



Draft Assessment Report

Evaluation of Active Substances

Plant Protection Products

Prepared according to **Regulation (EC) 1107/2009**
as it applies in Great Britain

Pydiflumetofen

Volume 3 – B.3 (PPP) – Miravis Plus

Data on application and efficacy

Great Britain

June 2023

Version History

When	What
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B.3. DATA ON APPLICATION AND EFFICACY

This Draft Assessment Report has been drafted by the HSE based on the information submitted by the applicant in their Biological Assessment Dossier for the product Miravis Plus. HSE considers that the applicant has satisfactorily addressed the Efficacy related requirements for approval of new active substances.

B.3.1. FIELD OF USE ENVISAGED

Miravis Plus is a fungicide for the control of foliar diseases in winter and spring barley, winter and spring wheat, winter and spring oat, winter and spring rye, winter and spring triticale, durum wheat, spelt, and winter and spring oilseed rape.

B.3.2. EFFECTS ON HARMFUL ORGANISMS

Pydiflumetofen is a foliar fungicide in the carboxamide chemical group that acts by inhibition of respiration at complex II (succinate-dehydrogenase).

Pydiflumetofen is a lipophilic molecule with limited solubility and limited xylem translocation; it does not move in the phloem and has no vapour activity. Pydiflumetofen has low uptake into leaf tissues, and has limited systemic properties, resulting in a substance with predominantly protectant properties. However, although translaminar and xylem systemic properties of pydiflumetofen are limited, the molecule also reduces intercellular mycelial growth and thus may provide some curative activity.

Pydiflumetofen is most active at stages of the fungal life cycle which are particularly energy demanding. It shows strong effects in early growth stages; it inhibits spore germination and germ tube growth and consequently hinders establishment of the fungus in the host plant.

B.3.3. DETAILS OF INTENDED USE

Use No.	Crop and/or situation (a)	F G I (b)	Pests or group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (m)	Remarks (*)
				Type (d-f)	Concentration of a.s. g/L (i)	Method / kind (f-h)	Timing / Growth stage and season (j)	Max number a) per use b) per crop / season (k)	Minimum Interval between applications	L product/ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season (l)	Water volume L/ha		
1	Barley (winter and spring)	F	<i>Pyrenophora teres</i> <i>Rhynchosporium secalis</i> <i>Ramularia collo-cygni</i> <i>Puccinia hordei</i> <i>Erysiphe graminis</i>	EC	62.5	Foliar	BBCH 30-59	a) 1 b) 1	N.A.	a) 2.65 b) 2.65	a) 166 b) 166	100-300	Defined by latest time of application	
			<i>Fusarium</i> spp.				BBCH 55-65			a) 3.2 b) 3.2	a) 200 b) 200			
2	Wheat (winter and spring), Durum wheat, Spelt	F	<i>Septoria tritici</i> <i>Septoria nodorum</i> <i>Puccinia recondita</i> <i>Pyrenophora tritici-repentis</i> <i>Erysiphe graminis</i>	EC	62.5	Foliar	BBCH 30-69	a) 1 b) 1	N.A.	a) 2.65 b) 2.65	a) 166 b) 166	100-300	Defined by latest time of application	
			<i>Fusarium</i> spp.				BBCH 61-69			a) 3.2 b) 3.2	a) 200 b) 200			
3	Oats (winter and spring)	F	<i>Fusarium</i> spp.	EC	62.5	Foliar	BBCH 55-65	a) 1 b) 1	N.A.	a) 3.2 b) 3.2	a) 200 b) 200	100-300	Defined by latest time of application	
4	Triticale (winter and spring), Rye (winter and spring)	F	<i>Fusarium</i> spp.	EC	62.5	Foliar	BBCH 61-69	a) 1 b) 1	N.A.	a) 3.2 b) 3.2	a) 200 b) 200	100-300	Defined by latest time of application	
5	Oilseed rape	F	<i>Sclerotinia sclerotiorum</i>	EC	62.5	Foliar	BBCH 57-69	a) 1 b) 1	N.A.	a) 3.2 b) 3.2	a) 200 b) 200	100-300	Defined by latest	1 application

	(winter and spring)												time of application	every 3 years
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- * For uses where the column “Remarks” is marked in grey further consideration is necessary. Uses should be crossed out when the notifier no longer supports this use(s).
- (a) For crops, the Codex classification should be taken into account; where relevant, the use situation should be described (e.g. fumigation of a structure)
- (b) Outdoor or field use (F), greenhouse application (G) or indoor application (I)
- (c) e.g. biting and suckling insects, soil born insects, foliar fungi, weeds
- (d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
- (e) GCPF Codes – GIFAP Technical Monograph N° 2, 1989
- (f) All abbreviations used must be explained
- (g) Method, e.g. high-volume spraying, low volume spraying, spreading, dusting, drench
- (h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plant – type of equipment used must be indicated
- (i) g/kg or g/L. Normally the rate should be given for the active substance (according to ISO) and not for the variant in order to compare the rate for same active substances used in different variants (e.g. fluroxypyr). In certain cases, where only one variant synthesised, it is more appropriate to give the rate for the variant (e.g. benthiavalicarb-isopropyl).
- (j) Growth stage at 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
- (k) Indicate the minimum and maximum number of application possible under practical conditions of use
- (l) The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha)
- (m) PHI - minimum pre-harvest interval

B.3.4. APPLICATION RATE AND CONCENTRATION OF THE ACTIVE SUBSTANCE

Miravis Plus contains 62.5 g a.s./L of the active substance pydiflumetofen. The application rates and timings for each pathogen/crop situation are shown in the table above (section B.3.3.).

B.3.5. METHOD OF APPLICATION

Miravis Plus is applied as a foliar spray using conventional crop spraying equipment in a water volume of 100-300 L/ha.

B.3.6. NUMBER AND TIMING OF APPLICATIONS AND DURATION OF PROTECTION

See section B.3.4. above.

B.3.7. NECESSARY WAITING PERIODS OR OTHER PRECAUTIONS TO AVOID PHYTOTOXIC EFFECTS ON SUCCEEDING CROPS

There are no restrictions proposed on the draft product label for Miravis Plus. A study was conducted to assess the effects of Miravis Plus on the seedling emergence of 6 different crops. The study methodology was based on OECD Guideline for the Testing of Chemicals No. 208. The tested crops included 2 monocotyledonous species (*Allium cepa* and *Triticum aestivum*) and 4 dicotyledonous species (*Cucumis sativus*, *Glycine max*, *Beta vulgaris* and *Brassica napus*). Miravis Plus was applied at 5 different application rates from 200 mL/ha up to the maximum proposed rate of 3200 mL/ha. No phytotoxic effects on seedling emergence were observed for any of the plant species at any of the application rates tested.

Miravis Plus is applied to cereal crops at BBCH 30-69 and oilseed rape at BBCH 57-69; therefore, a minimum of 80% interception can be expected, resulting in a maximum of 640 mL/ha Miravis Plus being applied to the soil. Additionally, some degradation of pydiflumetofen in the soil can be expected prior to sowing any succeeding crops. Based on the lack of herbicidal effects at the maximum proposed application rate, a low risk of phytotoxicity is expected in succeeding crops from the proposed uses of Miravis Plus. A full risk assessment on succeeding crops will be conducted at the product authorisation stage.

B.3.8. PROPOSED INSTRUCTIONS FOR USE

See sections B.3.3. and B.3.4. above.

B.3.9. EFFECTIVENESS

No data in spelt were submitted by the applicant as they propose to extrapolate from wheat. Spelt is a very minor crop in GB and NI and this extrapolation is typically acceptable.

Wheat (winter wheat, spring wheat, durum wheat)

194 effectiveness trials were successfully conducted between 2016 and 2018 in wheat (winter wheat, spring wheat and durum wheat) to assess the disease control provided by Miravis Plus. 78 trials were conducted in the Maritime EPPO climatic zone, 58 in the Mediterranean zone, and 58 in the North-East zone. For GB the focus is on the Maritime EPPO climatic zone data. The trials were conducted in accordance with EPPO standards and Good Experimental Practice (GEP). Applications of Miravis were made at BBCH 32-69 with water volumes of 150-300 L/ha. The summary tables below show the disease control results for each target as well as the yield and quality data from the effectiveness trials.

Foliar diseases

Table 3.9-1 – Effectiveness of Miravis Plus at 2.65 L/ha in wheat against foliar diseases

Target	EPPO climatic zone	Untreated		Miravis Plus 166 gai/ha (2.65 l/ha)		Aviator XPro 281 gai/ha (1.25 l/ha)		Proline 250EC 200 gai/ha (0.8 l/ha)	
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
		% disease severity		% control					
<i>Septoria tritici</i>	Maritime (n=41)	36.2	5.0 - 100	90.0	50.3 – 100	76.5	36.0 – 100	54.1	0.0 – 93.8
	Mediterranean (n=29)	24.8	5.3 – 94.7	87.0	55.8 – 100	82.5	23.6 – 100	75.7	29.3 – 100
	North East (n=20)	18.2	5.3 – 54.7	90.1	74.9 – 100	76.2	39.8 – 100	69.3	27.8 – 100
	Overall Mean across zones (n=90)	28.5	5.0 – 100	89.1	50.3 – 100	78.4	23.6 – 100	64.4	0.0 – 100
<i>Septoria nodorum</i>	Maritime (n=8)	33.8	5.0 – 100	86.7	66.1 – 100	79.9	53.9 – 96.1	53.9	29.6 – 80.0
	Mediterranean (n=3)	17.4	9.1 – 30.6	97.4	92.4 – 100	89.4	76.6 – 96.5	69.6	32.4 – 92.0
	North East (n=15)	21.3	5.1 – 54.8	84.9	50.1 – 99.6	61.5	22.5 – 97.0	55.4	24.6 – 95.3
	Overall Mean across zones (n=26)	24.7	5.0 – 100	86.9	50.1 – 100	70.4	22.5 – 97.0	56.6	24.6 – 95.3
<i>Puccinia recondita</i>	Maritime (n=24)	23.7	5.0 – 93.8	75.4	7.2 – 100	91.2	60.9 – 100	63.0	0.0 – 100
	Mediterranean (n=15)	42.3	6.1 – 100	68.3	38.7 – 89.9	84.4	62.5 – 100	64.7	0.0 – 100
	North East (n=13)	20.9	5.0 – 56.9	93.9	78.2 – 100	95.2	82.0 – 100	84.9	53.3 – 100
	Overall Mean across zones (n=52)	28.4	5.0 – 100	78.0	7.2 – 100	90.2	60.9 – 100	69.0	0.0 – 100
<i>Erysiphe graminis</i>	Maritime (n=15)	18.4	5.0 – 56.9	83.9	68.7 – 100	81.3	52.5 – 100	77.3	45.1 – 100
	Mediterranean (n=10)	17.8	7.6 – 54.4	86.3	47.4 – 100	76.8	28.3 – 100	76.4	7.5 – 99.6
	North East (n=11)	10.6	5.1 – 23.8	87.0	61.8 – 100	80.2	42.8 – 100	79.6	45.2 – 100
	Overall Mean across zones (n=36)	15.9	5.0 – 56.9	85.5	47.4 – 100	79.7	28.3 – 100	77.8	7.5 – 100
<i>Pyrenophora tritici-repentis</i>	Maritime (n=14)	21.5	5.6 – 91.9	94.6	71.6 – 100	56.7	2.9 – 92.0	52.2	20.4 – 90.9
	Mediterranean (n=7)	24.4	7.4 – 62.2	75.3	32.2 – 100	65.4	15.8 – 98.3	60.7	29.1 – 81.0
	North East (n=30)	21.2	5.4 – 64.1	91.4	67.8 – 100	65.9	27.4 – 99.2	62.3	28.4 – 99.6
	Overall Mean across zones (n=51)	21.7	5.4 – 91.9	90.1	32.2 – 100	63.3	2.9 – 99.2	59.3	20.4 – 99.6

Table 3.9-2 – Yield of wheat treated with Miravis Plus at 2.65 L/ha in the presence of foliar diseases

EPPO climatic zone	Untreated		Miravis Plus 166 gai/ha (2.65 l/ha)		Aviator XPro 281 gai/ha (1.25 l/ha)		Proline 250EC 200 gai/ha (0.8 l/ha)	
	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
Mean Yield								
	Yield (dt/ha)		Yield (% of control)					
Maritime (n=67)	79.9	39.5 – 109.1	120.0	101.4 – 174.0	115.3	100.1 – 149.5	109.7	85.4 – 132.4
Mediterranean (n=55)	57.7	8.0 – 96.2	112.6	97.1 – 149.7	114.9	94.7 – 217.9	112.5	88.1 – 187.0
North East (n=58)	63.5	30.2 – 98.1	116.6	95.8 – 187.9	111.5	96.2 – 161.8	111.0	94.7 – 156.6
Mean across zones (n=180)	67.8	8.0 – 109.1	116.6	95.8 – 187.9	114.0	94.7 – 217.9	111.0	88.1 – 187.0

Table 3.9-3 – Hectolitre weight (HLW) of wheat treated with Miravis Plus at 2.65 L/ha in the presence of foliar diseases

EPPO climatic zone	Untreated		Miravis Plus 166 gai/ha (2.65 l/ha)		Aviator XPro 281 gai/ha (1.25 l/ha)		Proline 250EC 200 gai/ha (0.8 l/ha)	
	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
Mean HLW								
	HLW (kg/ha)		HLW (% of control)					
Maritime (n=58)	70.9	41.6 – 86.8	104.3	99.4 – 123.2	103.5	98.5 – 123.9	102.2	95.8 – 111.0
Mediterranean (n=39)	76.5	41.5 – 90.0	102.2	92.3 – 111.8	101.9	92.7 – 112.5	101.8	95.4 – 111.6
North East (n=53)	74.2	52.7 – 84.0	102.7	95.0 – 115.5	101.7	96.4 – 108.9	101.5	96.1 – 110.0
Mean across zones (n=150)	73.5	41.5 – 90.0	103.2	92.3 – 123.2	102.4	92.7 – 123.9	102.3	95.4 – 111.6

Table 3.9-4 – Thousand grain weight (TGW) of wheat treated with Miravis Plus at 2.65 L/ha in the presence of foliar diseases

EPPO climatic zone	Untreated		Miravis Plus 166 gai/ha (2.65 l/ha)		Aviator XPro 281 gai/ha (1.25 l/ha)		Proline 250EC 200 gai/ha (0.8 l/ha)	
	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
Mean TGW								
	TGW (g)		TGW (% of control)					
Maritime (n=55)	38.8	15.9 – 54.5	114.2	92.0 – 205.6	110.1	96.4 – 187.3	106.8	81.2 – 190.0
Mediterranean (n=35)	42.9	28.1 – 64.3	107.0	83.6 – 125.0	108.4	66.1 – 151.4	107.5	97.6 – 137.6
North East (n=49)	39.8	29.6 – 56.0	109.3	97.5 – 141.6	105.9	92.8 – 122.9	104.7	97.0 – 118.6
Mean across zones (n=139)	40.2	15.9 – 64.3	110.7	83.6 – 205.6	108.2	66.1 – 187.3	106.2	97.0 – 190.0

Table 3.9-5 – Protein content of wheat treated with Miravis Plus at 2.65 L/ha in the presence of foliar diseases

EPPO climatic zone	Untreated		Miravis Plus 166 gai/ha (2.65 l/ha)		Aviator XPro 281 gai/ha (1.25 l/ha)		Proline 250EC 200 gai/ha (0.8 l/ha)	
	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
Mean % protein content								
	Protein content (%)		Protein content (% of control)					
Maritime (n=50)	12.4	9.3 – 16.0	97.9	83.1 – 117.9	99.1	88.6 – 116.2	98.9	90.0 – 108.7
Mediterranean (n=35)	12.3	7.4 – 17.2	99.1	86.1 – 108.3	99.7	86.9 – 111.1	99.5	90.0 – 107.3
North East (n=48)	12.9	9.7 – 15.5	98.6	88.4 – 108.7	99.5	91.6 – 114.2	99.5	89.1 – 115.9
Mean across zones (n=133)	12.6	7.4 – 17.2	98.5	83.1 – 117.9	99.4	86.9 – 116.2	99.3	89.1 – 115.9

The data provided demonstrate that the proposed application rate of Miravis Plus provides acceptable protection against some of the most important foliar diseases in wheat. In Table 3.9-1, it can be seen that Miravis Plus achieved higher levels of control of *Septoria tritici*, *Septoria nodorum*, *Erysiphe graminis*, and *Pyrenophora tritici-repentis*, when compared to the reference products Aviator Xpro (bixafen + prothioconazole) and Proline 250 EC (prothioconazole). Miravis Plus provided a higher level of control of *Puccinia recondita* than Proline 250EC, but Aviator Xpro was more effective against this target.

In the presence of foliar diseases, the yield and TGW after application of Miravis Plus were increased compared to the untreated control and slightly higher than after application of the reference products. The HLW and protein content were comparable to the untreated and the reference products.

Fusarium spp.

Table 3.9-6 – Effectiveness of Miravis Plus against *Fusarium* spp. at 3.2 L/ha in wheat

Target	EPPO climatic zone	Untreated		Miravis Plus 200 gai/ha (3.2 l/ha)	
		Mean	min-max	Mean	min-max
Disease severity					
		% disease severity		% control	
Fusarium spp.	Maritime (n=19)	31.8	7.9 – 87.5	70.1	36.2 - 89.6
	Mediterranean (n=9)	17.1	5.0 – 32.5	88.6	43.1 – 100
	North East (n=13)	29.5	5.2 – 81.9	73.5	37.7 – 98.5
Overall Mean across zones (n=41)		27.8	5.0 – 87.5	75.2	36.2 - 100
Disease incidence					
		% disease incidence		% control	
Fusarium spp.	Maritime (n=19)	74.7	16.5 – 100	35.3	0.0 – 81.5
	Mediterranean (n=16)	35.0	10.0 – 79.5	77.5	13.2 – 100
	North East (n=14)	76.9	15.5 – 100	35.7	0.0 – 87.1
Overall Mean across zones (n=49)		62.4	10.0 – 100	49.2	0.0 – 100
Deoxynivalenol (DON) mycotoxin content					
		DON (ppb)		% control	
Fusarium spp.	Maritime (n=9)	7110.9	542.0 – 40000.0	69.3	0.0 – 96.9
	Mediterranean (n=6)	1451.4	130.2 – 4700.0	53.2	8.5 – 96.0
	North East (n=9)	2608.7	228.7 – 11163.4	45.1	2.9 – 100
Overall Mean across zones (n=24)		4007.7	130.2 – 40000.0	56.2	0.0 – 100
Zearalenone (ZER) mycotoxin content					
		ZER (ppb)		% control	
Fusarium spp.	Maritime (n=6)	66.2	22.7 – 167.2	48.8	0.0 – 100
	Mediterranean (n=3)	93.7	31.0 – 140.0	100	100 – 100
	North East (n=3)	96.7	26.1 – 203.7	57.4	6.0 – 100
Overall Mean across zones (n=12)		80.7	22.7 – 203.7	63.8	0.0 – 100

Table 3.9-7 – Yield of wheat treated with Miravis Plus at 3.2 L/ha in the presence of *Fusarium* spp.

EPPO climatic zone	Untreated		Miravis Plus 200 gai/ha (3.2 l/ha)	
	Mean	min-max	Mean	min-max
Mean Yield				
	Yield (dt/ha)		Yield (% of control)	
Maritime (n=19)	82.0	50.6 – 113.0	118.7	103.8 – 172.2
Mediterranean (n=16)	59.3	8.2 – 95.1	110.6	99.8 – 151.2
North East (n=15)	56.0	30.2 – 77.6	120.1	92.4 – 190.1
Mean across zones (n=50)	66.9	8.2 – 113.0	116.5	92.4 – 172.2

Table 3.9-8 – Hectolitre weight (HLW) of wheat treated with Miravis Plus at 3.2 L/ha in the presence of *Fusarium* spp.

EPPO climatic zone	Untreated		Miravis Plus 200 gai/ha (3.2 l/ha)	
	Mean	min-max	Mean	min-max
Mean HLW				
	HLW (kg/hl)		HLW (% of control)	
Maritime (n=18)	69.4	53.3 – 80.3	106.5	99.8 – 136.1
Mediterranean (n=16)	77.2	67.8 – 86.4	102.4	99.4 – 107.0

North East (n=15)	73.9	59.5 – 82.6	103.0	97.6 – 116.2
Mean across zones (n=49)	73.3	53.3 – 86.4	104.1	97.6 – 136.1

Table 3.9-9 – Thousand grain weight (TGW) of wheat treated with Miravis Plus at 3.2 L/ha in the presence of *Fusarium* spp.

EPPO climatic zone	Untreated		Miravis Plus 200 gai/ha (3.2 l/ha)	
	Mean	min-max	Mean	min-max
Mean TGW				
	TGW (g)		TGW (% of control)	
Maritime (n=13)	41.5	29.9 – 48.7	110.0	99.0 – 120.8
Mediterranean (n=14)	43.3	32.9 – 58.3	105.2	92.6 – 124.3
North East (n=15)	40.2	30.3 – 50.7	109.3	99.9 – 130.9
Mean across zones (n=42)	41.6	29.9 – 58.3	108.2	92.6 – 130.9

Table 3.9-10 – Protein content of wheat treated with Miravis Plus at 3.2 L/ha in the presence of *Fusarium* spp.

EPPO climatic zone	Untreated		Miravis Plus 200 gai/ha (3.2 l/ha)	
	Mean	min-max	Mean	min-max
Mean % protein content				
	Protein content (%)		Protein content (% of control)	
Maritime (n=10)	11.8	8.8 – 13.9	98.1	96.1 – 100.5
Mediterranean (n=15)	12.3	9.4 – 14.6	99.6	88.5 – 117.0
North East (n=14)	13.4	10.1 – 15.5	98.3	88.6 – 102.1
Mean across zones (n=39)	12.6	8.8 – 15.5	98.7	88.5 – 117.0

The data provided demonstrate that the proposed application rate of Miravis Plus provides acceptable protection against *Fusarium* spp. in wheat. The tables for *Fusarium* spp. do not include the results for the reference products as they were not used in every trial. Orthogonal comparisons provided by the applicant have shown that Miravis Plus provides slightly higher control of *Fusarium* spp. than Aviator Xpro and Proline 250EC, and also reduced the levels of Deoxynivalenol mycotoxin and Zearalenone mycotoxin.

In the presence of *Fusarium* spp., the yield and TGW after application of Miravis Plus were increased compared to the untreated control and slightly higher than after application of the reference products. The HLW was slightly increased compared to the untreated control, but comparable to the reference products. The protein content was comparable to the untreated and the reference products.

Barley (winter barley, spring barley)

212 effectiveness trials were successfully conducted between 2016 and 2018 in barley (winter barley and spring barley) to assess the disease control provided by Miravis Plus. 72 trials were conducted in the Maritime EPPO climatic zone, 72 in the Mediterranean zone, and 68 in the North-East zone. For GB the focus is on the Maritime EPPO climatic zone data. The trials were conducted in accordance with EPPO standards and Good Experimental Practice (GEP). Applications of Miravis were made at BBCH 32-69 with water volumes of 150-400 L/ha. The summary tables below show the disease control results for each target as well as the yield and quality data from the effectiveness trials.

Foliar diseases

Table 3.9-11 – Effectiveness of Miravis Plus at 2.65 L/ha in barley against foliar diseases

Target	EPPO climatic zone	Untreated		Miravis Plus 166 gai/ha (2.65 l/ha)		Aviator XPro 225 gai/ha (1.0 l/ha)		Proline 250EC 200 gai/ha (0.8 l/ha)	
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
		% disease severity		% control					
<i>Pyrenophora teres</i>	Maritime (n=26)	28.5	5.0 – 90.0	90.0	65.4 – 99.3	76.2	37.7 – 100	69.3	31.5 – 100
	Mediterranean (n=28)	29.9	5.3 – 100	86.1	26.0 – 100	76.3	0.0 – 100	67.8	0.0 – 100
	North East (n=42)	20.0	5.0 – 81.5	91.5	57.9 – 100	84.2	13.8 – 100	73.0	22.4 – 100
	Overall Mean across zones (n=96)	25.2	5.0 – 100	89.5	26.0 – 100	79.7	0.0 – 100	70.5	0.0 – 100
<i>Rhynchosporium secalis</i>	Maritime (n=12)	16.6	5.0 – 70.7	88.1	51.8 – 100	81.7	34.3 – 100	77.1	45.6 – 100
	Mediterranean (n=13)	21.6	5.6 – 97.5	91.6	52.7 – 100	81.6	10.9 – 100	73.6	12.7 – 100
	North East (n=9)	18.3	7.4 – 27.8	94.5	82.3 – 100	91.7	78.3 – 100	73.1	35.4 – 100
	Overall Mean across zones (n=34)	19.0	5.0 – 97.5	91.1	51.8 – 100	84.3	10.9 – 100	74.7	12.7 – 100
<i>Ramularia collo-cygni</i>	Maritime (n=23)	47.7	5.8 – 100	91.6	55.4 – 100	55.8	0.4 – 100	49.5	0.0 – 100
	Mediterranean (n=15)	26.3	5.0 – 100	93.7	77.8 – 100	78.6	6.2 – 100	72.7	0.0 – 100
	North East (n=3)	11.5	5.9 – 22.6	95.3	90.0 – 99.7	82.8	68.7 – 96.5	72.9	54.4 – 96.5
	Overall Mean across zones (n=41)	37.2	5.0 – 100	92.5	55.4 – 100	66.1	0.4 – 100	59.7	0.0 – 100
<i>Puccinia hordei</i>	Maritime (n=15)	26.6	7.2 – 64.7	74.7	24.0 – 98.6	89.0	49.7 – 100	87.4	54.6 – 100
	Mediterranean (n=7)	29.2	5.2 – 75.3	76.8	46.0 – 100	66.0	43.4 – 90.4	67.1	37.5 – 89.2
	North East (n=11)	18.2	5.4 – 38.4	81.5	43.7 – 97.7	92.1	75.4 – 98.2	72.6	36.8 – 98.5
	Overall Mean across zones (n=33)	24.4	5.2 – 75.3	77.4	24.0 – 100	85.2	43.4 – 100	78.2	36.8 – 100
<i>Erysiphe graminis</i>	Maritime (n=16)	15.2	5.3 – 49.7	77.6	50.0 – 95.0	83.0	25.8 – 100	82.0	16.1 – 100
	Mediterranean (n=6)	20.8	6.2 – 60.9	71.2	38.8 – 100	69.4	15.4 – 100	68.4	12.8 – 100
	North East (n=16)	10.6	5.2 – 21.3	83.3	15.5 – 100	87.6	58.8 – 100	83.8	60.8 – 100
	Overall Mean across zones (n=38)	14.1	5.2 – 60.9	79.0	15.5 – 100	82.8	15.4 – 100	80.6	12.8 – 100

Table 3.9-12 – Yield of barley treated with Miravis Plus at 2.65 L/ha in the presence of foliar diseases

EPPO climatic zone	Untreated		Miravis Plus 166 gai/ha (2.65 l/ha)		Aviator XPro 225 gai/ha (1.0 l/ha)		Proline 250EC 200 gai/ha (0.8 l/ha)	
	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
Mean Yield								
	Yield (dt/ha)		Yield (% of control)					
Maritime (n=65)	76.0	37.3 – 111.9	114.8	98.7 – 138.3	112.3	100.8 – 135.8	110.7	99.8 – 133.0
Mediterranean (n=72)	49.6	12.1 – 88.7	116.7	93.2 – 160.9	113.2	92.4 – 154.4	112.5	91.6 – 146.6
North East (n=66)	57.0	21.5 – 89.2	116.1	101.5 – 146.0	114.5	103.2 – 137.6	110.7	11.5 – 138.8
Mean across zones (n=203)	60.5	12.1 – 111.9	115.9	93.2 – 160.9	113.3	92.4 – 154.4	111.3	11.5 – 146.6

Table 3.9-13 – Hectolitre weight (HLW) of barley treated with Miravis Plus at 2.65 L/ha in the presence of foliar diseases

EPPO climatic zone	Untreated		Miravis Plus 166 gai/ha (2.65 l/ha)		Aviator XPro 225 gai/ha (1.0 l/ha)		Proline 250EC 200 gai/ha (0.8 l/ha)	
	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
Mean HLW								
	HLW (kg/hl)		HLW (% of control)					
Maritime (n=61)	62.5	46.5 – 70.1	103.4	96.7 – 113.7	102.8	96.6 – 120.1	102.6	96.6 – 112.3
Mediterranean (n=56)	63.1	44.6 – 77.4	102.6	93.4 – 120.6	102.4	96.4 – 115.6	101.7	92.2 – 121.1
North East (n=50)	62.4	50.0 – 71.7	102.0	85.8 – 110.4	102.0	86.8 – 112.8	101.5	86.9 – 108.2
Mean across zones (n=167)	62.7	44.6 – 77.4	102.7	85.8 – 120.6	102.4	86.8 – 120.1	102.0	86.9 – 121.1

Table 3.9-14 – Thousand grain weight (TGW) of barley treated with Miravis Plus at 2.65 L/ha in the presence of foliar diseases

EPPO climatic zone	Untreated		Miravis Plus 166 gai/ha (2.65 l/ha)		Aviator XPro 225 gai/ha (1.0 l/ha)		Proline 250EC 200 gai/ha (0.8 l/ha)	
	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
Mean TGW								
	TGW (g)		TGW (% of control)					
Maritime (n=58)	45.1	20.5 – 57.1	106.9	93.2 – 124.5	106.5	91.0 – 122.3	105.5	95.5 – 118.7
Mediterranean (n=53)	44.4	25.8 – 56.1	103.9	81.9 – 122.8	104.3	93.6 – 138.4	102.9	94.2 – 122.7
North East (n=47)	47.6	32.2 – 62.3	106.7	83.6 – 126.8	104.7	83.7 – 118.8	104.3	82.8 – 121.7
Mean across zones (n=158)	45.6	20.5 – 62.3	105.8	81.9 – 126.8	105.2	83.7 – 138.4	104.3	82.8 – 122.7

Table 3.9-15 – Protein content of barley treated with Miravis Plus at 2.65 L/ha in the presence of foliar diseases

EPPO climatic zone	Untreated		Miravis Plus 166 gai/ha (2.65 l/ha)		Aviator XPro 225 gai/ha (1.0 l/ha)		Proline 250EC 200 gai/ha (0.8 l/ha)	
	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
Mean % protein content								
	Protein content (%)		Protein content (% of control)					
Maritime (n=55)	11.9	7.7 – 16.2	98.2	84.9 – 118.2	100.8	88.8 – 119.5	100.7	89.5 – 120.8
Mediterranean (n=46)	10.8	6.6 – 15.7	98.5	84.6 – 115.3	98.6	79.9 – 112.2	99.5	83.2 – 125.3
North East (n=44)	11.1	8.2 – 14.9	98.3	88.9 – 108.0	98.8	89.0 – 106.1	99.2	90.0 – 110.5
Mean across zones (n=145)	11.3	6.6 – 16.2	98.3	84.6 – 118.2	99.5	79.9 – 119.5	99.9	83.2 – 125.3

The data provided demonstrate that the proposed application rate of Miravis Plus provides acceptable protection against some of the most important foliar diseases in barley. In Table 3.9-11, it can be seen that Miravis Plus achieved higher levels of control of *Pyrenophora teres*, *Rhynchosporium secalis* and *Ramularia collo-cygni*, when compared to the reference products Aviator Xpro (bixafen + prothioconazole) and Proline 250 EC (prothioconazole). For *Erysiphe graminis*, Miravis Plus was comparable to Proline 250 EC, but provided lower levels of control than Aviator Xpro. For *Puccinia hordei*, control was lower than both Proline 250 EC and Aviator Xpro.

In the presence of foliar diseases, the yield after application of Miravis Plus was increased compared to the untreated control and slightly higher than after application of the reference products. The TGW was slightly increased compared to the untreated control, but comparable to the reference products. The HLW and protein content were comparable to the untreated and the reference products.

Fusarium spp.Table 3.9-16 – Effectiveness of Miravis Plus against *Fusarium* spp. at 3.2 L/ha in barley

Target	EPPO climatic zone	Untreated		Miravis Plus 200 gai/ha (3.2 l/ha)		Aviator XPro 225 gai/ha (1.0 l/ha)		Proline 250EC 200 gai/ha (0.8 l/ha)	
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
Disease severity									
		% disease severity		% control					
<i>Fusarium</i> spp.	Maritime (n=7)	12.5	5.1 – 24.4	76.3	39.4 – 91.5	65.4	25.2 – 92.1	65.6	31.7 – 92.5
	Mediterranean (n=8)	10.0	5.0 – 28.1	94.3	86.4 – 100	82.8	59.2 – 94.1	78.5	50.2 – 92.8
	North East (n=10)	18.1	5.0 – 47.3	75.3	51.0 – 98.4	71.4	39.0 – 95.7	67.9	24.4 – 95.3
Overall Mean across zones (n=25)		13.9	5.0 – 47.3	81.7	39.4 – 100	73.4	25.2 – 95.7	70.6	24.4 – 95.3
Disease incidence									
		% disease incidence		% control					
<i>Fusarium</i> spp.	Maritime (n=12)	64.9	15.0 – 99.0	61.4	22.0 – 100	46.3	0.0 – 100	45.0	0.0 – 100
	Mediterranean (n=14)	44.9	21.5 – 98.0	72.1	0.0 – 100	54.0	0.0 – 90.9	49.2	0.0 – 93.6
	North East (n=17)	55.9	13.5 – 100	52.1	12.2 – 91.4	44.4	3.6 – 92.8	42.1	4.1 – 90.7
Overall Mean across zones (n=43)		54.8	13.5 – 100	61.2	0.0 – 100	48.1	0.0 – 100	45.2	0.0 – 100
Deoxynivalenol (DON) mycotoxin content									
		DON (ppb)		% control					
<i>Fusarium</i> spp.	Maritime (n=2)	1119.5	320.0 – 1919.0	83.3	75.9 – 90.6	87.4	84.2 – 90.6	80.5	73.5 – 87.4
	Mediterranean (n=6)	413.0	240.0 – 660.0	52.5	0.0 – 100	58.7	21.2 – 100	58.8	20.0 – 100
	North East (n=7)	2233.6	194.5 – 6078.7	66.4	18.2 – 100	57.2	0.0 – 100	64.4	35.7 – 100
Overall Mean across zones (n=15)		1356.8	240.0 – 6078.7	63.1	0.0 – 100	61.8	0.0 – 100	64.3	20.0 – 100
Zearalenone (ZER) mycotoxin content									
		ZER (ppb)		% control					
<i>Fusarium</i> spp.	Maritime (n=3)	24.9	17.0 – 29.2	80.2	40.6 – 100	80.2	40.6 – 100	80.2	40.6 – 100
	Mediterranean (n=2)	6580.0	160.0 – 13000	100	100	100	100	100	100
	North East (n=4)	63.2	17.0 – 155.8	59.4	7.7 – 100	61.4	7.5 – 100	77.8	54.1 – 100
Overall Mean across zones (n=9)		1498.6	17.0 - 13000	75.4	7.7 – 100	76.2	7.5 – 100	83.5	40.6 – 100

Table 3.9-17 – Yield of barley treated with of Miravis Plus at 3.2 L/ha in the presence of *Fusarium* spp.

EPPO climatic zone	Untreated		Miravis Plus 200 gai/ha (3.2 l/ha)		Aviator XPro 225 gai/ha (1.0 l/ha)		Proline 250EC 200 gai/ha (0.8 l/ha)	
	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
Mean Yield								
	Yield (dt/ha)		Yield (% of control)					
Maritime (n=9)	80.2	54.2 – 102.5	112.1	101.8 – 120.2	109.5	103.0 – 122.5	107.8	101.0 – 116.8
Mediterranean (n=16)	46.4	15.1 – 79.9	121.5	91.6 – 166.3	117.2	98.9 – 151.6	115.3	96.9 – 146.6
North East (n=16)	52.9	34.1 – 69.9	116.9	102.7 – 141.5	115.5	105.9 – 127.8	111.0	99.2 – 128.5
Mean across zones (n=41)	56.4	15.1 – 102.5	117.6	91.6 – 166.3	114.8	98.9 – 151.6	112.0	96.9 – 146.6

Table 3.9-18 – Hectolitre weight (HLW) of barley treated with Miravis Plus at 3.2 L/ha in the presence of *Fusarium* spp.

EPPO climatic zone	Untreated		Miravis Plus 200 gai/ha (3.2 l/ha)		Aviator XPro 225 gai/ha (1.0 l/ha)		Proline 250EC 200 gai/ha (0.8 l/ha)	
	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
Mean HLW								
	HLW (kg/hl)		HLW (% of control)					
Maritime (n=9)	63.8	57.8 – 69.3	102.4	98.6 – 108.7	102.6	98.4 – 107.8	100.2	96.1 – 103.1
Mediterranean (n=15)	60.7	44.6 – 71.8	104.3	96.9 – 123.0	104.1	96.2 – 120.9	102.7	92.2 – 121.1
North East (n=17)	60.5	51.2 – 68.1	102.7	99.7 – 107.6	102.8	99.4 – 106.3	101.5	97.3 – 105.5
Mean across zones (n=41)	61.3	44.6 – 71.8	103.2	96.9 – 123.0	103.2	96.2 – 120.9	101.7	92.2 – 121.1

Table 3.9-19 – Thousand grain weight (TGW) of barley treated with Miravis Plus at 3.2 L/ha in the presence of *Fusarium* spp.

EPPO climatic zone	Untreated		Miravis Plus 200 gai/ha (3.2 l/ha)		Aviator XPro 225 gai/ha (1.0 l/ha)		Proline 250EC 200 gai/ha (0.8 l/ha)	
	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
Mean TGW								
	TGW (g)		TGW (% of control)					
Maritime (n=9)	47.5	36.6 – 57.0	109.2	99.0 – 117.8	104.3	97.1 – 116.7	105.2	97.3 – 115.9
Mediterranean (n=14)	46.2	33.8 – 55.9	106.7	97.6 – 118.4	106.0	97.6 – 122.6	103.8	95.2 – 117.5
North East (n=17)	46.9	31.4 – 55.6	106.3	101.6 – 114.1	105.5	97.7 – 113.1	103.8	95.3 – 110.0
Mean across zones (n=40)	46.8	31.4 – 57.0	107.1	97.6 – 118.4	105.4	97.1 – 122.6	104.1	95.2 – 117.5

Table 3.9-20 – Protein content of barley treated with Miravis Plus at 3.2 L/ha in the presence of *Fusarium* spp.

EPPO climatic zone	Untreated		Miravis Plus 200 gai/ha (3.2 l/ha)		Aviator XPro 225 gai/ha (1.0 l/ha)		Proline 250EC 200 gai/ha (0.8 l/ha)	
	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
Mean % protein content								
	Protein content (%)		Protein content (% of control)					
Maritime (n=7)	11.9	9.2 – 14.1	97.5	83.0 – 115.2	102.1	90.8 – 119.1	98.1	78.7 – 115.2
Mediterranean (n=12)	11.7	9.3 – 13.1	95.2	90.5 – 99.6	93.0	84.6 – 100	95.4	83.7 – 108.1
North East (n=16)	11.5	9.1 – 15.2	99.8	95.4 – 108.2	98.4	94.9 – 108.0	99.9	96.6 – 105.5
Mean across zones (n=35)	11.6	9.1 – 14.1	97.8	83.0 – 115.2	97.3	84.6 – 119.1	98.0	78.7 – 115.2

The data provided demonstrate that the proposed application rate of Miravis Plus provides acceptable protection against *Fusarium* spp. in barley. Miravis Plus provided higher control of *Fusarium* spp. than Aviator Xpro and Proline 250EC, and also reduced the levels of Deoxynivalenol mycotoxin and Zearalenone mycotoxin.

In the presence of *Fusarium* spp., the yield and TGW after application of Miravis Plus were increased compared to the untreated control and slightly higher than after application of the reference products. The HLW and protein content were comparable to the untreated and the reference products.

Rye (winter rye, spring rye)

20 effectiveness trials were successfully conducted between 2016 and 2018 in rye (winter rye and spring rye) to assess the control of *Fusarium* spp. provided by Miravis Plus. 8 trials were conducted in the Maritime EPPO climatic zone, 8 in the Mediterranean zone, and 7 in the North-East zone. For GB the focus is on the Maritime EPPO climatic zone data. The trials were conducted in accordance with EPPO standards and Good Experimental Practice (GEP). Applications of Miravis were made at BBCH 59-69 with water volumes of 200-400 L/ha. The

summary tables below show the disease control results for *Fusarium* spp. as well as the yield and quality data from the effectiveness trials.

Table 3.9-21 – Effectiveness of Miravis Plus against *Fusarium* spp. at 3.2 L/ha in rye

Target	EPPO climatic zone	Untreated		Miravis Plus 200 gai/ha (3.2 l/ha)		Aviator XPro 225 gai/ha (1.0 l/ha)		Proline 250EC 200 gai/ha (0.8 l/ha)	
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
Disease severity									
		% disease severity		% control					
<i>Fusarium</i> spp.	Maritime (n=3)	11.3	5.0 – 15.2	89.5	80.9 – 99.6	85.9	72.0 – 98.2	59.2	26.5 – 99.2
	Mediterranean (n=5)	18.9	6.5 – 27.1	79.0	58.4 – 99.5	71.6	49.3 – 95.8	76.2	58.5 – 97.4
	North East (n=2)	38.5	5.0 – 72.0	86.3	78.6 – 94.0	56.8	42.8 – 70.7	78.6	72.3 – 84.9
Overall Mean across zones (n=10)		20.5	5.0 – 72.0	83.6	58.4 – 99.6	72.9	42.8 – 98.2	71.6	26.5 – 99.2
Disease incidence									
		% disease incidence		% control					
<i>Fusarium</i> spp.	Maritime (n=6)	39.7	23.5 – 67.5	64.0	34.0 – 95.4	64.4	42.6 – 82.3	54.5	8.9 – 94.6
	Mediterranean (n=7)	50.8	7.5 – 99.0	63.7	5.1 – 100	55.1	1.0 – 100	57.2	2.6 – 95.9
	North East (n=7)	45.4	16.5 – 96.5	56.9	43.5 – 82.8	46.4	4.2 – 75.1	45.0	9.3 – 78.0
Overall Mean across zones (n=20)		45.6	7.5 – 99.0	61.4	5.1 – 100	54.8	1.0 – 100	52.1	2.6 – 95.9
Deoxynivalenol (DON) mycotoxin content									
		DON (ppb)		% control					
<i>Fusarium</i> spp.	Maritime (n=4)	862.8	335.0 – 2345.0	59.5	44.5 – 70.2	69.1	23.2 – 91.0	76.1	57.8 – 97.9
	Mediterranean (n=2)	717.5	305.0 – 1130.0	76.7	55.1 – 98.2	59.0	46.2 – 71.7	50.0	42.5 – 57.4
	North East (n=1)	423.4	-	41.3	-	96.7	-	87.8	-
Overall Mean across zones (n=7)		758.5	305.0 – 2345.0	61.8	41.3 – 98.2	70.2	23.2 – 96.7	70.3	42.5 – 97.9
Zearalenone (ZER) mycotoxin content									
		ZER (ppb)		% control					
<i>Fusarium</i> spp.	Maritime (n=2)	19.2	18.9 – 19.5	100	100 – 100	100	100 – 100	50.0	0.0 – 100
	Mediterranean (n=5)	127.0	30.0 – 223.2	68.6	4.2 – 100	64.5	0.0 – 100	66.3	4.8 – 100
	North East (n=1)	42.4	-	59.9	-	59.9	-	59.9	-
Overall Mean across zones (n=8)		89.5	18.9 – 223.2	75.4	4.2 – 100	72.8	0.0 – 100	61.4	0.0 – 100

Table 3.9-22 – Yield of rye treated with of Miravis Plus at 3.2 L/ha in the presence of *Fusarium* spp.

EPPO climatic zone	Untreated		Miravis Plus 200 gai/ha (3.2 l/ha)		Aviator XPro 281 gai/ha (1.25 l/ha)		Proline 250EC 200 gai/ha (0.8 l/ha)	
	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
Mean Yield								
	Yield (dt/ha)		Yield (% of control)					
Maritime (n=6)	63.9	29.5 – 100.0	111.1	104.1 – 120.6	113.8	107.1 – 123.6	111.7	94.4 – 148.6
Mediterranean (n=7)	44.8	25.2 – 70.4	109.5	106.2 – 117.3	106.9	101.2 – 112.6	112.4	102.1 – 137.4
North East (n=7)	56.6	35.5 – 104.4	112.2	105.5 – 120.2	111.6	99.8 – 120.4	111.9	103.1 – 121.0

Mean across zones (n=20)	54.7	25.2 – 104.4	110.9	104.1 – 120.6	110.6	99.8 – 123.6	112.0	94.4 – 148.6
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Table 3.9-23 – Hectolitre weight (HLW) of rye treated with Miravis Plus at 3.2 L/ha in the presence of *Fusarium* spp.

EPPO climatic zone	Untreated		Miravis Plus 200 gai/ha (3.2 l/ha)		Aviator XPro 281 gai/ha (1.25 l/ha)		Proline 250EC 200 gai/ha (0.8 l/ha)	
	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
Mean HLW								
	HLW (kg/hl)		HLW (% of control)					
Maritime (n=4)	72.0	76.4 – 65.2	102.5	100.6 – 104.6	102.6	100.2 – 105.4	101.4	99.5 – 105.5
Mediterranean (n=6)	72.5	63.8 – 80.0	103.9	99.7 – 112.9	104.0	100.3 – 110.6	103.7	99.3 – 112.9
North East (n=7)	74.4	69.1 – 77.7	100.4	98.8 – 102.5	100.3	99.0 – 102.5	100.2	98.7 – 101.8
Mean across zones (n=17)	73.2	63.8– 80.0	102.1	98.8 – 112.9	102.1	99.0 – 110.6	101.7	98.7 – 112.9

Table 3.9-24 – Thousand grain weight (TGW) of rye treated with Miravis Plus at 3.2 L/ha in the presence of *Fusarium* spp.

EPPO climatic zone	Untreated		Miravis Plus 200 gai/ha (3.2 l/ha)		Aviator XPro 281 gai/ha (1.25 l/ha)		Proline 250EC 200 gai/ha (0.8 l/ha)	
	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
Mean TGW								
	TGW (g)		TGW (% of control)					
Maritime (n=4)	33.4	29.7 – 36.8	106.0	100.3 – 110.8	106.2	101.5 – 108.0	101.4	93.0 – 105.3
Mediterranean (n=6)	40.8	27.9 – 49.3	101.9	97.0 – 106.6	102.9	94.6 – 111.6	101.2	95.4 – 106.6
North East (n=7)	37.3	32.2 – 44.3	103.5	100.1 – 109.1	104.1	101.7 – 106.3	104.6	102.7 – 108.0
Mean across zones (n=17)	37.6	27.9 – 49.3	103.4	97.0 – 110.8	104.2	94.6 – 111.6	102.6	93.0 – 108.0

Table 3.9-25 – Protein content of rye treated with Miravis Plus at 3.2 L/ha in the presence of *Fusarium* spp.

EPPO climatic zone	Untreated		Miravis Plus 200 gai/ha (3.2 l/ha)		Aviator XPro 281 gai/ha (1.25 l/ha)		Proline 250EC 200 gai/ha (0.8 l/ha)	
	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
Mean % protein content								
	Protein content (%)		Protein content (% of control)					
Maritime (n=4)	7.7	7.1 – 8.2	98.5	97.6 – 100.0	100.1	95.8 – 103.3	99.8	95.8 – 107.2
Mediterranean (n=6)	9.6	7.2 – 11.0	100.6	96.5 – 103.9	101.3	97.8 – 108.7	99.8	96.7 – 101.9
North East (n=7)	8.0	7.3 – 8.6	98.2	88.8 – 103.6	100.3	94.3 – 103.6	100.4	97.5 – 105.2
Mean across zones (n=17)	8.5	7.1 – 11.0	99.1	88.8 – 103.9	100.6	94.3 – 108.7	100.0	95.8 – 107.2

The data provided demonstrate that the proposed application rate of Miravis Plus provides acceptable protection against *Fusarium* spp. in rye. Miravis Plus provided higher control of *Fusarium* spp. than Aviator Xpro (bixafen + prothioconazole) and Proline 250 EC (prothioconazole), and also reduced the levels of Deoxynivalenol mycotoxin and Zearalenone mycotoxin.

In the presence of *Fusarium* spp., the yield after application of Miravis Plus was increased compared to the untreated control and comparable to the reference products. The HLW, TGW, and protein content were all comparable to the untreated and the reference products.

Triticale (winter triticale, spring triticale)

17 effectiveness trials were successfully conducted between 2016 and 2018 in triticale (winter triticale and spring triticale) to assess the control of *Fusarium* spp. provided by Miravis Plus. 5 trials were conducted in the Maritime EPPO climatic zone, 6 in the Mediterranean zone, and 6 in the North-East zone. For GB the focus is on the Maritime EPPO climatic zone data. The trials were conducted in accordance with EPPO standards and Good Experimental Practice (GEP). Applications of Miravis were made at BBCH 58-69 with water volumes of 150-300 L/ha. The summary tables below show the disease control results for *Fusarium* spp. as well as the yield and quality data from the effectiveness trials.

Table 3.9-26 – Effectiveness of Miravis Plus against *Fusarium* spp. at 3.2 L/ha in triticale

Target	EPPO climatic zone	Untreated		Miravis Plus 200 gai/ha (3.2 l/ha)		Aviator XPro 225 gai/ha (1.0 l/ha)		Proline 250EC 200 gai/ha (0.8 l/ha)	
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
Disease severity									
		% disease severity		% control					
<i>Fusarium</i> spp.	Maritime (n=5)	44.8	17.3 – 82.8	67.5	47.9 – 91.6	51.4	30.3 – 91.1	40.5	17.9 – 88.1
	Mediterranean (n=5)	26.2	9.6 – 47.9	87.3	72.3 – 100	84.0	64.2 – 100	86.8	75.3 – 96.4
	North East (n=3)	31.1	5.5 – 77.6	85.9	73.0 – 92.4	81.7	78.6 – 85.6	87.3	81.1 – 93.4
Overall Mean across zones (n=13)		34.5	5.5 – 82.8	79.4	47.9 – 100	70.9	30.3 – 100	69.1	17.9 – 96.4
Disease incidence									
		% disease incidence		% control					
<i>Fusarium</i> spp.	Maritime (n=5)	96.5	83.0 – 100	14.2	0.5 – 32.5	10.0	0.0 – 29.5	7.3	0.0 – 32.0
	Mediterranean (n=6)	79.8	47.5 – 100	50.7	20.5 – 100	43.4	16.5 – 100	42.2	12.0 – 100
	North East (n=6)	51.5	23.5 – 99.5	54.3	27.0 – 71.9	43.2	17.0 – 77.2	53.0	22.6 – 69.1
Overall Mean across zones (n=17)		74.7	23.5 – 100	41.2	0.5 – 100	33.5	0.0 – 100	35.7	0.0 – 100
Deoxynivalenol (DON) mycotoxin content									
		DON (ppb)		% control					
<i>Fusarium</i> spp.	Maritime (n=1)	904.0	-	73.6	-	7.1	-	67.6	-
	Mediterranean (n=2)	427.5	378.0 – 480.0	46.9	0.0 – 93.8	22.9	0.0 – 45.8	25.5	0.0 – 51.0
	North East (n=2)	724.0	450.0 – 998.0	61.7	32.3 – 91.1	76.4	66.7 – 86.1	73.5	69.1 – 77.8
Overall Mean across zones (n=5)		641.4	378.0 – 998.0	58.2	0.0 – 93.8	41.1	0.0 – 86.1	53.1	0.0 – 77.8
Zearalenone (ZER) mycotoxin content									
		ZER (ppb)		% control					
<i>Fusarium</i> spp.	Maritime (n=1)	17.0	-	100	-	100	-	100	-
	Mediterranean (n=2)	30.1	30.0 – 30.1	63.5	26.9 – 100	72.0	44.0 – 100	79.2	58.4 – 100
	North East (n=1)	22.0	-	100	-	0.0	-	100	-
Overall Mean across zones (n=4)		24.8	17.0 – 30.1	81.8	26.9 – 100	61.0	0.0 – 100	89.6	58.4 – 100

Table 3.9-27 – Yield of triticale treated with of Miravis Plus at 3.2 L/ha in the presence of *Fusarium* spp.

EPPO climatic zone	Untreated		Miravis Plus 200 gai/ha (3.2 l/ha)		Aviator XPro 281 gai/ha (1.25 l/ha)		Proline 250EC 200 gai/ha (0.8 l/ha)	
	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
Mean Yield								

	Yield (dt/ha)		Yield (% of control)					
	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
Maritime (n=5)	78.1	66.5 – 96.0	110.2	103.2 – 118.4	109.7	105.0 – 115.6	108.0	102.1 – 113.6
Mediterranean (n=6)	41.5	23.8 – 67.6	112.7	87.6 – 136.8	116.1	91.9 – 143.6	113.7	96.6 – 128.9
North East (n=6)	60.7	39.4 – 72.6	115.1	110.8 – 119.0	110.4	97.4 – 118.9	113.7	106.7 – 120.8
Mean across zones (n=17)	59.0	23.8 – 96.0	112.8	87.6 – 136.8	112.2	91.9 – 143.6	112.0	96.6 – 128.9

Table 3.9-28 – Hectolitre weight (HLW) of triticale treated with Miravis Plus at 3.2 L/ha in the presence of *Fusarium* spp.

EPPO climatic zone	Untreated		Miravis Plus 200 gai/ha (3.2 l/ha)		Aviator XPro 281 gai/ha (1.25 l/ha)		Proline 250EC 200 gai/ha (0.8 l/ha)	
	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
Mean HLW								
	HLW (kg/hl)		HLW (% of control)					
Maritime (n=5)	63.3	26.9 – 74.8	101.7	101.2 – 102.3	102.0	100.6 – 105.4	100.9	97.9 – 105.6
Mediterranean (n=4)	66.9	60.4 – 73.5	102.5	98.1 – 106.2	102.7	97.7 – 107.3	103.0	100.0 – 106.6
North East (n=6)	69.7	62.0 – 76.5	101.7	99.4 – 104.1	100.8	99.5 – 102.9	101.2	99.7 – 103.9
Mean across zones (n=15)	66.8	26.9 – 76.5	101.9	98.1 – 106.2	101.7	97.7 – 107.3	101.6	97.9 – 106.6

Table 3.9-29 – Thousand grain weight (TGW) of triticale treated with Miravis Plus at 3.2 L/ha in the presence of *Fusarium* spp.

EPPO climatic zone	Untreated		Miravis Plus 200 gai/ha (3.2 l/ha)		Aviator XPro 281 gai/ha (1.25 l/ha)		Proline 250EC 200 gai/ha (0.8 l/ha)	
	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
Mean TGW								
	TGW (g)		TGW (% of control)					
Maritime (n=5)	38.8	33.3 – 46.5	106.9	106.4 – 108.5	103.8	98.8 – 108.6	104.3	101.7 – 109.7
Mediterranean (n=4)	38.0	29.4 – 46.3	105.7	97.5 – 119.5	110.6	102.5 – 116.2	110.1	102.1 – 121.1
North East (n=6)	43.3	33.7 – 51.6	107.5	102.6 – 116.6	104.9	101.3 – 113.4	105.0	99.5 – 111.5
Mean across zones (n=15)	40.4	29.4 – 51.6	106.8	97.5 – 119.5	106.1	98.8 – 116.2	106.1	99.5 – 121.1

Table 3.9-30 – Protein content of triticale treated with Miravis Plus at 3.2 L/ha in the presence of *Fusarium* spp.

EPPO climatic zone	Untreated		Miravis Plus 200 gai/ha (3.2 l/ha)		Aviator XPro 281 gai/ha (1.25 l/ha)		Proline 250EC 200 gai/ha (0.8 l/ha)	
	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
Mean % protein content								
	Protein content (%)		Protein content (% of control)					
Maritime (n=1)	12.9	-	96.9	-	97.7	-	96.9	-
Mediterranean (n=4)	11.0	9.7 – 12.3	104.7	98.2 – 109.1	102.4	94.9 – 109.1	103.7	97.8 – 109.1
North East (n=6)	10.2	8.6 – 11.0	100.0	86.9 – 106.3	99.9	95.3 – 104.1	101.7	97.2 – 107.7
Mean across zones (n=11)	10.7	8.6 – 12.9	101.4	86.9 – 109.1	100.6	94.9 – 109.1	102.0	95.8 – 107.2

The data provided demonstrate that the proposed application rate of Miravis Plus provides acceptable protection against *Fusarium* spp. in triticale. Miravis Plus provided higher control of *Fusarium* spp. than Aviator Xpro (bixafen + prothioconazole) and Proline 250 EC (prothioconazole), and also reduced the levels of Deoxynivalenol mycotoxin and Zearalenone mycotoxin.

In the presence of *Fusarium* spp., the yield and TGW after application of Miravis Plus were increased compared to the untreated control and comparable to the reference products. The HLW and protein content were comparable to the untreated and the reference products.

Oats (winter oats, spring oats)

18 effectiveness trials were successfully conducted between 2016 and 2018 in oats (winter oats and spring oats) to assess the control of *Fusarium* spp. provided by Miravis Plus. 5 trials were conducted in the Maritime EPPO climatic zone, 6 in the Mediterranean zone, and 7 in the North-East zone. For GB the focus is on the Maritime EPPO climatic zone data. The trials were conducted in accordance with EPPO standards and Good Experimental Practice (GEP). Applications of Miravis were made at BBCH 58-69 with water volumes of 200-300 L/ha. The summary tables below show the disease control results for *Fusarium* spp. as well as the yield and quality data from the effectiveness trials.

Table 3.9-31 – Effectiveness of Miravis Plus against *Fusarium* spp. at 3.2 L/ha in oats

Table 3.9-31 – Effectiveness of Miravis Plus against <i>Fusarium</i> spp. at 3.2 L/ha in oats									
Target	EPPO climatic zone	Untreated		Miravis Plus 200 gai/ha (3.2 l/ha)		Aviator XPro 225 gai/ha (1.0 l/ha)		Proline 250EC 200 gai/ha (0.8 l/ha)	
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
Disease severity									
		% disease severity		% control					
<i>Fusarium</i> spp.	Maritime (n=3)	24.1	14.3 – 35.3	37.9	9.8 – 57.6	37.5	17.6 – 56.9	37.7	13.7 – 63.5
	Mediterranean (n=2)	11.3	6.9 – 15.6	88.6	77.1 – 100	75.0	54.2 – 95.7	93.8	87.5 – 100
	North East (n=3)	33.4	10.7 – 57.6	74.7	33.8 – 96.9	57.7	32.8 – 92.6	48.1	10.3 – 76.1
Overall Mean across zones (n=8)		24.4	56.9 – 57.6	64.4	9.8 – 100	54.5	17.6 – 95.7	55.6	10.3 – 100
Disease incidence									
		% disease incidence		% control					
<i>Fusarium</i> spp.	Maritime (n=5)	64.1	7.0 – 93.5	42.6	3.2 – 100	34.8	3.7 – 100	39.7	4.3 – 100
	Mediterranean (n=3)	39.2	24.0 – 58.0	78.0	56.9 – 100	65.3	50.0 – 91.7	76.9	43.1 – 100
	North East (n=7)	72.0	34.0 – 99.5	57.2	0.5 – 86.7	46.7	4.0 – 76.2	41.9	0.0 – 65.8
Overall Mean across zones (n=15)		62.8	7.0 – 99.5	56.5	0.5 – 100	46.5	3.7– 100	48.2	0.0 – 100
Deoxynivalenol (DON) mycotoxin content									
		DON (ppb)		% control					
<i>Fusarium</i> spp.	Maritime (n=4)	209.0	125.0 – 330.0	82.0	52.0 – 100	73.3	12.8 – 100	77.1	50.0 – 100
	Mediterranean (n=1)	240.0	-	100	-	100	-	100	-
	North East (n=1)	450.0	-	75.6	-	15.6	-	0.0	-
Overall Mean across zones (n=6)		254.3	125.0 – 450.0	83.9	52.0 – 100	68.1	12.8 – 100	68.1	0.0 – 100
Zearalenone (ZER) mycotoxin content									
		ZER (ppb)		% control					
<i>Fusarium</i> spp.	Maritime (n=2)	19.1	17.0 – 21.2	59.9	19.8 – 100	59.9	19.8 – 100	59.9	19.8 – 100
	Mediterranean (n=2)	52.5	30.0 – 75.0	100	100 – 100	100	100 – 100	100	100 – 100
	North East (n=2)	23.0	17.0 – 28.9	52.8	5.5 – 100	50.0	0.0 – 100	60.4	20.8 – 100
Overall Mean across zones (n=6)		31.5	17.0 – 75.0	70.9	5.5 – 100	70.0	0.0 – 100	73.4	19.8 – 100

Table 3.9-32 – Yield of oats treated with of Miravis Plus at 3.2 L/ha in the presence of *Fusarium* spp.

EPPO climatic zone	Untreated		Miravis Plus 200 gai/ha (3.2 l/ha)		Aviator XPro 281 gai/ha (1.25 l/ha)		Proline 250EC 200 gai/ha (0.8 l/ha)	
	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
Mean Yield								
	Yield (dt/ha)		Yield (% of control)					
Maritime (n=5)	66.3	45.5 – 91.1	106.5	101.1 – 110.6	108.4	101.1 – 116.8	107.4	101.7 – 115.2
Mediterranean (n=3)	27.4	10.4 – 39.5	114.3	106.8 – 128.1	104.8	96.4 – 109.9	111.4	104.4 – 119.5
North East (n=7)	57.9	39.8 – 89.8	110.7	95.0 – 121.8	110.3	95.8 – 119.5	108.1	95.4 – 115.9
Mean across zones (n=15)	54.6	10.4 – 91.1	110.0	95.0 – 128.1	108.6	95.8 – 119.5	108.5	95.4 – 119.5

Table 3.9-33 – Hectolitre weight (HLW) of oats treated with Miravis Plus at 3.2 L/ha in the presence of *Fusarium* spp.

EPPO climatic zone	Untreated		Miravis Plus 200 gai/ha (3.2 l/ha)		Aviator XPro 281 gai/ha (1.25 l/ha)		Proline 250EC 200 gai/ha (0.8 l/ha)	
	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
Mean HLW								
	HLW (kg/hl)		HLW (% of control)					
Maritime (n=4)	49.1	42.8 – 55.7	95.3	83.2 – 101.2	102.1	98.4 – 106.0	103.1	100.0 – 106.8
Mediterranean (n=3)	40.8	35.1 – 45.3	104.7	101.7 – 109.9	104.8	100.0 – 109.4	104.9	102.4 – 108.8
North East (n=7)	47.8	36.6 – 53.5	101.2	96.9 – 104.9	101.6	99.7 – 104.1	101.4	98.9 – 103.2
Mean across zones (n=14)	46.7	35.1 – 55.7	100.3	83.2 – 109.9	102.4	98.4 – 109.4	102.6	97.9 – 106.6

Table 3.9-34 – Thousand grain weight (TGW) of oats treated with Miravis Plus at 3.2 L/ha in the presence of *Fusarium* spp.

EPPO climatic zone	Untreated		Miravis Plus 200 gai/ha (3.2 l/ha)		Aviator XPro 281 gai/ha (1.25 l/ha)		Proline 250EC 200 gai/ha (0.8 l/ha)	
	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
Mean TGW								
	TGW (g)		TGW (% of control)					
Maritime (n=3)	37.7	35.6 – 39.6	104.8	102.5 – 107.1	107.7	100.5 – 113.8	107.2	104.3 – 108.7
Mediterranean (n=3)	30.3	25.0 – 34.7	102.8	89.3 – 117.5	105.2	92.0 – 115.5	104.9	93.0 – 116.2
North East (n=7)	36.2	29.1 – 41.9	103.1	95.8 – 108.2	103.8	99.4 – 106.7	102.0	94.9 – 105.5
Mean across zones (n=13)	35.2	25.0 – 41.9	103.4	89.3 – 117.5	105.0	92.0 – 115.5	103.9	93.0 – 116.2

Table 3.9-35 – Protein content of oats treated with Miravis Plus at 3.2 L/ha in the presence of *Fusarium* spp.

EPPO climatic zone	Untreated		Miravis Plus 200 gai/ha (3.2 l/ha)		Aviator XPro 281 gai/ha (1.25 l/ha)		Proline 250EC 200 gai/ha (0.8 l/ha)	
	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
Mean % protein content								
	Protein content (%)		Protein content (% of control)					
Maritime (n=3)	10.2	8.7 – 12.1	103.1	101.7 – 105.5	106.5	93.4 – 116.3	105.1	95.9 – 113.3
Mediterranean (n=3)	8.8	7.3 – 10.8	110.8	99.9 – 132.5	111.2	98.6 – 132.5	112.9	98.1 – 132.5
North East (n=7)	11.8	9.4 – 13.1	100.7	98.3 – 103.5	101.8	99.0 – 103.6	100.6	96.5 – 103.3
Mean across zones (n=13)	10.7	7.3 – 13.1	103.6	98.3 – 132.5	105.1	93.4 – 132.5	104.5	95.9 – 132.5

The data provided demonstrate that the proposed application rate of Miravis Plus provides acceptable protection against *Fusarium* spp. in oats. Miravis Plus provided comparable control (disease severity) of *Fusarium* spp. to Aviator Xpro (bixafen + prothioconazole) and Proline 250 EC (prothioconazole), and also reduced the levels of Deoxynivalenol mycotoxin and Zearalenone mycotoxin.

In the presence of *Fusarium* spp., the yield after application of Miravis Plus was increased compared to the untreated control and comparable to the reference products. The HLW, TGW and protein content were comparable to the untreated and the reference products.

Oilseed rape (winter oilseed rape, spring oilseed rape)

58 effectiveness trials were successfully conducted between 2016 and 2017 in winter oilseed rape to assess the control of *Sclerotinia sclerotiorum* provided by Miravis Plus. 36 trials were conducted in the Maritime EPPO climatic zone, 3 in the Mediterranean zone, and 19 in the North-East zone. For GB the focus is on the Maritime EPPO climatic zone data. The trials were conducted in accordance with EPPO standards and Good Experimental Practice (GEP). Applications of Miravis were made at BBCH 57-67 with water volumes of 150-300 L/ha. The summary tables below show the disease control results for *Sclerotinia sclerotiorum* as well as the yield and quality data from the effectiveness trials.

Table 3.9-36 – Effectiveness of Miravis Plus against *Sclerotinia sclerotiorum* at 3.2 L/ha in oilseed rape

Target	EPPO climatic zone	Untreated		Miravis Plus 200 gai/ha (3.2 l/ha)		Cantus Gold 200 gai/ha (0.5 l/ha)	
		Mean	min-max	Mean	min-max	Mean	min-max
Mean % disease control							
		% stems infected		% control			
<i>Sclerotinia sclerotiorum</i>	Maritime (n=36)	31.4	5.4 – 72.0	79.7	15.8 – 100	76.6	23.1 – 100
	Mediterranean (n=3)	32.0	22.0 – 38.0	83.3	73.7 – 94.4	62.1	34.2 – 90.9
	North East (n=19)	46.9	15.0 – 92.0	77.4	41.7 – 95.8	77.1	33.3 – 100
Overall Mean across zones (n=58)		36.5	5.4 – 92.0	79.1	15.8 – 95.8	76.0	23.1 – 100

Table 3.9-37 – Yield of oilseed rape treated with of Miravis Plus at 3.2 L/ha in the presence of *Sclerotinia sclerotiorum*

EPPO climatic zone	Untreated		A21857B 200 gai/ha (3.2 l/ha)		Cantus Gold 200 gai/ha (0.5 l/ha)	
	Mean	min-max	Mean	min-max	Mean	min-max
Mean Yield						
	Yield (dt/ha)		Yield (% of control)			
Maritime (n=36)	37.5	17.9 – 54.5	112.7	98.5 – 152.1	109.8	96.4 – 150.3
Mediterranean (n=3)	37.7	33.5 – 43.3	105.2	100.9 – 112.9	105.9	103.6 – 110.0
North East (n=19)	32.6	17.1 – 41.4	117.3	97.4 – 209.1	115.4	93.2 – 177.6
Overall Mean across zones (n=58)	35.9	17.1 – 54.5	113.8	97.4 – 209.1	111.4	93.2 – 177.6

Table 3.9-38 – Thousand grain weight (TGW) of oilseed rape treated with Miravis Plus at 3.2 L/ha in the presence of *Sclerotinia sclerotiorum*

EPPO climatic zone	Untreated		A21857B 200 gai/ha (3.2 l/ha)		Cantus Gold 200 gai/ha (0.5 l/ha)	
	Mean	min-max	Mean	min-max	Mean	min-max
Mean TGW						
	TGW (g)		TGW (% of control)			
Maritime (n=32)	4.54	2.08 – 5.61	104.5	91.9 – 120.4	102.2	87.4 – 109.9

Mediterranean (n=3)	4.59	4.09 – 4.88	101.9	96.7 – 104.9	102.1	99.4 – 104.2
North East (n=19)	4.88	3.91 – 6.37	104.6	95.2 – 116.7	102.2	89.0 – 112.7
Overall Mean across zones (n=54)	4.66	2.08 – 6.37	104.4	91.9 – 120.4	102.2	87.4 – 112.7

Table 3.9-39 – Oil content of oilseed rape treated with Miravis Plus at 3.2 L/ha in the presence of *Sclerotinia sclerotiorum*

EPPO climatic zone	Untreated		A21857B 200 gai/ha (3.2 l/ha)		Cantus Gold 200 gai/ha (0.5 l/ha)	
	Mean	min-max	Mean	min-max	Mean	min-max
Mean % oil content						
	Oil content (%)		Oil content (% of control)			
Maritime (n=16)	44.9	40.4 – 51.4	100.7	97.7 – 103.1	100.8	97.7 – 105.8
Mediterranean (n=1)	46.5	-	99.1	-	100.4	-
North East (n=9)	45.5	36.1 – 50.9	100.8	99.3 – 103.3	101.5	99.5 – 105.4
Overall Mean across zones (n=26)	45.2	40.4 – 51.4	100.7	97.7 – 103.3	101.0	97.7 – 105.8

The data provided demonstrate that the proposed application rate of Miravis Plus provides acceptable protection against *Sclerotinia sclerotiorum* in oilseed rape. Miravis Plus provided comparable control to the reference product Cantus Gold (boscalid + dimoxystrobin).

In the presence of *Sclerotinia sclerotiorum*, the yield after application of Miravis Plus was increased compared to the untreated control and comparable to Cantus Gold. TGW was slightly increased compared to the control, but comparable to Cantus Gold. Oil content was comparable to the untreated and Cantus Gold.

Conclusion

The submitted data demonstrate that pydiflumetofen is sufficiently effective against major target diseases in cereals and oilseed rape GB and NI. A yield benefit in the presence of disease has been demonstrated for all proposed uses of Miravis Plus. Additionally, data provided in the BAD suggest that the proposed application rates are realistic and the minimum effective.

A full consideration of the effectiveness and the minimum effective dose of Miravis Plus will be made at the product authorisation stage.

B.3.10. INFORMATION ON THE DEVELOPMENT OF RESISTANCE

See point B.3.7. of Volume 3 – B.3 (AS) of the pydiflumetofen Draft Assessment Report for information on resistance development for pydiflumetofen.

A detailed consideration of the resistance risk of Miravis Plus, along with a resistance management strategy, will be made at the product authorisation stage.

B.3.11. ADVERSE EFFECTS ON TREATED CROPS

Crop safety of Miravis Plus was assessed in all of the effectiveness trials and in 6 specific disease free trials in wheat, which were conducted for the purpose of breadmaking studies. In multiple effectiveness trials, disease failed to develop to assessable levels and can therefore be used to assess crop safety in the absence of disease. The effectiveness and breadmaking trials, which were all conducted in accordance with GEP, included assessments of phytotoxicity, yield and quality. These are the same trials as the effectiveness trials described under section B.3.9.

In terms of climate, the trials were conducted across the Maritime, Mediterranean and North-East EPPO climatic zones. A wide range of different crop varieties were tested across the trials.

Wheat (winter wheat, spring wheat, durum wheat)

Phytotoxicity was assessed in a total of 213 trials in wheat across the Maritime, North-East and Mediterranean EPPO climatic zones. Most of these trials were conducted in winter wheat, but 29 were in spring wheat and 21 were in durum wheat. Both of the proposed application rates for Miravis Plus, 2.65 L/ha and 3.2 L/ha, were tested in the trial series.

Out of the 213 trials, symptoms of phytotoxicity were observed after an application of Miravis Plus in 10 trials. 8 of these trials were in winter wheat (6 at 2.65 L/ha, 2 at 3.2 L/ha), 1 was in spring wheat at 3.2 L/ha and 1 was in durum wheat at 2.65 L/ha. There was no clear pattern as the symptoms reported varied, including necrosis, leaf tipping, general phytotoxicity, chlorosis, discolouration, and height reduction. Overall, where symptoms were observed they were generally minor and transient, and similar symptoms were typically also observed after application of the reference product(s). The data indicate that the risk of relevant phytotoxicity in wheat is low from the proposed use of Miravis Plus.

The yield of winter wheat was assessed in 6 disease free breadmaking studies after application of Miravis Plus at 3.2 L/ha. It was also assessed in 11 effectiveness trials where disease did not develop (9 at 2.65 L/ha, 2 at 3.2 L/ha). The yield of spring wheat was assessed in 1 effectiveness trial where disease did not develop, at both 2.65 L/ha and 3.2 L/ha. The yield of durum wheat was assessed in 2 effectiveness trials where disease did not develop (2 results at 2.65 L/ha, 1 at 3.2 L/ha).

In all of the disease free trials, the yield of winter wheat, spring wheat or durum wheat after application of Miravis Plus was statistically comparable to the untreated control. The data indicate that adverse effects on the yield of wheat are unlikely from the proposed use of Miravis Plus.

Grain quality was also assessed in the disease free trials, including assessments of thousand grain weight, hectolitre weight and protein content. No negative effects were observed across the trials, indicating that the proposed use of Miravis Plus is unlikely to adversely affect the quality of wheat.

Germination of wheat seed was assessed in 25 of the effectiveness trials, including 14 trials in winter wheat, 7 trials in spring wheat, and 4 trials in durum wheat. The mean germination across all 25 trials was comparable to both the untreated control and the reference product, indicating that the proposed use of Miravis Plus is unlikely to negatively affect germination of seed from treated crops of wheat.

Barley (winter barley, spring barley)

Phytotoxicity was assessed in a total of 225 trials in wheat across the Maritime, North-East and Mediterranean EPPO climatic zones. Most of these trials were conducted in winter barley, but 59 were in spring barley. Both of the proposed application rates for Miravis Plus, 2.65 L/ha and 3.2 L/ha, were tested in the trial series.

Out of the 225 trials, symptoms of phytotoxicity were observed after an application of Miravis Plus in 2 trials, both of which were in spring barley after an application at 2.65 L/ha. In both trials the symptoms reported were black spotting on the lower leaves. The symptoms were at low levels and decreased over time but were not transient. The data indicate that the risk of relevant phytotoxicity in barley is low from the proposed use of Miravis Plus.

The yield of winter barley after application of Miravis Plus was assessed in 13 effectiveness trials where disease did not develop (10 at 2.65 L/ha, 3 at 3.2 L/ha). There were no disease free trials in spring barley. In 10 of the disease free trials, the yield of winter barley after application of Miravis Plus was statistically comparable to the untreated control. In the other 3 trials, the yield was statistically higher after application of Miravis Plus. The data indicate that adverse effects on the yield of barley are unlikely from the proposed use of Miravis Plus.

Grain quality was also assessed in the disease free trials, including assessments of thousand grain weight, hectolitre weight and protein content. No negative effects were observed across the trials, indicating that the proposed use of Miravis Plus is unlikely to adversely affect the quality of barley.

Germination of barley seed was assessed in 18 of the effectiveness trials, including 13 trials in winter barley and 5 trials in spring barley. The mean germination across all 18 trials was comparable to both the untreated control and the reference product, indicating that the proposed use of Miravis Plus is unlikely to negatively affect germination of seed from treated crops of barley.

Rye (winter rye, spring rye)

Phytotoxicity was assessed in a total of 26 trials in winter rye across the Maritime, North-East and Mediterranean EPPO climatic zones. No trials were conducted in spring rye. No symptoms of phytotoxicity were observed in any of the trials, indicating that the risk of relevant phytotoxicity in rye is low from the proposed use of Miravis Plus.

The yield of winter rye after application of Miravis Plus was assessed in 5 effectiveness trials where disease did not develop. In 3 of the disease free trials, the yield of winter rye after application of Miravis Plus was statistically comparable to the untreated control. In the other 2 trials, the yield was statistically higher after application of Miravis Plus. The data indicate that adverse effects on the yield of rye are unlikely from the proposed use of Miravis Plus.

Grain quality was also assessed in the disease free trials, including assessments of thousand grain weight, hectolitre weight and protein content. No negative effects were observed across the trials, indicating that the proposed use of Miravis Plus is unlikely to adversely affect the quality of rye.

Germination of winter rye seed was assessed in 6 of the effectiveness trials. The mean germination across all 6 trials was comparable to both the untreated control and the reference product, indicating that the proposed use of Miravis Plus is unlikely to negatively affect germination of seed from treated crops of rye.

Triticale (winter triticale, spring triticale)

Phytotoxicity was assessed in a total of 19 trials in winter triticale across the Maritime, North-East and Mediterranean EPPO climatic zones. No trials were conducted in spring triticale. No symptoms of phytotoxicity were observed in any of the trials, indicating that the risk of relevant phytotoxicity in triticale is low from the proposed use of Miravis Plus.

The yield of winter triticale after application of Miravis Plus was assessed in 4 effectiveness trials where disease did not develop. In all of the disease free trials, the yield of winter triticale after application of Miravis Plus was statistically comparable to the untreated control, indicating that adverse effects on the yield of triticale are unlikely from the proposed use of Miravis Plus.

Grain quality was also assessed in the disease free trials, including assessments of thousand grain weight, hectolitre weight and protein content. No negative effects were observed across the trials, indicating that the proposed use of Miravis Plus is unlikely to adversely affect the quality of triticale.

Germination of winter triticale seed was assessed in 7 of the effectiveness trials. The mean germination across all 7 trials was comparable to both the untreated control and the reference product, indicating that the proposed use of Miravis Plus is unlikely to negatively affect germination of seed from treated crops of triticale.

Oats (winter oats, spring oats)

Phytotoxicity was assessed in a total of 24 trials in oats across the Maritime, North-East and Mediterranean EPPO climatic zones. This included 11 trials in winter oats and 13 trials in spring oats. No symptoms of phytotoxicity were observed in any of the trials, indicating that the risk of relevant phytotoxicity in oats is low from the proposed use of Miravis Plus.

The yield of oats after application of Miravis Plus was assessed in 10 effectiveness trials where disease did not develop. 7 of these trials were in winter oats and 4 trials were in spring oats. In all of the disease free trials, the yield of oats after application of Miravis Plus was statistically comparable to the untreated control, indicating that adverse effects on the yield of oats are unlikely from the proposed use of Miravis Plus.

Grain quality was also assessed in the disease free trials, including assessments of thousand grain weight, hectolitre weight and protein content. No negative effects were observed across the trials, indicating that the proposed use of Miravis Plus is unlikely to adversely affect the quality of oats.

Germination of oat seed was assessed in 11 of the effectiveness trials, including 5 trials in winter oats and 6 trials in spring oats. The mean germination across all 11 trials was comparable to both the untreated control and the reference product, indicating that the proposed use of Miravis Plus is unlikely to negatively affect germination of seed from treated crops of oats.

Oilseed rape (winter oilseed rape, spring oilseed rape)

Phytotoxicity was assessed in a total of 62 trials in winter oilseed rape across the Maritime, North-East and Mediterranean EPPO climatic zones. No trials were conducted in spring oilseed rape. No symptoms of phytotoxicity were observed in any of the trials, indicating that the risk of relevant phytotoxicity in oilseed rape is low from the proposed use of Miravis Plus.

The yield of winter oilseed rape after application of Miravis Plus was assessed in 4 effectiveness trials where disease did not develop. In all of the disease free trials, the yield of winter oilseed rape after application of Miravis Plus was statistically comparable to the untreated control, indicating that adverse effects on the yield of oilseed rape are unlikely from the proposed use of Miravis Plus.

Thousand grain weight of oilseed rape was also assessed in the disease free trials and no negative effects were observed, indicating that the proposed use of Miravis Plus is unlikely to adversely affect the quality of oilseed rape.

Germination of winter oilseed rape seed was assessed in 19 of the effectiveness trials. The mean germination across all 19 trials was comparable to both the untreated control and the reference product, indicating that the proposed use of Miravis Plus is unlikely to negatively affect germination of seed from treated crops of oilseed rape.

Effects on transformation processes

The results from 5 transformation studies in wheat, which included milling and baking tests demonstrated that wheat treated with Miravis Plus is comparable to the untreated control and no negative effects were observed.

The results from 6 trials in barley demonstrated no adverse effects on malting/brewing processing procedures.

Overall, the data indicate that negative effects on transformation processes are unlikely from the proposed uses of Miravis Plus.

B.3.12. OBSERVATIONS ON OTHER UNDESIRABLE OR UNINTENDED SIDE-EFFECTS

This point will be considered in full at the product authorisation stage. Effects on succeeding crops are considered in section B.3.7.

Impact on adjacent crops

Vapour drift

The applicant has provided the following information on the vapour pressure of pydiflumetofen:

Table 3.12-1 – Vapour pressure and Henry's Law constant

Active ingredient	Vapour Pressure (Pa)m at 25°C	Henry's Law Constant (kPa.m ³ .mol ⁻¹) at 25°C	Interpretation
pydiflumetofen	5.30 x 10 ⁻⁷	1.51 x 10 ⁻⁷	Non-volatile

Based on the information above, the risk to adjacent crops from vapour drift will be low, as any concentrations will be negligible and unlikely to have a negative impact on plants.

Spray drift

The maximum application rate of Miravis Plus is 3.2 L/ha, which delivers 200 g a.s./ha of pydiflumetofen. The proposed uses of Miravis Plus are in field crops, where the estimated drift of a plant protection product at a distance of 1 m from the crop being sprayed is 2.77% (██████████ & ██████████, 2000). When applied at the maximum application rate, a spray drift of 2.77% results in a PER_{off-field} (predicted environmental rate) at 1 m of 88.6 mL/ha of Miravis Plus, equivalent to 5.54 g a.s./ha pydiflumetofen.

A vegetative vigour test and a seedling emergence test were conducted in accordance with the OECD 227 and OECD 208 Guidelines respectively. No phytotoxic effects were observed in the seedling emergence test. In the vegetative vigour test, no phytotoxic effects were observed at application rates of 200 or 400 mL/ha Miravis Plus. Therefore, the amount of Miravis Plus that may drift onto adjacent crops at 1 m, is unlikely to have a negative effect on the plants. The risk to adjacent crops is likely to be acceptable without the need for a buffer zone or drift reducing technology.

Tank cleaning

No effects were observed in the vegetative vigour test at an application rate of 400 mL/ha. This is equivalent to 12.5% of the maximum application rate of Miravis Plus. According to ISO 16119, up to 2.6% of the spray solution will remain in the application equipment. Therefore, it is unlikely that any remaining residues of Miravis Plus will have a negative effect on crops subsequently treated with the same application equipment. The effectiveness of any proposed tank cleaning method will be evaluated at the product authorisation stage.

Effects on beneficial and other non-target organisms

In section B.9.6.2.4 of the ecotoxicology section of the DAR, Volume 3CP B9, the following conclusion is made on non-target arthropods:

'The in-field and off-field risk for other non-target arthropods from the intended uses of the product A21857B in oilseed rape and cereals is acceptable. The off-field risk is indicated to be acceptable based on the available data without the necessity to account for risk mitigation measures.'

B.3.13. REFERENCES 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	Previous evaluation
Volume 3CP point B.3	Unknown	2020	Section 3 Efficacy Data and Information Biological Assessment Dossier Product code: A21857B Product name: MIRAVIS PLUS Chemical active substance: ADEPIDYN™ technology, 62.5 g/L	N	Y	Biological Assessment Dossier for the representative product	Syngenta	N.A.