% on Leaf 2 (in 2 trials), when FHO04 at 2.0 L/ha provided only 50% on Leaf 1, and 49% on Leaf 2. In these trials, FHO04 at 3.0 L/ha provided 66% on Leaf 1, and 55% on Leaf 2.

Across 10 efficacy trials carried out in winter rye the Northeast EPPO climatic zone and Polish border countries, 2-3 weeks after the second application, FHO04 at 4.0 L/ha delivered 100% on Leaf 1 (in 2 trials), 97% on Leaf 2 (in 5 trials) and 95% on Leaf 3 (in 6 trials), when FHO04 at 3.0 L/ha provided 98% on Leaf 1, 95% on Leaf 2 and 93% on Leaf 3. FHO04 at 4.0 L/ha was significantly superior to FHO04 at 3.0 L/ha in 1 out of 5 trials on Leaf 2.

At the last valid assessment after the second application, FHO04 at 4.0 L/ha delivered 93% on Leaf 1 (in 9 trials), 87% on Leaf 2 (in 10 trials) and 92% on Leaf 3 (in 6 trials), when FHO04 at 3.0 L/ha provided 88% on Leaf 1, 81% on Leaf 2 and 87% on Leaf 3. FHO04 at 4.0 L/ha was significantly superior to FHO04 at 3.0 L/ha in 1 out of 9 trials on Leaf 1, in 5 out of 10 trials on Leaf 2 and in 3 out of 6 trials on Leaf 3.

On other cereal crops (1 trial on triticale and 1 trial on durum wheat), few data are available. However, the efficacy of FHO04 at 4.0 L/ha was overall superior to the efficacy of FHO04 at 3.0 L/ha.

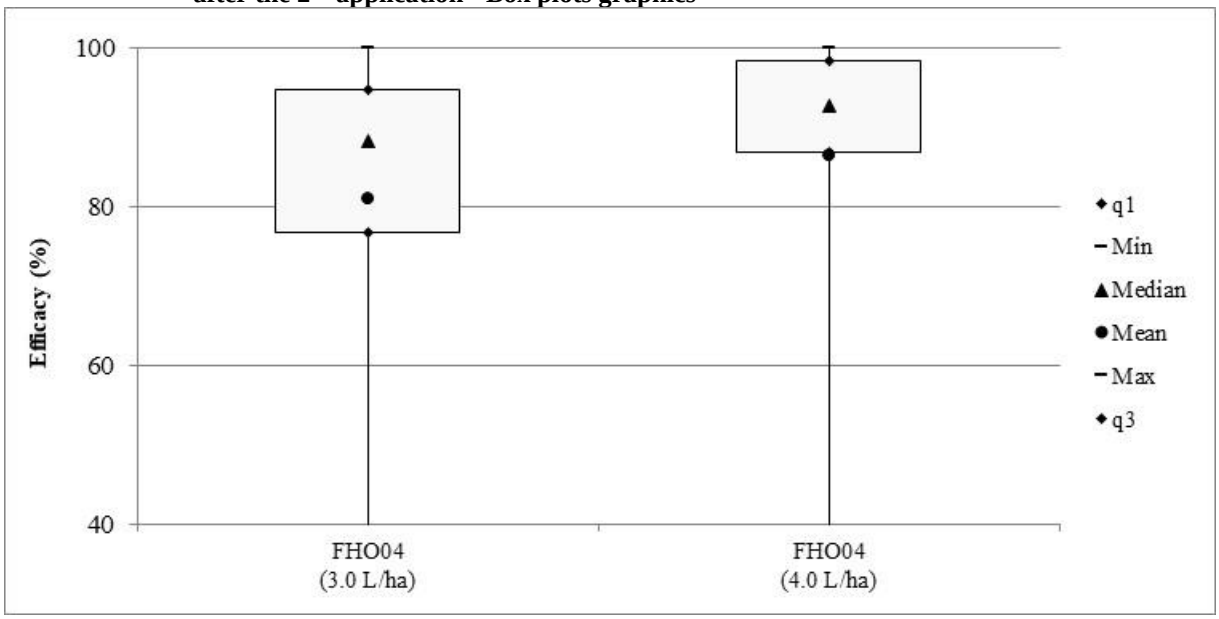
Finally, across 22 efficacy trials in winter cereals, 2-3 weeks after the second application, FHO04 at 4.0 L/ha delivered 99% on Leaf 1 (in 4 trials), 98% on Leaf 2 (in 7 trials) and 96% on Leaf 3 (in 11 trials), when FHO04 at 3.0 L/ha provided 96% on Leaf 1, 95% on Leaf 2 and 93% on Leaf 3. FHO04 at 4.0 L/ha was significantly superior to FHO04 at 3.0 L/ha in 2 out of 7 trials on Leaf 2.

At the last valid assessment after the second application, FHO04 at 4.0 L/ha delivered 87% on Leaf 1 (in 21 trials), 83% on Leaf 2 (in 19 trials) and 93% on Leaf 3 (in 11 trials), when FHO04 at 3.0 L/ha provided 80% on Leaf 1, 77% on Leaf 2 and 89% on Leaf 3. FHO04 at 4.0 L/ha was significantly superior to FHO04 at 3.0 L/ha in 4 out of 21 trials on Leaf 1, in 7 out of 19 trials on Leaf 2 and in 3 out of 11 trials on Leaf 3.

FHO04 at 4.0 L/ha delivered 76% on Leaf 1 (in 4 trials), 58% on Leaf 2 (in 2 trials), when FHO04 at 2.0 L/ha provided only 50% on Leaf 1, and 49% on Leaf 2. In these trials, FHO04 at 3.0 L/ha provided 66% on Leaf 1, and 55% on Leaf 2.

It can be considered that the choice of 4.0 L/ha as maximum recommended dose rate of FHO04 is justified against leaf spot of cereals (PUCCRE). Indeed, the dose effect is clearly illustrated by box plot graphics (Figure 3.2-6). According to the box plot graphics, the higher the dose of FHO04, the lower the dispersion and variation between means.

Figure 3.2-6 Minimum effective dose of FHO04 - Winter cereals - PUCCRE - Last valid assessment after the 2nd application - Box plots graphics



(22 trials - 51 assessments)

The mean efficacy increases in function of the dose rate of FHO04. FHO04 at 4.0 L/ha reached a superior efficacy than the lower dose rates and good efficacy to control brown rust of cereals (PUCCRE) confirming the selection of 4.0 L/ha as maximum registered dose.

Comments of zRMS:

Altogether 22 efficacy trials, 12 in the North Eastern zone and 10 in the Maritime zone, had tested minimum effective dose of FHO04 in control of PUCCRE.
Unlike in the case of SEPTTR, the dose response is mostly independent on the leaf stratum assessed, and it is sufficiently high to confirm the 4.0 L/ha as MED for this use either. The data from triticale speak the same as those for wheat but are too scarce for separate conclusion, while the PUCCRE data from durum wheat are irrelevant and useless, the same as are SEPTTR data for this crop. On the contrary, the data from rye are encouraging, demonstrating clearly the advantage of the 4.0 over the 3.0 L/ha dose rate of FHO04.
Overall, the target 4.0 L/ha of the FHO04 should be considered as MED in control of brown rust of cereals in winter soft wheat and in winter rye.

zRMS Abstract

3.2.2.4 Results of minimum effective dose tests to control yellow rust (*Puccinia striiformis* – PUCCST ~~PUCCSI~~)

A total of **13 valid efficacy trials** were carried out to justify the minimum effective dose of FHO04. against PUCCSI in winter wheat (9 trials), durum wheat (1 trial) or winter triticale (3 trials). These trials were carried out **from 2020 to 2023** in the Northeast EPPO climatic zone (8 trials in Poland, and 1 trial in Latvia) and Poland border countries (4 trials in Germany).
In accordance with EPPO guideline PP1/257, all data against *Puccinia striiformis* (~~PUCCSI~~ PUCCST) in winter and spring wheat, durum wheat, spelt, and triticale can be considered as comparable and merged in this section. However, an analysis by crop is also provided hereafter.
Table 3.2-17 summarises all observations.

Table 3.2-17: Minimum effective dose of FHO04 - Cereals- ~~PUCCSI~~ PUCCST*

Parameters	Assessment date	EPPO climatic zone	Parts	No. of trials	*Untreated*			Percentage of efficacy (%)												No. of assessments where FHO04 (4.0 L/ha) is significantly[(1)] >;=;< to	
								FHO04 2.0 L/ha				FHO04 3.0 L/ha				FHO04 4.0 L/ha					
								Prothioconazole + Sulphur				Prothioconazole + Sulphur				Prothioconazole + Sulphur					
								100+1250 g a.s./ha				150+1875 g a.s./ha				200+2500 g a.s./ha				FHO04	
					Mean	*Min*	*Max*	**Mean**	Min	Max	*S.D.*	**Mean**	Min	Max	*S.D.*	**Mean**	Min	Max	*S.D.*	**2.0 L/ha**	**3.0 L/ha**
Disease severity on winter wheat	2-3 weeks after the second application	Northeast	Leaf 1	3	***5.5***	*4.5*	*6.6*	-	-	-	-	**95.7**	93.5	100.0	*3.1*	**99.3**	98.6	100.0	*0.6*	-	1> ; 2= ; 0<
			Leaf 2	1	***8.9***	-	-	**100.0**	-	-	-	**100.0**	-	-	-	**99.6**	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<
				5	***7.2***	*5.3*	*8.9*	-	-	-	-	**96.5**	92.5	100.0	*3.0*	**99.3**	97.8	100.0	*0.8*	-	0> ; 5= ; 0<
			Leaf 3	5	***6.9***	*5.4*	*9.3*	-	-	-	-	**87.0**	55.5	100.0	*16.0*	**91.9**	68.1	100.0	*12.0*	-	1> ; 4= ; 0<
		Border countries of Poland (Germany)	Leaf 1	2	***19.2***	*14.1*	*24.3*	-	-	-	-	**55.7**	18.8	92.7	*36.9*	**62.5**	28.4	96.7	*34.1*	-	0> ; 2= ; 0<
			Leaf 2	2	***37.4***	*8.4*	*66.5*	-	-	-	-	**58.9**	19.4	98.3	*39.4*	**64.1**	29.0	99.2	*35.1*	-	0> ; 2= ; 0<
			Leaf 3	1	***76.8***	-	-	-	-	-	-	**98.9**	-	-	-	**99.1**	-	-	-	-	0> ; 1= ; 0<
		All EPPO climatic zones	Leaf 1	5	***11.0***	*4.5*	*24.3*	-	-	-	-	**79.7**	18.8	100.0	*30.6*	**84.6**	28.4	100.0	*28.1*	-	1> ; 4= ; 0<
			Leaf 2	7	***15.8***	*5.3*	*66.5*	-	-	-	-	**85.8**	19.4	100.0	*27.2*	**89.3**	29.0	100.0	*24.6*	-	0> ; 7= ; 0<
			Leaf 3	6	***18.6***	*5.4*	*76.8*	-	-	-	-	**88.9**	55.5	100.0	*15.2*	**93.1**	68.1	100.0	*11.3*	-	1> ; 5= ; 0<
	Last valid assessment after the 2nd application	Northeast	Leaf 1	1	***5.1***	-	-	**92.5**	-	-	-	**100.0**	-	-	-	**96.1**	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<
				4	***6.0***	*5.1*	*7.4*	-	-	-	-	**93.8**	90.2	100.0	*3.8*	**96.9**	96.1	97.3	*0.5*	-	0> ; 4= ; 0<
			Leaf 2	1	***8.9***	-	-	**100.0**	-	-	-	**100.0**	-	-	-	**99.6**	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<
				7	***7.3***	*4.6*	*9.8*	-	-	-	-	**84.9**	46.1	100.0	*17.8*	**90.2**	57.4	100.0	*14.1*	-	2> ; 5= ; 0<
			Leaf 3	5	***7.4***	*5.7*	*9.3*	-	-	-	-	**86.1**	55.5	100.0	*15.7*	**90.9**	68.1	100.0	*11.8*	-	1> ; 4= ; 0<
		Border countries of Poland (Germany)	Leaf 1	3	***26.8***	*6.2*	*56.3*	-	-	-	-	**64.3**	18.2	94.0	*33.0*	**71.3**	27.6	96.8	*31.0*	-	1> ; 2= ; 0<
			Leaf 2	2	***39.3***	*12.2*	*66.5*	-	-	-	-	**57.3**	16.3	98.3	*41.0*	**62.2**	25.1	99.2	*37.1*	-	0> ; 2= ; 0<
			Leaf 3	1	***76.8***	-	-	-	-	-	-	**98.9**	-	-	-	**99.1**	-	-	-	-	0> ; 1= ; 0<
		All EPPO climatic zones	Leaf 1	7	***14.9***	*5.1*	*56.3*	-	-	-	-	**81.1**	18.2	100.0	*26.2*	**85.9**	27.6	97.3	*24.0*	-	1> ; 6= ; 0<
			Leaf 2	9	***14.4***	*4.6*	*66.5*	-	-	-	-	**78.8**	16.3	100.0	*27.4*	**84.0**	25.1	100.0	*24.4*	-	2> ; 7= ; 0<
			Leaf 3	6	***18.9***	*5.7*	*76.8*	-	-	-	-	**88.2**	55.5	100.0	*15.1*	**92.3**	68.1	100.0	*11.2*	-	1> ; 5= ; 0<
Disease severity on winter triticale	2-3 weeks after the second application	Northeast	Leaf 2	2	***5.4***	*4.7*	*6.2*	-	-	-	-	**87.9**	87.3	88.5	*0.6*	**94.5**	94.3	94.7	*0.2*	-	1> ; 1= ; 0<
			Leaf 3	1	***6.2***	-	-	-	-	-	-	**88.5**	-	-	-	**94.3**	-	-	-	-	0> ; 1= ; 0<
	Last valid assessment after the 2nd application	Northeast	Leaf 1	1	***5.3***	-	-	-	-	-	-	**86.7**	-	-	-	**92.3**	-	-	-	-	0> ; 1= ; 0<
			Leaf 2	2	***7.6***	*5.9*	*9.3*	-	-	-	-	**83.7**	81.5	85.9	*2.2*	**90.2**	89.3	91.1	*0.9*	-	0> ; 2= ; 0<
			Leaf 3	2	***7.2***	*4.7*	*9.6*	-	-	-	-	**86.5**	85.7	87.3	*0.8*	**92.8**	90.9	94.7	*1.9*	-	1> ; 1= ; 0<
		Border countries of Poland (Germany)	Leaf 2	1	***6.4***	-	-	-	-	-	-	**59.9**	-	-	-	**77.5**	-	-	-	-	0> ; 1= ; 0<
			Leaf 3	1	***20.1***	-	-	-	-	-	-	**31.9**	-	-	-	**51.8**	-	-	-	-	0> ; 1= ; 0<
		All EPPO climatic zones	Leaf 1	1	***5.3***	-	-	-	-	-	-	**86.7**	-	-	-	**92.3**	-	-	-	-	0> ; 1= ; 0<
			Leaf 2	3	***7.2***	*5.9*	*9.3*	-	-	-	-	**75.8**	59.9	85.9	*11.4*	**86.0**	77.5	91.1	*6.0*	-	0> ; 3= ; 0<
			Leaf 3	3	***11.5***	*4.7*	*20.1*	-	-	-	-	**68.3**	31.9	87.3	*25.8*	**79.1**	51.8	94.7	*19.4*	-	1> ; 2= ; 0<

Parameters	Assessment date	EPPO climatic zone	Parts	No. of trials	*Untreated*			Percentage of efficacy (%)												No. of assessments where FHO04 (4.0 L/ha) is significantly[(1)] >;=;< to	
								FHO04 2.0 L/ha				FHO04 3.0 L/ha				FHO04 4.0 L/ha					
								Prothioconazole + Sulphur				Prothioconazole + Sulphur				Prothioconazole + Sulphur					
								100+1250 g a.s./ha				150+1875 g a.s./ha				200+2500 g a.s./ha				FHO04	
					Mean	*Min*	*Max*	**Mean**	Min	Max	*S.D.*	**Mean**	Min	Max	*S.D.*	**Mean**	Min	Max	*S.D.*	**2.0 L/ha**	**3.0 L/ha**
Disease severity on winter cereals	2-3 weeks after the second application	Northeast	Leaf 1	3	***5.5***	*4.5*	*6.6*	-	-	-	-	**95.7**	93.5	100.0	*3.1*	**99.3**	98.6	100.0	*0.6*	-	1> ; 2= ; 0<
			Leaf 2	1	***8.9***	-	-	**100.0**	-	-	-	**100.0**	-	-	-	**99.6**	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<
				6	***6.7***	*4.6*	*8.9*	-	-	-	-	**96.3**	92.5	100.0	*2.8*	**99.4**	97.8	100.0	*0.8*	-	0> ; 6= ; 0<
			Leaf 3	7	***6.5***	*4.7*	*9.3*	-	-	-	-	**87.2**	55.5	100.0	*13.5*	**92.7**	68.1	100.0	*10.2*	-	2> ; 5= ; 0<
		Border countries of Poland (Germany)	Leaf 1	2	***19.2***	*14.1*	*24.3*	-	-	-	-	**55.7**	18.8	92.7	*36.9*	**62.5**	28.4	96.7	*34.1*	-	0> ; 2= ; 0<
			Leaf 2	2	***37.4***	*8.4*	*66.5*	-	-	-	-	**58.9**	19.4	98.3	*39.4*	**64.1**	29.0	99.2	*35.1*	-	0> ; 2= ; 0<
			Leaf 3	1	***76.8***	-	-	-	-	-	-	**98.9**	-	-	-	**99.1**	-	-	-	-	0> ; 1= ; 0<
		All EPPO climatic zones	Leaf 1	5	***11.0***	*4.5*	*24.3*	-	-	-	-	**79.7**	18.8	100.0	*30.6*	**84.6**	28.4	100.0	*28.1*	-	1> ; 4= ; 0<
			Leaf 2	8	***14.4***	*4.6*	*66.5*	-	-	-	-	**86.9**	19.4	100.0	*25.6*	**90.6**	29.0	100.0	*23.3*	-	0> ; 8= ; 0<
			Leaf 3	8	***15.3***	*4.7*	*76.8*	-	-	-	-	**88.7**	55.5	100.0	*13.2*	**93.5**	68.1	100.0	*9.8*	-	2> ; 6= ; 0<
	Last valid assessment after the 2nd application	Northeast	Leaf 1	1	***5.1***	-	-	**92.5**	-	-	-	**100.0**	-	-	-	**96.1**	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<
				5	***5.9***	*5.1*	*7.4*	-	-	-	-	**92.4**	86.7	100.0	*4.4*	**96.0**	92.3	97.3	*1.9*	-	0> ; 5= ; 0<
			Leaf 2	1	***8.9***	-	-	**100.0**	-	-	-	**100.0**	-	-	-	**99.6**	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<
				9	***7.4***	*4.6*	*9.8*	-	-	-	-	**84.6**	46.1	100.0	*15.7*	**90.2**	57.4	100.0	*12.5*	-	2> ; 7= ; 0<
			Leaf 3	7	***7.3***	*4.7*	*9.6*	-	-	-	-	**86.2**	55.5	100.0	*13.3*	**91.4**	68.1	100.0	*10.1*	-	2> ; 5= ; 0<
		Border countries of Poland (Germany)	Leaf 1	3	***26.8***	*6.2*	*56.3*	-	-	-	-	**64.3**	18.2	94.0	*33.0*	**71.3**	27.6	96.8	*31.0*	-	1> ; 2= ; 0<
			Leaf 2	3	***28.4***	*6.4*	*66.5*	-	-	-	-	**58.2**	16.3	98.3	*33.5*	**67.3**	25.1	99.2	*31.1*	-	0> ; 3= ; 0<
			Leaf 3	2	***48.5***	*20.1*	*76.8*	-	-	-	-	**65.4**	31.9	98.9	*33.5*	**75.5**	51.8	99.1	*23.6*	-	0> ; 2= ; 0<
		All EPPO climatic zones	Leaf 1	8	***13.7***	*5.1*	*56.3*	-	-	-	-	**81.8**	18.2	100.0	*24.6*	**86.7**	27.6	97.3	*22.5*	-	1> ; 7= ; 0<
			Leaf 2	12	***12.6***	*4.6*	*66.5*	-	-	-	-	**78.0**	16.3	100.0	*24.5*	**84.5**	25.1	100.0	*21.4*	-	2> ; 10= ; 0<
			Leaf 3	9	***16.5***	*4.7*	*76.8*	-	-	-	-	**81.6**	31.9	100.0	*21.5*	**87.9**	51.8	100.0	*15.7*	-	2> ; 7= ; 0<

(1) Comparison based on statistics carried out in each trial report.

* only 3 trials in the entire dossier assess PUCCSI on TRZAW. Otherwise it is always PUCCST

The results are summarized by EPPO climatic zone in each summary table by disease. Only results for all valid efficacy trials (all EPPO climatic zones presented Table 3.2-17) are discussed hereafter to justify the minimum effective dose of FHO04 against ~~PUCCSI~~ PUCCST.

Across 13 efficacy trials, FHO04, applied at the proposed label rate of 4.0 L/ha, was compared to FHO04 at 2.0 L/ha (50% of maximum recommended dose) and 3.0 L/ha (75% of maximum recommended dose).

Across 10 efficacy trials carried out in winter wheat in the Northeast EPPO climatic zone and Polish border countries, 2-3 weeks after the second application, FHO04 at 4.0 L/ha delivered 85% on Leaf 1 (in 5 trials), 89% on Leaf 2 (in 7 trials) and 93% on Leaf 3 (in 6 trials), when FHO04 at 3.0 L/ha provided 80% on Leaf 1, 86% on Leaf 2 and 89% on Leaf 3. FHO04 at 4.0 L/ha was significantly superior to FHO04 at 3.0 L/ha in 1 out of 5 trials on Leaf 1, and 1 out of 6 trials on Leaf 3.

For information, in 1 trial, FHO04 at 4.0 L/ha delivered 100% on Leaf 2, when FHO04 at 2.0 L/ha also provided 100% on Leaf 2. In this trial, FHO04 at 3.0 L/ha also provided 100% Leaf 2.

At the last valid assessment after the second application, FHO04 at 4.0 L/ha delivered 86% on Leaf 1 (in 7 trials), 84% on Leaf 2 (in 9 trials) and 92% on Leaf 3 (in 6 trials), when FHO04 at 3.0 L/ha provided 81% on Leaf 1, 79% on Leaf 2 and 88% on Leaf 3. FHO04 at 4.0 L/ha was significantly superior to FHO04 at 3.0 L/ha in 1 out of 7 trials on Leaf 1, 2 out of 9 trials on Leaf 2 and 1 out of 6 trials on Leaf 3.

For information, in 1 trial, FHO04 at 4.0 L/ha delivered 96% on Leaf 1, and 100% on Leaf 2, when FHO04 at 2.0 L/ha provided 93% on Leaf 1, and 100% on Leaf 2. In this trial, FHO04 at 3.0 L/ha provided 100% on Leaf 1 and Leaf 2.

Across 3 efficacy trials carried out in winter triticale in the Northeast EPPO climatic zone and Polish border countries, 2-3 weeks after the second application, FHO04 at 4.0 L/ha delivered 95% on Leaf 2 (in 2 trials) and 94% on Leaf 3 (in 1 trial), when FHO04 at 3.0 L/ha provided 88% on Leaf 2 and 89% on Leaf 3. FHO04 at 4.0 L/ha was significantly superior to FHO04 at 3.0 L/ha in 1 out of 2 trials on Leaf 2.

At the last valid assessment after the second application, FHO04 at 4.0 L/ha delivered 92% on Leaf 1 (in 1 trial), 86% on Leaf 2 (in 3 trials) and 79% on Leaf 3 (in 3 trials), when FHO04 at 3.0 L/ha provided 87% on Leaf 1, 76% on Leaf 2 and 68% on Leaf 3. FHO04 at 4.0 L/ha was significantly superior to FHO04 at 3.0 L/ha in 1 out of 3 trials on Leaf 3.

Finally, across 13 efficacy trials in winter cereals, 2-3 weeks after the second application, FHO04 at 4.0 L/ha delivered 85% on Leaf 1 (in 5 trials), 91% on Leaf 2 (in 8 trials) and 94% on Leaf 3 (in 8 trials), when FHO04 at 3.0 L/ha provided 80% on Leaf 1, 87% on Leaf 2 and 89% on Leaf 3. FHO04 at 4.0 L/ha was significantly superior to FHO04 at 3.0 L/ha in 1 out of 5 trials on Leaf 1, and 2 out of 8 trials on Leaf 3.

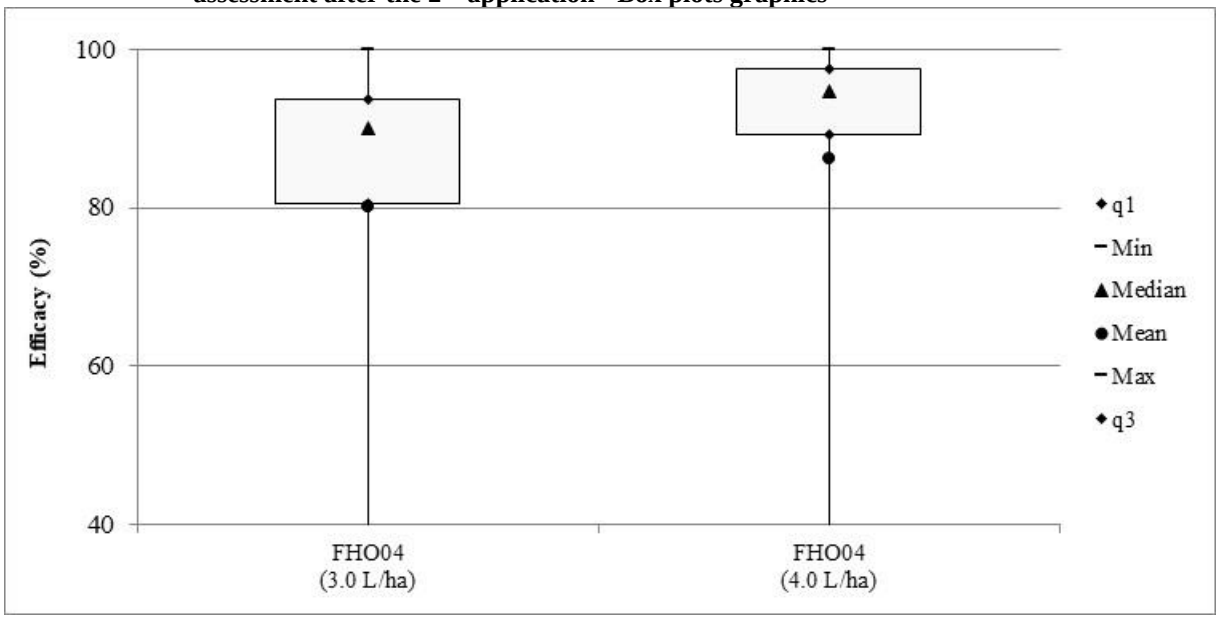
For information, in 1 trial, FHO04 at 4.0 L/ha delivered 100% on Leaf 2, when FHO04 at 2.0 L/ha also provided 100% on Leaf 2. In this trial, FHO04 at 3.0 L/ha also provided 100% Leaf 2.

At the last valid assessment after the second application, FHO04 at 4.0 L/ha delivered 87% on Leaf 1 (in 8 trials), 85% on Leaf 2 (in 12 trials) and 88% on Leaf 3 (in 9 trials), when FHO04 at 3.0 L/ha provided 82% on Leaf 1, 78% on Leaf 2 and 82% on Leaf 3. FHO04 at 4.0 L/ha was significantly superior to FHO04 at 3.0 L/ha in 1 out of 8 trials on Leaf 1, 2 out of 12 trials on Leaf 2 and 2 out of 9 trials on Leaf 3.

For information, in 1 trial, FHO04 at 4.0 L/ha delivered 96% on Leaf 1, and 100% on Leaf 2, when FHO04 at 2.0 L/ha provided 93% on Leaf 1, and 100% on Leaf 2. In this trial, FHO04 at 3.0 L/ha provided 100% on Leaf 1 and Leaf 2.

It can be considered that the choice of 4.0 L/ha as maximum recommended dose rate of FHO04 is justified against yellow rust of cereals (~~PUCCSI~~ PUCCST). Indeed, the dose effect is clearly illustrated by box plot graphics (Figure 3.2-7). According to the box plot graphics, the higher the dose of FHO04, the lower the dispersion and variation between means.

Figure 3.2-7 Minimum effective dose of FHO04 - Winter cereals - ~~PUCCSI~~ PUCCST - Last valid assessment after the 2nd application - Box plots graphics



(13 trials - 29 assessments)

The mean efficacy increases in function of the dose rate of FHO04. FHO04 at 4.0 L/ha reached a superior efficacy than the lower dose rates and good efficacy to control yellow rust of cereals (~~PUCCSI~~ PUCCST) confirming the selection of 4.0 L/ha as maximum registered dose.

Comments of zRMS:

Altogether 13 efficacy trials, 9 in the North Eastern zone and 4 in the Maritime zone, had tested minimum effective dose rate of FHO04 in control of PUCCST.
In rare cases the dose response was not observed at all; the 2.0 L/ha resulting in efficacy equivalent to that achieved by the target dose rate. It may suggest imprecise assessments, or imperfect plant coverage with the spray, on applications, which could be of minor importance for the DMI component but of major one – for the sulphur, thus compromising efficacy of the product as mixture. Overall, however, the summary presented allows to conclude that the target dose rate of 4.0 L/ha is also justified as MED in control of PUCCST. Since the data set includes 3 trials in winter triticale against 10 in winter soft wheat, the zRMS conclusion on the MED also refers to control of the yellow rust in this crop.

zRMS Abstract

3.2.2.5 Results of minimum effective dose tests to control disease complex of cereals

Finally, a total of **58 valid efficacy trials** were carried out to justify the minimum effective dose of FHO04. against SEPTTR (33 trials) , PUCCRE (22 trials) or ~~PUCCSI~~ PUCCST (10 trials) and PUCCSI (~~1~~3 trials) in winter wheat (87 trials), durum wheat (1 trial), winter triticale (6 trials) or winter rye (10 trials). Some trials contained more than one target disease, therefore the total number of trials for all diseases exceeds 58 valid trials. These trials were carried out **from 2020 to 2023** in the Northeast EPPO climatic zone (28 trials in Poland, 6 trials in Latvia and 4 trials in Lithuania) and Poland border countries (1 trial in Czech Republic, and 19 trials in Germany).
Table 3.2-18 summarises the minimum effective dose of FHO04 to control cereals disease complex from all valid efficacy trials provided in this dRR.

Table 3.2-18: Minimum effective dose of FHO04 - Winter cereals - All EPPO climatic zones - Last valid assessment after the 2nd application

Targets	Parameters	Parts	No. of trials	*Untreated*			Percentage of efficacy (%)											No. of assessments where FHO04 (4.0 L/ha) is significantly[(1)] >;=;< to FHO04	
							FHO04 2.0 L/ha				FHO04 3.0 L/ha				FHO04 4.0 L/ha					
							Prothioconazole + Sulphur													
							100+1250 g a.s./ha				150+1875 g a.s./ha				200+2500 g a.s./ha					
				Mean	*Min*	*Max*	**Mean**	Min	Max	*S.D.*	**Mean**	Min	Max	*S.D.*	**Mean**	Min	Max	*S.D.*	**2.0 L/ha**	**3.0 L/ha**
SEPTTR	Disease severity	Leaf 1	5	***16.4***	*5.0*	*37.8*	**52.3**	20.2	84.0	*23.1*	**72.4**	46.4	100.0	*18.8*	**77.2**	47.8	100.0	*17.1*	2> ; 3= ; 0<	1> ; 4= ; 0<
			16	***12.9***	*4.5*	*37.8*	-	-	-	-	**71.1**	5.2	100.0	*22.6*	**76.6**	24.8	100.0	*19.6*	-	5> ; 11= ; 0<
		Leaf 2	8	***10.3***	*5.0*	*19.3*	**71.9**	22.9	93.9	*21.2*	**78.0**	39.9	96.1	*17.5*	**84.9**	62.8	100.0	*12.4*	1> ; 7= ; 0<	0> ; 8= ; 0<
			26	***10.8***	*5.0*	*27.4*	-	-	-	-	**75.8**	10.6	98.6	*23.7*	**83.7**	19.8	100.0	*19.0*	-	6> ; 20= ; 0<
		Leaf 3	8	***12.6***	*6.2*	*24.8*	**54.5**	26.6	75.9	*15.0*	**67.8**	46.8	82.9	*12.9*	**74.9**	46.5	100.0	*18.4*	4> ; 4= ; 0<	1> ; 7= ; 0<
			24	***15.1***	*5.3*	*59.9*	-	-	-	-	**72.2**	3.9	94.2	*19.8*	**79.0**	12.7	100.0	*21.5*	-	7> ; 17= ; 0<
PUCCRE	Disease severity	Leaf 1	4	***16.4***	*7.9*	*29.4*	**50.1**	13.2	65.7	*21.4*	**65.9**	33.8	100.0	*23.5*	**76.4**	68.3	100.0	*13.6*	2> ; 2= ; 0<	1> ; 3= ; 0<
			21	***12.8***	*5.2*	*54.3*	-	-	-	-	**80.4**	2.9	100.0	*26.1*	**86.7**	6.5	100.0	*22.3*	-	4> ; 17= ; 0<
		Leaf 2	2	***10.4***	*4.7*	*16.0*	**49.3**	48.9	49.7	*0.4*	**54.8**	49.3	60.2	*5.5*	**58.1**	57.8	58.4	*0.3*	0> ; 2= ; 0<	0> ; 2= ; 0<
			19	***10.5***	*4.7*	*41.5*	-	-	-	-	**77.0**	5.6	97.5	*22.5*	**82.5**	13.5	100.0	*21.2*	-	7> ; 12= ; 0<
		Leaf 3	11	***7.5***	*5.9*	*9.9*	-	-	-	-	**89.0**	83.7	96.5	*3.8*	**93.1**	88.1	100.0	*3.3*	-	3> ; 8= ; 0<
PUCCST or PUCCSI	Disease severity	Leaf 1	1	***5.1***	-	-	**92.5**	-	-	-	**100.0**	-	-	-	**96.1**	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<
			8	***13.7***	*5.1*	*56.3*	-	-	-	-	**81.8**	18.2	100.0	*24.6*	**86.7**	27.6	97.3	*22.5*	-	1> ; 7= ; 0<
		Leaf 2	1	***8.9***	-	-	**100.0**	-	-	-	**100.0**	-	-	-	**99.6**	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<
			12	***12.6***	*4.6*	*66.5*	-	-	-	-	**78.0**	16.3	100.0	*24.5*	**84.5**	25.1	100.0	*21.4*	-	2> ; 10= ; 0<
		Leaf 3	9	***16.5***	*4.7*	*76.8*	-	-	-	-	**81.6**	31.9	100.0	*21.5*	**87.9**	51.8	100.0	*15.7*	-	2> ; 7= ; 0<

(1) Comparison based on statistics carried out in each trial report.

The results are summarized by EPPO climatic zone in each summary table by disease. Only results for all valid efficacy trials for the last valid assessment after the 2nd application and for all EPPO climatic zones, presented Table 3.2-18, are discussed hereafter to justify the minimum effective dose of FHO04 against cereals diseases.

Across 58 valid efficacy trials carried out in the Northeast EPPO climatic zone and border countries of Poland, FHO04, applied at the proposed label rate of 4.0 L/ha, was compared to FHO04 at 2.0 L/ha (50% of maximum recommended dose) and 3.0 L/ha (75% of maximum recommended dose).

Against SEPTTR, FHO04 applied at 4.0 L/ha delivered 77% on Leaf 1, 85% on Leaf 2 and 75% on Leaf 3 when FHO04 at 2.0 L/ha provided 52% on Leaf 1, 72% on Leaf 2 and 55% on Leaf 3. FHO04 at 4.0 L/ha was significantly superior to FHO04 at 2.0 L/ha in 2 out of 5 trials on Leaf 1, in 1 out of 8 trials on Leaf 2 and in 4 out of 8 trials on Leaf 3.

FHO04 applied at 4.0 L/ha delivered 77% on Leaf 1, 84% on Leaf 2 and 79% on Leaf 3 when FHO04 at 3.0 L/ha provided 72% on Leaf 1, 78% on Leaf 2 and 68% on Leaf 3. FHO04 at 4.0 L/ha was significantly superior to FHO04 at 3.0 L/ha in 5 out of 16 trials on Leaf 1, in 6 out of 26 trials on Leaf 2 and in 7 out of 24 trials on Leaf 3.

Against PUCCRE, FHO04 applied at 4.0 L/ha delivered 76% on Leaf 1, 58% on Leaf 2 when FHO04 at 2.0 L/ha provided 50% on Leaf 1, and 49% on Leaf 2. FHO04 at 4.0 L/ha was significantly superior to FHO04 at 2.0 L/ha in 2 out of 4 trials on Leaf 1.

FHO04 applied at 4.0 L/ha delivered 87% on Leaf 1, 83% on Leaf 2 and 93% on Leaf 3 when FHO04 at 3.0 L/ha provided 80% on Leaf 1, 77% on Leaf 2 and 89% on Leaf 3. FHO04 at 4.0 L/ha was significantly superior to FHO04 at 3.0 L/ha in 4 out of 21 trials on Leaf 1, in 7 out of 19 trials on Leaf 2 and in 3 out of 11 trials on Leaf 3.

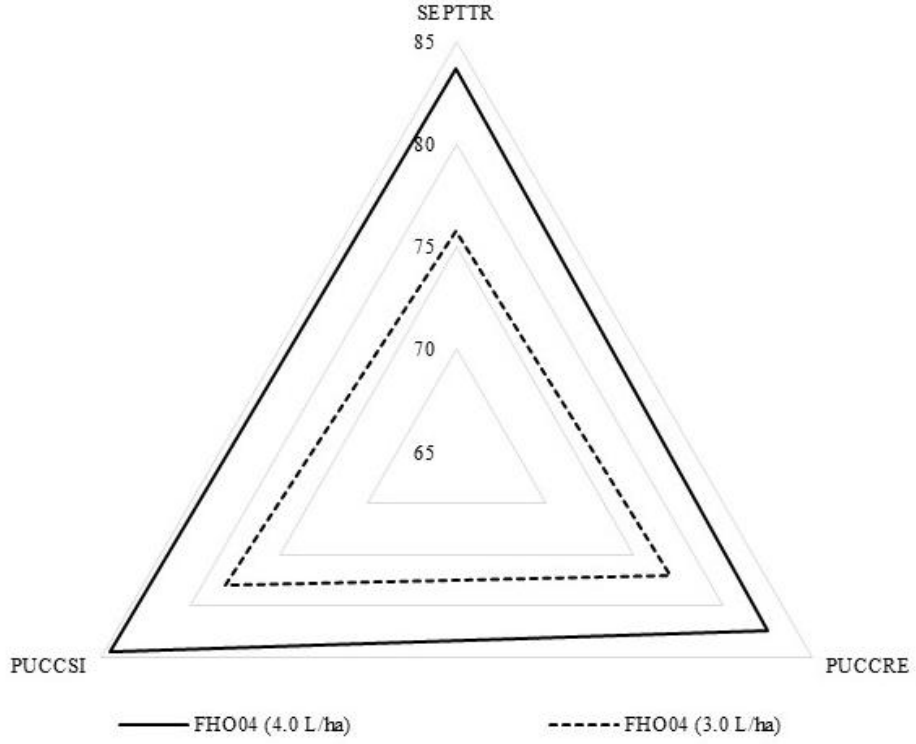
Against ~~PUCCSI~~ PUCCST, for information, in 1 trial, FHO04 applied at 4.0 L/ha delivered 96% on Leaf 1 and 100% on Leaf 2 when FHO04 at 2.0 L/ha provided 93% on Leaf 1 and 100% on Leaf 2.

FHO04 applied at 4.0 L/ha delivered 87% on Leaf 1, 85% on Leaf 2 and 88% on Leaf 3 when FHO04 at 3.0 L/ha provided 82% on Leaf 1, 78% on Leaf 2 and 82% on Leaf 3. FHO04 at 4.0 L/ha was significantly superior to FHO04 at 3.0 L/ha in 1 out of 8 trials on Leaf 1, in 2 out of 12 trials on Leaf 2 and in 2 out of 9 trials on Leaf 3.

It can be considered that the choice of 4.0 L/ha as maximum recommended dose rate of FHO04 is justified against the cereals diseases. The justification of the minimum effective dose of FHO04 against wheat disease complex can be illustrated by graphic from the last valid assessment after two applications (Figure 3.2-8). According to the efficacy results and as illustrated on the graphic hereafter, FHO04 at 4.0 L/ha is the best dose rate to control the requested diseases of cereals.

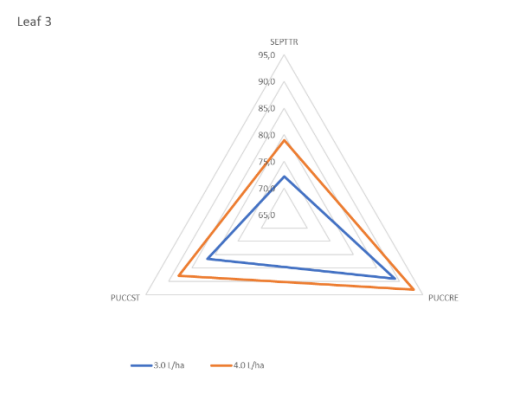
The mean efficacy increases in function of the dose rate of FHO04. FHO04 at 4.0 L/ha reached a superior efficacy than the lower rates and a good efficacy to control the disease complex on cereals confirming the selection of 4.0 L/ha as maximum registered dose.

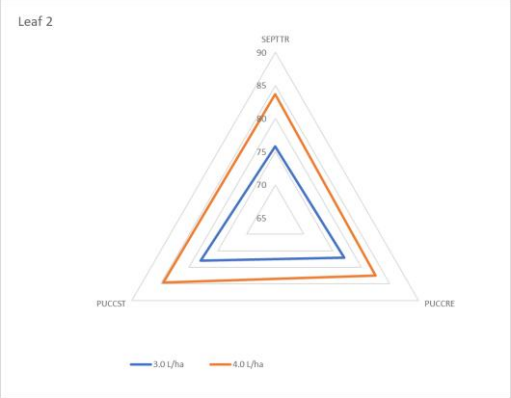
Figure 3.2-8 Minimum effective dose of FHO04 - Winter cereals - Disease complex (efficacy against SEPTTR, PUCCRE, ~~PUCCSI~~ PUCCST on Leaf 2) after two applications

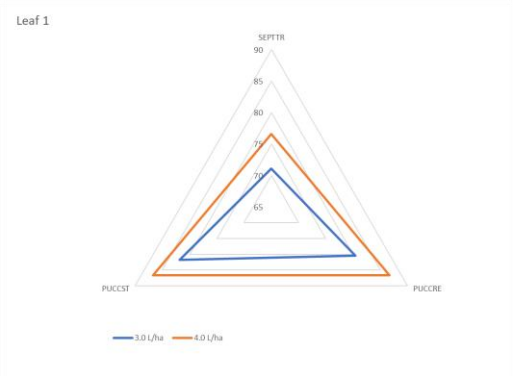


Comments of zRMS:

A quick glance at the other leaf strata, along with the leaf 2 as presented by the applicant, allows for the conclusion that FHO04 is predominantly acting on rust pathogens while its activity against SEPTTR is visibly lower, as evident in the leaves no. 1 and 3. The figures below are based on means presented by the applicant in the Table 3.2-18.
One may certainly argue that such conclusions are not in place in the MED chapter, the one frequently treated as formality to be dismissed as quickly as possible both by the applicant and the evaluators. However, such attitude would be incorrect with any new product, be it even just mixture of known actives. Moreover, the present MED chapter is based on the same 58 trials that also make foundation of Efficacy Tests chapter, and in this very sense it is crucial and most informing part of the whole efficacy section of the dossier.







To the opinion of zRMS, it is the PUCCRE data along with those of PUCCST which make the most coherent part of the data set, while the efficacy against SEPTTR is more dependent on leaf stratum assessed. Nevertheless, taken that pathogens occur in complex, and except for 2 data points with PUCCST on wheat (Table 3.2-17 and later reported in summary table 3.2-18), none of the presented data can reasonably support the view that the dose rate of 3.0 L/ha might be considered as MED. The dose rate **of 4.0 L/ha** of the FHO04 has been instead considered as the minimum effective dose in control of complex of pathogens **in winter wheat and winter rye**.
The conclusion on winter triticale must be based on further analysis of the remaining data from other trials, since trials included for MED analysis deliver limited information on SEPTTR and PUCCRE and consequently, speaking of control of the "pathogen complex" is irrelevant at this stage. Since durum wheat is minor crop in Poland and is claimed by the applicant following Art. 51, then discussing the nearly non–existing efficacy and MED of the test item in this crop (based on a single valid trial) is considered pointless.

zRMS Abstract

3.2.3 Efficacy tests (KCP 6.2)

A total of **28 efficacy trials** were carried out **from 2020 to 2023** in Poland to confirm the efficacy of FHO04 applied at 4.0 L/ha to control leaf diseases.
In addition, **25 efficacy trials** carried out in countries belonging to the Northeast EPPO climatic zone, but in the Northern registration zone are also provided to complete the data package. These trials were carried out **from 2020 to 2023** in Latvia (9 trials) and Lithuania (16 trials).
Moreover, **30 efficacy trials** carried out in border countries of Poland (1 trial in Czech Republic and 29 trials in Germany) in the Maritime EPPO climatic zone in the Central registration zone are also provided as supportive data.
24 out of 83 trials are not taken into account in the efficacy analysis below due to a low pest pressure conditions or an abnormal level of efficacy of the reference standards. Thus, these trials are excluded from the analysis of efficacy. However, the potential crop phytotoxicity symptoms observed in these trials are analysed in Section 3.4.
Finally, a total of **59 valid efficacy trials** carried out in winter wheat (42 trials), winter durum wheat (1 trial), winter triticale (6 trials) or winter rye (10 trials) were available to confirm the efficacy of FHO04 applied at 4.0 L/ha for the control of *Zymoseptoria tritici* (SEPTTR - 34 trials), *Puccinia recondita* (PUCCRE - 22 trials) and/or *Puccinia striiformis* (~~PUCCSI~~ PUCCST (10 trials) and PUCCSI (~~1~~3 trials)). These trials were carried out **from 2020 to 2023** in the Northeast EPPO climatic zone (28 trials in Poland, 6 trials in Latvia and 4 trials in Lithuania) and Poland border countries (1 trial in Czech Republic and 20 trials in Germany) in winter cereals. Some trials contained more than one target disease, therefore the total number of trials for all diseases exceeds 59 valid trials.

3.2.3.1 Material and Methods

Experimental details

All the trials were carried out by officially recognised organisations in accordance with the Principles of Good Experimental Practice (GEP). These trials were performed following EPPO guidelines or trial method recommendations published by the French CEB ("Commission des Essais Biologiques"). The "CEB" methods are in accordance with EPPO directives.
Main characteristics are summarised in Table 3.2-19.

Table 3.2-19: Details on trial methodology - Efficacy trials - Cereals

Guidelines	General guidelines	PP1/135 (4): Phytotoxicity assessment PP1/152 (4): Design and analysis of efficacy evaluation trials PP1/181 (4): Conduct and reporting of efficacy evaluation trials including good experimental practice
	Specific guidelines	PP 1/26(4): "Foliar and ear diseases on cereals"
Experimental design	Plot design	Randomized Complete Block (RCB)
	Plot size	From 15 m² to 39 m².
	Number of replications	4 replications
Crop	Number of trials	Interest of the association: 28 trials (25 trials in wheat, 1 trial in durum wheat, 2 trials in triticale) Minimum effective dose trials: 58 trials (41 trials in wheat, 1 trial in durum wheat, 6 trials in triticale, 10 trials in rye) Valid efficacy trials: 59 trials (42 trials in wheat, 1 trial in durum wheat, 6 trials in triticale, 10 trials in rye) Not valid efficacy trials only used for phytotoxicity assessment: 24 trials (17 trials in wheat, 1 trial in durum wheat, 4 trials in triticale, 2 trials in rye)
	Varieties	Winter wheat: *Apostel (2), Arkadia (2), Arktis (1), Artist (2), Belissa (2), Benchmark(2, Boregar (1), Bosporus (1), Bussard (1), Comandor (1), Dagmar (1), Dakotana (1), Edvins (3), Euforia (1), Flippen (1), Fredis (2), Genius (1), Informer (1), Inspiration (1), Janne (1), JB Asano (1), Joker (1), KWS Donovan (2), Medalistka (1), Ohio (1), Olivin (1), Opal (1), Opoka (1), Ostroga (1), Patras (4), Ponticus (1), RGT Bilanz (1), RGT Reform (3), Skagen (11), Tytanika (1).* Durum wheat: *Wintergold (2).* Winter triticale: *Grenado (1), Lombardo (6), Rotondo (1), SU Agendus (1), Trismart (1).* Winter rye*: Dańkowksie Granat (1), Dukat (1), Identor (1), Initiator (1), KWS Dolaro (1), KWS Igor (1), KWS Serafino (1), KWS Tayo (2), KWS Trebiano (1), Piano (1), Stannos (1).*
Target	Natural/artificial contamination	Natural
Application	Application timing	1st application BBCH 30-39 - 2nd applications BBCH 36-69 ~~37-65~~
	Number of applications	2 applications (82 trials) – From 8 to 56 day-interval 1 application (1 trial)
	Spray volumes	200-300 L/ha.
Assessment	Assessment dates	7-14-day intervals after each application
	Assessment types	Disease severity on leaves, Green leaf area (59 trials) Yield (33 trials in wheat, 1 trial in durum wheat, 5 trials in triticale, 10 trials in rye) Quality parameters: Moist content (33 trials in wheat, 1 trial in durum wheat, 5 trials in triticale, 10 trials in rye). Thousand grain weight (32 trials in wheat, 5 trials in triticale, 10 trials in rye). Specific weight (32 trials in wheat, 1 trial in durum wheat, 5 trials in triticale, 10 trials in rye).
Results & Analysis	Statistical analysis	ANOVA - Newman - Keuls test (5%)

Treatments and reference standards

FHO04 was tested at 2.0 L/ha, 3.0 L/ha and 4.0 L/ha and compared with different reference standards used in efficacy trials presented in Table 3.2-20.

Table 3.2-20: Presentation of reference standards used in trials - Efficacy trials - Cereals

Reference standard	Active substance(s)	Formulation		Application rate in trials (per treatment)	Rate of active substance per ha
		Type	Concentration of a.s.		
FHO04	**Prothioconazole** **Sulphur**	SC	50 g/L 625 g/L	2.0 L/ha 3.0 L/ha 4.0 L/ha	100+1250 g a.s./ha 150+1875 g a.s./ha 200+2500 g a.s./ha
Microthiol	**Sulphur**	EC	825 g/L	3.0 L/ha	2475 g a.s./ha
Proline	**Prothioconazole**	EC	250 g/L	0.8 L/ha	200 g a.s./ha
Protendo 300 EC	**Prothioconazole**	EC	300 g/L	0.65 L/ha	195 g a.s./ha
Prosaro	Tebuconazole **Prothioconazole**	EC	125 g/L 125 g/L	1.0 L/ha	125+125 g a.s./ha
Blizzard Xtra	Cyproconazole + Azoxystrobin	SC	80 g/L 200 g/L	1.0 L/ha	200+80 g a.s./ha
Makler 250 SE	Azoxystrobin	SE	250 g/L	1.0 L/ha	250 g a.s./ha
Adexar	Epoxiconazole Fluxapyroxad	SE	62.5 g/L 62.5 g/L	1.0 L/ha	62.5+62.5 g a.s./ha
Opera N	Epoxiconazole Pyraclostrobin	SE	62.5 g/L 85 g/L	1.0 L/ha	62.5+85.0 g a.s./ha

Assessment methods

In accordance with the CEB and EPPO guidelines, the symptoms were assessed in general on 25 leaves (at least on 15 leaves) by leaf level as percentage of area affected by diseases, from appearance of the first symptoms in the untreated (disease severity expressed in percentage) and at 7-14-day intervals. The efficacy is calculated from the disease severity data, according to ABBOTT formula.

$$Efficacy\ (\%) = \frac{(Disease\ severity_{Untreated\ control}) - (Disease\ severity_{Treatment})}{(Disease\ severity_{Untreated\ control})} \times 100$$

The potential effect on the green leaf area was also analysed in some efficacy trials. This assessment was expressed in Increase (%) of the green leaf area (corresponding to the reduction of the necrosis leaf area) compared to the untreated plot.

$$GLA\ Increasing\ (\%) = \frac{(100 - GLA_{Untreated\ control}) - (100 - GLA_{Treatment})}{(100 - GLA_{Untreated\ control})} \times 100$$

GLA = Percentage of green area on the leaves

Moreover, the potential effects on the yield and the yield parameters (thousand grain weight and/or specific weight) were also analysed in some efficacy trials. This assessment was expressed in percentage of the value in untreated plot.

$$Percentage\ of\ Untreated\ control\ (\%) = \frac{(Y_{Treatment})}{(Y_{Untreated\ control})} \times 100$$

Y: Yield or yield parameters

The yield results are considered as part of the assessment of the product's effectiveness when the target disease is observed. The results are reported in Section 0.

Phytotoxicity assessments

In efficacy trials, phytotoxicity was also assessed. Phytotoxicity assessments were carried out in accordance with EPPO guideline PP1/135 ("*Phytotoxicity assessment*"). Assessments were carried out at various intervals post application by recording visual percentage injury (0% = no injury, 100% = complete expression of injury symptom). Crop safety results are presented in Section 3.4.

Statistical analyses

Observed or calculated variables are subjected to an analysis of variance (ANOVA). When the result of the analysis is significant, a multiple comparison of treatments is performed. The averages are classified using the Newman and Keuls tests and divided into homogeneous groups (a, b, c, …). Treatment means

with no letter in common are significantly different in accordance with the test conducted at a 95% confidence level.

Results layout

The tabulated data presented in this section only represent the means of efficacies of selected treatments, without raw data. However, the statistics presented in conjunction with these data are derived from all data points from all treatments within the assessment. Tables of data comprising all treatments means are presented in the individual trial report summaries.
Only the trials and assessments with a sufficient infestation level in the untreated plot (thresholds of 5% coverage of foliar or ears area by the disease) and where the level of efficacy of the reference standards were as expected are considered in this synthesis. In practice, assessments from 4.5% were selected in the available data package notably to be able to select same number of assessments per trial.
According to PP 1/181, disease severity should be as high as possible. Therefore, assessments are presented after the second application. To group the trials, data are classified per plant levels (Flag leaf (Leaf 1), Flag leaf minus 1 (Leaf 2), Flag leaf minus 2 (Leaf 3).
2 different assessment timings have been considered: 2-3 weeks after the 2nd application and finally to have a large data package, the last valid assessment after the 2nd application.
The last observation is considered as valid when the standard efficacy was as expected and normal and when the infestation level was not very high. Indeed, near 100% attacked area, it is difficult to distinguish the diseases and the leaf senescence.
On foliar disease, only last leaves (Flag leaf and flag leaf minus 1) are considered in this synthesis. Indeed, these leaves contribute the most to the yield.
About the assessment of the increasing of green leaf area, only the trials where an effect is observed in the reference standards are considered in this synthesis. In practice, assessments from 10% of increasing of GLA for the reference standard Proline at 0.8 L/ha were selected.
According to the EPPO guideline PP1/257, about fungicides, an extrapolation can be considered as valid if:

- The crop, botanical family, cropping system, growth pattern can be considered as comparable. All cereals (winter and spring wheat, durum wheat, spelt, triticale and winter and spring rye) can be considered as comparable crops.
- The taxonomic relationship, biology, life cycle, behaviour, plant parts attacked, damage caused by diseases can be considered as comparable. Leaf spot, *Zymoseptoria tritici* (SEPTTR), brown rust, *Puccinia recondita* (PUCCRE) or yellow rust, *Puccinia striiformis* (PUCCST ~~PUCCSI~~) can be considered as comparable whatever the cereal crops.
- The growing conditions (field or protected) and cultivation techniques, growing systems, soil type can be considered as comparable. All cereals (winter and spring wheat, durum wheat, spelt, triticale and winter and spring rye) can be considered as agronomic comparable.

All data against *Zymoseptoria tritici* (SEPTTR) in winter and spring wheat, durum wheat, spelt, and triticale can be considered as comparable and merged in efficacy section.
~~All data against *Puccinia striiformis* (PUCCSI) in winter and spring wheat, durum wheat, spelt, and triticale can be considered as comparable and merged in efficacy section.~~
All data against *Puccinia recondita* (PUCCRE) in winter and spring wheat, durum wheat, spelt, rye, and triticale can be considered as comparable and merged in efficacy section.
These extrapolations are confirmed by Dutch authorities document[3] and national Polish guidance[4].
Extrapolation between different cereal crop species, and winter and spring variants for the same or comparable disease species is also supported by the proposed new EPPO guideline for major use to major use extrapolations, which is expected to be published later this year (draft version is document number 23-28136). Nevertheless, the Applicant is planning to perform additional trials on spring cereals in 2025 to further demonstrate the comparable efficacy of FHO04 between winter and spring cereals; in the current absence of this data, the Applicant requests that it is set as a post-registration data requirement.

3.2.3.2 Efficacy trials results for the control of leaf spot (*Zymoseptoria tritici* - SEPTTR)

The intended label claim against leaf spot (*Zymoseptoria tritici* - SEPTTR) in wheat is for ~~maximum~~ 2 applications of FHO04 at dose rate of 4.0 L/ha at BBCH 27-69.
A total of **34 valid efficacy trials** carried out in winter wheat (31 trials), durum wheat (1 trial) or triticale (2 trials) were available to confirm the efficacy of FHO04 applied at 4.0 L/ha for the control of leaf spot (*Zymoseptoria tritici* – SEPTTR). These trials were carried out **from 2020 to 2023** in the Northeast EPPO climatic zone (12 trials in Poland, 5 trials in Latvia and 4 trials in Lithuania) and Poland border countries (13 trials in Germany) in winter cereals.
In accordance with EPPO guideline PP1/257, all data against Zymoseptoria tritici (SEPTTR) in winter and spring wheat, durum wheat, spelt, and triticale can be considered as comparable and merged in this section. However, an analysis by crop is also provided hereafter.
All observations are summarised in comparison to all, or to particular ~~according to the~~ reference standards: Table 3.2-21 (All reference standards), Table 3.2-22 (Proline), Table 3.2-23 (Amistar), Table 3.2-24 (Prosaro), Table 3.2-25 (Blizzard Xtra), Table 3.2-26 (Adexar), and Table 3.2-27 (Opera N).

Table 3.2-21: Efficacy of FHO04 (4.0 L/ha) - Winter cereals - SEPTTR - Disease severity on leaves - Comparison with all references standards

Parameters	Assessment date	EPPO climatic zone	Parts	No. of trials	*Untreated*			Percentage of efficacy (%)								No. of assessments where FHO04 (4.0 L/ha) is significantly[(1)] >;=;< to All reference standards
								FHO04 (4.0 L/ha)				All reference standards				
								Prothioconazole + Sulphur				-				
								200+2500 g a.s./ha				-				
					Mean	*Min*	*Max*	**Mean**	Min	Max	*S.D.*	**Mean**	Min	Max	*S.D.*	
Disease severity on winter wheat	2-3 weeks after the second application	Northeast	Leaf 1	3	***5.1***	*5.1*	*5.3*	**91.5**	87.2	94.6	*3.1*	**93.3**	91.0	95.2	*1.7*	0> ; 3= ; 0<
			Leaf 2	9	***6.7***	*5.0*	*9.7*	**89.2**	68.5	97.9	*8.0*	**92.7**	86.8	97.3	*3.3*	0> ; 8= ; 1<
			Leaf 3	14	***8.4***	*5.3*	*17.6*	**82.9**	46.5	95.9	*14.0*	**84.8**	55.4	97.6	*12.0*	0> ; 13= ; 1<
		Border countries of Poland (Germany)	Leaf 1	1	***5.9***	-	-	**100.0**	-	-	-	**100.0**	-	-	-	0> ; 1= ; 0<
			Leaf 2	4	***9.4***	*6.7*	*14.8*	**84.7**	62.8	100.0	*13.8*	**76.4**	43.9	100.0	*20.6*	0> ; 4= ; 0<
			Leaf 3	6	***21.6***	*5.0*	*67.1*	**73.7**	41.9	100.0	*22.4*	**61.4**	31.0	100.0	*28.0*	1> ; 5= ; 0<
		All EPPO climatic zones	Leaf 1	4	***5.3***	*5.1*	*5.9*	**93.6**	87.2	100.0	*4.6*	**95.0**	91.0	100.0	*3.3*	0> ; 4= ; 0<
			Leaf 2	13	***7.6***	*5.0*	*14.8*	**87.8**	62.8	100.0	*10.3*	**87.7**	43.9	100.0	*14.0*	0> ; 12= ; 1<
			Leaf 3	20	***12.3***	*5.0*	*67.1*	**80.1**	41.9	100.0	*17.5*	**77.8**	31.0	100.0	*21.2*	1> ; 18= ; 1<
	Last valid assessment after the 2nd application	Northeast	Leaf 1	11	***12.4***	*4.5*	*37.8*	**75.6**	47.8	94.6	*14.7*	**80.8**	56.1	95.2	*14.2*	0> ; 10= ; 1<
			Leaf 2	16	***9.6***	*5.0*	*27.4*	**85.5**	57.4	97.9	*11.6*	**86.9**	62.8	96.9	*9.8*	0> ; 15= ; 1<
			Leaf 3	14	***8.4***	*5.3*	*17.6*	**82.9**	46.5	95.9	*14.0*	**84.4**	55.4	97.6	*11.7*	0> ; 13= ; 1<
		Border countries of Poland (Germany)	Leaf 1	4	***13.0***	*5.4*	*21.3*	**92.2**	83.9	100.0	*5.8*	**73.9**	47.1	100.0	*21.0*	1> ; 3= ; 0<
			Leaf 2	9	***12.0***	*5.2*	*20.9*	**85.8**	47.3	100.0	*17.7*	**71.7**	25.8	100.0	*27.5*	1> ; 8= ; 0<
			Leaf 3	8	***31.8***	*8.0*	*67.1*	**76.1**	41.9	100.0	*20.5*	**56.9**	19.7	100.0	*28.2*	2> ; 6= ; 0<
		All EPPO climatic zones	Leaf 1	15	***12.6***	*4.5*	*37.8*	**80.0**	47.8	100.0	*14.9*	**79.0**	47.1	100.0	*16.6*	1> ; 13= ; 1<
			Leaf 2	25	***10.5***	*5.0*	*27.4*	**85.6**	47.3	100.0	*14.1*	**81.4**	25.8	100.0	*19.7*	1> ; 23= ; 1<
			Leaf 3	22	***16.9***	*5.3*	*67.1*	**80.4**	41.9	100.0	*17.0*	**74.4**	19.7	100.0	*23.4*	2> ; 19= ; 1<
Disease severity on winter triticale	2-3 weeks after the second application	Northeast	Leaf 3	1	***7.3***	-	-	**89.1**	-	-	-	**90.2**	-	-	-	0> ; 1= ; 0<
	Last valid assessment after the 2nd application	Northeast	Leaf 3	1	***7.3***	-	-	**89.1**	-	-	-	**90.2**	-	-	-	0> ; 1= ; 0<
		Border countries of Poland (Germany)	Leaf 2	1	***11.9***	-	-	**100.0**	-	-	-	**99.6**	-	-	-	0> ; 1= ; 0<
			Leaf 3	1	***16.0***	-	-	**96.2**	-	-	-	**97.4**	-	-	-	0> ; 1= ; 0<
		All EPPO climatic zones	Leaf 2	1	***11.9***	-	-	**100.0**	-	-	-	**99.6**	-	-	-	0> ; 1= ; 0<
			Leaf 3	2	***11.6***	*7.3*	*16.0*	**92.7**	89.1	96.2	*3.6*	**93.8**	90.2	97.4	*3.6*	0> ; 2= ; 0<
Disease severity on winter durum wheat	2-3 weeks after the second application	Border countries of Poland (Germany) ~~Northeast~~	Leaf 1	1	***8.4***	-	-	**33.3**	-	-	-	**88.7**	-	-	-	0> ; 0= ; 1<
			Leaf 2	1	***12.1***	-	-	**21.6**	-	-	-	**71.5**	-	-	-	0> ; 0= ; 1<
			Leaf 3	1	***18.5***	-	-	**14.8**	-	-	-	**39.3**	-	-	-	0> ; 1= ; 0<
	Last valid assessment after the 2nd application		Leaf 1	1	***17.7***	-	-	**24.8**	-	-	-	**64.5**	-	-	-	0> ; 0= ; 1<
			Leaf 2	1	***21.7***	-	-	**19.8**	-	-	-	**65.3**	-	-	-	0> ; 0= ; 1<
			Leaf 3	1	***33.4***	-	-	**12.7**	-	-	-	**33.8**	-	-	-	0> ; 1= ; 0<

Parameters	Assessment date	EPPO climatic zone	Parts	No. of trials	*Untreated*			Percentage of efficacy (%)								No. of assessments where FHO04 (4.0 L/ha) is significantly[(1)] >;=;< to All reference standards
								FHO04 (4.0 L/ha)				All reference standards				
								Prothioconazole + Sulphur				-				
								200+2500 g a.s./ha				-				
					Mean	*Min*	*Max*	**Mean**	Min	Max	*S.D.*	**Mean**	Min	Max	*S.D.*	
Disease severity on winter cereals	2-3 weeks after the second application	Northeast	Leaf 1	3	***5.1***	*5.1*	*5.3*	**91.5**	87.2	94.6	*3.1*	**93.3**	91.0	95.2	*1.7*	0> ; 3= ; 0<
			Leaf 2	9	***6.7***	*5.0*	*9.7*	**89.2**	68.5	97.9	*8.0*	**92.7**	86.8	97.3	*3.3*	0> ; 8= ; 1<
			Leaf 3	15	***8.3***	*5.3*	*17.6*	**83.3**	46.5	95.9	*13.6*	**85.1**	55.4	97.6	*11.6*	0> ; 14= ; 1<
		Border countries of Poland (Germany)	Leaf 1	2	***7.2***	*5.9*	*8.4*	**66.6**	33.3	100.0	*33.4*	**94.4**	88.7	100.0	*5.7*	0> ; 1= ; 1<
			Leaf 2	5	***9.9***	*6.7*	*14.8*	**72.1**	21.6	100.0	*28.1*	**75.4**	43.9	100.0	*18.6*	0> ; 4= ; 1<
			Leaf 3	7	***21.2***	*5.0*	*67.1*	**65.3**	14.8	100.0	*29.2*	**58.3**	31.0	100.0	*27.0*	1> ; 6= ; 0<
		All EPPO climatic zones	Leaf 1	5	***6.0***	*5.1*	*8.4*	**81.5**	33.3	100.0	*24.5*	**93.7**	88.7	100.0	*3.9*	0> ; 4= ; 1<
			Leaf 2	14	***7.9***	*5.0*	*14.8*	**83.1**	21.6	100.0	*19.8*	**86.5**	43.9	100.0	*14.1*	0> ; 12= ; 2<
			Leaf 3	22	***12.4***	*5.0*	*67.1*	**77.6**	14.8	100.0	*21.6*	**76.6**	31.0	100.0	*21.9*	1> ; 20= ; 1<
	Last valid assessment after the 2nd application	Northeast	Leaf 1	11	***12.4***	*4.5*	*37.8*	**75.6**	47.8	94.6	*14.7*	**80.8**	56.1	95.2	*14.2*	0> ; 10= ; 1<
			Leaf 2	16	***9.6***	*5.0*	*27.4*	**85.5**	57.4	97.9	*11.6*	**86.9**	62.8	96.9	*9.8*	0> ; 15= ; 1<
			Leaf 3	15	***8.3***	*5.3*	*17.6*	**83.3**	46.5	95.9	*13.6*	**84.8**	55.4	97.6	*11.4*	0> ; 14= ; 1<
		Border countries of Poland (Germany)	Leaf 1	5	***14.0***	*5.4*	*21.3*	**78.7**	24.8	100.0	*27.4*	**72.0**	47.1	100.0	*19.1*	1> ; 3= ; 1<
			Leaf 2	11	***12.9***	*5.2*	*21.7*	**81.1**	19.8	100.0	*25.5*	**73.6**	25.8	100.0	*26.3*	1> ; 9= ; 1<
			Leaf 3	10	***30.4***	*8.0*	*67.1*	**71.7**	12.7	100.0	*27.6*	**58.7**	19.7	100.0	*29.1*	2> ; 8= ; 0<
		All EPPO climatic zones	Leaf 1	16	***12.9***	*4.5*	*37.8*	**76.6**	24.8	100.0	*19.6*	**78.1**	47.1	100.0	*16.4*	1> ; 13= ; 2<
			Leaf 2	27	***10.9***	*5.0*	*27.4*	**83.7**	19.8	100.0	*18.7*	**81.5**	25.8	100.0	*19.5*	1> ; 24= ; 2<
			Leaf 3	25	***17.2***	*5.3*	*67.1*	**78.7**	12.7	100.0	*21.1*	**74.3**	19.7	100.0	*24.1*	2> ; 22= ; 1<

(1) Comparison based on statistics carried out in each trial report.

Table 3.2-22: Efficacy of FHO04 (4.0 L/ha) - Winter cereals - SEPTTR - Disease severity on leaves - Comparison with Proline (0.8 L/ha) or Protendo 300 EC (0.65 L/ha)

Parameters	Assessment date	EPPO climatic zone	Parts	No. of trials	*Untreated*			Percentage of efficacy (%)								No. of assessments where FHO04 (4.0 L/ha) is significantly[(1)] >;=;< to Proline (0.8 L/ha) Protendo 300 EC (0.65 L/ha)
								FHO04 (4.0 L/ha) Prothioconazole + Sulphur 200+2500 g a.s./ha				Proline (0.8 L/ha) Protendo 300 EC (0.65 L/ha) Prothioconazole 195-200 g a.s./ha				
					Mean	*Min*	*Max*	**Mean**	Min	Max	*S.D.*	**Mean**	Min	Max	*S.D.*	
Disease severity on winter wheat	2-3 weeks after the second application	Northeast	Leaf 1	1	***5.3***	-	-	**87.2**	-	-	-	**91.0**	-	-	-	0> ; 1= ; 0<
			Leaf 2	5	***7.5***	*5.0*	*9.7*	**87.0**	68.5	97.9	*10.1*	**91.4**	86.8	96.3	*3.5*	0> ; 4= ; 1<
			Leaf 3	7	***8.5***	*5.3*	*17.6*	**77.6**	46.5	95.9	*17.8*	**83.1**	55.4	97.6	*15.4*	0> ; 6= ; 1<
		Border countries of Poland (Germany)	Leaf 1	1	***5.9***	-	-	**100.0**	-	-	-	**100.0**	-	-	-	0> ; 1= ; 0<
			Leaf 2	4	***9.4***	*6.7*	*14.8*	**84.7**	62.8	100.0	*13.8*	**76.4**	43.9	100.0	*20.6*	0> ; 4= ; 0<
			Leaf 3	5	***23.8***	*5.0*	*67.1*	**72.4**	41.9	100.0	*24.3*	**67.5**	37.1	100.0	*26.8*	0> ; 5= ; 0<
		All EPPO climatic zones	Leaf 1	2	***5.6***	*5.3*	*5.9*	**93.6**	87.2	100.0	*6.4*	**95.5**	91.0	100.0	*4.5*	0> ; 2= ; 0<
			Leaf 2	9	***8.3***	*5.0*	*14.8*	**86.0**	62.8	100.0	*11.9*	**84.7**	43.9	100.0	*15.9*	0> ; 8= ; 1<
			Leaf 3	12	***14.9***	*5.0*	*67.1*	**75.4**	41.9	100.0	*20.9*	**76.6**	37.1	100.0	*22.3*	0> ; 11= ; 1<
	Last valid assessment after the 2nd application	Northeast	Leaf 1	4	***7.2***	*4.5*	*13.4*	**76.5**	57.8	85.5	*11.3*	**82.6**	75.0	89.4	*6.0*	0> ; 3= ; 1<
			Leaf 2	10	***8.9***	*5.0*	*19.3*	**84.7**	57.4	97.9	*11.8*	**85.5**	62.8	96.9	*11.0*	0> ; 9= ; 1<
			Leaf 3	7	***8.5***	*5.3*	*17.6*	**77.6**	46.5	95.9	*17.8*	**83.1**	55.4	97.6	*15.4*	0> ; 6= ; 1<
		Border countries of Poland (Germany)	Leaf 1	2	***12.7***	*5.9*	*19.5*	**96.9**	93.8	100.0	*3.1*	**93.8**	87.7	100.0	*6.2*	0> ; 2= ; 0<
			Leaf 2	8	***12.9***	*6.7*	*20.9*	**84.0**	47.3	100.0	*18.0*	**77.4**	33.7	100.0	*23.6*	0> ; 8= ; 0<
			Leaf 3	6	***37.8***	*8.0*	*67.1*	**71.8**	41.9	100.0	*21.6*	**67.4**	34.0	100.0	*24.6*	0> ; 6= ; 0<
		All EPPO climatic zones	Leaf 1	6	***9.0***	*4.5*	*19.5*	**83.3**	57.8	100.0	*13.5*	**86.4**	75.0	100.0	*8.0*	0> ; 5= ; 1<
			Leaf 2	18	***10.7***	*5.0*	*20.9*	**84.4**	47.3	100.0	*14.9*	**81.9**	33.7	100.0	*18.2*	0> ; 17= ; 1<
			Leaf 3	13	***22.0***	*5.3*	*67.1*	**74.9**	41.9	100.0	*19.9*	**75.9**	34.0	100.0	*21.6*	0> ; 12= ; 1<
Disease severity on winter triticale	Last valid assessment after the 2nd application	Border countries of Poland (Germany)	Leaf 2	1	***11.9***	-	-	**100.0**	-	-	-	**99.6**	-	-	-	0> ; 1= ; 0<
			Leaf 3	1	***16.0***	-	-	**96.2**	-	-	-	**97.4**	-	-	-	0> ; 1= ; 0<
Disease severity on winter durum wheat	2-3 weeks after the second application	Border countries of Poland (Germany)	Leaf 1	1	***8.4***	-	-	**33.3**	-	-	-	**88.7**	-	-	-	0> ; 0= ; 1<
			Leaf 2	1	***12.1***	-	-	**21.6**	-	-	-	**71.5**	-	-	-	0> ; 0= ; 1<
			Leaf 3	1	***18.5***	-	-	**14.8**	-	-	-	**39.3**	-	-	-	0> ; 1= ; 0<
	Last valid assessment after the 2nd application	Northeast	Leaf 1	1	***17.7***	-	-	**24.8**	-	-	-	**64.5**	-	-	-	0> ; 0= ; 1<
			Leaf 2	1	***21.7***	-	-	**19.8**	-	-	-	**65.3**	-	-	-	0> ; 0= ; 1<
			Leaf 3	1	***33.4***	-	-	**12.7**	-	-	-	**33.8**	-	-	-	0> ; 1= ; 0<

Parameters	Assessment date	EPPO climatic zone	Parts	No. of trials	*Untreated*			Percentage of efficacy (%)								No. of assessments where FHO04 (4.0 L/ha) is significantly[1] >;=;< to Proline (0.8 L/ha) Protendo 300 EC (0.65 L/ha)
								FHO04 (4.0 L/ha)				Proline (0.8 L/ha) Protendo 300 EC (0.65 L/ha)				
								Prothioconazole + Sulphur				Prothioconazole				
								200+2500 g a.s./ha				195-200 g a.s./ha				
					Mean	*Min*	*Max*	**Mean**	Min	Max	*S.D.*	**Mean**	Min	Max	*S.D.*	
Disease severity on winter cereals	2-3 weeks after the second application	Northeast	Leaf 1	1	***5.3***	-	-	**87.2**	-	-	-	**91.0**	-	-	-	0> ; 1= ; 0<
			Leaf 2	5	***7.5***	*5.0*	*9.7*	**87.0**	68.5	97.9	*10.1*	**91.4**	86.8	96.3	*3.5*	0> ; 4= ; 1<
			Leaf 3	7	***8.5***	*5.3*	*17.6*	**77.6**	46.5	95.9	*17.8*	**83.1**	55.4	97.6	*15.4*	0> ; 6= ; 1<
		Border countries of Poland (Germany)	Leaf 1	2	***7.2***	*5.9*	*8.4*	**66.6**	33.3	100.0	*33.4*	**94.4**	88.7	100.0	*5.7*	0> ; 1= ; 1<
			Leaf 2	5	***9.9***	*6.7*	*14.8*	**72.1**	21.6	100.0	*28.1*	**75.4**	43.9	100.0	*18.6*	0> ; 4= ; 1<
			Leaf 3	6	***22.9***	*5.0*	*67.1*	**62.8**	14.8	100.0	*30.9*	**62.8**	37.1	100.0	*26.6*	0> ; 6= ; 0<
		All EPPO climatic zones	Leaf 1	3	***6.5***	*5.3*	*8.4*	**73.5**	33.3	100.0	*28.9*	**93.3**	88.7	100.0	*4.9*	0> ; 2= ; 1<
			Leaf 2	10	***8.7***	*5.0*	*14.8*	**79.5**	21.6	100.0	*22.4*	**83.4**	43.9	100.0	*15.6*	0> ; 8= ; 2<
			Leaf 3	13	***15.2***	*5.0*	*67.1*	**70.8**	14.8	100.0	*25.8*	**73.8**	37.1	100.0	*23.6*	0> ; 12= ; 1<
	Last valid assessment after the 2nd application	Northeast	Leaf 1	4	***7.2***	*4.5*	*13.4*	**76.5**	57.8	85.5	*11.3*	**82.6**	75.0	89.4	*6.0*	0> ; 3= ; 1<
			Leaf 2	10	***8.9***	*5.0*	*19.3*	**84.7**	57.4	97.9	*11.8*	**85.5**	62.8	96.9	*11.0*	0> ; 9= ; 1<
			Leaf 3	7	***8.5***	*5.3*	*17.6*	**77.6**	46.5	95.9	*17.8*	**83.1**	55.4	97.6	*15.4*	0> ; 6= ; 1<
		Border countries of Poland (Germany)	Leaf 1	3	***14.4***	*5.9*	*19.5*	**72.9**	24.8	100.0	*34.1*	**84.1**	64.5	100.0	*14.7*	0> ; 2= ; 1<
			Leaf 2	10	***13.7***	*6.7*	*21.7*	**79.2**	19.8	100.0	*26.0*	**78.4**	33.7	100.0	*22.6*	0> ; 9= ; 1<
			Leaf 3	8	***34.6***	*8.0*	*67.1*	**67.5**	12.7	100.0	*29.0*	**67.0**	33.8	100.0	*26.6*	0> ; 8= ; 0<
		All EPPO climatic zones	Leaf 1	7	***10.3***	*4.5*	*19.5*	**74.9**	24.8	100.0	*24.0*	**83.2**	64.5	100.0	*10.7*	0> ; 5= ; 2<
			Leaf 2	20	***11.3***	*5.0*	*21.7*	**81.9**	19.8	100.0	*20.4*	**82.0**	33.7	100.0	*18.1*	0> ; 18= ; 2<
			Leaf 3	15	***22.4***	*5.3*	*67.1*	**72.2**	12.7	100.0	*25.0*	**74.5**	33.8	100.0	*23.5*	0> ; 14= ; 1<

[1] Comparison based on statistics carried out in each trial report.

Table 3.2-23: Efficacy of FHO04 (4.0 L/ha) - Winter cereals - SEPTTR - Disease severity on leaves - Comparison with Makler 250 SE / Amistar (1.0 L/ha)

Parameters	Assessment date	EPPO climatic zone	Parts	No. of trials	*Untreated*			Percentage of efficacy (%)								No. of assessments where FHO04 (4.0 L/ha) is significantly[(1)] >;=;< to Makler 250 SE / Amistar (1.0 L/ha)
								FHO04 (4.0 L/ha)				Makler 250 SE / Amistar (1.0 L/ha)				
								Prothioconazole + Sulphur				Azoxystrobin				
								200+2500 g a.s./ha				250 g a.s./ha				
					Mean	*Min*	*Max*	**Mean**	Min	Max	*S.D.*	**Mean**	Min	Max	*S.D.*	
Disease severity on winter wheat	2-3 weeks after the second application	Northeast	Leaf 1	2	***5.1***	*5.1*	*5.1*	**93.6**	92.7	94.6	*1.0*	**94.4**	93.6	95.2	*0.8*	0> ; 2= ; 0<
			Leaf 2	3	***5.9***	*5.2*	*6.4*	**91.9**	91.1	93.4	*1.1*	**93.3**	92.0	95.0	*1.3*	0> ; 3= ; 0<
			Leaf 3	3	***7.5***	*6.4*	*8.1*	**89.5**	87.3	91.1	*1.6*	**90.2**	89.1	91.0	*0.8*	0> ; 3= ; 0<
		Border countries of Poland (Germany)	Leaf 3	1	***10.5***	-	-	**80.4**	-	-	-	**31.0**	-	-	-	1> ; 0= ; 0<
		All EPPO climatic zones	Leaf 1	2	***5.1***	*5.1*	*5.1*	**93.6**	92.7	94.6	*1.0*	**94.4**	93.6	95.2	*0.8*	0> ; 2= ; 0<
			Leaf 2	3	***5.9***	*5.2*	*6.4*	**91.9**	91.1	93.4	*1.1*	**93.3**	92.0	95.0	*1.3*	0> ; 3= ; 0<
			Leaf 3	4	***8.2***	*6.4*	*10.5*	**87.3**	80.4	91.1	*4.2*	**75.4**	31.0	91.0	*25.6*	1> ; 3= ; 0<
	Last valid assessment after the 2nd application	Northeast	Leaf 1	2	***5.1***	*5.1*	*5.1*	**93.6**	92.7	94.6	*1.0*	**94.4**	93.6	95.2	*0.8*	0> ; 2= ; 0<
			Leaf 2	3	***5.9***	*5.2*	*6.4*	**91.9**	91.1	93.4	*1.1*	**93.3**	92.0	95.0	*1.3*	0> ; 3= ; 0<
			Leaf 3	3	***7.5***	*6.4*	*8.1*	**89.5**	87.3	91.1	*1.6*	**90.2**	89.1	91.0	*0.8*	0> ; 3= ; 0<
		Border countries of Poland (Germany)	Leaf 1	2	***13.3***	*5.4*	*21.3*	**87.5**	83.9	91.0	*3.5*	**54.0**	47.1	60.9	*6.9*	1> ; 1= ; 0<
			Leaf 2	1	***5.2***	-	-	**100.0**	-	-	-	**25.8**	-	-	-	1> ; 0= ; 0<
			Leaf 3	2	***13.7***	*10.5*	*16.9*	**88.9**	80.4	97.3	*8.5*	**25.4**	19.7	31.0	*5.7*	2> ; 0= ; 0<
		All EPPO climatic zones	Leaf 1	4	***9.2***	*5.1*	*21.3*	**90.5**	83.9	94.6	*4.0*	**74.2**	47.1	95.2	*20.8*	1> ; 3= ; 0<
			Leaf 2	4	***5.8***	*5.2*	*6.4*	**94.0**	91.1	100.0	*3.6*	**76.4**	25.8	95.0	*29.2*	1> ; 3= ; 0<
			Leaf 3	5	***10.0***	*6.4*	*16.9*	**89.3**	80.4	97.3	*5.5*	**64.3**	19.7	91.0	*32.0*	2> ; 3= ; 0<
Disease severity on winter triticale	2-3 weeks after the second application	Northeast	Leaf 3	1	***7.3***	-	-	**89.1**	-	-	-	**90.2**	-	-	-	0> ; 1= ; 0<
	Last valid assessment after the 2nd application	Northeast	Leaf 3	1	***7.3***	-	-	**89.1**	-	-	-	**90.2**	-	-	-	0> ; 1= ; 0<

Parameters	Assessment date	EPPO climatic zone	Parts	No. of trials	*Untreated*			Percentage of efficacy (%)								No. of assessments where FHO04 (4.0 L/ha) is significantly[(1)] >;=;< to Makler 250 SE / Amistar (1.0 L/ha)
								FHO04 (4.0 L/ha)				Makler 250 SE / Amistar (1.0 L/ha)				
								Prothioconazole + Sulphur				Azoxystrobin				
								200+2500 g a.s./ha				250 g a.s./ha				
					Mean	*Min*	*Max*	**Mean**	Min	Max	*S.D.*	**Mean**	Min	Max	*S.D.*	
Disease severity on winter cereals	2-3 weeks after the second application	Northeast	Leaf 1	2	***5.1***	*5.1*	*5.1*	**93.6**	92.7	94.6	*1.0*	**94.4**	93.6	95.2	*0.8*	0> ; 2= ; 0<
			Leaf 2	3	***5.9***	*5.2*	*6.4*	**91.9**	91.1	93.4	*1.1*	**93.3**	92.0	95.0	*1.3*	0> ; 3= ; 0<
			Leaf 3	4	***7.4***	*6.4*	*8.1*	**89.4**	87.3	91.1	*1.4*	**90.2**	89.1	91.0	*0.7*	0> ; 4= ; 0<
		Border countries of Poland (Germany)	Leaf 3	1	***10.5***	-	-	**80.4**	-	-	-	**31.0**	-	-	-	1> ; 0= ; 0<
		All EPPO climatic zones	Leaf 1	2	***5.1***	*5.1*	*5.1*	**93.6**	92.7	94.6	*1.0*	**94.4**	93.6	95.2	*0.8*	0> ; 2= ; 0<
			Leaf 2	3	***5.9***	*5.2*	*6.4*	**91.9**	91.1	93.4	*1.1*	**93.3**	92.0	95.0	*1.3*	0> ; 3= ; 0<
			Leaf 3	5	***8.0***	*6.4*	*10.5*	**87.6**	80.4	91.1	*3.8*	**78.4**	31.0	91.0	*23.7*	1> ; 4= ; 0<
	Last valid assessment after the 2nd application	Northeast	Leaf 1	2	***5.1***	*5.1*	*5.1*	**93.6**	92.7	94.6	*1.0*	**94.4**	93.6	95.2	*0.8*	0> ; 2= ; 0<
			Leaf 2	3	***5.9***	*5.2*	*6.4*	**91.9**	91.1	93.4	*1.1*	**93.3**	92.0	95.0	*1.3*	0> ; 3= ; 0<
			Leaf 3	4	***7.4***	*6.4*	*8.1*	**89.4**	87.3	91.1	*1.4*	**90.2**	89.1	91.0	*0.7*	0> ; 4= ; 0<
		Border countries of Poland (Germany)	Leaf 1	2	***13.3***	*5.4*	*21.3*	**87.5**	83.9	91.0	*3.5*	**54.0**	47.1	60.9	*6.9*	1> ; 1= ; 0<
			Leaf 2	1	***5.2***	-	-	**100.0**	-	-	-	**25.8**	-	-	-	1> ; 0= ; 0<
			Leaf 3	2	***13.7***	*10.5*	*16.9*	**88.9**	80.4	97.3	*8.5*	**25.4**	19.7	31.0	*5.7*	2> ; 0= ; 0<
		All EPPO climatic zones	Leaf 1	4	***9.2***	*5.1*	*21.3*	**90.5**	83.9	94.6	*4.0*	**74.2**	47.1	95.2	*20.8*	1> ; 3= ; 0<
			Leaf 2	4	***5.8***	*5.2*	*6.4*	**94.0**	91.1	100.0	*3.6*	**76.4**	25.8	95.0	*29.2*	1> ; 3= ; 0<
			Leaf 3	6	***9.5***	*6.4*	*16.9*	**89.2**	80.4	97.3	*5.0*	**68.6**	19.7	91.0	*30.7*	2> ; 4= ; 0<

(1) Comparison based on statistics carried out in each trial report.

Table 3.2-24: Efficacy of FHO04 (4.0 L/ha) - Winter cereals - SEPTTR - Disease severity on leaves - Comparison with Prosaro (1.0 L/ha)

Parameters	Assessment date	EPPO climatic zone	Parts	No. of trials	*Untreated*			Percentage of efficacy (%)								No. of assessments where FHO04 (4.0 L/ha) is significantly[1] >;=;< to Prosaro (1.0 L/ha)
								FHO04 (4.0 L/ha)				Prosaro (1.0 L/ha)				
								Prothioconazole + Sulphur				Prothioconazole + Tebuconazole				
								200+2500 g a.s./ha				125+125 g a.s./ha				
					Mean	*Min*	*Max*	**Mean**	Min	Max	*S.D.*	**Mean**	Min	Max	*S.D.*	
Disease severity on winter wheat	2-3 weeks after the second application	Northeast	Leaf 3	3	***9.3***	*7.0*	*13.6*	**85.5**	79.4	90.7	*4.7*	**79.2**	77.9	80.8	*1.2*	0> ; 3= ; 0<
	Last valid assessment after the 2nd application	Northeast	Leaf 1	2	***28.9***	*20.0*	*37.8*	**61.7**	47.8	75.5	*13.9*	**62.8**	56.1	69.4	*6.7*	0> ; 2= ; 0<
			Leaf 3	3	***9.3***	*7.0*	*13.6*	**85.5**	79.4	90.7	*4.7*	**79.2**	77.9	80.8	*1.2*	0> ; 3= ; 0<

(1) Comparison based on statistics carried out in each trial report.

Table 3.2-25: Efficacy of FHO04 (4.0 L/ha) - Winter cereals - SEPTTR - Disease severity on leaves - Comparison with Blizzard Xtra (1.0 L/ha)

Parameters	Assessment date	EPPO climatic zone	Parts	No. of trials	*Untreated*			Percentage of efficacy (%)								No. of assessments where FHO04 (4.0 L/ha) is significantly[1] >;=;< to Blizzard Xtra (1.0 L/ha)
								FHO04 (4.0 L/ha)				Blizzard Xtra (1.0 L/ha)				
								Prothioconazole + Sulphur				Cyproconazole + Azoxystrobin				
								200+2500 g a.s./ha				200+80 g a.s./ha				
					Mean	*Min*	*Max*	**Mean**	Min	Max	*S.D.*	**Mean**	Min	Max	*S.D.*	
Disease severity on winter wheat	2-3 weeks after the second application	Northeast	Leaf 1	1	***5.5***	-	-	**92.3**	-	-	-	**97.3**	-	-	-	0> ; 1= ; 0<
			Leaf 2	1	***7.1***	-	-	**92.4**	-	-	-	**96.4**	-	-	-	0> ; 1= ; 0<
			Leaf 3	1	***7.8***	-	-	**91.8**	-	-	-	**90.9**	-	-	-	0> ; 1= ; 0<
	Last valid assessment after the 2nd application	Northeast	Leaf 2	1	***5.9***	-	-	**91.5**	-	-	-	**90.2**	-	-	-	0> ; 1= ; 0<
			Leaf 3	1	***7.8***	-	-	**91.8**	-	-	-	**90.9**	-	-	-	0> ; 1= ; 0<

(1) Comparison based on statistics carried out in each trial report.

Table 3.2-26: Efficacy of FHO04 (4.0 L/ha) - Winter cereals - SEPTTR - Disease severity on leaves - Comparison with Adexar (1.0 L/ha)

Parameters	Assessment date	EPPO climatic zone	Parts	No. of trials	*Untreated*			Percentage of efficacy (%)								No. of assessments where FHO04 (4.0 L/ha) is significantly[1] >;=;< to Adexar (1.0 L/ha)
								FHO04 (4.0 L/ha)				Adexar (1.0 L/ha)				
								Prothioconazole + Sulphur				Epoxiconazole + Fluxapyroxad				
								200+2500 g a.s./ha				62.5+62.5 g a.s./ha				
					Mean	*Min*	*Max*	**Mean**	Min	Max	*S.D.*	**Mean**	Min	Max	*S.D.*	
Disease severity on winter wheat	Last valid assessment after the 2nd application	Northeast	Leaf 1	2	***16.0***	*8.6*	*23.4*	**79.0**	72.9	85.2	*6.2*	**94.0**	93.1	94.8	*0.9*	0> ; 2= ; 0<
			Leaf 2	1	***27.4***	-	-	**91.5**	-	-	-	**91.4**	-	-	-	0> ; 1= ; 0<

(1) Comparison based on statistics carried out in each trial report.

Table 3.2-27: Efficacy of FHO04 (4.0 L/ha) - Winter cereals - SEPTTR - Disease severity on leaves - Comparison with Opera N (1.0 L/ha)

Parameters	**Assessment date**	**EPPO climatic zone**	**Parts**	**No. of trials**	***Untreated***			**Percentage of efficacy (%)**								**No. of assessments where FHO04 (4.0 L/ha) is significantly[(1)] >;=;< to Opera N (1.0 L/ha)**
								FHO04 (4.0 L/ha)				**Opera N (1.0 L/ha)**				
								Prothioconazole + Sulphur				Epoxiconazole + Pyraclostrobin				
								200+2500 g a.s./ha				62.5+85 g a.s./ha				
					Mean	*Min*	*Max*	**Mean**	Min	Max	*S.D.*	**Mean**	Min	Max	*S.D.*	
Disease severity on winter wheat	Last valid assessment after the 2nd application	Northeast	Leaf 1	1	***7.8***	-	-	**57.3**	-	-	-	**56.5**	-	-	-	0> ; 1= ; 0<
			Leaf 2	1	***13.5***	-	-	**62.2**	-	-	-	**74.6**	-	-	-	0> ; 1= ; 0<

(1) Comparison based on statistics carried out in each trial report.

34 trials are available to justify the efficacy of FHO04 at 4.0 L/ha in Poland. After the 2nd application, the disease in the untreated plot attacked from 5% to 38% of the flag leaves (Leaf 1) area, from 5% to 27% of the flag leaves minus 1 (Leaf 2) and from 5% to 67% of the flag leaves minus 2 (Leaf 3) area.

Northeast EPPO climatic zone

Across 20 efficacy trials in winter wheat, 2-3 weeks after the second application, FHO04 at 4.0 L/ha provided a good level of efficacy (92% in 3 trials on Leaf 1, 89% in 9 trials on Leaf 2 and 83% in 14 trials on Leaf 3).
Overall, FHO04 at 4.0 L/ha was similar or slightly inferior to Proline at 0.8 L/ha (87% *vs.* 91% in 1 trial on Leaf 1, 87% *vs.* 91% in 5 trials on Leaf 2 and 78% *vs.* 83% in 7 trials on Leaf 3). No significant difference was noted in the trial on Leaf 1, in 4 out of 5 trials on Leaf 2, and in 6 out of 7 trials on Leaf 3).
FHO04 at 4.0 L/ha was similar to Amistar at 1.0 L/ha (94% *vs.* 94% in 2 trials on Leaf 1, 92% *vs.* 93% in 3 trials on Leaf 2 and 90% *vs.* 90% in 3 trials on Leaf 3). No significant difference was noted in all trials.
FHO04 at 4.0 L/ha was similar or even superior to Prosaro at 1.0 L/ha (86% *vs.* 79% in 3 trials on Leaf 3). No significant difference was noted in all trials.
Even if few data are available, FHO04 at 4.0 L/ha was slightly inferior to Blizzard Xtra at 1.0 L/ha (92% *vs.* 97% in 1 trial on Leaf 1, 92% *vs.* 96% in 1 trial on Leaf 2 and 92% *vs.* 91% in 1 trial on Leaf 3). No significant difference was noted in this trial.
At the last valid assessment after the second application, FHO04 at 4.0 L/ha provided a good level of efficacy (76% in 11 trials on Leaf 1, 86% in 16 trials on Leaf 2 and 83% in 14 trials on Leaf 3).
Overall, FHO04 at 4.0 L/ha was similar or slightly inferior to Proline at 0.8 L/ha (77% *vs.* 83% in 4 trials on Leaf 1, 85% *vs.* 86% in 10 trials on Leaf 2 and 78% *vs.* 83% in 7 trials on Leaf 3). No significant difference was noted in 3 out of 4 trials on Leaf 1, in 9 out of 10 trials on Leaf 2, and in 6 out of 7 trials on Leaf 3).
Overall, FHO04 at 4.0 L/ha was similar to Amistar at 1.0 L/ha (94% *vs.* 94% in 2 trials on Leaf 1, 92% *vs.* 93% in 3 trials on Leaf 2 and 90% *vs.* 90% in 3 trials on Leaf 3). No significant difference was noted in all trials.
FHO04 at 4.0 L/ha was similar or even superior to Prosaro at 1.0 L/ha (62% *vs.* 63% in 2 trials on Leaf 1, and 86% *vs.* 79% in 3 trials on Leaf 3). No significant difference was noted in all trials.
Even if few data are available, FHO04 at 4.0 L/ha was similar to Blizzard Xtra at 1.0 L/ha (92% *vs.* 90% in 1 trial on Leaf 2 and 92% *vs.* 91% in 1 trial on Leaf 3). No significant difference was noted in this trial.
Even if few data are available, FHO04 at 4.0 L/ha was similar or inferior to Adexar at 1.0 L/ha (79% *vs.* 94% in 2 trials on Leaf 1 and 92% *vs.* 91% in 1 trial on Leaf 3). However, no significant difference was noted in all trials.
Even if few data are available, FHO04 at 4.0 L/ha was similar or inferior to Opera N at 1.0 L/ha (57% *vs.* 57% in 1 trial on Leaf 1 and 62% *vs.* 75% in 1 trial on Leaf 2). However, no significant difference was noted in all trials.
Even if few data are available in winter triticale, FHO04 at 4.0 L/ha was similar to Amistar at 1.0 L/ha (89% *vs.* 90% in 1 trial on Leaf 3). No significant difference was noted in this trial.
Finally, across 21 efficacy trials in winter cereals, 2-3 weeks after the second application, FHO04 at 4.0 L/ha provided a good level of efficacy (92% in 3 trials on Leaf 1, 89% in 9 trials on Leaf 2 and 83% in 15 trials on Leaf 3).
Overall, FHO04 at 4.0 L/ha was similar or slightly inferior to Proline at 0.8 L/ha (87% *vs.* 91% in 1 trial on Leaf 1, 87% *vs.* 91% in 5 trials on Leaf 2 and 78% *vs.* 83% in 7 trials on Leaf 3). No significant difference was noted in the trial on Leaf 1, in 4 out of 5 trials on Leaf 2, and in 6 out of 7 trials on Leaf 3).
FHO04 at 4.0 L/ha was similar to Amistar at 1.0 L/ha (94% *vs.* 94% in 2 trials on Leaf 1, 92% *vs.* 93% in 3 trials on Leaf 2 and 89% *vs.* 90% in 4 trials on Leaf 3). No significant difference was noted in all trials.
FHO04 at 4.0 L/ha was similar or even superior to Prosaro at 1.0 L/ha (86% *vs.* 79% in 3 trials on Leaf 3). No significant difference was noted in all trials.

Even if few data are available, FHO04 at 4.0 L/ha was slightly inferior to Blizzard Xtra at 1.0 L/ha (92% *vs.* 97% in 1 trial on Leaf 1, 92% *vs.* 96% in 1 trial on Leaf 2 and 92% *vs.* 91% in 1 trial on Leaf 3). No significant difference was noted in this trial.
At the last valid assessment after the second application, FHO04 at 4.0 L/ha provided a good level of efficacy (76% in 11 trials on Leaf 1, 86% in 16 trials on Leaf 2 and 83% in 15 trials on Leaf 3).
Overall, FHO04 at 4.0 L/ha was similar or slightly inferior to Proline at 0.8 L/ha (77% *vs.* 83% in 4 trials on Leaf 1, 85% *vs.* 86% in 10 trials on Leaf 2 and 78% *vs.* 83% in 7 trials on Leaf 3). No significant difference was noted in 3 out of 4 trials on Leaf 1, in 9 out of 10 trials on Leaf 2, and in 6 out of 7 trials on Leaf 3).
Overall, FHO04 at 4.0 L/ha was similar to Amistar at 1.0 L/ha (94% *vs.* 94% in 2 trials on Leaf 1, 92% *vs.* 93% in 3 trials on Leaf 2 and 89% *vs.* 90% in 4 trials on Leaf 3). No significant difference was noted in all trials.
FHO04 at 4.0 L/ha was similar or even superior to Prosaro at 1.0 L/ha (62% *vs.* 63% in 2 trials on Leaf 1, and 86% *vs.* 79% in 3 trials on Leaf 3). No significant difference was noted in all trials.
Even if few data are available, FHO04 at 4.0 L/ha was similar to Blizzard Xtra at 1.0 L/ha (92% *vs.* 90% in 1 trial on Leaf 2 and 92% *vs.* 91% in 1 trial on Leaf 3). No significant difference was noted in this trial.
Even if few data are available, FHO04 at 4.0 L/ha was similar or inferior to Adexar at 1.0 L/ha (79% *vs.* 94% in 2 trials on Leaf 1 and 92% *vs.* 91% in 1 trial on Leaf 3). However, no significant difference was noted in all trials.
Even if few data are available, FHO04 at 4.0 L/ha was similar or inferior to Opera N at 1.0 L/ha (57% *vs.* 57% in 1 trial on Leaf 1 and 62% *vs.* 75% in 1 trial on Leaf 2). However, no significant difference was noted in all trials.

Border countries of Poland

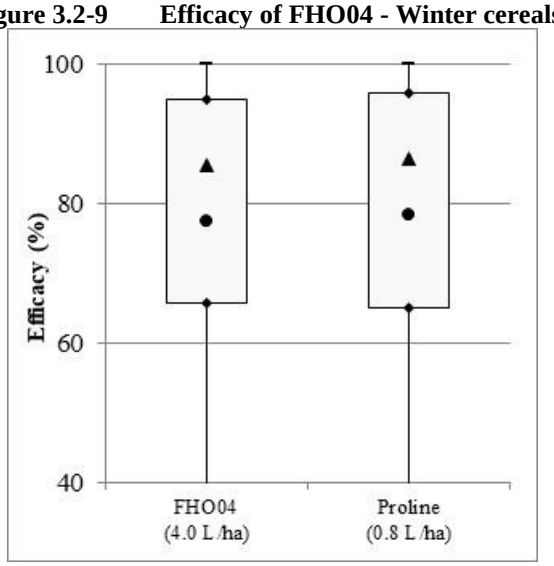
Across 11 efficacy trials in winter wheat, 2-3 weeks after the second application, FHO04 at 4.0 L/ha provided a good level of efficacy (100% in 1 trial on Leaf 1, 85% in 4 trials on Leaf 2 and 74% in 6 trials on Leaf 3).
Overall, FHO04 at 4.0 L/ha was similar or even superior to Proline at 0.8 L/ha (100% *vs.* 100% in 1 trial on Leaf 1, 85% *vs.* 76% in 4 trials on Leaf 2 and 72% *vs.* 68% in 5 trials on Leaf 3). No significant difference was noted in all trials on Leaf 1, Leaf 2, and Leaf 3.
Even if few data are available, FHO04 at 4.0 L/ha was superior to Amistar at 1.0 L/ha (80% *vs.* 31% in 1 trial on Leaf 3). No significant difference was noted in this trial.
At the last valid assessment after the second application, FHO04 at 4.0 L/ha provided a good level of efficacy (92% in 4 trials on Leaf 1, 86% in 9 trials on Leaf 2 and 76% in 8 trials on Leaf 3).
Overall, FHO04 at 4.0 L/ha was similar or even superior to Proline at 0.8 L/ha (97% *vs.* 94% in 2 trials on Leaf 1, 84% *vs.* 77% in 8 trials on Leaf 2 and 72% *vs.* 67% in 6 trials on Leaf 3). No significant difference was noted in all trials on Leaf 1, Leaf 2, and Leaf 3.
FHO04 at 4.0 L/ha was superior to Amistar at 1.0 L/ha (88% *vs.* 54% in 2 trials on Leaf 1, 100% *vs.* 26% in 1 trial on Leaf 2 and 89% *vs.* 25% in 2 trials on Leaf 3). This difference was significant in 1 out of 2 trials on Leaf 1 and in all trials on Leaf 2 and Leaf 3.
Even if few data are available in winter triticale (1 trial), FHO04 at 4.0 L/ha was similar to Proline at 0.8 L/ha (100% *vs.* 100% on Leaf 2 and 96% *vs.* 97% on Leaf 3 at the last valid assessment after the second application)
In durum wheat (1 trial), FHO04 at 4.0 L/ha was inferior to Proline at 0.8 L/ha (25% *vs.* 65% on Leaf 1, 20% *vs.* 65% on Leaf 2 and 13% *vs.* 34% on Leaf 3 at the last valid assessment after the second application). With low level of efficacy in the reference standard, this trial could be considered as non-valid.
Finally, across 13 efficacy trials in winter cereals, 2-3 weeks after the second application, FHO04 at 4.0 L/ha provided a medium level of efficacy (66% in 2 trials on Leaf 1, 72% in 5 trials on Leaf 2 and 65% in 7 trials on Leaf 3).
Overall, FHO04 at 4.0 L/ha was similar (except on Leaf 1) to Proline at 0.8 L/ha (67% *vs.* 94% in 2 trials on Leaf 1, 72% *vs.* 75% in 5 trials on Leaf 2 and 63% *vs.* 63% in 6 trials on Leaf 3). No significant

difference was at least noted in 1 out of 2 trials on Leaf 1, in 4 out of 5 trials on Leaf 2, and in the 6 trials on Leaf 3).
Even if few data are available, FHO04 at 4.0 L/ha was superior to Amistar at 1.0 L/ha (80% *vs.* 31% in 1 trial on Leaf 3). No significant difference was noted in this trial.
At the last valid assessment after the second application, FHO04 at 4.0 L/ha provided a medium level of efficacy (79% in 5 trials on Leaf 1, 81% in 11 trials on Leaf 2 and 72% in 10 trials on Leaf 3).
Overall, FHO04 at 4.0 L/ha was similar (except on Leaf 1) to Proline at 0.8 L/ha (73% *vs.* 84% in 3 trials on Leaf 1, 79% *vs.* 78% in 10 trials on Leaf 2 and 68% *vs.* 67% in 8 trials on Leaf 3). No significant difference was at least noted in 2 out of 3 trials on Leaf 1, in 9 out of 10 trials on Leaf 2, and in the 8 trials on Leaf 3).
FHO04 at 4.0 L/ha was superior to Amistar at 1.0 L/ha (88% *vs.* 54% in 2 trials on Leaf 1, 100% *vs.* 26% in 1 trial on Leaf 2 and 89% *vs.* 25% in 2 trials on Leaf 3). This difference was significant in 1 out of 3 trials on Leaf 1 and in all trials on Leaf 2 and Leaf 3.

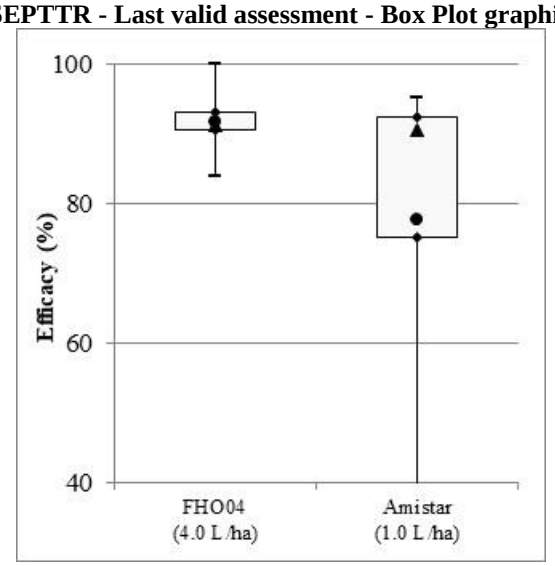
All EPPO climatic zones

A total of 31 efficacy trials across Northeast EPPO climatic zone and border countries of Poland are summarised to confirm the efficacy of FHO04 at 4.0 L/ha in winter wheat against SEPTTR.
2-3 weeks after the second application, FHO04 at 4.0 L/ha provided a good level of efficacy (94% in 4 trials on Leaf 1 and 88% in 13 trials on Leaf 2 and 80% in 20 trials on Leaf 3) overall similar to Proline, Prosaro, or Blizzard Xtra, or superior to Amistar.
At the last valid assessment after the second application, FHO04 at 4.0 L/ha provided a good level of efficacy (80% in 15 trials on Leaf 1 and 86% in 25 trials on Leaf 2 and 80% in 22 trials on Leaf 3) overall similar or even superior to Proline, Amistar, Prosaro, Blizzard Xtra or slightly inferior to Adexar or Opera N.
Even if few data are available in winter triticale (2 trials), 2-3 weeks after the second application, FHO04 at 4.0 L/ha provided a good level of efficacy (89% in 1 trial on Leaf 3) similar to Proline. At the last valid assessment after the second application, FHO04 at 4.0 L/ha provided a very good level of efficacy (100% in 1 trial on Leaf 2 and 93% in 2 trials on Leaf 3) overall similar to Proline, or Amistar.
In durum wheat (1 trial), FHO04 at 4.0 L/ha was inferior to Proline at 0.8 L/ha, but with low level of efficacy in the reference standard, this trial could be considered as non-valid.
Finally, a total of 34 efficacy trials across Northeast EPPO climatic zone and border countries of Poland are summarised to confirm the efficacy of FHO04 at 4.0 L/ha in cereals against SEPTTR.
2-3 weeks after the second application, FHO04 at 4.0 L/ha provided a medium level of efficacy (82% in 5 trials on Leaf 1 and 83% in 14 trials on Leaf 2 and 78% in 22 trials on Leaf 3) overall similar to Proline, Prosaro, or Blizzard Xtra, or superior to Amistar.
At the last valid assessment after the second application, FHO04 at 4.0 L/ha provided a medium level of efficacy (77% in 16 trials on Leaf 1 and 84% in 27 trials on Leaf 2 and 79% in 25 trials on Leaf 3) overall similar or even superior to Proline, Amistar, Prosaro, Blizzard Xtra or slightly inferior to Adexar or Opera N.
The difference between the reference standards (with more than 5 assessments) can be illustrated by box plot graphic on leaves (Leaf 1, Leaf 2 and Leaf 3) (Figure 3.2-9). Overall, FHO04 at 4.0 L/ha had at least (or even better) the same level of efficacy and the same dispersion and variation between means than the tested reference standards.

Figure 3.2-9 Efficacy of FHO04 - Winter cereals - SEPTTR - Last valid assessment - Box Plot graphic



Comparison with Proline (51 trials - 22 assessments)



Comparison with Amistar (7 trials - 15 assessments)

To conclude, FHO04 at 4.0 L/ha provided efficient and reliable control of SEPTTR in cereals crops overall similar to all tested reference standards: Proline, Amistar, Prosaro, Blizzard Xtra, Adexar or Opera N.
Based on this, the authorization of FHO04 is requested at 4.0 L /ha for the control of leaf spot of cereals (*Zymoseptoria tritici* - SEPTTR).

Comments of zRMS:

SEPTTR in wheat, triticale and durum wheat*

Comparison of the test item`s efficacy, in control of SEPTTR, to mean efficacy of **all standards** in 31 trials in soft **winter wheat** and in 2 trials in triticale (Table 3.2-21) shows in principle the statistical uniformity, standing for equivalence to the standards, of the FHO04 at its target dose rate of 4.0 L/ha. The significant advantage of FHO04 over the average performance of standards has been reported from 5 data points, and performance of the product significantly inferior to standards – from 3 data points only, over the total of 62 data points from the 31 winter soft wheat trials summarized. Much the same has been concluded from specific comparison to **standards containing prothioconazole** (Table 3.2-22): 5 data points per 37 indicate statistically significant inferior performance of FHO04 compared to standards, otherwise the performance is equivalent. Likewise in comparison to **strobilurin (azoxystrobin) references** (Table 3.2-23), although here the 5 data points, *per* total of 13, showing significant advantage of the test item come from trials where azoxystrobin had shown efficacy 25-54%, making validity of the data doubtful. The remaining 8 data points, nonetheless, indicate at least efficacy of the FHO04 bing equivalent to azoxystrobin. The comparisons to standards that are **two-way manufacturer`s mixtures** of: DMI x DMI (Table 3.2-24), DMI x Strobilurin (Table 3.2-25, 3.2-27) or DMI x SDHI (Table 3.2-26) were carried out only in winter soft wheat crop. None of these comparisons resulted in statistical significance in neither type of differences: the performance of the FHO04 has been shown fully equivalent to all these standards.

Efficacy in control of SEPTTR in **winter rye** was assessed in only one trial. The infection level in the UNCK plots in that trial was <<5% on the day of the 2nd application and on the following dates, therefore the trial is not included in the efficacy assessment.

Winter triticale has been represented by 2 trials only and no significant differences have been found between the test item and (1) the average of all standards, (2) the average of prothioconazole standards and (3) the strobilurin standards, in the efficacy against SEPTTR (efficacy of FHO04 equivalent to standards).

*In a single **winter durum wheat** trial the test item performed drastically low with no explanation offered on the fact, with 4 data points *per* 6 testifying to significantly inferior performance of the FHO04 compared to

average efficacy of standards. With the efficacy of 20%-33% and the standards performing 65%-89% (L3 data points excluded for the standards` performance <35%) there is no point to discuss efficacy in the crop at all.

PUCCRE PUCCST
zRMS Abstract

3.2.3.3 Efficacy trials results for the control of brown rust (*Puccinia recondita* - PUCCRE)

The intended label claim against brown rust (*Puccinia recondita* - PUCCRE) in wheat, triticale or rye is for ~~maximum~~ 2 applications of FHO04 at dose rate of 4.0 L/ha at BBCH 27-69.
A total of **22 valid efficacy trials** were carried out to confirm the efficacy of FHO04 applied at 4.0 L/ha to control of PUCCRE in winter wheat (10 trials), durum wheat (1 trial), winter triticale (1 trial) or winter rye (10 trials). These trials were carried out **from 2020 to 2023** in the Northeast EPPO climatic zone (12 trials in Poland) and Poland border countries (9 trials in Germany, 1 trial in Czech Republic) in winter cereals. However, an analysis by crop is also provided hereafter.
In accordance with EPPO guideline PP1/257, all data against *Puccinia recondita* (PUCCRE) in winter and spring wheat, durum wheat, spelt, rye, and triticale can be considered as comparable and merged in this section. All observations are summarised in comparison to all, or to particular ~~according to the~~ reference standards: Table 3.2-28 (All reference standards), Table 3.2-29 (Proline), Table 3.2-30 (Amistar), Table 3.2-31 (Prosaro (1.0 L/ha) [A] + Fandango (1.0 L/ha) [B]).

Table 3.2-28: Efficacy of FHO04 (4.0 L/ha) - Winter cereals - PUCCRE - Disease severity on leaves - Comparison with all references standards

Parameters	Assessment date	EPPO climatic zone	Parts	No. of trials	*Untreated*			Percentage of efficacy (%)								No. of assessments where FHO04 (4.0 L/ha) is significantly[(1)] >;=;< to All reference standards
								FHO04 (4.0 L/ha)				All reference standards				
								Prothioconazole + Sulphur				-				
								200+2500 g a.s./ha				-				
					Mean	*Min*	*Max*	**Mean**	Min	Max	*S.D.*	**Mean**	Min	Max	*S.D.*	
Disease severity on winter wheat	2-3 weeks after the second application	Northeast	Leaf 1	2	***5.3***	*5.3*	*5.4*	**97.1**	95.7	98.6	*1.4*	**96.0**	95.2	96.8	*0.8*	0> ; 2= ; 0<
			Leaf 2	2	***5.1***	*5.1*	*5.2*	**100.0**	100.0	100.0	*0.0*	**100.0**	100.0	100.0	*0.0*	0> ; 2= ; 0<
			Leaf 3	4	***5.8***	*5.1*	*6.5*	**97.7**	96.0	100.0	*1.6*	**97.2**	95.1	99.6	*1.8*	0> ; 4= ; 0<
	Last valid assessment after the 2nd application	Northeast	Leaf 1	5	***6.2***	*5.3*	*7.9*	**89.7**	68.8	98.6	*11.3*	**88.9**	64.1	99.0	*12.8*	0> ; 5= ; 0<
			Leaf 2	5	***7.9***	*4.7*	*11.7*	**86.5**	58.4	98.8	*14.8*	**86.9**	56.9	98.8	*15.4*	0> ; 5= ; 0<
			Leaf 3	4	***6.9***	*5.9*	*7.9*	**95.8**	92.1	100.0	*3.4*	**95.9**	92.4	99.6	*3.1*	0> ; 4= ; 0<
		Border countries of Poland (Czech Republic, Germany)	Leaf 1	5	***28.7***	*8.2*	*54.3*	**85.2**	68.3	100.0	*13.9*	**84.9**	65.0	100.0	*13.8*	0> ; 5= ; 0<
			Leaf 2	2	***17.1***	*16.0*	*18.1*	**75.6**	57.8	93.4	*17.8*	**79.8**	66.8	92.8	*13.0*	0> ; 2= ; 0<
		All EPPO climatic zones	Leaf 1	10	***17.5***	*5.3*	*54.3*	**87.5**	68.3	100.0	*12.9*	**86.9**	64.1	100.0	*13.5*	0> ; 10= ; 0<
			Leaf 2	7	***10.5***	*4.7*	*18.1*	**83.4**	57.8	98.8	*16.5*	**84.9**	56.9	98.8	*15.1*	0> ; 7= ; 0<
			Leaf 3	4	***6.9***	*5.9*	*7.9*	**95.8**	92.1	100.0	*3.4*	**95.9**	92.4	99.6	*3.1*	0> ; 4= ; 0<
Disease severity on winter triticale	2-3 weeks after the second application	Northeast	Leaf 3	1	***5.2***	-	-	**94.4**	-	-	-	**94.8**	-	-	-	0> ; 1= ; 0<
	Last valid assessment after the 2nd application	Northeast	Leaf 1	1	***5.4***	-	-	**100.0**	-	-	-	**100.0**	-	-	-	0> ; 1= ; 0<
			Leaf 2	1	***6.0***	-	-	**95.6**	-	-	-	**96.4**	-	-	-	0> ; 1= ; 0<
			Leaf 3	1	***7.9***	-	-	**90.7**	-	-	-	**93.0**	-	-	-	0> ; 1= ; 0<
Disease severity on winter durum wheat	Last valid assessment after the 2nd application	Border countries of Poland (Germany)	Leaf 1	1	*9.4*	-	-	**6.5**	-	-	-	**33.0**	-	-	-	0> ; 0= ; 1<
			Leaf 2	1	*4.7*	-	-	**13.5**	-	-	-	**8.7**	-	-	-	0> ; 1= ; 0<
Disease severity on winter rye	2-3 weeks after the second application	Northeast	Leaf 1	2	***6.6***	*5.9*	*7.3*	**100.0**	100.0	100.0	*0.0*	**100.0**	100.0	100.0	*0.0*	0> ; 2= ; 0<
			Leaf 2	5	***6.3***	*5.2*	*7.9*	**97.4**	92.5	100.0	*3.3*	**98.0**	94.7	100.0	*2.1*	0> ; 5= ; 0<
			Leaf 3	6	***6.1***	*5.2*	*6.5*	**95.1**	93.0	97.0	*1.2*	**96.8**	95.2	98.1	*1.0*	0> ; 5= ; 1<
	Last valid assessment after the 2nd application	Northeast	Leaf 1	6	***7.1***	*5.9*	*7.7*	**99.8**	98.6	100.0	*0.5*	**99.9**	99.3	100.0	*0.3*	0> ; 6= ; 0<
			Leaf 2	6	***7.7***	*7.5*	*8.1*	**91.2**	86.7	94.5	*2.4*	**94.3**	93.1	96.8	*1.3*	0> ; 4= ; 2<
			Leaf 3	6	***7.8***	*6.7*	*9.9*	**91.7**	88.1	93.9	*2.0*	**94.6**	93.7	95.4	*0.8*	0> ; 4= ; 2<
		Border countries of Poland (Germany)	Leaf 1	3	***11.9***	*5.2*	*24.3*	**80.2**	55.6	98.8	*18.1*	**79.0**	63.9	93.2	*12.0*	0> ; 3= ; 0<
			Leaf 2	4	***16.9***	*5.1*	*41.5*	**81.6**	54.0	100.0	*17.2*	**82.2**	66.1	99.2	*12.3*	0> ; 4= ; 0<
		All EPPO climatic zones	Leaf 1	9	***8.7***	*5.2*	*24.3*	**93.3**	55.6	100.0	*14.0*	**92.9**	63.9	100.0	*12.0*	0> ; 9= ; 0<
			Leaf 2	4	***11.4***	*5.1*	*41.5*	**87.4**	54.0	100.0	*12.0*	**89.5**	66.1	99.2	*9.8*	0> ; 8= ; 2<
			Leaf 3	6	***7.8***	*6.7*	*9.9*	**91.7**	88.1	93.9	*2.0*	**94.6**	93.7	95.4	*0.8*	0> ; 4= ; 2<

Parameters	Assessment date	EPPO climatic zone	Parts	No. of trials	*Untreated*			Percentage of efficacy (%)								No. of assessments where FHO04 (4.0 L/ha) is significantly[(1)] >;=;< to All reference standards
								FHO04 (4.0 L/ha)				All reference standards				
								Prothioconazole + Sulphur				-				
								200+2500 g a.s./ha				-				
					Mean	*Min*	*Max*	**Mean**	Min	Max	*S.D.*	**Mean**	Min	Max	*S.D.*	
Disease severity on winter cereals	2-3 weeks after the second application	Northeast	Leaf 1	4	***6.0***	*5.3*	*7.3*	**98.6**	95.7	100.0	*1.8*	**98.0**	95.2	100.0	*2.1*	0> ; 4= ; 0<
			Leaf 2	7	***6.0***	*5.1*	*7.9*	**98.2**	92.5	100.0	*3.0*	**98.6**	94.7	100.0	*2.0*	0> ; 7= ; 0<
			Leaf 3	11	***5.9***	*5.1*	*6.5*	**96.0**	93.0	100.0	*1.9*	**96.8**	94.8	99.6	*1.5*	0> ; 10= ; 1<
	Last valid assessment after the 2nd application	Northeast	Leaf 1	12	***6.6***	*5.3*	*7.9*	**95.6**	68.8	100.0	*8.8*	**95.3**	64.1	100.0	*9.9*	0> ; 12= ; 0<
			Leaf 2	12	***7.7***	*4.7*	*11.7*	**89.6**	58.4	98.8	*10.1*	**91.4**	56.9	98.8	*10.7*	0> ; 10= ; 2<
			Leaf 3	11	***7.5***	*5.9*	*9.9*	**93.1**	88.1	100.0	*3.3*	**94.9**	92.4	99.6	*2.1*	0> ; 9= ; 2<
		Border countries of Poland (Czech Republic, Germany)	Leaf 1	9	***21.0***	*5.2*	*54.3*	**74.8**	6.5	100.0	*28.4*	**77.2**	33.0	100.0	*20.1*	0> ; 8= ; 1<
			Leaf 2	7	***15.2***	*4.7*	*41.5*	**70.1**	13.5	100.0	*28.3*	**71.0**	8.7	99.2	*28.0*	0> ; 7= ; 0<
		All EPPO climatic zones	Leaf 1	21	***12.8***	*5.2*	*54.3*	**86.7**	6.5	100.0	*22.3*	**87.6**	33.0	100.0	*17.6*	0> ; 20= ; 1<
			Leaf 2	19	***10.5***	*4.7*	*41.5*	**82.5**	13.5	100.0	*21.2*	**83.9**	8.7	99.2	*21.4*	0> ; 17= ; 2<
			Leaf 3	11	***7.5***	*5.9*	*9.9*	**93.1**	88.1	100.0	*3.3*	**94.9**	92.4	99.6	*2.1*	0> ; 9= ; 2<

(1) Comparison based on statistics carried out in each trial report.

Table 3.2-29: Efficacy of FHO04 (4.0 L/ha) - Winter cereals - PUCCRE - Disease severity on leaves - Comparison with Proline (0.8 L/ha) or Protendo 300 EC (0.65 L/ha)

Parameters	Assessment date	EPPO climatic zone	Parts	No. of trials	*Untreated*			Percentage of efficacy (%)								No. of assessments where FHO04 (4.0 L/ha) is significantly[(1)] >;=;< to Proline (0.8 L/ha) Proline 275 (0.72 L/ha)
								FHO04 (4.0 L/ha) Prothioconazole + Sulphur 200+2500 g a.s./ha				Proline (0.8 L/ha) Proline 275 (0.72 L/ha) Prothioconazole 200 g a.s./ha				
					Mean	*Min*	*Max*	**Mean**	Min	Max	*S.D.*	**Mean**	Min	Max	*S.D.*	
Disease severity on winter wheat	2-3 weeks after the second application	Northeast	Leaf 3	1	***5.9***	-	-	**98.3**	-	-	-	**98.3**	-	-	-	0> ; 1= ; 0<
	Last valid assessment after the 2nd application	Northeast	Leaf 1	2	***7.5***	*7.2*	*7.9*	**77.9**	68.8	87.0	*9.1*	**76.8**	64.1	89.5	*12.7*	0> ; 2= ; 0<
			Leaf 2	2	***8.2***	*4.7*	*11.7*	**71.8**	58.4	85.2	*13.4*	**72.8**	56.9	88.6	*15.8*	0> ; 2= ; 0<
			Leaf 3	1	***5.9***	-	-	**98.3**	-	-	-	**98.3**	-	-	-	0> ; 1= ; 0<
		Border countries of Poland (Czech Republic, Germany)	Leaf 1	5	***28.7***	*8.2*	*54.3*	**85.2**	68.3	100.0	*13.9*	**84.9**	65.0	100.0	*13.8*	0> ; 5= ; 0<
			Leaf 2	2	***17.1***	*16.0*	*18.1*	**75.6**	57.8	93.4	*17.8*	**79.8**	66.8	92.8	*13.0*	0> ; 2= ; 0<
		All EPPO climatic zones	Leaf 1	7	***22.7***	*7.2*	*54.3*	**83.1**	68.3	100.0	*13.2*	**82.6**	64.1	100.0	*14.0*	0> ; 7= ; 0<
			Leaf 2	4	***12.6***	*4.7*	*18.1*	**73.7**	57.8	93.4	*15.9*	**76.3**	56.9	92.8	*14.9*	0> ; 4= ; 0<
			Leaf 3	1	***5.9***	-	-	**98.3**	-	-	-	**98.3**	-	-	-	0> ; 1= ; 0<
Disease severity on winter durum wheat	Last valid assessment after the 2nd application	Border countries of Poland (Germany)	Leaf 1	1	*9.4*	-	-	**6.5**	-	-	-	**33.0**	-	-	-	0> ; 0= ; 1<
			Leaf 2	1	*4.7*	-	-	**13.5**	-	-	-	**8.7**	-	-	-	0> ; 1= ; 0<
Disease severity on winter rye	2-3 weeks after the second application	Northeast	Leaf 2	3	***5.4***	*5.2*	*5.6*	**100.0**	100.0	100.0	*0.0*	**99.6**	98.7	100.0	*0.6*	0> ; 3= ; 0<
			Leaf 3	4	***6.2***	*5.7*	*6.5*	**94.6**	93.0	95.7	*1.0*	**96.5**	95.2	97.7	*1.1*	0> ; 3= ; 1<
	Last valid assessment after the 2nd application	Northeast	Leaf 1	4	***7.3***	*6.8*	*7.7*	**99.7**	98.6	100.0	*0.6*	**99.8**	99.3	100.0	*0.3*	0> ; 4= ; 0<
			Leaf 2	5	***7.7***	*7.5*	*8.1*	**90.1**	86.7	91.6	*2.0*	**93.6**	93.1	94.3	*0.5*	0> ; 2= ; 2<
			Leaf 3	4	***7.5***	*6.7*	*9.4*	**90.7**	88.1	92.8	*1.8*	**94.2**	93.7	95.2	*0.6*	0> ; 2= ; 2<
		Border countries of Poland (Germany)	Leaf 1	3	***11.9***	*5.2*	*24.3*	**80.2**	55.6	98.8	*18.1*	**79.0**	63.9	93.2	*12.0*	0> ; 3= ; 0<
			Leaf 2	4	***16.9***	*5.1*	*41.5*	**81.6**	54.0	100.0	*17.2*	**82.2**	66.1	99.2	*12.3*	0> ; 4= ; 0<
		All EPPO climatic zones	Leaf 1	7	***9.3***	*5.2*	*24.3*	**91.3**	55.6	100.0	*15.3*	**90.9**	63.9	100.0	*13.0*	0> ; 7= ; 0<
			Leaf 2	8	***12.3***	*5.1*	*41.5*	**85.8**	54.0	100.0	*13.0*	**87.9**	66.1	99.2	*10.4*	0> ; 6= ; 2<
			Leaf 3	4	***7.5***	*6.7*	*9.4*	**90.7**	88.1	92.8	*1.8*	**94.2**	93.7	95.2	*0.6*	0> ; 2= ; 2<

Parameters	Assessment date	EPPO climatic zone	Parts	No. of trials	*Untreated*			Percentage of efficacy (%)								No. of assessments where FHO04 (4.0 L/ha) is significantly[(1)] >;=;< to Proline (0.8 L/ha) Proline 275 (0.72 L/ha)
								FHO04 (4.0 L/ha)				Proline (0.8 L/ha) Proline 275 (0.72 L/ha)				
								Prothioconazole + Sulphur				Prothioconazole				
								200+2500 g a.s./ha				200 g a.s./ha				
					Mean	*Min*	*Max*	**Mean**	Min	Max	*S.D.*	**Mean**	Min	Max	*S.D.*	
Disease severity on winter cereals	2-3 weeks after the second application	Northeast	Leaf 2	3	***5.4***	*5.2*	*5.6*	**100.0**	100.0	100.0	*0.0*	**99.6**	98.7	100.0	*0.6*	0> ; 3= ; 0<
			Leaf 3	5	***6.1***	*5.7*	*6.5*	**95.3**	93.0	98.3	*1.8*	**96.9**	95.2	98.3	*1.2*	0> ; 4= ; 1<
	Last valid assessment after the 2nd application	Northeast	Leaf 1	6	***7.4***	*6.8*	*7.9*	**92.4**	68.8	100.0	*11.6*	**92.2**	64.1	100.0	*13.1*	0> ; 6= ; 0<
			Leaf 2	6	***7.9***	*4.7*	*11.7*	**84.0**	58.4	91.6	*11.7*	**86.7**	56.9	94.3	*13.4*	0> ; 4= ; 2<
			Leaf 3	5	***7.2***	*5.9*	*9.4*	**92.2**	88.1	98.3	*3.4*	**95.0**	93.7	98.3	*1.8*	0> ; 3= ; 2<
		Border countries of Poland (Czech Republic, Germany)	Leaf 1	9	***21.0***	*5.2*	*54.3*	**74.8**	6.5	100.0	*28.4*	**77.2**	33.0	100.0	*20.1*	0> ; 8= ; 1<
			Leaf 2	7	***15.2***	*4.7*	*41.5*	**70.1**	13.5	100.0	*28.3*	**71.0**	8.7	99.2	*28.0*	0> ; 7= ; 0<
		All EPPO climatic zones	Leaf 1	15	***15.5***	*5.2*	*54.3*	**81.9**	6.5	100.0	*24.7*	**83.2**	33.0	100.0	*19.1*	0> ; 14= ; 1<
			Leaf 2	13	***11.8***	*4.7*	*41.5*	**76.5**	13.5	100.0	*23.3*	**78.2**	8.7	99.2	*23.8*	0> ; 11= ; 2<
			Leaf 3	5	***7.2***	*5.9*	*9.4*	**92.2**	88.1	98.3	*3.4*	**95.0**	93.7	98.3	*1.8*	0> ; 3= ; 2<

(1) Comparison based on statistics carried out in each trial report.

Table 3.2-30: Efficacy of FHO04 (4.0 L/ha) - Winter cereals - PUCCRE - Disease severity on leaves - Comparison with Makler 250 SE / Amistar (1.0 L/ha)

Parameters	Assessment date	EPPO climatic zone	Parts	No. of trials	*Untreated*			Percentage of efficacy (%)								No. of assessments where FHO04 (4.0 L/ha) is significantly[(1)] >;=;< to Makler 250 SE / Amistar (1.0 L/ha)
								FHO04 (4.0 L/ha)				Makler 250 SE / Amistar (1.0 L/ha)				
								Prothioconazole + Sulphur				Azoxystrobin				
								200+2500 g a.s./ha				250 g a.s./ha				
					Mean	*Min*	*Max*	**Mean**	Min	Max	*S.D.*	**Mean**	Min	Max	*S.D.*	
Disease severity on winter wheat	2-3 weeks after the second application	Northeast	Leaf 1	2	***5.3***	*5.3*	*5.4*	**97.1**	95.7	98.6	*1.4*	**96.0**	95.2	96.8	*0.8*	0> ; 2= ; 0<
			Leaf 2	2	***5.1***	*5.1*	*5.2*	**100.0**	100.0	100.0	*0.0*	**100.0**	100.0	100.0	*0.0*	0> ; 2= ; 0<
			Leaf 3	2	***5.3***	*5.1*	*5.5*	**96.3**	96.0	96.6	*0.3*	**95.5**	95.1	95.8	*0.4*	0> ; 2= ; 0<
	Last valid assessment after the 2nd application	Northeast	Leaf 1	2	***5.3***	*5.3*	*5.4*	**97.1**	95.7	98.6	*1.4*	**96.0**	95.2	96.8	*0.8*	0> ; 2= ; 0<
			Leaf 2	2	***7.4***	*7.3*	*7.6*	**95.2**	94.7	95.6	*0.4*	**95.1**	95.0	95.2	*0.1*	0> ; 2= ; 0<
			Leaf 3	2	***7.6***	*7.3*	*7.9*	**92.5**	92.1	92.9	*0.4*	**92.8**	92.4	93.2	*0.4*	0> ; 2= ; 0<
Disease severity on winter triticale	2-3 weeks after the second application	Northeast	Leaf 3	1	***5.2***	-	-	**94.4**	-	-	-	**94.8**	-	-	-	0> ; 1= ; 0<
	Last valid assessment after the 2nd application	Northeast	Leaf 1	1	***5.4***	-	-	**100.0**	-	-	-	**100.0**	-	-	-	0> ; 1= ; 0<
			Leaf 2	1	***6.0***	-	-	**95.6**	-	-	-	**96.4**	-	-	-	0> ; 1= ; 0<
			Leaf 3	1	***7.9***	-	-	**90.7**	-	-	-	**93.0**	-	-	-	0> ; 1= ; 0<
Disease severity on winter rye	2-3 weeks after the second application	Northeast	Leaf 1	2	***6.6***	*5.9*	*7.3*	**100.0**	100.0	100.0	*0.0*	**100.0**	100.0	100.0	*0.0*	0> ; 2= ; 0<
			Leaf 2	2	***7.8***	*7.6*	*7.9*	**93.5**	92.5	94.5	*1.0*	**95.8**	94.7	96.8	*1.1*	0> ; 2= ; 0<
			Leaf 3	2	***5.9***	*5.2*	*6.5*	**96.1**	95.2	97.0	*0.9*	**97.4**	96.8	98.1	*0.6*	0> ; 2= ; 0<
	Last valid assessment after the 2nd application	Northeast	Leaf 1	2	***6.6***	*5.9*	*7.3*	**100.0**	100.0	100.0	*0.0*	**100.0**	100.0	100.0	*0.0*	0> ; 2= ; 0<
			Leaf 2	2	***7.8***	*7.6*	*7.9*	**93.5**	92.5	94.5	*1.0*	**95.8**	94.7	96.8	*1.1*	0> ; 2= ; 0<
			Leaf 3	2	***8.4***	*6.8*	*9.9*	**93.6**	93.4	93.9	*0.3*	**95.4**	95.4	95.4	*0.0*	0> ; 2= ; 0<
Disease severity on winter cereals	2-3 weeks after the second application	Northeast	Leaf 1	4	***6.0***	*5.3*	*7.3*	**98.6**	95.7	100.0	*1.8*	**98.0**	95.2	100.0	*2.1*	0> ; 4= ; 0<
			Leaf 2	4	***6.4***	*5.1*	*7.9*	**96.8**	92.5	100.0	*3.3*	**97.9**	94.7	100.0	*2.3*	0> ; 4= ; 0<
			Leaf 3	5	***5.5***	*5.1*	*6.5*	**95.8**	94.4	97.0	*1.0*	**96.1**	94.8	98.1	*1.2*	0> ; 5= ; 0<
	Last valid assessment after the 2nd application	Northeast	Leaf 1	5	***5.8***	*5.3*	*7.3*	**98.9**	95.7	100.0	*1.7*	**98.4**	95.2	100.0	*2.0*	0> ; 5= ; 0<
			Leaf 2	5	***7.3***	*6.0*	*7.9*	**94.6**	92.5	95.6	*1.1*	**95.6**	94.7	96.8	*0.9*	0> ; 5= ; 0<
			Leaf 3	5	***8.0***	*6.8*	*9.9*	**92.6**	90.7	93.9	*1.1*	**93.9**	92.4	95.4	*1.3*	0> ; 5= ; 0<

(1) Comparison based on statistics carried out in each trial report.

Table 3.2-31: Efficacy of FHO04 (4.0 L/ha) - Winter cereals - PUCCRE - Disease severity on leaves - Comparison with Prosaro (1.0 L/ha) [A] +Fandango (1.0 L/ha) [B]

Parameters	Assessment date	EPPO climatic zone	Parts	No. of trials	*Untreated*			Percentage of efficacy (%)								No. of assessments where FHO04 (4.0 L/ha) is significantly[(1)] >;=;< to Prosaro (1.0 L/ha) [A] + Fandango (1.0 L/ha) [B]
								FHO04 (4.0 L/ha)				**Prosaro (1.0 L/ha) [A] + Fandango (1.0 L/ha) [B]**				
								Prothioconazole + Sulphur				Prothioconazole + Fluoxastrobin Prothioconazole + Tebuconazole				
								200+2500 g a.s./ha				150+150 g a.s./ha 125+125 g a.s./ha				
					Mean	*Min*	*Max*	**Mean**	Min	Max	*S.D.*	**Mean**	Min	Max	*S.D.*	
Disease severity on winter wheat	2-3 weeks after the second application	Northeast	Leaf 3	1	***6.5***	-	-	**100.0**	-	-	-	**99.6**	-	-	-	0> ; 1= ; 0<
	Last valid assessment after the 2nd application	Northeast	Leaf 1	1	***5.4***	-	-	**98.5**	-	-	-	**99.0**	-	-	-	0> ; 1= ; 0<
			Leaf 2	1	***8.4***	-	-	**98.8**	-	-	-	**98.8**	-	-	-	0> ; 1= ; 0<
			Leaf 3	1	***6.5***	-	-	**100.0**	-	-	-	**99.6**	-	-	-	0> ; 1= ; 0<

(1) Comparison based on statistics carried out in each trial report.

22 trials are available to justify the efficacy of FHO04 at 4.0 L/ha in Poland. After the 2nd application, the disease in the untreated plot attacked from 5% to 54% of the flag leaves (Leaf 1) area, from 5% to 42% of the flag leaves minus 1 (Leaf 2) and from 6% to 10% of the flag leaves minus 2 (Leaf 3) area.

Northeast EPPO climatic zone

Across 5 efficacy trials in winter wheat, 2-3 weeks after the second application, FHO04 at 4.0 L/ha provided a high level of efficacy (97% in 2 trials on Leaf 1, 100% in 2 trials on Leaf 2 and 98% in 4 trials on Leaf 3).

FHO04 at 4.0 L/ha was similar to Amistar at 1.0 L/ha (97% *vs.* 96% in 2 trials on Leaf 1, 100% *vs.* 100% in 2 trials on Leaf 2 and 96% *vs.* 96% in 2 trials on Leaf 3). No significant difference was noted in all trials.

For information, FHO04 at 4.0 L/ha was similar to Proline at 0.8 L/ha (98% *vs.* 98% in 1 trial on Leaf 3). No significant difference was noted in this trial.

For information, FHO04 at 4.0 L/ha was similar to the program Prosaro at 1.0 L/ha at the first application and Fandango at 1.0 L/ha at the second application (100% *vs.* 100% in 1 trial on Leaf 3). No significant difference was noted in this trial.

At the last valid assessment after the second application, FHO04 at 4.0 L/ha provided a very good level of efficacy (90% in 5 trials on Leaf 1, 87% in 5 trials on Leaf 2 and 96% in 4 trials on Leaf 3).

Overall, FHO04 at 4.0 L/ha was similar to Proline at 0.8 L/ha (78% *vs.* 77% in 2 trials on Leaf 1, 72% *vs.* 73% in 2 trials on Leaf 2 and 98% *vs.* 98% in 2 trials on Leaf 3). No significant difference was noted in all trials.

FHO04 at 4.0 L/ha was similar to Amistar at 1.0 L/ha (97% *vs.* 96% in 2 trials on Leaf 1, 95% *vs.* 95% in 2 trials on Leaf 2 and 93% *vs.* 93% in 2 trials on Leaf 3). No significant difference was noted in all trials.

Even if few data are available, FHO04 at 4.0 L/ha was similar to the program Prosaro at 1.0 L/ha at the first application and Fandango at 1.0 L/ha at the second application (99% *vs.* 99% in 1 trial on Leaf 1, 99% *vs.* 99% in 1 trial on Leaf 2 and 100% *vs.* 100% in 1 trial on Leaf 3). No significant difference was noted in this trial.

Even if few data are available in winter triticale (1 trial), FHO04 at 4.0 L/ha was similar to Amistar at 1.0 L/ha (94% *vs.* 95% in 1 trial on Leaf 3, 2-3 weeks after the second application and 100% *vs.* 100% on Leaf 1, 96% *vs.* 96% on Leaf 2 and 91% *vs.* 93% on Leaf 3). No significant difference was noted in this trial.

Across 6 efficacy trials in winter rye, 2-3 weeks after the second application, FHO04 at 4.0 L/ha provided a high level of efficacy (100% in 2 trials on Leaf 1, 97% in 5 trials on Leaf 2 and 95% in 6 trials on Leaf 3).

Overall, FHO04 at 4.0 L/ha was similar to Proline at 0.8 L/ha (100% *vs.* 100% in 3 trials on Leaf 2 and 95% *vs.* 97% in 4 trials on Leaf 3). No significant difference was noted in the 3 trials on Leaf 2, and in 3 out of 4 trials on Leaf 3).

FHO04 at 4.0 L/ha was similar to Amistar at 1.0 L/ha (100% *vs.* 100% in 2 trials on Leaf 1, 94% *vs.* 96% in 2 trials on Leaf 2 and 96% *vs.* 97% in 2 trials on Leaf 3). No significant difference was noted in all trials.

At the last valid assessment after the second application, FHO04 at 4.0 L/ha provided a very good level of efficacy (100% in 6 trials on Leaf 1, 97% in 5 trials on Leaf 2 and 95% in 6 trials on Leaf 3).

Overall, FHO04 at 4.0 L/ha was similar to Proline at 0.8 L/ha (100% *vs.* 100% in 4 trials on Leaf 1, 90% *vs.* 94% in 5 trials on Leaf 2 and 91% *vs.* 94% in 4 trials on Leaf 3). No significant difference was noted in all trials on Leaf 1, in 2 out of 4 trials on Leaf 2, and in 2 out of 4 trials on Leaf 3).

FHO04 at 4.0 L/ha was similar to Amistar at 1.0 L/ha (100% *vs.* 100% in 2 trials on Leaf 1, 94% *vs.* 96% in 2 trials on Leaf 2 and 94% *vs.* 95% in 2 trials on Leaf 3). No significant difference was noted in all trials.

Finally, across 12 efficacy trials in winter cereals, 2-3 weeks after the second application, FHO04 at 4.0 L/ha provided a high level of efficacy (99% in 4 trials on Leaf 1, 98% in 7 trials on Leaf 2 and 96% in 11 trials on Leaf 3).

Overall, FHO04 at 4.0 L/ha was similar to Proline at 0.8 L/ha (100% *vs.* 100% in 3 trials on Leaf 2 and 95% *vs.* 97% in 5 trials on Leaf 3). No significant difference was noted in the 3 trials on Leaf 2, and in 4 out of 5 trials on Leaf 3).

FHO04 at 4.0 L/ha was similar to Amistar at 1.0 L/ha (99% *vs.* 98% in 4 trials on Leaf 1, 97% *vs.* 98% in 4 trials on Leaf 2 and 96% *vs.* 96% in 5 trials on Leaf 3). No significant difference was noted in all trials.
Even if few data are available, FHO04 at 4.0 L/ha was similar to the program Prosaro at 1.0 L/ha at the first application and Fandango at 1.0 L/ha at the second application (100% *vs.* 100% in 1 trial on Leaf 3). No significant difference was noted in this trial.
At the last valid assessment after the second application, FHO04 at 4.0 L/ha provided a very good level of efficacy (96% in 12 trials on Leaf 1, 90% in 12 trials on Leaf 2 and 93% in 11 trials on Leaf 3).
Overall, FHO04 at 4.0 L/ha was similar to Proline at 0.8 L/ha (92% *vs.* 92% in 6 trials on Leaf 1, 84% *vs.* 87% in 6 trials on Leaf 2 and 92% *vs.* 95% in 5 trials on Leaf 3). No significant difference was noted in all trials on Leaf 1, in 4 out of 6 trials on Leaf 2, and in 3 out of 5 trials on Leaf 3).
FHO04 at 4.0 L/ha was similar to Amistar at 1.0 L/ha (99% *vs.* 98% in 5 trials on Leaf 1, 95% *vs.* 96% in 5 trials on Leaf 2 and 93% *vs.* 94% in 5 trials on Leaf 3). No significant difference was noted in all trials.
Even if few data are available, FHO04 at 4.0 L/ha was similar to the program Prosaro at 1.0 L/ha at the first application and Fandango at 1.0 L/ha at the second application (99% *vs.* 99% in 1 trial on Leaf 1, 99% *vs.* 99% in 1 trial on Leaf 2 and 100% *vs.* 100% in 1 trial on Leaf 3). No significant difference was noted in this trial.

Border countries of Poland

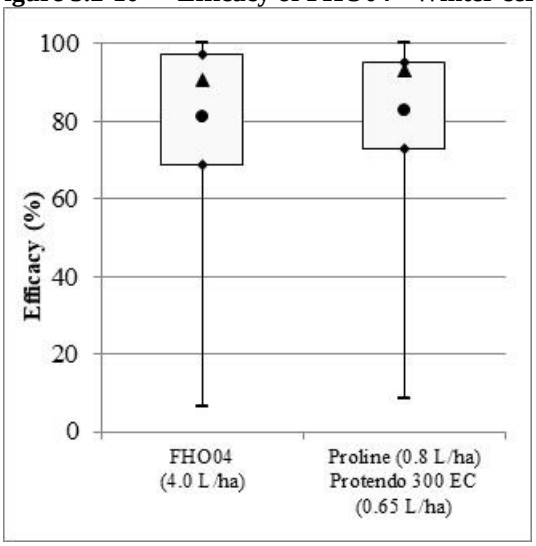
Across 5 efficacy trials in winter wheat,, at the last valid assessment after the second application, FHO04 at 4.0 L/ha provided a medium level of efficacy (85% in 5 trials on Leaf 1, and 76% in 2 trials on Leaf 2).
Overall, FHO04 at 4.0 L/ha was similar to Proline at 0.8 L/ha (85% *vs.* 85% in 5 trials on Leaf 1, and 76% *vs.* 80% in 7 trials on Leaf 2). No significant difference was noted in all trials.
In durum wheat (1 trial), FHO04 at 4.0 L/ha was inferior to Proline at 0.8 L/ha, but with low level of efficacy in the reference standard, this trial could be considered as non-valid.
Across 4 efficacy trials in winter rye, at the last valid assessment after the second application, FHO04 at 4.0 L/ha provided a good level of efficacy (80% in 3 trials on Leaf 1, and 82% in 4 trials on Leaf 2).
Overall, FHO04 at 4.0 L/ha was similar to Proline at 0.8 L/ha (80% *vs.* 79% in 3 trials on Leaf 1, and 82% *vs.* 82% in 4 trials on Leaf 2). No significant difference was noted in all trials.
Finally, across 10 efficacy trials in winter cereals, at the last valid assessment after the second application, FHO04 at 4.0 L/ha provided a medium level of efficacy (75% in 9 trials on Leaf 1, and 70% in 7 trials on Leaf 2).
Overall, FHO04 at 4.0 L/ha was similar to Proline at 0.8 L/ha (75% *vs.* 77% in 9 trials on Leaf 1, and 70% *vs.* 71% in 7 trials on Leaf 2). No significant difference was at least noted in 8 out of 9 trials on Leaf 1, and in the 7 trials on Leaf 2).

All EPPO climatic zones

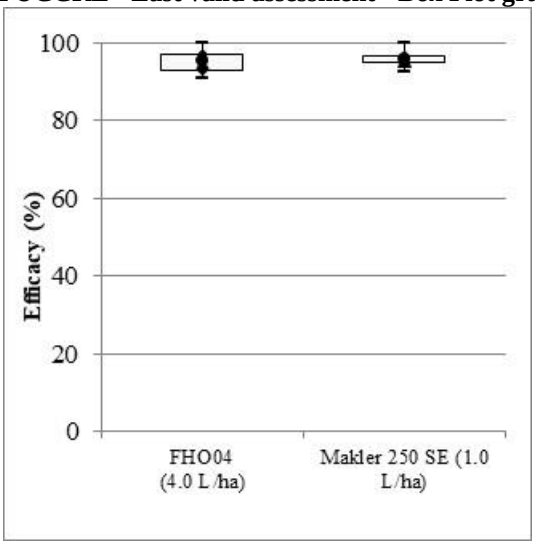
A total of 10 efficacy trials across Northeast EPPO climatic zone and border countries of Poland are summarised to confirm the efficacy of FHO04 at 4.0 L/ha in winter wheat against PUCCRE.
2-3 weeks after the second application, FHO04 at 4.0 L/ha provided a high level of efficacy (97% in 2 trials on Leaf 1, 100% in 2 trials on Leaf 2 and 98% in 4 trials on Leaf 3) similar to Proline, Amistar, or the program Prosaro / Fandango.
At the last valid assessment after the second application, FHO04 at 4.0 L/ha provided a good level of efficacy (88% in 10 trials on Leaf 1, 83% in 7 trials on Leaf 2 and 96% in 4 trials on Leaf 3) similar to Proline, Amistar, or the program Prosaro / Fandango.
Even if few data are available in winter triticale (1 trial), 2-3 weeks after the second application, FHO04 at 4.0 L/ha provided a good level of efficacy (94% in 1 trial on Leaf 1) similar to Amistar. At the last valid assessment after the second application, FHO04 at 4.0 L/ha provided a very good level of efficacy (100% on Leaf 1, 96% on Leaf 2 and 91% on Leaf 3) similar to Amistar.
In durum wheat (1 trial), FHO04 at 4.0 L/ha was inferior to Proline at 0.8 L/ha, but with low level of efficacy in the reference standard, this trial could be considered as non-valid.
A total of 10 efficacy trials across Northeast EPPO climatic zone and border countries of Poland are summarised to confirm the efficacy of FHO04 at 4.0 L/ha in winter rye against PUCCRE.

2-3 weeks after the second application, FHO04 at 4.0 L/ha provided a high level of efficacy (100% in 2 trials on Leaf 1, 97% in 5 trials on Leaf 2 and 95% in 6 trials on Leaf 3) similar to Proline, or Amistar.
At the last valid assessment after the second application, FHO04 at 4.0 L/ha provided a good level of efficacy (93% in 9 trials on Leaf 1, 87% in 4 trials on Leaf 2 and 92% in 6 trials on Leaf 3) similar to Proline, or Amistar.
Finally, a total of 22 efficacy trials across Northeast EPPO climatic zone and border countries of Poland are summarised to confirm the efficacy of FHO04 at 4.0 L/ha in cereals against PUCCRE.
2-3 weeks after the second application, FHO04 at 4.0 L/ha provided a high level of efficacy (99% in 4 trials on Leaf 1, 98% in 7 trials on Leaf 2 and 96% in 11 trials on Leaf 3) similar to Proline, Amistar, or the program Prosaro / Fandango.
At the last valid assessment after the second application, FHO04 at 4.0 L/ha provided a good level of efficacy (87% in 21 trials on Leaf 1, 83% in 19 trials on Leaf 2 and 93% in 11 trials on Leaf 3) similar to Proline, Amistar, or the program Prosaro / Fandango.
The difference between the reference standards (with more than 5 assessments) can be illustrated by box plot graphic on leaves (Leaf 1, Leaf 2 and Leaf 3) (Figure 3.2-10). Overall, FHO04 at 4.0 L/ha had at least the same level of efficacy and the same dispersion and variation between means than the tested reference standards.

Figure 3.2-10 Efficacy of FHO04 - Winter cereals - PUCCRE - Last valid assessment - Box Plot graphic



Comparison with Proline (16 trials - 33 assessments)



Comparison with Amistar (5 trials - 15 assessments)

To conclude, FHO04 at 4.0 L/ha provided efficient and reliable control of PUCCRE in cereals crops similar to all tested reference standards: Proline, or Amistar.
Based on this, the authorization of FHO04 is requested at 4.0 L /ha for the control of brown rust of cereals (*Puccinia recondita* - PUCCRE).

Comments of zRMS:

PUCCRE in wheat, rye, triticale and durum wheat*

Comparison of the test item`s efficacy, in control of PUCCRE, to mean efficacy of **all standards** in 10 trials in soft **winter wheat** (Table 3.2-28) shows statistical uniformity, standing for equivalence to the standards, of the FHO04 at its target dose rate of 4.0 L/ha. The same has been concluded from specific comparison to **standards containing prothioconazole** (Table 3.2-29), to **strobilurin references** (Table 3.2-30) and to the **two-way manufacturer`s mixtures** of: DMI x Strobilurin or DMI x DMI (Table 3.2-31): the performance of the test item on wheat is equivalent to all standards tested and to all possible values averaged between them.

Altogether 10 trial tested efficacy in control of PUCCRE in **winter rye** (Table 3.2-28). In 2 trials *per* 6 from the NE zone the efficacy difference <3% to the detriment of FHO04 was reported as statistically significant, which the zRMS has dismissed as meaningless at this stage, since neither the averaging efficacy of > 10 different standards using >4 MsoA, nor <3% differences offer any practical implications. Otherwise, including the remaining 4 Maritime trials, the performance of the test item proved equivalent to average of standards. However, comparison to **standards containing prothioconazole** (Table 3.2-29) reveals more adequately the reason underlying the previously mentioned differences: the significant difference > 4% to the detriment of the FHO04 has been reported in these same trials just in contrast to solo-prothioconazole products averaged separately from other standards. Contrastingly, no difference in performance of test item on rye was reported between the test item and **strobilurin-based standards** and between the test item and **DMI x Strobilurin** or **DMI x DMI** standards (Table 3.2-31).

Winter triticale has been represented by 1 trial only and no significant differences have been found between the test item and (1) the average of all standards, (2) the strobilurin standards, in the efficacy against PUCCRE (efficacy of FHO04 equivalent to standards).

***Winter durum wheat** data for PUCCRE (Table 3.2-28) should be rejected as invalid, if only for the standard`s averaged performance the level of 33%.

SEPTTR PUCCST
zRMS Abstract

3.2.3.4 Efficacy trials results for the control of yellow rust (*Puccinia striiformis* – PUCCST ~~PUCCSI~~)

Comments of zRMS:

For most of the time, including when referred to triticale crop, the applicant is using the EPPO code PUCCSI, standing for *Puccinia striiformis* f. sp. *tritici*, which can be only found on wheat. In the complete data set only 3 trials explicitly identify the pathogen assessed as PUCCSI, this is on winter soft wheat crop. Otherwise, and **including all the other instances** when winter wheat is meant, the testing units always code the assessed pathogen as PUCCST. The zRMS therefore can see no reason to discuss the efficacy of the test item in control of the very specific pathogen: PUCCSI, while majority of the data submitted plainly testify of another: PUCCST. The zRMS conclusions are thus concerned only with PUCCST.

The intended label claim against yellow rust (*Puccinia striiformis* – PUCCST ~~PUCCSI~~) in wheat and triticale is for ~~maximum~~ 2 applications of FHO04 at dose rate of 4.0 L/ha at BBCH 27-69.
A total of **13 valid efficacy trials** carried out in winter wheat (9 trials), durum wheat (1 trial) or triticale (3 trials) were available to confirm the efficacy of FHO04 applied at 4.0 L/ha for the control of yellow rust (*Puccinia striiformis* - PUCCST ~~PUCCSI~~). These trials were carried out **from 2020 to 2023** in the Northeast EPPO climatic zone (8 trials in Poland, and 1 trial in Latvia) and Poland border countries (4 trials in Germany) in winter cereals.
In accordance with EPPO guideline PP1/257, all data against *Puccinia striiformis* (PUCCST ~~PUCCSI~~) in winter and spring wheat, durum wheat, spelt, and triticale can be considered as comparable and merged in this section. However, an analysis by crop is also provided hereafter.
All observations are summarised in comparison to all, or to particular ~~according to the~~ reference standards: Table 3.2-32 (All reference standards), Table 3.2-33 (Proline), Table 3.2-34 (Amistar), Table 3.2-35 (Gigant), and Table 3.2-36 (Blizzard Xtra).

Table 3.2-32: Efficacy of FHO04 (4.0 L/ha) - Winter cereals – PUCCST* ~~PUCCSI~~ - Disease severity on leaves - Comparison with all references standards

Parameters	Assessment date	EPPO climatic zone	Parts	No. of trials	*Untreated*			Percentage of efficacy (%)								No. of assessments where FHO04 (4.0 L/ha) is significantly(1) >;=;< to All reference standards
								FHO04 (4.0 L/ha)				All reference standards				
								Prothioconazole + Sulphur				-				
								200+2500 g a.s./ha				-				
					Mean	*Min*	*Max*	**Mean**	Min	Max	*S.D.*	**Mean**	Min	Max	*S.D.*	
Disease severity on winter wheat	2-3 weeks after the second application	Northeast	Leaf 1	3	***5.5***	*4.5*	*6.6*	**99.3**	98.6	100.0	*0.6*	**99.3**	98.6	100.0	*0.6*	0> ; 3= ; 0<
			Leaf 2	5	***7.2***	*5.3*	*8.9*	**99.3**	97.8	100.0	*0.8*	**94.0**	73.3	100.0	*10.4*	0> ; 5= ; 0<
			Leaf 3	5	***6.9***	*5.4*	*9.3*	**91.9**	68.1	100.0	*12.0*	**95.6**	87.4	100.0	*4.7*	0> ; 4= ; 1<
		Border countries of Poland (Germany)	Leaf 1	2	***19.2***	*14.1*	*24.3*	**62.5**	28.4	96.7	*34.1*	**97.7**	97.0	98.3	*0.7*	0> ; 1= ; 1<
			Leaf 2	2	***37.4***	*8.4*	*66.5*	**64.1**	29.0	99.2	*35.1*	**99.8**	99.6	100.0	*0.2*	0> ; 1= ; 1<
			Leaf 3	1	***76.8***	-	-	**99.1**	-	-	-	**99.6**	-	-	-	0> ; 1= ; 0<
		All EPPO climatic zones	Leaf 1	5	***11.0***	*4.5*	*24.3*	**84.6**	28.4	100.0	*28.1*	**98.7**	97.0	100.0	*1.0*	0> ; 4= ; 1<
			Leaf 2	7	***15.8***	*5.3*	*66.5*	**89.3**	29.0	100.0	*24.6*	**95.7**	73.3	100.0	*9.2*	0> ; 6= ; 1<
			Leaf 3	6	***18.6***	*5.4*	*76.8*	**93.1**	68.1	100.0	*11.3*	**96.2**	87.4	100.0	*4.6*	0> ; 5= ; 1<
	Last valid assessment after the 2nd application	Northeast	Leaf 1	4	***6.0***	*5.1*	*7.4*	**96.9**	96.1	97.3	*0.5*	**91.0**	72.5	97.9	*10.7*	0> ; 4= ; 0<
			Leaf 2	7	***7.3***	*4.6*	*9.8*	**90.2**	57.4	100.0	*14.1*	**89.5**	73.3	100.0	*10.0*	0> ; 6= ; 1<
			Leaf 3	5	***7.4***	*5.7*	*9.3*	**90.9**	68.1	100.0	*11.8*	**95.1**	87.4	100.0	*5.0*	0> ; 4= ; 1<
		Border countries of Poland (Germany)	Leaf 1	3	***26.8***	*6.2*	*56.3*	**71.3**	27.6	96.8	*31.0*	**81.0**	53.0	98.0	*20.0*	1> ; 1= ; 1<
			Leaf 2	2	***39.3***	*12.2*	*66.5*	**62.2**	25.1	99.2	*37.1*	**91.6**	83.6	99.6	*8.0*	0> ; 1= ; 1<
			Leaf 3	1	***76.8***	-	-	**99.1**	-	-	-	**99.6**	-	-	-	0> ; 1= ; 0<
		All EPPO climatic zones	Leaf 1	7	***14.9***	*5.1*	*56.3*	**85.9**	27.6	97.3	*24.0*	**86.8**	53.0	98.0	*16.2*	1> ; 5= ; 1<
			Leaf 2	9	***14.4***	*4.6*	*66.5*	**84.0**	25.1	100.0	*24.4*	**90.0**	73.3	100.0	*9.6*	0> ; 7= ; 2<
			Leaf 3	6	***18.9***	*5.7*	*76.8*	**92.3**	68.1	100.0	*11.2*	**95.9**	87.4	100.0	*4.9*	0> ; 5= ; 1<
Disease severity on winter triticale	2-3 weeks after the second application	Northeast	Leaf 2	1	***4.6***	-	-	**100.0**	-	-	-	**100.0**	-	-	-	0> ; 1= ; 0<
			Leaf 3	2	***5.4***	*4.7*	*6.2*	**94.5**	94.3	94.7	*0.2*	**94.1**	93.6	94.6	*0.5*	0> ; 2= ; 0<
	Last valid assessment after the 2nd application	Northeast	Leaf 1	1	***5.3***	-	-	**92.3**	-	-	-	**95.5**	-	-	-	0> ; 1= ; 0<
			Leaf 2	2	***7.6***	*5.9*	*9.3*	**90.2**	89.3	91.1	*0.9*	**92.2**	88.9	95.5	*3.3*	0> ; 2= ; 0<
			Leaf 3	2	***7.2***	*4.7*	*9.6*	**92.8**	90.9	94.7	*1.9*	**93.9**	93.6	94.1	*0.3*	0> ; 2= ; 0<
		Border countries of Poland (Germany)	Leaf 2	1	***6.4***	-	-	**77.5**	-	-	-	**74.3**	-	-	-	0> ; 1= ; 0<
			Leaf 3	1	***20.1***	-	-	**51.8**	-	-	-	**51.1**	-	-	-	0> ; 1= ; 0<
		All EPPO climatic zones	Leaf 1	1	***5.3***	-	-	**92.3**	-	-	-	**95.5**	-	-	-	0> ; 1= ; 0<
			Leaf 2	3	***7.2***	*5.9*	*9.3*	**86.0**	77.5	91.1	*6.0*	**86.2**	74.3	95.5	*8.8*	0> ; 3= ; 0<
			Leaf 3	3	***11.5***	*4.7*	*20.1*	**79.1**	51.8	94.7	*19.4*	**79.6**	51.1	94.1	*20.2*	0> ; 3= ; 0<

Parameters	Assessment date	EPPO climatic zone	Parts	No. of trials	*Untreated*			Percentage of efficacy (%)								No. of assessments where FHO04 (4.0 L/ha) is significantly[(1)] >;=;< to All reference standards
								FHO04 (4.0 L/ha)				All reference standards				
								Prothioconazole + Sulphur				-				
								200+2500 g a.s./ha				-				
					Mean	*Min*	*Max*	**Mean**	Min	Max	*S.D.*	**Mean**	Min	Max	*S.D.*	
Disease severity on winter cereals	2-3 weeks after the second application	Northeast	Leaf 1	3	***5.5***	*4.5*	*6.6*	**99.3**	98.6	100.0	*0.6*	**99.3**	98.6	100.0	*0.6*	0> ; 3= ; 0<
			Leaf 2	6	***6.7***	*4.6*	*8.9*	**99.4**	97.8	100.0	*0.8*	**95.0**	73.3	100.0	*9.7*	0> ; 6= ; 0<
			Leaf 3	7	***6.5***	*4.7*	*9.3*	**92.7**	68.1	100.0	*10.2*	**95.2**	87.4	100.0	*4.1*	0> ; 6= ; 1<
		Border countries of Poland (Germany)	Leaf 1	2	***19.2***	*14.1*	*24.3*	**62.5**	28.4	96.7	*34.1*	**97.7**	97.0	98.3	*0.7*	0> ; 1= ; 1<
			Leaf 2	2	***37.4***	*8.4*	*66.5*	**64.1**	29.0	99.2	*35.1*	**99.8**	99.6	100.0	*0.2*	0> ; 1= ; 1<
			Leaf 3	1	***76.8***	-	-	**99.1**	-	-	-	**99.6**	-	-	-	0> ; 1= ; 0<
		All EPPO climatic zones	Leaf 1	5	***11.0***	*4.5*	*24.3*	**84.6**	28.4	100.0	*28.1*	**98.7**	97.0	100.0	*1.0*	0> ; 4= ; 1<
			Leaf 2	8	***14.4***	*4.6*	*66.5*	**90.6**	29.0	100.0	*23.3*	**96.2**	73.3	100.0	*8.7*	0> ; 7= ; 1<
			Leaf 3	8	***15.3***	*4.7*	*76.8*	**93.5**	68.1	100.0	*9.8*	**95.7**	87.4	100.0	*4.1*	0> ; 7= ; 1<
	Last valid assessment after the 2nd application	Northeast	Leaf 1	5	***5.9***	*5.1*	*7.4*	**96.0**	92.3	97.3	*1.9*	**91.9**	72.5	97.9	*9.8*	0> ; 5= ; 0<
			Leaf 2	9	***7.4***	*4.6*	*9.8*	**90.2**	57.4	100.0	*12.5*	**90.1**	73.3	100.0	*9.0*	0> ; 8= ; 1<
			Leaf 3	7	***7.3***	*4.7*	*9.6*	**91.4**	68.1	100.0	*10.1*	**94.7**	87.4	100.0	*4.3*	0> ; 6= ; 1<
		Border countries of Poland (Germany)	Leaf 1	3	***26.8***	*6.2*	*56.3*	**71.3**	27.6	96.8	*31.0*	**81.0**	53.0	98.0	*20.0*	1> ; 1= ; 1<
			Leaf 2	3	***28.4***	*6.4*	*66.5*	**67.3**	25.1	99.2	*31.1*	**85.8**	74.3	99.6	*10.5*	0> ; 2= ; 1<
			Leaf 3	2	***48.5***	*20.1*	*76.8*	**75.5**	51.8	99.1	*23.6*	**75.3**	51.1	99.6	*24.3*	0> ; 2= ; 0<
		All EPPO climatic zones	Leaf 1	8	***13.7***	*5.1*	*56.3*	**86.7**	27.6	97.3	*22.5*	**87.9**	53.0	98.0	*15.4*	1> ; 6= ; 1<
			Leaf 2	12	***12.6***	*4.6*	*66.5*	**84.5**	25.1	100.0	*21.4*	**89.0**	73.3	100.0	*9.6*	0> ; 10= ; 2<
			Leaf 3	9	***16.5***	*4.7*	*76.8*	**87.9**	51.8	100.0	*15.7*	**90.4**	51.1	100.0	*14.5*	0> ; 8= ; 1<

(1) Comparison based on statistics carried out in each trial report.

* only 3 trials in the entire dossier assess PUCCSI on TRZAW. Otherwise it is always PUCCST

Table 3.2-33: Efficacy of FHO04 (4.0 L/ha) - Winter cereals – PUCCST* ~~PUCCSI~~ - Disease severity on leaves - Comparison with Proline (0.8 L/ha) or Protendo 300 EC (0.65 L/ha)

Parameters	Assessment date	EPPO climatic zone	Parts	No. of trials	*Untreated*			Percentage of efficacy (%)								No. of assessments where FHO04 (4.0 L/ha) is significantly[(1)] >;=;< to Proline (0.8 L/ha) Protendo 300 EC (0.65 L/ha)
								FHO04 (4.0 L/ha) Prothioconazole + Sulphur 200+2500 g a.s./ha				Proline (0.8 L/ha) Protendo 300 EC (0.65 L/ha) Prothioconazole 195-200 g a.s./ha				
					Mean	*Min*	*Max*	**Mean**	Min	Max	*S.D.*	**Mean**	Min	Max	*S.D.*	
Disease severity on winter wheat	2-3 weeks after the second application	Northeast	Leaf 1	2	***6.0***	*5.4*	*6.6*	**99.0**	98.6	99.3	*0.3*	**98.9**	98.6	99.3	*0.4*	0> ; 2= ; 0<
			Leaf 2	3	***8.2***	*7.6*	*8.9*	**98.8**	97.8	99.6	*0.8*	**90.0**	73.3	98.4	*11.8*	0> ; 3= ; 0<
			Leaf 3	3	***7.5***	*6.0*	*9.3*	**87.9**	68.1	98.0	*14.0*	**94.9**	87.4	98.9	*5.3*	0> ; 2= ; 1<
		Border countries of Poland (Germany)	Leaf 1	2	***19.2***	*14.1*	*24.3*	**62.5**	28.4	96.7	*34.1*	**97.7**	97.0	98.3	*0.7*	0> ; 1= ; 1<
			Leaf 2	2	***37.4***	*8.4*	*66.5*	**64.1**	29.0	99.2	*35.1*	**99.8**	99.6	100.0	*0.2*	0> ; 1= ; 1<
			Leaf 3	1	***76.8***	-	-	**99.1**	-	-	-	**99.6**	-	-	-	0> ; 1= ; 0<
		All EPPO climatic zones	Leaf 1	4	***12.6***	*5.4*	*24.3*	**80.8**	28.4	99.3	*30.2*	**98.3**	97.0	99.3	*0.8*	0> ; 3= ; 1<
			Leaf 2	5	***19.9***	*7.6*	*66.5*	**84.9**	29.0	99.6	*28.0*	**93.9**	73.3	100.0	*10.3*	0> ; 4= ; 1<
			Leaf 3	4	***24.8***	*6.0*	*76.8*	**90.7**	68.1	99.1	*13.1*	**96.1**	87.4	99.6	*5.0*	0> ; 3= ; 1<
	Last valid assessment after the 2nd application	Northeast	Leaf 1	3	***6.3***	*5.1*	*7.4*	**96.9**	96.1	97.3	*0.5*	**89.3**	72.5	97.9	*11.9*	0> ; 3= ; 0<
			Leaf 2	5	***7.5***	*4.6*	*9.8*	**87.5**	57.4	99.6	*15.8*	**86.4**	73.3	97.8	*10.1*	0> ; 4= ; 1<
			Leaf 3	3	***7.5***	*6.0*	*9.3*	**87.9**	68.1	98.0	*14.0*	**94.9**	87.4	98.9	*5.3*	0> ; 2= ; 1<
		Border countries of Poland (Germany)	Leaf 1	2	***37.2***	*18.1*	*56.3*	**62.2**	27.6	96.8	*34.6*	**95.0**	92.1	98.0	*2.9*	0> ; 1= ; 1<
			Leaf 2	2	***39.3***	*12.2*	*66.5*	**62.2**	25.1	99.2	*37.1*	**91.6**	83.6	99.6	*8.0*	0> ; 1= ; 1<
			Leaf 3	1	***76.8***	-	-	**99.1**	-	-	-	**99.6**	-	-	-	0> ; 1= ; 0<
		All EPPO climatic zones	Leaf 1	5	***18.6***	*5.1*	*56.3*	**83.0**	27.6	97.3	*27.7*	**91.6**	72.5	98.0	*9.8*	0> ; 4= ; 1<
			Leaf 2	7	***16.6***	*4.6*	*66.5*	**80.3**	25.1	99.6	*26.5*	**87.9**	73.3	99.6	*9.8*	0> ; 5= ; 2<
			Leaf 3	4	***24.8***	*6.0*	*76.8*	**90.7**	68.1	99.1	*13.1*	**96.1**	87.4	99.6	*5.0*	0> ; 3= ; 1<
Disease severity on winter triticale	2-3 weeks after the second application	Northeast	Leaf 3	1	***4.7***	-	-	**94.7**	-	-	-	**93.6**	-	-	-	0> ; 1= ; 0<
	Last valid assessment after the 2nd application	Northeast	Leaf 2	1	***5.9***	-	-	**89.3**	-	-	-	**88.9**	-	-	-	0> ; 1= ; 0<
			Leaf 3	1	***4.7***	-	-	**94.7**	-	-	-	**93.6**	-	-	-	0> ; 1= ; 0<
		Border countries of Poland (Germany)	Leaf 2	1	***6.4***	-	-	**77.5**	-	-	-	**74.3**	-	-	-	0> ; 1= ; 0<
			Leaf 3	1	***20.1***	-	-	**51.8**	-	-	-	**51.1**	-	-	-	0> ; 1= ; 0<
		All EPPO climatic zones	Leaf 2	2	***6.2***	*5.9*	*6.4*	**83.4**	77.5	89.3	*5.9*	**81.6**	74.3	88.9	*7.3*	0> ; 2= ; 0<
			Leaf 3	2	***12.4***	*4.7*	*20.1*	**73.2**	51.8	94.7	*21.4*	**72.3**	51.1	93.6	*21.3*	0> ; 2= ; 0<

Parameters	Assessment date	EPPO climatic zone	Parts	No. of trials	*Untreated*			Percentage of efficacy (%)								No. of assessments where FHO04 (4.0 L/ha) is significantly[(1)] >;=;< to Proline (0.8 L/ha) Protendo 300 EC (0.65 L/ha)
								FHO04 (4.0 L/ha)				Proline (0.8 L/ha) Protendo 300 EC (0.65 L/ha)				
								Prothioconazole + Sulphur				Prothioconazole				
								200+2500 g a.s./ha				195-200 g a.s./ha				
					Mean	*Min*	*Max*	**Mean**	Min	Max	*S.D.*	**Mean**	Min	Max	*S.D.*	
Disease severity on winter cereals	2-3 weeks after the second application	Northeast	Leaf 1	2	***6.0***	*5.4*	*6.6*	**99.0**	98.6	99.3	*0.3*	**98.9**	98.6	99.3	*0.4*	0> ; 2= ; 0<
			Leaf 2	3	***8.2***	*7.6*	*8.9*	**98.8**	97.8	99.6	*0.8*	**90.0**	73.3	98.4	*11.8*	0> ; 3= ; 0<
			Leaf 3	4	***6.8***	*4.7*	*9.3*	**89.6**	68.1	98.0	*12.5*	**94.6**	87.4	98.9	*4.6*	0> ; 3= ; 1<
		Border countries of Poland (Germany)	Leaf 1	2	***19.2***	*14.1*	*24.3*	**62.5**	28.4	96.7	*34.1*	**97.7**	97.0	98.3	*0.7*	0> ; 1= ; 1<
			Leaf 2	2	***37.4***	*8.4*	*66.5*	**64.1**	29.0	99.2	*35.1*	**99.8**	99.6	100.0	*0.2*	0> ; 1= ; 1<
			Leaf 3	1	***76.8***	-	-	**99.1**	-	-	-	**99.6**	-	-	-	0> ; 1= ; 0<
		All EPPO climatic zones	Leaf 1	4	***12.6***	*5.4*	*24.3*	**80.8**	28.4	99.3	*30.2*	**98.3**	97.0	99.3	*0.8*	0> ; 3= ; 1<
			Leaf 2	5	***19.9***	*7.6*	*66.5*	**84.9**	29.0	99.6	*28.0*	**93.9**	73.3	100.0	*10.3*	0> ; 4= ; 1<
			Leaf 3	5	***20.8***	*4.7*	*76.8*	**91.5**	68.1	99.1	*11.8*	**95.6**	87.4	99.6	*4.6*	0> ; 4= ; 1<
	Last valid assessment after the 2nd application	Northeast	Leaf 1	3	***6.3***	*5.1*	*7.4*	**96.9**	96.1	97.3	*0.5*	**89.3**	72.5	97.9	*11.9*	0> ; 3= ; 0<
			Leaf 2	6	***7.3***	*4.6*	*9.8*	**87.8**	57.4	99.6	*14.5*	**86.8**	73.3	97.8	*9.3*	0> ; 5= ; 1<
			Leaf 3	4	***6.8***	*4.7*	*9.3*	**89.6**	68.1	98.0	*12.5*	**94.6**	87.4	98.9	*4.6*	0> ; 3= ; 1<
		Border countries of Poland (Germany)	Leaf 1	2	***37.2***	*18.1*	*56.3*	**62.2**	27.6	96.8	*34.6*	**95.0**	92.1	98.0	*2.9*	0> ; 1= ; 1<
			Leaf 2	3	***28.4***	*6.4*	*66.5*	**67.3**	25.1	99.2	*31.1*	**85.8**	74.3	99.6	*10.5*	0> ; 2= ; 1<
			Leaf 3	2	***48.5***	*20.1*	*76.8*	**75.5**	51.8	99.1	*23.6*	**75.3**	51.1	99.6	*24.3*	0> ; 2= ; 0<
		All EPPO climatic zones	Leaf 1	5	***18.6***	*5.1*	*56.3*	**83.0**	27.6	97.3	*27.7*	**91.6**	72.5	98.0	*9.8*	0> ; 4= ; 1<
			Leaf 2	9	***14.3***	*4.6*	*66.5*	**81.0**	25.1	99.6	*23.6*	**86.5**	73.3	99.6	*9.7*	0> ; 7= ; 2<
			Leaf 3	6	***20.7***	*4.7*	*76.8*	**84.9**	51.8	99.1	*18.3*	**88.2**	51.1	99.6	*17.1*	0> ; 5= ; 1<

(1) Comparison based on statistics carried out in each trial report.

* only 3 trials in the entire dossier assess PUCCSI on TRZAW. Otherwise it is always PUCCST

Table 3.2-34: Efficacy of FHO04 (4.0 L/ha) - Winter cereals - PUCCST* ~~PUCCSI~~ - Disease severity on leaves - Comparison with Makler 250 SE / Amistar (1.0 L/ha)

Parameters	Assessment date	EPPO climatic zone	Parts	No. of trials	*Untreated*			Percentage of efficacy (%)								No. of assessments where FHO04 (4.0 L/ha) is significantly(1) >;=;< to Makler 250 SE / Amistar (1.0 L/ha)
								FHO04 (4.0 L/ha)				Makler 250 SE / Amistar (1.0 L/ha)				
								Prothioconazole + Sulphur				Azoxystrobin				
								200+2500 g a.s./ha				250 g a.s./ha				
					Mean	*Min*	*Max*	**Mean**	Min	Max	*S.D.*	**Mean**	Min	Max	*S.D.*	
Disease severity on winter wheat	2-3 weeks after the second application	Northeast	Leaf 1	1	***4.5***	-	-	**100.0**	-	-	-	**100.0**	-	-	-	0> ; 1= ; 0<
			Leaf 2	1	***5.9***	-	-	**100.0**	-	-	-	**100.0**	-	-	-	0> ; 1= ; 0<
			Leaf 3	1	***6.6***	-	-	**95.8**	-	-	-	**93.2**	-	-	-	0> ; 1= ; 0<
	Last valid assessment after the 2nd application	Northeast	Leaf 1	1	***5.2***	-	-	**97.1**	-	-	-	**96.2**	-	-	-	0> ; 1= ; 0<
			Leaf 2	1	***7.8***	-	-	**93.7**	-	-	-	**94.5**	-	-	-	0> ; 1= ; 0<
			Leaf 3	1	***8.6***	-	-	**90.7**	-	-	-	**90.9**	-	-	-	0> ; 1= ; 0<
		Border countries of Poland (Germany)	Leaf 1	1	***6.2***	-	-	**89.3**	-	-	-	**53.0**	-	-	-	1> ; 0= ; 0<
		All EPPO climatic zones	Leaf 1	2	***5.7***	*5.2*	*6.2*	**93.2**	89.3	97.1	*3.9*	**74.6**	53	96.2	*21.6*	1> ; 1= ; 0<

(1) Comparison based on statistics carried out in each trial report.
* only 3 trials in the entire dossier assess PUCCSI on TRZAW. Otherwise it is always PUCCST

Table 3.2-35: Efficacy of FHO04 (4.0 L/ha) - Winter cereals - PUCCST* ~~PUCCSI~~ - Disease severity on leaves - Comparison with Gigant (1.0 L/ha)

Parameters	Assessment date	EPPO climatic zone	Parts	No. of trials	*Untreated*			Percentage of efficacy (%)								No. of assessments where FHO04 (4.0 L/ha) is significantly(1) >;=;< to Gigant (1.0 L/ha)
								FHO04 (4.0 L/ha)				Gigant (1.0 L/ha)				
								Prothioconazole + Sulphur				Prothioconazole + Isopyrazam				
								200+2500 g a.s./ha				150+125 g a.s./ha				
					Mean	*Min*	*Max*	**Mean**	Min	Max	*S.D.*	**Mean**	Min	Max	*S.D.*	
Disease severity on winter triticale	2-3 weeks after the second application	Northeast	Leaf 2	1	***4.6***	-	-	**100.0**	-	-	-	**100.0**	-	-	-	0> ; 1= ; 0<
			Leaf 3	1	***6.2***	-	-	**94.3**	-	-	-	**94.6**	-	-	-	0> ; 1= ; 0<
	Last valid assessment after the 2nd application	Northeast	Leaf 1	1	***5.3***	-	-	**92.3**	-	-	-	**95.5**	-	-	-	0> ; 1= ; 0<
			Leaf 2	1	***9.3***	-	-	**91.1**	-	-	-	**95.5**	-	-	-	0> ; 1= ; 0<
			Leaf 3	1	***9.6***	-	-	**90.9**	-	-	-	**94.1**	-	-	-	0> ; 1= ; 0<

(1) Comparison based on statistics carried out in each trial report.
* only 3 trials in the entire dossier assess PUCCSI on TRZAW. Otherwise it is always PUCCST

Table 3.2-36: Efficacy of FHO04 (4.0 L/ha) - Winter cereals - PUCCST* ~~PUCCSI~~ - Disease severity on leaves - Comparison with Blizzard Xtra (1.0 L/ha)

Parameters	Assessment date	EPPO climatic zone	Parts	No. of trials	*Untreated*			Percentage of efficacy (%)								No. of assessments where FHO04 (4.0 L/ha) is significantly(1) >;=;< to Blizzard Xtra (1.0 L/ha)
								FHO04 (4.0 L/ha)				Blizzard Xtra (1.0 L/ha)				
								Prothioconazole + Sulphur				Cyproconazole + Azoxystrobin				
								200+2500 g a.s./ha				200+80 g a.s./ha				
					Mean	*Min*	*Max*	**Mean**	Min	Max	*S.D.*	**Mean**	Min	Max	*S.D.*	
Disease severity on winter wheat	2-3 weeks after the second application	Northeast	Leaf 2	1	***5.3***	-	-	**100.0**	-	-	-	**100.0**	-	-	-	0> ; 1= ; 0<
			Leaf 3	1	***5.4***	-	-	**100.0**	-	-	-	**100.0**	-	-	-	0> ; 1= ; 0<
	Last valid assessment after the 2nd application	Northeast	Leaf 2	1	***5.6***	-	-	**100.0**	-	-	-	**100.0**	-	-	-	0> ; 1= ; 0<
			Leaf 3	1	***5.7***	-	-	**100.0**	-	-	-	**100.0**	-	-	-	0> ; 1= ; 0<

(1) Comparison based on statistics carried out in each trial report.
* only 3 trials in the entire dossier assess PUCCSI on TRZAW. Otherwise it is always PUCCST

13 trials are available to justify the efficacy of FHO04 at 4.0 L/ha in Poland. After the 2nd application, the disease in the untreated plot attacked from 5% to 56% of the flag leaves (Leaf 1) area, from 5% to 67% of the flag leaves minus 1 (Leaf 2) and from 5% to 77% of the flag leaves minus 2 (Leaf 3) area.

Northeast EPPO climatic zone

Across 7 efficacy trials in winter wheat, 2-3 weeks after the second application, FHO04 at 4.0 L/ha provided a high level of efficacy (99% in 3 trials on Leaf 1, 99% in 5 trials on Leaf 2 and 92% in 5 trials on Leaf 3).
Overall, FHO04 at 4.0 L/ha was similar to Proline at 0.8 L/ha (99% *vs.* 99% in 2 trials on Leaf 1, 99% *vs.* 90% in 3 trials on Leaf 2 and 88% *vs.* 95% in 3 trials on Leaf 3). No significant difference was noted in all trials on Leaf 1 and Leaf 2, and in 2 out of 3 trials on Leaf 3.
Even if few data are available, FHO04 at 4.0 L/ha was similar to Amistar at 1.0 L/ha (100% *vs.* 100% in 1 trial on Leaf 1 and Leaf 2 and 96% *vs.* 93% in 1 trial on Leaf 3). No significant difference was noted in the trial.
Even if few data are available, FHO04 at 4.0 L/ha was similar to Blizzard Xtra at 1.0 L/ha (100% *vs.* 100% in 1 trial on Leaf 2 and Leaf 3). No significant difference was noted in the trial.
At the last valid assessment after the second application, FHO04 at 4.0 L/ha provided a very good level of efficacy (97% in 4 trials on Leaf 1, 90% in 7 trials on Leaf 2 and 91% in 5 trials on Leaf 3).
Overall, FHO04 at 4.0 L/ha was similar to Proline at 0.8 L/ha (97% *vs.* 89% in 3 trials on Leaf 1, 88% *vs.* 86% in 5 trials on Leaf 2 and 88% *vs.* 95% in 3 trials on Leaf 3). No significant difference was noted in all trials on Leaf 1, in 4 out of 5 trials on Leaf 2, and in 2 out of 3 trials on Leaf 3).
Even if few data are available, FHO04 at 4.0 L/ha was similar to Amistar at 1.0 L/ha (97% *vs.* 96% in 1 trial on Leaf 1, 94% *vs.* 95% in 1 trial on Leaf 2 and 91% *vs.* 91% in 1 trial on Leaf 3). No significant difference was noted in the trial.
Even if few data are available, FHO04 at 4.0 L/ha was similar to Blizzard Xtra at 1.0 L/ha (100% *vs.* 100% in 1 trial on Leaf 2 and Leaf 3). No significant difference was noted in the trial.
Across 2 efficacy trials in winter triticale, 2-3 weeks after the second application, FHO04 at 4.0 L/ha provided a high level of efficacy (100% in 1 trial on Leaf 2 and 95% in 2 trials on Leaf 3).
Even if few data are available, FHO04 at 4.0 L/ha was similar to Proline at 0.8 L/ha (95% *vs.* 94% in 1 trial on Leaf 3). No significant difference was noted in the trial.
Even if few data are available, FHO04 at 4.0 L/ha was similar to Gigant at 1.0 L/ha (100% *vs.* 100% in 1 trial on Leaf 2 and 94% *vs.* 95% in 1 trial on Leaf 3). No significant difference was noted in the trial.
At the last valid assessment after the second application, FHO04 at 4.0 L/ha provided a very good level of efficacy (92% in 1 trial on Leaf 1, 90% in 2 trials on Leaf 2 and 93% in 3 trials on Leaf 3).
Even if few data are available, FHO04 at 4.0 L/ha was similar to Proline at 0.8 L/ha (89% *vs.* 89 in 1 trial on Leaf 2 and 95% *vs.* 94% in 1 trial on Leaf 3). No significant difference was noted in the trial.
Even if few data are available, FHO04 at 4.0 L/ha was similar to Gigant at 1.0 L/ha (92% vs. 96% in 1 trial on Leaf 1, 91% vs. 96% in 1 trial on Leaf 2 and 91% vs. 94% in 1 trial on Leaf 3). No significant difference was noted in the trial.
Finally, across 9 efficacy trials in winter cereals, 2-3 weeks after the second application, FHO04 at 4.0 L/ha provided a high level of efficacy (99% in 3 trials on Leaf 1, 99% in 6 trials on Leaf 2 and 93% in 7 trials on Leaf 3).
Overall, FHO04 at 4.0 L/ha was similar to Proline at 0.8 L/ha (99% *vs.* 99% in 2 trials on Leaf 1, 99% *vs.* 90% in 3 trials on Leaf 2 and 90% *vs.* 95% in 4 trials on Leaf 3). No significant difference was noted in all trials on Leaf 1 and Leaf 2, and in 3 out of 4 trials on Leaf 3.
Even if few data are available, FHO04 at 4.0 L/ha was similar to Amistar at 1.0 L/ha (100% *vs.* 100% in 1 trial on Leaf 1 and Leaf 2 and 96% *vs.* 93% in 1 trial on Leaf 3). No significant difference was noted in the trial.
Even if few data are available, FHO04 at 4.0 L/ha was similar to Gigant at 1.0 L/ha (100% *vs.* 100% in 1 trial on Leaf 2 and 94% *vs.* 95% in 1 trial on Leaf 3). No significant difference was noted in the trial.
Even if few data are available, FHO04 at 4.0 L/ha was similar to Blizzard Xtra at 1.0 L/ha (100% *vs.* 100% in 1 trial on Leaf 2 and Leaf 3). No significant difference was noted in the trial.
At the last valid assessment after the second application, FHO04 at 4.0 L/ha provided a very good level of efficacy (96% in 5 trials on Leaf 1, 90% in 9 trials on Leaf 2 and 91% in 7 trials on Leaf 3).

Overall, FHO04 at 4.0 L/ha was similar to Proline at 0.8 L/ha (97% *vs.* 89% in 3 trials on Leaf 1, 88% *vs.* 87% in 6 trials on Leaf 2 and 90% *vs.* 95% in 4 trials on Leaf 3). No significant difference was noted in all trials on Leaf 1, in 5 out of 6 trials on Leaf 2, and in 3 out of 4 trials on Leaf 3).
Even if few data are available, FHO04 at 4.0 L/ha was similar to Amistar at 1.0 L/ha (97% *vs.* 96% in 1 trial on Leaf 1, 94% *vs.* 95% in 1 trial on Leaf 2 and 91% *vs.* 91% in 1 trial on Leaf 3). No significant difference was noted in the trial.
Even if few data are available, FHO04 at 4.0 L/ha was similar to Gigant at 1.0 L/ha (92% *vs.* 96% in 1 trial on Leaf 1, 91% *vs.* 96% in 1 trial on Leaf 2 and 91% *vs.* 94% in 1 trial on Leaf 3). No significant difference was noted in the trial.
Even if few data are available, FHO04 at 4.0 L/ha was similar to Blizzard Xtra at 1.0 L/ha (100% *vs.* 100% in 1 trial on Leaf 2 and Leaf 3). No significant difference was noted in the trial.

Border countries of Poland

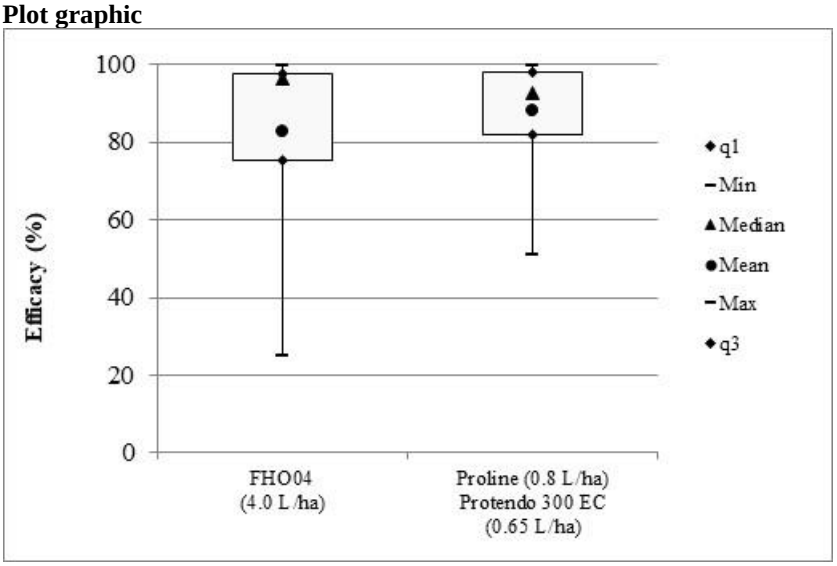
Across 3 efficacy trials in winter wheat, 2-3 weeks after the second application, FHO04 at 4.0 L/ha provided a medium level of efficacy (63% in 2 trials on Leaf 1, 64% in 2 trials on Leaf 2 and 99% in 1 trial on Leaf 3).
Overall, FHO04 at 4.0 L/ha was inferior to Proline at 0.8 L/ha (63% *vs.* 98% in 2 trials on Leaf 1, 64% *vs.* 100% in 2 trials on Leaf 2 and 99% *vs.* 100% in 1 trial on Leaf 3). However, no significant difference was noted in 1 out of 2 trials on Leaf 1 and Leaf 2, and in the trial on Leaf 3.
At the last valid assessment after the second application, FHO04 at 4.0 L/ha provided a medium level of efficacy (71% in 3 trials on Leaf 1, 62% in 2 trials on Leaf 2, and 99% in 1 trial on Leaf 3).
Overall, FHO04 at 4.0 L/ha was inferior to Proline at 0.8 L/ha (62% *vs.* 95% in 2 trials on Leaf 1, 62% *vs.* 92% in 2 trials on Leaf 2 and 99% *vs.* 100% in 1 trial on Leaf 3). However, no significant difference was noted in 1 out of 2 trials on Leaf 1 and Leaf 2, and in the trial on Leaf 3.
Even if few data are available, FHO04 at 4.0 L/ha was superior to Amistar at 1.0 L/ha (89% *vs.* 53% in 1 trial on Leaf 1). A significant difference was noted in this trial.
Even if few data are available in winter triticale (1 trial), FHO04 at 4.0 L/ha was similar to Proline at 0.8 L/ha (78% *vs.* 74% on Leaf 2 and 52% *vs.* 51% on Leaf 3). No significant difference was noted in this trial.
Finally, across 4 efficacy trials in winter cereals, 2-3 weeks after the second application, FHO04 at 4.0 L/ha provided a medium level of efficacy (63% in 2 trials on Leaf 1, 64% in 2 trials on Leaf 2 and 99% in 1 trial on Leaf 3).
Overall, FHO04 at 4.0 L/ha was inferior to Proline at 0.8 L/ha (63% *vs.* 98% in 2 trials on Leaf 1, 64% *vs.* 100% in 2 trials on Leaf 2 and 99% *vs.* 100% in 1 trial on Leaf 3). However, no significant difference was noted in 1 out of 2 trials on Leaf 1 and Leaf 2, and in the trial on Leaf 3.
At the last valid assessment after the second application, FHO04 at 4.0 L/ha provided a medium level of efficacy (71% in 3 trials on Leaf 1, 67% in 3 trials on Leaf 2, and 76% in 2 trials on Leaf 3).
Overall, FHO04 at 4.0 L/ha was inferior to Proline at 0.8 L/ha (62% *vs.* 95% in 2 trials on Leaf 1, 67% *vs.* 86% in 3 trials on Leaf 2 and 76% *vs.* 75% in 2 trials on Leaf 3). However, no significant difference was noted in 1 out of 2 trials on Leaf 1, in 2 out of 3 trials Leaf 2, and in both trials on Leaf 3.
Even if few data are available, FHO04 at 4.0 L/ha was superior to Amistar at 1.0 L/ha (89% *vs.* 53% in 1 trial on Leaf 1). A significant difference was noted in this trial.

All EPPO climatic zones

A total of 10 efficacy trials across Northeast EPPO climatic zone and border countries of Poland are summarised to confirm the efficacy of FHO04 at 4.0 L/ha in winter wheat against PUCCST ~~PUCCSI~~.
2-3 weeks after the second application, FHO04 at 4.0 L/ha provided a good level of efficacy (85% in 5 trials on Leaf 1, 89% in 7 trials on Leaf 2 and 93% in 6 trials on Leaf 3) slightly inferior to Proline and similar to Amistar, or Blizzard Xtra.
At the last valid assessment after the second application, FHO04 at 4.0 L/ha provided a good level of efficacy (86% in 7 trials on Leaf 1, 84% in 9 trials on Leaf 2 and 92% in 6 trials on Leaf 3) slightly inferior to Proline and similar to Amistar, or Blizzard Xtra.

Even if few data are available in winter triticale (3 trials), 2-3 weeks after the second application, FHO04 at 4.0 L/ha provided a good level of efficacy (100% in 1 trial on Leaf 2 and 95% in 2 trials on Leaf 3) similar to Proline, or Gigant.
At the last valid assessment after the second application, FHO04 at 4.0 L/ha provided a good level of efficacy (92% in 1 trial on Leaf 1, 86% in 3 trials on Leaf 2 and 79% in 3 trials on Leaf 3) slightly similar to Proline, or Gigant.
Finally, a total of 13 efficacy trials across Northeast EPPO climatic zone and border countries of Poland are summarised to confirm the efficacy of FHO04 at 4.0 L/ha in cereals against PUCCST ~~PUCCSI~~.
2-3 weeks after the second application, FHO04 at 4.0 L/ha provided a good level of efficacy (85% in 5 trials on Leaf 1, 91% in 8 trials on Leaf 2 and 94% in 8 trials on Leaf 3) slightly inferior to Proline and similar to Amistar, Gigant or Blizzard Xtra.
At the last valid assessment after the second application, FHO04 at 4.0 L/ha provided a good level of efficacy (87% in 8 trials on Leaf 1, 85% in 12 trials on Leaf 2 and 88% in 9 trials on Leaf 3) slightly inferior to Proline and similar to Amistar, Gigant or Blizzard Xtra.
The difference between the reference standards (with more than 5 assessments) can be illustrated by box plot graphic on leaves (Leaf 1, Leaf 2 and Leaf 3) (Figure 3.2-9). Overall, FHO04 at 4.0 L/ha had at least (or even better) the same level of efficacy and the same dispersion and variation between means than the tested reference standards.

Figure 3.2-11 Efficacy of FHO04 - Winter cereals - PUCCST ~~PUCCSI~~ - Last valid assessment - Box Plot graphic



Comparison with Proline (8 trials - 20 assessments)

To conclude, FHO04 at 4.0 L/ha provided efficient and reliable control of PUCCST ~~PUCCSI~~ in cereals crops slightly inferior to Proline and similar to Amistar, Gigant or Blizzard Xtra.
Based on this, the authorization of FHO04 is requested at 4.0 L /ha for the control of yellow rust (*Puccinia striiformis* - PUCCST ~~PUCCSI~~).

Comments of zRMS:

PUCCST on wheat (n=10) and triticale (n=3)

Data **on wheat** show equivalent efficacy between the FHO04 at 4.0 L/ha and all the averaged standards, except for efficacy in durum wheat. Excluding the durum data* the efficacy in control of PUCCST was the level of 90-99% at both the assessment terms. The control of PUCCST **on triticale** was visibly lower, 90-93% in the NE zone (n=2) and 52-78% in the Maritime zone (n=1), but in both cases efficacy of the test item was equivalent to that of averaged standards.
Comparison to **prothioconazole standards** alone reveals one instance of significantly lower performance of FHO04 compared to reference (-7%), in the NE zone, in soft winter wheat (first assessment). No such differences have been reported on triticale. Otherwise, the test item was found to perform with efficacy comparable to **strobilurin** and to **DMI + strobilurin** manufacturer`s mixture - in wheat (Tables 3.2-34, 3.2-36), and to the **DMI + SDHI** standards - in triticale (Table 3.2-35).

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* Although **durum wheat** data have not been tagged by the applicant, within the summaries presented above (*e.g.* Table 3.2-32), these data are listed in them nevertheless: the efficacy in TRZDU was 28-29% (L1, L2, first assessment), or 28-25% (L1, L2, last valid assessment).

PUCCRE SEPTTR
zRMS Abstract

3.2.3.5 Control of disease complex - Green leaf area

Attacks by pathogens reduce green leaf area and thus grain yield. Thus, the green area is a good indicator of the level of efficacy of a product. Therefore, a total of **59 valid efficacy trials** were carried out to confirm the effect of FHO04 applied at 4.0 L/ha on the green leaf area. These trials were carried out **from 2019 to 2023** in the Northeast EPPO climatic zone (28 trials in Poland, 6 trials in Latvia and 4 trials in Lithuania) and Poland border countries (20 trials in Germany and 1 trial in Czech Republic) in winter soft wheat (42 trials), winter durum wheat (1 trial), winter triticale (6 trials) and winter rye (10 trials).
Table 3.2-37 summarises the effect on the increase of the green leaf area after an application of FHO04 applied at 4.0 L/ha in winter cereal crops.

Table 3.2-37: Positive effect of FHO04 (4.0 L/ha) on the green leaf area (%) - Winter cereals

Crop Targets	Parameters	EPPO climatic zone	Parts	No. of trials	*Untreated*			Increase of green leaf area compared to Untreated (%)								Designation
								FHO04 (4.0 L/ha)				Reference standards				
								Prothioconazole + Sulphur				-				
								200+2500 g a.s./ha				-				
					Mean	*Min*	*Max*	**Mean**	Min	Max	*S.D.*	**Mean**	Min	Max	*S.D.*	
Winter wheat All diseases	Green leaf area (%)	Northeast	Plants	27	***43.6***	*0.0*	*77.5*	**30.8**	0.0	68.7	*18.5*	**30.5**	0.0	64.2	*18.4*	All reference standards
		Border countries of Poland	Plants	14	***24.8***	*0.0*	*63.8*	**41.6**	20.7	73.2	*16.6*	**40.2**	8.8	72.2	*21.3*	
		All EPPO climatic zones	Plants	41	***37.2***	*0.0*	*77.5*	**34.5**	0.0	73.2	*18.6*	**33.8**	0.0	72.2	*20.0*	
		Northeast	Plants	14	***38.7***	*0.0*	*75.3*	**25.7**	0.0	68.7	*19.8*	**25.7**	0.0	64.2	*20.6*	Proline (0.8 L/ha)
		Border countries of Poland	Plants	12	***22.5***	*0.0*	*63.8*	**42.5**	20.7	73.2	*17.7*	**40.5**	8.8	72.2	*22.7*	
		All EPPO climatic zones	Plants	26	***31.2***	*0.0*	*75.3*	**33.4**	0.0	73.2	*20.7*	**32.5**	0.0	72.2	*22.8*	
		Northeast	Plants	6	***55.3***	*46.0*	*67.1*	**41.0**	35.9	46.8	*3.2*	**41.0**	37.5	44.6	*2.6*	Amistar (1.0 L/ha)
		Northeast	Plants	3	***29.6***	*17.5*	*50.0*	**28.8**	17.5	40.0	*9.2*	**27.2**	14.3	40.0	*10.5*	Prosaro (1.0 L/ha)
		Northeast	Plants	2	***36.9***	*21.3*	*52.5*	**14.5**	7.9	21.1	*6.6*	**16.4**	14.3	18.4	*2.1*	Adexar (1.0 L/ha)
		Northeast	Plants	1	***15.0***	-	-	**13.2**	-	-	-	**8.0**	-	-	-	Opera N (1.0 L/ha)
		Northeast	Plants	1	***77.5***	-	-	**66.7**	-	-	-	**55.6**	-	-	-	Prosaro (1.0 L/ha) [A] + Fandango (1.0 L/ha) [B]
		Northeast	Plants	1	***70.0***	-	-	**50.0**	-	-	-	**54.2**	-	-	-	Amistar Xtra (1.0 L/ha)
		Border countries of Poland	Plants	2	***38.8***	*20.0*	*57.5*	**36.4**	35.3	37.5	*1.1*	**38.2**	29.4	46.9	*8.7*	Fandango (1.5 L/ha)
Winter triticale All diseases	Green leaf area (%)	Northeast	Plants	4	***55.3***	*48.5*	*60.0*	**37.0**	25.0	45.0	*7.7*	**39.9**	4.4	44.2	*9.2*	All reference standards
		Border countries of Poland	Plants	2	***27.8***	*18.0*	*37.5*	**28.5**	3.0	54.0	*25.5*	**34.0**	4.0	64.0	*30.0*	
		All EPPO climatic zones	Plants	6	***46.1***	*18.0*	*60.0*	**34.2**	3.0	54.0	*7.7*	**37.9**	4.0	64.0		
		Northeast	Plants	1	***60.0***	-	-	**25.0**	-	-	-	**25.0**	-	-	*9.2-*	Proline (0.8 L/ha)
		Border countries of Poland	Plants	2	***27.8***	*18.0*	*37.5*	**28.5**	3.0	54.0	*25.5*	**34.0**	4.0	64.0	*30.0*	
		All EPPO climatic zones	Plants	3	***38.5***	*18.0*	*60.0*	**27.3**	3.0	54.0	*20.9*	**31.0**	4.0	64.0	*24.9*	
		Northeast	Plants	2	***51.9***	*48.5*	*55.3*	**40.4**	35.7	45.0	*4.7*	**44.2**	39.8	48.6	*4.4*	Amistar (1.0 L/ha)
		Northeast	Plants	1	***57.3***	-	-	**42.4**	-	-	-	**46.2**	-	-	-	Gigant (1.0 L/ha)
Winter durum wheat All diseases	Green leaf area (%)	Border countries of Poland	Plants	1	***10.0***	-	-	**18.1**	-	-	-	**26.4**	-	-	-	Proline (0.8 L/ha)
Winter rye All diseases	Green leaf area (%)	Northeast	Plants	6	***76.0***	*71.3*	*78.8*	**46.4**	42.4	51.8	*3.3*	**50.2**	44.6	54.7	*3.4*	All reference standards
		Border countries of Poland	Plants	4	***19.7***	*5.0*	*36.3*	**41.8**	7.9	74.5	*32.6*	**46.6**	13.2	79.6	*31.5*	
		All EPPO climatic zones	Plants	10	***40.1***	*0.0*	*78.8*	**35.6**	0.0	74.5	*19.1*	**36.3**	0.0	79.6	*20.6*	
		Northeast	Plants	4	***77.2***	*75.3*	*78.8*	**47.2**	42.4	51.8	*3.8*	**51.9**	48.0	54.7	*2.4*	Proline (0.8 L/ha)
		Border countries of Poland	Plants	4	***19.7***	*5.0*	*36.3*	**41.8**	7.9	74.5	*32.6*	**46.6**	13.2	79.6	*31.5*	
		All EPPO climatic zones	Plants	8	***48.4***	*5.0*	*78.8*	**44.5**	0.0	74.5	*23.3*	**49.3**	0.0	79.6	*22.5*	
		Northeast	Plants	2	***73.6***	*71.3*	*75.8*	**44.8**	44.5	45.0	*0.3*	**46.9**	44.6	49.1	*2.3*	Amistar (1.0 L/ha)

Crop Targets	Parameters	EPPO climatic zone	Parts	No. of trials	*Untreated*			Increase of green leaf area compared to Untreated (%)								Designation
								FHO04 (4.0 L/ha)				Reference standards				
								Prothioconazole + Sulphur				-				
								200+2500 g a.s./ha				-				
					Mean	*Min*	*Max*	**Mean**	Min	Max	*S.D.*	**Mean**	Min	Max	*S.D.*	
Winter cereals All diseases	Green leaf area (%)	Northeast	Plants	38	***49.3***	*0.0*	*78.8*	**33.6**	0.0	68.7	*17.0*	**34.2**	0.0	64.2	*17.8*	All reference standards
		Border countries of Poland	Plants	21	***23.4***	*0.0*	*63.8*	**39.3**	3.0	74.5	*22.0*	**40.2**	4.0	79.6	*24.5*	
		All EPPO climatic zones	Plants	59	***40.1***	*0.0*	*78.8*	**35.6**	0.0	74.5	*19.1*	**36.3**	0.0	79.6	*20.6*	
		Northeast	Plants	19	***47.9***	*0.0*	*78.8*	**30.2**	0.0	68.7	*19.2*	**31.2**	0.0	64.2	*20.7*	Proline (0.8 L/ha)
		Border countries of Poland	Plants	19	***21.8***	*0.0*	*63.8*	**39.6**	3.0	74.5	*23.1*	**40.4**	4.0	79.6	*25.6*	
		All EPPO climatic zones	Plants	38	***34.8***	*0.0*	*78.8*	**34.9**	0.0	74.5	*21.8*	**35.8**	0.0	79.6	*23.7*	
		Northeast	Plants	10	***58.3***	*46.0*	*75.8*	**41.6**	35.7	46.8	*3.6*	**42.8**	37.5	49.1	*3.8*	Amistar (1.0 L/ha)
		Northeast	Plants	3	***29.6***	*17.5*	*50.0*	**28.8**	17.5	40.0	*9.2*	**27.2**	14.3	40.0	*10.5*	Prosaro (1.0 L/ha)
		Northeast	Plants	2	***36.9***	*21.3*	*52.5*	**14.5**	7.9	21.1	*6.6*	**16.4**	14.3	18.4	*2.1*	Adexar (1.0 L/ha)
		Northeast	Plants	1	***57.3***	-	-	**42.4**	-	-	-	**46.2**	-	-	-	Gigant (1.0 L/ha)
		Northeast	Plants	1	***15.0***	-	-	**13.2**	-	-	-	**8.0**	-	-	-	Opera N (1.0 L/ha)
		Northeast	Plants	1	***77.5***	-	-	**66.7**	-	-	-	**55.6**	-	-	-	Prosaro (1.0 L/ha) [A] + Fandango (1.0 L/ha) [B]
		Northeast	Plants	1	***70.0***	-	-	**50.0**	-	-	-	**54.2**	-	-	-	Amistar Xtra (1.0 L/ha)
		Border countries of Poland	Plants	2	***38.8***	*20.0*	*57.5*	**36.4**	35.3	37.5	*1.1*	**38.2**	29.4	46.9	*8.7*	Fandango (1.5 L/ha)

59 trials are available to show the effect on the green leaf area of FHO04 at 4.0 L/ha in Poland. The green leaf area in the untreated plot covered from 0% to 79%.

Northeast EPPO climatic zone

In winter wheat, after two applications, FHO04 at 4.0 L/ha showed an increase of 31% of green leaf area (in 27 trials), similar to Proline (26% *vs.* 26% in 14 trials), Amistar (41% *vs.* 41% in 6 trials), Prosaro (29% *vs.* 27% in 3 trials), and Adexar (15% *vs.* 16% in 3 trials), and for information in 1 trial, Opera N (13% *vs.* 8%), Amistar Xtra (50% *vs.* 54%), and better than the program Prosaro/Fandango (67% *vs.* 56% in 2 trials).
In winter triticale, after two applications, FHO04 at 4.0 L/ha showed an increase of 37% of green leaf area (in 4 trials), similar to Amistar (40% *vs.* 44% in 2 trials), and for information in 1 trial, Proline (25% *vs.* 25%) and, Gigant (42% *vs.* 46%).
In winter rye, after two applications, FHO04 at 4.0 L/ha showed an increase of 46% of green leaf area (in 6 trials), similar to Proline (47% *vs.* 52% in 4 trials), and Amistar (45% *vs.* 47% in 2 trials).
Finally, in winter cereals, after two applications, FHO04 at 4.0 L/ha showed an increase of 34% of green leaf area (in 38 trials), similar to Proline (30% *vs.* 31% in 19 trials), Amistar (42% *vs.* 43% in 10 trials), Prosaro (29% *vs.* 27% in 3 trials), and Adexar (15% *vs.* 16% in 3 trials), and for information in 1 trial, Gigant (42% *vs.* 46%), Opera N (13% *vs.* 8%), Amistar Xtra (50% *vs.* 54%), and better than the program Prosaro/Fandango (67% *vs.* 56% in 2 trials).

Border countries of Poland

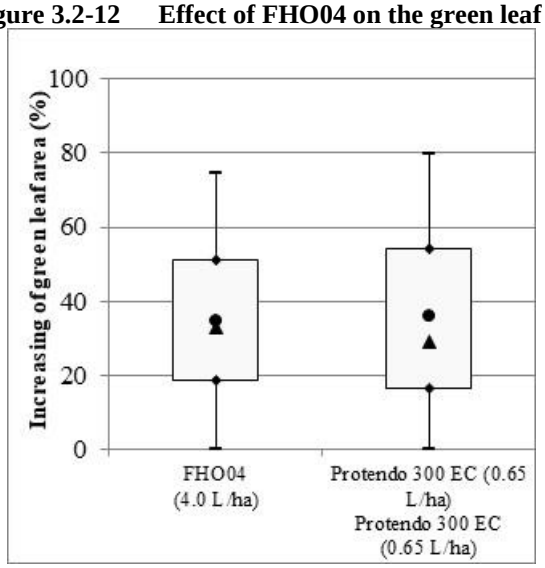
In winter wheat, after two applications, FHO04 at 4.0 L/ha showed an increase of 42% of green leaf area (in 14 trials), similar to Proline (43% *vs.* 41% in 12 trials), and Fandango (36% *vs.* 38% in 2 trials).
In winter triticale, after two applications, FHO04 at 4.0 L/ha showed an increase of 29% of green leaf area (in 2 trials), similar or slightly inferior to Proline (34%).
In winter rye, after two applications, FHO04 at 4.0 L/ha showed an increase of 42% of green leaf area (in 4 trials), similar or slightly inferior to Proline (47%).
For information, in 1 trial in durum wheat, after two applications, FHO04 at 4.0 L/ha showed an increase of 18% of green leaf area similar or slightly inferior to Proline (26%).
Finally, in winter cereals, after two applications, FHO04 at 4.0 L/ha showed an increase of 39% of green leaf area (in 21 trials), similar to Proline (40% *vs.* 40% in 19 trials), and Fandango (36% *vs.* 38% in 2 trials).

All EPPO climatic zones

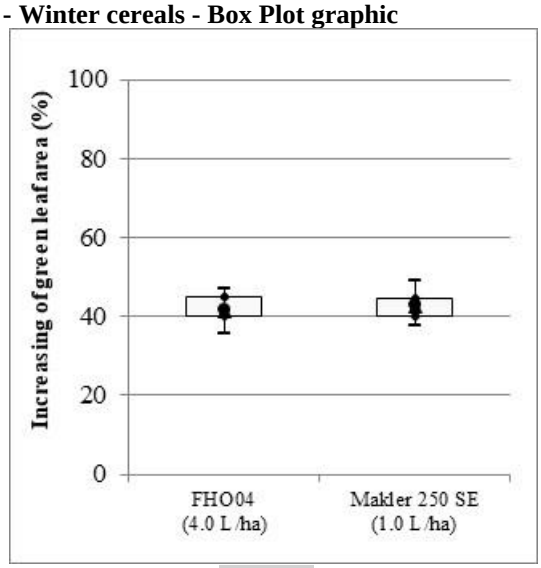
Finally, a total of 59 efficacy trials across EPPO climatic zones concerned in the Southern registration zone are summarised to show the effect on the green leaf area of FHO04 at 4.0 L/ha in winter cereals.
In winter wheat, after two applications, FHO04 at 4.0 L/ha showed an increase of 35% of green leaf area superior similar to Proline (33% *vs.* 33% in 26 trials), Amistar (41% *vs.* 41% in 6 trials), Prosaro (29% *vs.* 27% in 3 trials), and Adexar (15% *vs.* 16% in 3 trials), and for information in 1 trial, Opera N (13% *vs.* 8%), Amistar Xtra (50% *vs.* 54%), Fandango (36% *vs.* 38% in 2 trials) and better than the program Prosaro/Fandango (67% *vs.* 56% in 2 trials).
In winter triticale, after two applications, FHO04 at 4.0 L/ha showed an increase of 34% of green leaf area similar to Proline (27% *vs.* 31% in 3 trials), and Amistar (40% *vs.* 44% in 2 trials), for information in 1 trial, Gigant (42% *vs.* 46%).
For information, in 1 trial in durum wheat, after two applications, FHO04 at 4.0 L/ha showed an increase of 18% of green leaf area similar or slightly inferior to Proline (26%).
In winter rye, after two applications, FHO04 at 4.0 L/ha showed an increase of 36% of green leaf area similar to Proline (45% *vs.* 49% in 8 trials), and Amistar (45% *vs.* 47% in 2 trials).
Finally in winter cereals, two applications, FHO04 at 4.0 L/ha showed an increase of 36% of green leaf area superior similar to Proline (35% *vs.* 36% in 38 trials), Amistar (42% *vs.* 43% in 10 trials), Prosaro (29% *vs.* 27% in 3 trials), and Adexar (15% *vs.* 16% in 3 trials), and for information in 1 trial, Gigant (42% *vs.* 46%), Opera N (13% *vs.* 8%), Amistar Xtra (50% *vs.* 54%), Fandango (36% *vs.* 38% in 2 trials)and better than the program Prosaro/Fandango (67% *vs.* 56% in 2 trials). The difference between

the reference standards with at least 5 trials illustrated by box plot graphic (Figure 3.2-12). Overall, FHO04 applied at 4.0 L/ha had the same profile than Proline, or Amistar.
The difference between the reference standards with at least 5 trials illustrated by box plot graphic (Figure 3.2-12). Overall, FHO04 applied at 4.0 L/ha had the same profile than Proline, or Amistar.

Figure 3.2-12 Effect of FHO04 on the green leaf area - Winter cereals - Box Plot graphic



Comparison with Proline (38 trials)



Comparison with Amistar ~~Amsitar~~ (10 trials)

To conclude, FHO04 applied twice at 4.0 L/ha allowed to increase the green leaf area in winter cereals like the reference standards Proline or Amistar.

Comments of zRMS:

The average *per cent* increase in the GLA, across the North-Eastern and Maritime zone data **in winter wheat** was the level of 35%, compared to 34% achieved by the averaged standard reference products. The increase **on triticale** and **on rye** respectively was, on average, 34 vs 38% and 36 vs 36% (test vs standard) (Table 3.2-37).

Comments of zRMS:
trial count, trial years, extrapolation options, spring forms of the crops

Testing for the use against SEPTTR has been addressed by 31 trials in wheat (21 in the NE zone, including 12 in Poland, and 10 trials in Germany), 2 trials in triticale (DE, PL) and 1 trial in durum wheat (DE). Testing for the use against PUCCRE has been addressed by 10 trials in wheat (5 PL, 5, DE), 10 trials in rye (6 PL, 4 DE) and 1 trial in each triticale (PL) and durum wheat (DE). Testing for the use against PUCCST has been addressed by 9 valid trials in soft winter wheat (PL – 5, LV – 1, DE – 3) one trial in durum wheat (DE), and 3 trials in triticale PL – 2, DE – 1). All trials have been carried out in at least 2 growth seasons, mostly between 2020 and 2023.
Based on the data, and considering the minimum requirements set by the EPPO PP 1/226 (3) Number of efficacy trials, it is possible to authorize FHO04 for double application at 4.0 L/ha at BBCH 30-69
in control of SEPTTR, PUCCRT and PUCCST in soft winter wheat (TRZAW) and
in control of PUCCRR in winter rye (SECCW).

The issue with triticale:
SEPTTR - The applicant has submitted 2 valid trials addressing SEPTTR in triticale. The control efficacy recorded was 75% vs 84% (FHO04 vs Proline, L4) and 95% vs 96% (FHO04 vs Makler, L3), on 14 DAB at UNCK 6.5% and 5.5% PESSEV respectively. On the last valid assessment (23 or 36 DAB) the efficacy was 96-89% (FHO04) vs 97-90% (Proline or Makler respectively) (L3), or 100 vs 99.6% (FHO04 vs Proline) (L2), at UNCK 7.3-16% and 11.9% respectively. Taken the efficacy was high and comparable to standards, and considered the fact that 31 trials offer supportive data in control of SEPTTR in wheat, the zRMS considers extrapolation, of the use in control of SEPTTR, from wheat to triticale as **acceptable**.

PUCCRE - The national extrapolation table requires 1-2 trials in crop to which one extrapolates, with the emphasis on "2" in case of new products. The applicant has carried out 2 trials addressing PUCCRE. In the one considered valid - UPL Report No. F21EU-009-011-018 - the reported efficacy was 94%, compared to 95% by the strobilurin standard Makler (14 DAB, L3, PESSEV in the UNCK 5.2%). The PESSEV level on L4 and L2 on the same assessment day was <5%, making the efficacy assessments (respectively 93% and 100%, FHO04) invalid. On 28 DAB all available leaf strata had adequate PESSEV level (7.9%, 6.0%, 5.4%, L3, L2, L1 respectively) and the efficacy reported was 91 vs 93%, 96 vs 96% and 100 vs 100%, L3-L1, FHO04 vs Makler, respectively. The other trial - UPL Report No. F22EU-026-AMA-024 – had its PESSEV level of PUCCRE < 1% on 35 DAB (L3-L1) and still < 2.5% on 56 DAB (L1). However, taken into acount the high efficacy level demonstrated in F21EU-009-011-018 and the regular number of trials addressing PUCCRT in wheat (10), and addressing PUCCRR in rye (10), which can support the extrapolation, the zRMS considers extrapolation of the use in control of PUCCRE from wheat and rye to triticale as **justified**, irrespective of the new product situation.

PUCCST - The applicant has carried out 3 trials in triticale addressing PUCCST. The control efficacy observed was 92-95% (test item) compared to 94% (Proline), L4, L3 respectively, UNCK 10.4% and 4.7% respectively on 14 DAB, and it was 52-91%, 89-91% and 92% vs 51-91%, 89-91% and 92% (FHO04 L3, L2 and L1 vs Proline L3, L2, L1) (28, 32 and 35 DAB) at PESSEV UNCK 5.3-20.1% respectively. Taken into acount the regular number of trials addressing PUCCST in wheat (9), which can support the extrapolation, the zRMS considers extrapolation of the use in control of PUCCST from wheat to triticale as **acceptable**.

Spring forms of the crops:
On the contrary, extrapolation is not possible, based on the present data set, from winter forms of wheat and triticale to spring forms, as suggested by the applicant in the GAP table. The reason for that is the complete absence (n=0) of trials in spring forms, while the submission of 1-2 trials in the crop to which one extrapolates is, according to national requirements, the *sine qua non* condition making extrapolation possible.

Durum wheat, Spelt wheat
Both species are minor crops in Poland, and since the applicant is seeking authorization in these crops according to Article 51 of the Regulation (EC) No 1107/2009, the efficacy data are not required for them.

zRMS abstract

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

A total of **49 valid efficacy trials** with sufficient disease pressure were harvested to confirm the positive effect on the yield of winter soft wheat crops of FHO04 at 4.0 L/ha. These trials were carried out **from 2020 to 2023** in the Northeast EPPO climatic zone (22 trials in Poland, 4 trials in Latvia and 4 trials in Lithuania) and Poland border countries (18 trials in Germany and 1 trial in Czech Republic) in winter soft wheat (33 trials), winter durum wheat (1 trial), winter triticale (5 trials) and winter rye (10 trials).
Table 3.2-38 (All reference standards), Table 3.2-39 (Proline), Table 3.2-40 (Amistar), Table 3.2-41 (Prosaro), Table 3.2-42 (Adexar), Table 3.2-43 (Gigant) and Table 3.2-44 (Prosaro (1.0 L/ha) [A] + Fandango (1.0 L/ha) [B]) summarise the positive effect on the yield and yield parameters (TGW and HLW) of FHO04 at 4.0 L/ha in triticale crops with sufficient disease pressure (SEPTTR, PUCCRE, and/or PUCCST ~~PUCCSI~~).

Table 3.2-38: Positive effect on the yield of FHO04 (4.0 L/ha) - Winter cereals- Yield parameters - Comparison with all references standards

Crop	Parameters	EPPO climatic zone	Parts	No. of trials	*Untreated*			Percentage of Untreated (%)								No. of assessments where FHO04 (4.0 L/ha) is significantly[(1)] >;=;< to All reference standards
								FHO04 (4.0 L/ha)				All reference standards				
								Prothioconazole + Sulphur				-				
								200+2500 g a.s./ha				-				
					Mean	*Min*	*Max*	**Mean**	Min	Max	*S.D.*	**Mean**	Min	Max	*S.D.*	
TRZAW	Yield (t/ha)	Northeast	Grains	21	***6.5***	*2.2*	*10.9*	**111.2**	99.2	143.6	*9.1*	**111.5**	94.5	139.6	*10.2*	1> ; 20= ; 0<
		Border countries of Poland	Grains	12	***8.5***	*5.6*	*11.2*	**112.2**	102.7	150.9	*12.5*	**112.1**	102.3	146.4	*11.2*	0> ; 12= ; 0<
		All EPPO climatic zones	Grains	33	***7.2***	*2.2*	*11.2*	**111.6**	99.2	150.9	*10.5*	**111.7**	94.5	146.4	*10.6*	1> ; 32= ; 0<
	TGW (g)	Northeast	Grains	21	***41.6***	*35.4*	*55.3*	**102.4**	93.6	111.4	*4.0*	**103.0**	99.0	110.8	*3.6*	0> ; 21= ; 0<
		Border countries of Poland	Grains	11	***39.2***	*28.1*	*45.8*	**105.3**	99.8	118.6	*5.0*	**105.9**	97.9	119.5	*5.6*	0> ; 11= ; 0<
		All EPPO climatic zones	Grains	32	***40.8***	*28.1*	*55.3*	**103.4**	93.6	118.6	*4.6*	**104.0**	97.9	119.5	*4.6*	0> ; 32= ; 0<
	HLW (kg)	Northeast	Grains	21 20	***75.1***	*63.8*	*84.9*	**101.0**	97.0	103.8	*1.4* 1.5	**101.6** 101.5	98.9	103.3	*1.1*	0> ; 21 = ; 0<
		Border countries of Poland	Grains	12	***75.2***	*66.6*	*80.4*	**101.6**	98.5	104.4	*1.5*	**101.4**	98.8	106.1	*2.1*	0> ; 12= ; 0<
		All EPPO climatic zones	Grains	33 32	***75.1***	*63.8*	*84.9*	**101.2**	97.0	104.4	*1.5*	**101.5**	98.8	106.1	*1.5*	0> ; 33 = ; 0<
TRZDW	Yield (t/ha)	Maritime	Grains	1	***4.9***	-	-	**94.2**	-	-	-	**118.0**	-	-	-	0> ; 0= ; 1<
	HLW (kg)	Maritime	Grains	1	***73.8***	-	-	**100.6**	-	-	-	**102.0**	-	-	-	0> ; 1= ; 0<
TTLWI	Yield (t/ha)	Northeast	Grains	3	***6.4***	*5.9*	*6.9*	**109.1**	106.6	110.6	*1.8*	**110.0**	107.1	112.1	*2.1*	0> ; 3= ; 0<
		Border countries of Poland	Grains	2	***8.8***	*8.2*	*9.4*	**102.7**	100.4	105.0	*2.3*	**103.0**	101.3	104.6	*1.7*	0> ; 2= ; 0<
		All EPPO climatic zones	Grains	5	***7.4***	*5.9*	*9.4*	**106.5**	100.4	110.6	*3.7*	**107.2**	101.3	112.1	*4.0*	0> ; 5= ; 0<
	TGW (g)	Northeast	Grains	3	***41.2***	*40.0*	*42.2*	**102.6**	101.2	103.5	*1.0*	**104.3**	102.0	107.7	*2.5*	0> ; 3= ; 0<
		Border countries of Poland	Grains	2	***42.7***	*41.1*	*44.3*	**98.2**	96.8	99.6	*1.4*	**100.1**	99.1	101.1	*1.0*	0> ; 2= ; 0<
		All EPPO climatic zones	Grains	5	***41.8***	*40.0*	*44.3*	**100.8**	96.8	103.5	*2.5*	**102.6**	99.1	107.7	*2.9*	0> ; 5= ; 0<
	HLW (kg)	Northeast	Grains	3	***71.6***	*70.9*	*72.0*	**101.5**	100.0	102.2	*1.0*	**101.9**	101.2	102.4	*0.5*	0> ; 3= ; 0<
		Border countries of Poland	Grains	2	***66.4***	*64.2*	*68.6*	**100.7**	99.9	101.5	*0.8*	**101.5**	100.7	102.2	*0.8*	0> ; 2= ; 0<
		All EPPO climatic zones	Grains	5	***69.5***	*64.2*	*72.0*	**101.2**	99.9	102.2	*1.0*	**101.7**	100.7	102.4	*0.7*	0> ; 5= ; 0<
SECCW	Yield (t/ha)	Northeast	Grains	6	***5.6***	*4.9*	*6.2*	**108.8**	103.5	115.0	*4.4*	**108.7**	102.5	117.7	*5.9*	0> ; 6= ; 0<
		Border countries of Poland	Grains	4	***7.8***	*5.6*	*9.7*	**102.4**	96.5	106.2	*3.6*	**101.8**	95.7	107.4	*4.3*	0> ; 4= ; 0<
		All EPPO climatic zones	Grains	10	***6.5***	*4.9*	*9.7*	**106.3**	96.5	115.0	*5.2*	**105.9**	95.7	117.7	*6.3*	0> ; 10= ; 0<
	TGW (g)	Northeast	Grains	6	***29.1***	*27.6*	*29.9*	**103.5**	101.2	108.4	*2.5*	**104.0**	101.4	108.3	*2.5*	0> ; 6= ; 0<
		Border countries of Poland	Grains	4	***34.5***	*26.2*	*39.3*	**101.6**	99.2	104.6	*2.0*	**97.7**	91.2	101.5	*3.9*	0> ; 4= ; 0<
		All EPPO climatic zones	Grains	10	***31.3***	*26.2*	*39.3*	**102.7**	99.2	108.4	*2.5*	**101.4**	91.2	108.3	*4.4*	0> ; 10= ; 0<
	HLW (kg)	Northeast	Grains	6	***73.0***	*68.4*	*75.8*	**101.2**	100.1	102.2	*0.7*	**101.2**	100.3	102.7	*0.8*	0> ; 6= ; 0<
		Border countries of Poland	Grains	4	***72.8***	*65.6*	*78.8*	**100.8**	99.4	102.1	*1.0*	**100.2**	98.4	101.6	*1.3*	0> ; 4= ; 0<
		All EPPO climatic zones	Grains	10	***72.9***	*65.6*	*78.8*	**101.0**	99.4	102.2	*0.9*	**100.8**	98.4	102.7	*1.1*	0> ; 10= ; 0<
Winter cereals	Yield (t/ha)	Northeast	Grains	30	***6.3***	*2.2*	*10.9*	**110.5**	99.2	143.6	*8.0*	**110.8**	94.5	139.6	*9.0*	1> ; 29= ; 0<
		Border countries of Poland	Grains	19	***8.2***	*4.9*	*11.2*	**108.2**	94.2	150.9	*11.5*	**109.3**	95.7	146.4	*10.4*	0> ; 18= ; 1<
		All EPPO climatic zones	Grains	49	***7.1***	*2.2*	*11.2*	**109.6**	94.2	150.9	*9.6*	**110.2**	94.5	146.4	*9.6*	1> ; 47= ; 1<
	TGW (g)	Northeast	Grains	30	***39.1***	*27.6*	*55.3*	**102.7**	93.6	111.4	*3.6*	**103.3**	99.0	110.8	*3.3*	0> ; 30= ; 0<
		Border countries of Poland	Grains	17	***38.5***	*26.2*	*45.8*	**103.6**	96.8	118.6	*4.9*	**103.3**	91.2	119.5	*6.1*	0> ; 17= ; 0<
		All EPPO climatic zones	Grains	47	***38.9***	*26.2*	*55.3*	**103.0**	93.6	118.6	*4.1*	**103.3**	91.2	119.5	*4.5*	0> ; 47= ; 0<
	HLW (kg)	Northeast	Grains	30 29	***74.4*** 74.3	*63.8*	*84.9*	**101.0**	97.0	103.8	*1.3*	**101.5**	98.9	103.3	*1.0*	0> ; 30 29= ; 0<
		Border countries of Poland	Grains	19	***73.7***	*64.2*	*80.4*	**101.3**	98.5	104.4	*1.4*	**101.2**	98.4	106.1	*1.8*	0> ; 19= ; 0<
		All EPPO climatic zones	Grains	49 48	***74.1***	*63.8*	*84.9*	**101.2**	97.0	104.4	*1.3*	**101.4**	98.4	106.1	*1.4*	0> ; 49 = ; 0<

(1) Comparison based on statistics carried out in each trial report.

Table 3.2-39: Positive effect on the yield of FHO04 (4.0 L/ha) - Winter cereals - Yield parameters - Comparison with Proline (0.8 L/ha) or Protendo 300 EC (0.65 L/ha)

Crop	Parameters	EPPO climatic zone	Parts	No. of trials	*Untreated*			Percentage of Untreated (%)								No. of assessments where FHO04 (4.0 L/ha) is significantly[(1)] >;=;< to Proline (0.8 L/ha) Proline 275 (0.72 L/ha)
								FHO04 (4.0 L/ha)				Proline (0.8 L/ha) Proline 275 (0.72 L/ha)				
								Prothioconazole + Sulphur				Prothioconazole				
								200+2500 g a.s./ha				200 g a.s./ha				
					Mean	*Min*	*Max*	**Mean**	Min	Max	*S.D.*	**Mean**	Min	Max	*S.D.*	
TRZAW	Yield (t/ha)	Northeast	Grains	9	***8.0***	*4.2*	*10.9*	**108.7**	99.2	143.6	*12.7*	**108.5**	97.9	133.8	*9.9*	0> ; 9= ; 0<
		Border countries of Poland	Grains	12	***8.5***	*5.6*	*11.2*	**112.2**	102.7	150.9	*12.5*	**112.1**	102.3	146.4	*11.2*	0> ; 12= ; 0<
		All EPPO climatic zones	Grains	21	***8.3***	*4.2*	*11.2*	**110.7**	99.2	150.9	*12.7*	**110.5**	97.9	146.4	*10.8*	0> ; 21= ; 0<
	TGW (g)	Northeast	Grains	9	***42.4***	*35.9*	*55.3*	**101.9**	100.7	103.0	*0.7*	**101.3**	99.0	103.6	*1.6*	0> ; 9= ; 0<
		Border countries of Poland	Grains	11	***39.2***	*28.1*	*45.8*	**105.3**	99.8	118.6	*5.0*	**105.9**	97.9	119.5	*5.6*	0> ; 11= ; 0<
		All EPPO climatic zones	Grains	20	***40.6***	*28.1*	*55.3*	**103.8**	99.8	118.6	*4.1*	**103.8**	97.9	119.5	*4.9*	0> ; 20= ; 0<
	HLW (kg)	Northeast	Grains	9	***74.3***	*68.3*	*81.1*	**100.4**	97.0	103.8	*1.7*	**101.3**	99.6	103.1	*1.1*	0> ; 9= ; 0<
		Border countries of Poland	Grains	12	***75.2***	*66.6*	*80.4*	**101.6**	98.5	104.4	*1.5*	**101.4**	98.8	106.1	*2.1*	0> ; 12= ; 0<
		All EPPO climatic zones	Grains	21	***74.8***	*66.6*	*81.1*	**101.1**	97.0	104.4	*1.7*	**101.4**	98.8	106.1	*1.7*	0> ; 21= ; 0<
TRZDW	Yield (t/ha)	Maritime	Grains	1	***4.9***	-	-	**94.2**	-	-	-	**118.0**	-	-	-	0> ; 0= ; 1<
	HLW (kg)	Maritime	Grains	1	***73.8***	-	-	**100.6**	-	-	-	**102.0**	-	-	-	0> ; 1= ; 0<
TTLWI	Yield (t/ha)	Maritime	Grains	2	***8.8***	*8.2*	*9.4*	**102.7**	100.4	105.0	*2.3*	**103.0**	101.3	104.6	*1.7*	0> ; 2= ; 0<
	TGW (g)	Maritime	Grains	2	***42.7***	*41.1*	*44.3*	**98.2**	96.8	99.6	*1.4*	**100.1**	99.1	101.1	*1.0*	0> ; 2= ; 0<
	HLW (kg)	Maritime	Grains	2	***66.4***	*64.2*	*68.6*	**100.7**	99.9	101.5	*0.8*	**101.5**	100.7	102.2	*0.8*	0> ; 2= ; 0<
SECCW	Yield (t/ha)	Northeast	Grains	4	***5.9***	*5.7*	*6.2*	**106.4**	103.5	111.5	*3.1*	**105.5**	102.5	112.9	*4.3*	0> ; 4= ; 0<
		Border countries of Poland	Grains	4	***7.8***	*5.6*	*9.7*	**102.4**	96.5	106.2	*3.6*	**101.8**	95.7	107.4	*4.3*	0> ; 4= ; 0<
		All EPPO climatic zones	Grains	8	***6.9***	*5.6*	*9.7*	**104.4**	96.5	111.5	*3.9*	**103.7**	95.7	112.9	*4.7*	0> ; 8= ; 0<
	TGW (g)	Northeast	Grains	4	***29.0***	*27.6*	*29.8*	**102.7**	101.2	104.5	*1.3*	**103.5**	101.4	105.9	*1.6*	0> ; 4= ; 0<
		Border countries of Poland	Grains	4	***34.5***	*26.2*	*39.3*	**101.6**	99.2	104.6	*2.0*	**97.7**	91.2	101.5	*3.9*	0> ; 4= ; 0<
		All EPPO climatic zones	Grains	8	***31.8***	*26.2*	*39.3*	**102.2**	99.2	104.6	*1.8*	**100.6**	91.2	105.9	*4.2*	0> ; 8= ; 0<
	HLW (kg)	Northeast	Grains	4	***71.8***	*68.4*	*74.5*	**101.6**	101.3	102.2	*0.4*	**101.6**	101.0	102.7	*0.7*	0> ; 4= ; 0<
		Border countries of Poland	Grains	4	***72.8***	*65.6*	*78.8*	**100.8**	99.4	102.1	*1.0*	**100.2**	98.4	101.6	*1.3*	0> ; 4= ; 0<
		All EPPO climatic zones	Grains	8	***72.3***	*65.6*	*78.8*	**101.2**	99.4	102.2	*0.8*	**100.9**	98.4	102.7	*1.3*	0> ; 8= ; 0<
Winter cereals	Yield (t/ha)	Northeast	Grains	13	***7.3***	*4.2*	*10.9*	**108.0**	99.2	143.6	*10.8*	**107.6**	97.9	133.8	*8.7*	0> ; 13= ; 0<
		Border countries of Poland	Grains	19	***8.2***	*4.9*	*11.2*	**108.2**	94.2	150.9	*11.5*	**109.3**	95.7	146.4	*10.4*	0> ; 18= ; 1<
		All EPPO climatic zones	Grains	32	***7.8***	*4.2*	*11.2*	**108.1**	94.2	150.9	*11.2*	**108.6**	95.7	146.4	*9.8*	0> ; 31= ; 1<
	TGW (g)	Northeast	Grains	13	***38.3***	*27.6*	*55.3*	**102.2**	100.7	104.5	*1.0*	**102.0**	99.0	105.9	*1.9*	0> ; 13= ; 0<
		Border countries of Poland	Grains	17	***38.5***	*26.2*	*45.8*	**103.6**	96.8	118.6	*4.9*	**103.3**	91.2	119.5	*6.1*	0> ; 17= ; 0<
		All EPPO climatic zones	Grains	30	***38.4***	*26.2*	*55.3*	**103.0**	96.8	118.6	*3.8*	**102.7**	91.2	119.5	*4.8*	0> ; 30= ; 0<
	HLW (kg)	Northeast	Grains	13	***73.5***	*68.3*	*81.1*	**100.8**	97.0	103.8	*1.5*	**101.4**	99.6	103.1	*1.0*	0> ; 13= ; 0<
		Border countries of Poland	Grains	19	***73.7***	*64.2*	*80.4*	**101.3**	98.5	104.4	*1.4*	**101.2**	98.4	106.1	*1.8*	0> ; 19= ; 0<
		All EPPO climatic zones	Grains	32	***73.6***	*64.2*	*81.1*	**101.1**	97.0	104.4	*1.4*	**101.3**	98.4	106.1	*1.6*	0> ; 32= ; 0<

(1) Comparison based on statistics carried out in each trial report.

Table 3.2-40: Positive effect on the yield of FHO04 (4.0 L/ha) - Winter cereals - Yield parameters - Comparison with Makler 250 SE / Amistar (1.0 L/ha)

Crop	Parameters	EPPO climatic zone	Parts	No. of trials	*Untreated*			Percentage of Untreated (%)								No. of assessments where FHO04 (4.0 L/ha) is significantly[(1)] >;=;< to Makler 250 SE / Amistar (1.0 L/ha)
								FHO04 (4.0 L/ha)				Makler 250 SE / Amistar (1.0 L/ha)				
								Prothioconazole + Sulphur				Azoxystrobin				
								200+2500 g a.s./ha				250 g a.s./ha				
					Mean	*Min*	*Max*	**Mean**	Min	Max	*S.D.*	**Mean**	Min	Max	*S.D.*	
TRZAW	Yield (t/ha)	Northeast	Grains	6	***6.4***	*4.9*	*8.4*	**113.1**	110.0	122.3	*4.3*	**113.9**	111.1	119.6	*3.0*	0> ; 6= ; 0<
	TGW (g)	Northeast	Grains	6	***40.8***	*35.8*	*44.3*	**104.1**	100.8	110.0	*4.0*	**105.0**	100.5	110.6	*4.1*	0> ; 6= ; 0<
	HLW (kg)	Northeast	Grains	6	***71.1***	*63.8*	*78.6*	**101.3**	100.5	101.7	*0.4*	**101.6**	101.1	102.1	*0.4*	0> ; 6= ; 0<
TTLWI	Yield (t/ha)	Northeast	Grains	2	***6.7***	*6.5*	*6.9*	**108.3**	106.6	110.0	*1.7*	**108.9**	107.1	110.6	*1.7*	0> ; 2= ; 0<
	TGW (g)	Northeast	Grains	2	***41.8***	*41.3*	*42.2*	**102.2**	101.2	103.1	*1.0*	**102.6**	102.0	103.2	*0.6*	0> ; 2= ; 0<
	HLW (kg)	Northeast	Grains	2	***71.3***	*70.9*	*71.8*	**102.2**	102.2	102.2	*0.0*	**101.8**	101.2	102.4	*0.6*	0> ; 2= ; 0<
SECCW	Yield (t/ha)	Northeast	Grains	2	***5.1***	*4.9*	*5.2*	**113.8**	112.5	115.0	*1.3*	**115.1**	112.4	117.7	*2.7*	0> ; 2= ; 0<
	TGW (g)	Northeast	Grains	2	***29.2***	*28.5*	*29.9*	**105.0**	101.5	108.4	*3.5*	**104.9**	101.5	108.3	*3.4*	0> ; 2= ; 0<
	HLW (kg)	Northeast	Grains	2	***75.3***	*74.8*	*75.8*	**100.3**	100.1	100.4	*0.2*	**100.4**	100.3	100.5	*0.1*	0> ; 2= ; 0<
Winter cereals	Yield (t/ha)	Northeast	Grains	10	***6.2***	*4.9*	*8.4*	**112.3**	106.6	122.3	*4.0*	**113.2**	107.1	119.6	*3.5*	0> ; 10= ; 0<
	TGW (g)	Northeast	Grains	10	***38.7***	*28.5*	*44.3*	**103.9**	100.8	110.0	*3.6*	**104.5**	100.5	110.6	*3.7*	0> ; 10= ; 0<
	HLW (kg)	Northeast	Grains	10	***72.0***	*63.8*	*78.6*	**101.2**	100.1	102.2	*0.7*	**101.4**	100.3	102.4	*0.7*	0> ; 10= ; 0<

(1) Comparison based on statistics carried out in each trial report.

Table 3.2-41: Positive effect on the yield of FHO04 (4.0 L/ha) - Winter cereals - Yield parameters - Comparison with Prosaro (1.0 L/ha)

Crop	Parameters	EPPO climatic zone	Parts	No. of trials	*Untreated*			Percentage of Untreated (%)								No. of assessments where FHO04 (4.0 L/ha) is significantly[1] >;=;< to Prosaro (1.0 L/ha)
								FHO04 (4.0 L/ha)				Prosaro (1.0 L/ha)				
								Prothioconazole + Sulphur				Prothioconazole + Tebuconazole				
								200+2500 g a.s./ha				125+125 g a.s./ha				
					Mean	*Min*	*Max*	**Mean**	Min	Max	*S.D.*	**Mean**	Min	Max	*S.D.*	
TRZAW	Yield (t/ha)	Northeast	Grains	3	***3.7***	*2.2*	*4.8*	**114.8**	112.9	116.9	*1.6*	**120.5**	110.4	139.6	*13.5*	1> ; 2= ; 0<
	TGW (g)	Northeast	Grains	3	***43.1***	*41.2*	*46.9*	**100.9**	95.0	105.0	*4.3*	**103.4**	100.0	105.4	*2.4*	0> ; 3= ; 0<
	HLW (kg)	Northeast	Grains	3	***80.8***	*76.1*	*84.9*	**102.4**	101.9	102.9	*0.4*	**102.2**	101.8	102.2	*0.3*	0> ; 3= ; 0<

(1) Comparison based on statistics carried out in each trial report.

Table 3.2-42: Positive effect on the yield of FHO04 (4.0 L/ha) - Winter cereals - Yield parameters - Comparison with Adexar (1.0 L/ha)

Crop	Parameters	EPPO climatic zone	Parts	No. of trials	*Untreated*			Percentage of Untreated (%)								No. of assessments where FHO04 (4.0 L/ha) is significantly[1] >;=;< to Adexar (1.0 L/ha)
								FHO04 (4.0 L/ha)				Adexar (1.0 L/ha)				
								Prothioconazole + Sulphur				Epoxiconazole + Fluxapyroxad				
								200+2500 g a.s./ha				62.5+62.5 g a.s./ha				
					Mean	*Min*	*Max*	**Mean**	Min	Max	*S.D.*	**Mean**	Min	Max	*S.D.*	
TRZAW	Yield (t/ha)	Northeast	Grains	2	***3.8***	*3.0*	*4.6*	**113.0**	108.3	117.7	*4.7*	**106.0**	94.5	117.4	*11.5*	0> ; 2= ; 0<
	TGW (g)	Northeast	Grains	2	***38.0***	*35.4*	*40.5*	**102.5**	93.6	111.4	*8.9*	**105.2**	99.5	110.8	*5.7*	0> ; 2= ; 0<
	HLW (kg)	Northeast	Grains	2	***81.4***	*81.3*	*81.4*	**100.2**	98.9	101.5	*1.3*	**101.1**	98.9	103.3	*2.2*	0> ; 2= ; 0<

(1) Comparison based on statistics carried out in each trial report.

Table 3.2-43: Positive effect on the yield of FHO04 (4.0 L/ha) - Winter cereals - Yield parameters - Comparison with Gigant (1.0 L/ha)

Crop	Parameters	EPPO climatic zone	Parts	No. of trials	*Untreated*			Percentage of Untreated (%)								No. of assessments where FHO04 (4.0 L/ha) is significantly[1] >;=;< to Gigant (1.0 L/ha)
								FHO04 (4.0 L/ha)				Gigant (1.0 L/ha)				
								Prothioconazole + Sulphur				Prothioconazole + Isopyrazam				
								200+2500 g a.s./ha				150+125 g a.s./ha				
					Mean	*Min*	*Max*	**Mean**	Min	Max	*S.D.*	**Mean**	Min	Max	*S.D.*	
TTLWI	Yield (t/ha)	Northeast	Grains	1	***5.9***	-	-	**110.6**	-	-	-	**112.1**	-	-	-	0> ; 1= ; 0<
	TGW (g)	Northeast	Grains	1	***40.0***	-	-	**103.5**	-	-	-	**107.7**	-	-	-	0> ; 1= ; 0<
	HLW (kg)	Northeast	Grains	1	***72.0***	-	-	**100.0**	-	-	-	**102.2**	-	-	-	0> ; 1= ; 0<

(1) Comparison based on statistics carried out in each trial report.

Table 3.2-44: Positive effect on the yield of FHO04 (4.0 L/ha) - Winter cereals - Yield parameters - Comparison with Prosaro (1.0 L/ha) [A] +Fandango (1.0 L/ha) [B]

Crop	Parameters	EPPO climatic zone	Parts	No. of trials	*Untreated*			Percentage of Untreated (%)								No. of assessments where FHO04 (4.0 L/ha) is significantly[(1)] >;=;< to Prosaro (1.0 L/ha) [A] + Fandango (1.0 L/ha) [B]
								FHO04 (4.0 L/ha)				Prosaro (1.0 L/ha) [A] + Fandango (1.0 L/ha) [B]				
								Prothioconazole + Sulphur				Prothioconazole + Fluoxastrobin Prothioconazole + Tebuconazole				
								200+2500 g a.s./ha				150+150 g a.s./ha 125+125 g a.s./ha				
					Mean	*Min*	*Max*	**Mean**	Min	Max	*S.D.*	**Mean**	Min	Max	*S.D.*	
TRZAW	Yield (t/ha)	Northeast	Grains	1	***8.4***	-	-	**108.4**	-	-	-	**107.8**	-	-	-	0> ; 1= ; 0<
	TGW (g)	Northeast	Grains	1	***42.1***	-	-	**101.7**	-	-	-	**101.2**	-	-	-	0> ; 1= ; 0<
	HLW (kg)	Northeast	Grains	1	***77.8***	-	-	**102.8**	-	-	-	**102.9**	-	-	-	0> ; 1= ; 0<

(1) Comparison based on statistics carried out in each trial report.

33 trials are available to show the positive effect on the yield of FHO04 at 4.0 L/ha in winter soft wheat crops in Poland. The yield in the untreated plot was from 2.2 to 11.2 t/ha.
1 trial is available to show the positive effect on the yield of FHO04 at 4.0 L/ha in winter durum wheat crops in Poland. The yield in the untreated plot was 4.9 t/ha.
5 trials are available to show the positive effect on the yield of FHO04 at 4.0 L/ha in winter triticale crops in Poland. The yield in the untreated plot was from 5.9 to 9.4 t/ha.
10 trials are available to show the positive effect on the yield of FHO04 at 4.0 L/ha in winter rye crops in Poland. The yield in the untreated plot was from 4.9 to 9.7 t/ha.

Northeast EPPO climatic zone

About winter soft wheat, FHO04 at 4.0 L/ha showed a positive effect on the yield of 11 points compared to Untreated in 21 trials.
In detail, FHO04 at 4.0 L/ha was similar to Proline at 0.8 L/ha (109% *vs.* 109% in 9 trials). No significant difference was noted in all trials .
FHO04 at 4.0 L/ha was similar to Amistar at 1.0 L/ha (113% *vs.* 114% in 6 trials). No significant difference was noted in the 6 trials.
FHO04 at 4.0 L/ha was slightly inferior to Prosaro at 1.0 L/ha (115% *vs.* 121% in 3 trials). However, FHO04 at 4.0 L/ha was significantly superior in 1 out of 3 trials and no significant difference was noted in 2 out of 3 trials.
FHO04 at 4.0 L/ha was superior to Adexar at 1.0 L/ha (113% *vs.* 106% in 2 trials) even if no significant difference was noted in both trials.
For information, in 1 trial, FHO04 at 4.0 L/ha was similar to the program Prosaro/Fandango (108% *vs.* 108%). No significant difference was noted.
About winter triticale, FHO04 at 4.0 L/ha showed a positive effect on the yield of 9 points compared to Untreated in 3 trials.
In detail, FHO04 at 4.0 L/ha was similar to Amistar at 1.0 L/ha (108% *vs.* 109% in 2 trials). No significant difference was noted in both trials.
For information, in 1 trial, FHO04 at 4.0 L/ha was similar to Gigant at 1.0 L/ha (111% *vs.* 112%). No significant difference was noted.
About winter rye, FHO04 at 4.0 L/ha showed a positive effect on the yield of 9 points compared to Untreated in 6 trials.
In detail, FHO04 at 4.0 L/ha was similar to Proline at 0.8 L/ha (106% *vs.* 106% in 4 trials). No significant difference was noted in the 4 trials.
FHO04 at 4.0 L/ha was similar to Amistar at 1.0 L/ha (114% *vs.* 115% in 2 trials). No significant difference was noted in both trials.
Finally, FHO04 at 4.0 L/ha showed a positive effect on the yield of 11 points compared to Untreated in 30 trials on winter cereals.
In detail, FHO04 at 4.0 L/ha was similar to Proline at 0.8 L/ha (108% *vs.* 108% in 13 trials). No significant difference was noted in all trials .
Overall, the same conclusion can be noted with the other yield parameters TGW with a positive effect of 3 points in 30 trials or HLW with a positive effect of 1 point in 30 ~~29~~ trials even if the differences on these yield parameters are less pronounced.

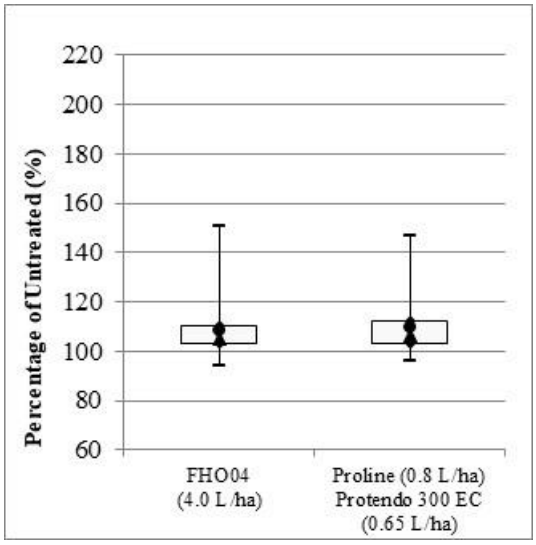
Border countries of Poland

About winter soft wheat, FHO04 at 4.0 L/ha showed a positive effect on the yield of 12 points compared to Untreated in 12 trials.
In detail, FHO04 at 4.0 L/ha was similar to Proline at 0.8 L/ha (112% *vs.* 112%). No significant difference was noted in the 12 trials .
Overall, the same conclusion can be noted with the other yield parameters TGW with a positive effect of 5 points in 11 trials or HLW with a positive effect of 2 points in 12 trials even if the differences on these yield parameters are less pronounced.
For information, in 1 trial about winter durum wheat, FHO04 at 4.0 L/ha showed a negative effect on the yield of 6 points compared to Untreated. FHO04 at 4.0 L/ha was significantly inferior to Proline at 0.8 L/ha (94% *vs.* 118%).
On the other hand, no effect was noted with the other yield parameter HLW with a slight positive effect of 1 point.
About winter triticale, FHO04 at 4.0 L/ha showed a slight positive effect on the yield of 3 points compared to Untreated in 2 trials.
About winter rye, FHO04 at 4.0 L/ha showed a slight positive effect on the yield of 2 points compared to Untreated in 4 trials. FHO04 at 4.0 L/ha was similar to Proline at 0.8 L/ha (102% *vs.* 102% in 4 trials). No significant difference was noted in the 4 trials.
Overall, the same conclusion can be noted with the other yield parameters TGW with a positive effect of 2 points in 4 trials or HLW with a positive effect of 1 point in 4 trials.
Finally, FHO04 at 4.0 L/ha showed a positive effect on the yield of 8 points compared to Untreated in 19 trials on winter cereals.
In detail, FHO04 at 4.0 L/ha was similar to Proline at 0.8 L/ha (108% *vs.* 109%). No significant difference was noted in 18 out of 19 trials .
Overall, the same conclusion can be noted with the other yield parameters TGW with a positive effect of 4 points in 17 trials or HLW with a positive effect of 1 point in 19 trials even if the differences on these yield parameters are less pronounced.

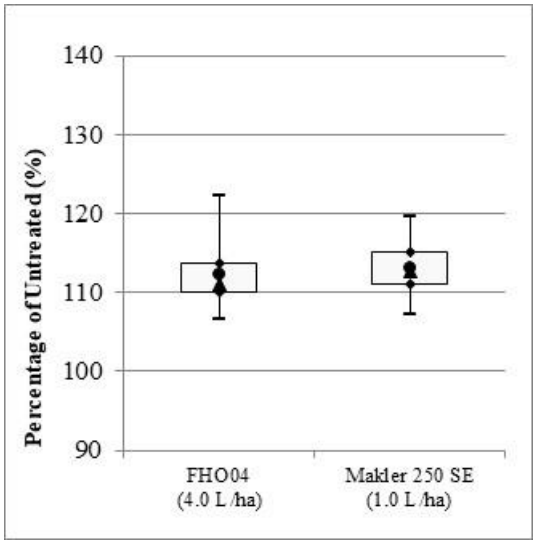
All EPPO climatic zones

A total of 33 efficacy trials across Northeast EPPO climatic zone and border countries of Poland are summarised to show the positive effect on the yield of FHO04 at 4.0 L/ha in winter soft wheat crops. FHO04 at 4.0 L/ha showed a positive effect on the yield of 12 points compared to Untreated.
A total of 5 efficacy trials across Northeast EPPO climatic zone and border countries of Poland are summarised to show the positive effect on the yield of FHO04 at 4.0 L/ha in winter triticale crops. FHO04 at 4.0 L/ha showed a positive effect on the yield of 7 points compared to Untreated.
A total of 10 efficacy trials across Northeast EPPO climatic zone and border countries of Poland are summarised to show the positive effect on the yield of FHO04 at 4.0 L/ha in winter rye crops. FHO04 at 4.0 L/ha showed a positive effect on the yield of 6 points compared to Untreated.
Finally, a total of 49 efficacy trials across Northeast EPPO climatic zone and border countries of Poland are summarised to show the positive effect on the yield of FHO04 at 4.0 L/ha in winter soft wheat crops. FHO04 at 4.0 L/ha showed a positive effect on the yield of 10 points compared to Untreated.
Overall, the same conclusion can be noted with the other yield parameters TGW with a slight positive effect of 3 points in 47 trials or HLW with a positive effect of 1 points in 49 ~~48~~ trials even if the differences on these yield parameters are less pronounced.
The difference between the reference standards with at least 5 trials can be illustrated by box plot graphic Figure 3.2-13). Overall, FHO04 at 4.0 L/ha had the same effect on the yield and the same dispersion and variation between means than Proline at 0.8 L/ha or Amistar at 1.0 L/ha.

Figure 3.2-13 Positive effect of FHO04 at 4.0 L/ha on the yield - Winter cereals - Percentage of the untreated



Comparison with Proline (35 trials)



Comparison with Amistar(10 trials)

To conclude, FHO04 at 4.0 L/ha allowed to increase the yield in winter cereals crops like the reference standards Proline at 0.8 L/ha, Amistar at 1.0 L/ha, Prosaro at 1.0 L/ha, Adexar at 1.0 L/ha or Gigant at 1.0 L/ha.

Comments of zRMS:
Yield and relevant quality indicators from efficacy trials

The submitted results from efficacy trials have demonstrated, that in majority of trials the FHO04 had visibly increased yield quantity and quality of winter cereal crops as compared to the untreated control. The results achieved for FHO04 were mostly comparable to those obtained with the use of reference products.
It can be concluded that FHO04 applied at the recommended dose rate of 4.0 L/ha has positive effect on the yield quantity and yield quality parameters (TGW, HLW) of the target winter cereal crops and does not cause any adverse effects on the yield.

zRMS Abstract

3.2.3.7 Zonal conclusion on efficacy of test product against cereals diseases

A total of **59 valid efficacy trials** carried out **from 2019 to 2023** are provided to confirm the efficacy of FHO04 at 4.0 L/ha in Poland in winter cereals. Table 3.2-45 summarises the efficacy of FHO04 to control cereals disease complex from all valid efficacy trials provided in this dRR.

Table 3.2-45: Efficacy of FHO04 - Wheat - All valid efficacy trials

Target	No. of applications	Part	No. of trials	*Untreated*		Percentage of efficacy (%) FHO04 - 4.0 L/ha Prothioconazole + Sulphur 200+2500 g a.s./ha		
				Min	*Max*	**Mean**	Min	Max
SEPTTR	2 ~~1~~	Leaf 1	16	*4.5*	*37.8*	**76.6**	24.8	100.0
		Leaf 2	27	*5.0*	*27.4*	**83.7**	19.8	100.0
		Leaf 3	25	*5.3*	*67.1*	**78.7**	12.7	100.0
PUCCRE	2 ~~1~~	Leaf 1	21	*5.2*	*54.3*	**86.7**	6.5	100.0
		Leaf 2	19	*4.7*	*41.5*	**82.5**	13.5	100.0
		Leaf 3	11	*5.9*	*9.9*	**93.1**	88.1	100.0
PUCCST ~~PUCCSI~~	2 ~~1~~	Leaf 1	8	*5.1*	*56.3*	**86.7**	27.6	97.3
		Leaf 2	12	*4.6*	*66.5*	**84.5**	25.1	100.0
		Leaf 3	9	*4.7*	*76.8*	**87.9**	51.8	100.0

In accordance with EPPO guideline PP1/257, all data against cereals disease complex (SEPTTR, PUCCRE, and/or PUCCST ~~PUCCSI~~) in winter and spring wheat, durum wheat, spelt, rye, and triticale can be considered as comparable and merged in this section. The efficacy of FHO04 was good against cereals disease complex (SEPTTR, PUCCRE, and/or PUCCST ~~PUCCSI~~).
Therefore, provided data are sufficient to justify the efficacy of FHO04 at 4.0 L/ha to control cereals disease complex.

Comments of zRMS:

The reason for this summary is unclear and the origin of the figures – uncertain. The number of applications (1) is incoherent with trial methodology presented in Table 3.2-19. Since all the conclusions important for the evaluation of the efficacy part of the dossier have already been presented and commented, the summary is redundant. For these reasons it has been ignored by zRMS.

The applicant`s response to zRMS within the commenting period:
"Table 3.2-45 provides a concise summary of efficacy of FHO04 against each disease, when considering all relevant data from EPPO-NE and EPPO-MAR supportive countries. The data is compiled from summary tables in earlier sub-sections."
The statement does not alter the outcome of the evaluation.

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

3.3.1 Introduction

FHO04 is a Suspension concentrate (SC) preparation containing 50 g/L prothioconazole and 625 g/L sulphur. This co-formulated fungicide is intended for the control of foliar diseases of cereals by foliar application method. Please refer to the GAP table in Table 3.2-3.
Prothioconazole is a broad-spectrum synthetic fungicide of the triazolinthione family of compounds with curative, preventive ~~preventative~~ and eradicative action It belongs to the Sterol Biosynthesys Inhibitors (SBI fungicides), SBI class I, group name: DMI (De-Methilation Inhibitors)~~, SBI Class I~~. SBI fungicides inhibit the C14 demethylation step within fungal sterol biosynthesis. Chemically, DMI's belong to different classes.
Sulphur is an inorganic (electrophile) element that is used as a contact fungicide providing effective control of various diseases. The Fungicide Resistance Action Committee (FRAC) classifies sulphur as a chemical with multi-site contact activity. Sulphur is classified under FRAC code M02 (FRAC, 2019).
The possibility of development of resistance or cross-resistance to the active substances contained in FHO04 is discussed thereafter based on the requirements detailed in EPPO standard PP1/213(4) '*Resistance risk analysis*'.

3.3.2 Mode of action

The biological mode of action of **prothioconazole** has been shown to be based on inhibition of the sterol biosynthesis pathway in fungi. Ergosterol is a unique component of the membrane of fungi, the inhibition of its biosynthesis makes the cell membrane rigid and leaky, so that the pathogen's hyphae cannot grow and infect the plant[6]. At the target site level prothioconazole inhibits C-14 demethylase of ergosterol precursors, which then accumulate at the expense of ergosterol and belongs to the group of compounds collectively termed as De-Methylation Inhibitors (DMIs). The molecule is classified by FRAC in group3 (G1, C-14 demethylase in sterol biosynthesis (erg11/cyp51).
Sulphur is a non-systemic multisite inorganic fungicide with a secondary biological activity against mites. It exerts its biological activity by contact, providing effective control of various diseases mainly caused by Ascomycete fungi. Sulphur inhibits the development and growth of diseases caused by fungal pathogens. Sulphur present on the leaves of treated plants acts as elemental sulphur. It can penetrate the fungal cells or mite cells due to its liposolubility and can break the cell membrane resulting in cell death due to dehydration. It also acts at the respiratory chain level (on cytochrome C) by disrupting electron transport and therefore preventing the ATP formation. The particle size of sulphur influences anti-fungal activity.

3.3.3 Mechanism and evidence of Resistance

Prothioconazole and other DMI fungicides are considered to have a medium risk of resistance development. Resistant isolates to DMI fungicides have been detected in several pathogens including amongst others *Fusarium graminearum, Microdochium nivale, Puccinia striiformis* (laboratory studies), *Blumeria graminis, Zymoseptoria tritici and Pyrenophora tritici-repentis* (field studies) in wheat and *Blumeria graminis, Pyrenophora teres* and *Rhynchosporium secalis* (field studies) in barley[6].
The primary mechanism of resistance is the accumulation of several independent mutations in the target site. Each individual mutation typically causes only a small reduction in sensitivity, and it is not observed to impact efficacy under field conditions until multiple mutations accumulate in an isolate that are large enough to cause a reduction in sensitivity. Hence, resistance to DMI's is mostly characterised by a slow, stepwise erosion of efficacy over several years of intensive use rather than by a rapid loss of control. More detailed information in this area is especially available for *Zymoseptoria tritici*, the causal agent of leaf blotch, the most important disease of wheat in Europe. A shift in sensitivity of *Zymoseptoria*

[6] http://www.frac.info/

tritici populations to DMI fungicides has been observed since their introduction in the 1980s. The decrease in sensitivity is supposed to be based on different mechanisms, such as mutations in the target gene coding for the cytochrome P450-dependent C14α- demethylase (CYP51), overexpression of the CYP51 gene and increased DMI efflux due to overexpression of transporter genes.
Sulphur being an active substance with multi-site activity, is considered as a low risk, without any significant signs of resistance development. There have been no reported cases of fungal pathogen resistance to sulphur[7].
The risk of fungal phytopathogens developing resistance to sulphur is restricted and in practice there have been no reported cases of fungal phytopathogens showing resistance to sulphur, following commercial use in the EU and worldwide for many years (EPPO, 2023[7] and FRAC, 2020[8]).

3.3.4 Cross-resistance

All DMI fungicides inhibit pathogens by interacting with the same target site (C14-demethylase) and are therefore considered to be cross-resistant with each other. Generally, compounds within each subgroup of SBI's (DMI's, amines, KRI's) are cross-resistant with other members within the same group, but there is no cross-resistance between members of different groups.
Furthermore, DMI's show no cross-resistance to any of the other major cereal fungicide classes.
In addition, while there have been cases of cross resistance to some of the target phytopathogens for FHO04, within individual fungicides groups such as DMI fungicides, there has been no cross resistance reported to other groups such as multi-site fungicides.
Consequently, FRAC Working Group guidelines recommend the use of DMI fungicides in mixture with fungicides from other groups, such as multisite fungicides.
There is no known cross-resistance between sulphur and other fungicides with multi-site contact activity such as dithio-carbamates, phthalimides, sulfamides, chloronitriles, quinones and others (FRAC codes M01 to M12).

3.3.5 Sensitivity data

No baseline or sensitivity data is provided as both active substances have been used commercially in Europe for many years.
The following information on the resistance status of various pathogens (for which control is claimed on the FHO04 label) is available, from the Sterol Biosynthesis Inhibitor (SBI) Working Group (2023 meeting), FRAC (Fungicide Resistance Action Committee)[9]:

3.3.5.1 Leaf spot (*Zymoseptoria tritici*) - Wheat

After the slight increase in the frequency of less sensitive isolates from 2002 to 2004, the situation had stabilised between 2005 and 2008. In 2009 a trend to slightly higher EC_{50} values was observed in important cereal growing areas (France, Germany, Ireland, United Kingdom), this trend has slowed down in 2010 to 2012 and was stable in 2013. 2014 sensitivity was in the same range as 2011.
In 2015 depending on the individual active ingredient and regions slight shifts of sensitivity of populations have been observed. Highest EC_{50} values were observed in areas of elevated disease pressure and sub-optimal use of azoles in spray programs (e.g. reduction of rates in comparison to the manufacturer's recommended rate and inappropriate use of effective mix-partners).
In 2016 and also in 2017 the sensitivity of the populations was overall stable on a European level with regional differences also based on different disease epidemics. In regions with lower sensitivity in 2015 the sensitivity of the populations was stable and, in some areas, even partially increased.

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7 List of Resistance Cases, EPPO Database on Resistance Cases, EPPO, Online, Link Accessed March 2023
8 List of first confirmed cases of plant pathogenic organisms resistant to disease control agents, Revised May 2020, FRAC, Online, Link
9 STEROL BIOSYNTHESIS INHIBITOR (SBI) WORKING GROUP Minutes from WG meeting on January 20th, 2023 and update on April, 20th, 2023 and September 6th, 2023 Link

In 2018 the sensitivity of the populations was overall stable on the European level. In 2019, the sensitivity of the populations was overall stable on European level with EC_{50} sensitivity values slightly higher compared to 2018 in some geographies but overall in the range of previous years.
In 2020, monitoring was carried out in Austria, Belgium, Bulgaria, Croatia, Czech Republic, Denmark, France, Germany, Hungary, Ireland, Italy, Latvia, Lithuania, Netherlands, Norway, Poland, Romania, Russia, Slovakia, Spain, Sweden, Switzerland, Turkey, Ukraine and United Kingdom. The sensitivity of populations was overall stable on European level with EC_{50} sensitivity values in the range of previous years.
Overall, as already reported in 2019, DMI EC50 sensitivity values were somewhat higher in the UK and Ireland than observed on the European continent where a gradient can be observed from North-West to South-East.
In *Zymoseptoria tritici*, different DMI haplotypes can lead to varying levels of sensitivity depending on the chemical structure. As DMIs are generally cross-resistant, resistance management approaches should be the same for all DMIs.
In 2021, monitoring was carried out in Austria, Belgium, Bulgaria, Croatia, Czech Republic, Denmark, Estonia, France, Germany, Hungary, Ireland, Italy, Latvia, Lithuania, Poland, Romania, Russia, Slovakia, Spain, Sweden, The Netherlands, Turkey, Ukraine, and the United Kingdom.
In 2022, monitoring was carried out in Austria, Belgium, Bulgaria, Czech Republic, Denmark, Estonia, France, Germany, Hungary, Ireland, Italy, Latvia, Lithuania, Netherlands, Norway, Poland, Romania, Russia, Slovakia, Spain, Sweden, Switzerland, Ukraine and United Kingdom.
Overall, the sensitivity of European populations monitored in 2022 stayed in the range observed in previous years. Slight shifts in sensitivity of populations have been observed depending on the individual active ingredient and regions. The field performance of DMI-containing fungicides was good when used according to the manufacturers and FRAC recommendations.
In regions with limited options in fungicides classes and/or a common practice of significantly reduced rates, DMIs are at higher risk and performance might be impacted.

3.3.5.2 Brown Rust (Puccinia recondita) - Wheat

Monitoring in 2020 has been carried out in Belgium, Czech Republic, Denmark, France, Germany, Hungary, Italy, Poland, Romania, Slovakia, Spain and United Kingdom. Disease pressure was low to moderate in most of the countries in Europe.
In 2022, monitoring was carried out in Belgium, France, Germany, Hungary, Italy, Lithuania, Poland, Romania, Slovakia, Spain, and the United Kingdom. Sensitivity data from 2022 for wheat brown rust showed that sensitivities were in the range of those of the last 20 years as observed in monitoring from other FRAC member companies.

3.3.5.3 Yellow Rust (Puccinia striiformis) - Wheat

In 2021, monitoring was carried out in Belgium, Czech Republic, France, Germany, Italy, Poland, and Romania. In 2022, monitoring was carried out in France, Germany, Italy, Netherlands, Poland, Romania, Spain and the United Kingdom.
The first monitoring in 2015 showed high sensitivity and low diversity, and from 2016 to 2022 a stable situation was reported

3.3.6 Use pattern

In the most intensive cereal growing regions of Europe and especially in seasons with high disease pressure up to four foliar sprays per crop are done. Treatment frequency in wheat is higher compared to rye and triticale. Selection pressure resulting from unrestricted use pattern would increase the risk of quick resistance development compared to a usage according to a management strategy. FHO04 is a Suspension concentrate (SC) preparation containing 50 g/L prothioconazole and 625 g/L sulphur. FHO04 is proposed for use cereals (wheat, triticale, rye and spelt) for the control of a range of diseases (leaf spot, brown and yellow rusts).

FHO04 is intended to be applied via foliar spray. Depending on the crop, FHO04 of formulated product (i.e. 200 and 2500 g of the actives substances prothioconazole and sulphur) per hectare are recommended with a number of applications of 2.
FHO04 is intended to be sprayed with a water volume ranging from 100 to 400 L/ha, depending on the typical local practice.

3.3.7 Resistance risk assessment of unrestricted use pattern

The development of resistance depends on three parts: the fungicide risk, the pathogen risk and the agronomic risk.

3.3.7.1 Inherent active substance associated risk

The active substances of the fungicide prothioconazole and sulphur, have been used in crop protection for many years and are well established in the market.
The DMI fungicides like prothioconazole are classified as substances exerting a **medium** risk of resistance development (FRAC, 2022).
Sulphur is considered to have a **low** risk of developing resistance (FRAC, 2022).

3.3.7.2 Inherent pathogen associated risk

The resistance risk of a pathogen to a fungicide is classified in three different situations - low, medium, and high.
In a low-risk situation, restrictions in the use pattern are not required. In a moderate-risk situation, restrictions in the use pattern should be recommended. In a high-risk situation, specific resistance management strategies are always required (including specific label warnings).
Generally, the risk increases when a pathogen undergoes many and short disease cycles per season, the dispersal through spores over time and space is high, sexual recombination is mandatory in the disease cycle, and the competitive ability of a resistant individual is at least as high as that of the wild type (in the absence of selection pressure). Furthermore, the risk is considered as high when resistance has evolved already after only a few years of fungicide product use. According to FRAC[10], the inherent resistance risk of the target pathogens for FHO04 are as follows. Pathogens not classified by FRAC are considered low risk.

Table 3.3-1: The inherent resistance risk of the target pathogens for FHO04

Pathogen	Crop	Risk	Risk class
Cereals diseases			
Zymoseptoria tritici	Wheat	Medium	2
Puccinia recondita	Wheat	Low	1
Puccinia striiformis	Wheat	Low	1

3.3.7.3 Inherent combined risk

When the pathogen risk is reported in a table with the inherent resistance risk of the DMIs group, the combined resistance risk for each pathogen/fungicide combination can be estimated as follow (FRAC, 2019)[11].

Table 3.3-2: Combined Inherent risk for each active substance contained in FHO04

Molecule Risk ↓	**Combined Risk**		
High = 3	3	6	9
Medium = 2 prothioconazole	**2**	**4**	**6**
Low=1	**1**	**2**	**3**

[10] FRAC Pathogen Risk List (September 2019), Online, Link
[11] https://www.frac.info/docs/default-source/publications/pathogen-risk/frac-pathogen-list-2019.pdf

sulphur			
Pathogen risk →	Low =1	Medium = 2	High = 3
Pathogen →	*Puccinia spp.* (PUCCSI, PUCCRE)	*Zymoseptoria tritici* (SEPTTR)	-

Combined Risk: 1 = low, 2 to 6 medium, 9 high (FRAC, 2019)

When considering the combined risk of resistance based upon the inherent risk of prothioconazole and sulphur, and the inherent risk of the target pathogens, according to the combined risk schematic developed by Brent and Hollomon and amended by FRAC[12+10] (Table 3.3-2), the combined inherent risk for prothioconazole and sulphur is **low to medium** for the diseases that a registration demand is asked. However, this table does not consider the agronomy risk.
The actual risk of resistance depends not only on the inherent risk of a particular fungicide - pathogen combination, as indicated in the previous table, but also on the conditions of fungicide use. In fact, there are important parameters of resistance risk in practice that must be included in an integral part of resistance risk assessment.
Different agronomic practices (rotation of crops, cultural techniques, irrigation, cultivars, use of alternate chemicals with different modes of action, and/or timing of application) help to reduce the selection pressure and the risk of resistance development. The agronomic risk interacts in a complex way, whereas the fungicide and pathogen risks are inherent. The agronomic risk varies depending on different factors (*e.g.* climatic conditions, agricultural practice).
The use of mitigation measures can reduce the agronomic risk, thus allowing reducing the combined risk to low levels. Table 3.3-3 reports the combined risk for FHO04 considering the agronomic risk.

Table 3.3-3: Possible combined risk for FHO04 in relation with the agronomic risk level

Molecule Risk ↓	**Combined risk**			**Agronomic Risk**
High=6	6 3 1.5	12 6 3	18 9 4.5	High =1 Medium = 0.5 Low = 0.25
Medium=4 (prothioconazole)	4 2 **1**	8 4 **2**	12 6 **3**	High =1 Medium = 0.5 **Low = 0.25**
Low=1 (sulphur)	1 0.5 **0.25**	2 1 **0.5**	3 1.5 **0.75**	High =1 Medium = 0.5 **Low = 0.25**
Pathogen risk →	Low =1	Medium = 2	High = 3	
Pathogen	*Puccinia spp.* (PUCCSI, PUCCRE)	*Zymoseptoria tritici* (SEPTTR)	-	

Highest possible value = 18 (high molecule risk high pathogen risk and high agronomy risk).

For all those diseases, fungicides are not systematically applied. Application is performed according to the disease contamination level and is based on the assessment carried out by the plant protection technical department of various partners. Those assessments are completed by modelling systems which refine the date of application. All the results are communicated to farmers through various supports. This process avoids excessive number of applications on pathogens.
According to the Good Agricultural Practices, FHO04 is applied twice in cereals in consequence the agronomic risk on those diseases is **low** and equal to 0.25. Considering the agronomic risk, the combined risk adapted to the use of FHO04 is the following one:

Table 3.3-4: Summary of the combined risk for FHO04

Pathogen	**Crop**	**Prothioconazole Combined Risk**	**Sulphur Combined Risk**
Zymoseptoria tritici (SEPTTR)	Wheat	2	0.5
Puccinia spp. (PUCCSI, PUCCRE, PUCCHD)	Wheat	1	0.25

When considering the impact of agronomic risk on the combined risk of resistance, according to the schematic modified according to Kuck, 2005[11] (where risk is rated from 0.25-18), the overall combined

[12] Brent, K and Hollomon, D, 2007, Fungicide Resistance in Crop Pathogens: How Can it Be Managed 2nd edition, Link

risk in combination with all levels of agronomic risk (0.25-1) gives an overall risk of less than 4. A score of less than 4 represents **low** overall risk, even in situations with the highest pathogen risk.
The multi-site activity of sulphur makes the development and proliferation of resistant pathogenic fungus strains unlikely, especially when the compounds are incorporated in annual spray programs, e.g. in combination with or in alternation with single-site acting fungicides that normally give a higher risk of development of resistant strains of the target pathogen as a response to repeated and unbalanced use of single-site acting fungicides.
Therefore, the risk of resistance is considered acceptable when FHO04 is used according to Good Agricultural Practices and label recommendations.

3.3.8 Management strategy

For fungicide groups or crop situations where there is a high risk of resistance development, there are specific FRAC Working Groups and/or specific recommended usage guidelines.
As sulphur has a low risk of resistance, there are no specific restrictions for their use related to resistance. However, FRAC guidance on the use of multi-site fungicides[13] does acknowledge the following advantages of their use - *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*.
In case of fungal pathogens in cereals, the relevant FRAC Working Group[14] notes that many fungicides belonging to the Azanapthalenes (FRAC code 13), Benzimidazoles (FRAC code 1), Phenylamides (FRAC code 4), Quinone inside Inhibitors (FRAC code 21), Quinone outside Inhibitors (FRAC code 11), Demethylation Inhibitors (FRAC code 3), and SDHI (FRAC code 7) groups should be used in mixture with partners with no cross resistance and/or a low risk of resistance development. A product containing sulphur which has a multi-site mode of action and low risk of resistance development is a good solution and match for this requirement.
Additionally, major points of risk reduction are the agronomic measures. In many crops, cultivation and other non-chemical methods according to Good Agricultural Practice are necessary to hold the resistance risk at a low level. This includes crop rotation, alternation of fungicides and reduced number of applications.

3.3.9 Implementation of the management strategy

Resistance management strategies are communicated in two forms: product label recommendations and practical use guidelines tailored to particular situations or regions. Label recommendations form the basis of the resistance management strategy, providing instruction relevant to all product usages, and all appropriate resistance management statements and restrictions for the relevant country.
Additionally, the FRAC guidelines for minimizing the risk of resistance developing to crop fungicides are available (eg. www.frac.info), and are communicated actively by FRAC to plant protection advisors in European countries.

3.3.10 Monitoring, reporting and reaction to changes in performance

UPL continuously monitors efficacy of its plant protection products in commercial situation at the farm level. Additionally, national official services recommending and monitoring good agricultural practices and IPM strategies also monitor the efficacy and screen any efficacy failure event suspected to be in response to a resistance problem. In case of an efficacy shift or possibility of resistance, they are investigated and if confirmed they are reported to the registration authority and appropriate action is taken.

[13] Importance of multisite fungicides in managing pathogen resistance, FRAC, June 2018, Online, Link
[14] Summary of Fungicide Resistance Management Guidelines by FRAC Working Group (WG) and Expert Fora (EF) relevant for Cereals and Corn, Online, Link

As a summary, the risk of resistance of ~~to~~ low to medium is considered acceptable when the product is used according to the GAPs and taking into account the proposed management strategies.

Comments of zRMS:
Risk of resistance

FHO04 is a new fungicide containing a mixture of two known active substances: prothioconazole (chemical group: triazoles, group name: DMI-fungicides, SBI: Class I; FRAC code: 3) and sulphur (chemical group: multi-site contact activity, group name: inorganic (electrophiles), FRAC code: M02). The mode of action of prothioconazole is inhibiting the ergosterol synthesis by the inhibition of the steroid reduction and the target site is C^{14}-demethylase in sterol biosynthesis. The most acknowledged mode of action of sulphur is disrupting electron transport while acting on cytochrome C, therefore preventing ATP formation. However, sulphur is also commonly classified as one of multi-site actives, the classification reflecting some knowledge of possible other sites of action and, at the same time, some level of uncertainty as to the precise identity of these other sites.
As the result, the FHO04 contains active substances with different modes of action with no documented cross resistance in the control of pathogens.
The resistance risk of prothioconazole belonging to DMI-fungicides has been defined by FRAC as medium, irrespective of the well-known properties of the entire DMI fungicide class, namely their ability to induce periodical fluctuations in susceptibility of the exposed pathogens. Sulphur, on the other hand, as contact fungicide, affects multiple biochemical sites in fungi and is consequently classified by FRAC as low-risk of resistance an active. Since multi-site fungicides are considered important components to the fungicide resistance management strategy, the combination of sulphur with other, medium-risk active, should be considered **appropriate**, from the resistance management perspective. Until now, there has been no product co-formulating prothioconazole with sulphur on the Polish market.

According to the FRAC Pathogen Risk List (revised in September 2019), *Zymoseptoria tritici* and *Puccinia sp. (P. striiformis, P. triticina P. recondita)* are defined as medium and low risk of resistance pathogens, respectively.
FRAC List of the first confirmed cases of plant pathogenic organisms resistant to disease control agents (revised in May 2020) includes the following cases of the cereal pathogens resistance to DMI-fungicides:

- ***Zymoseptoria tritici* (on wheat),**
- ***Puccinia striiformis* (on wheat),**
- *Erysiphe graminis (on wheat, barley),*
- *Fusarium spp (on wheat),*
- *Pseudocercosporella herpotrichoides = Oculimacula yallundae (on wheat),*
- *Pyrenophora teres (on barley),*
- *Pyrenophora tritici-repentis (on wheat),*
- *Rhynchosporium secalis (on barley),*
- *Ustilago avenae (on oat).*

No cases of target pathogen resistance have been described for M02 (including sulphur) fungicides by FRAC.

According to the results from monitoring studies reported by FRAC Sterol Biosynthesis Inhibitor (SBI) Working Group (Minutes from WG meeting on January 19st, 2024):

- For Wheat/ *Zymoseptoria tritici*: In 2023, in general, field performance of DMI-containing fungicides was good when used according to the manufacturers and FRAC recommendation. Overall, the sensitivity of European populations monitored in 2023 stayed in the range observed in previous years. Slight shifts in sensitivity of populations have been observed depending on the individual active ingredient and regions. In 2023, monitoring was carried out in Austria, Belgium, Bulgaria, Croatia, Czech Republic, Denmark, Estonia, France, Germany, Hungary, Ireland, Italy, Latvia, Lithuania, Netherlands, Norway, Poland, Romania, Russia, Slovakia, Spain, Sweden, Switzerland, Ukraine, and United Kingdom.
- For Wheat/ *Puccinia triticina*: In 2023 monitoring was carried out in France and Germany (limited number of samples). Data from 2023 for wheat brown rust showed that sensitivities were in the range of those of the last 20 years,
- For Wheat/ *Puccinia striiformis*: In 2023 monitoring was carried out in France, Germany, Poland, and the United Kingdom. The first monitoring in 2015 showed high sensitivity and low diversity, and from 2016 to 2023 a stable situation was reported.

The combined inherent risk for prothioconazole and sulphur has been therefore determined as low to medium for the target diseases. After including also the agronomic risk in the resistance risk assessment, the overall risk of resistance has been determined as low.
Nevertheless, based on the submitted data and in order to avoid possible development of resistance, the following **standard** resistance management tools are recommended to be included in the label of FHO04:

- *Use FHO04 in accordance with label recommendations, i.e. observing the maximum number applications per growth season, and the recommended dose rate,*
- *Include, in the adopted plant protection program, fungicides containing active substances from other groups according to the FRAC classification, with different modes of action (use the products alternately or in a tank mixture),*
- *Use FHO04 mainly preventively i.e. at the beginning of primary or secondary infection periods,*
- *Include, in the adopted disease plant protection program, control methods other than chemical, in accordance with the principles of integrated plant protection, e.g. cultivation of resistant varieties and the appropriate crop rotation.*

zRMS Abstract

3.4 Adverse effects on treated crops (KCP 6.4)

3.4.1 Phytotoxicity to host crop (KCP 6.4.1)

3.4.1.1 Material and Methods

Material and Methods used in efficacy trials are given within Section 3.2.3.1 and not repeated here.

3.4.1.2 Crop safety results in winter soft wheat

The crop sensitivity was assessed in **59 efficacy trials** performed from **2019 to 2023** (presented in Section 3.2.3) in winter wheat. All trials were carried out by testing facilities officially recognised according to Good Experimental Practice (GEP). Phytotoxicity assessments are summarised in Table 3.4-1.

Table 3.4-1: Selectivity of FHO04 (4.0 L/ha) – Winter soft wheat (TRZAW) - Efficacy trials

Number of trials with…		FHO04 - 4.0 L/ha Prothioconazole + Sulphur 200+2500 g a.s./ha	Reference standard
Maximum of phytotoxicity recorded during the trials	0%	59	58
	>0 - 4.9%	0	1
	5 - 9.9%	0	0
	10 - 14.9%	0	0
	15% and more	0	0
Level of symptoms at the last assessments	0%	59	59
	>0 - 4.9%	0	0
	5 - 9.9%	0	0
	10 - 14.9%	0	0
	15% and more	0	0

No phytotoxicity symptoms caused by FHO04 at the proposed dose of 4.0 L/ha were recorded in any of the ~~all~~ efficacy trials. The potential impact of variety on the occurrence of phytotoxicity was observed in 35 different varieties of winter soft wheat (Table 3.4-2).

Table 3.4-2: Phytotoxicity assessments of FHO04 - Varieties tested in efficacy trials

Crop	No of trials	No of varieties	Variety names (No of trials)
Winter soft wheat (TRZAW)	59	35	*Apostel (2), Arkadia (2), Arktis (1), Artist (2), Belissa (2), Benchmark(2), Boregar (1), Bosporus (1), Bussard (1), Comandor (1), Dagmar (1), Dakotana (1), Edvins (3), Euforia (1), Flippen (1), Fredis (2), Genius (1), Informer (1), Inspiration (1), Janne (1), JB Asano (1), Joker (1), KWS Donovan (2), Medalistka (1), Ohio (1), Olivin (1), Opal (1), Opoka (1), ~~Ostroga (1),~~ Patras (4), Ponticus (1), RGT Bilanz (1), RGT Reform (3), Skagen (11), Tytanika (1), Zeppelin (1)*

Therefore, no effect is expected in wheat crops if FHO04 is applied at the maximum requested rate of 4.0 L/ha according to the Good Agricultural Practices and label recommendations.

3.4.1.3 Crop safety results in winter durum wheat

The crop sensitivity was assessed in **2 efficacy trials** performed from **2019 to 2023** (presented in Section 3.2.3) in winter wheat. All trials were carried out by testing facilities officially recognised according to Good Experimental Practice (GEP). Phytotoxicity assessments are summarised in Table 3.4-3.

Table 3.4-3: Selectivity of FHO04 (4.0 L/ha) - Winter durum wheat (TRZDW) - Efficacy trials

Number of trials with…		FHO04 - 4.0 L/ha Prothioconazole + Sulphur 200+2500 g a.s./ha	Reference standard
Maximum of phytotoxicity recorded during the trials	0%	2	2
	>0 - 4.9%	0	0
	5 - 9.9%	0	0
	10 - 14.9%	0	0
	15% and more	0	0
Level of symptoms at the last assessments	0%	2	2
	>0 - 4.9%	0	0
	5 - 9.9%	0	0
	10 - 14.9%	0	0
	15% and more	0	0

No phytotoxicity symptoms caused by FHO04 at the proposed dose of 4.0 L/ha were recorded in any of the ~~all~~ efficacy trials. The potential impact of variety on the occurrence of phytotoxicity was observed in 1 variety of winter durum wheat (Table 3.4-4).

Table 3.4-4: Phytotoxicity assessments of FHO04 - Varieties tested in efficacy trials

Crop	No of trials	No of varieties	Variety names (No of trials)
Winter durum wheat (TRZDW)	2	1	*Wintergold (2).*

Therefore, no effect is expected in wheat crops if FHO04 is applied at the maximum requested rate of 4.0 L/ha according to the Good Agricultural Practices and label recommendations.

3.4.1.4 Crop safety results in winter triticale

The crop sensitivity was assessed in **10 efficacy trials** performed **from 2021 to 2023** (presented in Section 3.2.3) in winter triticale. All trials were carried out by testing facilities officially recognised according to Good Experimental Practice (GEP). Phytotoxicity assessments are summarised in Table 3.4-5.

Table 3.4-5: Selectivity of FHO04 (4.0 L/ha) - Winter triticale (TTLWI) - Efficacy trials

Number of trials with…		FHO04 - 4.0 L/ha Prothioconazole + Sulphur 200+2500 g a.s./ha	Reference standard
Maximum of phytotoxicity recorded during the trials	0%	10	10
	>0 - 4.9%	0	0
	5 - 9.9%	0	0
	10 - 14.9%	0	0
	15% and more	0	0
Level of symptoms at the last assessments	0%	10	10
	>0 - 4.9%	0	0
	5 - 9.9%	0	0
	10 - 14.9%	0	0
	15% and more	0	0

No phytotoxicity symptoms caused by FHO04 at the proposed dose of 4.0 L/ha were recorded in any of the ~~all~~ efficacy trials. The potential impact of variety on the occurrence of phytotoxicity was observed in 5 different varieties of winter triticale (Table 3.4-6).

Table 3.4-6: Phytotoxicity assessments of FHO04 - Varieties tested in efficacy trials

Crop	No of trials	No of varieties	Variety names (No of trials)
Winter triticale (TTLWI)	10	5	*Grenado (1), Lombardo (6), Rotondo (1), SU Agendus (1), Trismart (1).*

Therefore, no effect is expected in triticale crops if FHO04 is applied at the maximum requested rate of 4.0 L/ha according to the Good Agricultural Practices and label recommendations.

3.4.1.5 Crop safety results in winter rye

The crop sensitivity was assessed in **12 efficacy trials** performed **from 2021 to 2023** (presented in Section 3.2.3) in winter rye. All trials were carried out by testing facilities officially recognised according to Good Experimental Practice (GEP). Phytotoxicity assessments are summarised in Table 3.4-7.

Table 3.4-7: Selectivity of FHO04 (4.0 L/ha) - Winter rye (SECCW) - Efficacy trials

Number of trials with…		FHO04 - 4.0 L/ha Prothioconazole + Sulphur 200+2500 g a.s./ha	Reference standard
Maximum of phytotoxicity recorded during the trials	0%	12	12
	>0 - 4.9%	0	0
	5 - 9.9%	0	0
	10 - 14.9%	0	0
	15% and more	0	0
Level of symptoms at the last assessments	0%	12	12
	>0 - 4.9%	0	0
	5 - 9.9%	0	0
	10 - 14.9%	0	0
	15% and more	0	0

No phytotoxicity symptoms caused by FHO04 at the proposed dose of 4.0 L/ha were recorded in any of the ~~all~~ efficacy trials. The potential impact of variety on the occurrence of phytotoxicity was observed in 11 different varieties of winter rye (Table 3.4-8).

Table 3.4-8: Phytotoxicity assessments of FHO04 - Varieties tested in efficacy trials

Crop	No of trials	No of varieties	Variety names (No of trials)
Winter rye (SECCW)	12	11	*Dańkowksie Granat (1), Dukat (1), Identor (1), Initiator (1), KWS Dolaro (1), KWS Igor (1), KWS Serafino (1), KWS Tayo (2), KWS Trebiano (1), Piano (1), Stannos (1).*

Therefore, no effect is expected in rye crops if FHO04 is applied at the maximum requested rate of 4.0 L/ha according to the Good Agricultural Practices and label recommendations.

Comments of zRMS:
Phytotoxicity to host crop

No phytotoxicity symptoms were observed after application of FHO04 at recommended dose rate of 4.0 L/ha in any of the trials carried out on winter wheat, winter durum wheat, winter triticale and winter rye.
Based on the submitted trial results it can be concluded that FHO04 applied in accordance with label recommendations can be safely used on target winter cereal crops.

zRMS Abstract

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

3.4.2.1 Material and Methods

Material and Methods used in efficacy trials are given within Section 3.2.3.1 and not repeated here.

3.4.2.2 Effect on the yield of winter soft wheat

Sulphur and prothioconazole are existing active substances and no effect on the yield is known. However, ~~1~~ 3 efficacy trials without disease or under very low disease pressure conditions were ~~was~~ harvested in winter soft wheat. These trials ~~This disease-free efficacy trial~~ were ~~was~~ carried out **in 2019** in Germany, **in 2022** in Latvia and **in 2023** in Lithuania. All yield results are summarised in Table 3.4-9 and 3.4-10.
No adverse effect on the yield was noted after an application of FHO04 (4.0 L/ha). Indeed, no negative difference was noted with the untreated and the reference standards Proline and Prosaro. In addition, no adverse effect on the yield and no difference with the reference standards was noted in the 33 valid efficacy trials harvested (see Section 0).

Therefore, no adverse effect on the yield of wheat is expected if FHO04 is applied at the maximum requested rate of 4.0 L/ha according to the Good Agricultural Practices and label recommendations.

Table 3.4-9: Effect of FHO04 (4.0 L/ha) on the yield ~~in disease-free trials~~ - Winter wheat, comparison with standard Proline

Crop	Parameters	EPPO climatic zone	Parts	No. of trials	*Untreated*			Percentage of Untreated (%)								No. of assessments where FHO04 (4.0 L/ha) is significantly[(1)] >;=;< to	
								FHO04 (4.0 L/ha)				Proline (0.8 L/ha)					
								Prothioconazole + Sulphur				Prothioconazole					
								200+2500 g a.s./ha				200 g a.s./ha					
					Mean	*Min*	*Max*	**Mean**	Min	Max	*S.D.*	**Mean**	Min	Max	*S.D.*	**Untreated**	**Proline (0.8 L/ha)**
TRZAW	Yield (t/ha)	Border countries of Poland (Germany)	Grains	1	***9.2***	-	-	**101.1**	-	-	-	**100.2**	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<
TRZAW	Yield (t/ha)	Northeast	Grains	1	***4.8***	-	-	**100.6**	-	-	-	**100.5**	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<

(1) Comparison based on statistics carried out in each trial report.

Table 3.4-10: Effect of FHO04 (4.0 L/ha) on the yield - Winter wheat, comparison with standard Prosaro

Crop	Parameters	EPPO climatic zone	Parts	No. of trials	*Untreated*			Percentage of Untreated (%)								No. of assessments where FHO04 (4.0 L/ha) is significantly[(1)] >;=;< to	
								FHO04 (4.0 L/ha)				Prosaro (1.0 L/ha)					
								Prothioconazole + Sulphur				Tebuconaozle + Prothioconazole					
								200+2500 g a.s./ha				125 + 125 g a.s./ha					
					Mean	*Min*	*Max*	**Mean**	Min	Max	*S.D.*	**Mean**	Min	Max	*S.D.*	**Untreated**	**Prosaro (1.0 L/ha)**
TRZAW	Yield (t/ha)	Northeast	Grains	1	***2.6***	-	-	**118.7**	-	-	-	**114.0**	-	-	-	1> ; 0= ; 0<	0> ; 1= ; 0<

(1) Comparison based on statistics carried out in each trial report.

3.4.2.3 Effect on the yield of winter durum wheat

Sulphur and prothioconazole are existing active substances and no effect on the yield is known. No efficacy trial without disease is available to confirm the possible impact of FHO04 on the yield of

harvested winter durum wheat. However, no adverse effect on the yield and no difference with the reference standards was noted in the valid efficacy trial harvested (see Section 0).

Therefore, no adverse effect on the yield of durum wheat is expected if FHO04 is applied at the maximum requested rate of 4.0 L/ha according to the Good Agricultural Practices and label recommendations.

3.4.2.4 Effect on the yield of winter triticale

Sulphur and prothioconazole are existing active substances and no effect on the yield is known.
However, 1 efficacy trial conducted under very low disease pressure conditions was harvested in winter triticale. This trial was carried out **in 2021** in Germany. All yield results are summarised in Table 3.4-11.
No adverse effect on the yield was noted after an application of FHO04 (4.0 L/ha). Indeed, no negative difference was noted with the untreated and the reference standard Proline.
~~No efficacy trial without disease is available to confirm the possible impact of FHO04 on the yield of harvested winter triticale.~~ In addition ~~However,~~ no adverse effect on the yield and no difference with the reference standards was noted in the 5 valid efficacy trials harvested (see Section 0).

Therefore, no adverse effect on the yield of winter triticale is expected if FHO04 is applied at the maximum requested rate of 4.0 L/ha according to the Good Agricultural Practices and label recommendations.

Table 3.4-11: Effect of FHO04 (4.0 L/ha) on the yield - Winter triticale, comparison with standard Proline

Crop	Parameters	EPPO climatic zone	Parts	No. of trials	*Untreated*			Percentage of Untreated (%)								No. of assessments where FHO04 (4.0 L/ha) is significantly[(1)] >;=;< to	
								FHO04 (4.0 L/ha)				Proline (0.8 L/ha)					
								Prothioconazole + Sulphur				Prothioconazole					
								200+2500 g a.s./ha				200 g a.s./ha					
					Mean	*Min*	*Max*	**Mean**	Min	Max	*S.D.*	**Mean**	Min	Max	*S.D.*	**Untreated**	**Proline (0.8 L/ha)**
TTLWI	Yield (t/ha)	Border countries of Poland (Germany)	Grains	1	***7.1***	-	-	**120.4**	-	-	-	**115.9**	-	-	-	1> ; 0= ; 0<	0> ; 1= ; 0<

(1) Comparison based on statistics carried out in each trial report.

3.4.2.5 Effect on the yield of winter rye

Sulphur and prothioconazole are existing active substances and no effect on the yield is known. However, 1 efficacy trial without disease was harvested in winter rye. This disease-free efficacy trial was carried out **in 2022** in Germany in the Maritime EPPO climatic zone. All yield results are summarised in Table 3.4-12~~10~~. No adverse effect on the yield was noted after an application of FHO04 (4.0 L/ha). Indeed, no negative difference was noted with the untreated and the reference standard Proline. In addition, no adverse effect on the yield and no difference with the reference standards was noted in the 10 valid efficacy trials harvested (see Section 0).

Therefore, no adverse effect on the yield of winter rye is expected if FHO04 is applied at the maximum requested rate of 4.0 L/ha according to the Good Agricultural Practices and label recommendations.

Table 3.4-12 10: Effect of FHO04 (4.0 L/ha) on the yield ~~in disease free trials~~ - Winter rye, comparison with standard Proline

Crop	Parameters	EPPO climatic zone	Parts	No. of trials	*Untreated*			Percentage of Untreated (%)								No. of assessments where FHO04 (4.0 L/ha) is significantly(1) >;=;< to	
								FHO04 (4.0 L/ha)				Proline (0.8 L/ha)					
								Prothioconazole + Sulphur				Prothioconazole					
								200+2500 g a.s./ha				200 g a.s./ha					
					Mean	*Min*	*Max*	**Mean**	Min	Max	*S.D.*	**Mean**	Min	Max	*S.D.*	**Untreated**	**Proline (0.8 L/ha)**
SECCW	Yield (t/ha)	Maritime	Grains	1	***6.4***	-	-	**96.0**	-	-	-	**102.2**	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<

(1) Comparison based on statistics carried out in each trial report.

Comments of zRMS:
Effect on the yield of treated plants or plant product

Contrary to winter rye results presented in the Table 3.4-12 above, the yield analysis from the efficacy trials with normal infection pressure (Section 3.2.3.6 as indicated by the applicant) shows neither statistically significant nor even numerically meaningful differences between the yield from the test item- and reference-treated plots.

Based on the submitted results from disease free trials and from the trials carried out under very low disease pressure conditions it can be concluded that FHO04 applied at the recommended dose rate of 4.0 L/ha does not cause any adverse effects on the yield of the target winter cereal crops.
No negative impact of FHO04 on the yield was also noted in efficacy trials (see zRMS comment on Yield and relevant quality indicators from efficacy trials.

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

3.4.3.1 Material and Methods

Material and Methods used in efficacy trials are given within Section 3.2.3.1 and not repeated here.

3.4.3.2 Effect on the quality of winter soft wheat

Sulphur and prothioconazole are existing active substances and no effect on the quality is known.
However, the possible impact of FHO04 at 4.0 L/ha on the quality was assessed in 2 trials (disease-free trial and trial conducted under very low disease pressure conditions). These trials were carried out **in 2022** in Latvia and **in 2023** in Lithuania. All quality parameter results are summarised in the Table 3.4-16 ~~12~~ and 3.4-14.
No adverse effect on the quality parameters (thousand grain weight and specific weight) was noted after the application of FHO04 (4.0 L/ha). Indeed, no negative difference was noted with the untreated and the reference standards Prosaro and Proline.
~~No efficacy trial without disease is available to confirm the possible impact of FHO04 on the quality of harvested winter soft wheat.~~ In addition, no adverse effect on different quality parameters (thousand grain weight and specific weight) and no difference with the reference standards was noted in the 33 ~~32~~ valid efficacy trials harvested (see Section 0).

Therefore, no adverse effect on the quality of winter wheat is expected if FHO04 is applied at the maximum requested rate of 4.0 L/ha according to the Good Agricultural Practices and label

Table 3.4-11: Effect of FHO04 (4.0 L/ha) on the quality - Winter wheat, comparison with standard Prosaro

Crop	Parameters	EPPO climatic zone	Parts	No. of trials	*Untreated*			Percentage of Untreated (%)								No. of assessments where FHO04 (4.0 L/ha) is significantly(1) >;=;< to	
								FHO04 (4.0 L/ha)				Prosaro (1.0 L/ha)					
								Prothioconazole + Sulphur				Tebuconaozle + Prothioconazole					
								200+2500 g a.s./ha				125 + 125 g a.s./ha					
					Mean	*Min*	*Max*	**Mean**	Min	Max	*S.D.*	**Mean**	Min	Max	*S.D.*	**Untreated**	**Prosaro (1.0 L/ha)**
TRZAW	TGW (g)	Northeast	Grains	1	***40.1***	-	-	**107.7**	-	-	-	**106.0**	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<
	HLW (kg)	Northeast	Grains	1	***78.7***	-	-	**105.0**	-	-	-	**101.0**	-	-	-	1> ; 0= ; 0<	0> ; 1= ; 0<

(1) Comparison based on statistics carried out in each trial report.

Table 3.4-14: Effect of FHO04 (4.0 L/ha) on the quality - Winter wheat, comparison with standard Proline

Crop	Parameters	EPPO climatic zone	Parts	No. of trials	*Untreated*			Percentage of Untreated (%)								No. of assessments where FHO04 (4.0 L/ha) is significantly(1) >;=;< to	
								FHO04 (4.0 L/ha)				Proline (0.8 L/ha)					
								Prothioconazole + Sulphur				Prothioconazole					
								200+2500 g a.s./ha				200 g a.s./ha					
					Mean	*Min*	*Max*	**Mean**	Min	Max	*S.D.*	**Mean**	Min	Max	*S.D.*	**Untreated**	**Proline (0.8 L/ha)**
TRZAW	HLW (kg)	Northeast	Grains	1	***79.5***	-	-	**99.9**	-	-	-	**99.1**	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<

(1) Comparison based on statistics carried out in each trial report.

3.4.3.3 Effect on the quality of durum wheat

Sulphur and prothioconazole are existing active substances and no effect on the quality is known. No efficacy trial without disease is available to confirm the possible impact of FHO04 on the quality of harvested winter durum wheat. However, no adverse effect on different quality parameters (thousand grain weight and specific weight) and no difference with the reference standards was noted in the valid efficacy trial harvested (see Section 0).

Therefore, no adverse effect on the quality of durum wheat is expected if FHO04 is applied at the maximum requested rate of 4.0 L/ha according to the Good Agricultural Practices and label

3.4.3.4 Effect on the quality of winter triticale

Sulphur and prothioconazole are existing active substances and no effect on the quality is known.
One ~~No~~ efficacy trial ~~without~~ carried out under very low disease pressure conditions is available to confirm the possible impact of FHO04 on the quality of harvested winter triticale. This trial was carried out **in 2021** in Germany. All quality parameter results are summarised in the Table 3.4-16 ~~12~~.
No adverse effect on the quality parameters (thousand grain weight and specific weight) was noted after an application of FHO04 (4.0 L/ha). Indeed, no negative difference was noted with the untreated and the reference standard Proline. In addition, ~~However,~~ no adverse effect on different quality parameters (thousand grain weight and specific weight) and no difference with the reference standards was noted in the 5 valid efficacy trials harvested (see Section 0).

Therefore, no adverse effect on the quality of winter triticale is expected if FHO04 is applied at the maximum requested rate of 4.0 L/ha according to the Good Agricultural Practices and label

Table 3.4-15: Effect of FHO04 (4.0 L/ha) on the quality - Winter triticale, comparison with standard Proline

Crop	Parameters	EPPO climatic zone	Parts	No. of trials	*Untreated*			Percentage of Untreated (%)								No. of assessments where FHO04 (4.0 L/ha) is significantly[1] >;=;< to	
								FHO04 (4.0 L/ha)				Proline (0.8 L/ha)					
								Prothioconazole + Sulphur				Prothioconazole					
								200+2500 g a.s./ha				200 g a.s./ha					
					Mean	*Min*	*Max*	**Mean**	Min	Max	*S.D.*	**Mean**	Min	Max	*S.D.*	**Untreated**	**Proline (0.8 L/ha)**
TTLWI	TGW (g)	Border countries of Poland (Germany)	Grains	1	***35.0***	-	-	**107.4**	-	-	-	**106.3**	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<
	HLW (kg)	Border countries of Poland (Germany)	Grains	1	***67.4***	-	-	**102.6**	-	-	-	**101.2**	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<

(1) Comparison based on statistics carried out in each trial report.

3.4.3.5 Effect on the quality of winter rye

Sulphur and prothioconazole are existing active substances and no effect on the quality is known. However, the possible impact of FHO04 at 4.0 L/ha on the quality was harvested in winter rye. This disease-free efficacy trial was carried out **in 2022** in Germany in the Maritime EPPO climatic zone.
All quality parameter results are summarised in Table 3.4-16 ~~12~~.
No adverse effect on the quality parameters (thousand grain weight and specific weight) was noted after an application of FHO04 (4.0 L/ha). Indeed, no negative difference was noted with the untreated and the reference standard Proline. In addition, no adverse effect on different quality parameter (thousand grain weight and specific weight) and no difference with the reference standards was noted in the 10 valid efficacy trials harvested (see Section 0).

Therefore, no adverse effect on the quality of winter rye is expected if FHO04 is applied at the maximum requested rate of 4.0 L/ha according to the Good Agricultural Practices and label

Table 3.4-16 ~~12~~: Effect of FHO04 (4.0 L/ha) on the quality ~~in disease free trials~~ - Winter rye, comparison with standard Proline

Crop	Parameters	EPPO climatic zone	Parts	No. of trials	*Untreated*			Percentage of Untreated (%)								No. of assessments where FHO04 (4.0 L/ha) is significantly[1] >;=;< to	
								FHO04 (4.0 L/ha)				Proline (0.8 L/ha)					
								Prothioconazole + Sulphur				Prothioconazole					
								200+2500 g a.s./ha				200 g a.s./ha					
					Mean	*Min*	*Max*	**Mean**	Min	Max	*S.D.*	**Mean**	Min	Max	*S.D.*	**Untreated**	**Proline (0.8 L/ha)**
SECCW	TGW (g)	Border countries of Poland (Germany)	Grains	1	***23.5***	-	-	**100.4**	-	-	-	**104.4**	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<
	HLW (kg)	Border countries of Poland (Germany)	Grains	1	***70.0***	-	-	**99.1**	-	-	-	**101.7**	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<

[1] Comparison based on statistics carried out in each trial report.

Comments of zRMS:
Effects on the quality of plants or plant products

Based on the submitted results from disease free trials and from the trials carried out under very low disease pressure, it can be concluded that FHO04 applied at the recommended dose rate of 4.0 L/ha does not cause any adverse effects on the yield quality (TGW, HLW) of the target winter cereal crops.
No negative impact of FHO04 on the yield quality parameters was also noted in efficacy trials (see zRMS comment on Yield and relevant quality indicators from efficacy trials.

zRMS Abstract

3.4.4 Effects on transformation processes (KCP 6.4.4)

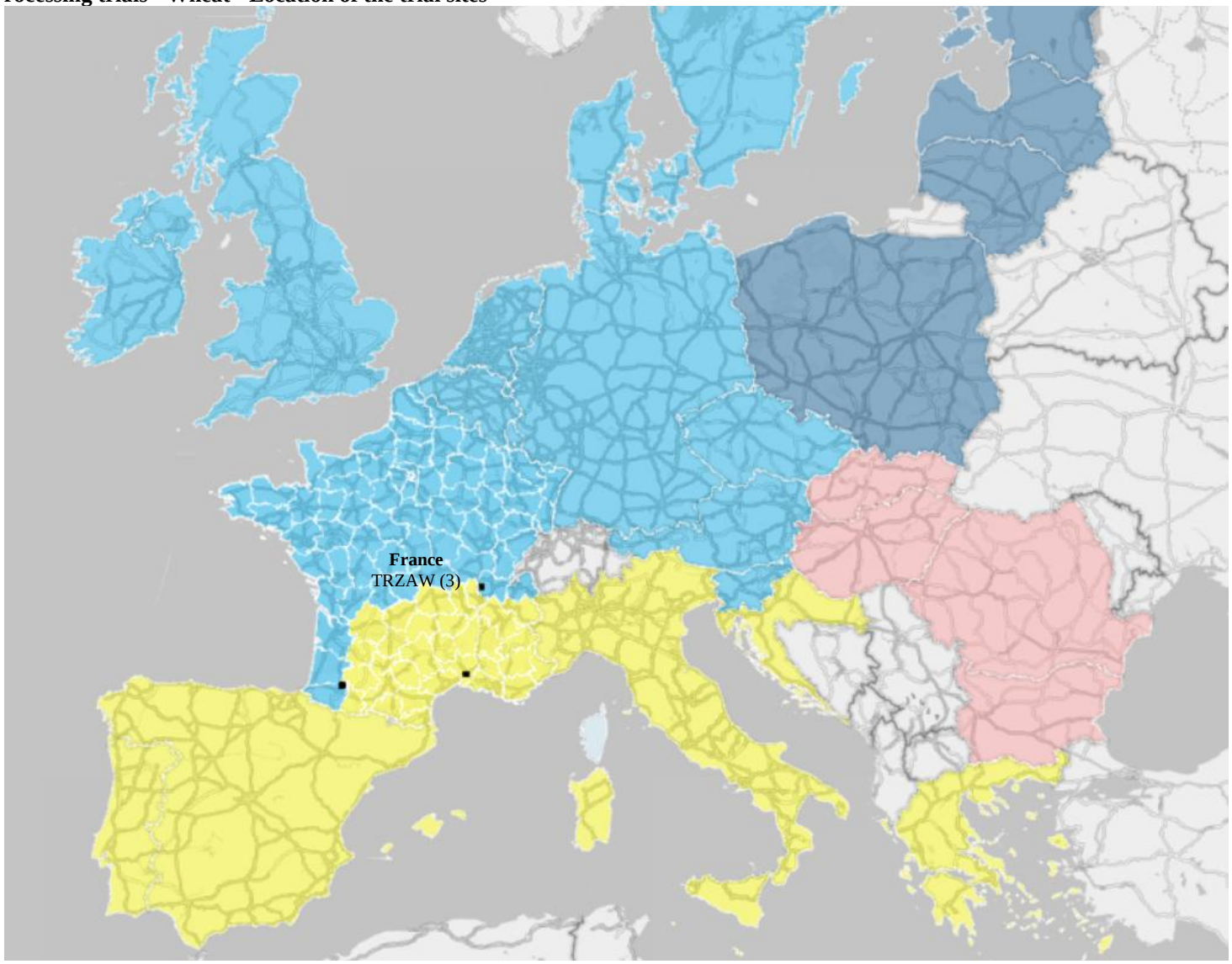
As FHO04 by its nature is a fungicidal compound, it is important to investigate the potential impact of any residues remaining on the crop at harvest on fermentation processes. However, sulphur and prothioconazole based products have been registered since a long time for disease control of cereals and no adverse effect on transformation processes have been reported. Therefore, no label restrictions regarding use on cereals for baking are mentioned. Therefore, the risk of the undesirable effect on crops used for baking can be considered as very low. However, the possible effect of FHO04 on the transformation processes was studied from a set of 3 confirmatory processing trials implemented in 2022 in France in the Maritime (2 trials) and the Mediterranean EPPO climatic zone. All trials were undertaken by contractors test facilities, all of which follow the EPPO guidelines and have Official Recognition status for undertaking trials in accordance with the principles of Good Experimental Practice (GEP). Bread making analyses were carried out by accredited laboratory (GLP). The detail of available trials is provided in Table 3.4-17 ~~13~~. Figure 3.4-1 presents the processing trials repartition.

Table 3.4-17 ~~13~~: Processing trials - Wheat - Presentation of trials

Crop(s)[1]	EPPO climatic zone[2]	Country	Year	Trial code	Type of trial[3]	GEP, non-GEP, official[4]
Winter soft wheat	Maritime	France	2022	2 trials	Wheat Bread making	GEP
	Mediterranean	France	2022	1 trial		

[1] According to the GAP table.
[2] According to EPPO guideline PP 1/241(1) "Guidance on comparable climates".
[3] GEP: Good Experimental Practices. Official: carried out by a national official organisation.

Figure 3.4-1 Processing trials - Wheat - Location of the trial sites



3.4.4.1 Material and methods

Experimental details

The 3 trials were carried out by officially recognized organisations in accordance with the Principles of Good Experimental Practice (GEP). Main characteristics are summarised in following Table 3.4-18 14.

Table 3.4-18 14: Details on trial methodology - Processing trials - Wheat

Guidelines	General guidelines	PP1/135 (4): Phytotoxicity assessment PP1/152 (4): Design and analysis of efficacy evaluation trials PP1/181 (4): Conduct and reporting of efficacy evaluation trials including good experimental practice
	Specific guidelines	PP1/243(2): Guideline for the efficacy evaluation of plant protection products; Effects of plant protection products on transformation processes. CEB 218: Effets non intentionnels sur qualité blé - prod. transf.
Experimental design	Plot design	Randomized Complete Block (RCB).
	Plot size	20- 50 27 m².
	Number of replications	3
Crop	Number of trials	3 trials
	Varieties	*Prestance (1) , SY Moisson (1), Venezio (1).*
Application	Application timing	1st application: BBCH 60 1-61 2nd application: BBCH 69-75
	Number of applications	2 applications.
	Spray volumes	200-250 L/ha.
Assessment	Assessment dates	Harvest and post-harvest.
	Assessment types	Phytotoxicity in %, yield, moisture, specific weight, protein content, impurity rate, Hagberg falling number, Zeleny index, Chopin alveogram and bread making test.
Results & Analysis	Statistical analysis	ANOVA - Newman-Keuls test (5%).

Treatments and reference standards

FHO04 was tested at 4.0 L/ha (N dose) and compared with reference standard JOAO Proline at 0.8 L/ha (Table 3.4-19 15).

Table 3.4-19 15: Presentation of reference standards used in trials - Breadmaking trials - Winter wheat

Reference standard	Active substance(s)	Formulation		Application rate in trials (per treatment)	Rate of active substance per ha
		Type	Concentration of a.s.		
FHO04	**Prothioconazole** **Sulphur**	SC	50 g/L 625 g/L	4.0 L/ha	200+2500 g a.s./ha
JOAO Proline	**Prothioconazole**	EC	250 g/L	0.8 L/ha	200 g a.s./ha

Assessment methods

At harvest, the potential effects on yield and different quality parameters like thousand grain weight, specific weight, protein content and impurity rate were analysed. To conclude, usual tests on the possible effect on the bread making process (Hagberg falling, Zeleny index, Chopin alveograph and then bread making) were performed. Concerning the sensory test, the global note of wheat variety with high baking properties is superior to 250. Between 200 and 250, bread making wheats will need an improver. Under 200, wheats are not bread making, they are used for feeding animals. Finally, a taint test was performed with 12 judges, trained and qualified for bread tasting, according to standard NF ISO 4120

Statistical analyses

Assessments data were analysed using an analysis of variance (ANOVA) on untransformed and/or transformed data. The probability of non-significance occurring between treatment means is calculated as the F probability value (p(F)). The Newman-Keuls test was applied to separate any treatment differences that may be highlighted by the ANOVA test. These differences are indicated by a letter. Treatments with no letter in common are significantly different at the 95% confidence level. Statistical analyses were carried out on yield, quality parameters and Hagberg falling. No repetition was carried out for Zeleny index, Chopin alveograph and bread making analyses (average sample).

3.4.4.2 Effect on the bread making process

The effect on the bread making process was assessed in 3 trials carried out in 2022. All trials were carried out by testing facilities officially recognised according to Good Experimental Practice (GEP) and laboratory analyses were carried out by laboratory officially recognised according to Good Laboratory Practice (GLP). The details of each trial concerning yield, quality parameters before bread making analysis, Hagberg falling number and Zeleny index, Chopin alveograph, baking test and taint test are presented in Table 3.4-20 16.

Table 3.4-20 16: Detailed results: Effect on the bread making process of FHO04 - Processing trials - Wheat

Parameters	Trial code	FHO04 4.0 L/ha		JOAO Proline 0.8 L/ha		*Tolerance*	Difference between FHO04 and JOAO Proline
Yield							
Yield (t/ha)	F22EU-036-AMA-001	11.1	a	11.5	a	Acceptability according to the analysis of variance (ANOVA) results	No difference
	F22EU-036-AMA-002	3.8	a	4.3	a		No difference
	F22EU-036-AMA-003	7.2	a	7.5	a		No difference
Quality of grains							
TGW (g)	F22EU-036-AMA-001	36.6	a	36.7	a	Acceptability according to the analysis of variance (ANOVA) results	No difference
	F22EU-036-AMA-002	39.9	a	40.0	a		No difference
	F22EU-036-AMA-003	39.3	b	41.5	a		A difference
HLW (kg/hL)	F22EU-036-AMA-001	78.5	a	78.7	a		No difference
	F22EU-036-AMA-002	73.6	a	72.7	a		No difference
	F22EU-036-AMA-003	73.0	a	75.6	a		No difference
Impurity rate (%)*	F22EU-036-AMA-001	0.51	a	0.34	a		No difference
	F22EU-036-AMA-002	2.23	a	1.46	a		No difference
	F22EU-036-AMA-003	1.22	a	1.29	a		No difference
Protein content (%)	F22EU-036-AMA-001	10.3	a	10.4	a		No difference
	F22EU-036-AMA-002	11.6	a	11.3	a		No difference
	F22EU-036-AMA-003	12.6	a	12.6	a		No difference
Technological analyses							
Hagberg (s)	F22EU-036-AMA-001	290.0	a	287.7	a	*>180s* Acceptability according to the analysis of variance (ANOVA) results	No difference
	F22EU-036-AMA-002	306.3	a	305.7	a		No difference
	F22EU-036-AMA-003	310.3	a	302.0	a		No difference
Zeleny (mL)	F22EU-036-AMA-001	20.0		21.0		Reproducibility limit (AFNOR NF EN ISO 5529)	No difference
	F22EU-036-AMA-002	25.0		24.0			No difference
	F22EU-036-AMA-003	24.0		25.0			No difference
Chopin alveograph							
W Strength	F22EU-036-AMA-001	105.0		105.0			No difference
	F22EU-036-AMA-002	236.0		208.0			No difference

Parameters	Trial code	FHO04 4.0 L/ha	JOAO ~~Proline~~ 0.8 L/ha	*Tolerance*	Difference between FHO04 and JOAO ~~Proline~~
(10E-4 J)	F22EU-036-AMA-003	219.0	226.0	Reproducibility limit (AFNOR NF EN ISO 27971)	No difference
P Tenacy (mm H2O)	F22EU-036-AMA-001	42.0	41.0		No difference
	F22EU-036-AMA-002	117.0	110.0		No difference
	F22EU-036-AMA-003	72.0	73.0		No difference
G Swelling	F22EU-036-AMA-001	18.4	18.9		No difference
	F22EU-036-AMA-002	15.6	14.9		No difference
	F22EU-036-AMA-003	21.5	21.7		No difference
L Expandability (mm)	F22EU-036-AMA-001	68.0	72.0		No difference
	F22EU-036-AMA-002	49.0	45.0		No difference
	F22EU-036-AMA-003	93.0	95.0		No difference
P/L Config.ratio	F22EU-036-AMA-001	0.6	0.6		No difference
	F22EU-036-AMA-002	2.4	2.4		No difference
	F22EU-036-AMA-003	0.8	0.8		No difference
Baking test					
Hydratation rate (%)	F22EU-036-AMA-001	59.5	59.4	Reproducibility limit (AFNOR NF V03-716 from December 2015)	No difference
	F22EU-036-AMA-002	61.4	60.8		No difference
	F22EU-036-AMA-003	59.4	59.5		No difference
Pastry (1-100)	F22EU-036-AMA-001	**99**	**97**		No difference
	F22EU-036-AMA-002	**93**	**90**		No difference
	F22EU-036-AMA-003	**96**	**94**		No difference
Bread (1-100)	F22EU-036-AMA-001	**72**	**73**		No difference
	F22EU-036-AMA-002	**48**	**49**		No difference
	F22EU-036-AMA-003	**46**	**45**		No difference
Bread volume (cm3)	F22EU-036-AMA-001	1481	1503		No difference
	F22EU-036-AMA-002	1363	1380		No difference
	F22EU-036-AMA-003	1433	1408		No difference
Bread crumb (1-100)	F22EU-036-AMA-001	**94**	**94**		No difference
	F22EU-036-AMA-002	**94**	**94**		No difference
	F22EU-036-AMA-003	**94**	**94**		No difference
Bread making (0-300)	F22EU-036-AMA-001	**265**	**264**		No difference
	F22EU-036-AMA-002	**235**	**233**		No difference
	F22EU-036-AMA-003	**236**	**233**		No difference
Taint test					
Trialngular tests	F22EU-036-AMA-001	There is a difference based on taste and texture -			No negative difference
	F22EU-036-AMA-002	There is a difference but no negative flavour			No negative difference
	F22EU-036-AMA-003	There is a difference based on taste and texture but no negative flavour			No negative difference

*Broken grain, shrunken grain, sprouted grain, rotten grain…

Table 3.4-21 ~~17~~ shows a summary of effects on these different parameters of FHO04 applied at 4.0 L/ha compared to the reference standard JOAO ~~Proline~~.

Table 3.4-21 ~~17~~: Effects on the bread making process parameters of FHO04 - Processing trials - Wheat

Quality parameters		No. of trials	Number of trials with acceptable difference between FHO04 (4.0 L/ha) and JOAO ~~Proline~~ (0.8 L/ha)
Yield (q/ha)		3	3
Quality parameters	Moisture (%)	3	3
	TGW (g)	3	2
	Specific weight (kg/hL)	3	3
	Impurity rate (%)	3	3
	Protein content (%)	3	3
Hagberg falling number		3	3
Zeleny index		3	3
Chopin alveogram	W	3	3
	P	3	3
	L	3	3
	G	3	3
	P/L	3	3
Baking test		3	3
Taint test		3	3

Regarding to the yield, quality parameters and technological analyses (Hagberg and Zeleny), overall, FHO04 showed similar results as JOAO. ~~than Proline~~
Regarding to the parameters measured with the Chopin alveogram, they were in reproducibility limits, for all the trials . Even if on trial no.1, it should be noticed that the strength W was low for all the tested and reference treatments. The baking test, despite some non-optimal rheological values (pastry values) common to all the tested and reference treatments, did not highlight any noticeable differences between the reference JOAO ~~Proline~~ and the tested treatment FHO04. Indeed, this is a sensory test after having baked the flour. It illustrates the baking quality and the ability of the flour to be used for breadmaking. The total note of superior bread making wheats is over 250. Between 200 and 250, bread making wheats will need an improver. Under 200, wheats are not suitable for making bread, they are used as fodder wheats.
In first trial, none of the parameters assessed throughout the baking test were significantly impacted by the tested products, the difference between each tested treatment and the reference JOAO ~~Proline~~ remaining within the reproducibility limits defined by the AFNOR standard. The breads were good, with a dough that accepted shaping without excessive tearing and held up well during baking. In 2 other trials, none of the parameters assessed throughout the baking test were impacted by the tested products, the difference between each tested treatment and the reference JOAO ~~Proline~~ remaining within the reproducibility limits defined by the AFNOR standard. Irrespective of the treatment, the dough showed a similar tendency to tear during shaping and proving phase, but the breads had a good performance during baking. During tasting sessions on bread, the tasters perceived differences between the tested treatments and the reference based on flavour and texture. However no negative organoleptic flavour was perceived, furthermore no deviation was retained.

Therefore, no adverse influence on the transformation processes is expected if FHO04 is used in accordance with good agricultural practices, including label instructions.

At the request of the Polish evaluators, further discussion related to the AFNOR NF V03-716 values follows:

- Although the pastry values of all tested products were outside the AFNOR range of 49-88, the higher values are not considered a negative effect, and the difference between all values was very small, indicating comparability. The values from all products indicate a higher quality pastry.
- Regarding the reproducibility limit values specified in the AFNOR guidance, an extract from the guidance document is shown below in Figure 3.4-2

Figure 3.4-2 AFNOR NF V03-716 reproducibility values

NF V 03-716

Tableau 5 — Écarts-type et limites de répétabilité pour les paramètres de notation

Paramètres	Plage de concentration testée	Écart-type de répétabilité (*Sr*)	Limite de répétabilité (*r*) $r = (Sr * 2{,}77)$
% Hydratation (/15 %)	59,4 à 62,5	0,62	1,7
Note de pâte (/100)	49 à 88	5,2	14
Note de pain (/100)	12 à 86	5,3	15
Volume moyen (cm^3)	1 255 à 2 163	57,5	159
Note de mie (/100)	82 à 99	2,7	8
Note totale (/300)	143 à 271	8,5	23

11.3 Limite de reproductibilité (*R*)

On entend par reproductibilité la valeur au-dessous de laquelle est située, avec une probabilité de 95 %, la valeur absolue de la différence entre 2 résultats d'essais obtenus sous les conditions de reproductibilité.

Les écarts-types de reproductibilité ont été estimés constants quel que soit le niveau moyen mesuré.

Tableau 6 — Écarts-type et limites de reproductibilité pour les paramètres de notation

Paramètres	Plage de concentration testée	Écart-type de reproductibilité (*Sr*)	Limite de reproductibilité (*r*) $r = (Sr * 2{,}77)$
% Hydratation (/15 %)	59,4 à 62,5	1,4	3,9
Note de pâte (/100)	49 à 88	8,6	24
Note de pain (/100)	12 à 86	9,3	26
Volume moyen (cm^3)	1 255 à 2 163	113	313
Note de mie (/100)	82 à 99	5,6	16
Note totale (/300)	143 à 271	15,7	43

Translation

NF V 03-716

Table 5- Standard deviations and repeatability limits for scoring parameters

Parameters	Tested concentration range	Repeatability standard deviation (Sr)	Repeatability limit (r) r - (Sr *2.77)
% Hydration (/15%)	59.4 to 62.5	0.62	1.7
Dough/Pastry score (/100)	49 to 88	5.2	14
Bread score (/100)	12 to 86	5.3	15
Average volume (cm3)	1255 to 2163	57.5	159
Crumb score (/100)	82 to 99	2.7	8
Total score (/300)	143 to 271	8.5	23

11.3 Limit of reproducibility (R)

Reproducibility is understood to be the value below which, with a probability of 95%, the absolute value of the difference between 2 test results obtained under the reproducibility conditions is located.
The reproducibility standard deviations were estimated to be constant regardless of the average level measured.

Table 6 - Standard deviations and reproducibility limits for the notation parameters

Parameters	Tested concentration range	Repeatability standard deviation (Sr)	Repeatability limit (r) r - (Sr *2.77)
% Hydration (/15%)	59.4 to 62.5	1.4	3.9
Dough/Pastry score (/100)	49 to 88	8.6	24
Bread score (/100)	12 to 86	9.3	26
Average volume (cm3)	1255 to 2163	113	313
Crumb score (/100)	82 to 99	5.6	16
Total score (/300)	143 to 271	15.7	43

Comments of zRMS on:
Effects on transformation processes

Results from 3 field phase trials conducted in 2022 in France, in the Maritime (2 trials) and the Mediterranean (1 trial) EPPO climatic zone and from 1 laboratory processing phase study have been submitted by the applicant to assess, whether FHO04 at 4.0 L/ha has any impact on bread making process in winter wheat. The field phase trials were carried out by the officially recognized testing unit in accordance with the Principles of Good Experimental Practice (GEP). Laboratory bread making analyses were carried out by Accredited GLP (Good Laboratory Practice) Laboratory in France.

Based on the submitted trial results, it can be concluded, that negative impact on the yield, quality of the grain and on the baking process is not expected after application of FHO04 at recommended dose rate of 4.0 L/ha. No significant differences between FHO04 and standard product JOAO in yield, yield quality parameters, protein content, Zeleny index, the Hagberg falling number, the Chopin alveograph and the bread-making quality parameters have been noted.

zRMS Abstract

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

Any potential impact of FHO04 on seeds would principally be related to the active substances. Sulphur and prothioconazole are used in Europe for many years and no effect on treated plants or plant products to be used for propagation is known in Europe. Moreover, no problem with respect to propagation has been encountered during the experimental testing of FHO04 which has been used to treat plants with no negative impact. Based on this, further investigation of the effects of treatments with FHO04 was considered unnecessary. However, a summary of the range of varieties tested and the extent of crop damage observed is provided in Section 3.4 to support the use of FHO04 on plants used for propagation purposes. Finally, it is concluded that no negative impact on plant propagation will occur to these crops.

Therefore, no effect on parts of plant used for propagating purposes is expected if FHO04 is applied in accordance with the Good Agricultural Practices and label recommendations.

Comments of zRMS:
Impact on treated plants or plant products to be used for propagation

In the 3.5.4 the applicant states: "*no problem with respect to propagation has been encountered during the experimental testing of FHO04 which has been used to treat plants with no negative impact*" and " *a summary of the range of varieties tested and the extent of crop damage observed is provided in Section 3.4* [...]".
Please note, that the Tables 3.4-2, 3.4-4, 3.4-6 and 3.4-8 do only list the varieties used in the trials comprising the present dossier, but no evidence of testing specifically for propagative capacity of thus produced seeds is given. Consequently, the zRMS assumes that no such testing took place and therefore the applicant`s statement of "no effect expected" is out of place, considered the FHO04 is new a fungicide, with novel actives` combination.
However, judging from the long history of use of both prothioconazole and sulphur in solo formulations, as well as from the impact (or the lack of such) of the historical co-formulations of sulphur with organic compounds other than SBI-s, zRMS is inclined to admit that indeed no negative impact should be expected, and to accept the applicant`s statement.
Notwithstanding, it is the opinion of zRMS that since the issue is on the menu of the dRR template, it should be covered adequately, particularly for a new product, at least with a decent reasoned case.

zRMS Abstract

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

3.5.1 Impact on succeeding crops (KCP 6.5.1)

Fungicides usually do not exhibit herbicidal activity. Phytotoxicity was considered as acceptable on cereals (wheat, rye and triticale) in any of the 83 efficacy trials where FHO04 was applied as a straight product up to 4.0 L/ha. For more details on phytotoxicity results, please refer to Section 3.4.
In addition, any potential impact of FHO04 on succeeding crops would principally be related to the active substances. Sulphur and prothioconazole are used in Europe for many years and no effect on succeeding crops is known in Europe.
Moreover, further information on the fate and behaviour of the active substances in the soil can be found in the relevant section in Part B Section 8 ("Environmental fate") of the Registration Report.
Based upon the seedling emergence study, the ER_{50} values correspond to an application of 16 L/ha. Therefore, it can be argued the amount of product applied according to the Good Agricultural Practices and label recommendations is 25% of the ER_{50}. Therefore, it can be concluded that no effect on succeeding crop is expected.

Therefore, no impact is expected on succeeding crops if FHO04 is used according to the Good Agricultural Practices and label recommendations.

Comments of zRMS:
Impact on succeeding crops

Since the dose rate of prothioconazole *per* ha proposed with the test item is similar to that in standard reference (solo) products, and the dose rate of sulphur is even lower, at least compared to some of the field fungicides currently in use, the zRMS estimates that there is probably no reason to expect negative effect of the product on succeeding crops.
This conclusion is, however, not based on the applicant`s reasoning, as the latter is incomplete in light of the requirements of the EPPO PP 1/207 (2) *Effects on succeeding crops*.
Please note, that the Part B Section 8 data are concerned, among others, with soil concentrations of the actives following the product`s application. Therefore it is the PEC_{soil} values (and not ER values), combined with the results of pot tests, testing for damage symptoms against a range of soil concentrations expected (EC), that would make the appropriate dataset for 3.5.1, producing, in effect, the TER values that allow for estimation of damage risk on a range of succeeding crops. Moreover, please observe that the tests carried out by Section 9, based on the values produced in the Section 8, should not only be referred to but also summarized, within Part B Section 3 (Efficacy).

zRMS Abstract

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

Fungicides usually do not exhibit herbicidal activity. Phytotoxicity was considered as acceptable on cereals (wheat, rye and triticale) in any of the 83 efficacy trials where FHO04 was applied as a straight product up to 4.0 L/ha. For more details on phytotoxicity results, please refer to Section 3.4.
In addition, any potential impact of FHO04 on adjacent crops would principally be related to the active substances. Sulphur and prothioconazole are used in Europe for many years and no effect on adjacent crops is known in Europe.
Moreover, further information on the non - target plant studies can be found in Part B Section 9 ("Ecotoxicological studies") of the Registration Report.
Based upon the vegetative vigour study, the ER_{50} values correspond to an application of 16 L/ha. Therefore, it can be argued the amount of product applied according to the Good Agricultural Practices and label recommendations is 25% of the ER_{50}. Therefore, it can be concluded that no effect on succeeding crop is expected.

Therefore, no impact is expected on adjacent crops if FHO04 is used according to the Good Agricultural Practices and label recommendations.

Tank cleaning

Fungicides usually do not exhibit herbicidal activity. Phytotoxicity was considered as acceptable on cereals (wheat, rye and triticale) in any of the 83 efficacy trials where FHO04 was applied as a straight product up to 4.0 L/ha. For more details on phytotoxicity results, please refer to Section 3.4.
In addition, any potential impact of residues of FHO04 in the tank would principally be related to the active substances. Sulphur and prothioconazole are used in Europe for many years and no effect after cleaning is known in Europe.
Standard tank cleaning procedure as specified on the label is considered to be sufficient.

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

The impact of FHO04 applied according to the label recommendations on adjacent crops is not expected. This conclusion is, however, not based on the applicant`s reasoning, as the latter is incomplete. The same as with reference to 3.5.1, please observe that the tests carried out by Section 9, based on the values produced in the Section 8, should not only be referred to but also summarized, within Part B Section 3 (Efficacy).

In order to avoid the risk of adverse effects on adjacent crops, being in accordance with the rules of good agricultural practice it is recommended to include, in the product label, the following remark: "*When using ~~OR 402 D~~ FHO04 (Patton Supra) do not allow spray drift to the neighbouring crop plantations*".

Tank cleaning
It is recommended to follow the principles of Good Plant Protection Practice when tank cleaning.

zRMS Abstract

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

No side-effect on beneficial and other non - target organisms were observed in the 83 efficacy trials carried out in on cereals (wheat, rye and triticale) where FHO04 was applied as a straight product up to 4.0 L/ha. Moreover, information on beneficial organisms' studies can be found in Part B Section 9 ("Ecotoxicological studies") of the Registration Report.

Therefore, no effect is expected on beneficial or other non - target organisms if FHO04 is used according to the Good Agricultural Practices and label recommendations.
From these results it can be concluded that the proposed use pattern of FHO04 will not pose any significant risk to beneficial organisms.

Comments of zRMS on:
Effects on beneficial and other non - target organisms (3.5.3)

Based on the submitted data from efficacy trials, the impact of FHO04 applied according to label recommendations on beneficial and other non – target organisms is not expected.

3.6 Other/special studies

No further information is available.

3.7 List of test facilities including the corresponding certificates

The majority of corresponding certificates, confirming that all the test facilities mentioned have been officially recognized as organizations for efficacy testing of plant protection products according to the

Directive 93/71/EC, are available in the GEP Certibase (www.gepcertibase.eu). Corresponding certificates are available in each trial report.

Table 3.7-1: List of test facilities

Testing facilities	Address	Year	Link GEP Certibase
Agreco Sp. z o.o.	Al. Lipowa 21 Iok. 1 53-124 Wroclaw Poland	2020-2023	1d691e7bbb5
AgroLab Baltic, SIA	Ozoli, Kursīšu Pagasts LV-3890 Saldus Novads Latvia	2020-2023	lngNkYop3k
UAB Agrolab Baltic	Bugenių km LT-89452 Mažeikių raj. Lithuania	2020-2023	1d61b33d88d
Eurofins Agroscience Services GmbH	Carl-Goerdeler-Weg 5 D-21684 Stade Germany	2021-2023	GgA4DE3pvO
Fertico Sp. Z O.O.	Grójecka 26 05-620 Błędów Poland	2023	1d5daecc0fb
Field Research Support (DE)	Leinechaussee 75 D-31515 Wunstorf Germany	2020-2023	6OPNMw8pAj
Field Research Support (PL)	Ul. Dworcowa 2 64-000 Koscian Poland	2023	jgK2W6Lp6v
Staphyt GmbH	Langenburger Straße 35 D-74572 Blaufelden-Herrentierbach Germany	2019	1d5daecc46f
		2023	lqPpwV34gD
Staphyt Sp. z o.o.	Zięb icka 2, 60-164 Poznan Poland	2023	zRwpbV5pvO

Appendix 1 Lists of data considered in support of the evaluation

List of data submitted

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status Published or Unpublished	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.1 /088	Oudin, V.	2019	The efficacy of FHO applied to winter wheat for the control of foliar diseases (SEPTTR) Staphyt, France, Report No. VON-19-38651-FR03 UPL Report No. F-19-EU-TRZAW-009E01-03FR GEP Unpublished	N	Y	New study	UPL
KCP 6.1 /089	Oudin, V. Turner, M.	2019	The efficacy of FHO applied to winter wheat for the control of foliar diseases (SEPTTR) Staphyt, United Kingdom, Report No. VON-19-38651-GB04 UPL Report No. F-19-EU-TRZAW-009E01-04GB GEP Unpublished	N	Y	New study	UPL
KCP 6.1 /090	Oudin, V. Turner, M.	2019	The efficacy of FHO applied to winter wheat for the control of foliar diseases (SEPTTR) Staphyt, United Kingdom, Report No. VON-19-38651-GB05 UPL Report No. F-19-EU-TRZAW-009E01-05GB GEP Unpublished	N	Y	New study	UPL
KCP 6.1 /091	Joynt, R.	2019	The efficacy of FHO applied to winter wheat for the control of foliar diseases (SEPTTR) ADAS, United Kingdom, Report No RM19-143 UPL Report No. F-19-EU-TRZAW-009E03-01GB GEP Unpublished	N	Y	New study	UPL
KCP 6.1 **KCP 6.2** **KCP 6.4.1 /001**	Furman-Fratczak, K.	2021	The efficacy of FGR06 and FHO04 applied post-emergence of wheat for the control of *Zymoseptoria tritici* (SEPTTR) in Europe. Agreco, Poland, Report No. 21UPL0904-1 UPL Report No. F21EU-006-011-019 GEP Unpublished	N	Y	New study	UPL
KCP 6.1 **KCP 6.2** **KCP 6.4.1 /002**	Furman-Fratczak, K.	2021	The efficacy of FGR06 and FHO04 applied post-emergence of wheat for the control of *Zymoseptoria tritici* (SEPTTR) in Europe. Agreco, Poland, Report No. 21UPL0904-2 UPL Report No. F21EU-006-011-020 GEP Unpublished	N	Y	New study	UPL

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status Published or Unpublished	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.1 KCP 6.2 KCP 6.4.1 /003	Furman-Fratczak, K.	2021	The efficacy of FGR06 and FHO04 applied post-emergence of wheat for the control of *Zymoseptoria tritici* (SEPTTR) in Europe. Agreco, Poland, Report No. 21UPL0904-3 UPL Report No. F21EU-006-011-021 GEP Unpublished	N	Y	New study	UPL
KCP 6.1 KCP 6.2 KCP 6.4.1 /004	Furman-Fratczak, K.	2021	The efficacy of FGR06 and FHO04 applied post-emergence of wheat for the control of *Zymoseptoria tritici* (SEPTTR) in Europe. Agreco, Poland, Report No. 21UPL0907-1 UPL Report No. F21EU-006-011-022 GEP Unpublished	N	Y	New study	UPL
KCP 6.1 KCP 6.2 KCP 6.4.1 /005	Furman-Fratczak, K.	2022	The efficacy of FGR06 and FHO04 applied post-emergence of wheat for the control of *Zymoseptoria tritici* (SEPTTR) in Europe. Agreco, Poland, Report No. 22UPL01071-1 UPL Report No. F22EU-024-AMA-016 GEP Unpublished	N	Y	New study	UPL
KCP 6.1 KCP 6.2 KCP 6.4.1 /006	Furman-Fratczak, K.	2022	The efficacy of FGR06 and FHO04 applied in winter wheat for the control of *Zymoseptoria tritici* (SEPTTR). Agreco, Poland, Report No. 22UPL01071-2 UPL Report No. F22EU-024-AMA-017 GEP Unpublished	N	Y	New study	UPL
KCP 6.1 KCP 6.2 KCP 6.4.1 /007	Furman-Fratczak, K.	2023	The efficacy of FGR06, FGR07 and FHO04 applied in cereals for the control of *Puccinia triticina* (PUCCRT) in Europe. Agreco, Poland, Report No. 23UPL01222-1 UPL Report No. F23EU-008-AMA-005 GEP Unpublished	N	Y	New study	UPL
KCP 6.1 KCP 6.2 KCP 6.4.1 /008	Rusek, K.	2023	The efficacy of FGR06 and FHO04 applied in cereals for the control of *Puccinia striiformis* (PUCCST), Poland 2023 Fertico, Poland, Report No. 113_02_F23_331 UPL Report No. F23EU-011-AMA-012 GEP Unpublished	N	Y	New study	UPL

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status Published or Unpublished	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.1 KCP 6.2 KCP 6.4.1 /009	Umiński, P.	2023	The efficacy of FGR06 and FHO04 applied in cereals for the control of *Blumeria graminis tritici* (ERYSGT), *Zymoseptoria tritici* (SEPTTR)on winter wheat in Poland. Field Research Support, Poland, Report No. FRS 529/23 – V1 UPL Report No. F23EU-014-AMA-016 GEP Unpublished	N	Y	New study	UPL
KCP 6.1 KCP 6.2 KCP 6.4.1 /010	Umiński, P.	2023	The efficacy of FGR06 and FHO04 applied in cereals for the control of *Blumeria graminis tritici* (ERYSGT), *Zymoseptoria tritici* (SEPTTR), *Pyrenophora tritici-repentis* (PYRNTR), Puccinia recondite (PUCCRE) on winter wheat in Poland Field Research Support, Poland, Report No. FRS 529/23 – V2 UPL Report No. F23EU-014-AMA-017 GEP Unpublished	N	Y	New study	UPL
KCP 6.1 KCP 6.2 KCP 6.4.1 /011	Pszczółkowski, M.	2023	The efficacy of FGR06 and FHO04 applied in cereals for the control of *Pyrenophora tritici-repentis* (PYRNTR) and *Zymoseptoria tritici* (SEPTTR) in Poland. Staphyt, Poland, Report No. MP2-23-105429-01-PL02 UPL Report No. F23EU-015-AMA-012 GEP Unpublished	N	Y	New study	UPL
KCP 6.1 KCP 6.2 KCP 6.4.1 /012	Siebold, M.	2022	Field study to evaluate the efficacy of FGR06 and FHO04 applied in cereals for the control of *Zymoseptoria tritici* (SEPTTR) in Europe. Field Research Support, Latvia, Report No. FRS198/22-V2-LV UPL Report No. F22EU-033-AMA-002 GEP Unpublished	N	Y	New study	UPL
KCP 6.1 KCP 6.2 KCP 6.4.1 /013	Siebold, M.	2022	Field study to evaluate the efficacy of FGR06 and FHO04 applied post-emergence of winter wheat for the control of *Puccinia striiformis* (PUCCST) in Europe. Field Research Support, Latvia, Report No. FRS200/22-V2-LV UPL Report No. F22EU-034-AMA-002 GEP Unpublished	N	Y	New study	UPL
KCP 6.1 KCP 6.2 KCP 6.4.1 /014	Siebold, M.	2022	Field study to evaluate the efficacy of FGR06 and FHO04 applied post-emergence of winter wheat for the control of *Puccinia striiformis* (PUCCST) in Europe. Field Research Support, Latvia, Report No. FRS200/22-V3-LV UPL Report No. F22EU-034-AMA-003 GEP Unpublished	N	Y	New study	UPL

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status Published or Unpublished	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.1 KCP 6.2 KCP 6.4.1 /015	Packwood, J.	2023	The efficacy of FGR06 and FHO04 applied in cereals for the control of *Pyrenophora tritici-repentis* (PYRNTR) in Europe. Eurofins, Latvia, Report No. S23-101657-06 UPL Report No. F23EU-015-AMA-009 GEP Unpublished	N	Y	New study	UPL
KCP 6.1 KCP 6.2 KCP 6.4.1 /016	Vaitiekiene, E.	2021	The efficacy of FCG08, FGR06 and FHO04 applied post-emergence of winter wheat for the control of *Zymoseptoria tritici* (SEPTTR) in Europe. Agrolab, Lithuania UPL Report No. F21EU-007-011-003 GEP Unpublished	N	Y	New study	UPL
KCP 6.1 KCP 6.2 KCP 6.4.1 /017	Vaitiekiene, E.	2021	The efficacy of FCG08, FGR06 and FHO04 applied post-emergence of winter wheat for the control of *Zymoseptoria tritici* (SEPTTR) in Europe. Agrolab, Lithuania UPL Report No. F21EU-007-011-004 GEP Unpublished	N	Y	New study	UPL
KCP 6.1 KCP 6.2 KCP 6.4.1 /018	Zöllner, H. Siebold, M.	2021	Field study to evaluate the efficacy of FGR06 and FHO04 applied in winter wheat for the control of *Zymoseptoria tritici* (SEPTTR) in Europe. Field Research Support, Germany, Report No. FRS275/21-V1 UPL Report No. F21EU-006-011-006 GEP Unpublished	N	Y	New study	UPL
KCP 6.1 KCP 6.2 KCP 6.4.1 /019	Zöllner, H. Siebold, M.	2021	Field study to evaluate the efficacy of FGR06 and FHO04 applied in triticale for the control of *Zymoseptoria tritici* (SEPTTR) and *Blumeria graminis tritici* (ERYSGT) in Europe. Field Research Support, Germany, Report No. FRS275/21-V2 UPL Report No. F21EU-006-011-007 GEP Unpublished	N	Y	New study	UPL
KCP 6.1 KCP 6.2 KCP 6.4.1 /020	Zöllner, H. Siebold, M.	2021	Field study to evaluate the efficacy of FGR06 and FHO04 applied in wheat for the control of *Puccinia striiformis* (PUCCST) and *Zymoseptoria tritici* (SEPTTR) in Europe. Field Research Support, Germany, Report No. FRS276/21-V2 UPL Report No. F21EU-008-011-005 GEP Unpublished	N	Y	New study	UPL

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KCP 6.1 **KCP 6.2** **KCP 6.4.1** **/021**	Siebold, M.	2022	Field study to evaluate the efficacy of FGR06 and FHO04 applied in cereals for the control of *Zymoseptoria tritici* (SEPTTR) in Europe. Field Research Support, Germany, Report No. FRS197/22-V3 UPL Report No. F22EU-024-AMA-005 GEP Unpublished	N	Y	New study	UPL
KCP 6.1 **KCP 6.2** **KCP 6.4.1** **/022**	Siebold, M.	2022	Field study to evaluate the efficacy of FGR06 and FHO04 applied in cereals for the control of *Puccinia striiformis* (PUCCST) in Europe. Field Research Support, Germany, Report No. FRS199/22-V2 UPL Report No. F22EU-025-AMA-004 GEP Unpublished	N	Y	New study	UPL
KCP 6.1 **KCP 6.2** **KCP 6.4.1** **/023**	Siebold, M.	2022	Field study to evaluate the efficacy of FGR06 and FHO04 applied in cereals for the control of *Puccinia triticina* (PUCCRT) in Europe. Field Research Support, Germany, Report No. FRS202/22-V2 UPL Report No. F22EU-026-AMA-004 GEP Unpublished	N	Y	New study	UPL
KCP 6.1 **KCP 6.2** **KCP 6.4.1** **/024**	Siebold, M.	2023	The effecacy of FGR06, FGR07 and FHO04 applied in cereals for the control of *Puccinia triticina* (PUCCRT) in Europe. Field Research Support, Germany, Report No. FRS028/23 UPL Report No. F23EU-008-AMA-004 GEP Unpublished	N	Y	New study	UPL
KCP 6.1 **KCP 6.2** **KCP 6.4.1** **/025**	Packwood, J.	2023	The efficacy of FGR06, FGR07 and FHO04 applied in cereals for the control of *Puccinia striiformis* (PUCCST) in Europe. Eurofins, Germany, Report No. S23-101654-02 UPL Report No. F23EU-012-AMA-005 GEP Unpublished	N	Y	New study	UPL
KCP 6.1 **KCP 6.2** **KCP 6.4.1** **/026**	Oudin, V.	2023	The efficacy of FGR06 and FHO04 applied in cereals for the control of *Blumeria graminis tritici* (ERYSGT) in Europe. GEP Trial, GERMANY, 2023. Staphyt, Germany, Report No. VON-23-105349-01-DE07 UPL Report No. F23EU-014-AMA-003 GEP Unpublished	N	Y	New study	UPL

Annex point	Author	Year	**Title** **Source (where different from company)** **Company, Report No.** **GLP or GEP status** **Published or Unpublished**	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.1 **KCP 6.2** **KCP 6.4.1** **/027**	Packwood, J.	2023	The efficacy of FGR06 and FHO04 applied in cereals for the control of *Pyrenophora tritici-repentis* (PYRNTR) in Europe. Eurofins, Germany, Report No. S23-101657-04 UPL Report No. F23EU-015-AMA-004 GEP Unpublished	N	Y	New study	UPL
KCP 6.1 **KCP 6.2** **KCP 6.4.1** **/028**	Oudin, V. Schmidt, I.	2019	The efficacy of FHO applied to winter wheat for the control of foliar diseases (SEPTTR) Staphyt, Germany, Report No. VON-19-38651-DE02 UPL Report No. F-19-EU-TRZAW-009E01-02DE GEP Unpublished	N	Y	New study	UPL
KCP 6.2 **KCP 6.4.1** **/029**	Furman-Fratczak, K.	2020	The efficacy of FGF06 and FHO04 applied to wheat for the control of foliar diseases. Agreco, Poland, Report No. 20UPL0688-1 UPL Report No. F20EU-002-010-015 GEP Unpublished	N	Y	New study	UPL
KCP 6.2 **KCP 6.4.1** **/030**	Furman-Fratczak, K.	2021	The efficacy of FGR06 and FHO04 applied in cereals for the control of *Puccinia striiformis* (PUCCST) in Europe. Agreco, Poland, Report No. 21UPL0905-1 UPL Report No. F21EU-008-011-016 GEP Unpublished	N	Y	New study	UPL
KCP 6.2 **KCP 6.4.1** **/031**	Furman-Fratczak, K.	2021	The efficacy of FGR06 and FHO04 applied in cereals for the control of *Puccinia striiformis* (PUCCST) in Europe. Agreco, Poland, Report No. 21UPL0908-1 UPL Report No. F21EU-008-011-017 GEP Unpublished	N	Y	New study	UPL
KCP 6.2 **KCP 6.4.1** **/032**	Furman-Fratczak, K.	2021	The efficacy of FGR06 and FHO04 applied in cereals for the control of *Puccinia triticina* (PUCCRT) in Europe. Agreco, Poland, Report No. 21UPL0906-1 UPL Report No. F21EU-009-011-016 GEP Unpublished	N	Y	New study	UPL

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KCP 6.2 **KCP 6.4.1** **/033**	Furman-Fratczak, K.	2021	The efficacy of FGR06 and FHO04 applied in cereals for the control of *Puccinia triticina* (PUCCRT) in Europe. Agreco, Poland, Report No. 21UPL0906-2 UPL Report No. F21EU-009-011-017 GEP Unpublished	N	Y	New study	UPL
KCP 6.2 **KCP 6.4.1** **/034**	Furman-Fratczak, K.	2021	The efficacy of FGR06 and FHO04 applied in cereals for the control of *Puccinia triticina* (PUCCRT) in Europe. Agreco, Poland, Report No. 21UPL0909-1 UPL Report No. F21EU-009-011-018 GEP Unpublished	N	Y	New study	UPL
KCP 6.2 **KCP 6.4.1** **/035**	Furman-Fratczak, K.	2021	The efficacy of FGR06 and FHO04 applied in cereals for the control of *Puccinia triticina* (PUCCRT) in Europe. Agreco, Poland, Report No. 21UPL0910-1 UPL Report No. F21EU-009-011-019 GEP Unpublished	N	Y	New study	UPL
KCP 6.2 **KCP 6.4.1** **/036**	Furman-Fratczak, K.	2021	The efficacy of FGR06 and FHO04 applied in cereals for the control of *Puccinia triticina* (PUCCRT) in Europe. Agreco, Poland, Report No. 21UPL0910-2 UPL Report No. F21EU-009-011-020 GEP Unpublished	N	Y	New study	UPL
KCP 6.2 **KCP 6.4.1** **/037**	Furman-Fratczak, K.	2022	The efficacy of FGR06 and FHO04 applied in winter wheat for the control of *Puccinia striiformis* (PUCCST). Agreco, Poland, Report No. 22UPL01072-1 UPL Report No. F22EU-025-AMA-017 GEP Unpublished	N	Y	New study	UPL
KCP 6.2 **KCP 6.4.1** **/038**	Furman-Fratczak, K.	2022	The efficacy of FGR06 and FHO04 applied in winter wheat for the control of *Puccinia striiformis* (PUCCST). Agreco, Poland, Report No. 22UPL01072-2 UPL Report No. F22EU-025-AMA-018 GEP Unpublished	N	Y	New study	UPL

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KCP 6.2 **KCP 6.4.1** **/039**	Furman-Fratczak, K.	2022	The efficacy of FGR06 and FHO04 applied in winter rye for the control of *Puccinia triticina* (PUCCRT). Agreco, Poland, Report No. 22UPL01073-1 UPL Report No. F22EU-025-AMA-026 GEP Unpublished	N	Y	New study	UPL
KCP 6.2 **KCP 6.4.1** **/040**	Furman-Fratczak, K.	2022	The efficacy of FGR06 and FHO04 applied in winter rye for the control of *Puccinia triticina* (PUCCRT). Agreco, Poland, Report No. 22UPL01073-2 UPL Report No. F22EU-025-AMA-027 GEP Unpublished	N	Y	New study	UPL
KCP 6.2 **KCP 6.4.1** **/041**	Furman-Fratczak, K.	2022	The efficacy of FGR06 and FHO04 applied in winter wheat for the control of *Puccinia triticina* (PUCCRT). Agreco, Poland, Report No. 22UPL01074-1 UPL Report No. F22EU-026-AMA-019 GEP Unpublished	N	Y	New study	UPL
KCP 6.2 **KCP 6.4.1** **/042**	Furman-Fratczak, K.	2022	The efficacy of FGR06 and FHO04 applied in winter rye for the control of *Puccinia triticina* (PUCCRT). Agreco, Poland, Report No. 22UPL01075-1 UPL Report No. F22EU-026-AMA-028 GEP Unpublished	N	Y	New study	UPL
KCP 6.2 **KCP 6.4.1** **/043**	Furman-Fratczak, K.	2022	The efficacy of FGR06 and FHO04 applied in winter rye for the control of *Puccinia triticina* (PUCCRT). Agreco, Poland, Report No. 22UPL01075-2 UPL Report No. F22EU-026-AMA-029 GEP Unpublished	N	Y	New study	UPL
KCP 6.2 **KCP 6.4.1** **/044**	Rusek, K.	2023	The efficacy of FGR06 and FHO04 applied in cereals for the control of *Puccinia striiformis* (PUCCST), Poland 2023 Fertico, Poland, Report No. 113_01_F23_330 UPL Report No. F23EU-011-AMA-011 GEP Unpublished	N	Y	New study	UPL

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KCP 6.2 **KCP 6.4.1** **/045**	Rusek, K.	2023	The efficacy of FGR06 and FHO04 applied in cereals for the control of *Puccinia striiformis* (PUCCST), Poland 2023 Fertico, Poland, Report No. 114_01_F23_332 UPL Report No. F23EU-011-AMA-013 GEP Unpublished	N	Y	New study	UPL
KCP 6.2 **KCP 6.4.1** **/046**	Ruja, E.	2020	The efficacy of FGF06 and FHO04 applied to wheat for the control of foliar diseases. Agrolab, Latvia UPL Report No. F20EU-002-010-022 GEP Unpublished	N	Y	New study	UPL
KCP 6.2 **KCP 6.4.1** **/047**	Packwood, J.	2023	The efficacy of FGR06 and FHO04 applied in cereals for the control of *Puccinia striiformis* (PUCCST) in Europe. Eurofins, Latvia, Report No. S23-101655-02 UPL Report No. F23EU-013-AMA-005 GEP Unpublished	N	Y	New study	UPL
KCP 6.2 **KCP 6.4.1** **/048**	Ruja, E.	2020	The efficacy of FGF06 and FHO04 applied to wheat for the control of foliar diseases. Agrolab, Lithuania UPL Report No. F20EU-002-010-007 GEP Unpublished	N	Y	New study	UPL
KCP 6.2 **KCP 6.4.1** **/049**	Ruja, E.	2020	The efficacy of FGF06 and FHO04 applied to wheat for the control of foliar diseases. Agrolab, Lithuania UPL Report No. F20EU-002-010-016 GEP Unpublished	N	Y	New study	UPL
KCP 6.2 **KCP 6.4.1** **/050**	Hötzel, S. Siebold, M.	2020	The efficacy and ratio justification of FGF06 and FHO04 applied to winter wheat for the control of foliar diseases. Field Research Support, Germany, Report No. FRS055/20-V1 UPL Report No. F20EU-001-010-001 GEP Unpublished	N	Y	New study	UPL

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KCP 6.2 **KCP 6.4.1** **/051**	Mahkamov, S. Siebold, M.	2020	The efficacy and ratio justification of FGF06 and FHO04 applied to winter wheat for the control of foliar diseases. Field Research Support, Germany, Report No. FRS055/20-V2 UPL Report No. F20EU-001-010-004 GEP Unpublished	N	Y	New study	UPL
KCP 6.2 **KCP 6.4.1** **/052**	Birkinshaw, N.	2021	The efficacy of FGR06 and FHO04 applied in cereals for the control of *Puccinia striiformis* (PUCCST) in Europe. Eurofins, Germany, Report No. S21-03654-07 UPL Report No. F21EU-008-011-002 GEP Unpublished	N	Y	New study	UPL
KCP 6.2 **KCP 6.4.1** **/053**	Zöllner, H. Siebold, M.	2021	Field study to evaluate the efficacy of FGR06 and FHO04 applied in rye for the control of *Puccinia triticina* (PUCCRT) and *Rhynchosporium secalis* (RHYNSE) in Europe. Field Research Support, Germany, Report No. FRS277/21-V2 UPL Report No. F21EU-009-011-007 GEP Unpublished	N	Y	New study	UPL
KCP 6.2 **KCP 6.4.1** **/054**	Siebold, M.	2022	Field study to evaluate the efficacy of FGR06 and FHO04 applied in cereals for the control of *Puccinia striiformis* (PUCCST) in Europe. Field Research Support, Germany, Report No. FRS199/22-V1 UPL Report No. F22EU-025-AMA-003 GEP Unpublished	N	Y	New study	UPL
KCP 6.2 **KCP 6.4.1** **/055**	Siebold, M.	2022	Field study to evaluate the efficacy of FGR06 and FHO04 applied in cereals for the control of *Puccinia striiformis* (PUCCST) in Europe. Field Research Support, Germany, Report No. FRS201/22-V1 UPL Report No. F22EU-025-AMA-024 GEP Unpublished	N	Y	New study	UPL
KCP 6.2 **KCP 6.4.1** **/056**	Siebold, M.	2022	Field study to evaluate the efficacy of FGR06 and FHO04 applied in cereals for the control of *Puccinia triticina* (PUCCRT) in Europe. Field Research Support, Germany, Report No. FRS202/22-V1 UPL Report No. F22EU-026-AMA-003 GEP Unpublished	N	Y	New study	UPL

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KCP 6.2 **KCP 6.4.1** **/057**	Siebold, M.	2022	Field study to evaluate the efficacy of FGR06 and FHO04 applied in cereals for the control of *Puccinia triticina* (PUCCRT) in Europe. Field Research Support, Germany, Report No. FRS205/22-V2 UPL Report No. F22EU-026-AMA-027 GEP Unpublished	N	Y	New study	UPL
KCP 6.2 **KCP 6.4.1** **/058**	Siebold, M.	2023	The efficacy of FGR06 and FHO04 applied in cereals for the control of *Puccinia triticina* (PUCCRT) in Europe. Field Research Support, Germany, Report No. FRS029/23 UPL Report No. F23EU-009-AMA-006 GEP Unpublished	N	Y	New study	UPL
KCP 6.2 **KCP 6.4.1** **/059**	Siebold, M.	2023	The efficacy of FGR06 and FHO04 applied in cereals for the control of *Blumeria graminis tritici* (ERYSGT) in Europe. Field Research Support, Czech Republic, Report No. F-23-G-559-01 UPL Report No. F23EU-014-AMA-004 GEP Unpublished	N	Y	New study	UPL
KCP 6.4.1 **/060**	Ruja, E.	2020	The efficacy of FGF06 and FHO04 applied to wheat for the control of foliar diseases. Agrolab, Latvia UPL Report No. F20EU-002-010-008 GEP Unpublished	N	Y	New study	UPL
KCP 6.4.1 **/061**	Siebold, M.	2022	Field study to evaluate the efficacy of FGR06 and FHO04 applied post-emergence of winter wheat for the control of *Puccinia triticina* (PUCCRT) in Europe. Field Research Support, Latvia, Report No. FRS203/22-V5-LV UPL Report No. F22EU-035-AMA-005 GEP Unpublished	N	Y	New study	UPL
KCP 6.4.1 **/062**	Lelešius, E.	2023	The efficacy of FGR06 and FHO04 applied in cereals for the control of *Puccinia triticina* (PUCCRT) in Europe. Agrolab, Latvia UPL Report No. F23EU-010-AMA-004 GEP Unpublished	N	Y	New study	UPL

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KCP 6.4.1 /063	Vaitiekiene, E.	2021	The efficacy of FGR06 and FHO04 applied in cereals for the control of *Puccinia striiformis* (PUCCST) in Europe. Agrolab, Lithuania UPL Report No. F21EU-008-011-019 GEP Unpublished	N	Y	New study	UPL
KCP 6.4.1 /064	Vaitiekiene, E.	2021	The efficacy of FGR06 and FHO04 applied in cereals for the control of *Puccinia striiformis* (PUCCST) in Europe. Agrolab, Lithuania UPL Report No. F21EU-008-011-020 GEP Unpublished	N	Y	New study	UPL
KCP 6.4.1 /065	Vaitiekiene, E.	2021	The efficacy of FGR06 and FHO04 applied in cereals for the control of *Puccinia triticina* (PUCCRT) in Europe. Agrolab, Lithuania UPL Report No. F21EU-009-011-022 GEP Unpublished	N	Y	New study	UPL
KCP 6.4.1 /066	Siebold, M.	2022	Field study to evaluate the efficacy of FGR06 and FHO04 applied in cereals for the control of *Zymoseptoria tritici* (SEPTTR) in Europe. Field Research Support, Lithuania, Report No. FRS198/22-V1-LT UPL Report No. F22EU-033-AMA-001 GEP Unpublished	N	Y	New study	UPL
KCP 6.4.1 /067	Siebold, M.	2022	Field study to evaluate the efficacy of FGR06 and FHO04 applied post-emergence of winter wheat for the control of *Puccinia striiformis* (PUCCST) in Europe. Field Research Support, Lithuania, Report No. FRS200/22-V1-LT UPL Report No. F22EU-034-AMA-001 GEP Unpublished	N	Y	New study	UPL
KCP 6.4.1 /068	Siebold, M.	2022	Field study to evaluate the efficacy of FGR06 and FHO04 applied post-emergence of winter wheat for the control of *Puccinia triticina* (PUCCRT) in Europe. Field Research Support, Lithuania, Report No. FRS203/22-V3-LT UPL Report No. F22EU-035-AMA-003 GEP Unpublished	N	Y	New study	UPL

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KCP 6.4.1 /069	Siebold, M.	2022	Field study to evaluate the efficacy of FGR06 and FHO04 applied post-emergence of winter wheat for the control of *Puccinia triticina* (PUCCRT) in Europe. Field Research Support, Lithuania, Report No. FRS203/22-V4-LT UPL Report No. F22EU-035-AMA-004 GEP Unpublished	N	Y	New study	UPL
KCP 6.4.1 /070	Packwood, J.	2023	The efficacy of FGR06 and FHO04 applied in cereals for the control of *Puccinia triticina* (PUCCRT) in Europe. Eurofins, Lithuania, Report No. S23-101652-02 UPL Report No. F23EU-010-AMA-005 GEP Unpublished	N	Y	New study	UPL
KCP 6.4.1 /071	Lelešius, E.	2023	The efficacy of FGR06 and FHO04 applied in cereals for the control of *Puccinia triticina* (PUCCRT) in Europe. Agrolab, Lithuania UPL Report No. F23EU-010-AMA-006 GEP Unpublished	N	Y	New study	UPL
KCP 6.4.1 /072	Packwood, J.	2023	The efficacy of FGR06 and FHO04 applied in cereals for the control of *Puccinia triticina* (PUCCRT) in Europe. Eurofins, Lithuania, Report No. S23-101652-03 UPL Report No. F23EU-010-AMA-007 GEP Unpublished	N	Y	New study	UPL
KCP 6.4.1 /073	Lelešius, E.	2023	The efficacy of FGR06 and FHO04 applied in cereals for the control of *Puccinia striiformis* (PUCCST) in Europe. Agrolab, Lithuania UPL Report No. F23EU-013-AMA-006 GEP Unpublished	N	Y	New study	UPL
KCP 6.4.1 /074	Lelešius, E.	2023	The efficacy of FGR06 and FHO04 applied in cereals for the control of *Puccinia striiformis* (PUCCST) in Europe. Agrolab, Lithuania UPL Report No. F23EU-013-AMA-007 GEP Unpublished	N	Y	New study	UPL

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KCP 6.4.1 **KCP 6.4.2** **/075**	Oudin, V. Schmidt, I.	2019	The efficacy of FHO applied to winter wheat for the control of foliar diseases (SEPTTR) Staphyt, Germany, Report No. VON-19-38651-DE01 UPL Report No. F-19-EU-TRZAW-009E01-01DE GEP Unpublished	N	Y	New study	UPL
KCP 6.4.1 **/076**	Birkinshaw, N.	2021	The efficacy of FGR06 and FHO04 applied in cereals for the control of *Puccinia triticina* (PUCCRT) in Europe. Eurofins, Germany, Report No. S21-03654-10 UPL Report No. F21EU-009-011-003 GEP Unpublished	N	Y	New study	UPL
KCP 6.4.1 **/077**	Birkinshaw, N.	2021	The efficacy of FGR06 and FHO04 applied in cereals for the control of *Puccinia triticina* (PUCCRT) in Europe. Eurofins, Germany, Report No. S21-03654-12 UPL Report No. F21EU-009-011-005 GEP Unpublished	N	Y	New study	UPL
KCP 6.4.1 **/078**	Siebold, M.	2022	Field study to evaluate the efficacy of FGR06 and FHO04 applied in cereals for the control of *Puccinia striiformis* (PUCCST) in Europe Field Research Support, Germany, Report No. FRS201/22-V2 UPL Report No. F22EU-025-AMA-025 GEP Unpublished	N	Y	New study	UPL
KCP 6.4.1 **/079**	Birkinshaw, N.	2022	The efficacy of FGR06 and FHO04 applied in cereals for the control of *Puccinia triticina* (PUCCRT) in Europe. Eurofins, Germany, Report No. S22-03523-03 UPL Report No. F22EU-026-AMA-023 GEP Unpublished	N	Y	New study	UPL
KCP 6.4.1 **/080**	Birkinshaw, N.	2022	The efficacy of FGR06 and FHO04 applied in cereals for the control of *Puccinia triticina* (PUCCRT) in Europe. Eurofins, Germany, Report No. S22-03523-04 UPL Report No. F22EU-026-AMA-024 GEP Unpublished	N	Y	New study	UPL

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KCP 6.4.1 /081	Siebold, M.	2022	Field study to evaluate the efficacy of FGR06 and FHO04 applied in cereals for the control of *Puccinia triticina* (PUCCRT) in Europe. Field Research Support, Germany, Report No. FRS204/22 UPL Report No. F22EU-026-AMA-025 GEP Unpublished	N	Y	New study	UPL
KCP 6.4.1 KCP 6.4.2 KCP 6.4.3 /082	Siebold, M.	2022	Field study to evaluate the efficacy of FGR06 and FHO04 applied in cereals for the control of *Puccinia triticina* (PUCCRT) in Europe. Field Research Support, Germany, Report No. FRS205/22-V1 UPL Report No. F22EU-026-AMA-026 GEP Unpublished	N	Y	New study	UPL
KCP 6.4.1 /083	Siebold, M.	2023	The efficacy of FGR06 and FHO04 applied in cereals for the control of *Puccinia striiformis* (PUCCST) in Europe. Field Research Support, Germany, Report No. FRS030/23 UPL Report No. F23EU-011-AMA-004 GEP Unpublished	N	Y	New study	UPL
KCP 6.4.4 /084	Siebold, M. Genty, M.	2022	Unintentional effects of FHO04 and FGR06 on bread making process in winter wheat (field part). Field Research Support, Germany, Report No. FRS162/22-V1-FR UPL Report No. F22EU-036-AMA-001 GEP Unpublished	N	Y	New study	UPL
KCP 6.4.4 /085	Siebold, M. Peyrou-Pouquet, P.	2022	Unintentional effects of FHO04 and FGR06 on bread making process in winter wheat (field part). Field Research Support, Germany, Report No. FRS162/22-V2-FR UPL Report No. F22EU-036-AMA-002 GEP Unpublished	N	Y	New study	UPL
KCP 6.4.4 /086	Siebold, M. Laurent, C.	2022	Unintentional effects of FHO04 and FGR06 on bread making process in winter wheat (field part). Field Research Support, Germany, Report No. FRS162/22-V3-FR UPL Report No. F22EU-036-AMA-003 GEP Unpublished	N	Y	New study	UPL

Annex point	Author	Year	**Title** **Source (where different from company)** **Company, Report No.** **GLP or GEP status** **Published or Unpublished**	**Vertebrate study Y/N**	**Data protection claimed Y/N**	**Justification if data protection is claimed**	**Owner**
KCP 6.4.4 /087	Siebold, M. Laurent, C.	2022	Processing trial report - Unintentional effects of FHO04 and FGR06 on bread making process in winter wheat (field part). Syntech, Germany, Report No. EU-22-1236 UPL Report No. F22EU-036-AMA GEP Unpublished	N	Y	New study	UPL