

REGISTRATION REPORT

Part A

Risk Management

Product code: FGF11

Product name(s): Telaron Alpha

Chemical active substance(s):

Azoxystrobin, 160 g/L

Prothioconazole, 200 g/L

Central Zone

Zonal Rapporteur Member State: Poland

NATIONAL ASSESSMENT - Poland

(new authorization)

Applicant: UPL Holdings Coöperatief U.A.

Submission date: November 2024

MS Finalisation date: May 2025 (initial National Assessment),
update August 2025, January 2026, February 2026, March 2026,
April 2026, May 2026 (final National Assessment)

Version history

When	What
November 2024	dRR Part A – Version 1 submitted by applicant
May 2025	Initial zRMS assessment In order to facilitate tracking of changes of the intended uses of the product due to the performed evaluation, amendments of the GAP table and in the product label (Appendix 2) and Lists of data considered for national authorization (Appendix 4) are highlighted in grey, while not agreed use pattern is struck through and shaded.
August 2025	Final report (National 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. Not agreed or not relevant information are struck through and shaded for transparency.
January 2026	Final report (National Assessment updated following the addition of the new storage stability study assessment) Additional evaluations and conclusions of the zRMS are presented in grey commenting boxes. Minor changes are introduced directly in the text and highlighted in purple. Not agreed or not relevant information are struck through and shaded for transparency.
February 2026	zRMS assessment (National Assessment updated following the addition of the new summaries for selected uses to show efficacy from assessments after the first application in the efficacy section) Minor changes are introduced directly in the text and highlighted in green. Not agreed or not relevant information are struck through and shaded for transparency.
March 2026	Final report (National Assessment updated following the commenting period). No additional information or assessments after the commenting period.
April 2026	Final report (Core Assessment updated following the comments received from Polish Ministry of Agriculture for the efficacy section) Additional information/assessments included by the zRMS in the report in response to comments received from Polish Ministry of Agriculture are highlighted in red. Not agreed or not relevant information are struck through and shaded for transparency. An exception is made for the GAP table (column 15), where the assessment conclusions are indicated by color coding. For the better clarity, updates to the conclusions related to the efficacy section have been implemented in a non-visible manner. The revisions concern the introduction of conditional approvals for uses 1, 3, and 5.
May 2026	Final report (Core Assessment updated following the comments received from Polish Ministry of Agriculture for the toxicology section) Additional information/assessments included by the zRMS in the report in response to comments received from Polish Ministry of Agriculture are highlighted in turquoise (see table 2.4.1 Classification and labelling under Regulation (EC) No 1272/2008). In addition, the change to the name of the plant protection product in Appendix 2 Copy of the product label has also been included.

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PART A

RISK MANAGEMENT

This document - part A - of the application (draft Registration Report format) gives a general overview of the product endpoints and of the overall assessment conditions and risk management related to the use pattern (GAP) applied for the national registration as well as to the data protection and to the existing data access agreements.

1 Details of the application

This document describes the acceptable use conditions required for the registration of FGF11 containing Azoxystrobin 160 g/l + Prothioconazole 200 g/l in Poland.

The risk assessment conclusions are based on the information, data and assessments provided in the Registration Report, Part B, sections 1-10. The information, data and assessments provided in part B of the dRR include the assessment of further data and/or information as required for the national registration/re-registration by the EU review. It also includes assessments of data and information relating to the product FGF11 where that data has not been considered in the EU review. Otherwise, the safe use assessments of Azoxystrobin 160 g/l + Prothioconazole 200 g/l were done on the basis of the endpoints agreed in the EU review of azoxystrobin and prothioconazole.

This document describes the specific conditions of use and labelling required for the registration of FGF11 in Poland.

1.1 Application background

The aim of this registration application is the registration of the product FGF11 - an SC-formulation containing 160 g/L a.s. azoxystrobin + 200 g/l a.s. prothiconazole, for use as a fungicide intended for the control of foliar pathogens on cereals.

The product is recommended to be applied as foliar spray. The complete GAP for the national applications is provided below, under point 2.3.

1.2 Letters of Access

An Access Agreement is part of this application (see Appendix 3).

1.3 Justification for submission of tests and studies

In order to obtain the registration of the product FGF11, this application and the supporting dossier (dRR) should meet the data requirements of the Commission Regulation (EU) No 284/2013, with an assessment according to Uniform Principles (Commission Regulation (EU) No 546/2011), using agreed endpoints. This application was submitted in order to allow the registration of this product in Poland in accordance with the above. The reference list included in Part A Appendix 4 defines the list of studies and reports submitted by the applicant and relied on as well as a list of studies submitted by the applicant but not relied on for the authorisation. Furthermore, Appendix 4 includes studies already evaluated at EU peer review and studies necessary but not submitted.

1.4 Data protection claims

In order to obtain the registration of the product FGF11, this application and the supporting dossier (dRR) should meet the data requirements of the Commission Regulation (EU) No 284/2013, with an assessment according to Uniform Principles (Commission Regulation (EU) No 546/2011), using agreed

endpoints. This application was submitted in order to allow the registration of this product in Poland in accordance with the above. The reference list included in Part A Appendix 4 defines the list of studies and reports submitted by the applicant and relied on as well as a list of studies submitted by the applicant but not re-lied on for the authorisation. Furthermore, Appendix 4 includes studies already evaluated at EU peer re-view and studies necessary but not submitted.

2 Details of the authorization decision

2.1 Product identity

Product code	FGF11
Product name in MS	Patton Alpha
Authorization number	Not yet authorized
Function	Fungicide
Applicant	UPL Holdings Coöperatief U.A.
Active substance(s) (incl. content)	Azoxystrobin 160 g/L Prothioconazole 200 g/L
Formulation type	Suspension Concentrate [SC]
Packaging	professional user 0.5, 1, 2, 3, 5, 10 and 20L (HDPE/EVOH, HDPE/PA and HDPE/F)
Coformulants of concern for national authorizations	None
Restrictions related to identity	None
Mandatory tank mixtures	None
Recommended tank mixtures	In the case of a mixture with other pesticide products, it is advisable to first establish the physical compatibility of each mixture by preparing a small amount separately before use

2.2 Conclusion

The evaluation of the application for Patton Alpha (FGF11) resulted in the decision to grant the authorization.

Based on the currently available MSDSs and other information provided by applicant or manufacturer of co-formulant, the product **FGF11/ Patton Alpha** does not contain any unacceptable co-formulant/ingredient listed in the **Commission Regulation (EU) 2021/383** amending **Annex III** to Regulation (EC) No 1107/2009. According to the current knowledge and available information none of the co-formulants in the plant protection product **FGF11/ Patton Alpha** meets the **Annex to Regulation (EU) 2023/574** criteria for identification of co-formulants that are unacceptable for inclusion in a plant protection products. Taking this into account, none of the co-formulants/ingredients in this product is considered to be a candidate for inclusion in Annex III of Regulation (EU) 1107/2009.

Detailed assessment of co-formulants according to Article 3 of **Regulation (EU) 2023/574** can be found in annex to Part C of this submission.

2.3 Substances of concern for national monitoring

Not applicable.

2.4 Classification and labelling

2.4.1 Classification and labelling under Regulation (EC) No 1272/2008

The following classification is proposed in accordance with Regulation (EC) No 1272/2008:

Hazard class(es), categories:	Acute toxicity (inhalation:dust,mist) Category 4 Skin sens., Category 1 Hazardous to the aquatic environment – Acute Hazard, Category 1 Hazardous to the aquatic environment – Chronic Hazard, Category 1
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The following labelling information is derived from the classification and to be mentioned in the safety data sheet. The information which is determined for the **label is formatted bold**:

Hazard pictograms:	GHS07, GHS09
Signal word:	Warning
Hazard statement(s):	H317 - May cause an allergic skin reaction H332 - Harmful if inhaled. H400 - Very toxic to aquatic life. H410 - Very toxic to aquatic life with long lasting effects.
Precautionary statement(s):	P261 - Avoid breathing dust, fume, gas, mist, spray, vapours. P271 - Use only outdoors or in a well-ventilated area. P280 - Wear protective gloves. P302 + P352 - IF ON SKIN: Wash with plenty of water/... P304+P340 - IF INHALED: Remove person to fresh air and keep comfortable for breathing. P312 - Call a POISON CENTER, doctor if you feel unwell. P333 + P313 - If skin irritation or rash occurs: Get medical advice/attention. P362+P364 - Take off contaminated clothing and wash it before reuse. P391 - Collect spillage. P501 - Dispose of contents and container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.
Additional labelling phrases:	To avoid risks to human health and the environment, comply with the instructions for use [EUH401]
SP 1	Do not contaminate water with the product or its container (Do not clean application equipment near surface water/Avoid contamination via drains from farmyards and roads).

Special rule for labelling of plant protection product (PPP):	
EUH401	To avoid risks to man and the environment, comply with the instructions for use.
Further labelling statements under Regulation (EC) No 1272/2008:	
None	-

See Part C for justifications of the classification and labelling proposals.

2.4.2 Standard phrases under Regulation (EU) No 547/2011

SP 1	Do not contaminate water with the product or its container (Do not clean application equipment near surface water/Avoid contamination via drains from farmyards and roads).
SPe3	To protect aquatic organisms respect vegetative buffer zone of 10 m to surface water bodies for winter and spring cereals.

2.4.3 Other phrases (according to Article 65 (3) of the Regulation (EU) No 1107/2009)

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2.5 Risk management

2.5.1 Restrictions linked to the PPP

The authorization of the PPP is linked to the following conditions (mandatory labelling):

Operator protection:	
respective code if available	Work wear (arms, body and legs covered) during mixing and loading and gloves during application
Worker protection:	
respective code if available	Workwear; Inspection, irrigation
Resident and bystander protection	
	None
Integrated pest management (IPM)/sustainable use:	
	Follow strictly the instructions of use on the label
Environmental protection	
SP1	Do not contaminate water with the product or its container (Do not clean application equipment near surface water/Avoid contamination via drains from farmyards and roads).
Spe3	To protect aquatic organisms, respect vegetative buffer zone of 10 m to surface water bodies for use in winter and spring cereals.
Other specific restrictions	
-	

The authorization of the PPP is linked to the following conditions (voluntary labelling):

Integrated pest management (IPM)/sustainable use:	
-	

2.5.2 Specific restrictions linked to the intended uses

Some of the authorised uses are linked to the following conditions in addition to those listed under point 2.5.1 (mandatory labelling):

Integrated pest management (IPM)/sustainable use:		Relevant for use no.
-		
Environmental protection:		Relevant for use no.
	A vegetative filter strip (VFS) is required for the protection of aquatic organisms	1,2,3,5,6

2.6 Intended uses (only NATIONAL GAP)

GAP rev. 1, date: 2026-04 2025-08-3 2024-09-02

PPP (product name/code): Code: FGF11 (Trade name: Patton Alpha)
Active substance 1: Prothioconazole
Active substance 2: Azoxystrobin
Applicant: UPL Holdings Cooperatief U.A.
Zone(s): Central
Verified by MS: Yes
Field of use: Fungicide

Formulation type: Suspension concentrate
Conc. of as 1: 200 g/L
Conc. of as 2: 160 g/L
Professional use: ☒
Non professional use: ☐

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15							
Use- No. *	Member state(s)	Crop and/or situation (crop destination / purpose of crop)	F, Fn, G, Gpn or I **	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/ synergist per ha	zRMS Conclusion							
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max			Phys-chem	Analytical methods	Toxicology	Residues	Fate and behavior	Ecotoxicology	Relevance of metabolites in groundwater	Efficacy
1	PL	Winter wheat, spring wheat, durum wheat, spelt TRZAW, TRZAS, TRZDU, TRZDU, TRZSP	F	Wheat: septoria leaf blotch (<i>Zymoseptoria tritici</i>) SEPTTR, yellow rust (<i>Puccinia striiformis</i>) PUECST brown rust (<i>Puccinia recondita</i>) PUCCRE	Foliar spray application	30-69 10-33	a) 1 b) 1	-	a) 1.0 b) 1.0	160 g/ha azoxystrobin + 200 g/ha prothioconazole	100-400	35	Applications are growth stage re- stricted	A	A	A	A	A	R Aquatic (R1)	A	A TRZAW (SEPTTR, PUCCST, PUCCRE)
																			A Remaining species		R TRZAS/PUCCST TRZAS/PUCCRE TRZAS/SEPTTR - In PL only condi- tional registration is possible - (final decision is left at the Authority dis- cretion)
																					N TRZDU TRZSP Durum wheat and spelt- possible authorization based on the art. 51-minor uses

2	PL	Winter triticale, spring triticale TTLWI, TTLSO	F	Wheat: septoria leaf blotch (<i>Zymoseptoria tritici</i>) SEPTTR, yellow rust (<i>Puccinia striiformis</i>) PUCCST, brown rust (<i>Puccinia recondita</i>) PUCCRE	Foliar spray application	30-69 30-37	a) 1 b) 1	-	a) 1.0 b) 1.0	160 g/ha azoxystrobin + 200 g/ha prothioconazole	100-400	35	Applications are growth stage re-stricted	A	A	A	A	A	R Aquatic (R1)	A	A TTLWI (SEPTTR, PUCCST, PUCCRE) TTLSO (PUCCST)
																		A Remaining species		N TTLSO (PUCCRE, SEPTTR)	
3	PL	Winter barley, spring barley HORVW, HORVS	F	Net blotch (<i>Pyrenophora teres</i>) PYRNTE, Ramularia (<i>Ramularia collo-cygni</i>) RAMUCC, Leaf blotch (<i>Rhynchosporium secali</i>) RHYNSE, Rust (<i>Puccinia hordei</i>) PUCCHD	Foliar spray application	30-59	a) 1 b) 1	-	a) 1.0 b) 1.0	160 g/ha azoxystrobin + 200 g/ha prothioconazole	100-400	35	Applications are growth stage re-stricted	A	A	A	A	A	R Aquatic (R1)	A	A HORVW PUCCHD R HORVS/PUCCHD HORVS/PYRNTE HORVW/PYRNTE - in PL only conditional registration is possible - (final decision is left at the Authority discretion)
																		A Remaining species		N RAMUCC, RHYNSE	
4	PL	Winter oilseed rape, spring oilseed rape BRSNW, BRSNS	F	Cottony rot (cc) Black spot (<i>Alternaria brassicae</i>) Cottony rot (<i>Sclerotinia sclerotiorum</i>) [SCLESC]	Foliar spray application	61-73 61-67 69	a) 1 b) 1	-	a) 1.0 b) 1.0	160 g/ha azoxystrobin + 200 g/ha prothioconazole	100-400	35	Applications are growth stage re-stricted	A	A	A	R** A	A	A	A	A BRSNW N BRSNS Spring oilseed rape-possible authorization based on the art. 51-minor uses
5	PL	Winter rye, spring rye SECCW, SECCS	F	Brown rust (<i>Puccinia recondita</i>) PUCCRR	Foliar spray application	30-69	a) 1 b) 1	-	a) 1.0 b) 1.0	160 g/ha azoxystrobin + 200 g/ha prothioconazole	100-400	35	Applications are growth stage re-stricted	A	A	A	A	A	R Aquatic (R1)	A	N SECCS Spring rye- possible authorization based on the art. 51-minor uses

Remarks columns:	1	Numeration necessary to allow references	7	Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
	2	Use official codes/nomenclatures of EU Member States	8	The maximum number of application possible under practical conditions of use must be provided.
	3	For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)	9	Minimum interval (in days) between applications of the same product
	4	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	10	For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
	5	Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.	11	The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
	6	Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench	12	If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”.
		Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.	13	PHI - minimum pre-harvest interval
			14	Remarks may include: Extent of use/economic importance/restrictions
			15	Overall conclusions - explanation for the column 15 is below

A	Acceptable
R	Acceptable with further restriction
C	To be confirmed by cMS
N	Not acceptable / evaluation not possible

Remark:

~~*** The interval from sampling until extraction for 1,2,4 T and TA in the Bousquet's study (647-2023; 2023) was longer than the storage stability period for 1,2,4 T and TA in oilseed rape from S. Baxter, B. Phipps study (QG/21/002). Therefore additional data on storage stability for 1,2,4 T and TA in oilseed rape are required (data gap).~~

3 Background of authorization decision and risk management

3.1 Physical and chemical properties (Part B, Section 2)

‘Patton Alpha’ (FGF11) is a suspension concentrate (SC) formulation. All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is that of light brown liquid (suspension), with a characteristic odour. It is not explosive, has no oxidising properties. The product has a flash point of >102 °C. It has a self-ignition temperature of >600 °C. In aqueous solution, it has a pH value around 6.73 at 20.1 °C. FGF11 is considered to be “Surface active”. There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0 °C and 42 days at 45 °C, neither the active ingredient content nor the technical properties were changed. A shelf life of at least 2 years at ambient temperature is expected when the product is stored in the COEX/EVOH, COEX/PA and COEX/F packaging material (based on results of accelerated and after one year of storage stability study); an ambient temperature shelf-life study is currently underway to confirm this expected shelf-life. Its technical characteristics are acceptable for a suspension concentrate formulation.

The intended concentration of use is 0.25%v/v (1 L/ha product, with 400 L water per ha) to 1%v/v (1 L/ha product, with 100 L water per ha).

The formulation is not classified with respect to its physical and chemical properties.

3.2 Efficacy (Part B, Section 3)

FGF11 is a suspension concentrate (SC) formulation containing 160 g/L azoxystrobin and 200 g/L prothioconazole that is intended for use as a fungicide for the control of multiple targets in cereals and oilseed rape.

Data on efficacy and crop safety from trials carried out in cereals and oilseed rape within the Maritime, North-east and South-east EPPO climatic zones between 2022-2024 are summarised in support of this application for the authorisation of FGF11 in the Central Registration zone / in Great Britain.

All trials were carried out by organisations that are officially recognised as competent to carry out efficacy testing in accordance with Regulation (EU) 284/2013 by the authorities in the relevant countries for this submission and following relevant EPPO and national guidelines.

3.3 Efficacy data

Preliminary tests

Two (2) preliminary studies conducted in greenhouses between 2023 and 2024 to justify the combination and the ratio of the active substances contained in FGF11. These studies generated data on efficacy against SEPTTR in winter wheat.

Data generated in the greenhouse preliminary studies clearly show the efficacy of the tank mixture of azoxystrobin and prothioconazole products applied at rates of 160 g azoxystrobin/ha + 200 g prothioconazole/ha therefore at rates matching those delivered by FGF11 applied at the proposed label rate of 1.0 L product/ha to be higher and more consistent compared to that given by the same rates of azoxystrobin and prothioconazole applied alone. Additionally, FGF11 combines the complementary activity of two active ingredients with different modes of action target sites to give effective preventative, curative and eradicated control of various fungal diseases, therefore is an important part of management strategy in reducing of resistance risk. In addition, the use of the combination of azoxystrobin and prothioconazole in FGF11 give effective diseases control with the use of only a single product, whereas the application of more than one alternative product either in tank mixture or applied separately may be less practical and economical. Furthermore, addition of azoxystrobin in FGF11 have a positive effect on green leaf maintainance – delay in leaf yellowing have potential effect on yield increasing. Based on this,

the combination of the two active substances in FGF11 and at the amounts delivered when applied at the proposed label rate of 1.0 L product/ha is fully justified.

Data generated in the greenhouse preliminary studies clearly show the efficacy of the tank mixture of azoxystrobin and prothioconazole products applied at ratio of 160 g azoxystrobin/ha + 200 g prothioconazole/ha therefore at ratio in FGF11 when applied at the proposed label rate of 1.0 L product/ha to be higher and more consistent compared to ratios containing reduced amounts of azoxystrobin or prothioconazole. Based on the data from these 2 studies, the ratio of 160 g azoxystrobin/ha + 200 g prothioconazole/ha in FGF11 when applied at the proposed label rate of 1.0 L product/ha is fully justified.

Minimum effective dose

Minimum effective dose for control of target foliar diseases in winter wheat, spring wheat, durum wheat, spelt, winter triticale and spring triticale

One hundred and twenty two (122) of the 123 trials carried out between 2022 and 2023 generated data on the efficacy of FGF11 applied at a range of rates against target foliar diseases in wheat (winter, spring, durum), spelt and triticale (winter and spring).

Minimum effective dose for control of Septoria leaf spot (SEPTTR)

A total of 16 efficacy trials from all EPPO zones have been submitted to determine the minimum effective dose for the control of *Zymoseptoria tritici* (SEPTTR) in winter wheat after 1 application. In the North-East zone, 4 trials were conducted between 2022 and 2023. Also 3 trials from Germany can be support for the Polish registration. The test product at claimed dose presented medium level of control on L4 (69,3%) and L5 (70,3%). Good efficacy with the results of 90% on L2, 87,2% on L3 was in 1 out of 7 trials. Slight inferior results was noted at the lower dose of 0,75 l/ha.

A total of 3 efficacy trials from the Maritime and South-East EPPO zones have been submitted to determine the minimum effective dose for the control of *Zymoseptoria tritici* (SEPTTR) in spring wheat after 1 application. No results after 1 application were available in the North-East EPPO zone. This use cannot be accepted in Poland.

A total of 3 efficacy trials from the Maritime and South-East EPPO zones have been submitted to determine the minimum effective dose for the control of *Zymoseptoria tritici* (SEPTTR) in durum wheat after 1 application. No results after 1 application were available in the North-East zone. This use cannot be accepted in Poland. Durum wheat is minor crop in Poland and the registration under art. 51 is possible in this case.

Only 2 efficacy trials have been submitted to determine the minimum effective dose for the control of *Zymoseptoria tritici* (SEPTTR) in spelt after 1 application. Both trials were conducted in 2022 in the Maritime EPPO climatic zone. No results after 1 application were available in the North-East and South-East EPPO zone. This use cannot be accepted in Poland. Spelt is minor crop in Poland and the registration under art. 51 is possible in this case.

A total of 8 efficacy trials from all EPPO zones have been submitted to determine the minimum effective dose for the control of *Zymoseptoria tritici* (SEPTTR) in winter triticale after 1 application. In the North-East zone, 2 trials were carried out in 2023. Also 3 trials from Germany can be support for the Polish registration. The test product at the claimed dose rate presented good efficacy with the results of 100% on L2, 96,4% on L3, 83,3% on L4 and 87,7% on L5. Comparable effect was visible at the lower dose of 0,75 l/ha on L2, L3 and L5 and medium efficacy was noted on L4.

Data generated in trials carried out in North-east EPPO climatic zones clearly show the efficacy of FGF11 applied at 1.0 L product/ha once per growing season against SEPTTR in wheat and triticale to be higher and more consistent compared to that of lower rates (0.75 L and 0.5 L product/ha).

It is therefore reasonable to conclude that the proposed label rate of 1.0 L product/ha is fully justified as the minimum effective dose for the control of SEPTTR in winter wheat and winter triticale by FGF11.

Minimum effective dose for control of Yellow rust (PUCCST/PUCCSI)

A total of 6 efficacy trials from all EPPO zones have been submitted to determine the minimum effective dose for the control of *Puccinia striiformis* (PuccST) in winter wheat after 1 application. In the North-East zone, only 1 trial was carried out in 2023. Also 1 trial from Germany can be support for the Polish registration. The test product at the claimed dose rate presented high efficacy with the results of 90,9% on L3 and 100% on L4. No significant differences between the dose rates of 1 l/ha and 0,75 l/ha. ~~Due to the limited number of trials, this use cannot be accepted in Poland.~~

Only 1 efficacy trial has been submitted to determine the minimum effective dose for the control of *Puccinia striiformis* (PuccST) in spring wheat after 1 application. This trial was conducted in 2022 in the Maritime EPPO climatic zone. ~~No results after 1 application were available in the North East and South East EPPO zone. This use cannot be accepted in Poland.~~

A total of 2 efficacy trials from the North-East and South-East EPPO zones have been submitted to determine the minimum effective dose for the control of *Puccinia striiformis* (PuccST) in winter triticale after 1 application. In the North-East EPPO climatic zone, only 1 trial was conducted in 2023. FGF11 applied at dose rate of 1 l/ha achieved medium level of control on L2 (75%) and higher efficacy on L3 (100%). Similar effect was observed at the lower dose rates of 0,75 l/ha and 0,5 l/ha. ~~This use cannot be accepted in Poland because of very limited number of trials.~~

Only 1 efficacy trial has been submitted to determine the minimum effective dose for the control of *Puccinia striiformis* (PuccST) in spring triticale after 1 application. This trial was conducted in 2023 in the North-East EPPO climatic zone. FGF11 at 1 l/ha achieved full effectiveness on L5. High level of control was observed also at the lower dose rates of 0,75 l/ha and 0,5 l/ha. ~~Due to the limited number of trials, this use cannot be accepted in Poland.~~

Minimum effective dose for control of Brown rust (PUCCRE/PUCCRT)

A total of 4 efficacy trials from all EPPO zones have been submitted to determine the minimum effective dose for the control of *Puccinia recondita* (PUCCRE/PUCCRT) in winter wheat after 1 application. In the North-East zone, only 1 trial was carried out in 2023. The test product at the claimed dose rate presented high level of control with the result of 93,2% on L4. Comparable effect was visible at the lowers doses. ~~This use cannot be accepted in Poland because of very limited number of trials.~~

A total of 4 efficacy trials from the North-East and South-East EPPO zones have been submitted to determine the minimum effective dose for the control of *Puccinia recondita* (PUCCRE/PUCCRT) in winter triticale after 1 application. In the North-East EPPO zone, only 1 trial was conducted in 2023. FGF11 at 1 l/ha achieved good level of control with the result of 91% on L4. Comparable effect was observed at the lower dose of 0,75 l/ha and slight inferior at 0,5 l/ha. ~~This use cannot be accepted in Poland because of very limited number of trials.~~

Only 2 efficacy trials have been submitted to determine the minimum effective dose for the control of *Puccinia recondita* (PUCCRE/PUCCRT) in spring wheat after 1 application. Both trials were conducted in 2023 in the South-East EPPO climatic zone. ~~No results after 1 application were available in the Maritime and North East EPPO zone. This use cannot be accepted in Poland.~~

Minimum effective dose for control of target foliar diseases in winter and spring rye

Minimum effective dose for control of Brown rust (PUCCRR)

No results after 1 application were available in any EPPO climatic zone. The CMSs belonging to the Maritime and South-East zone are kindly asked to consider the use of FGF11 at 1 l/ha in winter and spring rye against *Puccinia recondita* f.sp. *recondita* (PUCCRR) at the national level. These uses cannot be accepted in Poland (under art. 33). However, spring rye is minor crops in Poland and the registration under art. 51 is possible in this case.

Minimum effective dose for control of target foliar diseases in winter and spring barley

All 33 efficacy trials carried out between 2022 and 2023 generated data on the efficacy of FGF11 applied at a range of rates against target disease in winter and spring barley. The data from these trials are summarised in support of justification of the minimum effective dose rate for control of target diseases in barley by FGF11.

Minimum effective dose for control of Net blotch (PYRNTE)

A total of 7 efficacy trials from the North-East and South-East EPPO zones have been submitted to determine the minimum effective dose for the control of *Pyrenophora teres* (PYRNTE) in winter barley after 1 application. In the North-East EPPO climatic zone, 2 trials were conducted in 2023. FGF11 applied at dose rate of 1 l/ha achieved good level of control on L4 with the result of 90,7%. Medium effectiveness was observed on L5 (78,3%) in 1 trial. Comparable effect was noted at the lower dose rate of 0,75 l/ha. ~~However, this use cannot be accepted because of the limited number of trials.~~

A total of 5 efficacy trials from all EPPO zones have been submitted to determine the minimum effective dose for the control of *Pyrenophora teres* (PYRNTE) in spring barley after 1 application. In the North-East zone, 2 trials were carried out between 2022 and 2023. The test product at the claimed dose presented medium level of control with the results of 79,83% on L3 and 63,9% on L4. The lower dose rates of 0,75 l/ha and 0,5 l/ha obtained comparable effect. ~~Due to limited number of trials and no extrapolation possible, this use cannot be accepted in Poland.~~

Minimum effective dose for control of Rust (PUCCHD)

A total of 2 efficacy trials from the Maritime and North-East EPPO zones have been submitted to determine the minimum effective dose for the control of *Puccinia hordei* (PUCCHD) in winter barley after 1 application. In the North-East zone, 1 trial was carried out in 2023. Also 1 trial from Germany can be support for the Polish registration. The test product at the claimed dose presented medium level of control on L4 (59,8%) and L5 (66,6%). Superior result was observed on L3 (98,88%) in other trial. Significant inferior effectiveness was noted at the lower doses. ~~This use cannot be accepted because of the limited number of trials.~~

~~No results after 1 application were available in spring barley in any EPPO climatic zones. The cMSs belonging to the MAR and SE zone are kindly asked to consider this use at the national level. This use cannot be accepted in Poland.~~

Minimum effective dose for control of Ramularia (RAMUCC)

Only 1 trial has been submitted to determine the minimum effective dose for the control of *Ramularia collo-cygni* (RAMUCC) in winter barley after 1 application. This trial was conducted in 2023 in the South-East EPPO climatic zone. No results after 1 application were available in the Maritime and North-East EPPO zone. The cMSs belonging to the MAR zone are kindly asked to consider this use at the national level. This use cannot be accepted in Poland.

No results after 1 application were available in spring barley in any EPPO climatic zones. The cMSs belonging to the MAR and SE zone are kindly asked to consider this use at the national level. This use cannot be accepted in Poland.

Minimum effective dose for control of Leaf blotch (RHYNSE)

A total of 2 efficacy trials from the Maritime and North-East EPPO zones have been submitted to determine the minimum effective dose for the control of *Rhynchosporium secalis* (RHYNSE) in winter barley after 1 application. In the North-East zone, no trials were carried out. However, 1 trial from Germany can be support for the Polish registration. FGF11 at 1 l/ha presented medium level of control and it was significant superior effect compared to the lower doses of 0,75 l/ha and 0,5 l/ha.

No results after 1 application were available in spring barley in any EPPO climatic zones. The cMSs belonging to the MAR and SE zone are kindly asked to consider this use at the national level. This use cannot be accepted in Poland.

Minimum effective dose for control of target diseases in winter and spring oilseed rape

A total of 23 trials carried out between 2022 and 2023 generated data on the efficacy of FGF11 applied at a range of rates against SCLESC in winter oilseed rape. The data from these trials are summarised in support of justification of the minimum effective dose rate for control of target disease in oilseed rape by FGF11.

Minimum effective dose for control of Cottony rot (SCLESC)

A total of 23 efficacy trials from all EPPO zones have been submitted to determine the minimum effective dose for the control of *Sclerotinia sclerotiorum* (SCLESC) in winter oilseed rape. In the North-East zone, 5 trials were carried out between 2022 and 2023. The test product at the claimed dose presented good efficacy on stems with the result of 84,9%. No significant differences between dose rates of 1 l/ha and the lower dose of 0,75 l/ha were observed. Slight inferior effect was noted at 0,5 l/ha. The observations on the leaves were not available in the NE zone. 3 efficacy trials conducted in Germany can support the registration in Poland.

No efficacy trials were available for spring oilseed rape in any EPPO climatic zone. The cMSs belonging to the MAR and SE zone are kindly asked to consider this use at the national level. Due to the inability to extrapolate, this use cannot be accepted on the registration under art. 33 in Poland. However, spring oilseed rape is minor crop in Poland and the registration under art. 51 is possible in this case.

The efficacy of FGF11 applied at 1.0 L product/ha against SCLESC in winter oilseed rape is higher and more consistent compared to that of lower rates (0.75 L and 0.5 L product/ha).

It is therefore reasonable to conclude that the proposed label rate of 1.0 L product/ha is fully justified as the minimum effective dose for the control of SCLESC in winter oilseed rape by FGF11.

Minimum effective dose for control of target ear diseases in winter wheat, spring wheat, durum wheat and spelt

Fourteen (14) of the 40 trials carried out in 2023 generated data on the efficacy of FGF11 applied at a range of rates against target ear disease in winter wheat. The data from these trials are summarized in support of justification of the minimum effective dose rate for control of target ear disease in winter wheat by FGF11.

Minimum effective dose for control of Fusarium ear blight (FUSASP)

A total of 14 efficacy trials from all EPPO zones have been submitted to determine the minimum effective dose for the control of *Fusarium* sp. (FUSASP) in winter wheat. In the North-East zone, 6 trials were carried out in 2023. The test product at claimed dose presented good control with the result of 84,0% on ears. No significant differences between the doses 1 l/ha and 0,75 l/ha were observed. The lower dose of 0,5 l/ha had inferior result in 2 out of 6 trials.

No efficacy trials were available for other wheat crops in any EPPO climatic zone. The cMSs belonging to the MAR and SE zone are kindly asked to consider these uses at the national level. Due to the inability to extrapolate, these uses cannot be accepted on the registration under art. 33 in Poland. However, durum wheat and spelt are minor crops in Poland and the registration under art. 51 is possible in these cases.

Data generated in trials carried out in North-East EPPO climatic zones clearly show the efficacy of FGF11 applied at 1.0 L product/ha once per growing season against FUSASP in winter wheat to be higher and more consistent compared to that of lower rates (0.75 L and 0.5 L product/ha).

It is therefore reasonable to conclude that the proposed label rate of 1.0 L product/ha is fully justified as the minimum effective dose for the control of FUSASP in winter wheat by FGF11.

Efficacy tests

Efficacy against target foliar diseases in winter wheat, spring wheat, durum wheat, spelt, winter triticale and spring triticale

A total of 123 trials carried out between 2022 and 2023 have generated data on the efficacy of FGF11 applied the proposed label rate of 1.0 L product/ha against target foliar diseases in wheat (winter, spring, durum), spelt and triticale (winter and spring).

Efficacy against Septoria leaf spot (SEPTTR)

A total of 16 trials from all EPPO zones have been submitted to evaluate the effectiveness of FGF11 applied at dose rate of 1 l/ha once per growing season for the control of *Zymoseptoria tritici* (SEPTTR) in winter wheat. In the North-East zone, 4 trials were conducted in 2023. Also 3 trials from Germany can be support for the Polish registration. The test product at claimed dose presented medium level of

control in most of trials with the results of 69,3% on L4 and 70,3% on L5. Superior effect was visible on L2 (90,9%) and L3 (87,2%) but in only 1 trial. The test product at 0,8 l/ha had comparable effectiveness.

A total of 3 trials from the Maritime and South-East EPPO zones have been submitted to evaluate the effectiveness of FGF11 applied at dose rate of 1 l/ha once per growing season for the control of *Zymoseptoria tritici* (SEPTTR) in spring wheat. No results after 1 application were available in the North-East EPPO zone. This use cannot be accepted in Poland.

A total of 3 trials from the Maritime and South-East EPPO zones have been submitted to evaluate the effectiveness of FGF11 applied at dose rate of 1 l/ha once per growing season for the control of *Zymoseptoria tritici* (SEPTTR) in durum wheat. No results after 1 application were available in the North-East zone. This use cannot be accepted in Poland. Durum wheat is minor crop in Poland and the registration under art. 51 is possible in this case.

Only 2 trials have been submitted to evaluate the effectiveness of FGF11 applied at dose rate of 1 l/ha once per growing season for the control of *Zymoseptoria tritici* (SEPTTR) in spelt. Both trials were conducted in 2022 in the Maritime EPPO climatic zone. No results after 1 application were available in the North-East and South-East EPPO zone. This use cannot be accepted in Poland. Spelt is minor crop in Poland and the registration under art. 51 is possible in this case.

A total of 8 trials from all EPPO zones have been submitted to evaluate the effectiveness of FGF11 applied at dose rate of 1 l/ha once per growing season for the control of *Zymoseptoria tritici* (SEPTTR) in winter triticale. In the North-East zone, 2 trials were carried out in 2023. Also 3 trials from Germany can be support for the Polish registration. Moreover, the extrapolation from winter wheat is possible. The test product at the claimed dose rate presented good efficacy with the results of 100% on L2, 96,4% on L3, 83,3% on L4 and 87,7% on L5. Comparable effect was visible for the reference product.

No results after 1 application were available in spring triticale in any EPPO climatic zone. The cMSs belonging to the Maritime and South-East zone are kindly asked to consider this use at the national level. This use cannot be accepted in Poland.

Data generated across trials carried out in the North-East EPPO climatic zones demonstrate that FGF11 applied at the proposed label rate of 1.0 L product/ha once per growing season generally gives effective control of SEPTTR in wheat and triticale that is consistently comparable and mostly not statistically significantly different to that given by the standard reference products applied at label rates.

Based on the summarized data, it is therefore considered that claims for control of SEPTTR in winter wheat and winter triticale by FGF11, applied at the proposed label rate of 1.0 L product/ha and according to other label recommendations, are fully supported.

Efficacy against Yellow rust (PUCCST/PUCCSI)

A total of 6 trials from all EPPO zones have been submitted to evaluate the effectiveness of FGF11 applied at dose rate of 1 l/ha once per growing season for the control of *Puccinia striiformis* (PUCCST) in winter wheat. In the North-East zone, only 1 trial was carried out in 2023. Also 1 trial from Germany can be support for the Polish registration. The test product at the claimed dose rate presented high efficacy with the results of 90,9% on L3 and 100% on L4. No significant differences between test and reference product were noted. ~~Due to the limited number of trials, this use cannot be accepted in Poland.~~

Only 1 trial has been submitted to evaluate the effectiveness of FGF11 applied at dose rate of 1 l/ha once per growing season for the control of *Puccinia striiformis* (PUCCST) in spring wheat. This trial was conducted in 2022 in the Maritime EPPO climatic zone. ~~No results after 1 application were available in the North-East and South-East EPPO zone. This use cannot be accepted in Poland.~~

A total of 2 trials from the North-East and South-East EPPO zones have been submitted to evaluate the effectiveness of FGF11 applied at dose rate of 1 l/ha once per growing season for the control of *Puccinia striiformis* (PUCCST) in winter triticale. In the North-East EPPO climatic zone, only 1 trial was conducted in 2023. FGF11 applied at dose rate of 1 l/ha achieved medium level of control on L2 (75%) and

higher efficacy on L3 (100%). Similar effect was observed for the reference product at 0,8 l/ha. ~~This use cannot be accepted in Poland because of very limited number of trials.~~

Only 1 trial has been submitted to evaluate the effectiveness of FGF11 applied at dose rate of 1 l/ha once per growing season for the control of *Puccinia striiformis* (PuccST) in spring triticale. This trial was conducted in 2023 in the North-East EPPO climatic zone. FGF11 at 1 l/ha achieved full effectiveness on L5. High level of control was observed also for the reference product at 0,8 l/ha. ~~Due to the limited number of trials, this use cannot be accepted in Poland. However, PuccST on spring triticale is minor use in Poland and the registration under art. 51 is possible.~~

~~No results after 1 application were available in any EPPO climatic zone. The cMSs belonging to the Maritime and South East zone are kindly asked to consider these uses at the national level. These uses cannot be accepted in Poland. However, Durum wheat and spelt are minor crops in Poland and the registration under art. 51 is possible in these cases.~~

Efficacy against Brown rust (PUCCRE/PUCCRT)

A total of 4 trials from all EPPO zones have been submitted to evaluate the effectiveness of FGF11 applied at dose rate of 1 l/ha once per growing season for the control of *Puccinia recondita* (PUCCRE/PUCCRT) in winter wheat. In the North-East zone, only 1 trial was carried out in 2023. The test product at the claimed dose rate presented high level of control with the result of 93,2% on L4. Comparable effect was visible for the reference product. ~~This use cannot be accepted in Poland because of very limited number of trials.~~

A total of 4 trials from the North-East and South-East EPPO zones have been submitted to evaluate the effectiveness of FGF11 applied at dose rate of 1 l/ha once per growing season for the control of *Puccinia recondita* (PUCCRE/PUCCRT) in winter triticale. In the North-East EPPO zone, only 1 trial was conducted in 2023. FGF11 at 1 l/ha achieved good level of control with the result of 91% on L4. Comparable effect was observed for the reference product at 0,8 l/ha. ~~This use cannot be accepted in Poland because of very limited number of trials.~~

Only 2 trials have been submitted to evaluate the effectiveness of FGF11 applied at dose rate of 1 l/ha once per growing season for the control of *Puccinia recondita* (PUCCRE/PUCCRT) in spring wheat. Both trials were conducted in 2023 in the South-East EPPO climatic zone. ~~No results after 1 application were available in the Maritime and North East EPPO zone. This use cannot be accepted in Poland.~~

~~No results after 1 application were available for other wheat crops in any EPPO climatic zone. The cMSs belonging to the Maritime and South East zone are kindly asked to consider these uses at the national level. These uses cannot be accepted in Poland. However, Durum wheat and spelt are minor crops in Poland and the registration under art. 51 is possible in these cases.~~

Positive effects on green leaf area

Positive effects on green leaf area were assessed on a total of 112 of the trials carried out between 2022 and 2023 that generated data on the efficacy of FGF11 applied at the proposed label rate of 1.0 L product/ha in 2 applications against target foliar diseases in winter wheat (58 trials), spring wheat (16 trials), durum wheat (10 trials), spelt (6 trials), winter triticale (21 trials) and spring triticale (1 trial). Of these trials, 28 were carried out in the North-east EPPO climatic zone.

Target foliar diseases that occurred in these trials were PUCCRE on 9 trials, PUCCRT on 5 trials, PUCCSI on 5 trials, PuccST on 11 trials, SEPTTR on 48 trials, PUCCRE and SEPTTR on 16 trials, PUCCRT and SEPTTR on 3 trials, PUCCRE and PUCCSI on 2 trials, SEPTTR and PUCCSI on 3 trials, SEPTTR and PuccST on 5 trials, PUCCRE, SEPTTR and PuccST on 3 trials, PUCCRT, SEPTTR and PUCCSI on 1 trial and PUCCRE, SEPTTR and PUCCSI on 1 trial.

FGF11 applied at the proposed label rate of 1.0 L product/ha increased green leaf area on the upper leaves in all trials and on a whole plant leaf area basis in great majority of the trials compared to the untreated control. The effects were statistically significant in the majority of cases. These increases produced by FGF11 were generally comparable to those produced by the standard reference products applied at label rates.

These increases in green leaf area were a direct function of the efficacy of FGF11 against the single or multiple target diseases that developed in the trials and the direct effects of disease having prematurely reduced green leaf area in the untreated control.

These increases in green leaf persistence produced by FGF11 applied in 2 applications at the proposed label rate of 1.0 L product/ha therefore provide supplementary evidence in support of label claims for control of target foliar diseases in wheat and triticale.

Positive effects on crop yield and quality in efficacy trials

Evaluations of crop yield were carried out on a total of 61 of the trials carried out between 2022 and 2023 that generated data on the efficacy of FGF11 applied at the proposed label rate of 1.0 L product/ha in 2 applications against target foliar diseases in winter wheat (39 trials), spring wheat (6 trials), durum wheat (5 trials), spelt (4 trials) and winter triticale (7 trials). Of these trials, 14 were carried out in the North-east EPPO climatic.

Evaluations of quality of grain sampled at harvest were also carried out on all 61 trials, with hectolitre weight (HLW) determined on all trials and thousand grain weight (TGW) determined on 45 of the trials.

Target diseases that occurred in these trials were Puccinia on 4 trials, Puccinia on 3 trials, Puccinia on 1 trial, Puccinia on 3 trials, Septoria on 23 trials, Puccinia and Septoria on 12 trials, Puccinia and Septoria on 3 trials, Septoria and Puccinia on 1 trial, Septoria and Puccinia on 5 trials, Puccinia and Puccinia on 1 trial, Puccinia, Septoria and Puccinia on 3 trials, Puccinia, Septoria and Puccinia on 1 trial and Puccinia, Septoria and Puccinia on 1 trial.

FGF11 applied at the proposed label rate of 1.0 L product/ha increased crop yield compared to the untreated control on 58 of the 61 trials, with the increases being statistically significant on 38 of the trials. These increases produced by FGF11 were generally comparable to those produced by the standard reference products applied at label rates.

Where evaluations of grain quality were carried out on these trials, FGF11 applied at the proposed label rate of 1.0 L product/ha increased TGW compared to the untreated control on 43 of the 45 trials where this quality parameter was assessed, with differences being statistically significant in 17 trials, and HLW in 54 of the 61 trials where this quality parameter was assessed, with differences being statistically significant in 20 trials. These increases produced by FGF11 were generally comparable to those produced by the standard reference products applied at label rates.

The increases in crop yield and grain quality given by both FGF11 and the standard reference products can be considered to be a direct function of control of the target diseases occurring in the trials and their adverse effects on yield in the untreated control.

These increases in crop yield and grain quality produced by FGF11 applied in 2 applications at the proposed label rate of 1.0 L product/ha therefore provide further evidence in support of label claims for control of target foliar diseases in wheat and triticale.

Efficacy against target foliar diseases in winter and spring rye

Efficacy against Brown rust (Puccinia)

No results after 1 application were available in any EPPO climatic zone. The CMSs belonging to the Maritime and South-East zone are kindly asked to consider the use of FGF11 at 1 l/ha in winter and spring rye against *Puccinia recondita* f.sp. *recondita* (Puccinia) at the national level. These uses cannot be accepted in Poland (under art. 33). However, spring rye is minor crops in Poland and the registration under art. 51 is possible in this case.

Positive effects on green leaf area

Positive effects on green leaf area were assessed on a total of 11 of the trials carried out between 2022 and 2023 that generated data on the efficacy of FGF11 applied at the proposed label rate of 1.0 L product/ha against Puccinia in winter rye. Of these trials, 3 were carried out in the Maritime EPPO climatic

zone, 3 were carried out in the North-east EPPO climatic zone and 5 were carried out in the South-east EPPO climatic zone.

FGF11 applied at the proposed label rate of 1.0 L product/ha significantly increased green leaf area compared to the untreated control in these trials, with the increases being statistically significant on 13 of the 17 data points. These increases produced by FGF11 were generally similar to or higher than those produced by the standard reference products applied at label rates with no statistically significant difference in any trial.

The increases in green leaf area given by both FGF11 and the standard reference products can be considered to be a direct function of control of PUCCRR and their adverse effects on green plant tissue in the untreated control.

These increases in green leaf area produced by FGF11 applied at the proposed label rate of 1.0 L product/ha in 2 applications therefore provide further evidence in support of label claims for control of PUCCRR in rye.

Positive effects on crop yield and quality in efficacy trials

Evaluations of crop yield were carried out on a total of 7 of the trials carried out between 2022 and 2023 that generated data on the efficacy of FGF11 applied at the proposed label rate of 1.0 L product/ha against PUCCRR in winter rye. Of these trials, 2 were carried out in the Maritime EPPO climatic zone, 2 were carried out in the North-east EPPO climatic zone and 3 were carried out in the South-east EPPO climatic zone.

Evaluations of quality of grain sampled at harvest were also carried out on all 7 trials, with hectolitre/specific weight (HLW) determined on all trials and thousand grain weight (TGW) determined on 3 of the trials.

FGF11 applied at the proposed label rate of 1.0 L product/ha increased crop yield compared to the untreated control on all of the 7 trials, with the increases being statistically significant on 4 of the trials. These increases produced by FGF11 were generally comparable to those produced by the standard reference products applied at label rates without statistically significant differences in any trial.

Where evaluations of grain quality were carried out on these trials, FGF11 applied at the proposed label rate of 1.0 L product/ha increased TGW compared to the untreated control on all 3 trials where this quality parameter was assessed, with differences being statistically significant in 2 trials. HLW was not increased in any of the trials.

The increases in crop yield and grain quality given by both FGF11 and the standard reference products can be considered to be a direct function of control of the target diseases occurring in the trials and their adverse effects on yield in the untreated control.

These increases in crop yield and grain quality produced by FGF11 applied at the proposed label rate of 1.0 L product/ha in 2 applications therefore provide further evidence in support of label claims for control of PUCCRR in rye.

Efficacy against target foliar diseases in winter and spring barley

A total of 9 trials in spring barley and 24 trials in winter barley carried out between 2022 and 2023 have generated data on the efficacy of FGF11 applied the proposed label rate of 1.0 L product/ha against target diseases in barley.

Efficacy against Net blotch (PYRNTE)

A total of 7 efficacy trials from the North-East and South-East EPPO zones have been submitted to evaluate the effectiveness of FGF11 applied at dose rate of 1 l/ha once per growing season for the control of *Pyrenophora teres* (PYRNTE) in winter barley. In the North-East EPPO climatic zone, 2 trials were conducted in 2023. FGF11 applied at dose rate of 1 l/ha achieved good level of control on L4 with the result of 90,7%. Medium effectiveness was observed on L5 (78,3%) in 1 trial. Comparable effect was noted for the reference product Proline at 0,8 l/ha. ~~However, this use cannot be accepted because of the limited number of trials.~~

A total of 5 efficacy trials from all EPPO zones have been submitted to evaluate the effectiveness of FGF11 applied at dose rate of 1 l/ha once per growing season for the control of *Pyrenophora teres* (PYRNTE) in spring barley. In the North-East zone, 2 trials were carried out between 2022 and 2023. The test product at the claimed dose presented medium level of control with the results of 79,83% on L3 and 63,9% on L4. The reference product Proline at 0,8 l/ha obtained comparable effect. ~~Due to limited number of trials and no extrapolation possible, this use cannot be accepted in Poland.~~

Efficacy against Rust (PUCCHD)

A total of 2 efficacy trials from the Maritime and North-East EPPO zones have been submitted to evaluate the effectiveness of FGF11 applied at dose rate of 1 l/ha once per growing season for the control of *Puccinia hordei* (PUCCHD) in winter barley. In the North-East zone, 1 trial was carried out in 2023. Also 1 trial from Germany can be support for the Polish registration. The test product at the claimed dose presented medium level of control on L4 (59,8%) and L5 (66,6%). Superior result was observed on L3 (98,88%) in other trial. No significant differences between test and reference product were noted. ~~This use cannot be accepted because of the limited number of trials.~~

~~No results after 1 application were available in spring barley in any EPPO climatic zones. The cMSs belonging to the MAR and SE zone are kindly asked to consider this use at the national level. This use cannot be accepted in Poland.~~

Efficacy against Ramularia (RAMUCC)

Only 1 trial has been submitted to evaluate the effectiveness of FGF11 applied at dose rate of 1 l/ha once per growing season for the control of *Ramularia collo-cygni* (RAMUCC) in winter barley. This trial was conducted in 2023 in the South-East EPPO climatic zone. No results after 1 application were available in the Maritime and North-East EPPO zone. The cMSs belonging to the MAR zone are kindly asked to consider this use at the national level. This use cannot be accepted in Poland.

No results after 1 application were available in spring barley in any EPPO climatic zones. The cMSs belonging to the MAR and SE zone are kindly asked to consider this use at the national level. This use cannot be accepted in Poland.

Efficacy against Leaf blotch (RHYNSE)

A total of 2 efficacy trials from the Maritime EPPO zone have been submitted to evaluate the effectiveness of FGF11 applied at dose rate of 1 l/ha once per growing season for the control of *Rhynchosporium secalis* (RHYNSE) in winter barley. In the North-East zone, no trials were carried out. However, 1 trial from Germany can be support for the Polish registration. FGF11 at 1 l/ha presented medium level of control and it was significant superior effect compared to the reference product Proline at 0,8 l/ha. However, this use cannot be accepted in Poland because of limited number of trials.

No results after 1 application were available in spring barley in any EPPO climatic zones. The cMSs belonging to the MAR and SE zone are kindly asked to consider this use at the national level. This use cannot be accepted in Poland.

Positive effects on green leaf area

Positive effects on green leaf area were assessed on a total of 26 of the trials carried out between 2022 and 2023 that generated data on the efficacy of FGF11 applied at the proposed label rate of 1.0 L product/ha in 2 applications against target foliar diseases in winter barley (20 trials) and spring barley (6 trials). Of these trials, 7 were carried out in the Maritime EPPO climatic zone, 7 were carried out in the North-east EPPO climatic zone and 12 were carried out in the South-east EPPO climatic zone.

Target diseases that occurred in these trials were PYRNTE in 17 trials, RAMUCC in 1 trial, PUCCHD in 1 trial, PUCCHD and RAMUCC in 2 trials, PUCCHD and PYRNTE in 2 trials, RAMUCC and RHYNSE in 1 trial, PUCCHD, RAMUCC and RHYNSE in 1 trial and PYRNTE, RAMUCC and RHYNSE in 1 trial.

FGF11 applied at the proposed label rate of 1.0 L product/ha significantly increased green leaf area compared to the untreated control in these trials, with the increases being statistically significant on 22

of the 33 datapoints. These increases produced by FGF11 were generally similar to or higher than those produced by the standard reference products applied at label rates with statistically significant differences in 4 of the data points.

The increases in green leaf area given by both FGF11 and the standard reference products can be considered to be a direct function of control of the target diseases occurring in the trials and their adverse effects on green plant tissue in the untreated control.

These increases in green leaf area produced by FGF11 applied at the proposed label rate of 1.0 L product/ha in 2 applications therefore provide further evidence in support of label claims for control of target diseases.

Positive effects on crop yield and quality in efficacy trials

Evaluations of crop yield were carried out on a total of 14 of the trials carried out between 2022 and 2023 that generated data on the efficacy of FGF11 applied at the proposed label rate of 1.0 L product/ha in 2 applications against target foliar diseases in winter barley (9 trials) and spring barley (5 trials). Of these trials, 5 were carried out in the Maritime EPPO climatic zone, 6 were carried out in the North-east EPPO climatic zone and 3 were carried out in the South-east EPPO climatic zone.

Evaluations of quality of grain sampled at harvest were also carried out on all 14 trials, with hectolitre/specific weight (HLW) determined on all trials and thousand grain weight (TGW) determined on 9 of the trials.

Target diseases that occurred in these trials were PYRNTE on 6 trials, PYRNTE and PUCCHD on 3 trials, PYRNTE and RAMUCC on 1 trial, PYRNTE, RAMUCC and RHYNSE on 1 trial, PUCCHD and RAMUCC on 1 trial, PUCCHD, RAMUCC and RHYNSE on 1 trial and RHYNSE on 1 trial.

FGF11 applied at the proposed label rate of 1.0 L product/ha increased crop yield compared to the untreated control on all of the 14 trials, with the increases being statistically significant on 10 of the trials. These increases produced by FGF11 were generally comparable to or higher than those produced by the standard reference products applied at label rates with statistically significant differences in 1 of the trials.

Where evaluations of grain quality were carried out on these trials, FGF11 applied at the proposed label rate of 1.0 L product/ha increased TGW compared to the untreated control on 7 of the 9 trials where this quality parameter was assessed, with differences being statistically significant in 4 trials, and HLW in 6 of the 14 trials where this quality parameter was assessed, with differences being statistically significant in all of these 6 trials. These increases produced by FGF11 were generally comparable to those produced by the standard reference products applied at label rates, with statistically significant differences in TGW in 1 of the trials.

The increases in crop yield and grain quality given by both FGF11 and the standard reference products can be considered to be a direct function of control of the target diseases occurring in the trials and their adverse effects on yield in the untreated control.

These increases in crop yield and grain quality produced by FGF11 applied at the proposed label rate of 1.0 L product/ha in 2 applications therefore provide further evidence in support of label claims for control of target diseases.

Efficacy against target disease in winter and spring oilseed rape

A total of 23 trials carried out between 2022 and 2023 have generated data on the efficacy of FGF11 applied the proposed label rate of 1.0 L product/ha once per growing season against SCLESC in winter oilseed rape.

Efficacy against Cottony rot (SCLESC)

A total of 23 trials carried out between 2022 and 2023 generated data on the efficacy of a single application of FGF11 at the proposed label rate of 1.0 L product/ha against target diseases in oilseed rape. Of these trials, 8 were carried out in the Maritime EPPO climatic zone, 5 were carried out within the North-

east EPPO climatic zone and 10 were carried out within the South-east EPPO climatic zone. All of these trials were conducted in winter oilseed rape.

No efficacy trials were available for spring oilseed rape in any EPPO climatic zone. The cMSs belonging to the MAR and SE zone are kindly asked to consider this use at the national level. Due to the inability to extrapolate, this use cannot be accepted on the registration under art. 33 in Poland. However, spring oilseed rape is minor crop in Poland and the registration under art. 51 is possible in this case.

Data generated across trials carried out in the North-East EPPO climatic zones demonstrate that a single application of FGF11 at the proposed label rate of 1.0 L product/ha generally gives effective control of SCLESC in winter oilseed rape that is consistently comparable and not statistically significantly different to that given by the standard reference products applied at label rates.

Based on the summarized data, it is therefore considered that claims for control of SCLESC in winter oilseed rape by FGF11, applied at the proposed label rate of 1.0 L product/ha and according to other label recommendations, are fully supported.

Positive effects on crop yield and quality in efficacy trials

Evaluations of crop yield were carried out on a total of 14 of the trials carried out between 2022 and 2023 that generated data on the efficacy of FGF11 applied at the proposed label rate of 1.0 L product/ha once per growing season against target foliar diseases in winter oilseed rape. Of these trials, 5 were carried out in the Maritime EPPO climatic zone, 2 were carried out in the North-east EPPO climatic zone and 7 were carried out in the South-east EPPO climatic zone.

Evaluations of quality of seed sampled at harvest were also carried out on all 14 trials, with the oil content determined on all trials and thousand grain weight (TGW) determined on 13 of the trials.

Target disease that occurred in these trials was SCLESC in all trials.

FGF11 applied at the proposed label rate of 1.0 L product/ha increased crop yield compared to the untreated control on 9 of the 14 trials, with the increases being statistically significant on 4 of the trials. These increases produced by FGF11 were generally comparable to or slightly higher than those produced by the standard reference products applied at label rates with statistically significant differences in 1 of the trials.

Where evaluations of seed quality were carried out on these trials, FGF11 applied at the proposed label rate of 1.0 L product/ha increased TGW compared to the untreated control on 2 of the 13 trials where this quality parameter was assessed, with differences not being statistically significant in any trial, and the oil content in 2 of the 14 trials, with differences being statistically significant in both trials. These increases produced by FGF11 were generally comparable to those produced by the standard reference products applied at label rates, with no statistically significant differences in any trial.

The increases in crop yield and seed quality given by both FGF11 and the standard reference products can be considered to be a direct function of control of the target diseases occurring in the trials and their adverse effects on yield in the untreated control.

These increases in crop yield and grain quality produced by FGF11 applied at the proposed label rate of 1.0 L product/ha once per growing season therefore provide further evidence in support of label claims for control of SCLESC in oilseed rape.

Efficacy against target ear diseases in winter wheat, spring wheat, durum wheat and spelt

A total of 40 trials carried out in 2023 have generated data on the efficacy of FGF11 applied the proposed label rate of 1.0 L product/ha against target ear diseases in winter wheat.

Efficacy against Fusarium ear blight (FUSASP)

A total of 40 trials carried out in 2023 generated data on the efficacy of FGF11 applied at the proposed label rate of 1.0 L product/ha once per growing season against FUSASP (29), FUSASGR (1 trial), FUSACU (2 trials) and GIBBZE (8 trials) in winter wheat. Of these trials, 15 were carried out in the North-East EPPO climatic zone.

In the North-East zone, 15 trials were carried out in 2023. The test product at claimed dose presented medium level of control with the result of 78,2% on ears. No significant differences between test and reference product Proline were observed in all trials.

No efficacy trials were available for other wheat crops in any EPPO climatic zone. The cMSs belonging to the MAR and SE zone are kindly asked to consider these uses at the national level. Due to the inability to extrapolate, these uses cannot be accepted on the registration under art. 33 in Poland. However, durum wheat and spelt are minor crops in Poland and the registration under art. 51 is possible in these cases.

Based on the summarized data, it is therefore considered that claims for control of FUSASP in winter wheat by FGF11, applied at the proposed label rate of 1.0 L product/ha once per growing season and according to other label recommendations, are fully supported.

Positive effects on green leaf area

Positive effects on green leaf area were assessed on a total of 28 of the trials carried out in 2023 that generated data on the efficacy of FGF11 applied at the proposed label rate of 1.0 L product/ha once per growing season against FUSASP in winter wheat. Of these trials, 4 were carried out in the Maritime EPPO climatic zone, 13 were carried out in the North-east EPPO climatic zone and 11 were carried out in the South-east EPPO climatic zone.

FGF11 applied at the proposed label rate of 1.0 L product/ha increased green leaf area on the upper leaves and on a whole plant leaf area basis in great majority of the trials compared to the untreated control. The effects were statistically significant in the majority of cases. These increases produced by FGF11 were generally comparable to those produced by the standard reference products applied at label rates.

These increases in green leaf area were a direct function of the efficacy of FGF11 against the target disease that developed in the trials and the direct effects of disease having prematurely reduced green leaf area in the untreated control.

These increases in green leaf persistence produced by FGF11 applied at the proposed label rate of 1.0 L product/ha once per growing season therefore provide supplementary evidence in support of label claims for control of FUSASP in winter wheat.

Positive effects on crop yield and quality in efficacy trials

Evaluations of crop yield were carried out on all 40 trials carried out in 2023 that generated data on the efficacy of FGF11 applied at the proposed label rate of 1.0 L product/ha once per growing season against FUSASP in winter wheat. Of these trials, 10 were carried out in the Maritime EPPO climatic, 15 were carried out in the North-east EPPO climatic zone and 15 were carried out in the South-east EPPO climatic zone.

Evaluations of quality of grain sampled at harvest were also carried out on all 40 trials, with hectolitre weight (HLW) determined on all trials, thousand grain weight (TGW) determined on 22 of the trials and mycotoxin content determined on 17 of the trials.

FGF11 applied at the proposed label rate of 1.0 L product/ha increased crop yield compared to the untreated control on 34 of the 40 trials, with the increases being statistically significant on 15 of the trials. These increases produced by FGF11 were generally comparable to those produced by the standard reference product applied at label rate.

Where evaluations of grain quality were carried out on these trials, FGF11 applied at the proposed label rate of 1.0 L product/ha increased TGW compared to the untreated control on 17 of the 22 trials where this quality parameter was assessed, with differences being statistically significant in 6 trials, and HLW in 23 of the 40 trials where this quality parameter was assessed, with differences being statistically significant in 10 trials. These increases produced by FGF11 were generally comparable to those produced by the standard reference product applied at label rate.

Where evaluation of mycotoxin content was carried out on 17 of the trials, FGF11 applied at the proposed label rate of 1.0 L product/ha reduced mycotoxin content on all trials where this quality parameter

was assessed. These reductions produced by FGF11 were generally comparable to those produced by the standard reference product applied at label rate.

These increases in yield, TGW and HLW and reductions in mycotoxin content given by both FGF11 and the standard reference products can be considered to be a direct function of control of the FUSASP occurring in the trials and their adverse effects on yield in the untreated control.

These increases in yield, TGW and HLW and reductions in mycotoxin content produced by FGF11 applied at the proposed label rate of 1.0 L product/ha once per growing season therefore provide further evidence in support of label claims for control of FUSASP in wheat.

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

FGF11 contains two active ingredients, azoxystrobin and prothioconazole, both of which have fungicidal activity against various diseases in cereals and oilseed rape and different modes of action target sites.

Azoxystrobin is a Quinone outside inhibitor (QoI) fungicide belonging to the FRAC Mode of Action group C3 (FRAC code 11). It acts at the Quinone ‘outside’ (Qo) binding site of the cytochrome bc1 complex. Strobilurins and related compounds inhibit mitochondrial respiration by binding to the ubiquinol oxidation (Qo) site formed by domains of cytochrome b and the iron-sulphur protein within the cytochrome bc1 complex. Because ATP production is compromised, energy-demanding stages of fungal development, such as spore germination, are particularly affected.

Prothioconazole belongs to DMI (demethylation-inhibiting) fungicide in FRAC Mode of Action group G1 (FRAC code 3), a Mode of Action group within the Sterol Biosynthesis Inhibitors (SBI). The mode of action of prothioconazole and other DMI fungicides is to block sterol biosynthesis by inhibiting the Cytochrome P450-dependent C-14 demethylase reaction leading to a reduction in the normal sterol pathway end products and an accumulation of abnormal sterols.

The actual risk for the evolution of resistance depends on three different parameters: mechanism of resistance against the compound (intrinsic fungicide risk), biology of the fungal pathogen (target risk) and agronomic factors (agronomic risk). The calculated overall risk of resistance arising for an ‘unrestricted use pattern’ is low (1) with respect to the fungal pathogens *Puccinia sp.*, *Rhynchosporium secali*, and *Fusarium* species in cereals and *Sclerotinia sclerotiorum* in oilseed rape, low to medium (2) with respect to *Zymoseptoria tritici* and *Pyrenophora teres* in cereals, and moderate (3) with respect to *Ramularia collocygni* in barley.

FGF11 combines the complementary activity of two fungicide MoA to give effective preventative, curative and eradicated control of various fungal diseases. The risk management strategy to reduce the risk of resistance developing to prothioconazole and azoxystrobin from the use of FGF11 is based on Good Agricultural Practice (GAP) and current measures advocated by FRAC.

FGF11, containing azoxystrobin and prothioconazole, combines the complementary activity of these two fungicide MoAs. The use pattern of FGF11 is restricted to application at the proposed label rate of 1.0 L product/ha, shown to give effective control of all target diseases, and with a maximum of one application per season in cereals and oilseed rape. In commercial practice, applications of FGF11 will be used in sequence and tank mixtures with other fungicides with different modes of action as part of spray programs to give control of all foliar diseases in a crop. All of these factors further reduce the risk of resistance from that for an unrestricted use pattern. It can therefore be considered that the overall risk of resistance developing to azoxystrobin and prothioconazole in target diseases when FGF11 is applied according to label recommendations is low to medium (dependent on the target pathogen) and acceptable.

3.3.2 Adverse effects on treated crops

Phytotoxicity to host crops

Phytotoxicity in wheat

Assessments for phytotoxic symptoms and other effects on crop growth and development have been carried out on all 121 trials conducted between 2022 and 2023 that generated data on the efficacy of FGF11 applied at the proposed label rate of 1.0 L product/ha against target diseases in winter wheat (104 trials) and spring wheat (17 trials). Of these trials, 38 were carried out in the North-East EPPO climatic zone.

Assessments for phytotoxic symptoms and other adverse effects on crop growth and development have also been carried out at regular intervals following a single application of FGF11 applied at the proposed label rate of 1.0 L product/ha, on a total of 6 trials conducted in 2023, in which no or only low levels of disease developed, and these trials are used in support of demonstrating crop safety only. All these trials were carried out in winter wheat in the Maritime EPPO climatic.

FGF11 applied at the proposed label rate of 1.0 L product/ha caused no phytotoxic symptoms or other adverse effects on crop growth and development on any of the 121 efficacy or 6 low disease trials carried out in winter and spring wheat.

Therefore, on the basis of the absence of phytotoxic symptoms or other adverse effects on crop growth and development across trials, it is reasonable to conclude that a single application of FGF11 at the proposed label rate of 1.0 L product/ha, and applied according to label recommendations, is crop safe on winter and spring wheat.

Phytotoxicity in triticale

Assessments for phytotoxic symptoms and other effects on crop growth and development have been carried out on all 24 trials conducted between 2022 and 2023 that generated data on the efficacy of FGF11 applied at the proposed label rate of 1.0 L product/ha against target diseases in winter triticale (23 trials) and spring triticale (1 trial). Of these trials, 8 were carried out within the North-East EPPO climatic zone.

FGF11 applied at the proposed label rate of 1.0 L product/ha caused no phytotoxic symptoms or other adverse effects on crop growth and development on any of these 24 efficacy trials carried out in winter and spring triticale.

Therefore, on the basis of the absence of phytotoxic symptoms or other adverse effects on crop growth and development across trials, it is reasonable to conclude that a single application of FGF11 at the proposed label rate of 1.0 L product/ha, and applied according to label recommendations, is crop safe on winter and spring triticale.

Phytotoxicity in rye

Assessments for phytotoxic symptoms and other effects on crop growth and development have been carried out on all 14 trials conducted between 2022 and 2023 that generated data on the efficacy of FGF11 applied at the proposed label rate of 1.0 L product/ha against target diseases in winter rye. Of these trials 3 were carried out in the North-East EPPO climatic zone.

Assessments for phytotoxic symptoms and other adverse effects on crop growth and development have also been carried out at regular intervals following 2 applications of FGF11 applied at the proposed label rate of 1.0 L product/ha, on 1 trial conducted in 2023, in which only low levels of disease developed, and this trial is used in support of demonstrating crop safety only. The trial was carried out in the Maritime EPPO climatic zone on winter rye.

FGF11 applied at the proposed label rate of 1.0 L product/ha caused no phytotoxic symptoms or other adverse effects on crop growth and development on any of the 14 efficacy or 1 low disease trials carried out in winter rye.

Therefore, on the basis of the absence of phytotoxic symptoms or other adverse effects on crop growth and development across trials, it is reasonable to conclude that a single application of FGF11 at the proposed label rate of 1.0 L product/ha, and applied according to label recommendations, is crop safe on winter and spring rye.

Phytotoxicity in barley

Assessments for phytotoxic symptoms and other effects on crop growth and development have been carried out on all 33 trials conducted between 2022 and 2023 that generated data on the efficacy of FGF11 applied at the proposed label rate of 1.0 L product/ha against target diseases in winter barley (24 trials) and spring barley (9 trials). Of these trials, 9 were carried out within the North-east EPPO climatic zone.

FGF11 applied at the proposed label rate of 1.0 L product/ha caused no phytotoxic symptoms or other adverse effects on crop growth and development on any of these 33 efficacy trials carried out in winter and spring barley.

Therefore, on the basis of the absence of phytotoxic symptoms or other adverse effects on crop growth and development across trials, it is reasonable to conclude that a single application of FGF11 at the proposed label rate of 1.0 L product/ha, and applied according to label recommendations, is crop safe on winter and spring barley.

Phytotoxicity in oilseed rape

Assessments for phytotoxic symptoms and other effects on crop growth and development have been carried out on all 23 trials conducted between 2022 and 2023 that generated data on the efficacy of FGF11 applied at the proposed label rate of 1.0 L product/ha against SCLESC in oilseed rape. Of these trials, 5 were carried out within the North-east EPPO climatic zone. All of these trials were conducted in winter oilseed rape.

Therefore, on the basis of the absence of phytotoxic symptoms or other adverse effects on crop growth and development across trials, it is reasonable to conclude that a single application of FGF11 at the proposed label rate of 1.0 L product/ha, and applied according to label recommendations, is crop safe on winter and spring oilseed rape crops.

Effects on yield of treated plants or plant products

Yield of plants/plant products in wheat (in the absence of disease)

A total of 6 low disease trials carried out in 2023 generated data on crop yield at normal commercial harvest following a single application of FGF11 applied at the proposed label rate of 1.0 L product/ha in the absence of significant disease (<5% pest severity at any assessment) in wheat. All these trials were carried out on winter wheat within the Maritime EPPO climatic zone.

A single application of FGF11 at the proposed label rate of 1.0 L product/ha caused no significant phytotoxic symptoms or pronounced adverse effects on crop yield on any of these 6 low disease trials carried out in wheat.

Also, evaluations of crop yield at normal commercial harvest were carried out on 85 of the efficacy trials conducted between 2022 and 2023 that generated data on the efficacy of FGF11 applied at the proposed label rate of 1 L product/ha against foliar diseases and fusarium in wheat.

Whilst FGF11 produced increases in crop yield, compared to the untreated control, as a direct function of control of target disease in the majority of these trials, there was no evidence of 1 or 2 applications of FGF11 at the proposed label rate of 1.0 L product/ha having an adverse impact on crop yield on any of the efficacy trials.

Additionally, applications of FGF11 applied at the proposed label rate of 1.0 L product/ha caused no phytotoxic symptoms or adverse effects on crop growth and development on any of the trials carried out on winter and spring wheat.

On this basis, it is reasonable to consider that a single application of FGF11 at the proposed label rate of 1.0 L product/ha and applied according to label recommendations, has no adverse impact on crop yield in wheat (winter and spring).

Yield of plants/plant products in spelt (in the absence of disease)

A total of 2 low disease trials carried out in 2023 generated data on crop yield at normal commercial harvest following 2 applications of FGF11 applied at the proposed label rate of 1.0 L product/ha in the

absence of significant disease (<5% pest severity at any assessment) in spelt. All these trials were carried out within the Maritime EPPO climatic zone.

Two applications of FGF11 at the proposed label rate of 1.0 L product/ha caused no significant phytotoxic symptoms or pronounced adverse effects on crop yield on any of these 2 low disease trials carried out in spelt.

Also, evaluations of crop yield at normal commercial harvest were carried out on 4 of the efficacy trials conducted between 2022 and 2023 that generated data on the efficacy of FGF11 applied at the proposed label rate of 1 L product/ha against foliar diseases in spelt.

Whilst FGF11 produced increases in crop yield, compared to the untreated control, as a direct function of control of target disease in the majority of these trials, there was no evidence of 2 applications of FGF11 at the proposed label rate of 1.0 L product/ha having an adverse impact on crop yield on any of the efficacy trials.

Additionally, applications of FGF11 applied at the proposed label rate of 1.0 L product/ha caused no phytotoxic symptoms or adverse effects on crop growth and development on any of the trials carried out on spelt.

On this basis, it is reasonable to consider that a single application of FGF11 at the proposed label rate of 1.0 L product/ha and applied according to label recommendations, has no adverse impact on crop yield in spelt.

Yield of plants/plant products in triticale

Evaluations of crop yield at normal commercial harvest were carried out on 5 of the efficacy trials conducted between 2022 and 2023 that generated data on the efficacy of FGF11 applied at the proposed label rate of 1 L product/ha against foliar diseases in triticale.

Whilst FGF11 produced increases in crop yield, compared to the untreated control, as a direct function of control of target disease in the majority of these trials, there was no evidence of 2 applications of FGF11 at the proposed label rate of 1.0 L product/ha having an adverse impact on crop yield on any of the trials.

Additionally, 2 applications of FGF11 applied at the proposed label rate of 1.0 L product/ha caused no phytotoxic symptoms or adverse effects on crop growth and development on any of the trials carried out on triticale.

On this basis, it is reasonable to consider that a single application of FGF11 at the proposed label rate of 1.0 L product/ha and applied according to label recommendations, has no adverse impact on crop yield in triticale (winter and spring).

Yield of plants/plant products in rye (in the absence of disease)

A total of 1 low disease trial carried out in 2023 generated data on crop yield at normal commercial harvest following a single application of FGF11 applied at the proposed label rate of 1.0 L product/ha in the absence of significant disease (<5% pest severity at any assessment) in rye. This trial was carried out on winter rye within the Maritime EPPO climatic zone.

Two applications of FGF11 at the proposed label rate of 1.0 L product/ha caused no significant phytotoxic symptoms or pronounced adverse effects on crop yield on this low disease trial carried out in rye.

Also, evaluations of crop yield at normal commercial harvest were carried out on 7 of the efficacy trials conducted between 2022 and 2023 that generated data on the efficacy of FGF11 applied at the proposed label rate of 1 L product/ha against foliar diseases in rye.

Whilst FGF11 produced increases in crop yield, compared to the untreated control, as a direct function of control of target disease in the majority of these trials, there was no evidence of 2 applications of FGF11 at the proposed label rate of 1.0 L product/ha having an adverse impact on crop yield on any of the efficacy trials.

Additionally, applications of FGF11 applied at the proposed label rate of 1.0 L product/ha caused no phytotoxic symptoms or adverse effects on crop growth and development on any of the trials carried out on winter rye.

On this basis, it is reasonable to consider that a single application of FGF11 at the proposed label rate of 1.0 L product/ha and applied according to label recommendations, has no adverse impact on crop yield in rye (winter and spring).

Yield of plants/plant products in barley

Evaluations of crop yield at normal commercial harvest were carried out on 14 of the efficacy trials conducted between 2022 and 2023 that generated data on the efficacy of FGF11 applied at the proposed label rate of 1 L product/ha against foliar diseases in barley.

Whilst FGF11 produced increases in crop yield, compared to the untreated control, as a direct function of control of target disease in the majority of these trials, there was no evidence of 2 applications of FGF11 at the proposed label rate of 1.0 L product/ha having an adverse impact on crop yield on any of the trials.

On this basis, it is reasonable to consider that a single application of FGF11 at the proposed label rate of 1.0 L product/ha and applied according to label recommendations, has no adverse impact on crop yield in barley (winter and spring).

Yield of plants/plant products in winter and spring oilseed rape

Evaluations of crop yield at normal commercial harvest were carried out on 14 of the efficacy trials conducted between 2022 and 2023 that generated data on the efficacy of FGF11 applied at the proposed label rate of 1 L product/ha against SCLESC in oilseed rape.

Whilst FGF11 produced increases in crop yield, compared to the untreated control, as a direct function of control of target disease in the majority of these trials, there was no evidence of a single application of FGF11 at the proposed label rate of 1.0 L product/ha having an adverse impact on crop yield on any of the trials.

On this basis, it is reasonable to consider that a single application of FGF11 at the proposed label rate of 1.0 L product/ha and applied according to label recommendations, has no adverse impact on crop yield in oilseed rape (winter and spring).

Effects on quality of plants and plant products

Quality of plants/plant products in wheat (in the absence of disease)

A total of 6 low disease trials carried out in 2023 generated data on quality parameters of the harvested grain following a single application of FGF11 applied at the proposed label rate of 1.0 L product/ha in the absence of significant disease (<5% pest severity at any assessment) in wheat. All these trials were carried out on winter wheat within the Maritime EPPO climatic zone.

A single application of FGF11 at the proposed label rate of 1.0 L product/ha caused no significant phytotoxic symptoms or pronounced adverse effects on quality parameters (HLW, TGW) on any of these 6 low disease trials carried out in wheat.

Also, evaluations of quality parameters (HLW, TGW) were carried out on 85 of the efficacy trials conducted between 2022 and 2023 that generated data on the efficacy of FGF11 applied at the proposed label rate of 1 L product/ha against foliar diseases and fusarium in wheat.

Whilst FGF11 produced increases in quality of the harvested grain, compared to the untreated control, as a direct function of control of target disease in the majority of these trials, there was no evidence of 1 or 2 applications of FGF11 at the proposed label rate of 1.0 L product/ha having an adverse impact on quality of the harvested grain on any of the efficacy trials.

On this basis, it is reasonable to consider that a single application of FGF11 at the proposed label rate of 1.0 L product/ha and applied according to label recommendations, has no adverse impact on quality of the harvested grain in wheat (winter and spring).

Quality of plants/plant products in spelt (in the absence of disease)

A total of 2 low disease trials carried out in 2023 generated data on quality parameters of the harvested grain following two applications of FGF11 applied at the proposed label rate of 1.0 L product/ha in the absence of significant disease (<5% pest severity at any assessment) in spelt. All these trials were carried out within the Maritime EPPO climatic zone.

Two applications of FGF11 at the proposed label rate of 1.0 L product/ha caused no significant phytotoxic symptoms or pronounced adverse effects on quality parameters (HLW, TGW) on any of these 2 low disease trials carried out in spelt.

Also, evaluations of quality parameters (HLW, TGW) were carried out on 4 of the efficacy trials conducted between 2022 and 2023 that generated data on the efficacy of FGF11 applied at the proposed label rate of 1 L product/ha against foliar diseases in spelt.

Whilst FGF11 produced increases in quality of the harvested grain, compared to the untreated control, as a direct function of control of target disease in the majority of these trials, there was no evidence of 2 applications of FGF11 at the proposed label rate of 1.0 L product/ha having an adverse impact on quality of the harvested grain on any of the efficacy trials.

On this basis, it is reasonable to consider that a single application of FGF11 at the proposed label rate of 1.0 L product/ha and applied according to label recommendations, has no adverse impact on quality of the harvested grain in spelt.

Quality of plants/plant products in durum wheat

Evaluations of quality parameters of the harvested grains (TGW and HLW) was carried out on 1 of the efficacy trials conducted in 2022 that generated data on the efficacy of FGF11 applied at the proposed label rate of 1 L product/ha against foliar diseases in durum wheat.

Whilst FGF11 produced increases in grain quality parameters, compared to the untreated control, as a direct function of control of target disease in this trial, there was no evidence of 2 applications of FGF11 at the proposed label rate of 1.0 L product/ha having an adverse impact on seed quality parameters on this trial.

Additionally, two applications of FGF11 applied at the proposed label rate of 1.0 L product/ha caused no phytotoxic symptoms or adverse effects on crop growth and development on any of the trials carried out on durum wheat.

On this basis, it is reasonable to consider that a single application of FGF11 at the proposed label rate of 1.0 L product/ha and applied according to label recommendations, has no adverse impact on quality of the grains in durum wheat.

Quality of plants/plant products in triticale

Evaluations of quality parameters of the harvested grains (TGW and HLW) was carried out on 5 of the efficacy trials conducted between 2022 and 2023 that generated data on the efficacy of FGF11 applied at the proposed label rate of 1 L product/ha against foliar diseases in triticale.

Whilst FGF11 produced increases in grain quality parameters, compared to the untreated control, as a direct function of control of target disease in some of these trials, there was no evidence of a single application of FGF11 at the proposed label rate of 1.0 L product/ha having an adverse impact on grain quality parameters on any of the trials.

Additionally, two applications of FGF11 applied at the proposed label rate of 1.0 L product/ha caused no phytotoxic symptoms or adverse effects on crop growth and development on any of the trials carried out on triticale.

On this basis, it is reasonable to consider that a single application of FGF11 at the proposed label rate of 1.0 L product/ha and applied according to label recommendations, has no adverse impact on quality of the seeds in triticale (winter and spring).

Quality of plants/plant products in rye (in the absence of disease)

One (1) low disease trial carried out in 2023 generated data on quality parameters of the harvested grain following a single application of FGF11 applied at the proposed label rate of 1.0 L product/ha in the absence of significant disease (<5% pest severity at any assessment) in rye. This trial was carried out on winter rye within the Maritime EPPO climatic zone.

Two applications of FGF11 at the proposed label rate of 1.0 L product/ha caused no significant phytotoxic symptoms or pronounced adverse effects on quality parameters (HLW) on any of this 1 disease trials carried out in wheat.

Also, evaluations of quality parameters (HLW, TGW) were carried out on 7 of the efficacy trials conducted between 2022 and 2023 that generated data on the efficacy of FGF11 applied at the proposed label rate of 1 L product/ha against foliar diseases in rye.

Whilst FGF11 produced increases in quality of the harvested grain, compared to the untreated control, as a direct function of control of target disease in the majority of these trials, there was no evidence of 2 applications of FGF11 at the proposed label rate of 1.0 L product/ha having an adverse impact on quality of the harvested grain on any of the efficacy trials.

Additionally, applications of FGF11 applied at the proposed label rate of 1.0 L product/ha caused no phytotoxic symptoms or adverse effects on crop growth and development on any of the trials carried out on winter rye.

On this basis, it is reasonable to consider that a single application of FGF11 at the proposed label rate of 1.0 L product/ha and applied according to label recommendations, has no adverse impact on quality of the harvested grain in rye (winter and spring).

Quality of plants/plant products in barley

Evaluations of quality parameters of the harvested grains (TGW and HLW) was carried out on 14 of the efficacy trials conducted between 2022 and 2023 that generated data on the efficacy of FGF11 applied at the proposed label rate of 1 L product/ha against foliar diseases in triticale.

Whilst FGF11 produced increases in grain quality parameters, compared to the untreated control, as a direct function of control of target disease in some of these trials, there was no evidence of a single application of FGF11 at the proposed label rate of 1.0 L product/ha having an adverse impact on grain quality parameters on any of the trials.

Additionally, two applications of FGF11 applied at the proposed label rate of 1.0 L product/ha caused no phytotoxic symptoms or adverse effects on crop growth and development on any of the trials carried out on barley.

On this basis, it is reasonable to consider that a single application of FGF11 at the proposed label rate of 1.0 L product/ha and applied according to label recommendations, has no adverse impact on quality of the seeds in barley (winter and spring).

Quality of plants/plant products in winter and spring oilseed rape

Evaluations of quality parameters of the harvested seeds (TGW and/or oil content) were carried out on 14 of the efficacy trials conducted between 2022 and 2023 that generated data on the efficacy of FGF11 applied at the proposed label rate of 1 L product/ha against SCLESC in oilseed rape.

Whilst FGF11 produced increases in seed quality parameters, compared to the untreated control, as a direct function of control of target disease in some of these trials, there was no evidence of a single application of FGF11 at the proposed label rate of 1.0 L product/ha having an adverse impact on seed quality parameters on any of the trials.

Additionally, single applications of FGF11 applied at the proposed label rate of 1.0 L product/ha caused no phytotoxic symptoms or adverse effects on crop growth and development on any of the trials carried out on winter oilseed rape.

On this basis, it is reasonable to consider that a single application of FGF11 at the proposed label rate of 1.0 L product/ha and applied according to label recommendations, has no adverse impact on quality of the

Effects on transformation processes

Transformation processes and taints in wheat

Processing (wheat milling, bread making), with subsequent taint testing of the white bread, has been carried out on grains sampled from 2 trials carried out within the Maritime EPPO climatic zones in 2022 on winter wheat.

In all trials, FGF11 was applied twice at the proposed label rate of 1.0 L product/ha, with intervals between applications of 14 days. This represents a number higher than the maximum number of applications for FGF11. On all trials, samples of grains from crop treated with FGF11 were compared to that of samples of grains from crop treated with the standard reference product (Joao) applied at the authorised rate and according to label recommendations.

Two applications of FGF11 at the proposed label rate of 1.0 L product/ha, with intervals between applications of 14 days and pre-harvest intervals between the final application and sampling of between 70 and 75 days, had no effects on the processing procedure (wheat milling and bread making) and caused no significant taints of white bread produced from grain sampled from any of these 2 trials.

Based on the absence of effects on processing or taints of the white bread produced from grains on any of these trials, it is therefore reasonable to conclude that a single application of FGF11 at the proposed label rate of 1.0 L product/ha and when applied according to other label recommendations in winter wheat has no adverse effects on wheat milling and bread making and causes no taints of white bread.

Transformation processes and taints in barley

Processing (beer brewing), with subsequent taint testing of the beer, has been carried out on grains sampled from 4 trials carried out within the Maritime EPPO climatic zones in 2022. Of these trials 2 were carried out in winter barley and 2 were carried out in spring barley

In all trials, FGF11 was applied twice at the proposed label rate of 1.0 L product/ha, with intervals between applications of 13-14 days. This represents a number higher than the maximum number of applications for FGF11. On all trials, samples of grains from crop treated with FGF11 were compared to that of samples of grains from crop treated with the standard reference product (Prosaro) applied at the authorised rate and according to label recommendations.

Two applications of FGF11 at the proposed label rate of 1.0 L product/ha, with intervals between applications of 13-14 days and pre-harvest intervals between the final application and sampling of between 46 and 57 days, had no effects on the processing procedure (beer brewing) and caused no significant taints of beer produced from grain sampled from any of these 4 trials.

Based on the absence of effects on processing or taints of the beer produced from grains on any of these trials, it is therefore reasonable to conclude that a single application of FGF11 at the proposed label rate of 1.0 L product/ha and when applied according to other label recommendations in winter and spring barley has no adverse effects on beer brewing and causes no taints of beer.

Transformation processes and taints in oilseed rape

FGF11 is a fungicide and therefore main impact is expected on processing steps including yeasts or other microorganisms. The only widely used processing step for oilseed rape is oil making which only includes mechanical and chemical steps.

Furthermore, products containing azoxystrobin or prothioconazole, either applied alone or as mixtures, have been approved and widely used as fungicides in oilseed rape in EU countries for many years and are well proven to have no adverse effects on processing and taint.

Therefore, no data are presented, and it is reasonable to conclude that FGF11 applied following label recommendations has no adverse effects on processing and taint and can safely be applied on oilseed rape intended for transformation.

Impact on treated plants or plant parts to be used for propagation

Products containing azoxystrobin or prothioconazole, either applied alone or as mixtures, have been approved and widely used as fungicides in cereals and oilseed rape in EU countries for many years and are well proven to have no adverse effects on the viability of plant parts for propagation.

These products containing azoxystrobin and/or prothioconazole have no label restrictions regarding their use on crops for seed production.

Furthermore, as azoxystrobin and prothioconazole are fungicides with little or no effects on plant growth and development and as no adverse effects on any crop have been observed following application of FGF11 in any trial, they are highly unlikely to affect the viability of progeny seed on cereals and oilseed rape.

Therefore, it is reasonable to conclude that FGF11 applied following label recommendations has no adverse effects on the viability of the progeny seed and can safely be applied on cereals and oilseed rape intended for seed production.

3.3.3 Observations on other undesirable or unintended side-effects

Impact on succeeding crops

The sensitivity of a representative range of different monocotyledonous and dicotyledonous plant species sown following the application of FGF11 at 1.9 L/ha has been established in an OECD 208 Seedling emergence and seedling growth test. This included representative species of the main families to which the majority of main crop types belong and also indicator species considered to be most sensitive to phytotoxicity and effects of plant protection products on emergence.

TER values were not calculated as the ER10 values of the most sensitive species could only be calculated as limits (≤ 1.9 L/ha for RAPS and GLMAX).

The tested application rate of 1.9 L/ha in this study was almost double of the proposed application rate of FGF11 of 1.0 L/ha. Azoxystrobin and prothioconazole are not persistent in soil with a DT50 of 78 and 2.8 days and have no known soil activity. Both active substances as well as mixtures of azoxystrobin and prothioconazole are well-known and on the market for many years already and no adverse effects on succeeding or replacement crops have been reported.

It is therefore assumed that it is safe to sow any crop type after commercial harvest of cereals and oilseed rape on which FGF11 has been applied at the proposed label rate of 1 L product/ha and according to other label recommendations.

In the event of crop failure for any reason following the application of FGF11 at the proposed label rate of 1 L product/ha, it is assumed that any crop type can safely be sown.

The risk of adverse impact on succeeding and replacement crops sown or planted following a single application of FGF11 at the proposed label rate of 1 L product/ha in cereals and oilseed rape is minimal and therefore acceptable, with no restrictions necessary.

Impact on other plants including adjacent crops

The pre- and post-emergence sensitivity of a representative range of different monocotyledonous and dicotyledonous plant species to FGF11 applied at 1.9 L product/ha has been established in OECD 208 (seedling emergence and seedling growth) and OECD 227 (vegetative vigour tests) studies. These included representative species of the main families to which the majority of major crop types belong and species considered to be most sensitive to phytotoxicity and effects of plant protection products. The sensitivity of the crop types tested can therefore also be considered to be representative of that of the majority of other plant species.

TER values were not calculated as the ER50 values of the most sensitive species could only be calculated as limits (≤ 1.9 L/ha for RAPS and GLMAX in the OECD 208 seedling emergence test).

The tested application rate of 1.9 L/ha in this study was almost double of the proposed application rate of FGF11 of 1.0 L/ha and is manyfold above the maximum off-field predicted environmental rate (PER_{off-field}) of 0.0277 L product/ha (4.4+5.5 g a.s./ha) at 1 m from the edge of the area of application. Azoxystrobin and prothioconazole are not persistent in soil with a DT₅₀ of 78 and 2.8 days and have no known soil activity. Both active substances as well as mixtures of azoxystrobin and prothioconazole are well-known and on the market for many years already and no adverse effects on other plants including adjacent crops have been reported.

The risk of adverse impact on other plants including adjacent crops from spray drift when FGF11 is applied at the proposed label rate of 1 L product/ha in cereals and oilseed rape, and according to label recommendations to avoid drift, is therefore considered as minimal and poses no unacceptable risk with no restrictions necessary.

Tank cleaning

Tests have been carried out to determine the effectiveness of the tank cleaning procedure for FGF11 as summarized in in Part B Sections 1, 2 and 4 of the submission for approval of FGF11.

A small-scale jar test (UPL/2023/1576) was carried out in 2024. Analysis of residues in tank washings were carried out by a GLP accredited laboratory.

The diluted spray was prepared in the jar by mixing FGF11 with water, at a concentration matching the proposed label rate of 1 L product/ha in the minimum proposed water volume of 100 L/ha. Following emptying of the jar, it was then thoroughly rinsed 3 times with water, and the amount of az and [Company] in each of the rinses and in the organic solvent used to remove residues from the jar following the final rinsing was determined. The three sequential rinsings reduced the az and [Company] concentrations to an average of 0.18% and 0.31% of the original spray concentrations (mean of 3 samples), after the final rinsing (compared to 18.56% and 23.56% after a single rinse and 3.6% and 6.29% after two rinses).

Azoxystrobin and [Company] concentrations of 0.18% and 0.31% of the original spray concentrations equates to 0.0018 and 0.0031 L product/ha respectively. These are well below the NOER of >1.9 L product/ha for all tested species in the OECD 227 Vegetative vigour test. Even a single and a double rinse would result in application rates well below the NOER.

On this basis, standard recommended tank cleaning procedures are sufficient to reduce residues of FGF11 in the spray equipment to well below those likely to cause damage to the crop on which the sprayer is next used, following use to apply FGF11 at the proposed label rate of 1 L product/ha.

Effects on beneficial and other non-target organisms

Neither positive nor adverse effects on other plants including adjacent crops were detected while carrying out the above-mentioned efficacy trials following application of FGF11.

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

3.4 Methods of analysis (Part B, Section 5)

Sufficiently sensitive and selective analytical methods are available for the active substances and relevant impurities in FGF11.

3.4.1 Analytical method for the formulation

An HPLC-UV method was successfully validated for the determination of the content of the active substances prothioconazole and azoxystrobin in the formulated product FGF11 with regard to linearity, precision, accuracy, non-analyte interference and specificity. It is considered to be acceptable. Further,

a HPLC-UV method was successfully validated for the determination of Z-azoxystrobin.

Two analytical methods for the determination of the relevant impurities prothioconazole-desthio and toluene in the formulated product FGF11 in the presence of the active substances prothioconazole and azoxystrobin have been successfully validated. The methods are based on HPLC-UV for prothioconazole-desthio and toluene. Both methods are considered to be acceptable.

3.4.2 Analytical methods for residues

Prothioconazole

Sufficiently sensitive analytical methods are available and validated for all components included in the prothioconazole residue definition, for soil, water, air, food of plant origin, food of animal origin and in body fluids.

The Applicant submitted a number of methods for analysis of residues of prothioconazole for the generation of pre-authorization data and methods for post-authorization control and monitoring purposes.

The details of the evaluation of new and additional studies are referred in Appendix 2 of Part B5.

Since many MRLs have been lowered to 0.01 mg/kg, the validated LOQ of the EU agreed methods by Weeren and Pelz (2000) and Class (2001) are not sufficient to monitor these lowered MRLs for food of plant origin. To cover the current residue definition and MRL limits, the applicant provided the analytical method of Pearson (2022, Report No. QG/20/011) and its ILV (Boubakri, 2023, Report No. S21-08354) for the determination of prothioconazole-desthio residues in/on matrices of plant origin (high water content, high acid, high oil content and high protein/high starch content) with LOQ of 0.005 mg/kg. The ILV is acceptable. The analytical method of Pearson (2022, Report No. QG/20/011) was successfully independently validated. The details of the evaluation of new study is referred in Appendix 2 of Part B5.

The Applicant provided new method (D. Kleinhenz, 2023, Report No. S21-08355) validated for the determination of prothioconazole-desthio (as sum of isomers) in five different matrices of food of animal origin (milk, egg, fat, liver and meat) with the LOQ of 0.004 mg/kg for milk and 0.01 mg/kg for remaining matrices and its ILV (T. Rastogi, 2023, Report No. S21-08868) for the determination of prothioconazole-desthio residues in milk and fat with LOQ of 0.004 mg/kg and 0.01 mg/kg, respectively. Additionally, analytical method and its ILV for determination of prothioconazole-desthio in honey is available.

The Applicant provided new method (N. Boubakri, 2023, Report No. S21-08361) validated for the determination of prothioconazole-desthio in urine with the LOQ of 0.01 mg/L.

No additional data are required.

Applicant submitted the LC-MS/MS analytical method (D. Kaiser, 2022, Report No. S21-08359) with its ILV (S. Jooß, 2023, Report No. S21-08869) for the determination of prothioconazole and prothioconazole-desthio in drinking water with LOQ of 0.05 µg/L.

Additionally the Applicant provided analytical method for determination of prothioconazole with LOQ of 0.006 mg/kg and prothioconazole-desthio with 0.002 mg/kg in soil (M. Kaiser, 2022, Report No. S21-08358).

No additional data are required.

Azoxystrobin

Sufficiently sensitive analytical methods are available and validated for all components included in the azoxystrobin residue definition, for soil, water, air, food of plant origin, food of animal origin and in body fluids.

The Applicant submitted a number of methods for analysis of residues of azoxystrobin for the generation of pre-authorization data and methods for post-authorization control and monitoring purposes. The details of the evaluation of additional studies are referred in Appendix 2 of Part B5.

In “Peer Review of the pesticide risk assessment of the active substance azoxystrobin” (EFSA Journal 2010; 8(4):1542) it is stated that “*Monitoring of residues of azoxystrobin in groundwater, drinking water and surface water can be done by GC-MSD. Pending on the data gap identified in section 4, the residue definition for water might change and therefore further methods could be required in the future.* ILV for the analytical method for drinking water is required (data gap).

Applicant has data access to analytical method (Amic 2012, S11-03538, VV-401211) and its ILV (Brown 2019, RES-00193, VV-619234) to quantify azoxystrobin in water using LC-MS/MS with LOQ = 0.05 µg/L. These methods are currently being evaluated as part of the ongoing active substance renewal for azoxystrobin.

Adequate method is available for the determination of residues of azoxystrobin in human whole blood. Applicant has data access to analytical method of Gemrot F., 2011 / Report S10-03815 (VV-398250). Therefore, no further consideration of monitoring method for body fluids is necessary.

No additional data are required.

3.5 Mammalian toxicology (Part B, Section 6)

FGF11 product is not acutely toxic with respect to oral and dermal route of exposure. Inhalation LC₅₀ value was obtained by means of the additivity formula and resulted in 4.00 mg/L air. Therefore, the product should be classified according to Regulation (EC) No.1272/2008 as Acute Tox. 4 (H332) and skin sensitizer (H317).

The formulation is not irritant to skin or eyes ~~nor skin sensitizer~~ based on the Regulation (EC) No.1272/2008. ~~Additional labelling phrase EUH208 is allocated due to the content of relevant co-formulant (refer Part C).~~

3.5.1 Acute toxicity

Toxicity of FGF11 was assessed based on the calculation method according to criteria for mixture of the Regulation (EC) no. 1272/2008. The formulation is not irritant to skin or eyes nor skin sensitizer based on the Regulation (EC) No.1272/2008. FGF11 needs to be classified for acute inhalation toxicity as Acute Tox. 4 (H332) also ~~with additional labelling phrase EUH208.~~ as skin sensitizer (H317).

Endpoint, method	Result	Classification (acc. to the criteria in Reg. 1272/2008)
LD ₅₀ oral (calculation)	> 2000 mg/kg bw	None
LD ₅₀ dermal (calculation)	> 2000 mg/kg bw	None
LC ₅₀ inhalation (calculation)	4.00 mg/L air	Acute Tox. 4, H332
Skin irritation (calculation)	Not irritant	None
Eye irritation (calculation)	Not irritation	None
Skin sensitisation (calculation)	~~None~~ Sensitizer	~~None~~ H317

3.5.2 Operator exposure

The potential total systemic exposure of the operator, wearing workwear covering the body, arms and legs and gloves, at mixing and loading and during application, corresponds to 31.4% of the AOEL for

azoxystrobin, 23.1% of the AOEL for prothioconazole and 0.1% of the AOEL for prothioconazole-desthio (considering 50% conversion factor PTZ to PTZ desthio), regarding the critical use in cereals during tractor mounted application. Since prothioconazole-desthio is formed only after mixing and loading, gloves is recommended ~~only during the application phase.~~ **for all task due to the product CLP classification as skin sensitizer (H317).**

There is no unacceptable risk for operators regarding the critical use in cereals during tractor mounted application.

3.5.3 Worker exposure

The potential total systemic exposure of the operator, wearing workwear covering the body, arms and legs, during irrigation and inspection, corresponds to 5.6% of the AOEL for azoxystrobin, 3.6% of the AOEL for prothioconazole and 0.07% of the AOEL for prothioconazole-desthio, regarding the critical use in cereals during tractor mounted application.

There is no unacceptable risk for worker regarding the critical use in cereals during tractor mounted application.

3.5.4 Bystander and resident exposure

For residents, considering **2-3m buffer strip and no drift reduction**, the exposure estimation to one application of azoxystrobin (adults 4.5% AOEL, children 12.2% AOEL), prothioconazole (adults 3% AOEL, children 8% AOEL), prothioconazole-desthio results (adults 2.8% AOEL, children 8.1% AOEL)

Considering **5m buffer strip and no drift reduction** the exposure estimation to one application of azoxystrobin (adults 3.9% AOEL, children 9.9% AOEL), prothioconazole (adults 2.5% AOEL, children 6.5% AOEL), prothioconazole-desthio results (adults 2.7% AOEL, children 8.1% AOEL)

There is no unacceptable risk for bystanders and residents regarding the critical use in cereals during tractor mounted application.

3.5.5 Combined exposure

Combined exposure for operator, worker (using workwear) also bystanders and residents, **Hazard Index is below < 1 HI**. There is no unacceptable risk resulting from combined effects.

3.6 Residues and consumer exposure (Part B, Section 7)

Wheat, rye, barley and oilseed rape are the major crops in northern Europe (SANTE/2019/12752). A minimum of eight trials are required.

Based on the SANTE/2019/12752, 8 residue trials on wheat can be used for extrapolation to rye, triticale and spelt before and after forming of the edible part.

3.6.1 Residues

Prothioconazole

1. Winter wheat, spring wheat, durum wheat, spelt wheat, winter triticale, spring triticale, winter rye, spring rye

Eight N-EU trials were conducted in accordance with the following GAP: 2 x 200 g a.s. /ha, application interval - 14 days, 2nd application at BBCH 69, outdoor.

Available results show that the in force MRL of prothioconazole on wheat of 0.1 mg/kg and on rye of 0.05 (Reg. (EU) 2024/1318) will not be exceeded. The current EU MRL for prothioconazole is sufficient to support the proposed uses.

The trials are supported by valid storage stability data and validated analytical methods.

The proposed uses on wheat, rye, triticale, spelt are considered acceptable.

2. Barley

One magnitude of residue study was submitted in the framework of this application (Bougrier 2024; 646-2023).

Eight N-EU trials were conducted in accordance with the following GAP: 2 x 200 g a.s. /ha, application interval - 14 days, 2nd application at BBCH 69, outdoor.

Available results show that the in force MRL of prothioconazole on barley of 0.2 mg/kg (Reg. (EU) 2024/1318) will not be exceeded. The current EU MRL for prothioconazole is sufficient to support the proposed use.

The trials are supported by valid storage stability data and validated analytical methods.

The proposed use on barley is considered acceptable.

3. Oilseed rape

Five new magnitude of residue studies were submitted in the framework of this application.

Study 647-2023; Bousquet 2023

Eight N-EU trial was conducted in accordance with the following GAP: 2 x 175 g a.s. /ha, application interval – 14 days, 2nd application at BBCH 80 (outdoor) to determine of the residues of prothioconazole metabolites: PTZ-alpha-OH-desthio, PTZ-3-OH-desthio, PTZ-4-OH-desthio, PTZ-5-OH-desthio, PTZ-6-OH-desthio and 1,2,4-triazole (T), triazole alanine (TA) in oilseed rape specimens: seed and forage.

The study on the magnitude of residues is valid with regard to storage stability for PTZ-OH-desthio metabolites, except 1,2,4-T and TA. These trials can be used to support the intended use on oilseed rape (for PTZ-OH-desthio metabolites, not for 1,2,4-T and TA).

January 2026:

The Applicant provided new storage stability study (Jooß, 2025; Study Code S23-105428). The Bousquet's study (647-2023; 2023) on the magnitude of residues of 1,2,4-T and TA is supported by new valid storage stability data.

Eight trials were conducted in accordance with the following GAP: 2 x 175 g a.s. /ha, application interval - 14 days, 2nd application at BBCH 80 (outdoor) to determine of the residues of triazole derived metabolites (TDM's) (triazole acetic acid and triazole lactic acid) in oilseed rape specimens: seed and rest of plant.

Available results show that the in force MRL of prothioconazole on oilseed rape of 0.15 mg/kg (Reg. (EU) 2024/1318) will not be exceeded. The current EU MRL for prothioconazole is sufficient to support the proposed use.

The proposed use on oilseed rape is considered acceptable.

The effects of processing on the nature of prothioconazole residues have been investigated. As residues of prothioconazole do not exceed the trigger values defined in Reg (EU) No 283/2013 (except TDMs), there is no need to investigate the effect of industrial and/or household processing on prothioconazole residues except for TDMs.

Regarding TDMs, studies show that they remained stable under the standard hydrolysis conditions. Studies on magnitude of residues in processed commodities in wheat after treatment with prothioconazole were presented in the Triazole Derivate Metabolites Addendum - Confirmatory data (B.7.5.2, UK, 2018).

Residues of prothioconazole residues (except TDMs) in succeeding crops have been sufficiently investigated taking into account the specific circumstances of the cGAP uses being considered here. It is very unlikely that residues exceeding residues in primary crops will be present in succeeding crops. Regarding TDMs, in the framework of the confirmatory data, several field rotational crop trials have been conducted to investigate the magnitude of TDM residues in rotational crops after the use of triazole active substances. Residues of TA, TLA and TAA were found above 0.01 mg/kg in succeeding crops. These results were considered in the consumer risk assessment performed in the framework of the review of TDMs confirmatory data.

Considering dietary burden and based on the intended uses, no significant modification of the intake was calculated for livestock. Further investigation of residues as well as the modification of MRLs in commodities of animal origin is therefore not necessary.

Regarding TDM arising from prothioconazole uses, as concluded by the UK, “further consideration is not required due to the fact that none of the TDMs were identified” in the available livestock metabolism studies conducted with prothioconazole.

Azoxystrobin

1. Winter wheat, spring wheat, durum wheat, spelt wheat, winter tritcale, spring tritcale, winter rye, spring rye

Sufficient residue studies on wheat (8 trials) conducted according to the residue definition for monitoring and for risk assessment have already been evaluated. Please refer to the Azoxystrobin EU renewal (dRAR) for a summary and conclusions for these studies.

All trials are overdosed (1 x 250 g a.s./ha instead of 1 x 160 g a.s./ha). Consequently, these trials can be considered as a worst-case situation.

Available results show that the in force MRL of azoxystrobin on wheat and rye of 0.5 mg/kg (Reg. (EU) 2024/2633) will not be exceeded. The current EU MRL for azoxystrobin is sufficient to support the proposed uses.

The trials are supported by valid storage stability data and validated analytical methods.

The proposed uses on winter wheat, spring wheat, durum wheat, spelt wheat, winter tritcale, spring tritcale, winter rye, spring rye are considered acceptable.

2. Barley

Sufficient residue studies on barley (8 trials) conducted according to the residue definition for monitoring and for risk assessment have already been evaluated. Please refer to the Azoxystrobin EU renewal (dRAR) for a summary and conclusions for these studies.

All trials are overdosed (1 x 250 g a.s./ha instead of 1 x 160 g a.s./ha). Consequently, these trials can be considered as a worst-case situation.

Available results show that the in force MRL of azoxystrobin on barley of 1.5 mg/kg (Reg. (EU) 2024/2633) will not be exceeded. The current EU MRL for azoxystrobin is sufficient to support the proposed use.

The trials are supported by valid storage stability data and validated analytical methods.

The proposed use on barley is considered acceptable.

3. Oilseed rape

New residues study on oilseed rape (8 trials) conducted according to the residue definition for monitoring and for risk assessment was provided by Applicant (Study 2 North 2024, S23-102956).

All trials are overdosed (2 x 160 g a.s./ha instead of 1 x 160 g a.s./ha). Consequently, these trials can be considered as a worst-case situation.

Available results show that the in force MRL of azoxystrobin on oilseed rape of 0.7 mg/kg (Reg. (EU) 2024/2633) will not be exceeded. The current EU MRL for azoxystrobin is sufficient to support the proposed use.

The trials are supported by valid storage stability data and validated analytical methods.

The proposed use on winter oilseed rape is considered acceptable.

The effects of processing on the nature of azoxystrobin residues were not considered necessary for risk assessment.

Residues in succeeding crops have been sufficiently investigated taking into account the specific circumstances of the cGAP uses being considered here. It is very unlikely that residues will be present in succeeding crops.

Considering dietary burden and based on the intended uses, no significant modification of the intake was calculated for livestock. Further investigation of residues as well as the modification of MRLs in commodities of animal origin is therefore not necessary.

3.6.1 Consumer exposure

Prothioconazole

Exposure of consumers to prothioconazole (residue definition for risk assessment part 1) as given in EC Review Report, 2021): Prothioconazole and any other relevant metabolite exclusively linked to the parent compound, i.e. ‘Sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers)’ has been calculated with EFSA PRIMo rev. 3.1.

Consumer risk assessment for Prothioconazole: prothioconazole-desthio (sum of isomers)

TMDI (% ADI) according to EFSA PRIMo	42% (based on NL toddler – main contributor: wheat)
IEDI (% ADI) according to EFSA PRIMo	Further refinement not required as TMDI shows no exceedance
IESTI (% ARfD) according to EFSA PRIMo*	Bovine: Kidney: 51% (based on unprocessed commodities, children) Bovine: Kidney: 28% (based on unprocessed commodities, adults) Barley / cooked: 15% (based on processed commodities, children) Barley / beer: 29% (based on processed commodities, adults)
NTMDI (% ADI) **	N/A
NEDI (% ADI)**	N/A
NESTI (% ARfD) **	N/A

* include raw and processed commodities if both values are required for PRIMo

** if national model is available

The proposed uses of prothioconazole in the formulation FGF11 do not represent unacceptable acute and chronic risks for the consumer with regard to residues of prothioconazole-desthio (sum of isomers).

Azoxystrobin

Exposure of consumers to azoxystrobin has been calculated with EFSA PRIMo rev. 3.1.

Consumer risk assessment for Azoxystrobin

TMDI (% ADI) according to EFSA PRIMo	82% (based on NL toddler)
IEDI (% ADI) according to EFSA PRIMo	-
IESTI (% ARfD) according to EFSA PRIMo*	Not required – no ARfD allocated
NTMDI (% ADI) **	N/A
NEDI (% ADI)**	N/A
NESTI (% ARfD) **	N/A

* include raw and processed commodities if both values are required for PRIMo

** if national model is available

The proposed uses of azoxystrobin in the formulation FGF11 do not represent unacceptable acute and chronic risks for the consumer.

Triazole derivative metabolites (TDM)s:

Consumer exposure assessments for all four TDMs have been conducted by United Kingdom, 2018 and EFSA 2018 during evaluation of the pesticide risk assessment for the triazole derivative metabolites in light of confirmatory data to which explicit reference is made. Exposure of consumers to TDMs has been calculated with EFSA PRIMo rev. 3.1.

Consumer risk assessment for 1,2,4-Triazole:

TMDI (% ADI) according to EFSA PRIMo	Not applicable, no MRLs set.
IEDI (% ADI) according to EFSA PRIMo	88% (based on NL toddler)
IESTI (% ARfD) according to EFSA PRIMo***	Unprocessed commodities Results for children 0.72% Wheat 0.32% Rye 0.28% Barley 0.07% Rapeseeds/canola seeds Results for adults 0.42% Wheat 0.24% Rye 0.24% Barley 0.03% Rapeseeds/canola seeds Processed commodities Results for children 0.6% Wheat / milling (flour) 0.3% Wheat / milling (wholemeal)-baking 0.2% Rye / boiled 0.2% Barley / cooked 0.2% Rye / milling (wholemeal)-baking 0.1% Barley / milling (flour) 0.0% Rapeseeds / oils Results for adults 0.4% Barley / beer 0.22% Wheat / bread/pizza 0.19% Wheat / pasta 0.17% Wheat / bread (wholemeal)
NTMDI (% ADI) **	N/A
NEDI (% ADI)**	N/A
NESTI (% ARfD) **	N/A

* if national model is available

** include raw and processed commodities if both values are required for PRIMo 3.1

The proposed uses of prothioconazole in the formulation FGF11 do not represent unacceptable acute and chronic risks for the consumer with regard to residues of 1,2,4-Triazole.

Consumer risk assessment for Triazole Lactic Acid (TLA):

TMDI (% ADI) according to EFSA PRIMo	Not applicable, no MRLs set.
IEDI (% ADI) according to EFSA PRIMo	Normal mode: 1% (based on NL toddler; main contributor: milk; cattle)
IESTI (% ARfD) according to EFSA PRIMo*	Unprocessed commodities Results for children 0.11% Wheat 0.05% Rye 0.04% Barley 0.03% Rapeseeds/canola seeds Results for adults 0.06% Wheat 0.04% Rye 0.04% Barley 0.01% Rapeseeds/canola seeds Processed commodities Results for children 0.1% Wheat / milling (flour) 0.0% Wheat / milling (wholemeal)-baking

	0.0% Rye / boiled 0.0% Barley / cooked 0.0% Rye / milling (wholemeal)-baking 0.0% Barley / milling (flour) 0.0% Rapeseeds / oils Results for adults 0.1% Barley / beer 0.03% Wheat / bread/pizza 0.03% Wheat / pasta 0.03% Wheat / bread (wholemeal)
NTMDI (% ADI) **	N/A
NEDI (% ADI)**	N/A
NESTI (% ARfD) **	N/A

* if national model is available

** include raw and processed commodities if both values are required for PRIMo 3.1

The proposed uses of prothioconazole in the formulation FGF11 do not represent unacceptable acute and chronic risks for the consumer with regard to residues of triazole lactic acid (TLA).

Consumer risk assessment for Triazole Acetic Acid (TAA):

TMDI (% ADI) according to EFSA PRIMo	Not applicable, no MRLs set.
IEDI (% ADI) according to EFSA PRIMo	Normal mode: 1% (based on NL toddler; main contributor: maize/corn)
IESTI (% ARfD) according to EFSA PRIMo*	Unprocessed commodities Results for children 1.14% Wheat 0.50% Rye 0.44% Barley 0.02% Rapeseeds/canola seeds Results for adults 0.66% Wheat 0.38% Rye 0.38% Barley 0.01% Rapeseeds/canola seeds Processed commodities Results for children 1.0% Wheat / milling (flour) 0.4% Wheat / milling (wholemeal)-baking 0.3% Rye / boiled 0.3% Barley / cooked 0.3% Rye / milling (wholemeal)-baking 0.1% Barley / milling (flour) 0.0% Rapeseeds / oils Results for adults 0.6% Barley / beer 0.35% Wheat / bread/pizza 0.30% Wheat / pasta 0.28% Wheat / bread (wholemeal)
NTMDI (% ADI) **	N/A
NEDI (% ADI)**	N/A
NESTI (% ARfD) **	N/A

** if national model is available

*** include raw and processed commodities if both values are required for PRIMo 3.1

The proposed uses of prothioconazole in the formulation FGF11 do not represent unacceptable acute and chronic risks for the consumer with regard to residues of triazole acetic acid (TAA).

Consumer risk assessment for Triazole Alanine (TA):

TMDI (% ADI) according to EFSA PRIMo	Not applicable, no MRLs set.
IEDI (% ADI) according to EFSA PRIMo	6% (based on NL toddler)
IESTI (% ARfD) according to EFSA PRIMo*	Unprocessed commodities Results for children 2.99% Wheat 1.31% Rye 1.16% Barley 0.48% Rapeseeds/canola seeds Results for adults 1.74% Wheat 1.00% Rye 1.00% Barley 0.18% Rapeseeds/canola seeds Processed commodities Results for children 2.5% Wheat / milling (flour) 1.1% Wheat / milling (wholemeal)-baking 0.8% Rye / boiled 0.8% Barley / cooked 0.7% Rye / milling (wholemeal)-baking 0.4% Barley / milling (flour) 0.2% Rapeseeds / oils Results for adults 1.5% Barley / beer 0.91% Wheat / bread/pizza 0.79% Wheat / pasta 0.72% Wheat / bread (wholemeal)
NTMDI (% ADI) **	N/A
NEDI (% ADI)**	N/A
NESTI (% ARfD) **	N/A

* include raw and processed commodities if both values are required for PRIMo

** if national model is available

The proposed uses of prothioconazole in the formulation FGF11 do not represent unacceptable acute and chronic risks for the consumer with regard to residues of triazole alanine (TA).

Based on the different calculations made to estimate the risk for consumer through diet and other means it can be concluded that the use of product FGF11 does not lead to unacceptable risks for consumers when applied according to the recommendations.

3.7 Environmental fate and behaviour (Part B, Section 8)

Predicted environmental concentrations (PEC) were calculated for both active substances azoxystrobin and prothioconazole and their relevant metabolites for the environmental exposure risk assessment. The assessments undertaken for the soil, groundwater and surface water compartments are described in the following sections.

3.7.1 Predicted environmental concentrations in soil (PEC_{soil})

Soil exposure for azoxystrobin and prothioconazole and their relevant metabolites were calculated using approach described in respective FOCUS guidance for the intended uses of FGF11. For all compounds,

EU agreed data were taken into account. Soil exposure for the formulated product was also calculated. The results for PEC_{soil} for the active substances and their metabolites were used for the ecotoxicological risk assessment.

3.7.2 Predicted environmental concentrations in groundwater (PEC_{gw})

Azoxystrobin

The groundwater exposure assessment was conducted according to FOCUS guidance using models PEARL v5.5.5 and PELMO v6.6.4. The active substance azoxystrobin was assessed along with its major soil metabolites R401553, R402173 and R234886. All endpoints were taken from the peer review conclusion for azoxystrobin (EFSA Journal 2010; 8(4):1542 and RAR Addendum on confirmatory data, December 2014).

The maximum 80th percentile PEC_{gw} values for the azoxystrobin and metabolites R401553 and R402173 were <0.001 µg/L for all relevant Polish scenarios, no leaching is expected into groundwater of the active substance or its relevant metabolites when applied according to the recommended use patterns.

PEC_{GW} for toxicologically non-relevant metabolite R234886 in acidic soils were <0.1 µg/L in all scenarios and crops, whereas in alkaline soils were above 0.1 µg/L in Hamburg scenario with the maximum value of 0.138 µg/L (PEARL model) following application to spring cereals at BBCH 30-69. Since PEC_{GW} values do not exceed the threshold concentration of 0.75 µg/L for non-relevant metabolites, no further assessment is thus necessary.

Prothioconazole

The groundwater exposure assessment was conducted according to FOCUS guidance using models PEARL v5.5.5 and PELMO v6.6.4. The active substance prothioconazole was assessed along with its major soil metabolites, prothioconazole S-methyl (M01) and prothioconazole-desthio (M04). All endpoints were taken from the peer review conclusion for prothioconazole (EFSA, 2007).

The maximum 80th percentile PEC_{gw} values for the parent compound and metabolites were <0.001 µg/L for all relevant Polish scenarios, no leaching is expected into groundwater of the active substance or its relevant metabolites when applied according to the recommended use patterns.

3.7.3 Predicted environmental concentrations in surface water (PEC_{sw})

The surface water modelling was performed for the intended use pattern of FGF11 in line with recommendations of respective FOCUS guidance documents using most up-to-date versions of the models. Obtained PEC_{SW/SED} values were used in the risk assessment for aquatic organisms.

As the formulation contains more than one active substance, the evaluation of PEC_{SW} for the formulation has been assessed. The results for PEC_{SW} calculations are used in the ecotoxicological risk assessment.

3.7.4 Predicted environmental concentrations in air (PEC_{air})

Based on the available data contamination of the atmosphere with azoxystrobin and prothioconazole from the intended uses of FGF11 is considered to be negligible.

3.8 Ecotoxicology (Part B, Section 9)

3.8.1 Effects on terrestrial vertebrates

Acute and chronic risk to birds and mammals following the proposed use of FGF11 were performed in accordance with EFSA guidance on birds and mammals (2009).

Birds

The acute and chronic risk from the two active substances (azoxystrobin and prothioconazole) was acceptable at the screening level for the intended uses in cereals and oilseed rape. The acute risk from the

metabolite prothioconazole-desthio was acceptable at the screening level whereas the reproductive risk was acceptable at Tier 1. The risk to the mixture was calculated using the Finney's equation for acute toxicity and was acceptable at the screening level.

The risk from exposure to contaminated drinking water and secondary poisoning was also indicated to be acceptable following the proposed use of FGF11 according to GAP submitted.

Mammals

The acute and long-term risk for prothioconazole and azoxystrobin as well as the acute risk for metabolite prothioconazole-desthio were indicated to be acceptable for mammals at the screening level for the intended uses in cereals and oilseed rape. The long-term risks for the metabolite prothioconazole-desthio were solved in the Tier 1 assessment, except for the small herbivorous mammal "vole" scenario following application to cereals of prothioconazole-desthio. As such, additional refinement options were required for the long-term risk from the metabolite prothioconazole-desthio in cereals: refinement of the deposition factor together with refinement of DT_{50} in food items resulted in a $TER > 5$ and an acceptable risk to mammals is presented for this scenario.

The TERa for mixture toxicities were above the trigger value of 10 indicating low risk for mammals for applications on cereals and oilseed rape at the screening level.

The risk from exposure to contaminated drinking water and secondary poisoning was considered acceptable following the proposed use of FGF11.

In conclusion, an acceptable overall risk for mammals is indicated for the intended GAP uses of FGF11.

3.8.2 Effects on aquatic species

The evaluation of the risk for aquatic and sediment-dwelling organisms was performed in accordance with the recommendations of the "Guidance document on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters in the context of Regulation (EC) No 1107/2009", as provided by the Commission Services (SANTE-2015-00080, 15 January 2015).

Azoxystrobin and its metabolites

For azoxystrobin, based on the results of the risk assessments at FOCUS Step 3, the risk was acceptable based on the EU agreed weight-of-evidence approach for aquatic invertebrates, with no need to apply any further mitigation measures for application on spring cereals and oilseed rape.

For the metabolites R401553, R402173 and R234886 of azoxystrobin an acceptable risk was indicated at FOCUS Step 1, 2 without applying any mitigation measures.

Prothioconazole and its metabolites

For prothioconazole and its metabolites prothioconazole-S-methyl, and 1,2,4-triazole, an acceptable risk was indicated at FOCUS Step 1, 2 for application to cereals and oilseed rape without applying any mitigation measures.

For the metabolite prothioconazole-desthio (M04), an acceptable risk was indicated based on FOCUS Step 4 PEC_{SW} for scenarios relevant for Poland R1 in cereals when including the following risk mitigation measures:

- Winter and spring cereals (BBCH > 30 < 69): 10 m vegetative buffer strip + 10 m no-spray buffer zone

In case of use in spring and winter oilseed rape the risk mitigation for scenarios relevant for Poland (D3, D4 and R1) are not required.

Mixture assessment

Mixture toxicity assessment has been performed considering EFSA 2013 and the calculation sheet AGD_AquaMix (v. 1.22).

In line with the argumentation already provided earlier, mixture toxicity has been presented for azoxystrobin + prothioconazole and for azoxystrobin + prothioconazole-desthio

Chronic toxicity data available on single aa.ss. have been also considered in the mixture risk assessment. Azoxystrobin results to be the toxicity driver for the majority of the exposure scenario on fish, aquatic invertebrates and algae.

For Algae, MDR calculations indicate values between 0.2 and 5, i.e. the observed and calculated mixture toxicities are considered in agreement with the assumption of additive toxicity. Since synergism could be excluded, assessment for Algae has been finalised at the Screening Step, according to the simplified approach according to EFSA 2013.

For acute exposure on aquatic invertebrates, more-than additive (i.e. synergistic) mixture toxicity is theoretically indicated since MDR is greater than 5. But input data are very heterogenous, considering the exposure designs and the calculation of the endpoints thus not suitable enough to address properly the MDR on aquatic invertebrates, which is the most sensitive organism when exposed to azoxystrobin or formulation.

Finally, through ETRmix-CA approach a safe risk can be demonstrated for aquatic invertebrates and for fish.

RQmix approach was performed for chronic assessment, and a safe risk could be demonstrated, since for all the scenarios in which the RQmix was above the trigger, a toxicity driver was always identified, and thus the risk assessment should be relied upon the one determined for relative a.s.

Formulation assessment

Risk assessment performed with formulation toxicity data on aquatic invertebrates and fish demonstrated a safe risk when application of formulation FGF11 is implemented with mitigation measure as 10 m buffer strip for all proposed uses. However, in case of oilseed rape the mixture toxicity assessment indicated that no buffer zone is required for scenarios relevant for Poland.

3.8.3 Effects on bees

Risk assessment based on SANCO and EPPO:

The acute hazard quotients (HQs) are lower than the trigger value of 50 for both honeybees and bumble bees, indicating that both active substances (azoxystrobin and prothioconazole) and the formulation FGF11 pose a low risk to bees following the application of the formulation according to the use pattern proposed.

Risk assessment based on EFSA 2013:

The chronic risk according to EFSA GD 2013 is not required yet in Poland. The chronic and larvae toxicity studies performed with formulation FGF11 in order to fulfil the data requirements EU Reg 284/2009 have been evaluated by zRMS in Appendix 2 in Core Dossier and have been considered acceptable.

3.8.4 Effects on other arthropod species other than bees

The evaluation of the risk for non-target arthropods was performed in accordance with the recommendations of the “Guidance Document on Terrestrial Ecotoxicology”, as provided by the Commission Ser-

vices (SANCO/10329/2002 rev.2 (final), October 17, 2002), and in consideration of the recommendations of the guidance document ESCORT 2. Toxicity data from studies with FGF11 were used to perform risk assessment for the formulated product.

Toxicity data from studies with FGF11 were used to perform risk assessment for the formulated product. An acceptable in-field and off-field risk was shown for the intended use in cereals for *Aphidius rhopalosiphii*, *Typhlodromus pyri*, *Coccinella septempunctata* and *Chrysoperla carnea* thereby also covering the use in oilseed rape.. The risk to non-target arthropods from exposure to FGF11 is considered safe.

3.8.5 Effects on soil organisms

In The evaluation of the risk for earthworms and other non-target soil organisms (meso- and macrofauna) was performed in accordance with the recommendations of the “Guidance Document on Terrestrial Ecotoxicology”, as provided by the Commission Services (SANCO/10329/2002 rev 2 (final), October 17, 2002).

Soil meso and macro fauna

Exposure to azoxystrobin, prothioconazole and their metabolites indicated an acceptable risk for earthworms and other non-target soil organisms for the intended uses in cereals and oilseed rape using Tier 1 assessments.

The risk to non-target soil meso- and macrofauna from the intended uses of the formulated product FGF11 was indicated to be acceptable at Tier 1 assessment.

Soil microbial activity

An acceptable risk for soil microorganisms (N-transformation) is indicated for azoxystrobin, prothioconazole and their metabolites as well as the formulation FGF11 for the intended uses in cereals and oilseed rape.

3.8.6 Effects on non-target terrestrial plants

The risk assessment is based on the “Guidance Document on Terrestrial Ecotoxicology”, (SANCO/10329/2002 rev.2 final, 2002).

Risk assessments for FGF11 demonstrated an acceptable risk to non-target terrestrial plants for the intended uses in cereals and oilseed rape.

3.8.7 Effects on other terrestrial organisms (Flora and Fauna)

No other relevant data were identified in the EU review of the active substances and are considered necessary.

3.9 Relevance of metabolites (Part B, Section 10)

The metabolite R234886 of azoxystrobin is predicted to occur in groundwater at concentrations above 0.1 µg/L when the product FGF11 is applied to alkaline soils (see Point 3.7.2).

The relevance of the groundwater metabolite R234886 has already been assessed and agreed at EU level (see **Azoxystrobin, EFSA Journal 2010; 8(4):1542** and **Addendum, EC, 2014**). The relevance assessment is also applicable for the GAP and groundwater scenarios considered in this dRR (i.e., the conclusions reached at Step 4 and 5 of the relevance assessment made at the EU-level are valid also with regard to the PEC_{gw} calculated for the GAP and groundwater scenarios considered in this dRR). R234886 is not considered relevant according to the criteria laid down in the EC guidance document SANCO/221/2000 –rev.10.

4 Conclusion of the national comparative assessment (Art. 50 of Regulation (EC) No 1107/2009)

Not relevant for FGF11 since prothioconazole and azoxystrobin are not candidates for substitution.

5 Further information to permit a decision to be made or to support a review of the conditions and restrictions associated with the authorization

1. Efficacy

The following claimed uses have not been accepted to be registered on the ground of article 33 of regulation 1107/2009 in case of efficacy section:

1. ~~Winter wheat (TRZAW): yellow rust (PUCGST)~~
~~Justification: insufficient number of efficacy trials after 1 application (1 trial from the NE zone and 1 trial from Germany) and after 2 applications (a total of 3 trials)~~
~~National registration requirements: min. 6 efficacy trials/2 seasons~~
~~Additional remarks: conditional registration is proposed (2-3 efficacy trials were submitted)~~
2. ~~Winter wheat (TRZAW): brown rust (PUCCRE)~~
~~Justification: insufficient number of efficacy trials after 1 application (1 trial from the NE zone) and after 2 applications (a total of 5 trials)~~
~~National registration requirements: min. 6 efficacy trials/2 seasons~~
~~Additional remarks: conditional registration is proposed (5 efficacy trials were submitted)~~
3. Spring wheat (TRZAS): septoria leaf blotch (SEPTTR), yellow rust (PUCGST), brown rust (PUCCRE)
Justification: not supported by efficacy trials after 1 application and insufficient number of efficacy trials after 2 applications (2 trials and 3 trials, respectively) for PUCGST (2 trials from the NE zone and 1 trial from Germany) and, PUCCRE (3 trials from the NE zone) and SEPTTR (2 trials from the NE zone and 3 trials from Germany)
National registration requirements: for SEPTTR, PUCGST and PUCCRE min. 6 efficacy trials/2 seasons for each uses or extrapolation of efficacy data from winter wheat (however full data package for winter wheat is necessary) but additional trials after one application are necessary
For SEPTTR possible extrapolation of efficacy data from winter wheat, however 1-2 efficacy trials are also required for spring wheat
Additional remarks: For this use requested on the ground of article 33 of regulation 1107/2009 a conditional approval is proposed subject to the submission of required trials as a post-authorization data. The final decision on conditional approval is left at the Authority discretion.
4. Spring wheat (TRZAS): Fusarium (FUSASP)
Justification: not supported by efficacy trials after 1 application
National registration requirements: possible extrapolation of efficacy data from winter wheat, however 1-2 efficacy trials are also required for spring wheat
5. Durum wheat (TRZDU): septoria leaf blotch (SEPTTR), yellow rust (PUCGST), brown rust (PUCCRE)
Justification: not supported by efficacy trials after 1 application
National registration requirements: min. 4 3 efficacy trials/2 seasons for each uses
6. Durum wheat (TRZDU): Fusarium (FUSASP)
Justification: not supported by efficacy trials after 1 application
National registration requirements: min. 4 3 efficacy trials/2 seasons
7. Spelt (TRZSP): septoria leaf blotch (SEPTTR), yellow rust (PUCGST), brown rust (PUCCRE)
Justification: not supported by efficacy trials after 1 application
National registration requirements: min. 4 3 efficacy trials/2 seasons for each uses
8. Spelt (TRZSP): Fusarium (FUSASP)
Justification: not supported by efficacy trials after 1 application
National registration requirements: min. 4 3 efficacy trials/2 seasons

9. ~~Winter triticale (TTLWI): yellow rust (PUCGST)~~
~~Justification: insufficient number of efficacy trials after 1 application (1 trial from the NE zone) and after 2 applications (a total of 2 trials)~~
~~National registration requirements: min. 6 efficacy trials/2 seasons or extrapolation of efficacy data from winter wheat (however full data package for winter wheat is necessary)~~
10. ~~Winter triticale (TTLWI): brown rust (PUCCRE)~~
~~Justification: insufficient number of efficacy trials after 1 application (1 trial from the NE zone) and after 2 applications (a total of 2 trials)~~
~~National registration requirements: min. 6 efficacy trials/2 seasons or extrapolation of efficacy data from winter wheat (however full data package for winter wheat is necessary)~~
11. Spring triticale (TTL SO): septoria leaf blotch (SEPTTR), brown rust (PUCCRE)
Justification: not supported by efficacy trials after 1 and 2 applications
National registration requirements: for SEPTTR and PUCCRE min. 6 efficacy trials/2 seasons for each uses or For SEPTTR possible extrapolation of efficacy data from winter wheat, however 1-2 efficacy trials after one application are also required for spring triticale.
12. ~~Spring triticale (TTL SO): yellow rust (PUCGST)~~
~~Justification: insufficient number of efficacy trials after 1 application (1 trial from the NE zone) and after 2 applications (a total of 1 trial)~~
~~National registration requirements: min. 6 efficacy trials/2 seasons or extrapolation of efficacy data from winter wheat (however full data package for winter wheat is necessary)~~
13. Winter barley (HORVW): net blotch (PYRNTE)
Justification: insufficient number of efficacy trials after 1 application (a total of 4 efficacy trials: 2 trials after 1 application from the NE zone) and 4 trials after 2 applications (a total of 4 trials), all trials conducted in the NE zone
National registration requirements: min. 6 efficacy trials/2 seasons
Additional remarks: conditional registration is proposed (2 4 efficacy trials were submitted)
Additional remarks: For this use requested on the ground of article 33 of regulation 1107/2009 a conditional approval is proposed subject to the submission of required trials as a post-authorization data. The final decision on conditional approval is left at the Authority discretion.
14. ~~Winter barley (HORVW): brown rust (PUCCHD)~~
~~Justification: insufficient number of efficacy trials after 1 application (1 trial from the NE zone and 1 trial from Germany) and after 2 applications (a total of 4 trials)~~
~~National registration requirements: min. 6 efficacy trials/2 seasons~~
~~Additional remarks: conditional registration is proposed (2 4 efficacy trials were submitted)~~
15. Winter barley (HORVW): leaf spot of barley (RAMUCC)
Justification: not supported by efficacy trials after 1 and 2 applications
National registration requirements: min. 6 efficacy trials/2 seasons
16. Winter barley (HORVW): leaf blotch (RHYNSE)
Justification: insufficient number of efficacy trials after 1 application (1 trial from Germany)
National registration requirements: min. 6 efficacy trials/2 seasons
17. Spring barley (HORVS): net blotch (PYRNTE)
Justification: insufficient number of efficacy trials after 1 application (a total of 4 efficacy trials: 2 trials after 1 application from the NE zone) and 4 trials after 2 applications, all trials conducted in the NE zone (a total of 4 trials)
National registration requirements: min. 6 efficacy trials/2 seasons
Additional remarks: conditional registration is proposed (2 4 efficacy trials were submitted)
Additional remarks: For this use requested on the ground of article 33 of regulation 1107/2009 a conditional approval is proposed subject to the submission of required trials as a post-authorization data. The final decision on conditional approval is left at the Authority discretion.
18. Spring barley (HORVS): brown rust (PUCCHD)
Justification: not supported by efficacy trials after 1 application and only 1 trial after 2 applications
National registration requirements: min. 6 efficacy trials/2 seasons or extrapolation of efficacy data from winter barley but additional trials after one application are necessary
Additional remarks: For this use requested on the ground of article 33 of regulation 1107/2009 a

- conditional approval is proposed subject to the submission of required trials as a post-authorization data. The final decision on conditional approval is left at the Authority discretion.*
19. Spring barley (HORVS): leaf spot of barley (RAMUCC)
Justification: not supported by efficacy trials after 1 application
National registration requirements: min. 6 efficacy trials/2 seasons
 20. Spring barley (HORVS): leaf blotch (RHYNSE)
Justification: not supported by efficacy trials after 1 application
National registration requirements: min. 6 efficacy trials/2 seasons
 21. Winter rye (SECCW): brown rust (PUCCRR)
Justification: not supported by efficacy trials after 1 application and insufficient number of efficacy trials after 2 applications (a total of 3 trials: 3 trials from the NE zone and 1 trial from Germany)
National registration requirements: min. 6 efficacy trials/2 seasons or extrapolation of efficacy data from winter wheat but additional trials after one application are necessary
Additional remarks: For this use requested on the ground of article 33 of regulation 1107/2009 a conditional approval is proposed subject to the submission of required trials as a post-authorization data. The final decision on conditional approval is left at the Authority discretion.
 22. Spring rye (SECCS): brown rust (PUCCRR)
Justification: not supported by efficacy trials after 1 and 2 applications
National registration requirements: min. 2-3 efficacy trials/2 seasons
 23. Spring oilseed rape (BRSNS): sclerotinia stem rot (SCLESC)
Justification: not supported by efficacy trials after 1 application
National registration requirements: possible extrapolation of efficacy data from winter oilseed rape, however 1-2 efficacy trials are also required for spring oilseed rape

There is possible registration on the grounds of article 51 of regulation 1107/2009 (without efficacy trials) for the following uses:

- Durum wheat (TRZDU)
- Spelt (TRZSP)
- Spring rye (SECCS)
- Spring oilseed rape (BRSNS)
- Spring triticale (TTLSO): yellow rust (PUCCST)

Additional remarks:

1. National registration requirements are based on the updated harmonization arrangements, updated extrapolation table (update of 28.01.2025), including additional note regarding required trials for extrapolated crops: “The higher number of trials required refers to plant protection products containing a new active substance, a new mixture of previously unused active substances, a new use”.
2. For these uses for which extrapolation is not possible:
 - the requirement to submit a minimum of 6 efficacy trials in major crops and 2-3 efficacy trials for known uses or 4 trials for new uses in minor crops,
 - trials from 2 crop seasons are required, while it is possible to reduce the number of seasons to 1 - only if the expert accepts the substantive argumentation of such a decision presented by the applicant, supported by more than the required minimum number of trials.
3. Location of required trials: North-East EPPO zone (including Poland) or countries neighboring Poland (Czech Republic, Germany, Slovakia). In case of new uses/new active substance/new mixture of known active substances, submission of efficacy trials from the NE zone (in addition to trials from neighboring countries) is obligatory. Minimum 2-3 efficacy trials from the NE zone should be presented.

2. Metabolism and Residues

Noticed data gaps is:

- Storage stability study for oilseeds for 1,2,4 T and TA

The interval from sampling until extraction for 1,2,4 T and TA in the Bousquet's study (647-2023; 2023) was longer than the storage stability period for 1,2,4 T and TA in oilseed rape from S. Baxter, B. Phipps

study (QC/21/002). Therefore additional data on storage stability for 1,2,4 T and TA in oilseed rape are required (data gap).

Appendix 1 Copy of the product authorization

Appendix 2 Copy of the product label

Komentarz oceniających:

Etykieta została sprawdzona w zakresie fizykochemii, metod analitycznych, toksykologii i istotności toksykologicznej metabolitów, pozostałości, losu i zachowania, ekotoksykologii oraz skuteczności. Zmiany wynikające z oceny wprowadzono do poniższej etykiety w widoczny sposób, poprzez zaznaczenie ich szarym podświetleniem tekstu (fragmenty dodane) lub ~~przekreśleniem~~ i jasno-szarym czcionką (fragmenty usunięte).

Sekcja właściwości fizykochemiczne:

1. Środek nie wykazuje właściwości wybuchowych i utleniających, znakowanie środka wynikające z wyżej wymienionych właściwości fizykochemicznych zgodnie z zapisami Rozporządzenia Parlamentu Europejskiego i Rady (WE) NR 1272/2008 z dnia 16 grudnia 2008 r. nie jest wymagane.
2. Okres ważności: 2-letnie badania stabilności są rozpoczęte. Można uznać 2-letni okres przechowywania warunkowo na podstawie 42-dniowych badań przyspieszonego starzenia w temperaturze 45°C oraz **po 1 roku w temperaturze otoczenia** środka przechowywanego w opakowaniach wykonanych z HDPE/EVOH. Na podstawie zapisów wytycznej Ministerstwa Rolnictwa i Rozwoju Wsi w sprawie zasad zatwierdzania opakowań środków ochrony roślin z dnia 05/09/2023 dla środków ochrony roślin w postaci roztworu wodnego (formulacja SC) możliwa jest ekstrapolacja wyników badań środka ochrony roślin przechowywanego w opakowaniach wykonanych z HDPE/EVOH na opakowania HDPE/PA i HDPE/F. W związku z powyższym wszystkie opakowania wymienione w punkcie 4.1 Sekcji 1,2,4 oraz w punkcie 2.1 dokumentu A można uznać za odpowiednie do celów transportu i magazynowania środka ochrony roślin.
3. Brak uwag do zaproponowanych w etykiecie zapisów dotyczących warunków przechowywania i bezpiecznego usuwania środka ochrony roślin.
4. Brak uwag do nazw grup chemicznych, do których przyporządkowano substancje czynne. Skorygowano zawartości substancji czynnych (zgodnie z punktem 2.6.1 Sekcji 1,2,4 gęstość 1,1228 g/mL).
5. Zgodnie z informacjami zawartymi w tabeli 2-1, w punkcie 2.9.1 i 2.9.2 Sekcji 1 Raportu Rejestracyjnego środek nie jest dedykowany do łącznego stosowania.

Sekcja skuteczność:

1. Na podstawie przedłożonej przez wnioskodawcę dokumentacji możliwa jest rejestracja środka Patton Alpha w zakresie skuteczności do ochrony pszenicy ozimej ~~pszenicy jarej~~ przed septoriozą paskowaną liści pszenicy (SEPTTR), **rdzą żółtą zbóż i traw (PUCCST), rdzą brunatną pszenicy (PUCCRE), pszenżyta ozimego przed septoriozą paskowaną liści pszenicy (SEPTTR), rdzą żółtą zbóż i traw (PUCCST), rdzą brunatną pszenicy (PUCCRE), pszenżyta jarego przed rdzą żółtą zbóż i traw (PUCCST), jęczmienia ozimego i jarego przed plamistością siatkową jęczmienia (PYRNTE) i przed rdzą jęczmienia (PUCCHD), rzepaku ozimego przed zgnilizną twardzikową (SCLESC) oraz pszenicy ozimej przed fuzariozą kłosów (FUSASP) w dawce 1 l/ha, 1 raz w sezonie wegetacyjnym.**
2. W przedłożonym przez wnioskodawcę biodossier, średnią skuteczność dla zastosowania środka w pszenicy ozimej, pszenicy jarej, pszenicy durum, pszenicy orkisz, pszenżycie ozimym, pszenżycie jarym, życie ozimym, życie jarym, jęczmieniu ozimym i jęczmieniu jarym, obliczono po wykonaniu drugiego zabiegu. Nie jest błędem wykonanie większej niż wnioskowana liczba zabiegów w badaniach skuteczności w powyższych uprawach, ale problemem jest brak wyników skuteczności po wykonaniu pierwszego zabiegu w przedmiotowym dRR. Zgodnie z ustaleniami harmonizacyjnymi: „W przypadku, gdy np. ze względu na biologię agrofaga i/lub przyjęty sposób postępowania [program ochrony itp.] stosowano w badaniach więcej aplikacji podczas gdy celem jest zarejestrowanie środka zalecanego do zastosowania w mniejszej liczbie aplikacji (większa liczba aplikacji w badaniach załączonych w BAD/dRR w porównaniu do liczby aplikacji wskazanych w GAP i w projekcie etykiety), w dRR/BAD nie może zabraknąć wyników oceny po aplikacji środka w liczbie odpowiadającej wnioskowanej liczbie zabiegów w danym zastosowaniu (zgodnie z tabelą GAP).” Zgodnie z tymi wytycznymi ekspert opracował nowe tabele, w których zawarł średnią skuteczność środka po pierwszym zabiegu. ~~W rezultacie, z uwagi na niewielką liczbę wyników skuteczności po pierwszym zabiegu, dostępnych w przedłożonym pakiecie badań, dla których PESSEV wynosił ≥5% (dla zwiększenia zakresu danych, w niektórych badaniach uwzględniono także PESSEV ≥4%), zaakceptowano tylko niewielki zakres wnioskowanych dla Polski zastosowań.~~
3. Z uwagi na niewystarczającą liczbę badań i brak możliwości ekstrapolacji, nie można zaakceptować poniższych zastosowań:
 - septorioza paskowana liści pszenicy (SEPTTR): pszenica jara (brak badań **z 1 zabiegami i 5 badań z 2 zabiegami**), pszenica durum (brak badań), pszenica orkisz (brak badań), pszenżyto jare (brak badań).

Z uwagi na fakt, że pszenica durum i pszenica orkisz są uprawami małoobszarowymi w Polsce, proponuje się rejestrację w trybie art. 51,

- rdza żółta zbóż i traw (PUCCST): pszenica ozima (przedłożono tylko 2 badania skuteczności z 1 zabiegiem i 3 badania z 2 zabiegami), pszenica jara (brak badań z 1 zabiegiem i 2 badania z 2 zabiegami), pszenica durum (brak badań), pszenica orkisz (brak badań), pszenżyto ozime (przedłożono tylko 1 badanie skuteczności z 1 zabiegiem i 2 badania z 2 zabiegami), pszenżyto jare (przedłożono tylko 1 badanie skuteczności z 1 i 2 zabiegami). Z uwagi na fakt, że pszenica durum i pszenica orkisz są uprawami małoobszarowymi, a rdza żółta na pszenżycie jarym zastosowaniem małoobszarowym w Polsce, proponuje się rejestrację w trybie art. 51,
- rdza brunatna pszenicy (PUCCRE): pszenica ozima (przedłożono tylko 1 badanie skuteczności z 1 zabiegiem i 5 badań z 2 zabiegami), pszenica jara (brak badań z 1 zabiegiem i 3 badania z 2 zabiegami), pszenica durum (brak badań), pszenica orkisz (brak badań), pszenżyto ozime (przedłożono tylko 1 badanie skuteczności z 1 zabiegiem i 2 badania z 2 zabiegami), pszenżyto jare (brak badań). Z uwagi na fakt, że pszenica durum i pszenica orkisz są uprawami małoobszarowymi w Polsce, proponuje się rejestrację w trybie art. 51,
- rdza brunatna żyta (PUCCRR): żyto ozime (brak badań z 1 zabiegiem i 3 badania z 2 zabiegami), żyto jare (brak badań). Z uwagi na fakt, że żyto jare jest uprawą małoobszarową w Polsce, proponuje się rejestrację w trybie art. 51,
- plamistość siatkowa jęczmienia (PYRNTE): jęczmień ozimy (przedłożono tylko 4 badania: 2 badania skuteczności z 1 zabiegiem i 4 badania z 2 zabiegami), jęczmień jary (przedłożono tylko 4 badania: 2 badania skuteczności z 1 zabiegiem i 4 badania z 2 zabiegami),
- rdza jęczmienia (PUCCHD): jęczmień ozimy (przedłożono tylko 2 badania skuteczności z 1 zabiegiem i 4 badania z 2 zabiegami), jęczmień jary (brak badań z 1 zabiegiem i 1 badanie z 2 zabiegami),
- ramularioza (RAMUCC): jęczmień ozimy (brak badań), jęczmień jary (brak badań),
- rynchosporioza (RHYNSE): jęczmień ozimy (przedłożono tylko 1 badanie skuteczności z 1 zabiegiem), jęczmień jary (brak badań),
- fuzarioza kłosów (FUSASP): pszenica jara (brak badań), pszenica durum (brak badań), pszenica orkisz (brak badań). Z uwagi na fakt, że pszenica durum i pszenica orkisz są uprawami małoobszarowymi w Polsce, proponuje się rejestrację w trybie art. 51.

Ponadto, z etykiety usunięto dwa zastosowania, które nie są wnioskowane w tabeli GAP: plamistość liści jęczmienia oraz czerń krzyżowych.

Wprowadzono także zapis o średnim poziomie skuteczności środka w ochronie przed septoriozą paskowaną liści oraz fuzariozą kłosów w pszenicy ozimej.

4. Biorąc pod uwagę, że mieszanina substancji zawarta w środku Patton Alpha jest powszechnie znana w ochronie zbóż, proponujemy zezwolenie warunkowe dla następujących zastosowań: pszenica ozima/PUCCST i PUCCRE, jęczmień ozimy/PYRNTE, jęczmień jary/PYRNTE i PUCCHD, jęczmień ozimy/PUCCHD, żyto ozime/PUCCRR i pszenica jara/SEPTTR, PUCCST i PUCCRE.
5. Mając na uwadze powyższe, zawężeniu uległy fazy rozwojowe dla zaakceptowanych zastosowań: BBCH 30-33 dla pszenicy ozimej (septorioza paskowana liści pszenicy) oraz BBCH 30-37 dla pszenżyta ozimego. W przypadku rzepaku ozimego, końcową fazą która pojawiła się w badaniach było BBCH 67, dlatego ostateczny zaakceptowany zakres BBCH to 61-69.
6. Dodano zapis procedury mycia opryskiwacza.

Sekcja metody analityczne:

1. Brak uwag.

Sekcja toksykologia i istotność toksykologiczna metabolitów:

1. W części dotyczącej klasyfikacji zagrożeń (CLP/GHS 1272/2008) zmodyfikowane zostały zwroty określające zagrożenie oraz zwroty wskazujące środki ostrożności, zgodnie z wynikami szacowania toksyczności ostrej wykonanej metodą kalkulacyjną. Zwrot P280 „Stosować rękawice ochronne” jest zalecany jako działanie ostrożnościowe wynikające z klasyfikacji EUH208 jest zalecany dla operatora ze względu na klasyfikację środka ochrony roślin jako uczulającego i oznaczonego w kategorii zagrożeń ze zwrotem H317.
2. W części dotyczącej pierwszej pomocy zostały zaproponowane zmiany wynikające ze zaktualizowanej klasyfikacji CLP.

Sekcja pozostałości:

1. Pod kątem pozostałości możliwe jest zastosowanie środka w ochronie pszenicy, pszenżyta, żyta, jęczmienia oraz rzepaku.
2. W przypadku rzepaku dla metabolitów triazolowych 1,2,4-T oraz TA brakuje badań stabilności próbek. Zgodnie z ustaleniami harmonizacyjnymi z dnia 14 maja 2025 możliwe jest dopuszczenie warunkowe zezwolenia, pod warunkiem uzupełnienia danych przez Wnioskodawcę.
3. W zakresie zapisów dotyczących roślin następnych nie ma potrzeby wpisywania restrykcji. Opcjonalnie można do etykiety dodać następujący zapis:
„Okres od ostatniego zastosowania środka na rośliny do dnia, w którym można siać lub sadzić rośliny uprawiane następnie: nie ma ograniczeń co do okresu od ostatniego zastosowania środka do dnia, w którym można siać lub sadzić rośliny uprawiane następnie.”

Sekcja los i zachowanie w środowisku:

1. Brak uwag.

Sekcja ekotoksykologia:

1. Do zarządzania ryzykiem dla organizmów wodnych dopisano odpowiednie uprawy.
2. Dopisano zwrot P501 do etykiety instrukcji stosowania.

Posiadacz zezwolenia:
UPL Holdings Coöperatief U.A., Claudius Prinsenlaan 144a, Block A, 4818CP Breda, Królestwo Ni-derlandów, tel.: +31 85 071 23 00, e-mail: uplholdingscoop@upl-ltd.com

Podmiot wprowadzający środek ochrony roślin na terytorium Rzeczypospolitej Polskiej:
UPL Polska Sp. z o.o., ul. Stawki 40, 01-040 Warszawa, tel.: +48 22 434 00 90, e-mail: sekretariat@upl-ltd.com

Podmiot odpowiedzialny za końcowe pakowanie i etykietowanie środka ochrony roślin:
.....

Podmiot odpowiedzialny za końcowe etykietowanie środka ochrony roślin:
.....

Telaron Patton Alpha

Środek przeznaczony do stosowania przez użytkowników profesjonalnych

Substancje czynne:
azoksystrobina - 160 g/l (15,3% 14,3%)
protiokonazol - 200 g/l (18,3% 17,8%)

Zezwolenie MRiRW nr R - xx/2025 z dnia xx.xx.2025 r.

	
Uwaga	
H317	Może powodować reakcję alergiczną skóry.
H332	Działa szkodliwie w następstwie wdychania.
H410	Działa bardzo toksycznie na organizmy wodne, powodując długotrwałe skutki.
EUH401	W celu uniknięcia zagrożeń dla zdrowia ludzi i środowiska, należy postępować zgodnie z instrukcją użycia.

EUH208	Zawiera 1,2-benzisothiazolin-3-one. Może powodować wystąpienie reakcji alergicznej
P261	Unikać wdychania pyłu/dymu/gazu/mgły/par/ rozpylonej cieczy.
P271	Stosować wyłącznie na zewnątrz lub w dobrze wentylowanym pomieszczeniu
P280	Stosować rękawice ochronne/odzież ochronną.
P302+P352	W PRZYPADKU KONTAKTU ZE SKÓRĄ: Umyć dużą ilością wody.
P302+P352	W PRZYPADKU KONTAKTU ZE SKÓRĄ: Umyć dużą ilością wody.
P304+P340	W PRZYPADKU DOSTANIA SIĘ DO DRÓG ODDECHOWYCH: wyprowadzić lub wynieść poszkodowanego na świeże powietrze i zapewnić mu warunki do swobodnego oddychania.
P312	W przypadku złego samopoczucia skontaktować się z OŚRODKIEM ZATRUĆ/lekarzem.
P333+P313	W przypadku wystąpienia podrażnienia skóry lub wysypki: Zasięgnąć porady/zgłosić się pod opiekę lekarza.
P333+P313	W przypadku wystąpienia podrażnienia skóry lub wysypki: Zasięgnąć porady/zgłosić się pod opiekę lekarza.
P362+P364	Zdjąć zanieczyszczoną odzież i uprać ją przed ponownym użyciem.
P391	Zebrać wyciek.
P501	Zawartość/pojemnik usuwać do odpowiedniego miejsca utylizacji zgodnie z lokalnymi i krajowymi przepisami

OPIS DZIAŁANIA

FUNGICYD w postaci koncentratu w formie stężonej zawiesiny do rozcieńczania wodą (SC), o działaniu węglowym i układowym do stosowania zapobiegawczego, interwencyjnego oraz wyniszczającego w ochronie przed chorobami powodowanymi przez grzyby.

Zgodnie z klasyfikacją FRAC substancja czynna azoksystrobina zaliczona jest do grupy 11 (fungicydy QoI), a substancja czynna protiokonazol zaliczona jest do grupy 3 (fungicydy SBI-DMI).

STOSOWANIE ŚRODKA

Środek przeznaczony do stosowania przy użyciu samobieżnego lub ciągnikowego opryskiwacza polowego.

Pszenica ozima, pszenica jara, ~~pszenica durum, pszenica orkisz~~

Septorioza paskowana liści pszenicy, rdza żółta zbóż i traw, rdza brunatna pszenicy

Maksymalna / zalecana dawka dla jednorazowego zastosowania: 1,0 l/ha.

Środek wykazuje średni poziom skuteczności w ochronie przed septoriozą paskowaną liści pszenicy.

Termin stosowania: środek stosować zapobiegawczo lub bezpośrednio po zaobserwowaniu pierwszych objawów chorób wiosną od fazy początku wzrostu źdźbła (strzelanie w źdźbło) do fazy końca kwitnienia 3-kolanka co najmniej 2 cm nad kolankiem 2 (BBCH 30-69 33).

Liczba zabiegów: 1.

Pszenica ozima

Fuzarioza kłosów

Maksymalna / zalecana dawka dla jednorazowego zastosowania: 1,0 l/ha.

Środek wykazuje średni poziom skuteczności w ochronie przed fuzariozą kłosów.

Termin stosowania: środek stosować zapobiegawczo lub bezpośrednio po zaobserwowaniu pierwszych objawów chorób od zakończenia fazy kłoszenia (wszystkie kłoski wydobywają się z pochwy, kłos całkowicie widoczny) do fazy końca kwitnienia (wszystkie kłoski zakończyły kwitnienie, widoczne zaschnięte pylniki) (BBCH 59-69).

Liczba zabiegów: 1.

Zalecana ilość wody: 100 - 400 l/ha.

Zalecane opryskiwanie: drobnokropliste.
Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1

Pszonżyto ozime, ~~pszonżyto jare~~

Septorioza paskowana liści, rdza żółta zbóż i traw, rdza brunatna

Maksymalna / zalecana dawka dla jednorazowego zastosowania: 1,0 l/ha.

Termin stosowania: środek stosować zapobiegawczo lub bezpośrednio po zaobserwowaniu pierwszych objawów chorób od fazy początku wzrostu źdźbła (strzelanie w źdźbło) do fazy końca kwitnienia ~~widocznego liścia flagowego, ale jeszcze nie rozwiniętego, gdy kłos zaczyna pęcznieć~~ (BBCH 30-69 ~~37~~).

Liczba zabiegów: 1.

Zalecana ilość wody: 100 - 400 l/ha.

Zalecane opryskiwanie: drobnokropliste.

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1

Pszonżyto jare

Rdza żółta zbóż i traw

Maksymalna / zalecana dawka dla jednorazowego zastosowania: 1,0 l/ha.

Termin stosowania: środek stosować zapobiegawczo lub bezpośrednio po zaobserwowaniu pierwszych objawów chorób od fazy początku wzrostu źdźbła (strzelanie w źdźbło) do fazy końca kwitnienia (BBCH 30-69).

Liczba zabiegów: 1.

Zalecana ilość wody: 100 - 400 l/ha.

Zalecane opryskiwanie: drobnokropliste.

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1

Jęczmień ozimy, jęczmień jary

Plamistość siatkowa jęczmienia, ramularia, plamistość liści jęczmienia, rdza jęczmienia

Maksymalna / zalecana dawka dla jednorazowego zastosowania: 1,0 l/ha.

Termin stosowania: środek stosować zapobiegawczo lub bezpośrednio po zaobserwowaniu pierwszych objawów chorób od fazy początku wzrostu źdźbła (strzelanie w źdźbło) do fazy końca kwitnienia (BBCH 30-69).

Liczba zabiegów: 1.

Zalecana ilość wody: 100 - 400 l/ha.

Zalecane opryskiwanie: drobnokropliste.

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1

Żyto ozime, ~~żyto jare~~

Rdza brunatna żyta

Maksymalna / zalecana dawka dla jednorazowego zastosowania: 1,0 l/ha.

Termin stosowania: środek stosować zapobiegawczo lub bezpośrednio po zaobserwowaniu pierwszych objawów chorób od fazy początku wzrostu źdźbła (strzelanie w źdźbło) do fazy końca kwitnienia (BBCH 30-69).

Liczba zabiegów: 1.

Zalecana ilość wody: 100 - 400 l/ha.

Zalecane opryskiwanie: drobnokropliste.

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1

Rzepak ozimy, ~~rzepak jary~~

Zgnilizna twardzikowa, ezerń krzyżowych

Maksymalna / zalecana dawka dla jednorazowego zastosowania: 1,0 l/ha.

Termin stosowania: środek stosować zapobiegawczo lub bezpośrednio po zaobserwowaniu pierwszych objawów chorób od początku fazy początku kwitnienia (10% otwartych kwiatów na głównym kwiatostanie, wydłużanie się głównego kwiatostanu) do końcowej fazy kwitnienia – ~~gdy większość płatków opada fazy, gdy 30% łuszczyzn osiągnęło typową wielkość~~ (BBCH 61-69 73 67).

Liczba zabiegów: 1.

Zalecana ilość wody: 100 - 400 l/ha.

Zalecane opryskiwanie: drobnokropliste.

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1

ŚRODKI OSTROŻNOŚCI, OKRESY KARENCJI I SZCZEGÓLNE WARUNKI STOSOWANIA

Okres od ostatniego zastosowania środka do dnia zbioru rośliny uprawnej (okres karencji):

Pszenica ozima, pszenica jara, pszenica durum, pszenica orkisz, żyto ozime, żyto jare, jęczmień ozimy, jęczmień jary, pszenżyto ozime, pszenżyto jare, rzepak ozimy, rzepak jary – **35 dni**.

Środek zawiera dwie substancje czynne o różnym mechanizmie działania: azoksystrobinę, należącą do grupy fungicydów strobilurynowych, z grupy inhibitorów oddychania na poziomie komórkowym – inhibitorów cytochromu bc1 - QoI (wg FRAC Grupa 11) oraz protiokonazol, związek triazolowy, z grupy inhibitorów syntezy steroli – inhibitorów demetylacji, SBI - DMI (wg FRAC Grupa 3). Wielokrotne stosowanie środka lub środków zawierających substancje czynne o takim samym mechanizmie działania może doprowadzić do zmniejszenia skuteczności działania środka. W ramach strategii przeciwdziałania rozwojowi odporności w populacjach sprawców chorób zaleca się m.in.:

- stosować środek głównie zapobiegawczo (profilaktycznie),
- nie stosować środka w dawkach niższych niż jest zalecana na etykiecie,
- stosować środek przemiennie ze środkami grzybobójczymi zawierającymi substancje czynne z innych grup chemicznych, o odmiennym mechanizmie działania.

Podczas stosowania środka nie dopuścić do:

- znoszenia cieczy użytkowej na sąsiednie rośliny uprawne,
- nakładania się cieczy użytkowej na stykach pasów zabiegowych i uwrociach.

SPORZĄDZANIE CIECZY UŻYTKOWEJ

Ciecz użytkową przygotować bezpośrednio przed zastosowaniem.

Przed przystąpieniem do sporządzania cieczy użytkowej dokładnie ustalić potrzebną jej objętość wraz z ilością środka. Zawartością opakowania przed użyciem wstrząsnąć. Napełniając opryskiwacz postępować zgodnie z instrukcją producenta opryskiwacza. W przypadku braku instrukcji odmierzoną ilość środka dodać do zbiornika opryskiwacza napełnionego częściowo wodą (z włączonym mieszadłem).

Opróżnione opakowania przepłukać trzykrotnie wodą, a popłuczyny wlać do zbiornika opryskiwacza z cieczą użytkową, uzupełnić wodą do potrzebnej ilości i dokładnie wymieszać. Po wlewaniu środka do zbiornika opryskiwacza niewyposażonego w mieszadło hydrauliczne, ciecz mechanicznie wymieszać. W przypadku przerw w opryskiwaniu, przed ponownym przystąpieniem do pracy ciecz użytkową w zbiorniku opryskiwacza dokładnie wymieszać

POSTĘPOWANIE Z RESZTKAMI CIECZY UŻYTKOWEJ I MYCIE APARATURY

Resztki cieczy użytkowej oraz wodę użytą do mycia aparatury należy:

- jeżeli jest to możliwe, po uprzednim rozcieńczeniu zużyć na powierzchni, na której przeprowadzono zabieg lub
- unieszkodliwić z wykorzystaniem rozwiązań technicznych zapewniających biologiczną degradację substancji czynnych środków ochrony roślin lub
- unieszkodliwić w inny sposób, zgodnie z przepisami o odpadach.

Po pracy aparaturę dokładnie wymyć. Trzykrotne płukanie zbiornika wodą pozwala na usunięcie resztek substancji zawartych w środku do poziomu bezpiecznego dla następnych upraw chronionych z użyciem tego samego opryskiwacza.

ŚRODKI OSTROŻNOŚCI DLA OSÓB STOSUJĄCYCH ŚRODEK, PRACOWNIKÓW ORAZ OSÓB POSTRONNYCH

Przed zastosowaniem środka należy poinformować o tym fakcie wszystkie zainteresowane strony, które mogą być narażone na znoszenie cieczy użytkowej i które zwróciły się o taką informację.

Nie jeść, nie pić ani nie palić podczas używania produktu.
Unikać wdychania rozpylonej cieczy.

Stosować rękawice ochronne i odzież roboczą (kombinezon) w trakcie przygotowywania cieczy użytkowej oraz w trakcie wykonywania zabiegu.

Zdjąć zanieczyszczoną odzież i wyprać ją przed ponownym użyciem.
Zanieczyszczoną odzież ochronną nie wносить poza miejsce pracy

Okres od zastosowania środka do dnia, w którym na obszar, na którym zastosowano środek mogą wejść ludzie oraz zostać wprowadzone zwierzęta (okres prewencji):
nie wchodzić do czasu całkowitego wyschnięcia cieczy użytkowej na powierzchni roślin.

ŚRODKI OSTROŻNOŚCI ZWIĄZANE Z OCHRONĄ ŚRODOWISKA NATURALNEGO

Nie zanieczyszczać wód środkiem ochrony roślin lub jego opakowaniem. Nie myć aparatury w pobliżu wód powierzchniowych. Unikać zanieczyszczania wód poprzez rowy odwadniające z gospodarstw i dróg.

Unikać niezgodnego z przeznaczeniem uwalniania do środowiska.

W celu ochrony organizmów wodnych konieczne jest wyznaczenie zadarnionej strefy ochronnej o szerokości 10 m od zbiorników i cieków wodnych w uprawie zbóż ozimych i jarych.

W celu ochrony roślin oraz stawonogów niebędących celem działania środka konieczne jest wyznaczenie strefy ochronnej o szerokości 1 m od terenów nieużytkowanych rolniczo.

WARUNKI PRZECHOWYWANIA I BEZPIECZNEGO USUWANIA ŚRODKA OCHRONY ROŚLIN I OPAKOWANIA

Chronić przed dziećmi.

Środek ochrony roślin przechowywać:

- w oryginalnych opakowaniach,
- w sposób uniemożliwiający kontakt z żywnością, napojami lub paszą, skażenie środowiska oraz dostęp osób trzecich,
- w temperaturze 0 °C-30°C.

Zabrania się wykorzystywania opróżnionych opakowań po środkach ochrony roślin do innych celów. Niewykorzystany środek przekazać do podmiotu uprawnionego do odbierania odpadów niebezpiecznych.

Opróżnione opakowania po środku zwrócić do sprzedawcy środków ochrony roślin będących środkami niebezpiecznymi.

PIERWSZA POMOC

Antidotum: brak, stosować leczenie objawowe.

W razie konieczności zasięgnięcia porady lekarza, należy pokazać opakowanie lub etykietę.

W przypadku kontaktu ze skórą: Umyć dużą ilością wody.

W przypadku dostania się do dróg oddechowych: wyprowadzić lub wynieść poszkodowanego na świeże powietrze i zapewnić mu warunki do swobodnego oddychania.

~~W przypadku złego samopoczucia skontaktować się z ośrodkiem zatruc/lekarzem~~

W przypadku wystąpienia podrażnienia skóry lub wysypki: Zasięgnąć porady/zgłosić się pod opiekę lekarza.

Okres ważności - 2 lata

Data produkcji -

Zawartość netto -

Nr partii -

Appendix 3 Letter of Access

The Letters of Access are confidential and are provided separate to this submission.

Appendix 4 Lists of data considered for national authorization

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 2.2.2	Patil, B.	2024	Title – Oxidizing properties of Azoxystrobin 160 + Prothioconazole 200 g/L SC Study Report No 230-2-11-35140 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 2.3.1	Patil, B.	2024	Title – Flash point of Azoxystrobin 160 + Prothioconazole 200 g/L SC Study Report No 221-2-11-35148 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 2.3.3	Patil, B.	2024	Title – Autoflammability of Azoxystrobin 160 + Prothioconazole 200 g/L SC Study Report No 241-2-11-35141 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 2.4.1	Patil, B.	2024	Title – Acidity & alkalinity of Azoxystrobin 160 + Prothioconazole 200 g/L SC Study Report No 220-2-11-35147 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 2.4.1	Prajapati, P.N.	2025	Title – pH of Azoxystrobin 160 + Prothioconazole 200 g/L SC Study Report No 210-2-11-39423 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 2.4.2	Patil, B.	2024	Title – pH of Azoxystrobin 160 + Prothioconazole 200 g/L SC Study Report No 210-2-11-35142 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 2.5.1	Patil, B.	2024	Title – Viscosity of Azoxystrobin 160 + Prothioconazole 200 g/L SC Study Report No 214-2-11-35135 GLP	N	Y	Data/study report never submitted before to Poland	UPL

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Unpublished				
KCP 2.5.2	Patil, B.	2024	Title – Surface tension of Azoxystrobin 160 + Prothioconazole 200 g/L SC Study Report No 222-2-11-35139 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 2.6.1	Patil, B.	2024	Title – Density of Azoxystrobin 160 + Prothioconazole 200 g/L SC Study Report No 204-2-11-35144 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 2.7.2 (also covers annex points KCP 2.1, 2.8.2, 2.8.3.1, 2.8.3.2, 2.8.5.1.1, 2.8.5.1.2, 2.8.7.2)	Patil, B.	2024	Title – Accelerated storage stability and corrosion characteristics of Azoxystrobin 160 + Prothioconazole 200 g/L SC Study Report No 234-2-11-35150 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 2.7.4	Patil, B.	2024	Title - Storage stability of Azoxystrobin 160 + Prothioconazole 200 g/L SC at low temperature Study Report No 211-2-11-35157 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 2.7.4	Prajapati, P.N.	2025	Title - Storage stability of Azoxystrobin 160 + Prothioconazole 200 g/L SC at low temperature Company Report No UPL/2025/0048 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 2.7.6	Patil, B.	2025	Title – One year storage stability and corrosion characteristics study of Azoxystrobin 160 + Prothioconazole 200 g/L SC Company Report No UPL/2023/1625 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 4.2.2	Patil, B.	2024	Title – Effectiveness of cleaing procedures of Azoxystrobin 160 + Prothioconazole 200 g/L SC Study Report No 284-2-11-35133 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 5.1.1-01	Patil, B.	2024	Title - Validation of analytical method for determination of active ingredients of Azoxystrobin 160 + Prothioconazole 200 g/L SC Company Report No UPL/2023/1623 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 5.1.1-02	Patil, B.	2024	Title - Validation of analytical method for determination of associated impurity (z-isomer of azoxystrobin) of Azoxystrobin 160 + Prothioconazole 200 g/L SC Company Report No UPL/2023/1628 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 5.1.1-03	Patil, B.	2024	Title - Validation of analytical method for determination of associated impurity (toluene) of Azoxystrobin 160 + Prothioconazole 200 g/L SC Company Report No UPL-2023-1629 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
CP 5.1.1-04	Patil, B.	2024	Title - Validation of analytical method for determination of associated impurity (prothioconazole-desthio) of Azoxystrobin 160 + Prothioconazole 200 g/L SC Company Report No UPL/2023/1630 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 5.1.2-01	Pearson, J.	2022	Title - Prothioconazole-desthio: Method Validation in Crops Company Report No QG/20/011 GLP Unpublished	N	Y	Data/study report never submitted before to Poland Remark: Evaluated in RR of FHO04 / Patton Supra (01.2025)	UPL
KCP 5.1.2-02	Giancola, D.	2023	Title - Hydroxy Metabolites of prothioconazole-desthio: Method Validation in Crops Company Report No QG/22/001	N	Y	Data/study report never submitted before to Poland Remark:	UPL

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			GLP Unpublished			Evaluated in RR of FHO04 / Patton Supra (01.2025)	
KCP 5.1.2-03	Phipps, B.	2024	Title - Triazole Derived Metabolites (TDM's) (1,2,4-triazole, triazole acetic acid, triazole alanine and triazole lactic acid): Method Validation in Crops Company Report No QG/20/012 GLP Unpublished	N	Y	Data/study report never submitted before to Poland Remark: Evaluated in RR of FHO04 / Patton Supra (01.2025)	UPL
KCP 5.1.2/04	Rastogi, T.	2024	Title - Validation of the Analytical Method for Determination of Azoxystrobin in OSR WholePlant and OSR Seeds Company Report No UPL/2023/1991 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 5.1.2/05	Horstmann, C.	2024	Title - Azoxystrobin 160 + Prothioconazole 200 g/L SC: Chronic Oral Toxicity Test on the Honey Bee (Apis mellifera L.) in the Laboratory Company Report No UPL/2023/1657 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 5.1.2/06	Horstmann, C.	2024	Title - Azoxystrobin 160 + Prothioconazole 200 g/L SC: Effects (Acute Contact and Oral) on Honey Bees (Apis mellifera L.) in the Laboratory Company Report No UPL/2023/1780 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 5.1.2/07	Horstmann, C.	2024	Title - Azoxystrobin 160 g/L + Prothioconazole 200 g/L SC: Acute Contact and Oral Toxicity to Bumblebees (Bombus terrestris L.) in the Laboratory Company Report No UPL/2023/2345 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 5.1.2/08	Venturi, S.	2024	Title - Effects of Azoxystrobin 160 + Prothioconazole 200 g/L SC on honeybees (Apis mellifera L.) 22-day larval toxicity test with repeated exposure Company Report No UPL/2023/2016 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 5.1.2/09	Bauer, J. & Mollandin, G.	2024	Title - Azoxystrobin 160g/L + Prothioconazole 200g/L SC: Toxicity to Pseudokirchneriella subcapitata in an Algal Growth Inhibition Test Company Report No UPL/2024/0581 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 5.1.2/10	Bauer, J. & Mollandin, G.	2024	Title - Azoxystrobin 160 g/L + Prothioconazole 200 g/L SC: Acute Toxicity to Daphnia magna in a Semi-Static 48-hour Immobilisation Test Company Report No UPL/2024/0702 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 5.1.2/11	Stürtz, S. & Horstmann, C.	2024	Title - Azoxystrobin 160 + Prothioconazole 200 g/L SC: Effects on Terrestrial (Non-Target) Plants: Vegetative Vigour Test Company Report No UPL/2023/2350 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 5.1.2/12	Stürtz, S. & Horstmann, C.	2024	Title - Azoxystrobin 160 + Prothioconazole 200 g/L SC: Effects on Terrestrial (Non-Target) Plants: Seedling Emergence and Seedling Growth Test Company Report No UPL/2023/2349 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 5.2/01	Boubakri, N.	2023	Title - Independent Laboratory Validation of Multi-Residue Method QuEChERS for Determination of Prothioconazole-desthio in Different Matrices of Plant Origin Company Report No S21-08354 GLP Unpublished	N	Y	Data/study report never submitted before to Poland Remark: Evaluated in RR of FHO04 / Patton Supra (01.2025)	UPL
KCP 5.2/02	Kleinhenz, D.	2023	Title - Development and Validation of an Analytical Method for Determination of Prothioconazole-desthio in Food of Animal Origin Company Report No S21-08355 GLP Unpublished	N	Y	Data/study report never submitted before to Poland Remark: Evaluated in RR of FHO04 / Patton Supra (01.2025)	UPL
KCP 5.2/03	Rastogi, T.	2023	Title - Independent Laboratory Validation of Prothioconazole-desthio in Different Matrices of Animal Origin	N	Y	Data/study report never submitted before to Poland	UPL

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Company Report No S21-08868 GLP Unpublished			Remark: Evaluated in RR of FHO04 / Patton Supra (01.2025)	
KCP 5.2/04	Hitchens, J.	2023	Title - Prothioconazole-desthio and hydroxy metabolites: Method Validation in Honey Company Report No QG/21/009 GLP Unpublished	N	Y	Data/study report never submitted before to Poland Remark: Evaluated in RR of FHO04 / Patton Supra (01.2025)	UPL
KCP 5.2/05	Wanger, J.	2023	Title - Independent Laboratory Validation of an Analytical Method for the Determination of Prothioconazole-desthio in Honey Company Report No S21-08357 GLP Unpublished	N	Y	Data/study report never submitted before to Poland Remark: Evaluated in RR of FHO04 / Patton Supra (01.2025)	UPL
KCP 5.2/06	Kaiser, M.	2022	Title - Development and Validation of an Analytical Method for Determination of Prothioconazole and Prothioconazole-desthio in Soil Company Report No S21-08358 GLP Unpublished	N	Y	Data/study report never submitted before to Poland Remark: Evaluated in RR of FHO04 / Patton Supra (01.2025)	UPL
KCP 5.2/07	Kaiser, M.	2022	Title - Development and Validation of an Analytical Method for Determination of Prothioconazole and Prothioconazole-desthio in Water Company Report No S21-08359 GLP Unpublished	N	Y	Data/study report never submitted before to Poland Remark: Evaluated in RR of FHO04 / Patton Supra (01.2025)	UPL
KCP 5.2/08	Jooß, S.	2023	Title - Independent Laboratory Validation of an Analytical Method for the Determination of Prothioconazole-desthio in Water Company Report No S21-08869 GLP Unpublished	N	Y	Data/study report never submitted before to Poland Remark: Evaluated in RR of FHO04 / Patton Supra (01.2025)	UPL
KCP 5.2/09	Boubakri, N.	2023	Title - Development and Validation of an Analytical Method for Determination of Prothioconazole-desthio in Urine Company Report No S21-08361 GLP Unpublished	N	Y	Data/study report never submitted before to Poland Remark: Evaluated in RR of FHO04 / Patton Supra (01.2025)	UPL

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.1/001	Alicia Moreno Muñoz	2024	Azoxystrobin and prothioconazole ratio discovery for Zymoseptoria tritici control on wheat UPL Iberia SA F23EU-041-MOA-002-MOR GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.1/002	Anne Monfort	2024	Azoxystrobin and prothioconazole ratio discovery for Zymoseptoria tritici control on wheat UPL Europe Ltd F24EU-001-MOA-002-CRJ GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/001 KCP 6.4.1/001	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of Zymoseptoria tritici (SEPTTR) on winter wheat in Europe, 2022. EAS Agrartest, Rosenow F22EU-006-MOA-001 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/002 KCP 6.4.1/002	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of Zymoseptoria tritici (SEPTTR) on winter wheat in Europe, 2022. EAS Germany, Detmold F22EU-006-MOA-002 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/003 KCP 6.4.1/003	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of Zymoseptoria tritici (SEPTTR) on winter wheat in Europe, 2022. EAS Ireland F22EU-006-MOA-004 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/004 KCP 6.4.1/004	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of Zymoseptoria tritici (SEPTTR) on winter wheat in Europe, 2022. EAS Ireland F22EU-006-MOA-005 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.2/005 KCP 6.4.1/005	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of Zymoseptoria tritici (SEPTTR) on winter wheat in Europe, 2022. EAS UK, North West F22EU-006-MOA-006 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/006 KCP 6.4.1/006	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of Zymoseptoria tritici (SEPTTR) on winter wheat in Europe, 2022. Lithuanian Research Centre for Agriculture and Forestry F22EU-006-MOA-008 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/007 KCP 6.4.1/007	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of Zymoseptoria tritici (SEPTTR) on winter wheat in Europe, 2022. EUROFINS AGROSCIENCE SERVICES sp z o.o. F22EU-006-MOA-009 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/008 KCP 6.4.1/008	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of Zymoseptoria tritici (SEPTTR) on winter wheat in Europe, 2022. EAS Poland, Kazmierz F22EU-006-MOA-010 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/009 KCP 6.4.1/009	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of Zymoseptoria tritici (SEPTTR) on winter wheat in Europe, 2022. EAS Hungary, Székesfehérvár F22EU-006-MOA-011 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/010 KCP 6.4.1/010	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of Zymoseptoria tritici (SEPTTR) on winter wheat in Europe, 2022. EAS Hungary, Székesfehérvár F22EU-006-MOA-012 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.2/011 KCP 6.4.1/011	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of <i>Zymoseptoria tritici</i> (SEPTTR) on winter wheat in Europe, 2022. EUROFINS AGROSCIENCE SERVICES F22EU-006-MOA-013 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/012 KCP 6.4.1/012	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of <i>Zymoseptoria tritici</i> (SEPTTR) on winter wheat in Europe, 2022. EAS Bulgaria, Letnitsa F22EU-006-MOA-014 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/013 KCP 6.4.1/013	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of <i>Puccinia striiformis</i> (PUCCST) on winter wheat in Europe, 2022. Agrartest GmbH F22EU-007-MOA-001 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/014 KCP 6.4.1/014	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of <i>Puccinia striiformis</i> (PUCCST) on winter wheat in Europe, 2022. Eurofins PHYLLIAE SAS F22EU-007-MOA-002 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/015 KCP 6.4.1/015	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of <i>Puccinia striiformis</i> (PUCCST) on winter wheat in Europe, 2022. EUROFINS AGROSCIENCE SERVICES F22EU-007-MOA-003 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/016 KCP 6.4.1/016	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of <i>Puccinia striiformis</i> (PUCCST) on winter wheat in Europe, 2022. EAS Ireland F22EU-007-MOA-004 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.2/017 KCP 6.4.1/017	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of Puccinia striiformis (PuccST) on winter wheat in Europe, 2022. EAS Ireland F22EU-007-MOA-005 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/018 KCP 6.4.1/018	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of Puccinia striiformis (PuccST) on winter wheat in Europe, 2022. EUROFINS AGROSCIENCE SERVICES F22EU-007-MOA-006 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/019 KCP 6.4.1/019	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of Puccinia striiformis (PuccST) on winter wheat in Europe, 2022. Lithuanian Research Centre for Agriculture and Forestry F22EU-007-MOA-008 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/020 KCP 6.4.1/020	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of Puccinia striiformis (PuccST) on winter wheat in Europe, 2022. EAS Poland, Kazmierz F22EU-007-MOA-009 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/021 KCP 6.4.1/021	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of Puccinia striiformis (PuccST) on winter wheat in Europe, 2022. Eurofins Agrosience services sp. z o.o. F22EU-007-MOA-010 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/022 KCP 6.4.1/022	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of Puccinia striiformis (PuccST) on winter wheat in Europe, 2022. Eurofins Agrosience Services EOOD F22EU-007-MOA-014 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.2/023 KCP 6.4.1/023	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of Puccinia recondita (PUCCRE) on winter wheat in Europe, 2022. Agrartest GmbH F22EU-008-MOA-001 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
~~KCP 6.2/024 KCP 6.4.1/024~~	~~Natalie Birkinshaw~~	~~2023~~	~~The efficacy of FGF11 applied for the control of Puccinia recondita (PUCCRE) on winter wheat in Europe, 2022. EUROFINS AGROSCIENCE SERVICES F22EU-008-MOA-003 GEP Unpublished~~	~~N~~	~~Y~~	~~Data/study report never submitted before to Poland~~	~~UPL~~
KCP 6.2/025 KCP 6.4.1/025	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of Puccinia recondita (PUCCRE) on winter wheat in Europe, 2022. Agrartest GmbH F22EU-008-MOA-004 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
~~KCP 6.2/026 KCP 6.4.1/026~~	~~Natalie Birkinshaw~~	~~2023~~	~~The efficacy of FGF11 applied for the control of Puccinia recondita (PUCCRE) on winter wheat in Europe, 2022. EAS UK, South-East F22EU-008-MOA-005 GEP Unpublished~~	~~N~~	~~Y~~	~~Data/study report never submitted before to Poland~~	~~UPL~~
~~KCP 6.2/027 KCP 6.4.1/027~~	~~Natalie Birkinshaw~~	~~2023~~	~~The efficacy of FGF11 applied for the control of Puccinia recondita (PUCCRE) on winter wheat in Europe, 2022. EAS UK, South-East F22EU-008-MOA-006 GEP Unpublished~~	~~N~~	~~Y~~	~~Data/study report never submitted before to Poland~~	~~UPL~~
KCP 6.2/028 KCP 6.4.1/028	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of Puccinia recondita (PUCCRE) on winter wheat in Europe, 2022. Lithuanian Research Centre for Agriculture and Forestry F22EU-008-MOA-008 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL

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KCP 6.2/029 KCP 6.4.1/029	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of Puccinia recondita (PUCCRE) on winter wheat in Europe, 2022. EAS Poland, Kazmierz F22EU-008-MOA-009 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
~~KCP 6.2/030 KCP 6.4.1/030~~	~~Natalie Birkinshaw~~	~~2023~~	~~The efficacy of FGF11 applied for the control of Puccinia recondita (PUCCRE) on winter wheat in Europe, 2022. EAS Hungary, Székesfehérvár F22EU-008-MOA-011 GEP Unpublished~~	~~N~~	~~Y~~	~~Data/study report never submitted before to Poland~~	~~UPL~~
~~KCP 6.2/031 KCP 6.4.1/031~~	~~Natalie Birkinshaw~~	~~2023~~	~~The efficacy of FGF11 applied for the control of Puccinia recondita (PUCCRE) on winter wheat in Europe, 2022. EAS Hungary, Székesfehérvár F22EU-008-MOA-012 GEP Unpublished~~	~~N~~	~~Y~~	~~Data/study report never submitted before to Poland~~	~~UPL~~
~~KCP 6.2/032 KCP 6.4.1/032~~	~~Natalie Birkinshaw~~	~~2023~~	~~The efficacy of FGF11 applied for the control of Puccinia recondita (PUCCRE) on winter wheat in Europe, 2022. Eurofins Agrosience Services EOOD F22EU-008-MOA-014 GEP Unpublished~~	~~N~~	~~Y~~	~~Data/study report never submitted before to Poland~~	~~UPL~~
KCP 6.2/033 KCP 6.4.1/033	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Zymoseptoria tritici (SEPTTR) on wheat in Europe, 2023 EAS Germany, Detmold F23EU-022-MOA-001 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
~~KCP 6.2/034 KCP 6.4.1/034~~	~~Natalie Birkinshaw~~	~~2024~~	~~The efficacy of FGF11 applied for the control of Zymoseptoria tritici (SEPTTR) on wheat in Europe, 2023 EAS France, Bretagne F23EU-022-MOA-002 GEP Unpublished~~	~~N~~	~~Y~~	~~Data/study report never submitted before to Poland~~	~~UPL~~

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.2/035 KCP 6.4.1/035	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Zymoseptoria tritici (SEPTTR) on wheat in Europe, 2023 EUROFINS AGROSCIENCE SERVICES sp z o.o. F23EU-022-MOA-003 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/036 KCP 6.4.1/036	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Zymoseptoria tritici (SEPTTR) on wheat in Europe, 2023 EAS Poland F23EU-022-MOA-004 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/037 KCP 6.4.1/037	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Zymoseptoria tritici (SEPTTR) on wheat in Europe, 2023 EAS Dobrich F23EU-022-MOA-005 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/038 KCP 6.4.1/038	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Zymoseptoria tritici (SEPTTR) on wheat in Europe, 2023 EUROFINS AGROSCIENCE SERVICES F23EU-022-MOA-006 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/039 KCP 6.4.1/039	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Puccinia striiformis (PUCCST) on winter wheat in Europe, 2023 Agrartest GmbH F23EU-025-MOA-001 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/040 KCP 6.4.1/040	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Puccinia striiformis (PUCCST) on winter wheat in Europe, 2023 EAS France, Centre Beauce F23EU-025-MOA-002 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL

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KCP 6.2/041 KCP 6.4.1/041	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Puccinia striiformis (PuccST) on winter wheat in Europe, 2023 EAS Ireland F23EU-025-MOA-003 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/042 KCP 6.4.1/042	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Puccinia striiformis (PuccST) on winter wheat in Europe, 2023 EAS Poland, Jasienica F23EU-025-MOA-004 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/043 KCP 6.4.1/043	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Puccinia striiformis (PuccST) on winter wheat in Europe, 2023 EAS Dobrich F23EU-025-MOA-005 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/044 KCP 6.4.1/044	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Puccinia striiformis (PuccST) on winter wheat in Europe, 2023 EUROFINS AGROSCIENCE SERVICES SRL F23EU-025-MOA-006 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/045 KCP 6.4.1/045	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Puccinia striiformis (PuccST) on winter wheat in Europe, 2023 EAS Romania, Timisoara F23EU-025-MOA-007 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/046 KCP 6.4.1/046	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Puccinia recondita (PuccRE) on wheat in Europe, 2023 EAS Germany, Detmold F23EU-027-MOA-001 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL

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KCP 6.2/047 KCP 6.4.1/047	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Puccinia recondita (PUCCRE) on wheat in Europe, 2023 Agrartest GmbH F23EU-027-MOA-002 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
~~KCP 6.2/048 KCP 6.4.1/048~~	~~Natalie Birkinshaw~~	~~2024~~	~~The efficacy of FGF11 applied for the control of Puccinia recondita (PUCCRE) on wheat in Europe, 2023 EAS France, Alsace F23EU-027-MOA-003 GEP Unpublished~~	~~N~~	~~Y~~	~~Data/study report never submitted before to Poland~~	~~UPL~~
~~KCP 6.2/049 KCP 6.4.1/049~~	~~Natalie Birkinshaw~~	~~2024~~	~~The efficacy of FGF11 applied for the control of Puccinia recondita (PUCCRE) on wheat in Europe, 2023 EAS France, Centre Beauce F23EU-027-MOA-004 GEP Unpublished~~	~~N~~	~~Y~~	~~Data/study report never submitted before to Poland~~	~~UPL~~
~~KCP 6.2/050 KCP 6.4.1/050~~	~~Natalie Birkinshaw~~	~~2024~~	~~The efficacy of FGF11 applied for the control of Puccinia recondita (PUCCRE) on wheat in Europe, 2023 EAS UK, South-East F23EU-027-MOA-005 GEP Unpublished~~	~~N~~	~~Y~~	~~Data/study report never submitted before to Poland~~	~~UPL~~
~~KCP 6.2/051 KCP 6.4.1/051~~	~~Natalie Birkinshaw~~	~~2024~~	~~The efficacy of FGF11 applied for the control of Puccinia recondita (PUCCRE) on wheat in Europe, 2023 EAS UK, South-East F23EU-027-MOA-006 GEP Unpublished~~	~~N~~	~~Y~~	~~Data/study report never submitted before to Poland~~	~~UPL~~
KCP 6.2/052 KCP 6.4.1/052	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Puccinia recondita (PUCCRE) on wheat in Europe, 2023 EAS Poland, Jasienica F23EU-027-MOA-007 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL

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KCP 6.2/053 KCP 6.4.1/053	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of <i>Puccinia recondita</i> (PUCCRE) on wheat in Europe, 2023 Eurofins Agrosience Services – EOOD F23EU-027-MOA-008 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/054 KCP 6.4.1/054	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of <i>Puccinia recondita</i> (PUCCRE) on wheat in Europe, 2023 EUROFINS AGROSCIENCE SERVICES F23EU-027-MOA-009 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/055 KCP 6.4.1/055	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of <i>Puccinia recondita</i> (PUCCRE) on wheat in Europe, 2023 EAS Hungary, Székesfehérvár F23EU-027-MOA-010 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/056 KCP 6.4.1/056	Natalie Birkinshaw	2024	The efficacy of FGF11 applied in wheat for the control of <i>Fusarium</i> sp. in Maritime Europe 2023. EAS Germany, Beimerstetten F23EU-033-MOA-003 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.4.1/057 KCP 6.4.2/001 KCP 6.4.3/001	Natalie Birkinshaw	2024	The efficacy of FGF11 applied in wheat for the control of <i>Fusarium</i> sp. in Maritime Europe 2023. EAS France, Normandie F23EU-033-MOA-004 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.4.1/058 KCP 6.4.2/002 KCP 6.4.3/002	Natalie Birkinshaw	2024	The efficacy of FGF11 applied in wheat for the control of <i>Fusarium</i> sp. in Maritime Europe 2023. EAS France, Alsace F23EU-033-MOA-006 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL

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KCP 6.2/057 KCP 6.4.1/059	Natalie Birkinshaw	2024	The efficacy of FGF11 applied in wheat for the control of Fusarium sp. in Maritime Europe 2023. EAS Ireland F23EU-033-MOA-007 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/058 KCP 6.4.1/060	Natalie Birkinshaw	2024	The efficacy of FGF11 applied in wheat for the control of Fusarium sp. in Maritime Europe 2023. EUROFINS AGROSCIENCE SERVICES F23EU-033-MOA-008 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.4.1/061 KCP 6.4.2/003 KCP 6.4.3/003	Natalie Birkinshaw	2024	The efficacy of FGF11 applied in wheat for the control of Fusarium sp. in Maritime Europe 2023. EAS UK F23EU-033-MOA-009 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/059 KCP 6.4.1/062	Natalie Birkinshaw	2024	The efficacy of FGF11 applied in wheat for the control of Fusarium sp. in North-East Europe. EUROFINS AGROSCIENCE SERVICES sp z o.o. F23EU-034-MOA-001 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/060 KCP 6.4.1/063	Natalie Birkinshaw	2024	The efficacy of FGF11 applied in wheat for the control of Fusarium sp. in North-East Europe. EUROFINS AGROSCIENCE SERVICES sp z o.o. F23EU-034-MOA-002 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/061 KCP 6.4.1/064	Natalie Birkinshaw	2024	The efficacy of FGF11 applied in wheat for the control of Fusarium sp. in North-East Europe. EAS Poland F23EU-034-MOA-003 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.2/062 KCP 6.4.1/065	Piotr Umiński	2024	The efficacy of FGF11 applied in wheat for the control of Fusarium sp. in Poland Europe 2023. Field Research Support F23EU-034-MOA-004 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/063 KCP 6.4.1/066	Piotr Umiński	2024	The efficacy of FGF11 applied in wheat for the control of Fusarium sp. in Poland Europe 2023. Field Research Support F23EU-034-MOA-005 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/064 KCP 6.4.1/067	Piotr Umiński	2024	The efficacy of FGF11 applied in wheat for the control of Fusarium sp. in Poland Europe 2023. Field Research Support F23EU-034-MOA-006 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/065 KCP 6.4.1/068	Natalie Birkinshaw	2024	The efficacy of FGF11 applied in wheat for the control of Fusarium sp. in South-East Europe. Eurofins Agrosience Services EOOD F23EU-035-MOA-001 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/066 KCP 6.4.1/069	Natalie Birkinshaw	2024	The efficacy of FGF11 applied in wheat for the control of Fusarium sp. in South-East Europe. EUROFINS AGROSCIENCE SERVICES SRL F23EU-035-MOA-003 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/067 KCP 6.4.1/070	Natalie Birkinshaw	2024	The efficacy of FGF11 applied in wheat for the control of Fusarium sp. in South-East Europe. EAS Romania, Timisoara F23EU-035-MOA-004 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.2/068 KCP 6.4.1/071	Natalie Birkinshaw	2024	The efficacy of FGF11 applied in wheat for the control of Fusarium sp. in South-East Europe. EAS Hungary, Székesfehérvár F23EU-035-MOA-005 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/069 KCP 6.4.1/072	Natalie Birkinshaw	2024	The efficacy of FGF11 applied in wheat for the control of Fusarium sp. in South-East Europe. EAS Hungary, Székesfehérvár F23EU-035-MOA-006 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/070 KCP 6.4.1/073	Piotr Umiński	2024	Evaluate the efficacy of FGF11 applied for the control of foliar diseases in cereals in Poland, 2023. Field Research Support F23EU-037-MOA-001 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/071 KCP 6.4.1/074	Piotr Umiński	2024	Evaluate the efficacy of FGF11 applied for the control of foliar diseases in cereals in Poland, 2023. Field Research Support F23EU-037-MOA-004 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/072 KCP 6.4.1/075	Krzysztof Rusek	2024	Evaluate the efficacy of FGF11 applied for the control of foliar diseases in cereals in Poland, 2023. Fertico Sp.z o.o. F23EU-037-MOA-005 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/073 KCP 6.4.1/076	Katarzyna Furman-Fratczak	2024	Evaluate the efficacy of FGF11 applied for the control of foliar diseases in cereals in Poland, 2023. Agreco sp. z o.o. F23EU-037-MOA-007 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL

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KCP 6.2/074 KCP 6.4.1/077	Piotr Umiński	2024	Evaluate the efficacy of FGF11 applied for the control of foliar diseases in cereals in Poland, 2023. Field Research Support F23EU-037-MOA-008 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/075 KCP 6.4.1/078	Krzysztof Rusek	2024	Evaluate the efficacy of FGF11 applied for the control of foliar diseases in cereals in Poland, 2023. Fertico F23EU-037-MOA-009 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/076 KCP 6.4.1/079	Gheorghe Botoman	2024	Evaluate the efficacy of FGF11 applied for the control of foliar diseases in cereals in Romania, 2023. AgroProspect S.R.L F23EU-039-MOA-001 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/077 KCP 6.4.1/080	Gheorghe Botoman	2024	Evaluate the efficacy of FGF11 applied for the control of foliar diseases in cereals in Romania, 2023. AgroProspect S.R.L F23EU-039-MOA-002 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/078 KCP 6.4.1/081	Andrés SEDANO	2024	The efficacy of FGR06 applied in wheat for the control of Fusarium sp. in Europe. STAPHYT F23EU-040-AMA-001 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/079 KCP 6.4.1/082	Gaëtan Wallart	2024	The efficacy of FGR06 applied in wheat for the control of Fusarium sp. in Europe. EPHYDIA F23EU-040-AMA-002 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.2/080 KCP 6.4.1/083	Gaëtan Wallart	2024	The efficacy of FGR06 applied in wheat for the control of Fusarium sp. in Europe. EPHYDIA F23EU-040-AMA-003 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/081 KCP 6.4.1/084	Natalie Birkinshaw	2024	The efficacy of FGR06 applied in wheat for the control of Fusarium sp. in Europe. EAS Germany, Stade F23EU-040-AMA-006 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.4.1/085 KCP 6.4.2/004 KCP 6.4.3/004	Natalie Birkinshaw	2024	The efficacy of FGR06 applied in wheat for the control of Fusarium sp. in Europe. Eurofins—De Bredelaar F23EU-040-AMA-007 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/082 KCP 6.4.1/086	Natalie Birkinshaw	2024	The efficacy of FGR06 applied in wheat for the control of Fusarium sp. in Europe. EAS Ireland F23EU-040-AMA-008 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/083 KCP 6.4.1/087	Natalie Birkinshaw	2024	The efficacy of FGR06 applied in wheat for the control of Fusarium sp. in Europe. EAS Ireland F23EU-040-AMA-009 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.4.1/088 KCP 6.4.2/005 KCP 6.4.3/005	Natalie Birkinshaw	2024	The efficacy of FGR06 applied in wheat for the control of Fusarium sp. in Europe. EAS UK F23EU-040-AMA-010 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.4.1/089 KCP 6.4.2/006 KCP 6.4.3/006	Natalie Birkinshaw	2024	The efficacy of FGR06 applied in wheat for the control of Fusarium sp. in Europe. EAS-UK, Wilson Field F23EU-040-AMA-011 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/084 KCP 6.4.1/090	Evaldas Lelešius	2024	The efficacy of FGR06 applied in wheat for the control of Fusarium sp. in Europe. Agrolab A/S F23EU-040-AMA-012 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/085 KCP 6.4.1/091	Piotr Umiński	2024	The efficacy of FGR06 applied in wheat for the control of Fusarium sp. in Europe. Field Research Support F23EU-040-AMA-025 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/086 KCP 6.4.1/092	Piotr Umiński	2024	The efficacy of FGR06 applied in wheat for the control of Fusarium sp. in Europe. Field Research Support F23EU-040-AMA-026 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/087 KCP 6.4.1/093	Piotr Umiński	2024	The efficacy of FGR06 applied in wheat for the control of Fusarium sp. in Europe. Field Research Support F23EU-040-AMA-027 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/088 KCP 6.4.1/094	Piotr Umiński	2024	The efficacy of FGR06 applied in wheat for the control of Fusarium sp. in Europe. Field Research Support F23EU-040-AMA-028 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.2/089 KCP 6.4.1/095	Krzysztof Rusek	2024	The efficacy of FGR06 applied in wheat for the control of Fusarium sp. in Europe. Fertico F23EU-040-AMA-029 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/090 KCP 6.4.1/096	Krzysztof Rusek	2024	The efficacy of FGR06 applied in wheat for the control of Fusarium sp. in Europe. Fertico Sp. z o.o. F23EU-040-AMA-030 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/091 KCP 6.4.1/097	Natalie Birkinshaw	2024	The efficacy of FGR06 applied in wheat for the control of Fusarium sp. in Europe. Latvian Plant Protection Research Centre F23EU-040-AMA-031 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/092 KCP 6.4.1/098	Evaldas Lelešius	2024	The efficacy of FGR06 applied in wheat for the control of Fusarium sp. in Europe. SIA AgroLab Baltic F23EU-040-AMA-032 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/093 KCP 6.4.1/099	Natalie Birkinshaw	2024	The efficacy of FGR06 applied in wheat for the control of Fusarium sp. in Europe. Institute of Agriculture, LRCAF F23EU-040-AMA-033 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/094 KCP 6.4.1/100	Evaldas Lelešius	2024	The efficacy of FGR06 applied in wheat for the control of Fusarium sp. in Europe. UAB Agrolab Baltic F23EU-040-AMA-034 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.2/095 KCP 6.4.1/101	Aleksa Dimitrijevic	2024	The efficacy of FGR06 and FGF11 applied in wheat for the control of Fusarium sp. in Southeast zone – Romania 2023. Sagea Agromania F23EU-040-AMA-035 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/096 KCP 6.4.1/102	Aleksa Dimitrijevic	2024	The efficacy of FGR06 and FGF11 applied in wheat for the control of Fusarium sp. in Southeast zone – Romania 2023. Sagea Agromania F23EU-040-AMA-036 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/097 KCP 6.4.1/103	Aleksa Dimitrijevic	2024	The efficacy of FGR06 and FGF11 applied in wheat for the control of Fusarium sp. in Southeast zone – Bulgaria 2023. Sagea OOD F23EU-040-AMA-037 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/098 KCP 6.4.1/104	Penyo Penev	2024	The efficacy of FGR06 and FGF11 applied in wheat for the control of Fusarium sp. in Southeast zone – Bulgaria 2023 SAGEA OOD F23EU-040-AMA-038 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/099 KCP 6.4.1/105	Natalie Birkinshaw	2024	The efficacy of FGR06 applied in wheat for the control of Fusarium sp. in Europe. EAS Hungary, Székesfehérvár F23EU-040-AMA-039 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/100 KCP 6.4.1/106	Natalie Birkinshaw	2024	The efficacy of FGR06 applied in wheat for the control of Fusarium sp. in Europe. EAS Hungary, Székesfehérvár F23EU-040-AMA-040 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.2/101 KCP 6.4.1/107	Natalie Birkinshaw	2024	The efficacy of FGR06 applied in wheat for the control of Fusarium sp. in Europe. EAS Bulgaria, Letnitsa F23EU-040-AMA-041 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/102 KCP 6.4.1/108	Natalie Birkinshaw	2024	The efficacy of FGR06 applied in wheat for the control of Fusarium sp. in Europe. EUROFINS AGROSCIENCE SERVICES F23EU-040-AMA-042 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/103 KCP 6.4.1/109	Mircea Coman	2024	The efficacy of FGR06 applied in wheat for the control of Fusarium sp. in Europe. Syntech Research Agrico SRL F23EU-040-AMA-043 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/104 KCP 6.4.1/110	Hia Dimitrov	2024	The efficacy of FGR06 applied in wheat for the control of Fusarium sp. in Europe. Syntech Research Bulgaria EOOD F23EU-040-AMA-044 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/105 KCP 6.4.1/111	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of Zymoseptoria tritici (SEPTTR), Puccinia recondita (PUCCRE) and Puccinia striiformis (PUCCST) on spring wheat in Europe, 2022. EAS Germany, Stade F22EU-009-MOA-001 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/106 KCP 6.4.1/112	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of Zymoseptoria tritici (SEPTTR), Puccinia recondita (PUCCRE) and Puccinia striiformis (PUCCST) on spring wheat in Europe, 2022. EAS Ireland F22EU-009-MOA-002 GEP	N	Y	Data/study report never submitted before to Poland	UPL

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Unpublished				
KCP 6.2/107 KCP 6.4.1/113	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of Zymoseptoria tritici (SEPTTR), Puccinia recondita (PUCCRE) and Puccinia striiformis (PUCCST) on spring wheat in Europe, 2022. EAS Poland, Kazmierz F22EU-009-MOA-003 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/108 KCP 6.4.1/114	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of Zymoseptoria tritici (SEPTTR), Puccinia recondita (PUCCRE) and Puccinia striiformis (PUCCST) on spring wheat in Europe, 2022. EUROFINS AGROSCIENCE SERVICES F22EU-009-MOA-007 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/109 KCP 6.4.1/115	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of Zymoseptoria tritici (SEPTTR), Puccinia recondita (PUCCRE) and Puccinia striiformis (PUCCST) on spring wheat in Europe, 2022. EAS Romania, Timisoara F22EU-009-MOA-009 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/110 KCP 6.4.1/116	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of Zymoseptoria tritici (SEPTTR), Puccinia recondita (PUCCRE) and Puccinia striiformis (PUCCST) on spring wheat in Europe, 2022. Agrartest GmbH F22EU-009-MOA-011 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/111 KCP 6.4.1/117	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of Zymoseptoria tritici (SEPTTR), Puccinia recondita (PUCCRE) and Puccinia striiformis (PUCCST) on spring wheat in Europe, 2022. EAS UK, Wilson Field F22EU-009-MOA-012 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.2/112 KCP 6.4.1/118	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of Zymoseptoria tritici (SEPTTR), Puccinia recondita (PUCCRE) and Puccinia striiformis (PUCCST) on spring wheat in Europe, 2022. EAS Poland, Kazmierz F22EU-009-MOA-013 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/113 KCP 6.4.1/119	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Zymoseptoria tritici (SEPTTR) on wheat in Europe, 2023 EAS Germany, Stade F23EU-022-MOA-014 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/114 KCP 6.4.1/120	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Zymoseptoria tritici (SEPTTR) on wheat in Europe, 2023 VKST Field Trials F23EU-022-MOA-015 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/115 KCP 6.4.1/121	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Zymoseptoria tritici (SEPTTR) on wheat in Europe, 2023 EAS UK, North West F23EU-022-MOA-016 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/116 KCP 6.4.1/122	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Zymoseptoria tritici (SEPTTR) on wheat in Europe, 2023 EAS Poland F23EU-022-MOA-017 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/117 KCP 6.4.1/123	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Zymoseptoria tritici (SEPTTR) on wheat in Europe, 2023 EAS Romania, Timisoara F23EU-022-MOA-019 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.2/118 KCP 6.4.1/124	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Puccinia striiformis (PuccST) on winter wheat in Europe, 2023 EUROFINS AGROSCIENCE SERVICES F23EU-025-MOA-016 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/119 KCP 6.4.1/125	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Puccinia recondita (PUCCRE) on wheat in Europe, 2023 EAS Poland F23EU-027-MOA-016 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/120 KCP 6.4.1/126	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Puccinia recondita (PUCCRE) on wheat in Europe, 2023 EAS Romania, Timisoara F23EU-027-MOA-018 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/121 KCP 6.4.1/127	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Puccinia recondita (PUCCRE) on wheat in Europe, 2023 EAS Hungary, Székesfehérvár F23EU-027-MOA-019 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/122 KCP 6.4.1/128	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of Zymoseptoria tritici (SEPTTR) on durum wheat in Europe, 2022. AGRARTEST GmbH F22EU-010-MOA-001 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/123 KCP 6.4.1/129	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of Zymoseptoria tritici (SEPTTR) on durum wheat in Europe, 2022. EAS Romania, Timisoara F22EU-010-MOA-005 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.2/124 KCP 6.4.1/130	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of Zymoseptoria tritici (SEPTTR) on durum wheat in Europe, 2022. EAS Bulgaria, Pazardjik F22EU-010-MOA-006 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/125 KCP 6.4.1/131	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of Puccinia striiformis (PUCCST) on durum wheat in Europe, 2022. Agrartest GmbH F22EU-011-MOA-001 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/126 KCP 6.4.1/132	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of Puccinia striiformis (PUCCST) on durum wheat in Europe, 2022. EAS Romania, Timisoara F22EU-011-MOA-006 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/127 KCP 6.4.1/133	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of Puccinia recondita (PUCCRE) on durum wheat in Europe, 2022. EAS Romania, Timisoara F22EU-012-MOA-005 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/128 KCP 6.4.1/134	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of Puccinia recondita (PUCCRE) on durum wheat in Europe, 2022. EAS Bulgaria, Pazardjik F22EU-012-MOA-006 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/129 KCP 6.4.1/135	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Zymoseptoria tritici (SEPTTR) on durum wheat in Europe, 2023 EAS Agrartest, Rosenow F23EU-023-MOA-001 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.2/130 KCP 6.4.1/136	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Zymoseptoria tritici (SEPTTR) on durum wheat in Europe, 2023 Eurofins Agroscience Services EOOD F23EU-023-MOA-008 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/131 KCP 6.4.1/137	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Zymoseptoria tritici (SEPTTR) on durum wheat in Europe, 2023 EAS Romania, Timisoara F23EU-023-MOA-009 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/132 KCP 6.4.1/138	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of Zymoseptoria tritici (SEPTTR), Puccinia recondita (PUCCRE) and Puccinia striiformis (PUCCST) on spelt wheat in Europe, 2022. Agrartest GmbH F22EU-014-MOA-001 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/133 KCP 6.4.1/139	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of Zymoseptoria tritici (SEPTTR), Puccinia recondita (PUCCRE) and Puccinia striiformis (PUCCST) on spelt wheat in Europe, 2022. Agrartest GmbH F22EU-014-MOA-003 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/134 KCP 6.4.1/140	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of Zymoseptoria tritici (SEPTTR), Puccinia recondita (PUCCRE) and Puccinia striiformis (PUCCST) on spelt wheat in Europe, 2022. Agrartest GmbH F22EU-014-MOA-005 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/135 KCP 6.4.1/141	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Zymoseptoria tritici (SEPTTR) on triticale and spelt wheat in Europe, 2023 EAS Germany, Heidelberg F23EU-024-MOA-008	N	Y	Data/study report never submitted before to Poland	UPL

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			GEP Unpublished				
KCP 6.4.1/142 KCP 6.4.2/007 KCP 6.4.3/007	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Zymoseptoria tritici (SEPTTR) on triticale and spelt wheat in Europe, 2023 EAS Germany, Beimerstetten F23EU-024-MOA-009 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.4.1/143 KCP 6.4.2/008 KCP 6.4.3/008	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Puccinia striiformis (PUCCST) on triticale and spelt wheat in Europe, 2023 Agrartest GmbH F23EU-026-MOA-005 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/136 KCP 6.4.1/144	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Puccinia striiformis (PUCCST) on triticale and spelt wheat in Europe, 2023 EAS Germany, Heidelberg F23EU-026-MOA-006 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/137 KCP 6.4.1/145	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Puccinia striiformis (PUCCST) on triticale and spelt wheat in Europe, 2023 EAS Dobrich F23EU-026-MOA-007 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/138 KCP 6.4.1/146	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Puccinia striiformis (PUCCST) on triticale and spelt wheat in Europe, 2023 EAS Romania, Timisoara F23EU-026-MOA-008 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.2/139 KCP 6.4.1/147	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Puccinia striiformis (PuccST) on triticale and spelt wheat in Europe, 2023 EAS Hungary, Székesfehérvár F23EU-026-MOA-009 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/140 KCP 6.4.1/148	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of Zymoseptoria tritici (SEPTTR), Puccinia recondita (PuccRE) and Puccinia striiformis (PuccST) on triticale in Europe, 2022. Agrartest GmbH F22EU-013-MOA-001 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/141 KCP 6.4.1/149	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of Zymoseptoria tritici (SEPTTR), Puccinia recondita (PuccRE) and Puccinia striiformis (PuccST) on triticale in Europe, 2022. EAS Poland, Kazmierz F22EU-013-MOA-004 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/142 KCP 6.4.1/150	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of Zymoseptoria tritici (SEPTTR), Puccinia recondita (PuccRE) and Puccinia striiformis (PuccST) on triticale in Europe, 2022. EAS Romania, Timisoara F22EU-013-MOA-005 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/143 KCP 6.4.1/151	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of Zymoseptoria tritici (SEPTTR), Puccinia recondita (PuccRE) and Puccinia striiformis (PuccST) on triticale in Europe, 2022. EAS Germany, Stade F22EU-013-MOA-007 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.2/144 KCP 6.4.1/152	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of Zymoseptoria tritici (SEPTTR), Puccinia recondita (PUCCRE) and Puccinia striiformis (PUCCST) on triticale in Europe, 2022. EAS Poland, Kazmierz F22EU-013-MOA-009 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/145 KCP 6.4.1/153	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of Zymoseptoria tritici (SEPTTR), Puccinia recondita (PUCCRE) and Puccinia striiformis (PUCCST) on triticale in Europe, 2022. EAS Romania F22EU-013-MOA-011 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/146 KCP 6.4.1/154	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of Zymoseptoria tritici (SEPTTR), Puccinia recondita (PUCCRE) and Puccinia striiformis (PUCCST) on triticale in Europe, 2022. EAS Romania, Timisoara F22EU-013-MOA-016 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/147 KCP 6.4.1/155	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Zymoseptoria tritici (SEPTTR) on triticale and spelt wheat in Europe, 2023 EAS Agrartest, Rosenow F23EU-024-MOA-002 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/148 KCP 6.4.1/156	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Zymoseptoria tritici (SEPTTR) on triticale and spelt wheat in Europe, 2023 EAS Agrartest, Rosenow F23EU-024-MOA-003 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/149 KCP 6.4.1/157	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Zymoseptoria tritici (SEPTTR) on triticale and spelt wheat in Europe, 2023 EUROFINS AGROSCIENCE SERVICES sp z o.o. F23EU-024-MOA-004	N	Y	Data/study report never submitted before to Poland	UPL

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			GEP Unpublished				
~~KCP 6.2/150 KCP 6.4.1/158~~	~~Natalie Birkinshaw~~	~~2024~~	~~The efficacy of FGF11 applied for the control of Zymoseptoria tritici (SEPTTR) on triticale and spelt wheat in Europe, 2023 EAS Romania, Timisoara F23EU-024-MOA-005 GEP Unpublished~~	~~N~~	~~Y~~	~~Data/study report never submitted before to Poland~~	~~UPL~~
~~KCP 6.2/151 KCP 6.4.1/159~~	~~Natalie Birkinshaw~~	~~2024~~	~~The efficacy of FGF11 applied for the control of Zymoseptoria tritici (SEPTTR) on triticale and spelt wheat in Europe, 2023 EAS Hungary, Székesfehérvár F23EU-024-MOA-006 GEP Unpublished~~	~~N~~	~~Y~~	~~Data/study report never submitted before to Poland~~	~~UPL~~
KCP 6.2/152 KCP 6.4.1/160	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Puccinia striiformis (PUCCST) on triticale and spelt wheat in Europe, 2023 EAS Germany, Stade F23EU-026-MOA-001 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
~~KCP 6.2/153 KCP 6.4.1/161~~	~~Natalie Birkinshaw~~	~~2024~~	~~The efficacy of FGF11 applied for the control of Puccinia striiformis (PUCCST) on triticale and spelt wheat in Europe, 2023 EUROFINS AGROSCIENCE SERVICES F23EU-026-MOA-002 GEP Unpublished~~	~~N~~	~~Y~~	~~Data/study report never submitted before to Poland~~	~~UPL~~
KCP 6.2/154 KCP 6.4.1/162	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Puccinia striiformis (PUCCST) on triticale and spelt wheat in Europe, 2023 EAS Poland F23EU-026-MOA-003 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.2/155 KCP 6.4.1/163	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Puccinia striiformis (PuccST) on triticale and spelt wheat in Europe, 2023 EAS Romania, Timisoara F23EU-026-MOA-004 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/156 KCP 6.4.1/164	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Puccinia recondita (PuccRE) on triticale in Europe, 2023 EAS Poland F23EU-028-MOA-003 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/157 KCP 6.4.1/165	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Puccinia recondita (PuccRE) on triticale in Europe, 2023 EUROFINS AGROSCIENCE SERVICES F23EU-028-MOA-004 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/158 KCP 6.4.1/166	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Puccinia recondita (PuccRE) on triticale in Europe, 2023 EAS Hungary, Székesfehérvár F23EU-028-MOA-005 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/159 KCP 6.4.1/167	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Puccinia recondita (PuccRE) on triticale in Europe, 2023 EAS Hungary, Székesfehérvár F23EU-028-MOA-006 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/160 KCP 6.4.1/168	Piotr Umiński	2024	Evaluate the efficacy of FGF11 applied for the control of foliar diseases in cereals in Poland, 2023. Field Research Support F23EU-037-MOA-002 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.2/161 KCP 6.4.1/169	Katarzyna Furman-Fratczak	2024	Evaluate the efficacy of FGF11 applied for the control of foliar diseases in cereals in Poland, 2023. Agreco sp. z o.o. F23EU-037-MOA-003 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/162 KCP 6.4.1/170	Katarzyna Furman-Fratczak	2024	Evaluate the efficacy of FGF11 applied for the control of foliar diseases in cereals in Poland, 2023. Agreco sp. z o.o. F23EU-037-MOA-010 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/163 KCP 6.4.1/171	Gheorghe Botoman	2024	Evaluate the efficacy of FGF11 applied for the control of foliar diseases in cereals in Romania, 2023. AgroProspect S.R.L F23EU-039-MOA-003 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/164 KCP 6.4.1/172	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of Puccinia recondita (PUCCRE) on winter rye in Europe, 2022. EAS France, Val de Loire F22EU-017-MOA-003 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/165 KCP 6.4.1/173	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of Puccinia recondita (PUCCRE) on winter rye in Europe, 2022. EUROFINS AGROSCIENCE SERVICES F22EU-017-MOA-004 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/166 KCP 6.4.1/174	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of Puccinia recondita (PUCCRE) on winter rye in Europe, 2022. EAS UK, South-East F22EU-017-MOA-005 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
~~KCP 6.2/167 KCP 6.4.1/175~~	~~Natalie Birkinshaw~~	~~2023~~	~~The efficacy of FGF11 applied for the control of Puccinia recondita (PUCCRE) on winter rye in Europe, 2022. EAS UK, South East F22EU-017-MOA-006 GEP Unpublished~~	~~N~~	~~Y~~	~~Data/study report never submitted before to Poland~~	~~UPL~~
KCP 6.2/168 KCP 6.4.1/176	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of Puccinia recondita (PUCCRE) on winter rye in Europe, 2022. EAS Poland, Kazmierz F22EU-017-MOA-009 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/169 KCP 6.4.1/177	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of Puccinia recondita (PUCCRE) on winter rye in Europe, 2022. EAS Poland, Kazmierz F22EU-017-MOA-010 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
~~KCP 6.2/170 KCP 6.4.1/178~~	~~Natalie Birkinshaw~~	~~2023~~	~~The efficacy of FGF11 applied for the control of Puccinia recondita (PUCCRE) on winter rye in Europe, 2022. EAS Romania, Timisoara F22EU-017-MOA-013 GEP Unpublished~~	~~N~~	~~Y~~	~~Data/study report never submitted before to Poland~~	~~UPL~~
~~KCP 6.2/171 KCP 6.4.1/179~~	~~Natalie Birkinshaw~~	~~2023~~	~~The efficacy of FGF11 applied for the control of Puccinia recondita (PUCCRE) on winter rye in Europe, 2022. EAS Bulgaria, Pazardjik F22EU-017-MOA-014 GEP Unpublished~~	~~N~~	~~Y~~	~~Data/study report never submitted before to Poland~~	~~UPL~~
KCP 6.2/172 KCP 6.4.1/180	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Puccinia recondita (PUCCRE) on winter rye in Europe, 2023 EAS Germany, Stade F23EU-029-MOA-002 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.2/173 KCP 6.4.1/181	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Puccinia recondita (PUCCRE) on winter rye in Europe, 2023 EAS Ireland F23EU-029-MOA-003 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.4.1/182 KCP 6.4.2/009 KCP 6.4.3/009	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Puccinia recondita (PUCCRE) on winter rye in Europe, 2023 EAS UK, South East F23EU-029-MOA-004 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/174 KCP 6.4.1/183	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Puccinia recondita (PUCCRE) on winter rye in Europe, 2023 EAS Poland, Kazmierz F23EU-029-MOA-006 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/175 KCP 6.4.1/184	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Puccinia recondita (PUCCRE) on winter rye in Europe, 2023 EAS Romania, Timisoara F23EU-029-MOA-007 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/176 KCP 6.4.1/185	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Puccinia recondita (PUCCRE) on winter rye in Europe, 2023 EAS Hungary, Székesfehérvár F23EU-029-MOA-008 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/177 KCP 6.4.1/186	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Puccinia recondita (PUCCRE) on winter rye in Europe, 2023 EAS Hungary, Székesfehérvár F23EU-029-MOA-009 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.2/178 KCP 6.4.1/187	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of Pyrenophora teres (PYRNTE) on winter barley in Europe, 2022. EAS Germany, Detmold F22EU-015-MOA-002 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/179 KCP 6.4.1/188	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of Pyrenophora teres (PYRNTE) on winter barley in Europe, 2022. EAS France, Normandie F22EU-015-MOA-003 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/180 KCP 6.4.1/189	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of Pyrenophora teres (PYRNTE) on winter barley in Europe, 2022. Eurofins Agrosience Services F22EU-015-MOA-005 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/181 KCP 6.4.1/190	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of Pyrenophora teres (PYRNTE) on winter barley in Europe, 2022. EAS UK, Wilson Field F22EU-015-MOA-006 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/182 KCP 6.4.1/191	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of Pyrenophora teres (PYRNTE) on winter barley in Europe, 2022. EAS Poland, Kazmierz F22EU-015-MOA-010 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/183 KCP 6.4.1/192	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of Pyrenophora teres (PYRNTE) on winter barley in Europe, 2022. EAS Hungary, Székesfehérvár F22EU-015-MOA-011 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.2/184 KCP 6.4.1/193	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of Pyrenophora teres (PYRNTE) on winter barley in Europe, 2022. EAS Romania, Timisoara F22EU-015-MOA-013 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/185 KCP 6.4.1/194	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of Pyrenophora teres (PYRNTE) on winter barley in Europe, 2022. Eurofins Agrosience Services EOOD F22EU-015-MOA-014 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/186 KCP 6.4.1/195	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Pyrenophora teres (PYRNTE) on winter barley in Europe, 2023 EAS Germany, Detmold F23EU-030-MOA-001 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/187 KCP 6.4.1/196	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Pyrenophora teres (PYRNTE) on winter barley in Europe, 2023 EAS France, Centre Beauce F23EU-030-MOA-003 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/188 KCP 6.4.1/197	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Pyrenophora teres (PYRNTE) on winter barley in Europe, 2023 EAS France, Normandie F23EU-030-MOA-004 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/189 KCP 6.4.1/198	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Pyrenophora teres (PYRNTE) on winter barley in Europe, 2023 EAS France, Bretagne F23EU-030-MOA-005 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.2/190 KCP 6.4.1/199	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Pyrenophora teres (PYRNTE) on winter barley in Europe, 2023 EAS UK, Wilson Field F23EU-030-MOA-006 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/191 KCP 6.4.1/200	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Pyrenophora teres (PYRNTE) on winter barley in Europe, 2023 EAS UK, Wilson Field F23EU-030-MOA-007 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/192 KCP 6.4.1/201	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Pyrenophora teres (PYRNTE) on winter barley in Europe, 2023 EAS Poland, Jasienica F23EU-030-MOA-008 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/193 KCP 6.4.1/202	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Pyrenophora teres (PYRNTE) on winter barley in Europe, 2023 EAS Poland F23EU-030-MOA-009 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/194 KCP 6.4.1/203	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Pyrenophora teres (PYRNTE) on winter barley in Europe, 2023 Eurofins Agroscience Services EOOD F23EU-030-MOA-010 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/195 KCP 6.4.1/204	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Pyrenophora teres (PYRNTE) on winter barley in Europe, 2023 Eurofins Agroscience Services EOOD F23EU-030-MOA-011 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.2/196 KCP 6.4.1/205	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Pyrenophora teres (PYRNTE) on winter barley in Europe, 2023 EUROFINS AGROSCIENCE SERVICES SRL F23EU-030-MOA-012 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/197 KCP 6.4.1/206	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Pyrenophora teres (PYRNTE) on winter barley in Europe, 2023 EUROFINS AGROSCIENCE SERVICES SRL F23EU-030-MOA-013 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/198 KCP 6.4.1/207	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Pyrenophora teres (PYRNTE) on winter barley in Europe, 2023 EAS Hungary, Székesfehérvár F23EU-030-MOA-014 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/199 KCP 6.4.1/208	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Pyrenophora teres (PYRNTE) on winter barley in Europe, 2023 EAS Hungary, Székesfehérvár F23EU-030-MOA-015 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/200 KCP 6.4.1/209	Katarzyna Furman-Fratczak	2024	Evaluate the efficacy of FGF11 applied for the control of foliar diseases in cereals in Poland, 2023. Agreco sp. z o.o. F23EU-037-MOA-011 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/201 KCP 6.4.1/210	Piotr Umiński	2024	Evaluate the efficacy of FGF11 applied for the control of foliar diseases in cereals in Poland, 2023. Field Research Support F23EU-037-MOA-012 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.2/202 KCP 6.4.1/211	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of Pyrenophora teres (PYRNTE) on spring barley in Europe, 2022. EUROFINS AGROSCIENCE SERVICES F22EU-016-MOA-002 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/203 KCP 6.4.1/212	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Pyrenophora teres (PYRNTE) on spring barley in Europe, 2023 EAS Ireland F23EU-031-MOA-003 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/204 KCP 6.4.1/213	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Pyrenophora teres (PYRNTE) on spring barley in Europe, 2023 EUROFINS AGROSCIENCE SERVICES sp z o.o. F23EU-031-MOA-005 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/205 KCP 6.4.1/214	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Pyrenophora teres (PYRNTE) on spring barley in Europe, 2023 Natural Resources Institute Finland (Luke) F23EU-031-MOA-006 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/206 KCP 6.4.1/215	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Pyrenophora teres (PYRNTE) on spring barley in Europe, 2023 Eurofins Agroscience Services EOOD F23EU-031-MOA-007 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/207 KCP 6.4.1/216	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Pyrenophora teres (PYRNTE) on spring barley in Europe, 2023 EAS Romania, Timisoara F23EU-031-MOA-008 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.2/208 KCP 6.4.1/217	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Pyrenophora teres (PYRNTE) on spring barley in Europe, 2023 EAS Hungary, Székesfehérvár F23EU-031-MOA-009 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/209 KCP 6.4.1/218	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of Pyrenophora teres (PYRNTE) on spring barley in Europe, 2022. Natural Resources Institute Finland (LUKE) F22EU-015-MOA-007 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/210 KCP 6.4.1/219	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of Pyrenophora teres (PYRNTE) on winter barley in Europe, 2022. Institute of Agriculture, LRCAF F22EU-015-MOA-008 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/211 KCP 6.4.1/220	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of sclerotinia sclerotiorum on oil seed rape in Europe, 2022. EAS Germany, Stade F22EU-018-MOA-002 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/212 KCP 6.4.1/221	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of sclerotinia sclerotiorum on oil seed rape in Europe, 2022. Agrartest GmbH F22EU-018-MOA-003 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/213 KCP 6.4.1/222	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of sclerotinia sclerotiorum on oil seed rape in Europe, 2022. EAS uk, NorthWest F22EU-018-MOA-005 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.2/214 KCP 6.4.1/223	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of sclerotinia sclerotiorum on oil seed rape in Europe, 2022. EAS UK, North East F22EU-018-MOA-006 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/215 KCP 6.4.1/224	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of sclerotinia sclerotiorum on oil seed rape in Europe, 2022. Institute of Agriculture, LAMMC F22EU-018-MOA-007 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/216 KCP 6.4.1/225	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of sclerotinia sclerotiorum on oil seed rape in Europe, 2022. EAS Hungary, Székesfehérvár F22EU-018-MOA-011 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/217 KCP 6.4.1/026	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of sclerotinia sclerotiorum on oil seed rape in Europe, 2022. EAS Hungary, Székesfehérvár F22EU-018-MOA-012 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/218 KCP 6.4.1/227	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of sclerotinia sclerotiorum on oil seed rape in Europe, 2022. EAS Bulgaria, Pazardjik F22EU-018-MOA-013 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/219 KCP 6.4.1/228	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of sclerotinia sclerotiorum on oil seed rape in Europe, 2023 EAS Germany, Beimerstetten F23EU-032-MOA-001 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.2/221 KCP 6.4.1/230	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of sclerotinia sclerotiorum on oil seed rape in Europe, 2023 EAS France, Bretagne F23EU-032-MOA-003 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/222 KCP 6.4.1/231	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of sclerotinia sclerotiorum on oil seed rape in Europe, 2023 EUROFINS AGROSCIENCE SERVICES F23EU-032-MOA-004 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/223 KCP 6.4.1/232	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of sclerotinia sclerotiorum on oil seed rape in Europe, 2023 EAS UK, North West F23EU-032-MOA-007 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/224 KCP 6.4.1/233	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of sclerotinia sclerotiorum on oil seed rape in Europe, 2023 EAS Poland F23EU-032-MOA-009 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/225 KCP 6.4.1/234	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of sclerotinia sclerotiorum on oil seed rape in Europe, 2023 Eurofins Agroscience Services EOOD F23EU-032-MOA-010 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/226 KCP 6.4.1/235	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of sclerotinia sclerotiorum on oil seed rape in Europe, 2023 EAS Romania, Timisoara F23EU-032-MOA-011 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.2/227 KCP 6.4.1/236	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of sclerotinia sclerotiorum on oil seed rape in Europe, 2023 EUROFINS AGROSCIENCE SERVICES SRL F23EU-032-MOA-012 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/228 KCP 6.4.1/237	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of sclerotinia sclerotiorum on oil seed rape in Europe, 2023 EAS Romania, Timisoara F23EU-032-MOA-013 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/229 KCP 6.4.1/238	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of sclerotinia sclerotiorum on oil seed rape in Europe, 2023 EAS Hungary, Székesfehérvár F23EU-032-MOA-014 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/230 KCP 6.4.1/239	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of sclerotinia sclerotiorum on oil seed rape in Europe, 2023 EAS Hungary, Székesfehérvár F23EU-032-MOA-015 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/231 KCP 6.4.1/240	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of sclerotinia sclerotiorum on oil seed rape in Europe, 2023 EAS Hungary, Székesfehérvár F23EU-032-MOA-016 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/232 KCP 6.4.1/241	Katarzyna Furman-Fratczak	2024	The efficacy of FGF11 applied for the control of sclerotinia sclerotiorum on oil seed rape in Poland, 2022. Agreco sp. z o.o. F23EU-038-MOA-001 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.2/233 KCP 6.4.1/242	Katarzyna Furman-Fratczak	2024	The efficacy of FGF11 applied for the control of sclerotinia sclerotiorum on oil seed rape in Poland, 2022. Agreco sp. z o.o. F23EU-038-MOA-002 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.2/234 KCP 6.4.1/243	Katarzyna Furman-Fratczak	2024	The efficacy of FGF11 applied for the control of sclerotinia sclerotiorum on oil seed rape in Poland, 2022. Agreco sp. z o.o. F23EU-038-MOA-003 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.4.4/01	Natalie Birkinshaw	2024	The evaluation of Non intentional Effects of of FGF11 on quality of Wheat and Bread making, 2022. EUROFINS AGROSCIENCE SERVICES PHYLIAE F22EU-023-MOA-001 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.4.4/02	Natalie Birkinshaw	2024	The evaluation of Non intentional Effects of of FGF11 on quality of Wheat and Bread making, 2022. EAS France, Centre Beauce F22EU-023-MOA-002 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.4.4/03	Julien Rivet	2023	Unintentional effects of FBQ03, FGR06 and FGF11 on beer and malt making process in barley (field part). ESSAIS + F22EU-038-AMA-001 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.4.4/04	Cyprien Tendart	2023	Unintentional effects of FBQ03, FGR06 and FGF11 on beer and malt making process in barley (field part). CERESTIS F22EU-038-AMA-003 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.4.4/05	Delphine Thevenet	2023	Unintentional effects of FBQ03, FGR06 and FGF11 on beer and malt making process in barley (field part). CERESTIS F22EU-038-AMA-005 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.4.4/06	Cyprien Tendart	2023	Unintentional effects of FBQ03, FGR06 and FGF11 on beer and malt making process in barley (field part). CERESTIS F22EU-038-AMA-006 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.4.4/07	Aude-Emeline Gless	2023	Study of unintentional effects of FBQ03, FGR06 and FGF11 products applied on winter and spring barley, Harvest 2022, on malt and beer quality and Process IBFM R-A-F-1216 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.5/01	Susanne Stürtz, Claudia Horstmann	2024	Azoxystrobin 160 + Prothioconazole 200 g/L SC: Effects on Terrestrial (Non-Target) Plants: Vegetative Vigour Test Ibacon GmbH UPL/2023/2350 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.5/02	Susanne Stürtz, Claudia Horstmann	2024	Azoxystrobin 160 + Prothioconazole 200 g/L SC: Effects on Terrestrial (Non-Target) Plants: Seedling Emergence and Seedling Growth Test Ibacon GmbH UPL/2023/2349 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL
KCP 6.5/03	Bhavana S. Patil	2024	Effectiveness of cleaning procedures of azoxystrobin 160 + prothioconazole 200 g/L SC Jai Research Foundation UPL/2023/1576	N	Y	Data/study report never submitted before to Poland	UPL

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			GLP Unpublished				
KCP 7.2/01a KCP 7.2/01b	EFSA OPEX	2024	Exposure assessment for operator, worker, resident and bystander: product FGF11 (azoxystrobin and prothioconazole) EFSA Online OPEX calculator v.1.0.2 non GLP Unpublished	N	N	-	UPL Europe
KCP 7.2/02a KCP 7.2/02b	EFSA OPEX	2024	Exposure assessment for operator, worker, resident and bystander: product FGF11 (azoxystrobin and prothioconazole-desthio) EFSA Online OPEX calculator v.1.0.2 non GLP Unpublished	N	N	-	UPL Europe
KCP 8.1-01	Giancola, D.	2023	Prothioconazole-desthio and 5 hydroxy metabolites: Frozen Storage Stability in Honey Study No.: QG/21/007 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL Europe Ltd.
KCP 8.1-02	Mealing, H.	2024	Triazole Derivative Metabolites: Frozen Storage Stability in Honey for 6 months Study No.: QG/21/006 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL Europe Ltd.
KCP 8.1-03	Giancola, D.	2025	Prothioconazole-desthio and 5 hydroxy metabolites: Frozen Storage Stability in crops Study No.: QG/21/001 GLP Unpublished The study is currently ongoing. The finalized version of the study report will be provided when it is available (expected January 2025).	N	Y	Data/study report never submitted before to Poland Remark: Evaluated in RR of FHO04 / Patton Supra (01.2025)	UPL Europe Ltd.
KCP 8.1/04	Baxter, B. Phipps	2025	Triazole Derived Metabolites: Frozen Storage Stability in Crops for 12 Months; Study No.: QG/21/002 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL Europe Ltd.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 8.1/05	Jooß, S.	2025	Storage Stability of the Triazole Derivative Metabolites (TDMs) in Plant Matrices under Deep Frozen Conditions. Study No.: S23-105428 Eurofins Agrosience Services EAG Laboratories GmbH GLP Unpublished	N	Y	Study report never submitted before to PL	UPL Europe Limited
KCP 8.1-0456	Appeltauer A.	2022	Azoxystrobin - Determination of Residues of Azoxystrobin and R230310 (z-isomer) in Honey after Two Applications of A12705B to Winter Oilseed rape at 5 Sites in Northern and Southern Europe in 2021 Report No S21-01128 Document No VV-931501 GLP Unpublished A data access agreement is in place for UPL to rely on this study for the registration of FGF11. Please refer to the Azoxystrobin EU renewal (dRAR) for a summary and conclusions for this study.	N	Y	Data/study report never submitted before to Poland	Syngenta
KCP 8.3.1-01	Andrews, G., Pearson, J.	2017	Azoxystrobin – Residue Study on Wheat in Northern Europe in 2016 Report No NC16012 Document No VV-467714 GLP Unpublished A data access agreement is in place for UPL to rely on this study for the registration of FGF11. Please refer to the Azoxystrobin EU renewal (dRAR) for a summary and conclusions for this study.	N	Y	Data/study report never submitted before to Poland	Syngenta
KCP 8.3.1-02	Ertus, C.	2020	Azoxystrobin - Residue Study on Spring Wheat in Czech Republic, Hungary, Greece and the Netherlands in 2019 Report No B9119 Document No VV-748850 GLP Unpublished A data access agreement is in place for UPL to rely on this study	N	Y	Data/study report never submitted before to Poland	Syngenta

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			for the registration of FGF11. Please refer to the Azoxystrobin EU renewal (dRAR) for a summary and conclusions for this study.				
KCP 8.3.1-03	Andrews, G., Pearson, J.	2017	~~Azoxystrobin – residue study on wheat in Southern Europe in 2016 Report No NC16013 Document No VV-467712 GLP Unpublished A data access agreement is in place for UPL to rely on this study for the registration of FGF11. Please refer to the Azoxystrobin EU renewal (dRAR) for a summary and conclusions for this study.~~	N	Y	~~Data/study report never submitted before to Poland~~	Syngenta
KCP 8.3.1-04	Brown, D.	2020	~~Azoxystrobin – Magnitude of Residue Study on Spring Wheat in Spain and Portugal in 2019 Report No RES-00188 Document No VV-864619 A data access agreement is in place for UPL to rely on this study for the registration of FGF11. Please refer to the Azoxystrobin EU renewal (dRAR) for a summary and conclusions for this study.~~	N	Y	~~Data/study report never submitted before to Poland~~	Syngenta
KCP 8.3.1-05	Lebrun, F.	2024	Magnitude of the residue of prothioconazole metabolites in wheat in Northern and Southern Europe – 2023 Report No.; 645-2023 GLP Unpublished	N	Y	Data/study report never submitted before to Poland Remark: Evaluated in RR of FHO04 / Patton Supra (01.2025)	UPL Europe Ltd.
KCP 8.3.2-01	Souchier, M.	2017	Azoxystrobin – Residue Study on Barley in the United Kingdom, Northern France and Germany in 2016 Report No S16-03841 Document No VV-467864 GLP Unpublished A data access agreement is in place for UPL to rely on this study	N	Y	Data/study report never submitted before to Poland	Syngenta

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			for the registration of FGF11. Please refer to the Azoxystrobin EU renewal (dRAR) for a summary and conclusions for this study.				
KCP 8.3.2-02	Ziske, J., Link, T.	2020	Azoxystrobin - Residue Study on Spring Barley in Greece, Germany and Hungary in 2019 Report No IF19-04928654 Document No VV-865884 GLP Unpublished A data access agreement is in place for UPL to rely on this study for the registration of FGF11. Please refer to the Azoxystrobin EU renewal (dRAR) for a summary and conclusions for this study.	N	Y	Data/study report never submitted before to Poland	Syngenta
KCP 8.3.2-03	Hoskins, M.	2022	Azoxystrobin – Residue Study on Barley in UK and Northern France, Initiated in 2022 Report No 685286; Document No VV-931335 GLP Unpublished A data access agreement is in place for UPL to rely on this study for the registration of FGF11. Please refer to the Azoxystrobin EU renewal (dRAR) for a summary and conclusions for this study.	N	Y	Data/study report never submitted before to Poland	Syngenta
KCP 8.3.2-04	Souchier, M.	2017	Azoxystrobin – Residue Study on Barley in the Southern France, Italy and Spain in 2016 Report No S16-03842 Document No VV-467632 GLP Unpublished A data access agreement is in place for UPL to rely on this study for the registration of FGF11. Please refer to the Azoxystrobin EU renewal (dRAR) for a summary and conclusions for this study.	N	Y	Data/study report never submitted before to Poland	Syngenta

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 8.3.2-05	Ziske, J., Link, T.	2020	Azoxystrobin—Residue Study on Spring Barley in Spain, Greece and Italy in 2019 Report No IF19-04928660; Document No VV-870172 GLP Unpublished A data access agreement is in place for UPL to rely on this study for the registration of FGF11. Please refer to the Azoxystrobin EU renewal (dRAR) for a summary and conclusions for this study.	N	Y	Data/study report never submitted before to Poland	Syngenta
KCP 8.3.2-06	Bougrier, M.	2024	Magnitude of the residue of prothioconazole metabolites in barley in Northern and Southern Europe – 2023 Study Number: 646-2023 GLP Unpublished Draft version of the report is available. The finalized version of the study report will be provided when it is available.	N	Y	Data/study report never submitted before to Poland	UPL Europe Ltd.
KCP 8.3.3-01	North, L.	2024	Determination of residues of Azoxystrobin after two applications of FFC03 in Oilseed rape at 7 sites in Southern Europe 2023 Report No S23-102957 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	ARYSTA LifeScience S.A.S.
KCP 8.3.3-02	North, L.	2024	Determination of residues of Azoxystrobin after two applications of FFC03 in Oilseed rape and its processed fractions at 8 sites in Northern Europe 2023 Report No S23-102956 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	ARYSTA LifeScience S.A.S.
KCP 8.3.3-03	Toscano Saes, R., Coleman, H.	2023	Magnitude of Residues of Prothioconazole-desthio and Hydroxyprothioconazole-desthio metabolites Following Two Applications of Prothioconazole 250 g/L DC (FCR06) to Oilseed rape in southern Europe, 2022; Study No.: QG22006 GLP	N	Y	Data/study report never submitted before to Poland	UPL Europe Ltd.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Unpublished				
KCP 8.3.3-04	Toscano Saes, R., Coleman, H.	2023	Magnitude of Residues of Prothioconazole-desthio and Hydroxyprothiocon-azole-desthio metabolites Following Two Applications of Prothioconazole 250 g/L DC (FGR06) to Oilseed rape in northern Europe, 2022 Study No.: QG22007 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL Europe Ltd.
KCP 8.3.3-05	Toscano Saes, R., Coleman, H.	2023	Magnitude of Residues of Prothioconazole-desthio and Hydroxyprothiocon-azole-desthio Metabolites Following Two Applications of a Prothioconazole 250 g/L DC Formulation to Oilseed Rape in Northern and Southern Europe, 2021 Study No.: NZ/21/002 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL Europe Ltd.
KCP 8.3.3-06	Hardy, J., Coleman, H.	2024	Magnitude of Residues of Prothioconazole-desthio, Hydroxyprothioconazole-desthio metabolites, Triazole Lactic Acid and Triazole Acetic Acid Following Two Applications of a 250 g/L EC Formulation to Oilseed Rape in Southern Europe, 2020 Study No.: QG20008 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL Europe Ltd.
KCP 8.3.3-07	Bousquet, C.	2024	Magnitude of the residue of prothioconazole metabolites in oilseed rape in Northern and Southern Europe – 2023 Study Number: 647-2023 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL Europe Ltd.
KCP 8.3.3-08	Toscano Saes, R.	2023	Magnitude of Residues of Triazole Derived Metabolites (TDM's) (triazole acetic acid and triazole lactic acid) Following Two Applications of Prothioconazole 250 g/L DC (FGR06) to Oilseed Rape in Southern Europe, 2022 Study number: EE/23/006 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL Europe Ltd.
KCP 8.3.3-09	Phipps, B.	2023	Magnitude of Residues of Triazole Derived Metabolites (TDM's) (triazole acetic acid and triazole lactic acid) in Oilseed Rape Following Two Applications of Prothioconazole 250 g/L	N	Y	Data/study report never submitted before to Poland	UPL Europe Ltd.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			DC (FGR06) in Northern Europe, 2022 Study number EE/23/007 GLP Unpublished				
KCP 8.3.3-10	Gibson, G., Toscano Saes, R.	2022	Magnitude of Residues of Triazole Derived Metabolites (TDM's) (triazole acetic acid and triazole lactic acid) Following Two Applications of Prothio-conazole 250 g/L DC (FGR06) to Oilseed Rape in Northern and Southern Europe, 2021 Study number NZ/21/003 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL Europe Ltd.
KCP 8.10.1-01	Andrews, G., Coleman, H.	2024	Magnitude of Residues of Prothioconazole-desthio and Hydroxyprothioconazole-desthio Metabolites in Honey Following Two Tunnel Applications of a Prothioconazole 250 g/L EC Formulation (FF-065) to Phacelia in Northern and Southern Europe, 2021 Study No.: QG21003 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL Europe Ltd.
KCP 8.10.1-02	Lebrun, F.	2024	Magnitude of the residue of triazole derivative metabolites in phacelia honey in Northern and Southern Europe – 2023 Study No.: 644-2023 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL Europe Ltd.
KCP 8.10.1-03	Bocksch, S.	2008	Azoxystrobin (ICI5504) and cyproconazole (SAN19) – Residues in honey following exposure of bees to treated winter oil-seed rape in Germany during 2007 Report No T011298-06-REG Document No VV-382035 GLP Unpublished A data access agreement is in place for UPL to rely on this study for the registration of FGF11. Please refer to the Azoxystrobin EU renewal (dRAR) for a summary and conclusions for this study.	N	Y	Data/study report never submitted before to Poland	Syngenta

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 8.10.1-04	Lebrun, F.	2019	Magnitude of the residue of azoxystrobin in oilseed rape pollen and nectar Raw Agricultural Commodity after two foliar applications of ALB 121 in Southern Europe – 2018 Report No 349-2018 Document No VV-906202 GLP Unpublished A data access agreement is in place for UPL to rely on this study for the registration of FGF11. Please refer to the Azoxystrobin EU renewal (dRAR) for a summary and conclusions for this study.	N	Y	Data/study report never submitted before to Poland	Syngenta
KCP 8.10.1-05	Appeltauer, A.	2022	Azoxystrobin - Determination of Residues of Azoxystrobin and R230310 (z-isomer) in Honey after Two Applications of A12705B to Winter Oilseed rape at 5 Sites in Northern and Southern Europe in 2021 Report No S21-01128 Document No VV-931501 GLP Unpublished A data access agreement is in place for UPL to rely on this study for the registration of FGF11. Please refer to the Azoxystrobin EU renewal (dRAR) for a summary and conclusions for this study	N	Y	Data/study report never submitted before to Poland	Syngenta
KCP 9.2.4/01	Worthington, M.	2024a	Azoxystrobin – A leaching assessment for azoxystrobin and its metabolites using the PEARL 5.5.5, PELMO 6.6.4 and MACRO 5.5.4 FOCUS groundwater models following spray application to cereals and oilseed rape in Central Europe. Company report No.: S24-101230-02-002 Eurofins Agrosience Services Regulatory GmbH non-GLP, Unpublished	N	N	-	UPL Europe
KCP 9.2.4/02	Worthington, M.	2024b	Prothioconazole – A leaching assessment for prothioconazole and its metabolites using the PEARL 5.5.5, PELMO 6.6.4 and MACRO 5.5.4 FOCUS groundwater models following spray application to cereals and oilseed rape in Central Europe Company report No.: S24-101230-02-003 Eurofins Agrosience Services Regulatory GmbH	N	N	-	UPL Europe

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			non-GLP, Unpublished				
KCP 9.2.5/01	Fortin-McCuaig, M.	2024a	Azoxystrobin – A European Environmental Fate Assessment for azoxystrobin and its metabolites using the FOCUS surface water models at Steps 1 to 4 following spray application to cereals and oilseed rape in Central Europe Company Report No.: S24-101230-02-004 Eurofins Agrosience Services Regulatory GmbH non-GLP, Unpublished	N	N	-	UPL Europe
KCP 9.2.5/02	Fortin-McCuaig, M.	2024b	Prothioconazole – A European Environmental Fate Assessment for prothioconazole and its metabolites using the FOCUS surface water models at Steps 1 to 4 following spray application to cereals and oilseed rape in Central Europe. Company Report No.: S24-101230-02-005 Eurofins Agrosience Services Regulatory GmbH non-GLP, Unpublished	N	N	-	UPL Europe
KCP 10.2.1/01	Bauer J., Mollandin, G.	2024	Azoxystrobin 160 g/L + Prothioconazole 200 g/L SC: Acute Toxicity to <i>Daphnia magna</i> in a Semi-Static 48-hour Immobilisation Study No.: 179211220 GLP, Unpublished	N	Y	Data/study report never submitted before to Poland	ARYSTA LifeScience S.A.S.
KCP 10.2.1/02	Bauer J., Mollandin, G.	2024	Azoxystrobin 160g/L + Prothioconazole 200g/L SC: Toxicity to <i>Pseudokirchneriella subcapitata</i> in an Algal Growth Inhibition Test Study No.: 179211210 GLP, Unpublished	N	Y	Data/study report never submitted before to Poland	ARYSTA LifeScience S.A.S.
KCP 10.3.1.1.1/01 KCP 10.3.1.1.2/01	Schabio, S., Horstmann, C.	2024	Azoxystrobin 160 + Prothioconazole 200 g/L SC: Effects (Acute Contact and Oral) on Honey Bees (<i>Apis mellifera</i> L.) in the Laboratory Study No.: 179211035 GLP, Unpublished	N	Y	Data/study report never submitted before to Poland	ARYSTA LifeScience S.A.S.
KCP 10.3.1.1.1/02 KCP 10.3.1.1.2/02	Schabio, S., Horstmann, C.	2024	Azoxystrobin 160 g/L + Prothioconazole 200 g/L SC: Acute Contact and Oral Toxicity to Bumblebees (<i>Bombus terrestris</i> L.) in the Laboratory Study No.: 179211105 GLP, Unpublished	N	Y	Data/study report never submitted before to Poland	UPL Europe Ltd.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 10.3.1.2/01	Schabio, S., Horstmann, C.	2024	Azoxystrobin 160 + Prothioconazole 200 g/L SC: Chronic Oral Toxicity Test on the Honey Bee (<i>Apis mellifera</i> L.) in the Laboratory Study No.: 179211136 GLP, Unpublished	N	Y	Data/study report never submitted before to Poland	ARYSTA LifeScience S.A.S.
KCP 10.3.1.3/01	Venturi, S.	2024	Effects of AZOXYSTROBIN 160 + PROTHIOCONAZOLE 200 g/L SC on honeybees (<i>Apis mellifera</i> L.) 22-day larval toxicity test with repeated exposure Study No.: BT212/23 GLP, Unpublished	N	Y	Data/study report never submitted before to Poland	ARYSTA LifeScience S.A.S.
KCP 10.3.1.5/01	Portail, B.	2024	Azoxystrobin 160 g/L + Prothioconazole 200 g/L SC - A Semi-Field Study to Evaluate Side Effects on Honeybees (<i>Apis mellifera</i> L.) in <i>Phacelia tanacetifolia</i> in Germany 2024, Study number S24-102790, GLP, Unpublished This study is ongoing and will be provided once completed.	N	Y	Data/study report never submitted before to Poland	UPL Europe Ltd.
KCP 10.3.1.5/02	Roig, J.	2024	A Semi-Field Study to Evaluate Side Effects of Azoxystrobin 160 + Prothioconazole 200 SC on the Honey Bee (<i>Apis mellifera</i> L.) on <i>Phacelia tanacetifolia</i> according to CEB 230 in France in 2024, Study number S24-102576, GLP, Unpublished This study is ongoing and will be provided once completed.	N	Y	Data/study report never submitted before to Poland	UPL Europe Ltd.
KCP 10.3.2.2/01	Leopold, J.	2024	Azoxystrobin 160 g/L + Prothioconazole 200 g/L SC: Effects on the Parasitoid <i>Aphidius rhopalosiphii</i> (Hymenoptera, Braconidae), Extended Laboratory Study - Limit Test Study No.: 179211002 GLP, Unpublished	N	Y	Data/study report never submitted before to Poland	ARYSTA LifeScience S.A.S
KCP 10.3.2.2/02	Leopold, J.	2024	Azoxystrobin 160 g/L + Prothioconazole 200 g/L SC: Effects on the Predatory Mite <i>Typhlodromus pyri</i> (Acari: Phytoseiidae), Extended Laboratory Study - Aged Residue Test Study No.: 179211060 GLP, Unpublished	N	Y	Data/study report never submitted before to Poland	ARYSTA LifeScience S.A.S

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 10.3.2.2/03	Leopold, J.	2024	Azoxystrobin 160 g/L + Prothioconazole 200 g/L SC: Effects on the Ladybird Beetle <i>Coccinella septempunctata</i> (Coleoptera, Coccinellidae), Extended Laboratory Study - Limit Test Study No.: 179211012 GLP, Unpublished	N	Y	Data/study report never submitted before to Poland	ARYSTA LifeScience S.A.S.
KCP 10.3.2.2/04	Leopold, J.	2024	Azoxystrobin 160 g/L + Prothioconazole 200 g/L SC: Effects on the Lacewing <i>Chrysoperla carnea</i> (Neuroptera: Chrysopidae), Extended Laboratory Study - Limit Test Study No.: 179211047 GLP, Unpublished	N	Y	Data/study report never submitted before to Poland	ARYSTA LifeScience S.A.S.
KCP 10.4.1.1/01	Hübner, S.	2024	Azoxystrobin 160 + Prothioconazole 200 g/L SC: Effects on Reproduction and Growth of Earthworms <i>Eisenia andrei</i> in Artificial Soil Study No.: 179211022 GLP, Unpublished	N	Y	Data/study report never submitted before to Poland	ARYSTA LifeScience S.A.S.
KCP 10.4.2.1/01	Hübner, S.	2024	Azoxystrobin 160 + Prothioconazole 200 g/L SC: Effects on Reproduction of the Predatory Mite <i>Hypoaspis aculeifer</i> in Artificial Soil Study No.: 179211089 GLP, Unpublished	N	Y	Data/study report never submitted before to Poland	ARYSTA LifeScience S.A.S.
KCP 10.4.2.1/02	Hübner, S.	2024	Azoxystrobin 160 + Prothioconazole 200 g/L SC: Effects on Reproduction of Collembola (<i>Folsomia candida</i>) in Artificial Soil Study No.: 179211016 GLP, Unpublished	N	Y	Data/study report never submitted before to Poland	ARYSTA LifeScience S.A.S.
KCP 10.5/01	Hammesfahr, U.	2024	Azoxystrobin 160 + Prothioconazole 200 g/L SC: Effects on the Activity of the Soil Microflora in the Laboratory (Nitrogen Transformation) Study No.: 179211080 GLP, Unpublished	N	Y	Data/study report never submitted before to Poland	ARYSTA LifeScience S.A.S.
KCP 10.6.2/01	Stürtz, S., Horstmann, C.	2024	Azoxystrobin 160 + Prothioconazole 200 g/L SC: Effects on Terrestrial (Non-Target) Plants: Seedling Emergence and Seedling Growth Test Study No.: 179211086 GLP, Unpublished	N	Y	Data/study report never submitted before to Poland	ARYSTA LifeScience S.A.S.

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KCP 10.6.2/02	Stürtz, S., Horstmann, C.	2024	Azoxystrobin 160 + Prothioconazole 200 g/L SC: Effects on Terrestrial (Non-Target) Plants: Vegetative Vigour Test Study No.: 179211087 GLP, Unpublished	N	Y	Data/study report never submitted before to Poland	ARYSTA LifeScience S.A.S.

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

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
-	-	-	-	-	-	-	-

List of data submitted by the applicant and not relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 8.3.1-03	Andrews, G., Pearson, J.	2017	Azoxystrobin - residue study on wheat in Southern Europe in 2016 Report No NC16013 Document No VV-467712 GLP Unpublished A data access agreement is in place for UPL to rely on this study for the registration of FGF11. Please refer to the Azoxystrobin EU renewal (dRAR) for a summary and conclusions for this study.	N	Y	Data/study report never submitted before to Poland	Syngenta
KCP 8.3.1-04	Brown, D.	2020	Azoxystrobin – Magnitude of Residue Study on Spring Wheat in Spain and Portugal in 2019 Report No RES-00188 Document No VV-864619 A data access agreement is in place for UPL to rely on this study for the registration of FGF11.	N	Y	Data/study report never submitted before to Poland	Syngenta

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Please refer to the Azoxystrobin EU renewal (dRAR) for a summary and conclusions for this study.				
KCP 8.3.2-04	Souchier, M.	2017	Azoxystrobin – Residue Study on Barley in the Southern France, Italy and Spain in 2016 Report No S16-03842 Document No VV-467632 GLP Unpublished A data access agreement is in place for UPL to rely on this study for the registration of FGF11. Please refer to the Azoxystrobin EU renewal (dRAR) for a summary and conclusions for this study.	N	Y	Data/study report never submitted before to Poland	Syngenta
KCP 8.3.2-05	Ziske, J., Link, T.	2020	Azoxystrobin – Residue Study on Spring Barley in Spain, Greece and Italy in 2019 Report No IF19-04928660; Document No VV-870172 GLP Unpublished A data access agreement is in place for UPL to rely on this study for the registration of FGF11. Please refer to the Azoxystrobin EU renewal (dRAR) for a summary and conclusions for this study.	N	Y	Data/study report never submitted before to Poland	Syngenta
KCP 8.3.3-01	North, L.	2024	Determination of residues of Azoxystrobin after two applications of FFC03 in Oilseed rape at 7 sites in Southern Europe 2023 Report No S23-102957 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	ARYSTA LifeScience S.A.S.
KCP 8.3.3-03	Toscano Saes, R., Coleman, H.	2023	Magnitude of Residues of Prothioconazole-desthio and Hydroxyprothioconazole-desthio metabolites Following Two Applications of Prothioconazole 250 g/L DC (FGR06) to Oilseed rape in southern Europe, 2022; Study No.: QG22006 GLP	N	Y	Data/study report never submitted before to Poland	UPL Europe Ltd.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Unpublished				
KCP 8.3.3-06	Hardy, J., Coleman, H.	2024	Magnitude of Residues of Prothioconazole-desthio, Hydroxy-prothioconazole-desthio metabolites, Triazole Lactic Acid and Triazole Acetic Acid Following Two Applications of a 250 g/L EC Formulation to Oilseed Rape in Southern Europe, 2020 Study No.: QG20008 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL Europe Ltd.
KCP 8.3.3-08	Toscano Saes, R.	2023	Magnitude of Residues of Triazole Derived Metabolites (TDM's) (triazole acetic acid and triazole lactic acid) Following Two Applications of Prothio-conazole 250 g/L DC (FGR06) to Oilseed Rape in Southern Europe, 2022 Study number: EE/23/006 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	UPL Europe Ltd.

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

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 6.1/03	██████	2020	Storage Stability of Triazole Alanine (TA), Triazole Acetic Acid (TAA) and Triazole Lactic Acid (TLA) in Animal Matrices under Deep Frozen Conditions. ██████ ██████ ID: 869333. ██████ ID: P 5069 G. GLP Unpublished	Y		Remark: Evaluated in RR of FHO04 / Patton Supra (01.2025)	Triazole Derivative Metabolite Group