



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.8 (PPP) – Miravis Plus

Environmental Fate & Behaviour

Great Britain

June 2023

Version History

When	What
October 2022	Initial GB DAR
June 2023	Post Expert Committee on Pesticides (ECP) Independent Scientific Advice (ISA)

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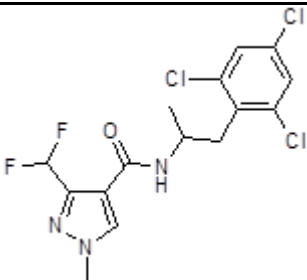
B.8. ENVIRONMENTAL FATE AND BEHAVIOUR

Pydiflumetofen is a new fungicidal active substance developed by Syngenta.

This draft assessment report product assessment (DAR CP) evaluates the submission for regulatory approval of pydiflumetofen in Great Britain under retained Regulation (EC) No 1107/2009. Pydiflumetofen is a fungicide intended for application to cereal and oilseed rape crops. The structure of pydiflumetofen is shown in Table CP B.8. 1.

The models and version numbers used by HSE are listed in Table CP B.8. 2. The GAP table submitted by the applicant for assessment is listed in Table B.8. 3.

Table CP B.8. 1 Structural formula of pydiflumetofen.

<p>Structural formula of pydiflumetofen:</p> <p>N-methoxy-N-[1-methyl-2-(2,4,6-trichlorophenyl)-ethyl]-3-(difluoromethyl)-1-methylpyrazole-4-carboxamide</p>	
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The models and version numbers used by the UK are listed below

Table CP B.8. 2 Models used in the calculation of PECs for pydiflumetofen product ‘Miravis Plus’

Assessment Model	Model Version
FOCUS groundwater model PEARL	v 4.4.4
FOCUS groundwater model PELMO	v 5.5.3
FOCUS groundwater model MACRO	v 5.5.4

Table CP B.8. 3 GAP table for 'Miravis Plus'

1	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. *	Crop and/or situation (crop destination / purpose of crop)	F, Fn, G, Gn, Gpn or I **	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/ synergist per ha
				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		
855a	Wheat, spring (TRZAS)	F	Erysiphe graminis (ERYSGR)	Foliar	BBCH30- 69	a) 1 b) 1	n.a.	a) 2.65 b) 2.65	a) 166 b) 166	100-300	related to BBCH	Maximum of 1 application per crop & season
861a	Wheat, winter (TRZAW)	F	Erysiphe graminis (ERYSGR)	Foliar	BBCH30- 69	a) 1 b) 1	n.a.	a) 2.65 b) 2.65	a) 166 b) 166	100-300	related to BBCH	Maximum of 1 application per crop & season
829	Barley, spring (HORVS)	F	Fusarium spp. (FUSASP)	Foliar	BBCH 55 – 65	a) 1 b) 1	n/a	a) 3.2 b) 3.2	a) 200 b) 200	100-300	related to BBCH	Maximum of 1 application per crop & season
835	Barley, winter (HORVW)	F	Fusarium spp. (FUSASP)	Foliar	BBCH 55 - 65	a) 1 b) 1	n/a	a) 3.2 b) 3.2	a) 200 b) 200	100-300	related to BBCH	Maximum of 1 application per crop & season
860	Wheat, spring (TRZAS)	F	Fusarium spp. (FUSASP)	Foliar	BBCH61- 69	a) 1 b) 1	n.a.	a) 3.2 b) 3.2	a) 200 b) 200	100-300	related to BBCH	Maximum of 1 application per crop & season
866	Wheat, winter (TRZAW)	F	Fusarium spp. (FUSASP)	Foliar	BBCH61- 69	a) 1 b) 1	n.a.	a) 3.2 b) 3.2	a) 200 b) 200	100-300	related to BBCH	Maximum of 1 application per crop & season
867	Oilseed Rape, spring (BRSNS)	F	Sclerotinia sclerotiorum (SCLESC)	Foliar	BBCH57- 69	a) 1 b) 1	n.a.	a) 3.2 b) 3.2	a) 200 b) 200	100-300	related to BBCH	1 application every 3 years
868	Oilseed Rape, winter (BRSNW)	F	Sclerotinia sclerotiorum (SCLESC)	Foliar	BBCH57- 69	a) 1 b) 1	n.a.	a) 3.2 b) 3.2	a) 200 b) 200	100-300	related to BBCH	1 application every 3 years
855b	Wheat, spring (TRZAS)	F	Erysiphe graminis (ERYSGR)	Foliar	BBCH41- 69	a) 1 b) 1	n.a.	a) 2.65 b) 2.65	a) 166 b) 166	100-300	related to BBCH	Secondary GAP Consider this line only if use 855a (BBCH 30-69) is not supportable
861b	Wheat, winter (TRZAW)	F	Erysiphe graminis (ERYSGR)	Foliar	BBCH41- 69	a) 1 b) 1	n.a.	a) 2.65 b) 2.65	a) 166 b) 166	100-300	related to BBCH	Secondary GAP Consider this line only if use 861a (BBCH 30-69) is not supportable

B.8.1. FATE AND BEHAVIOUR IN SOIL

B.8.1.1. Route and rate of degradation in soil

For full details of the assessment of degradation in soil see the associated CA.B.8 document. Endpoints from the CA assessment for use in PEC calculations are listed in tables for each compartment below.

B.8.1.2. Mobility in soil

For full details of the assessment of soil adsorption and mobility in soil see the associated CA.B.8 document. Endpoints from the CA assessment for use in PEC calculations are listed in tables for each compartment below.

B.8.2. PREDICTED ENVIRONMENTAL CONCENTRATIONS IN SOIL (PEC_s)

The only substance triggering assessment of exposure in soil is the active substance, pydiflumetofen.

B.8.2.1. Predicted environmental concentration in soil for ecotoxicological assessment

The CA assessment proposes:

- a DFOP DT50 of 8540 days (DT90 >10000 days) (DFOP parameters $k_1 = 0.05381$, $k_2 = 0.000043$, $g = 0.2484$) as a 1st tier and
- an SFO DT50 of 1310 days as a 2nd tier refinement

from field dissipation studies for use in soil exposure assessment.

The SFO parameter was obtained from a field dissipation study which utilised treated plots cropped with grass. As such this is similar, but not identical to the situation in which pydiflumetofen might be used in. However a much longer dissipation rate was recorded in a field study where the treated bare soil plots were covered with a thin layer of sand immediately after application to prevent losses such as volatilisation and soil surface photolysis; in addition the plots were maintained vegetation-free. As such this longer dissipation rate may be more conservative expression of dissipation under practical field conditions. Following presentation to the Expert Committee on Pesticides (ECP) in the process of seeking Independent Scientific Advice (ISA), the ECP advice was that as a higher tier the longest non-normalised dissipation DT50 and DT90 from the four grassed sites (SFO DT50 1310 days) could be used in the PEC_{soil} calculations. This was due to the grassed sites having a closer reflection of the intended use to environmental conditions in the field.

Given the very slow dissipation seen, accumulation must also be taken into account.

The requested GAPs can be distilled down to three uses as shown below.

Table CP B.8. 4 Summary of requested GAPs for PECsoil calculations

Crop	Cereals	Cereals	Oil Seed Rape
Application rate (g a.s./ha)	166	200	200
Number of applications/interval (d)	1/-	1/-	1/-
Relative application date/BBC growth stage	-/30	-/55	-/57
Crop interception (%)	80	90	80
Soil loading after interception (g a.s./ha)	33.2	20	40
Depth of soil layer (relevant for PEC _{S,plateau}) (cm)	5 cm for 1 year and 20 years 20cm for longer term	5 cm for 1 year and 20 years 20cm for longer term	5 cm for 1 year and 20 years 20cm for longer term
Product dose l/ha	2.65	3.2	3.2
Product dose g/ha ^a	2907	3510.4	3510.4
Models used for calculation	PECsoil spreadsheet	PECsoil spreadsheet	PECsoil spreadsheet

^a assuming formulation density of 1.097 g/cm³ (Volume 3, section CP B.2.6, 2016)

PECsoil calculations have been made assuming 5cm soil depth and soil bulk density of 1.5 g/cm³. As pydiflumetofen is a persistent substance, accumulation in soil has been calculated. For both cereals and oilseed rape use the calculations are based on the same soil properties. The soil depth of 5cm has been used in the calculation of soil accumulation for 20 years as there is the potential in the UK for cereal crops to be established using no- or minimum tillage and thus limiting the depth of soil mixing of the residue. This is in line with current HSE practice. Given the magnitude of the DT50 and DT90 values, the calculated plateau concentrations are predicted to occur after 20 years. The proposed uses of pydiflumetofen are on cereals and oilseed rape. HSE consider it unlikely that there would be no deeper cultivation of arable land over the much longer periods of time required to reach a plateau. Thus for the calculation of the 'final' peak and plateau concentrations, the accumulated plateau has been calculated over a 20cm soil depth. The peak concentration is then calculated by adding the concentration from a single application mixed over 5cm depth to the accumulated plateau calculated over 20cm.

Frequency of use is considered to be annual for cereals and oilseed rape; in addition, because use on oilseed rape every year is likely to be an extreme worst-case, an interval of once every three years has also been taken into consideration (although it can be argued that as rape is frequently grown in rotation with cereals that use every year would occur). The accumulation calculation calculates two values,

- the 'steady state', i.e. the concentration immediately before the next application, and
- the 'peak' i.e. the maximum concentration reached following an application after the 'steady state' has been reached.

Accumulation calculations are normally conducted for up to 20 years use. Given the very slow dissipation of pydiflumetofen observed in studies, the use period has been extended until there is no increase in concentration. Concentrations are shown from 20 years use (or after 22 years in the case of a 1 in 3 rotational scenario for oilseed rape) and for the highest predicted concentration when the plateau is reached beyond that.

Tier 1 - PECsoil with DFOP DT50 of 8540 days (DT90 >10000 days).

DFOP parameters are $k_1 = 0.05381$, $k_2 = 0.000043$, $g = 0.2484$.

Calculations have been conducted with Excel spreadsheets able to utilise DFOP parameters'. Excel was used to calculate an accumulation factor which can be used to calculate the final 'steady state' plateau concentration. In

the case of the DFOP parameters it seems that the plateau is not predicted to occur until much longer than 100 years continuous annual applications. Therefore the concentrations after 20 years have also been given.

The Excel spreadsheet calculated an accumulation factor of 47.513 after many years use. Therefore the following accumulated residues based on initial PECsoil of 0.044 mg/kg for 166 g a.s./ha with 80% interception are calculated.

Table CP B.8. 5 PECsoil for use on cereals at BBCH 30, 166 g pydiflumetofen/ha, 80% crop interception

	PECsoil
PECini	0.044
'Steady state' (mg/kg) after 20 years, 5cm depth	0.567
'Peak' (mg/kg) after 20 years (5cm)	0.611
'Steady state' (mg/kg) final, 20 cm depth ¹	0.526
'Peak' (mg/kg) final ¹ (5 cm)	0.570

¹ Note: final values reflect a plateau reached after more than 100 years

Note that a worst case accumulated PECsoil was derived following 20 years consecutive use with mixing over a 5 cm soil later. Although accumulation continued beyond 20 years, taking into account a deeper mixing zone of 20cm for this longer time period (to reflect likely agronomic activities) the steady state level was lower.

The Excel spreadsheet calculated an accumulation factor of 47.513. Therefore the following accumulated residues based on initial PECsoil of 0.027 mg/kg for 200 g a.s./ha with 90% interception are calculated.

Table CP B.8. 6 PECsoil for use on cereals at BBCH 55, 200 g pydiflumetofen/ha, 90% crop interception

	PECsoil
PECini	0.027
'Steady state' (mg/kg) after 20 years, 5cm depth	0.341
'Peak' (mg/kg) after 20 years	0.368
'Steady state' (mg/kg) final, 20 cm depth ¹	0.317
'Peak' (mg/kg) final ¹	0.344

¹ Note: final values reflect a plateau reached after more than 100 years

Note that a worst case accumulated PECsoil was derived following 20 years consecutive use with mixing over a 5 cm soil later. Although accumulation continued beyond 20 years, taking into account a deeper mixing zone of 20cm for this longer time period (to reflect likely agronomic activities) the steady state level was lower.

The Excel spreadsheet calculated an accumulation factor of 47.513. Therefore the following accumulated residues based on initial PECsoil of 0.053 mg/kg for 200 g a.s./ha with 80% interception are calculated.

Table CP B.8. 7 PECsoil for use on oilseed rape at BBCH 57, 200 g pydiflumetofen/ha, 80% crop interception

	PECsoil
PECini	0.053
'Steady state' (mg/kg) after 20 years, 5cm depth	0.683
'Peak' (mg/kg) after 20 years	0.736
'Steady state' (mg/kg) final, 20 cm depth ¹	0.634
'Peak' (mg/kg) final ¹	0.687

¹ Note: final values reflect a plateau reached after more than 100 years

Note that a worst case accumulated PECsoil was derived following 20 years consecutive use with mixing over a 5 cm soil later. Although accumulation continued beyond 20 years, taking into account a deeper mixing zone of 20cm for this longer time period (to reflect likely agronomic activities) the steady state level was lower.

Tier 2 - PECsoil with SFO DT50 1310 days

Table CP B.8. 8 PECsoil for use on cereals at BBCH 30, 166 g pydiflumetofen/ha, 80% crop interception

		TWA
PECINI mg/kg (1st)	0.044	0.044
1	0.044	0.044
2	0.044	0.044
4	0.044	0.044
7	0.044	0.044
14	0.044	0.044
21	0.044	0.044
28	0.044	0.044
48	0.043	0.044
100	0.042	0.043
Accumulated PECsoil after 20 years		
‘Steady state’ (mg/kg), 5cm depth	0.202	
‘Peak’ (mg/kg)	0.247	
Accumulated PECsoil after 36 years		
‘Steady state’ (mg/kg), 20 cm depth ¹	0.052	
‘Peak’ (mg/kg) ¹	0.096	

¹ Note: if final accumulation was calculated over 5cm, steady state would be 0.208 mg/kg and peak 0.252 mg/kg

Table CP B.8. 9 PECsoil for use on cereals at BBCH 55, 200 g pydiflumetofen/ha, 90% crop interception

		TWA
PECINI mg/kg (1st)	0.027	0.027
1	0.027	0.027
2	0.027	0.027
4	0.027	0.027
7	0.027	0.027
14	0.026	0.027
21	0.026	0.027
28	0.026	0.026
48	0.026	0.026
100	0.025	0.026
Accumulated PECsoil after 20 years		
‘Steady state’ (mg/kg), 5cm depth	0.122	
‘Peak’ (mg/kg)	0.149	
Accumulated PECsoil after 32 years		
‘Steady state’ (mg/kg), 20 cm depth ¹	0.031	
‘Peak’ (mg/kg) ¹	0.058	

¹ Note: if final accumulation was calculated over 5cm, steady state would be 0.125 mg/kg and peak 0.152 mg/kg

Table CP B.8. 10 PECsoil for use on oilseed rape at BBCH 57, 200 g pydiflumetofen/ha, 80% crop interception

		TWA
PECINI mg/kg (1st)	0.053	0.053
1	0.053	0.053
2	0.053	0.053
4	0.053	0.053
7	0.053	0.053
14	0.053	0.053
21	0.053	0.053
28	0.053	0.053
48	0.052	0.053
100	0.051	0.052
Accumulated PECsoil after 20 years (annual application)		
‘Steady state’ (mg/kg), 5cm depth	0.244	
‘Peak’ (mg/kg)	0.297	
Accumulated PECsoil after 39 years (annual application)		
‘Steady state’ (mg/kg), 20 cm depth ¹	0.063	
‘Peak’ (mg/kg) ¹	0.116	
Accumulated PECsoil after 22 years (application every 3rd year)		
‘Steady state’ (mg/kg), 5cm depth	0.067	
‘Peak’ (mg/kg)	0.120	
Accumulated PECsoil after 28 years (application every 3rd year)		
‘Steady state’ (mg/kg), 20 cm depth ²	0.017	
‘Peak’ (mg/kg) ²	0.070	

¹ Note: if final accumulation was calculated over 5cm, steady state would be 0.250 mg/kg and peak 0.304 mg/kg

² Note: if final accumulation was calculated over 5cm, steady state would be 0.068 mg/kg and peak 0.121 mg/kg

To summarise, the maximum PECsoil values for the range of GAPs are:

1st tier – 0.736 mg a.s./ha

2nd tier – 0.297 mg a.s./kg

Initial PEC has also been calculated for the formulation ‘Miravis Plus’ as follows. As the formulation is composed of different components, and each is assumed to dissipate independently of the others, only the initial PECsoil after a single application has been calculated.

Table CP B.8. 11 PECsoil for the formulation ‘Miravis Plus’

Use	PECsoil (mg formulation/kg)
Cereals, 2907 g/ha, 80% interception	0.775
Cereals, 3510.4 g/ha, 90% interception	0.468
Oilseed rape, 3510.4 g/ha, 80% interception	0.936

B.8.2.2. Predicted environmental concentration in soil for residues in rotational crops assessment

PECsoil is also required for the assessment of residues in rotational crops; this is based on the requirements of the OECD guidance document on residues in rotational crops (ENV/JM/MONO(2018)9), hereafter referred to as OECD 2018.

The requirements are:

- Rotational crops studies are needed if DT90 is greater than 100 days
- Rotational crop studies which take account of accumulation are needed if DT90 is greater than 500 days or DT50 is greater than 150 days.

As noted, the CA assessment proposes

- a DFOP DT50 of 8540 days (DT90 >10000 days) (DFOP parameters $k_1 = 0.05381$, $k_2 = 0.000043$, $g = 0.2484$) as a 1st tier and
- an SFO DT50 of 1310 days as a second tier refinement

for use in PECsoil calculation. Therefore both these requirements are met as pydiflumetofen has a DT50 well in excess of these values irrespective of which endpoint is used.

Following presentation to the ECP in the process of seeking ISA, the ECP advised that the refinement of the longest non-normalised dissipation DT50 and DT90 from the four grassed sites (SFO DT50 1310 days) could be used in the PECsoil calculations. This was due to the grassed sites having a closer reflection of the intended use to environmental conditions.

In addition the ECP advised that, with respect to the calculation of soil exposure for consumer risk assessment from residues in rotational crops, the calculations of soil exposure should take into account crop interception. In this particular case, given the exclusive post-emergence use of the active substance, calculations assuming the default assumption recommended by OECD 2018 of zero crop interception (intended to be of relevance to all to all potential future uses of an active ingredient in any rotational system) were advised to be overly conservative.

With respect to the assessment of residues in rotational crops, the applicant had notified a further possible use of pydiflumetofen which may need consideration in addition to the proposed uses on cereals and oilseed rape (see MRL assessment uses, in section 1.5.3 (Volume 1). This is use in carrots¹ with a GAP of two applications of 70 g a.s./ha. Application would be at crop growth stage BBCH 14-49 with a minimum 14 day interval. For the purposes of soil exposure calculation the two applications are added together; given the magnitude of the dissipation DT50 value, the extent of dissipation in the 14 day interval would be negligible. In addition, it is assumed by HSE that the application is subject to 25% crop interception, in line with FOCUS Groundwater guidance on crop interception values to be used for use on carrot. It is considered by HSE that the FOCUS Groundwater crop interception values are the most appropriate set of crop interception values to use as this is in alignment with PECsoil, PECgw and PECsw calculations in GB regulatory practice.

Annual applications of pydiflumetofen to the same crop site are assumed (as per OECD, 2018). Whilst the annual dose applied to carrot, 140 g a.s./ha, is lower than for the requested use on cereals and oilseed rape (200 g a.s./ha), the more advanced growth stages proposed in the cereals and oilseed rape GAP attract crop interception values of 80-90%. Thus the use on carrot is the worst case in terms of soil exposure with soil exposure of 105 g a.s./ha after interception compared to 20 g a.s./ha for cereals and 40 g a.s./ha for oilseed rape. Therefore, the calculations of soil exposure for consumer risk assessment from residues in rotational crops are only conducted for the use on carrots and use the 2nd tier assumption of an SFO DT50 of 1310 days as this represents the worst case.

The following results are recorded and can be used in consumer risk assessment.

¹ There are additional uses for parsley root and parsnips; considering the GAPs, carrots is a suitable representative worst case for these uses in this rotational crops assessment.

Table CP B.8. 12 PECsoil for use in residues in rotational crops assessment, dose 140 g a.s./ha, SFO DT50 – 1310 days

Accumulation factor long term use	f_{acc}	(-)	4.6940
Application rate corresponding to soil residues from long term use	$A_{plateau}$	g a.s./ha	492.9
Application rate corresponding to total soil residues from long term use and crop failure	A_{total}	g a.s./ha	632.9

B.8.3. PREDICTED ENVIRONMENTAL CONCENTRATIONS IN GROUND WATER (PEC_{GW})

Report:	K-CP 9.2.4/01. [REDACTED] (2020), Pydiflumetofen - A Leaching Assessment for Parent Using the FOCUS Groundwater Models Following Spray Application to Spring and Winter Cereals Report No. RAJ1319B Document No. VV-855540
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Guideline(s): FOCUSgw Generic guidance v 2.2
GLP/GEP: No; modelling report thus GLP not relevant
Deviation(s): No major deviation identified
Acceptability Yes

Report:	K-CP 9.2.4/02. [REDACTED] (2020), Pydiflumetofen - A Leaching Assessment for Parent Using the FOCUS Groundwater Models Following Spray Application to Summer and Winter Oil Seed Rape Report No. RAJ1321B Document No. VV-855549
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Guideline(s): FOCUSgw Generic guidance v 2.2
GLP/GEP: No; modelling report thus GLP not relevant
Deviation(s): No major deviation identified
Acceptability Yes

Report:	K-CP 9.2.4/03. [REDACTED], (2019), Pydiflumetofen – An Extended Leaching Assessment Using the PEARL 4.4.4 and PELMO 5.5.3 Groundwater Models Following Spray Application to Spring and Winter Cereals Report No. RAJ1311B Document No. VV-854830
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Guideline(s): FOCUSgw Generic guidance v 2.2
GLP/GEP: No; modelling report thus GLP not relevant
Deviation(s): Major deviation identified – extension of period of simulation
Acceptability Yes

Report:	K-CP 9.2.4/04. [REDACTED], (2019), Pydiflumetofen – An Extended Leaching Assessment Using the PEARL 4.4.4 and PELMO 5.5.3 Groundwater Models Following Spray Application to Summer and Winter Oilseed Rape Report No. RAJ1310B Document No. VV-854828
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Guideline(s): FOCUSgw Generic guidance v 2.2
GLP/GEP: No; modelling report thus GLP not relevant
Deviation(s): Major deviation identified – extension of period of simulation
Acceptability Yes

Report:	K-CP 9.2.4/05. [REDACTED], (2019), Pydiflumetofen – An Extended Leaching Assessment with Limited Applications Using the PEARL 4.4.4 and PELMO 5.5.3 Groundwater Models Following Spray Application to Brassicas, Carrots, Cucurbits, Pome Fruit, Potatoes, Spring and Winter Cereals, Summer and Winter Oilseed Rape, Tomatoes, and Vines Report No. RAJ1344B Document No. VV-855100
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Guideline(s):	FOCUSgw Generic guidance v 2.2
GLP/GEP:	No; modelling report thus GLP not relevant
Deviation(s):	Major deviation identified – extension of period of simulation
Acceptability	Yes

The CA assessment proposes the following endpoints for groundwater exposure modelling of pydiflumetofen. Pydiflumetofen is the only substance triggering groundwater assessment.

Table CP B.8. 13 Substance input parameters for FOCUSgw modelling of pydiflumetofen

Compound	Pydiflumetofen
Molar mass (g/mol)	426.7
Water solubility (mg/L)	1.5 (25°C)
Saturated vapour pressure (Pa)	1.84 x 10 ⁻⁷ (20°C) 5.30 x 10 ⁻⁷ (25°C)
DT₅₀ in soil (d) field	1334 (geomean, normalisation to pF2, 20 °C with Q ₁₀ of 2.58, n = 5)
K_{foc} / K_{fom} (mL/g)	1706 / 989.56 (geomean, n = 6)
1/n	0.876 (arithmetic mean, n = 6)
Plant uptake factor	0
Washoff Factor (1/m) (PEARL)	0.0001 (default)
Foliar DT₅₀ (d)	10 (default)

The DT50 reflects the results of field dissipation studies conducted using a design optimised for generating DegT50 values in the soil bulk matrix. The results of field dissipation studies conducted on plots where grass was allowed to grow were discounted from the calculation of DegT50 values for modelling purposes.

The following GAP details were simulated by the applicant.

Table CP B.8. 14 GAP details used in FOCUSgw modelling of pydiflumetofen

Use No.	855a	855b*	829, 860	829, 860
Crop	Spring Cereals	Spring Cereals	Spring Cereals	Spring Cereals
Application rate (g a.s./ha)	166	166	200	200
Number of applications/interval (d)	1/-	1/-	1/-	1/-
Relative application date/BBCH growth stage	-/30	-/41	-/55	-/69
Crop interception (%)	80	90	90	90
Frequency of application	annual	annual	annual	annual
FOCUS models used for calculation	PEARL v4.4.4, PELMO v5.5.3, MACRO v5.5.4	PEARL v4.4.4, PELMO v5.5.3, MACRO v5.5.4	PEARL v4.4.4, PELMO v5.5.3, MACRO v5.5.4	PEARL v4.4.4, PELMO v5.5.3, MACRO v5.5.4
Use No.	861a	861b*	835, 866	835, 866
Crop	Winter Cereals	Winter Cereals	Winter Cereals	Winter Cereals
Application rate (g a.s./ha)	166	166	200	200
Number of applications/interval (d)	1/-	1/-	1/-	1/-
Relative application date/BBCH growth stage	-/30	-/41	-/55	-/69
Crop interception (%)	80	90	90	90
Frequency of application	annual	annual	annual	annual
FOCUS models used for calculation	PEARL v4.4.4, PELMO v5.5.3, MACRO v5.5.4	PEARL v4.4.4, PELMO v5.5.3, MACRO v5.5.4	PEARL v4.4.4, PELMO v5.5.3, MACRO v5.5.4	PEARL v4.4.4, PELMO v5.5.3, MACRO v5.5.4
Use No.	867	867	868	868
Crop	Summer Oil Seed Rape	Summer Oil Seed Rape	Winter Oil Seed Rape	Winter Oil Seed Rape
Application rate (g a.s./ha)	200	200	200	200
Number of applications/interval (d)	1/-	1/-	1/-	1/-
Relative application date/BBCH growth stage	-/57	-/69	-/57	-/69
Crop interception (%)	80	80	80	80
Frequency of application	Triennial (every third year)	Triennial (every third year)	Triennial (every third year)	Triennial (every third year)
FOCUS models used for calculation	PEARL v4.4.4, PELMO v5.5.3, MACRO v5.5.4	PEARL v4.4.4, PELMO v5.5.3, MACRO v5.5.4	PEARL v4.4.4, PELMO v5.5.3, MACRO v5.5.4	PEARL v4.4.4, PELMO v5.5.3, MACRO v5.5.4

*Relevant for extended 66 year assessment only NOTE: MACRO was not used to conduct any non-standard extended groundwater leaching assessments

The following application dates were used in the simulations.

Table CP B.8. 15 Application dates used in FOCUSgw modelling of pydiflumetofen

Crop ^a	Scenario	Application dates (absolute)
Spring Cereals BBCH 30 Use no. 855a	Châteaudun	16 April
	Hamburg	28 April
	Kremsmünster	27 April
	Okehampton	22 April
Spring Cereals BBCH 41 Use no. 855b	Châteaudun	06 May
	Hamburg	12 May
	Kremsmünster	11 May
	Okehampton	03 May
Spring Cereals BBCH 55 Use no. 829, 860	Châteaudun	01 June
	Hamburg	30 May
	Kremsmünster	30 May
	Okehampton	17 May
Spring Cereals BBCH 69 Use no. 855a, 855b, 829, 860	Châteaudun	22 June
	Hamburg	28 June
	Kremsmünster	28 June
	Okehampton	18 June
	Porto	22 June
Winter Cereals BBCH 30 Use no. 861a	Châteaudun	15 April
	Hamburg	04 May
	Kremsmünster	24 April
	Okehampton	21 April
Winter Cereals BBCH 41 Use no. 861b	Châteaudun	02 May
	Hamburg	14 May
	Kremsmunster	09 May
	Okehampton	30 April
Winter Cereals BBCH 55 Use no. 835, 866	Châteaudun	23 May
	Hamburg	27 May
	Kremsmünster	29 May
	Okehampton	11 May
Winter Cereals BBCH 69 Use no. 861a, 861b, 835, 866	Châteaudun	14 June
	Hamburg	22 June
	Kremsmünster	25 June
	Okehampton	07 June

Crop ^a	Scenario	Application dates (absolute)
Summer Oil Seed Rape , BBCH 57, Use No. 867	Okehampton	12 May
Summer Oil Seed Rape, BBCH 69, Use No. 867	Okehampton	13 June
Winter Oil Seed Rape BBCH 57 Use No. 868	Châteaudun	14 April
	Hamburg	02 May
	Kremsmünster	02 May
	Okehampton	27 April
Winter Oil Seed Rape BBCH 69 Use No. 868	Châteaudun	14 May
	Hamburg	30 May
	Kremsmünster	30 May
	Okehampton	25 May

^a for uses numbers see GAP details in Table CP B.8.3

Standard FOCUSgw modelling is run for 6 + 20 years for annual crops and 6+ 60 years for crops grown with a frequency of one year in three; the first 6 years is a ‘warm-up’ period and discarded from the results used for regulatory decision-making. However during the European assessment of this active substance, non-standard groundwater modelling was requested by the European regulators. This was because European regulators noted that towards the end of some standard FOCUSgw simulations, the predicted concentrations in soil water at 1m depth were increasing year on year whilst remaining below 0.1 µg/L. As a result, European regulators requested that simulations were performed for longer than the standard time periods to investigate leaching potential over longer periods of time.

Given this experience, the applicant also submitted the results of similar extended non-standard FOCUSgw simulations for consideration in GB. The simulations were performed assuming annual application but extended to annual applications over 6 + 60 years.

The applicant also submitted non-standard modelling designed to assess groundwater contamination if registration was allowed for 16 years followed by 50 years of no use. The 16 years was chosen to reflect a 10 year approval period and an additional six year period to reflect uncertainties in the regulatory decision-making process. The first six years of the 16 year application period is discarded from consideration as this is the usual six year ‘warm-up’ period.

Results of the modelling are presented below. Note that the results of the standard modelling are the 80th percentile annual average (or triennial average in the case of oilseed rape grown on a one year in three frequency).

Table CP B.8. 16 PEC_{GW} for pydiflumetofen with FOCUS PEARL v4.4.4 /PELMO v5.5.3 and MACRO v5.5.4 from the ‘standard’ 26 year assessment following single application to cereals, annual application

Crop ^a	Scenario	80 th Percentile PEC _{GW} at 1 m Soil Depth (µg/L)
Spring Cereals BBCH 30 Use no. 855a	Châteaudun*	< 0.001
	Hamburg	< 0.001
	Kremsmünster	< 0.001
	Okehampton	< 0.001
Spring Cereals BBCH 55 Use no. 829, 860	Châteaudun*	< 0.001
	Hamburg	< 0.001
	Kremsmünster	< 0.001
	Okehampton	< 0.001
Spring Cereals BBCH 69 Use no. 829, 860	Châteaudun*	< 0.001
	Hamburg	< 0.001
	Kremsmünster	< 0.001
	Okehampton	< 0.001
Winter Cereals BBCH 30 Use no. 861a	Châteaudun*	< 0.001
	Hamburg	< 0.001
	Kremsmünster	< 0.001
	Okehampton	< 0.001
Winter Cereals BBCH 55 Use no. 835, 866	Châteaudun*	< 0.001
	Hamburg	< 0.001
	Kremsmünster	< 0.001
	Okehampton	< 0.001
Winter Cereals BBCH 69 Use no. 835, 866	Châteaudun*	< 0.001
	Hamburg	< 0.001
	Kremsmünster	< 0.001
	Okehampton	< 0.001

*For MACRO only Chateaudun scenario is defined

^a for uses numbers see GAP details in Table CP B.8.3

Table CP B.8. 17 PEC_{GW} for pydiflumetofen with FOCUS PEARL v4.4.4, FOCUS PELMO v5.5.3 and FOCUS MACRO v5.5.4 from the ‘standard’ 66 year assessment following single application to oil seed rape, application one in every three years

Crop ^a	Scenario	80 th Percentile PEC _{GW} at 1 m Soil Depth (µg/L)		
		PEARL	PELMO	MACRO
Summer Oil Seed Rape, BBCH 57, Use no. 867	Okehampton	0.010	0.008	NA
Summer Oil Seed Rape, BBCH 69, Use no. 867	Okehampton	0.010	0.008	NA
Winter Oil Seed Rape BBCH 57 Use no. 868	Châteaudun	< 0.001	< 0.001	< 0.001
	Hamburg	0.008	0.003	NA
	Kremsmünster	0.002	0.001	NA
	Okehampton	0.017	0.018	NA
Winter Oil Seed Rape BBCH 69 Use no. 868	Châteaudun	< 0.001	< 0.001	< 0.001
	Hamburg	0.008	0.003	NA
	Kremsmünster	0.002	0.001	NA
	Okehampton	0.017	0.018	NA

NA = not applicable, scenario not parameterised in MACRO, MACRO only being parameterised for Châteaudun

^a for uses numbers see GAP details in Table CP B.8.3

As noted, the standard simulations on cereals resulted in all scenarios being predicted to have 80th percentile annual average concentrations <0.001 µg/L.

For oilseed rape, even though the applications were made once every three years, the standard longer term simulations, i.e. a total of 6 + 60 years use reflecting a rotational use frequency of 1 year in every three, predicted triennial average concentrations > 0.001 µg/L but < 0.1 µg/L. This suggests that whilst pydiflumetofen is strongly adsorbed to soil, the very slow degradation results in very gradual transport through the soil until ultimately the accumulating residue reaches 1 metre depth. Scrutiny of the detailed model output shows that there was a pattern of increasing concentrations toward the end of the standard simulation period. This had also been observed for more vulnerable GAPs simulated for European regulatory purposes.

To consider the impact of a much longer period of continuous use of pydiflumetofen, the results of the applicants non-standard FOCUS_{gw} modelling assuming 6+60 years of annual applications are shown below. The values presented are the highest three-year average values, NOT the 80th percentile annual average. The applicant triennial concentrations were calculated by summing the substance mass and water volume fluxes for each three year period and then dividing the three year mass flux by the three year volume flux. This is the FOCUS method of calculating triennial average concentrations.

Table CP B.8. 18 PEC_{GW} for pydiflumetofen from ‘non-standard’ FOCUS PEARL v4.4.4 and FOCUS PELMO v5.5.3 modelling assuming annual usage over 66 year period to cereals, highest triennial average

Crop ^a	Scenario	High 3 yr average PEC _{gw} at 1 m Soil Depth (µg/L)	
		FOCUS PEARL 4.4.4	FOCUS PELMO 5.5.3
Spring Cereals Use no. 855a BBCH 30	Châteaudun	< 0.001	< 0.001
	Hamburg	0.097	0.031
	Kremsmünster	0.035	0.011
	Okehampton	0.137	0.123
Spring Cereals Use no. 855b BBCH 41	Châteaudun	< 0.001	< 0.001
	Hamburg	0.025	0.006
	Kremsmünster	0.006	0.002
	Okehampton	0.038	0.033
Spring Cereals Use no. 829, 860 BBCH 55	Châteaudun	< 0.001	< 0.001
	Hamburg	0.037	0.009
	Kremsmünster	0.01	0.003
	Okehampton	0.055	0.048
Spring Cereals Use no. 829, 860 BBCH 69	Châteaudun	< 0.001	< 0.001
	Hamburg	0.037	0.009
	Kremsmünster	0.01	0.003
	Okehampton	0.054	0.048
Winter Cereals Use no. 861a BBCH 30	Châteaudun	< 0.001	< 0.001
	Hamburg	0.093	0.046 (0.045 period 20) ¹
	Kremsmünster	0.041	0.024 (0.023 period 20) ¹
	Okehampton	0.171	0.17 (0.167 period 20)¹
Winter Cereals Use no. 861b BBCH 41	Châteaudun	< 0.001	< 0.001
	Hamburg	0.025	0.009
	Kremsmünster	0.008	0.004
	Okehampton	0.051	0.049
Winter Cereals Use no. 835, 866 BBCH 55	Châteaudun	< 0.001	< 0.001
	Hamburg	0.036	0.014
	Kremsmünster	0.012	0.006
	Okehampton	0.072	0.069
Winter Cereals Use no. 835, 866 BBCH 69	Châteaudun	< 0.001	< 0.001
	Hamburg	0.036	0.014
	Kremsmünster	0.012	0.006
	Okehampton	0.071	0.069

¹ Values in parentheses are from HSE attempts to validate PELMO modelling. Period 20 is the average of years 64, 65 and 66.

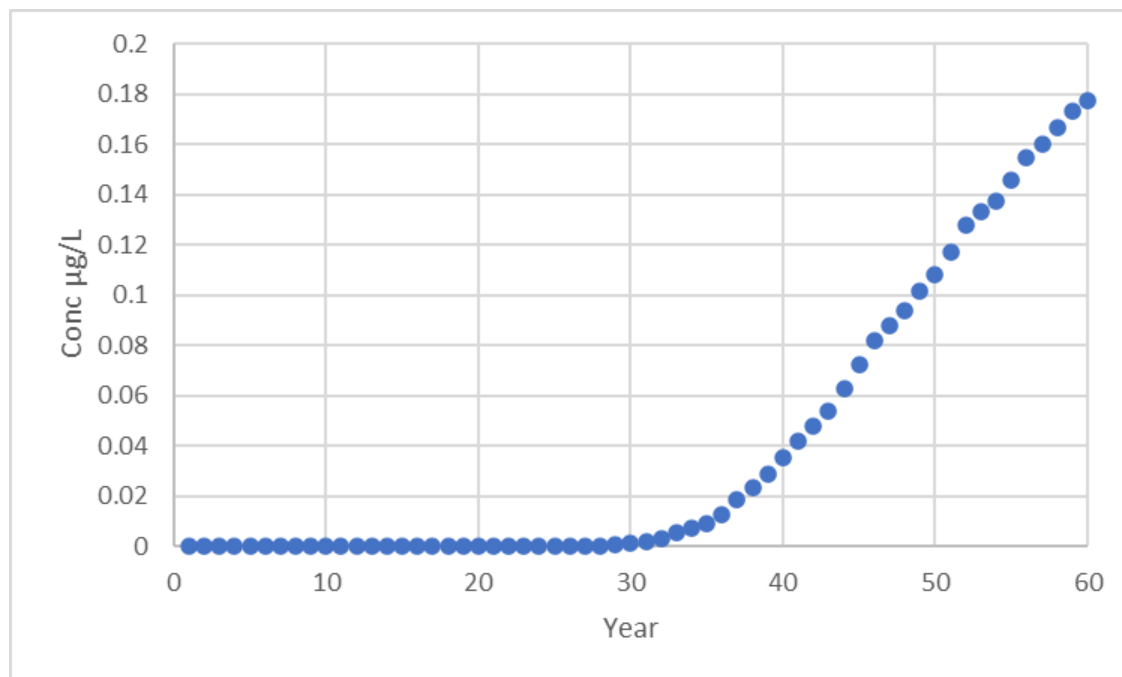
^a for uses numbers see GAP details in Table CP B.8.3

As can be seen, the simulations of longer application periods of 66 years in cereals indicate that concentrations of pydiflumetofen would increase. In the case of later applications assuming crop interception of 90% the highest three year average is <0.1 µg/L for all scenarios. However, in the case of the earlier applications at BBCH 30 and assuming 80% interception, the highest three year average was predicted to be >0.1 µg/L at the Okehampton scenario with both PEARL and PELMO. In addition, PEARL predicted the concentration at Hamburg to be close to, but less than, 0.1 µg/L.

HSE was able to reproduce selective results with PEARL but could not reproduce the values with PELMO. Therefore the calculations for winter cereals at BBCH 30 and with winter oilseed rape at BBCH 57 were performed as these appeared to give the highest predicted concentrations. HSE results are given in parentheses in the results tables.

HSE reproduced the modelling for winter cereals with application at BBCH 30 to consider the concentrations in more detail. Simulation was only performed with PEARL as PEARL appeared to generally predict higher concentrations than PELMO.

Figure CP B.8. 1 Profile of predicted groundwater concentrations (annual average, $\mu\text{g/L}$ at 1m depth, Okehampton scenario) following 6+60 years annual applications of pydiflumetofen to cereals



This shows a clear increase in predicted concentrations at the end of the simulation period with the concentrations only rising to $>0.001 \mu\text{g/L}$ at year 30.

Results for oilseed rape are shown below.

Table CP B.8. 19 PEC_{GW} for pydiflumetofen from ‘non-standard’ FOCUS PEARL v4.4.4 and FOCUS PELMO v5.5.3 modelling assuming annual usage over 66 year period to oilseed rape, highest triennial average

Crop ^a	Scenario	High 3 yr average PEC _{gw} at 1 m Soil Depth (µg/L)	
		FOCUS PEARL 4.4.4	FOCUS PELMO 5.5.3
Summer Oil Seed Rape, Use no. 867, BBCH 57	Okehampton	0.026	0.024
Summer Oil Seed Rape, Use no. 867, BBCH 69	Okehampton	0.026	0.024
Winter Oil Seed Rape Use no. 868 BBCH 57	Châteaudun	< 0.001	< 0.001
	Hamburg	0.019 (0.142 period 20) ¹	0.007 (0.075 period 20) ¹
	Kremsmünster	0.006 (0.070 period 20) ¹	0.003 (0.044 period 20) ¹
	Okehampton	0.036 (0.224 period 20) ¹	0.042 (0.261 period 20) ¹
Winter Oil Seed Rape Use no. 868 BBCH 69	Châteaudun	< 0.001	< 0.001
	Hamburg	0.019	0.007
	Kremsmünster	0.006	0.003
	Okehampton	0.036	0.042

^a for uses numbers see GAP details in Table CP B.8.3

¹ Values in parentheses are from HSE attempts to validate PEARL and PELMO modelling. . Period 20 is the average of years 64, 65 and 66.

The predicted concentrations from the non-standard modelling in oilseed rape were higher than those from the standard modelling . The higher concentrations reflect the fact that the non-standard simulation used annual applications over 66 years as opposed to applications once every three years during the 66 year period in the standard modelling. In the HSE modelling for earlier application to winter oilseed rape (BBCH 57 with 80% crop interception), the Okehampton scenario predicted a highest triennial concentration of 0.226 µg/L for the last three years of the simulation. The pattern of concentrations at 1m depth was similar to that seen for earlier application to winter cereals. The higher concentrations predicted are likely to be due to the higher annual soil loading with the oilseed rape use (40 g a.s./ha) compared to cereals (33.2 g a.s./ha).

The applicant also investigated the impact of modelling a 16 year use period of annual use followed by 50 years of non-use. This was to reflect a situation where pydiflumetofen was approved for a 10 year period with an additional 6 years to reflect uncertainty in regulatory decision-making. The results for cereals are shown below.

Table CP B.8. 20 PEC_{GW} for pydiflumetofen with FOCUS PEARL v4.4.4 and FOCUS PELMO v5.5.3 from a 16 year use period on winter and spring cereals followed by 50 years with no treatment, highest triennial average

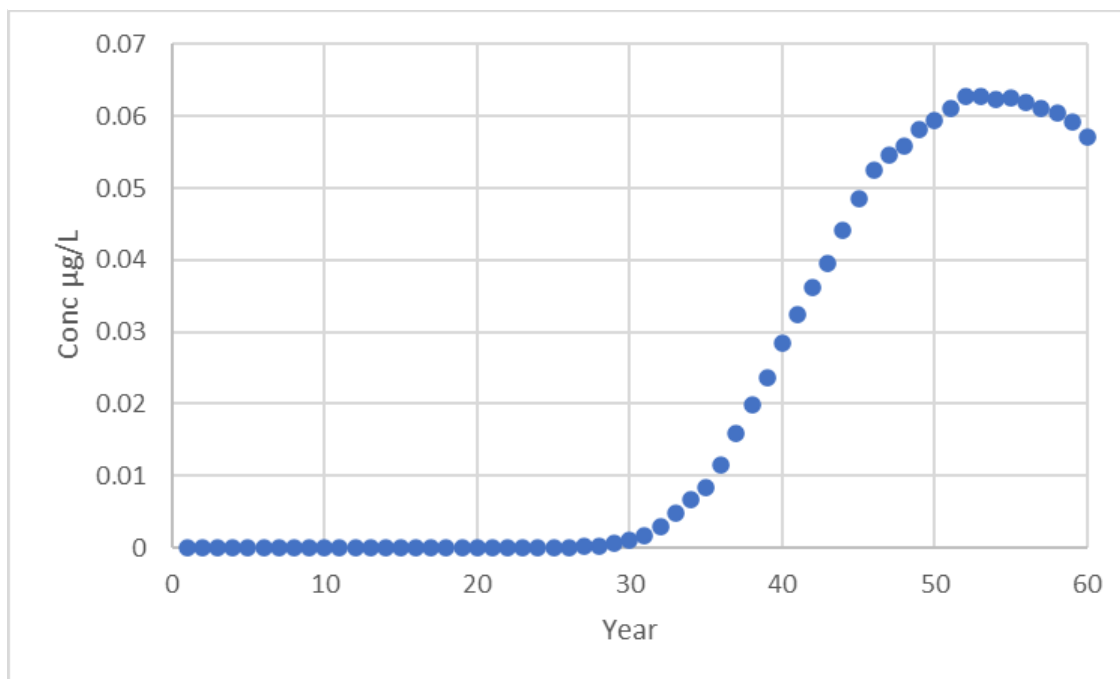
Crop ^a	Scenario	High 3 yr average PEC _{gw} at 1 m Soil Depth (µg/L)	
		FOCUS PEARL 4.4.4	FOCUS PELMO 5.5.3
Spring Cereals Use no. 829, 860 BBCH 55	Châteaudun	< 0.001	< 0.001
	Hamburg	0.016	0.005
	Kremsmünster	0.006	0.002
	Okehampton	0.023	0.020
Spring Cereals Use no. 855a, 826, 860 BBCH 69	Châteaudun	< 0.001	< 0.001
	Hamburg	0.016	0.005
	Kremsmünster	0.005	0.002
	Okehampton	0.023	0.020
Spring Cereals Use no. 855a BBCH 30	Châteaudun	< 0.001	< 0.001
	Hamburg	0.040	0.015
	Kremsmünster	0.018	0.006
	Okehampton	0.053	0.048
Winter Cereals Use no. 835, 866 BBCH 55	Châteaudun	< 0.001	< 0.001
	Hamburg	0.015	0.007
	Kremsmünster	0.007	0.004
	Okehampton	0.028	0.028
Winter Cereals Use no. 855a, 835, 866 BBCH 69	Châteaudun	< 0.001	< 0.001
	Hamburg	0.015	0.007
	Kremsmünster	0.007	0.004
	Okehampton	0.028	0.028
Winter Cereals Use no. 861a BBCH 30	Châteaudun	< 0.001	< 0.001
	Hamburg	0.037	0.022 (0.021, period 20) ¹
	Kremsmünster	0.020	0.012 (0.012, period 20) ¹
	Okehampton	0.063	0.063 (0.062, period 19&20) ¹

^a for uses numbers see GAP details in Table CP B.8.3

¹ Values in parentheses are from HSE attempts to validate PELMO modelling. Period 20 is the average of years 64, 65 and 66; period 19 is the average of years 61, 62 and 63.

As noted, the predicted highest triennial average concentrations were all <0.1 µg/L. HSE also repeated the simulation of application to winter cereals at BBCH 30 for the Okehampton scenario using PEARL to consider the profile of the groundwater concentrations in more detail.

Figure CP B.8. 2 Profile of predicted groundwater concentrations (PEARL, annual average, µg/L at 1m depth, Okehampton scenario) following 6+10 years annual applications of pydiflumetofen to cereals



Note: 0 on the concentration axis is <0.001 µg/L

The simulation had applications made for 16 years. Due to the ‘warm-up’ period required in FOCUS simulations, results from the first six years are discarded. Therefore applications ceased at year 10 on the graph above (the first six years not being shown). Concentrations increased to >0.001 µg/L around year 30 and did not reach a peak until year 52 on the graph. Thus according to this simulation, even if pydiflumetofen applications ceased, e.g. due to a subsequent non-approval decision, accumulated soil residues could continue to travel through the soil profile and not reach a peak of concentration until well after application had ceased; in this simulation the peak concentration is not reached until just over 40 years after the final application was made.

The applicant also modelled the 16 year use period of annual use followed by 50 years of non-use for oilseed rape.

Table CP B.8. 21 PEC_{GW} for pydiflumetofen with FOCUS PEARL v4.4.4 and FOCUS PELMO v5.5.3 from a 16 year use period on winter and spring oilseed rape followed by 50 years with no treatment, highest triennial average

Crop ^a	Scenario	High 3 yr average PEC _{gw} at 1 m Soil Depth (µg/L)	
		FOCUS PEARL 4.4.4	FOCUS PELMO 5.5.3
Summer Oil Seed Rape 1x200 g a.s./ha BBCH 57-69 Use no. 867 ^a	Okehampton	0.067	0.067
Winter Oil Seed Rape 1x200 g a.s./ha, BBCH 57-69 Use no. 868 ^a	Châteaudun	< 0.001	< 0.001
	Hamburg	0.015 (0.057 period 19) ¹	0.035 (0.034 period 20) ¹
	Kremsmünster	0.007 (0.033 period 20) ¹	0.023 (0.022 period 20) ¹
	Okehampton	0.028 (0.081 period 18) ¹	0.096 (0.094 period 18) ¹

^a for uses numbers see GAP details in Table CP B.8.3

¹ Values in parentheses are from HSE attempts to validate PEARL and PELMO modelling. Period 20 is the average of years 64, 65 and 66; period 19 is the average of years 61, 62 and 63; period 18 is the average of years 58, 59 and 60.

The HSE simulation for winter oilseed rape at Okehampton using PEARL predicted that the highest three year average concentration was 0.081 µg/L which occurred in the 18th period, i.e. years 52 and 54 of the 60 year

simulation (i.e. 66 year simulation with first six years discarded). This seems to be more in keeping with the other simulation results. With respect to the applicant PELMO results for oilseed rape, HSE considered it unlikely that the highest triennial concentration from a simulation where there were no applications in the final 50 years should be higher than from a simulation where there were annual applications for the whole of the simulation; HSE notes that its own simulation of annual application to oilseed rape over a 66 year period returned significantly higher concentrations than those of the applicant and that the applicant results for the annual application for 66 years to oilseed rape may be inconsistent with the other results. As demonstrated, the HSE result for 16 years annual application at Okehampton with PELMO indicated that the predicted concentrations were lower than from 66 years of annual applications.

As noted, the predicted 80th percentile annual average concentrations from the simulations of 16 consecutive years application followed by 50 year with no applications were all <0.1 µg/L.

B.8.3.1. Summary and Conclusions on PEC_{gw} assessment

The results of the ‘standard’ FOCUS_{gw} simulations for cereals assuming continuous annual applications over a 20 year period suggest that there is a low risk of contamination of shallow groundwater (at 1m depth) at >0.1 µg pydiflumetofen/L. All predicted 80th percentile annual average concentrations were <0.1 µg/L for UK-relevant scenarios.

Similarly, the results for oilseed rape simulated over a longer time period but with applications made once every three years predicted a low risk of contamination of shallow groundwater. However the results suggested that the very slow degradation of pydiflumetofen may result in very slow leaching of an accumulating residue to 1m depth such that annual average concentrations increased to > 0.001 µg/L but remained <0.1 µg/L.

To simulate the possibility of very long-term use of pydiflumetofen, the applicant conducted ‘non-standard’ simulations where pydiflumetofen was assumed to be applied to either cereal or oilseed rape crops every year for 60 years. The results suggested that concentrations could increase to >0.1 µg/L in UK-relevant scenarios for early applications to cereals (applications at BBCH 30) and oilseed rape. In addition all scenarios showed an upward trend indicating the potential for concentrations to rise even further if the simulations were continued.

Additional simulations suggested that even with a relatively limited period such as a single ‘approval period’ of 10 years (plus 6 for the standard FOCUS warm-up period), concentrations in groundwater could increase for decades after application had ceased. This appears to be an unusual behaviour relating to the combination of strong soil adsorption and extremely slow degradation predicted in the soil bulk matrix. The predicted concentrations remained <0.1 µg/L in the duration of the simulations although some scenarios appeared to have not plateaued and started a decline by the end of the simulation. However HSE considers it unlikely that had the simulation been extended that the concentrations would have risen to >0.1 µg/L.

It is not known whether the 1st tier FOCUS groundwater exposure models used in this assessment are able to accurately predict the long-term behaviour of substances with such combinations of properties. It is also noted that the very long non-standard simulations simulating 66 years of uninterrupted use on the same area of soil are unlikely to be representative of real world use. In general it is assumed that the FOCUS models and associated scenarios are sufficiently conservative for the purposes of a tier 1 leaching assessment for most standard substances, and that leaching potential can be appropriately addressed following 20 year (plus 6 year warm up) simulations. The additional modelling provided by the applicant suggest that the standard 20 year simulations may not be sufficient to capture the bulk of the leaching that occurred with pydiflumetofen. However HSE notes that the long term modelling does not take into account other processes such as plant uptake (which generally has a small impact on predicted concentrations), the potential for time-dependent adsorption behaviour, other surface processes or even phenomena such as microbial adaptation which could contribute to reduced masses of pydiflumetofen leaching to depth over such long periods of time. HSE also notes that the DegT50 values used as the basis of the DT50 input parameter in the model were from studies where very slow degradation occurred. As such, the SFO DT50s were extrapolated far beyond the study duration of approximately two years. This in itself gives uncertainty over the predicted groundwater concentrations.

Consequently there is uncertainty over the FOCUS_{gw} modelling and the indicated risk of leaching over a longer period of time. However the modelling results suggest there would be a relatively low risk of pydiflumetofen contaminating groundwater at >0.1 µg/L if approval was limited to a single approval period of ten years. At the time the applicant would have to make a submission for renewal of approval, they would have

to provide additional robust information to demonstrate a low risk of groundwater contamination over a longer usage period. The following are proposed as possible options to address this requirement:

- i) Conduct new DegT50 field studies that are not terminated until 90% disappearance of pydiflumetofen has occurred. Both the EFSA (2014) guidance (containing the DegT50 study design) and the OECD (2016) guidance on conduct of field dissipation studies recommend that studies are continued until the test substance has reached $\leq 10\%$ of initial measure concentration. The currently available field dissipation studies were all terminated well before 90% disappearance was reached. Consequently there is uncertainty over the kinetic parameters generated although this is not so great to exclude use in risk assessment. The applicant attempted to generate 'better' DegT50 values from the existing field dissipation studies by resampling three to five years after study termination (Volume 3, section CA B.8.1.1.1.2.1.3). In the view of HSE these were flawed by the fact that the studies had been decommissioned and the sites subject to cultivation and cropping before being resampled.
- ii) Conduct other studies to generate robust, refined input parameters for modelling such as aged sorption studies.

These data requirements will be set at the time of the first approval to forewarn the applicant that additional information is required to address the long-term risk of leaching of pydiflumetofen as a condition of renewal of approval.

It is noted that the more typical option would be to set a data requirement for groundwater monitoring. However, given the predicted extremely long travel times to shallow groundwater, HSE considers that a requirement for monitoring data by itself may not be able to give sufficient reassurance with respect to the risk to groundwater. This is because the absence of detections in groundwater within the first ten years of approval may not be a good indicator of long term leaching behaviour of pydiflumetofen, i.e. because after 16 years of applications, concentrations in groundwater were not predicted to rise above 0.001 $\mu\text{g/L}$ until 20 years after applications ceased and continued to increase for an additional 20 years.

The ECP were asked to provide their ISA with respect to the groundwater assessment and HSE proposals for further information requirements for the renewal of approval. The ECP were content with the approach taken in the groundwater assessment. In contrast to the HSE view the ECP advised that, with respect to further information for renewal of approval, the applicant should be required to undertake monitoring of soil residues, including detailed sampling of both bulk residues and soil pore water to gain longer term details of the movement of the residue plume as it accumulates and migrates through the soil profile.

B.8.4. FATE AND BEHAVIOUR IN WATER AND SEDIMENT

B.8.4.1. Aerobic mineralisation in surface water

For full details of the assessment of degradation in aquatic systems see the associated CA.B.8 document. Endpoints from the CA assessment for use in PEC calculations are listed in tables for each compartment below.

B.8.4.2. Water/sediment study

For full details of the assessment of degradation in aquatic systems see the associated CA.B.8 document. Endpoints from the CA assessment for use in PEC calculations are listed in tables for each compartment below.

B.8.5. PREDICTED ENVIRONMENTAL CONCENTRATIONS IN SURFACE WATER AND SEDIMENT (PEC_{sw} , PEC_{sd})

For the GB/NI assessment, the entry routes to surface water of spray drift and drainage are accounted for separately. The GAP assessed is shown below.

Table CP B.8. 22 Summary of requested GAPs for PEC_{sw} and PEC_{sed} calculations

Crop	Cereals (spring and winter)	Cereals (spring and winter)	Oil Seed Rape (spring and winter)
Application rate (g a.s./ha)	166	200	200
Number of applications/interval (d)	1 / -	1 / -	1 / -
Application timing (No. days until drainage period)	BBCH 30-59 (0 days until drainflow assumed)	BBCH 55-65 (0 days until drainflow assumed)	BBCH 57-69 (0 days until drainflow assumed)
CAM (Chemical application method)	Foliar spray	Foliar spray	Foliar spray
Min crop interception (%) ^a	80	90	80
Product dose l/ha	2.65	3.2	3.2
Product dose g/ha ^b	2907	3510.4	3510.4

^a used in drainage calculation^b assuming formulation density of 1.097 g/cm³ (Volume 3, section CP B.2.6, 2016)

The input parameters proposed by the applicant to be used in the PEC_{sw} and PEC_{sed} calculations are shown below.

Table CP B.8. 23 Applicant proposed input parameters related to active substance pydiflumetofen and its metabolites for PEC_{sw}/sed calculations

Compound	Pydiflumetofen	SYN545547	NOA449410	SYN548261
Molar mass (g/mol)	426.7	396 (correction factor 0.928)	176 (correction factor 0.412)	291 (correction factor 0.682)
K _{FOC} (mL/g)	1706 (geometric mean, n = 6)	607.9 (geomean, n = 5)	2.1 (geomean, n = 5)	0 (worst case default)
DT _{50,soil} (d)	8540 (worst case un-normalised, field value)	- ^a	- ^a	- ^a
DT _{50,water} (d)	26.2 (max. dissipation DT ₅₀ in water, n=2)	- ^b	1000 (default)	1000 (default)
DT _{50,sed} (d)	1000 (default; no clear decline in sediment)	455 (max whole system)	1000 (default)	1000 (default)
Maximum occurrence observed (% molar basis with respect to the parent)	Sediment: 79.0	Soil: - Water: 2.3 (aerobic water / sed study) Sediment: 12.3 (aerobic water / sed study)	Soil: - Water: 5.4 (photolysis) Sediment: -	Soil: - Water: 7.3 (photolysis) Sediment: -

^a No soil metabolites of pydiflumetofen trigger assessment for PEC_{sw} or PEC_{sed}^b PEC_{sw} assessment not triggered

B.8.5.1. PEC_{sw} and PEC_{sed} via spray drift

The GB/NI approach for calculating predicted concentrations in surface water and sediment assumes a static water body 30cm deep overlaid by a 5cm sediment layer with a bulk density of 1.3 g/cm³. Spray drift assumptions use the Rautmann spray drift data set with 90th percentile spray drift values for 'standard' hydraulic nozzles.

B.8.5.1.1. Pydiflumetofen

The following PEC_{sw} and PEC_{sed} values are calculated for pydiflumetofen. It should be noted that the spray drift assumptions are identical for cereal and oilseed rape crops.

A default DT₅₀ of 1000 days is assumed for dissipation from sediment. This is because there was no clear decline phase from sediment in the two water/sediment systems reported in CA B.8.2.2.1.1. This equates to an accumulation factor of 4.474. The PEC_{sed} values for a single application are multiplied by the accumulation factor to give a representation of potential accumulation in sediment.

Table CP B.8. 24 PEC_{sw} and PEC_{sed} via spray drift for pydiflumetofen

Crop	Spray drift buffer (m)	Maximum PEC_{sw,spraydrift} (µg/L)	PEC_{sed,spraydrift} (µg/kg)	Accumulated PEC_{sed,spraydrift} (µg/kg)
Winter/Spring cereals 1 x 166 g a.s./ha	1	1.533	5.589	25.003
Winter/Spring cereals 1 x 200 g a.s./ha	1	1.847	6.733	30.121
Oil Seed Rape 1 x 200 g a.s./ha	1	1.847	6.733	30.121

PEC_{sw} values for a range of buffer distances

Table CP B.8. 25 PEC_{sw} via spray drift for 166 g pydiflumetofen/ha at various buffer distances

Distance (m)	PEC _{sw} ini (µg/L)
1 m	1.533
5 m	0.315
6 m	0.266
7 m	0.227
8 m	0.199
9 m	0.177
10 m	0.160
11 m	0.149
12 m	0.133
13 m	0.127
14 m	0.116
15 m	0.111
16 m	0.100
17 m	0.094
18 m	0.089
19 m	0.089
20 m	0.083

Table CP B.8. 26 PEC_{sw} via spray drift for 200 g pydiflumetofen/ha at various buffer distances

Distance (m)	PEC _{sw} ini (µg/L)
1 m	1.847
5 m	0.380
6 m	0.320
7 m	0.273
8 m	0.240
9 m	0.213
10 m	0.193
11 m	0.180
12 m	0.160
13 m	0.153
14 m	0.140
15 m	0.133
16 m	0.120
17 m	0.113
18 m	0.107
19 m	0.107
20 m	0.100

B.8.5.1.2. Formulation ‘Miravis Plus’

The following PEC_{sw} and PEC_{sed} values are calculated for the formulation ‘Miravis Plus’.

Table CP B.8. 27 PEC_{sw} via spray drift for 2907 g ‘Miravis Plus’/ha at various buffer distances

Distance (m)	PEC _{sw} ini (µg formulation/L)
1 m	26.841
5 m	5.523
6 m	4.651
7 m	3.973
8 m	3.488
9 m	3.101
10 m	2.810
11 m	2.616
12 m	2.326
13 m	2.229
14 m	2.035
15 m	1.938
16 m	1.744
17 m	1.647
18 m	1.550
19 m	1.550
20 m	1.454

Table CP B.8. 28 PEC_{sw} via spray drift for 3510.4 g ‘Miravis Plus’/ha at various buffer distances

Distance (m)	PEC _{sw} ini (µg formulation/L)
1 m	32.413
5 m	6.670
6 m	5.617
7 m	4.798
8 m	4.212
9 m	3.744
10 m	3.393
11 m	3.159
12 m	2.808
13 m	2.691
14 m	2.457
15 m	2.340
16 m	2.106
17 m	1.989
18 m	1.872
19 m	1.872
20 m	1.755

B.8.5.1.3. Water/sediment metabolite SYN545547

SYN545547 did not trigger assessment of PEC_{sw} as it was only found in small amounts (maximum 2.3%) in the water phase of the aerobic water/sediment study and did not show convincing evidence of accumulation in the water phase. However, values were seen to increase in sediment with no discernible or clear decline phase in either of the two water/sediment systems. The applicant calculated whole system degradation rates for this metabolite using sequential parent-metabolite kinetic modelling but the kinetic parameters for the metabolite are considered by HSE to be highly uncertain.

The PEC_{sed} value has been calculated on the basis of the maximum amount observed in sediment (12.3% AR). The effective application rate of the metabolite has been calculated from the parent application rate corrected for molecular weight difference.

A default DT₅₀ of 1000 days is assumed for dissipation from sediment. This is because there was no clear decline phase from sediment in the two water/sediment systems reported in CA B.8.2.2.1.1. This equates to an accumulation factor of 4.474. The PEC_{sed} values for a single application are multiplied by the accumulation factor to give a representation of potential accumulation in sediment.

Table CP B.8. 29 PEC_{sed} values via spray drift for metabolite SYN545547

Crop	Spray drift buffer (m)	PEC_{sed}, spraydrift (µg/kg)	Accumulated PEC_{sed}, spraydrift (µg/kg)
Winter/Spring cereals 1 x 166 g a.s./ha	1	0.807	3.610
Winter/Spring cereals 1 x 200 g a.s./ha	1	0.973	4.353
Oil Seed Rape 1 x 200 g a.s./ha	1	0.973	4.353

B.8.5.1.4. Aqueous photolysis metabolite NOA449410

Metabolite NOA449410 was formed in levels sufficient in the aqueous photolysis study to trigger PEC_{sw} assessment. PEC_{sw} has been calculated based on the maximum level formed in the aqueous photolysis study (5.4% AR, mean of two replicates). The effective application rate of the metabolite has been calculated from the parent application rate corrected for molecular weight difference and its maximum formation.

Table CP B.8. 30 PEC_{sw} values via spray drift for metabolite NOA449410

Crop	Spray drift buffer (m)	Maximum PEC_{sw}, spraydrift (µg/L)
Winter/Spring cereals 1 x 166 g a.s./ha	1	0.034
Winter/Spring cereals 1 x 200 g a.s./ha	1	0.041
Oil Seed Rape 1 x 200 g a.s./ha	1	0.041

B.8.5.1.5. Aqueous photolysis metabolite SYN548261

Metabolite SYN548261 was formed in levels sufficient in the aqueous photolysis study to trigger PEC_{sw} assessment. PEC_{sw} has been calculated based on the maximum level formed in the aqueous photolysis study (7.3% AR, mean of two replicates). The effective application rate of the metabolite has been calculated from the parent application rate corrected for molecular weight difference and its maximum formation.

Table CP B.8. 31 PEC_{sw} values via spray drift for metabolite SYN548261

Crop	Spray drift buffer (m)	Maximum PEC _{sw} , spraydrift (µg/L)
Winter/Spring cereals 1 x 166 g a.s./ha	1	0.076
Winter/Spring cereals 1 x 200 g a.s./ha	1	0.092
Oil Seed Rape 1 x 200 g a.s./ha	1	0.092

B.8.5.2. PEC_{sw} and PEC_{sd} via drainflow

The GB/Ni approach for assessment of surface water contamination by substances via drainflow assumes a water body 1 m wide, 100m long and 30 cm deep underlaid by 5cm sediment layer with bulk density of 1.3 g/cm³. This gives a water body containing 30,000 l water. The water body is adjacent to an agricultural field of 1ha. Assuming a rainfall event of 10mm, a drainflow event of 100,000 litres of water occurs which removes a % of the substance under consideration. Losses are shown below.

Table CP B.8. 32 Percentage of substance assumed lost to drains based on Koc value

Koc (mL/g)	Mobility Classification	Lost to Drains (%)
0-14	Very mobile	1.9
15-74	Mobile	1.9
75-499	Moderately mobile	0.7
500-999	Slightly mobile	0.5
1000-4000	Slightly mobile	0.02
>4000	Non-mobile	0.008

The 100,000 litres of water from the agricultural field is deposited in the receiving water body with the result that the mass of substance assumed to be removed from the field is diluted in 130,000 litres of water.

With a geometric mean K_{oc} of 1706 mL/g, pydiflumetofen is assumed to have 0.02% lost to drains.

The GB/Ni approach is to base the losses via drainage on single years use. Accumulated residues are not taken into account as it would be unrealistic to assume that the whole accumulated residues would be available and that there would not have been losses of the substance to drainflow in intervening years.

In the case of pydiflumetofen, as application to cereals can commence from BBCH GS 30, application is assumed to occur within the drainflow period (1 October – 30 April) and thus no losses via dissipation are considered. Whilst application to oilseed rape is assumed to occur at a later growth stage, application is still assumed to occur within the drainflow period.

A default DT₅₀ of 1000 days is assumed for dissipation from sediment. This is because there was no clear decline phase from sediment in the two water/sediment systems reported in CA B.8.2.2.1.1. This equates to an

accumulation factor of 4.474. The PEC_{sed} values for a single application are multiplied by the accumulation factor to give a representation of potential accumulation in sediment.

The following PEC_{sw} and PEC_{sed} values are calculated for pydiflumetofen.

Table CP B.8. 33 PEC_{sw} and PEC_{sed} via drainflow for pydiflumetofen

Crop	Maximum PEC_{sw,drainflow} (µg/L)	PEC_{sed, drainflow} (µg/kg)	Accumulated PEC_{sed, drainflow} (µg/kg)
Winter/Spring cereals 1 x 166 g a.s./ha, 80% interception	0.051	0.186	0.832
Winter/Spring cereals 1 x 200 g a.s./ha, 90% interception	0.031	0.112	0.501
Oil Seed Rape 1 x 200 g a.s./ha, 80% interception	0.062	0.224	1.002

It is noted that the PEC_{sw}, drainflow concentrations for pydiflumetofen are lower than the PEC_{sw} from spray drift with the maximum 20m no spray buffer zone for both the 166 g a.s./ha and 200 g a.s./ha doses. Therefore the surface water and sediment exposure from metabolites forming from pydiflumetofen entering the water via drainflow will be lower than those predicted to occur via spray drift exposure.

B.8.6. FATE AND BEHAVIOUR IN AIR

B.8.6.1. Route and rate of degradation in air and transport via air

Pydiflumetofen has a vapour pressure of 1.84×10^{-7} Pa at 20°C. Therefore transport via air of pydiflumetofen was not studied since its vapour pressure is less than the FOCUSair trigger value for short-range transport exposure assessment of 10^{-5} Pa for substances applied to plants. In addition, pydiflumetofen has a photochemical oxidative degradation in air DT50 of 5.85 hours (12 hour OH concentration of 1.5×10^6 radicals/cm³) and thus does not trigger assessment of long-range atmospheric transport (trigger value is DT50 ≥ 2 days).

B.8.6.2. Predicted environmental concentrations from airborne transport

The transport via air of pydiflumetofen was not assessed since its vapour pressure is below the FOCUSair trigger value for short-range transport and its atmospheric DT50 is below the FOCUSair trigger value for long-range transport exposure assessments.

B.8.7. PREDICTED ENVIRONMENTAL CONCENTRATIONS FROM OTHER ROUTES OF EXPOSURE

There are no other routes of exposure if the product is used according to good agricultural practice. Therefore no further estimations are considered necessary.

B.8.8. 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
KCP 9.2.4	██████	2019	Pydiflumetofen – An Extended Leaching Assessment Using the PEARL 4.4.4 and PELMO 5.5.3 Groundwater Models Following Spray Application to Spring and Winter Cereals Report No. RAJ1311B Document No. VV-854830 Test Facility Syngenta - Jealott's Hill Not GLP Unpublished	N	N		SYN	N.A.
KCP 9.2.4	██████	2019	Pydiflumetofen – An Extended Leaching Assessment Using the PEARL 4.4.4 and PELMO 5.5.3 Groundwater Models Following Spray Application to Summer and Winter Oilseed Rape Report No. RAJ1310B Document No. VV-854828 Test Facility Syngenta - Jealott's Hill Not GLP Unpublished	N	N		SYN	N.A.
KCP 9.2.4	██████	2020	Pydiflumetofen – An Extended Leaching Assessment with Limited Applications Using the PEARL 4.4.4 and PELMO 5.5.3 Groundwater Models Following Spray Application to Brassicas, Carrots, Cucurbits, Pome Fruit, Potatoes, Spring and Winter	N	N		SYN	N.A.

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
			Cereals, Summer and Winter Oilseed Rape, Tomatoes, and Vines Report No. RAJ1344B Document No. VV-855100 Test Facility Syngenta - Jealott's Hill Not GLP Unpublished					
KCP 9.2.4		2020	Pydiflumetofen - A Leaching Assessment for Parent Using the FOCUS Groundwater Models Following Spray Application to Spring and Winter Cereals Report No. RAJ1319B Document No. VV-855540 Test Facility Syngenta - Jealott's Hill Not GLP Unpublished	N	N		SYN	N.A.
KCP 9.2.4		2019	Pydiflumetofen - A Leaching Assessment for Parent Using the FOCUS Groundwater Models Following Spray Application to Summer and Winter Oil Seed Rape Report No. RAJ1321B Document No. VV-855549 Test Facility Syngenta - Jealott's Hill Not GLP Unpublished	N	N		SYN	N.A.