REGISTRATION REPORT
Part B
Section 8
Environmental Fate

Detailed summary of the risk assessment

Product code: 19202

Product name(s): **KINVARA**

Chemical active substance(s):

MPCA, 233 g/L

Fluroxypyr (acid), 50g/L

Clopyralid, 28 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(formulation renewal)

Applicant: XXXX

Submission date: 31/01/2024

Evaluation date: October 2024

MS Finalisation date: March 2025

Version history

When	What
January 2024	Article 43 of Regulation (EC) No. 1107/2009
October 2024	Conclusions of zRMS
February 2025	Applicant revisions
March 2025	Final version by zRMS

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8 Fate and behaviour in the environment (KCP 9)

This document reviews the environmental fate studies and modelling for the product Kinvara, containing the active substances MCPA, fluroxypyr and clopyralid, which were included into Annex I of Directive 91/414 (Regulation EEC No 3600/92, Commission Regulation (EC) No 1490/2002). A full risk assessment according to Uniform Principles is provided which demonstrates that the product is safe for the environment.

Where appropriate this document refers to the conclusions of the EU review of the three active substances: MCPA, fluroxypyr and clopyralid. This will be where:

- the active substance data is relied upon in the risk assessment of the formulation; or when
- the EU review concluded that additional data/information should be considered at national re-registration.

This Part B document only reviews data (Annex II or Annex III) and additional information that has not previously been considered within the EU review process, as part of the Annex I inclusion decision. New Annex II data are only included if they are considered essential for the evaluation and in this case a full study summary has been provided. In the case where the formulation has been previously evaluated, at European level, detailed summaries have not been provided.

This product was not the representative formulation. The product has been previously evaluated in the Central Zone according to Uniform Principles and only new studies are provided in full detail in this document. For the active substance.

The peer-reviewed reports for:

- MCPA – SANCO/4062/2001-final 11/07/2008
- Fluroxypyr – EFSA Journal 2011;9(3):2091 and zRMS Ireland confirmatory data 2014
- Clopyralid – EFSA Journal 2018; 16(8):5389

are considered to provide the relevant review information or a reference to where such information can be found for each substance. Each section for every substance will begin with a table providing the EU end-points to be used in this evaluation.

For the implementation of the uniform principles of Annex VI, the conclusions of the review reports on MCPA, fluroxypyr and clopyralid (and in particular Appendices I and II thereof) as finalised in the Standing Committee on the Food Chain and Animal Health shall be taken into account. In this overall assessment Member States should/must/may pay particular attention to the following points for each active substance present in the formulation:

- MCPA
    - o “Must pay particular attention to the potential for groundwater contamination, when the substance in applied in regions with vulnerable soil and/or climatic conditions.”
    - o “Conditions of authorisation should include risk mitigation measures, where appropriate Member States must pay particular attention to the protection of aquatic organisms and must ensure that the conditions of authorisation include risk mitigation measures, where appropriate, such as buffer zones.”
- Fluroxypyr
    - o “Must pay particular attention to the protection of groundwater”
    - o “Must pay particular attention to the impact on aquatic organisms and must ensure that the conditions of authorisation include, where appropriate, risk mitigation measures”
- Clopyralid
    - o “The protection of non-target plants and groundwater under vulnerable conditions.”

- "Conditions of authorisation should include risk mitigation measures and monitoring programmes should be initiated to verify potential groundwater contamination in vulnerable zones, where appropriate"

These concerns have been addressed within the current submission.

Information on the detailed composition of Kinvara can be found in the confidential dossier of this submission (Registration Report - Part C).

8.1 Critical GAP and overall conclusions

Table 8.1-1: Critical use pattern of the formulated product

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use-No. *	Member state(s)	Crop and/or situation (crop destination / purpose of crop)	F, Fn, Fpn 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	**Conclusion**
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max			Groundwater
Zonal uses (field or outdoor uses, certain types of protected crops)														
1	AT, IE, NI, BE, RO, CZ, DE, HU, PL	Wheat,Barley, Oats, Rye, Triticale	F	Annual and perennial broadleaf weeds	Foliar spray	BBCH 24 - 39	1	N/A	3	0.7 (MCPA) 0.15 (Fluroxypyr) 0.084 (Clopyralid)	200 – 400		BBCH 25-39 (AT) BE – 3 L/ha RO - 2-3 L/ha CZ -2-3 L/ha HU – 2-3 L/ha PL – 2-3 L/ha - winter wheat, spring wheat, winter triticale, spring barley, rye, winter oats	
2	AT, IE, NI, BE, CZ, DE	Established Grassland (> 1 yr)	F	Annual and perennial broadleaf weeds	Foliar spray	Mar – ~~Sept~~ August 15th	1	N/A	3	0.7 (MCPA) 0.15 (Fluroxypyr) 0.084 (Clopyralid)	200 – 400	AT, IE, NI, CZ, DE, BE (PHI 7d)	IE, NI (1st Mar-31st Aug) BE – 2.25 or 2.5 L/ha	
3	BE	New Grassland	F	Annual and perennial	Foliar spray	Mar – ~~End~~	1	N/A	3	0.7 (MCPA)	200 – 400		BE –	

		(< 1 year)		broadleaf weeds		~~Sept~~ Sept August 15th (min. BBCH 20)				0.15 (Fluroxypyr) 0.084 (Clopyralid)			2.25/2.5 L/ha	

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

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

Explanation for column 15 “Conclusion”

A	Safe use
R	Further refinement and/or risk mitigation measures required
C	To be confirmed by cMS
N	No safe use

Table 8.1-2: Assessed (critical) uses during approval of MCPA concerning the Section Environmental Fate

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. *	Member state(s)	Crop and/or situation (crop destination / purpose of crop)	F, Fn, Fpn 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)	g product/ha a) max. rate per appl.	g as/ha a) max. rate per appl.	Water L/ha min/max		
		Winter cereals		Broadleaf Weeds	foliar spray	BBCH 24-39	1		3 L/ha	700 g/ha			
		Spring Cereals		Broadleaf Weeds	foliar spray	BBCH 24-39	1		3 L/ha	700 g/ha			

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

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

Table 8.1-3: Assessed (critical) uses during approval of fluroxypyr (acid) concerning the Section Environmental Fate

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. *	Member state(s)	Crop and/or situation (crop destination / purpose of crop)	F, Fn, Fpn 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		
		Winter cereals		Broadleaf Weeds	foliar spray	BBCH 24-39	1		3 L/ha	150g/ha			
		Spring Cereals		Broadleaf Weeds	foliar spray	BBCH 24-39	1		3 L/ha	150 g/ha			

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
** F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application

Table 8.1-4: Assessed (critical) uses during approval of clopyralid concerning the Section Environmental Fate

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. *	Member state(s)	Crop and/or situation (crop destination / purpose of crop)	F, Fn, Fpn 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		
		Winter cereals		Broadleaf Weeds	foliar spray	BBCH 24-39	1		3 L/ha	80g/ha			
		Spring Cereals		Broadleaf Weeds	foliar spray	BBCH 24-39	1		3 L/ha	80 g/ha			

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
** F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application

8.2 Metabolites considered in the assessment

The active substance clopyralid does not form any potentially relevant metabolites in soils or surface water. The potentially relevant metabolites of MCPA and fluroxypyr covered in this assessment are listed on the tables below. As will be detailed in the section 8.5 below the metabolite pyridinol has a pH dependent behaviour in soil. The EFSA (2011) peer review of fluroxypyr clearly demonstrated that the alkaline endpoints for pyridinol are worst-case and cover the risk of pyridinol in acid soils. Therefore, in order to achieve a concise assessment only the alkaline behaviour of pyridinol has been explicitly covered in this report. The environmental fate calculations relevant to pyridinol in acidic soils are covered by the calculations using the alkaline endpoints.

Table 8.2-1: Metabolites of MCPA potentially relevant for exposure assessment

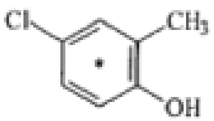
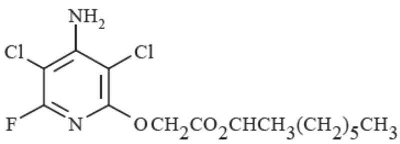
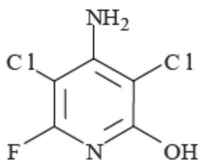
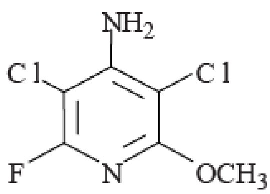
Abbreviation	Molar Mass	Structural Formula	Maximum Observed in Compartment	Exposure Assessment Required
PCOC	142.6		Soil: 55% Water/Sediment: 11.6%	PEC_{GW} PEC_{SOIL} PEC_{SW}

Table 8.2-2 Metabolites of fluroxypyr-acid potentially relevant for exposure assessment

Abbreviation	**Molar Mass**	**Structural Formula**	**Maximum Observed in Compartment**	**Exposure Assessment Required**
Fluroxypyr (MHE) (precursor)	367.3		Soil: 100% Water/Sediment: 100%	PEC_{GW}- Assessed as fluroxypyr (acid) PEC_{SOIL} PEC_{SW}
Pyridinol	197		Soil: 23.9% Water/Sediment: 55.5%	PEC_{GW} PEC_{SOIL} PEC_{SW}
Methoxypyridine	211		Soil: 38.2%	PEC_{GW} PEC_{SOIL} PEC_{SW}

8.3 Rate of degradation in soil (KCP 9.1.1)

The EU agreed end-points for the rate of degradation in soil for each of the active substances and metabolites are presented in Table 8.3-1. The endpoints provided for fluroxypyr and its metabolites are the endpoints agreed based on the confirmatory data submitted for the active substance. End-points used in the evaluation that have not been previously agreed are presented in Table 8.3-2.

Table 8.3-1: Agreed EU end-points for all active substances and metabolites used in the evaluation (UNEP Publications 1998, OECD SIDS, Risk assessment 4-chloro-2-methylphenol; EFSA Journal 2011; 9(3): 2091; zRMS Ireland 2014; EFSA Journal 2018, 16(8))

Substance name	DT_{50} [Days]	Source
PCOC	21	UNEP (1998)
Fluroxypyr	13.9	EFSA (2011)
Fluroxypyr-MHE	1.0	EFSA (2011)
Pyridinol	17.6	EFSA (2011)
Methoxypyridine	111.11	Ireland (2014)
3-CP	1000 (default)	EFSA (2011)
Clopyralid	7.05	EFSA (2018)

Table 8.3-2: End-points used in the evaluation that were not previously agreed

Substance name	DT_{50} [Days]	Source
MCPA	26.7	Provided by Nufarm in a data-sharing agreement, Annex II

Summary

The rate of degradation in soil of the active substances and metabolites was evaluated during the Annex I Inclusion. The values presented Table 8.3-1and Table 8.3-2result from the following information:

- The degradation rate for MCPA was calculated from additional information supplied to the applicant by NuFarm (see section IIIA 9.1.1). The available biodegradation data for the metabolite PCOC is somewhat contradictory; the selection of a reasonable worst-case value has been used in this evaluation and is presented and discussed in this document (informed by UNEP 1998, see section 9.1.1).
- The degradation rates for fluroxypyr and its metabolites used in this evaluation are those proposed in EFSA (2011) following submission of the confirmatory data (see section IIIA 9.1.1) and no additional studies have been performed.
- The degradation rate for clopyralid is that proposed by EFSA (2018).

The proposed pathway of each active substance in soil is presented in the following figures:

- MCPA Figure 8.3-1
- Fluroxypyr-MHE and fluroxypyr Figure 8.3-2
- Clopyralid Figure 8.3-3

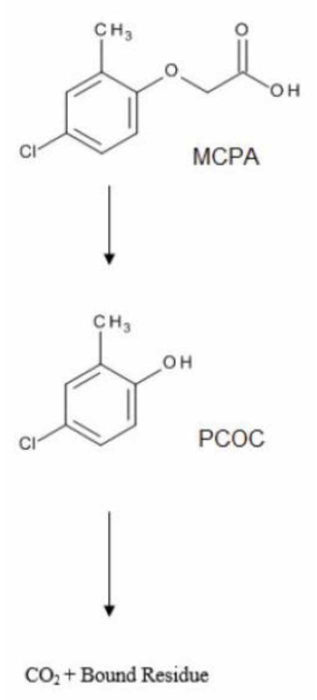


Figure 8.3-1: Proposed route of degradation of MCPA in soil

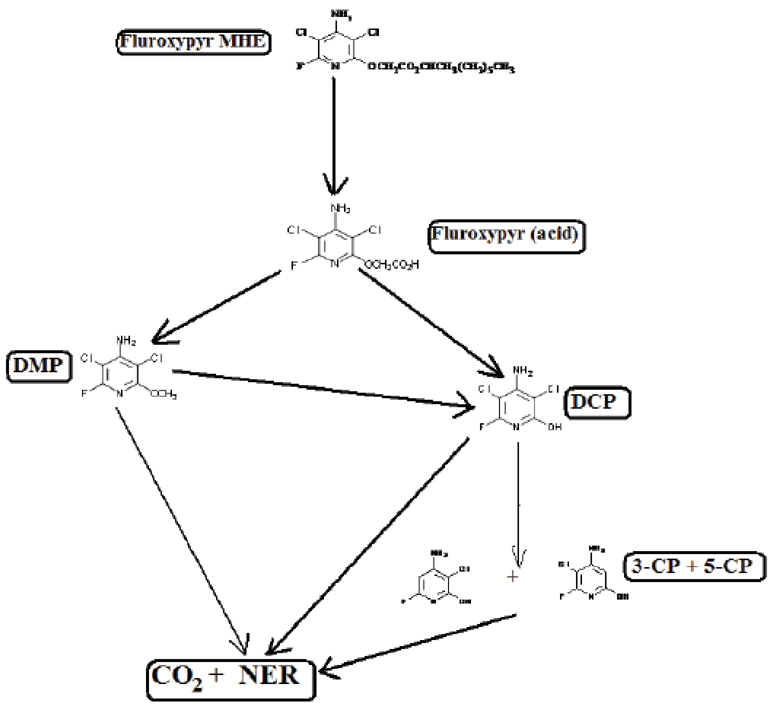


Figure 8.3-2: Proposed soil degradation pathway of fluroxypyr-MHE and fluroxypyr (described as "Fluroxypyr acid") as presented in the Addendum: Confirmatory information of the DAR (rMS Ireland 2014). Methoxypyridine is referred to as DMP and pyridinol as DCP.

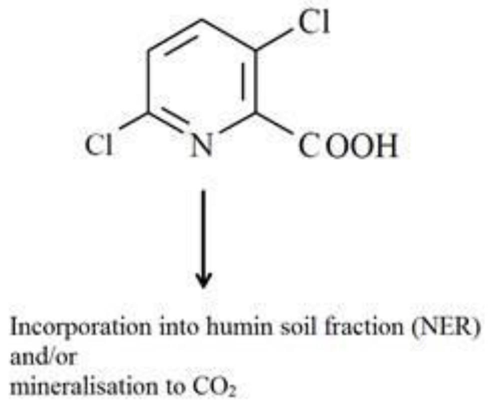


Figure 8.3-3: Proposed route of degradation of clopyralid in soil

8.3.1 Aerobic degradation in soil (KCP 9.1.1.1)

8.3.1.1 MCPA and its metabolites

Studies on aerobic degradation in soil with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance.

The EC (2008) agreed summary of data on MCPA degradation in soil is provided in the figure below. The data is not normalised and the suggested 24 day value stems from an experiment conducted at 25 °C. The equivalent normalised endpoint value from this dataset is 26.7 days which is the value used within this report.

Rate of degradation

Laboratory studies	**MCPA**
DT_{50}lab (20 °C, aerobic):	DT_{50lab} (20°C, aerobic): range from 7 to 41 d (14 soils, data from literature). The DT_{50} value of 24 d (25°C) chosen for PEC_{soil} calculations was obtained from the route of degradation study.
DT_{90}lab (25 °C, aerobic):	79 d (from the route of degradation study).
DT_{50}lab (10 °C, aerobic):	78 d (calculated value).
DT_{50}lab (20 °C, anaerobic):	DT_{50lab} (20°C, anaerobic): no degradation.

Figure 8.3-4: MCPA soil degradation data from EC (2008)

The peer review does not provide a full list of the studies but for completeness those have been provided below. Studies on the degradation of MCPA in 14 different soils have been conducted as part of the peer review, providing a DT_{50lab} range between 7 – 41 days. The value of 24 days, used in the modelling in the peer review was obtained from the route of degradation study. Although Smith (1989) was included in the original DAR for Annex I inclusion, it is an open literature paper and summarises secondary literature sources, it does not contain any primary data. In a data-sharing agreement, Nufarm provided a geometric mean DT_{50} normalised for temperature and moisture of 26.7 days. This value is used in this assessment for the generation of PEC_{soil} and PEC_{GW} values provided by the Notifier.

Studies on the degradation of the MCPA metabolite PCOC have been conducted in a few studies in different soils and were reviewed in UNEP (1998), providing a range of soil DT_{50} values between 14 – 21 days. The conclusion of UNEP (1998) is that the use of a DT_{50} of 21 days seems appropriate according to the "realistic worst-case" concept.

The reported concentration of PCOC formed during degradation in soil is typically 2 to 5% of the applied amount of the phenoxy herbicide. In one study (Duah-Yentumi & Kuwatsuka 1980) in an acid soil with pH 5.3, a maximum of 55% of the applied MCPA was reached after 25 days (UNEP, 1998).

Table 8.3-3 Available laboratory degradation data on MCPA.

Soil Type	Study DT_{50}	Temp (°C)	Water Content (%)	pH	Normalised DT_{50} (Q10=2.58)	Included in EC (2008)	Source
Sandy loam	32.1	26	19	7.2	56.69	Yes	Foster and McKercher (1973) cited in Smith (1989)
Clay loam	41	26	100	7.8	72	Yes	Foster and McKercher (1973) cited in Smith (1989)
Clay loam	15	26	100	6.2	26	Yes	Foster and McKercher (1973) cited in Smith (1989)
Loam	14.6	26	19	7.6	25.78	Yes	Foster and McKercher (1973) cited in Smith (1989)
Sandy Loam	22	23	12.7	7	10.5	Yes	Foster and McKercher (1973) cited in Smith (1989)
Clay	<7	20	85% FC	7.7	4	Yes	Smith and Hayden (1981) cited in Smith (1989)
Clay loam	<7	20	23.8	6	5	Yes	Smith and Hayden (1981) cited in Smith (1989)
Sandy loam	<7	20	85% FC	7.6	5	Yes	Smith and Hayden (1981) cited in Smith (1989)
Clay	13	20	23.8	7.7	4.46	Yes	Smith (1982) cited in Smith (1989)
Clay loam	14	20	85% FC	6	12	Yes	Smith (1982) cited in Smith (1989)
Sandy loam	14	20	85% FC	7.6	12	Yes	Smith (1982) cited in Smith (1989)
Sandy clay	28	23	100% FC	5.2	36	Yes	Satter (1982) cited in Smith (1989)
Sandy Loam	~8	23	12.7	7	10.6	Yes	Kirkland and Fryer (1972) cited in Smith (1989)
Sandy clay	28	25	100% FC	4.7	36	Yes	Satter et al 1980 cited in Smith (1989)
Sandy loam	24	23-29	75% FMC	8.03	**~26.7**	Yes	Matt (1990)- geometric mean of experimental values normalized for temperature and moisture*
Sandy loam	6	23	19	7	8	No	Muller and Buser (1997)
Sandy loam	7	20	13.3	7	5	No	Thorseten and Lode (2001)
Loam	16	20	17.5	5.5	12	No	Thorseten and Lode (2001)
Geomean All					13.3		
Arithmetic mean All					20.1		
Geomean Soil pH ≥6					11.58		

* provided by Nufarm via a data-sharing agreement. Fourteen out of the fifteen DT_{50} values included in EC (2008) are derived from Smith (1989). Smith (1989) does not contain any primary data and summarises secondary literature sources.

8.3.1.2 Fluroxypyr and its metabolites

Studies on aerobic degradation in soil with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance.

Degradation studies on fluroxypyr and its metabolites are available from the EFSA (2011) peer review of the active substance as summarised below. Subsequent to EFSA (2011), zRMS Ireland (2014) agreed that the degradation data for fluroxypyr acid should incorporate the degradation of the precursor (fluroxypyr-MHE) as a worst case assumption.

Table 8.3-4: Summary of aerobic degradation rates for fluroxypyr-MHE - laboratory studies

Laboratory Degradation studies of fluroxypyr-MHE							
Soil Type	**pH**	**temp/ soil moisture %**	**DT_{50}/DT_{90}**	**DT_{50}**	**X^2**	**Kinetic Fit**	**Evaluated on EU level Y/N Reference**
Sandy Loam	7.7	20/33.4	1.8/6.0	1.8	23.6	SFO	Y, EFSA 2011
Clay Loam	7.7	20/23.8	0.8/2.7	0.8	18.5	SFO	Y, EFSA 2011
Silty clay loam	8.1	20/19.2	1.5/5.0	1.5	36.6	SFO	Y, EFSA 2011
Loamy sand	6.7	20/23.4	1.3/4.3	1.3	24.7	SFO	Y, EFSA 2011
Silty clay loam	5.9	26/20.0	0.3/1.0	0.5	7.4	SFO	Y, EFSA 2011
Sandy loam	7.5	26/6.4	0.3/1.0	0.5	3.1	SFO	Y, EFSA 2011
Clay loam	6.8	26/21.0	0.4/1.3	0.7	8.4	SFO	Y, EFSA 2011
Clay Loam	7	26/19.1	0.5/1.7	0.9	16.6	SFO	Y, EFSA 2011
Clay loam	6.1	25/15.8	0.7/2.3	1.1	10.3	SFO	Y, EFSA 2011
Clay Loam	7.7	25/12.8	0.9/3.0	1.4	10.9	SFO	Y, EFSA 2011
Silty clay loam	7.9	25/13.6	0.7/2.3	1.1	0.9	SFO	Y, EFSA 2011
Loamy sand	5.7	25/9.6	0.9/3.0	1.4	2.6	SFO	Y, EFSA 2011
Geomean (n=12)				**1.0**			
Maximum (n=12)				1.8			

Table 8.3-5: Summary of aerobic degradation rates for fluroxypyr-MHE and fluroxypyr - laboratory studies

Laboratory Degradation studies of Parent (fluroxypyr-MHE+fluroxypyr)							
Soil Type	pH	**temp/ soil moisture %**	**DT_{50}/DT_{90}**	**DT50**	**X^2**	**Kinetic Fit**	**Evaluated on EU level Y/N Reference**
Sandy Loam	7.7	20/33.4	10.8/35.9	10.8	10.7	SFO	Y, EFSA 2011
Clay Loam	7.7	20/23.8	7.2/23.9	6.4	7.7	SFO	Y, EFSA 2011
Silty clay loam	8.1	20/19.2	12.7/41.2	9.3	15.8	SFO	Y, EFSA 2011
Loamy sand	6.7	20/23.4	7.8/25.9	7.8	8.5	SFO	Y, EFSA 2011
Silty clay loam	5.9	26/20.0	12.8/42.5	17.0	2.5	SFO	Y, EFSA 2011
Sandy loam	7.5	26/6.4	30.2/100.3	25.1	4.1	SFO	Y, EFSA 2011
Clay loam	6.8	26/21.0	14.4/47.8	20.9	9.5	SFO	Y, EFSA 2011
Clay Loam	7	26/19.1	8.8/29.2	8.1	5.8	SFO	Y, EFSA 2011
Clay loam	6.1	25/15.8	20.3/67.4	21.8	8	SFO	Y, EFSA 2011
Clay Loam	7.7	25/12.8	2.9/9.6	2.7	10.2	SFO	Y, EFSA 2011
Silty clay loam	7.9	25/13.6	6.90/22.91	6.3	6.52	SFO	Y, EFSA 2011
Loamy sand	5.7	25/9.6	17.1/56.8	21.1	13.1	SFO	Y, EFSA 2011
Loamy sand	n.d.	25/9.6	41.8/138.8 1)	38.4 1)	6.8	SFO	Y, EFSA 2011
Sandy loam	n.d.	25/10.8	49.4/163.2 1)	39.6 1)	6.38	SFO	Y, EFSA 2011
Geomean (n=14)				13.1			
Median (n=14)				**13.9**			
Maximum				39.6			

1) Kinetic endpoint for fluroxypyr acid only

Table 8.3-6: Summary of aerobic degradation rates for pyridinol - laboratory studies

Laboratory Soil Degradation studies of pyridinol								
Soil Type	**pH**	**temp/ soil moisture %**	**DT_{50}/DT_{90}**	**f.f kdp/kf**	**DT_{50} Norm**	**X^2**	**Kinetic Fit**	**Evaluated on EU level Y/N Reference**
Sandy Loam	7.7	20/33.4	16.3/54.2	0.184[1)]	16.3	28.9	SFO	Y, EFSA 2011
Clay Loam	7.7	20/23.8	15.7/52.1	0.089[1)]	14.0	26.6	SFO	Y, EFSA 2011
Silty clay loam	8.1	20/19.2	17.2/57.1	0.152[1)]	12.6	22.7	SFO	Y, EFSA 2011
Loamy sand	6.7	20/23.4	4.1/13.6	0.427[1)]	4.1	10.1	SFO	Y, EFSA 2011
Silty clay loam	5.9	26/20.0	43.8/145.5	0.358[1)]	58.0	17.1	SFO	Y, EFSA 2011
Sandy loam	7.5	26/6.4	13.8/45.8	0.25[1)]	11.5	20.6	SFO	Y, EFSA 2011
Clay loam	6.8	26/21.0	17/56.5	0.299[1)]	24.6	18.7	SFO	Y, EFSA 2011
Clay	7	26/19.1	9.2/30.6	0.360[1)]	8.4	13.6	SFO	Y, EFSA 2011
Clay loam	6.1	25/15.8	54.5/181.0	0.666[1)]	58.7	7.1	SFO	Y, EFSA 2011
Clay Loam	7.7	25/12.8	12/39.8	0.280[1)]	11.2	18.4	SFO	Y, EFSA 2011
Silty clay loam	7.9	25/13.6	14.7/48.8	0.117[1)]	13.5	11.2	SFO	Y, EFSA 2011
Loamy sand	5.7	25/9.6	85.2/283.0	0.254[1)]	105.4	26.8	SFO	Y, EFSA 2011
Sandy Loam	5.9	20/50	14.72/48.91	0.664[2)]	14.7	10.98	SFO	Y, Ireland 2014
Loamy sand	7.8	20/50	11.84/39.34	0.760[2)]	11.8	10.52	SFO	Y, Ireland 2014
Silt loam	6.3	20/50	29.06/95.53	0.727[2)]	29.1	11.31	SFO	Y, Ireland 2014
Loam	5.8	20/20	10.84/36.00	0.740[2)]	10.8	21.48	SFO	Y, Ireland 2014
Arithmetic Mean				0.286[1)]/0.723[2)]				
Geomean (n=16)					**17.6**			
Median (n=16)					13.8			
Maximum					105.4			

[1)] From fluroxypyr acid
[2)] From methoxypyridine

Table 8.3-7: Summary of aerobic degradation rates for methoxypyridine - laboratory studies

Soil Type	pH	temp/ soil moisture %	DT_{50}/DT_{90}	f.f kdp/kf	DT_{50}	X^2	Kinetic Fit	Evaluated on EU level Y/N Reference
Sandy Loam	7.7	20/33.4	64.5/214.2	0.183	65.4	57	SFO	Y, EFSA 2011
Clay Loam	7.7	20/23.8	208.9/692.3	0.160	185.5	27	SFO	Y, EFSA 2011
Silty clay loam	8.1	20/19.2	743.1/2468.5	0.119	542.5	30.3	SFO	Y, EFSA 2011
Loamy sand	6.7	20/23.4	16.7/55.5	0.118	16.7	16.2	SFO	Y, EFSA 2011
Silty clay loam	5.9	26/20.0	110.5/367.1	0.149	146.4	10.5	SFO	Y, EFSA 2011
Sandy loam	7.5	26/6.4	142.2/472.4	0.115	118.0	11.9	SFO	Y, EFSA 2011
Clay loam	6.8	26/21.0	80.7/2663.2	0.420	1160.9	12.8	SFO	Y, EFSA 2011
Clay	7.0	26/19.1	295.9/983.0	0.286	271.7	17.5	SFO	Y, EFSA 2011
Clay loam	6.1	25/15.8	>1000[1)]	0.221	1000.0	--	SFO	Y, EFSA 2011
Clay Loam	7.7	25/12.8	47.8/158.8	0.317	44.5	9.7	SFO	Y, EFSA 2011
Silty clay loam	7.9	25/13.6	101.0/335.5	0.201	92.7	14.9	SFO	Y, EFSA 2011
Loamy sand	5.7	25/9.6	196.7/653.4	0.126	243.3	6.4	SFO	Y, EFSA 2011
Sandy Loam	5.9	20/50	4.63/37.91	---	17.9	8.81	DFOP/slow phase DFOP	Y, Ireland 2014
Loamy sand	7.8	20/50	6.72/61.40	---	30.4	5.21	DFOP/slow phase DFOP	Y, Ireland 2014
Silt loam	6.3	20/50	12.23/11787	---	49.2	8.29	DFOP/slow phase DFOP	Y, Ireland 2014
Loam	5.8	20/20	24.72/10292	---	33.7	2.48	DFOP/slow phase DFOP	Y, Ireland 2014
Arithmetic Mean (n=16)				0.201				
Geomean (n=16)					**111.1**			
Median					105.4			
Maximum					1160.9			

8.3.1.3 Clopyralid

The agreed modeling endpoint for clopyralid soil degradation is based on field studies of the substance. The laboratory soil degradation data from EFSA (2005) and EFSA (2018) are summarised below.

Table 8.3-8: Summary of aerobic degradation rates for clopyralid- laboratory studies

Soil Type	pH	T °C /MWHC	DT_{50}/DT_{90}	DT_{50} Norm	Kinetic Fit	Reference
Parabraunerde (silt loam)	7.7	20/18.63	44.4/147.3	34.2	SFO	EFSA (2005) and EFSA (2018)
Marcham (sandy clay loam)	8.3	20/20.19	34.5/114.7	32.4	SFO	
Castle Rising (sandy loam)	8	20/65.13	26.3/87.3	26.3	SFO	
Speyer 2.1 (sand)	6.5	20/12.58	64.6/214.6	64.6	SFO	
Speyer 2.2 (sand)	6.3	20/18.56	16.2/53.8	16.2	SFO	
Marshall county (silt loam)	6	25/23.42	8.6/28.5	11.6	SFO	
A (sandy loam)	6.2	20/24.28	16.5/54.8	16.5	SFO	EFSA (2018)
B (clay loam)	7.6	20/28.05	23/76.4	23	SFO	
C (clay loam)	5.6	20/48.17	4.9/16.2	4.9	SFO	

D (loam)	7.5	20/35.30	9.8/32.4	9.8	SFO	
Maximum value				**64.6**		
Geometric mean				19.1		
pH dependent				no		

8.3.2 Anaerobic degradation in soil (KCP 9.1.1.1)

Studies on anaerobic degradation in soil with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance. Anaerobic degradation is not considered relevant concerning the use of this formulation on cereals and grassland.

8.4 Field studies (KCP 9.1.1.2)

Field degradation/dissipation studies were not performed with the formulation since it is possible to extrapolate the data obtained for the active substance.

Field degradation/dissipation were not considered relevant for MCPA or fluroxypyr and all agreed endpoints were derived using laboratory data at the EU level.

Field studies on clopyralid were considered by EFSA (2018) and used to derive the modelling degradation endpoint for the substance.

8.4.1 Soil dissipation testing on a range of representative soils (KCP 9.1.1.2.1)

Table 8.4-1: Summary of aerobic degradation rates for clopyralid-field studies

Soil Type	Location	pH	DT_{50} actual	DT_{50} Norm	Kinetic Fit
Loamy sand	Germany	4.3	21	13	SFO
Loam	UK	6.2	16.7	13.5	SFO
Silty clay loam	France	7	16.3	7.5	SFO
Silty clay loam	France	8.2	0.16	2.07	DFOP/SFO
Clay loam	France	7.1	6.04	2.7	DFOP/SFO
Silty clay loam	Germany	7.5	16.2	5.69	SFO
Sandy clay loam	Denmark	7.5	23.7	8.46	SFO
Clay loam	Spain	8	13.7	12.3	SFO
Silty clay loam	Germany	7.4	10.2	9.34	SFO
Silt loam	France	7.3	9.11	7.41	SFO
Geometric mean				**7.05**	
pH dependent				no	

8.4.2 Soil accumulation testing (KCP 9.1.1.2.2)

Soil accumulation studies were not performed, since it is possible to extrapolate from data obtained with the active substances. These tests were not necessary for the substances contained within the formulation.

8.5 Mobility in soil (KCP 9.1.2)

Studies on mobility in soil with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substances.

MCPA

The agreed EU soil sorption values for MCPA based on EFSA (2008) are K_{foc} = 74 and 1/n = 0.68 and there are not agreed EU sorption endpoints for PCOC. Based on previous submissions and discussion with member states, which considered Annex II data on the substances, it was indicated that the values for MCPA were not sufficiently conservative. The values listed below were agreed to as appropriate values for the risk assessment.

Non-EU but agreed endpoints used in this evaluation

Endpoint	MCPA	PCOC
K_{FOC} (mL/g)	55.5	400 (UNEP, 1988)
1/n	0.68	1 (worst case default)

Fluroxypyr Acid

EFSA (2011) derived an agreed list of soil sorption endpoints for fluroxypyr and its metabolites. The sorption of pyridinol in soil was determined to be pH dependent. Assessments covered here will only considered the worst case values based on alkaline soils.

Agreed EU Endpoints used in the Evaluation (EFSA 2011)

Endpoint	**Fluroxypyr-MHE**	**Fluroxypyr(acid)**	**Pyridinol**		**Methoxypyridine**	**3-CP**
K_{FOC} (mL/g)	19550 (arithmetic mean, n=4)	67 (geometric mean, n=4)	**68 (arithmetic mean of alkaline soils, n=2)***	700 (Geometric mean of acidic soils, n=7)	311 (geometric mean, n=4)	0 (worst case default)
1/n	0.90 (FOCUS default)	0.92 (arithmetic mean, n=4)	**0.72 (arithmetic mean of alkaline soils, n=2)***	0.81 700 (Geometric mean of acidic soils, n=7)	0.84 (arithmetic mean, n=4)	1.0 (worst case default)

*All environmental fate calculations covered in this report will utilise these alkaline endpoints as they cover the risk in all of the soils.

Clopyralid

The EFSA (2018) peer review of clopyralid contains correct data for clopyralid sorption but not valid modelling endpoints. Specifically, the peer review had to finish their review of the data before the EFSA (2017) guidance on the OECD 106 soil sorption checklist had been finalised even though it was already established the EFSA (2017) would have to be implemented in all EU risk assessments of clopyralid. The EFSA (2017) guidance document has therefore been applied here to derive sorption endpoints as required for EU fate modelling.

New proposed endpoints used in this evaluation (Hawley 2021)

Endpoint	Clopyralid
K_{FOC} (mL/g)	4.05 (geometric, n=4)
1/n	0.881 (arithmetic mean, n=4)

8.5.1 MCPA

The K_{OC} value of MCPA in EC (2008) is reported as a range from 10 – 157 L/kg from eight different soils. Whilst it is noted that sorption is pH dependent, i.e. non-linear sorption that shows less adsorption with increasing pH, this is only likely to be significant for pH < 4 and is therefore not relevant for this assessment. The Freundlich exponent (1/n) value is the arithmetic mean of values taken from 8 soils. The values ranged from 0.50 – 0.72 and the arithmetic mean value of 0.68 was used for modelling presented in this report. For clarification the raw data table showing the data table and which data were relied upon is provided in Table 8.5-1.

What is very unclear, and not justified in the DAR or review report, about the sorption dataset it why adsorption and desorption K_{foc} values were mixed and matched in an inconsistent manner. The z-RMS is correct that the current EFSA guidance is to use only adsorption values although their reference to EFSA (2014) is ambiguous. What is also clear when the data is presented in this manner is that one of the studies needs to be thrown out. The OC content and K_d value reported for the California soil fail to meet the minimum standards for reliability for use in a risk assessment. As a result, when you actually apply current EFSA guidance you end up with a K_{foc} of 56.59 not 45.3. At a core level this difference is insignificant and the lower value is more protective, so the decision was taken to not amend the endpoints.

A refined K_{foc} of 55.5 is used in some of the refined groundwater calculations provided below. This is a value which has been previously proposed by the French competent authorities ANSES to deal with the idiosyncrasies in the MCPA data. Specifically, is slightly conservative relative to both the geomean when EFSA (2014) is applied and the arithmetic mean when the EC (2005) logic is applied while also accounting for the potential of pH dependence. Critical is a protective means of representing the current EFSA data on MCPA which is consistent with current best practices.

Table 8.5-1: Sorption studies on MCPA reported in the DAR.

Soil name	Soil type (USDA)	Key soil properties		Average adsorption distribution coefficient	K_{fOC} [mL/g]			1/n		
		pH (in H2O)	OC [%]	K_d [mL/g]	Adsorption	Desorption	Average	Adsorption	Desorption	Average
California	Clay loam	7.8	1.2	Not Reported	**38**	69	53.5	**0.72**	0.82	0.77
Florida	Sand	5	0.52		**157**	264	210.5	**0.71**	1.37	1.04
Ohio	Silt loam	5.8	1.22		**95**	101	98	**0.7**	0.76	0.73
Ohio	Sandy loam	7.3	0.81		**60**	112	86	**0.7**	0.84	0.77
Illinois	Silt loam	5.9	2.23	1.49	33	101	**67**	0.707	Not Reported	**0.707**
California	*Sandy loam*	*7.5*	*0.22*	*0.05*	*9.6*	*40.4*	***25***	*0.5*		***0.5***
North Dakota	Loam	6.8	3.08	1.99	36	94	**65**	0.721		**0.721**
Massachusetts	Clay	7	1.26	1.07	46	124	**85**	0.686		**0.686**
EC LoEP			**Arithmetic mean of values in bold (n = 8)**		**74.00**			**0.68**		
EC Approach Excluding Outliers			Arithmetic mean (n = 7)		81			0.71		
			Geometric mean (n = 7)		74.4			0.71		
Applying EFSA 2014 to DAR data			Geomean (n = 7)		56.59			-		
			Arithmetic mean (n = 7)		69.83			0.71		

Values in bold indicate those which were used by EC (2005) for endpoint derivation, and cells shaded grey indicate data that were not used. The information in grey is not considered relevant because the OC content falls below the 0.3% minimum acceptable threshold and italics indicate where the Kd value falls below the minimum acceptable threshold of 0.1.

UNEP (1998) states a lack of experimental data on the K_{OC} of PCOC but provides a range between 14 – 700 L kg^{-1}, based on various QSAR operators. An estimated K_{OC} value of 400 L kg^{-1} was calculated from the K_{OW} (log K_{OC} = 0.81 logK_{OW} + 0.10) and is presented as a reasonable value for use in risk assessment. Without any standard laboratory test results from which to calculate a geometric mean, this value was used in the calculation of PEC_{SW}. No Freundlich exponent value was available for PCOC, so a worst-case value of 1.0 has been used.

8.5.2 Fluroxypyr and its metabolites

The agreed soil sorption endpoints for fluroxypyr and its metabolites are available from the Addendum: Confirmatory Information of the DAR for fluroxypyr (Ireland, 2017).

Table 8.5-2: Soil sorption data for fluroxypyr-MHE

Batch sorption experiments of fluroxypyr-MHE				
Soil	**OC%**	**Soil pH**	**Kd**	**Kdoc**
Silt loam	2.33	5.9	260	12000
Sandy loam	0.22	7.5	95	43000
Loam	3.08	6.8	190	6200
Clay	1.26	7	210	17000
Arithmetic mean (n=4)			188.75	**19550**

Table 8.5-3: Soil sorption data for fluroxypyr-acid

Batch sorption experiments of fluroxypyr (acid)					
Soil	OC%	Soil pH	Kf	Koc	1/n
Silt loam	2.33	5.9	1.7	78	0.92
Sandy loam	0.22	7.5	0.11	51	0.93
Loam	3.08	6.8	1.9	62	0.95
Clay	1.26	7	1	81	0.88
arithmetic mean (n=4)					0.92
geometric mean (n=4)				**67**	

Table 8.5-4: Soil sorption data for pyridinol

Batch sorption experiments of pyridinol					
Soil	OC%	Soil pH	Kf	Koc	1/n
Sandy loam	0.46	6.8	43.7	1791	0.85
Sand	1.68	6.4	28.9	1741	0.81
Clay	2.44	5.7	4.2	913	0.81
Silt loam	1.66	6.8	11.9	708	0.87
Loamy sand	0.93	4.7	3.21	345	0.790
Silt loam	2.9	6.4	10.21	352	0.744
Clay loam	3.71	7.7	4.31	76	0.731
Loam	4.06	5.7	13.68	337	0.754
Clay	1.68	7.5	1.03	61	0.717
pH dependent				yes	
Acidic soils (n=7)	700 (Geometric mean)				0.81
Alkaline soils (n=2)	**68 (Geometric mean)**				0.72

Table 8.5-5: Soil sorption data for methoxypyridine

Batch sorption experiments of methoxypyridine					
Soil	OC%	Soil pH	Kf	Koc	1/n
Sandy clay loam	2.6	7	7.14	274.6	0.81
Loamy sand	2	5.8	9.28	464	0.96
Silty clay loam	3.8	7.4	8.93	235	0.84
Clay soil	1.9	7.1	5.93	312	0.75
arithmetic mean (n=4)				321.4	0.84
Geomean (n=4)				**311**	

8.5.3 Clopyralid

The soil sorption endpoint data on clopyralid assessed as part of the EU review of the active substance is provided in Table 8.5-6. When it came to deriving an agreed endpoint from the data it was recognized that many of the studies were unreliable and should not be considered further. At the time EFSA was working what has become 'Outcome of the pesticide peer review meeting on the OECD 106 evaluators checklist' (EFSA, 2017) which provides the clear framework for addressing the reliability of soil sorption studies. However, the EFSA (2017) guidance was not applied by EFSA (2018), even though it was necessary and enforceable at the time of publication, most likely because the endpoint review had to be completely well ahead of the date of final publication.

Now that EFSA (2017) has been published it clear that the approach used by EFSA (2018) is not acceptable under the guidance and isn't fully relevant to EU risk assessments of clopyralid. As part of this assessment a new report (CP 9.1.1/01 Hawley, 2021; summarised in Appendix 3.1) has applied the EFSA (2017) guidance to the EFSA (2018) data to derive the relevant endpoint values for clopyralid.

Table 8.5-6: Soil sorption data for clopyralid

Study Report	Soil	OC%	pH	K_d	Kfoc	Kdoc	1/n
Reeves and Mittelstaedt (2002)	Merzenhausen	1	7.19	0.051	0.57	5.1	0.9*
	Kaldenkirchen (Ap horizon)	0.98	5.34	0.048	2.72	4.9	0.9*
	Lanna	2.06	6.62	0.151	0.26	7.3	0.9*
	Overhetfeld	0.93	6.49	0.032	1.34	3.4	0.9*
Buntain and Simmonds (2015)	Calke	3.15	5.7	0.139	0.5	4.4	0.9* (0.489)**
	Longwoods	3.13	7.4	0.069	2.5	2.2	0.9*
	Lufa 2.1	0.68	4.9	0.04	4.1	5.9	0.9*
	Quilen	4.02	6.9	0.356	3.9	8.9	0.804
	DU-L-PF	6.47	6.3	0.282	2.1	4.4	0.829
Geometric mean (n=9)					**1.41**	4.82	-
Arithmetic mean (n = 9)					-	-	**0.836**
Refined: Geometric mean in accordance with EFSA (2018) Soil Sorption Checklist					**4.05**		-
Refined: Arithmetic mean in accordance with EFSA (2018) Soil Sorption Checklist							**0.881**

The values shaded in grey are considered unreliable for endpoint derivation
*EFSA (2013) considered 6 of values invalid and replaced them with default values for endpoint derivation
**EFSA (2018) LoEP value.

8.5.4 Column leaching (KCP 9.1.2.1)

The available adsorption/desorption studies provided the required information. Therefore, no column leaching studies are required.

8.5.5 Lysimeter studies (KCP 9.1.2.2)

The available adsorption/desorption studies provided the required information. Therefore, no lysimeter studies are required.

8.5.6 Field leaching studies (KCP 9.1.2.3)

The available adsorption/desorption studies provided the required information. Therefore, no field leaching studies are required.

8.6 Degradation in the water/sediment systems (KCP 9.2, KCP 9.2.1, KCP 9.2.2, KCP 9.2.3)

Studies on degradation in water/sediment systems with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance.

8.6.1 MCPA and its metabolites

The agreed EU water/sediment degradation data for MCPA has been reproduced below from EC (2008). The values reported are the means of two studies whereas current guidance is to use the worst-case when only two studies are available.

Water/sediment study:	(mean of 2 sediments)
DT_{50} water: DT_{90} water: DT_{50} whole system: DT_{90} whole system:	13.5 d 44.7 d 16.9 d 56.2 d
Distribution in water / sediment systems (active substance)	63% of applied dose was converted to CO_2 in 84 d. Less than 20% was detected in the sediment system.
Distribution in water / sediment systems (metabolites)	Only CO_2 was identified as a significant metabolite
Accumulation in water and/or sediment	No accumulation of parent or metabolites.

Figure 8.6-1: Water/Sediment degradation data for MCPA from EC (2008)

In aqueous solutions, PCOC (2-methyl-4-chlorophenol) is the major photodegradation product, representing 11.6 % of the applied dose (EC, 2008). In UNEP (1998) PCOC was regarded as readily biodegradable in soil and surface water and a biodegradation half-life of 21 days was assumed for both compartments.

8.6.2 Fluroxypyr and its metabolites

Agreed water/sediment degradation rates for fluroxypyr and its metabolites are available from EFSA (2011).

Table 8.6-1: Water/Sediment degradation data for Fluroxypyr

Parent (fluroxypyr-MHE+fluroxypyr (acid), distribution: (fluroxypyr MHE- almost totally disappearing from the systems after 7 days; fluroxypyr acid-88-93% after 1-2 weeks, up to 80% in water phase, up to 20% in sediment phase)						
Water/sediment system	**pH water**	**$DegT_{50}$ whole syst. (d)**	**$DegT_{90}$ whole syst. (d)**	**Kinetic, Fit**	**$DissT_{50}$ water (d)**	**$DissT_{50}$ sed. (d)**
Thornham ditch	7.5	38.1	126.5	SFO	N.D.	N.D.
Crimplesham ditch	3.1-3.8	31.3	103.9	SFO	N.D.	N.D.
Maximum value		**38.1**				

Table 8.6-2: Water/Sediment degradation data for pyridinol

Pyridinol (max in system 46% after 8 weeks, mainly in water phase; max in water/sediment system: 55.5% (44% in water phase, 11.5% in sediment phase)						
Water/sediment system	**pH water**	**DegT50 whole syst. (d)**	**DegT90 whole syst. (d)**	**Kinetic, Fit**	**DissT50 water (d)**	**DissT50 sed. (d)**
Thornham ditch	7.5	27.8	92.3	SFO	N.D.	N.D.
Crimplesham ditch	3.1-3.8	35.5	118	SFO	N.D.	N.D.
Maximum value		**35.5**				

Table 8.6-3: Water/Sediment degradation data for 3-CP

3-CP (max in system 25.2% after 4 weeks, mainly in water phase)						
Water/sediment system	**pH water**	**DegT50 whole syst. (d)**	**DegT90 whole syst. (d)**	**Kinetic, Fit**	**DissT50 water (d)**	**DissT50 sed. (d)**
Thornham ditch	8.2	N.D	N.D		N.D.	N.D.

8.6.3 Clopyralid

Two sediment/water studies were evaluated by EFSA (2018) but it was not possible to derive a reliable degradation rate from either study.

Table 8.6-4: Water/sediment degradation data for clopyralid from EFSA (2018).

Distribution: max in water 100% at 0 d, max. in sediment 26% at 100 d					
Water/sediment system	pH	T	DT_{50} whole syst	DT_{50} water	DT_{50} sed
Loamy sand	6.5	20	>500	128	>500
Sandy silt loam	8.16	20	>500	167	>500

8.7 Predicted Environmental Concentrations in soil (PEC_{soil}) (KCP 9.1.3)

<table>
<tr><td>zRMS Comments:</td><td>
The used endpoints for all active substances used in PECs assessment were agreed at the EU level or accepted during the evaluation (PCOC metabolite).
The following application pattern was used in PECs assessment:

MCPA: 700 g as/ha;
Fluroxypyr (acid): 150 g as/ha;
Fluroxypyr-MHE: 216.1 g as/ha;
Clopyralid: 84 g as/ha.

The PECs values for active substances and their metabolites were accepted.
MCPA. The DT_{50} = 72 d was used for PECs assessment and accepted as a worse case. The initial PEC_S value for active substance was assessed of 0.747 mg a.s./kg soil.
Additionally, the metabolite PCOC was considered; this metabolite was not identified during active substance evaluation (2008) PECs = 0.062 mg a.s./kg soil.
Fluroxypyr. Both forms of active substance were considered – meptyl and acid. The initial and cumulative PEC_S values for active substance and its metabolites are presented in the table below:
<table>
<tr><th>Compound</th><th>PECs mg/kg soil</th><th>PECs, accum mg/kg soil</th></tr>
<tr><td>Fluroxypyr-MHE</td><td>0.230</td><td>nr</td></tr>
<tr><td>Fluroxypyr</td><td>0.160</td><td>nr</td></tr>
<tr><td>Pyridinol (DCP)</td><td>0.030</td><td>0.032</td></tr>
<tr><td>Methoxypyridine (DMP)</td><td>0.0.37</td><td>0.190</td></tr>
</table>
nr – not relevant
Clopyralid. The DT_{50} = 65 d was used for PECs assessment and accepted as a worse case. The initial PEC_S values for active substance was assessed of 0.085 mg a.s./kg soil.
Formulation. The application rate of formulation of 3.0 L formulation/ha was used in PECs assessment; the PECs = 3.60 mg/kg soil.
These values will be used in further risk assessment.
</td></tr>
</table>

The predicted environmental concentration in soil (PEC_{soil}) of fluroxypyr MHE, Fluroxypyr, pyridinol, methoxypyridine, MCPA, PCOC and clopyralid were calculated using the standard FOCUS (1997) methodology. The results are summarized below in

Table 8**.7-1**.

Table 8.7-1: Summary of PEC_{soil} values

PECsoil Summary				
Substance	**PEC_{ini} (mg/kg)**	**PEC_{acc} (mg/kg)**	**Refined**	
			PEC_{ini} (mg/kg)	**PEC_{acc} (mg/kg)**
MCPA	0.747	0.747	-	-
PCOC	0.062	0.062	-	-
Fluroxypyr-MHE	0.230	0.230	-	-
Fluroxypyr	0.160	0.160	-	-
Pyridinol (DCP)	0.030	0.032	-	-
Methoxypyridine (DMP)	0.0.37	0.190	0.024	0.128
Clopyralid	0.085	0.087	-	-

8.7.1 Justification for new endpoints

No new endpoints have been used in the PEC_{SOIL} calculations.

8.7.2 Active substance(s) and relevant metabolite(s)

Predicted environmental concentrations in soil were estimated using the PEC Soil Calculator (version 1.0) (HSE, 2015). The tool assumes SFO degradation and calculations for metabolites were based on total annual applications adjusted for molecular weight differences and occurrence in soil. For methoxypyridine refined PECsoil was calculated using the more realistic parent to two metabolites in parallel functionality in the model ESCAPE v2.0.

Table 8.7-2: Input parameters related to application for PEC_{soil} calculations

Use No.	
Crop	Cereals
Application rate (g as/ha)	MCPA:700 Fluroxypyr (acid):150 Fluroxypyr-MHE:216.1 Clopyralid:84
Number of applications/interval	1
Crop interception (%)	20 %
Depth of soil layer (relevant for plateau concentration) (cm)	5 cm

Table 8.7-3: Input parameter for active substance(s) and relevant metabolite(s) for PEC_{soil} calculation

Compound	Molecular weight (g/mol)	Max. occurrence (%)	Normalised application rate*	DT_{50}	Value in accordance to EU endpoint
				(days)	Reference
MCPA	200.6	-	560	72 (worst case lab) 26.7 **	EC (2008) N**
PCOC	142.6	55.0	46.18	21.0	N, UNEP 1998
Fluroxypyr-MHE	367.3	-	172.8	1.8 (worst case laboratory)	EFSA (2011)
Fluroxypyr (acid)	255	100	120	39.6 (worst case laboratory)	EFSA (2011)
Pyridinol	197	23.9	22.2	105.4 (worst case lab)	EFSA (2011)
Methoxypyridine	211	38.2	Calculated as metabolite of fluroxypyr-acid	1160.9 (worst case lab)	EFSA (2011)
Clopyralid	192	-	64	65 (worst case lab and field)***	EFSA (2018)

*Application rate adjusted for crop interception, maximum occurrence, and molecular mass
** Provided by Nufarm via a data-sharing agreement, geometric mean of experimental values normalized for temperature and moisture.
***In EFSA (2018) the worst case, un-normalised field DT_{50} value of 23.7 d was used for PECsoil calculations.

8.7.2.1 MCPA and its metabolites

Table 8.7-4: PEC_{soil} for MCPA

PEC_{soil} (mg/kg dws) for MCPA					
PEC_{soil}		Cereals			
(mg/kg)		Single application			
		DT_{50} = 72 d		DT_{50} = 26.7 d	
		Actual	TWA	Actual	TWA
Initial		0.747	-	0.747	-
Short term	24h	0.740	0.743	0.728	0.737
	2d	0.732	0.740	0.709	0.728
	4d	0.718	0.732	0.673	0.709
Long term	7d	0.698	0.722	0.623	0.683
	14d	0.653	0.699	0.519	0.626
	21d	0.610	0.676	0.433	0.576
	28d	0.570	0.654	0.361	0.531
	50d	0.470	0.598	0.215	0.427
	100d	0.285	0.479	0.056	0.266

Table 8.7-5: PEC$_{soil}$ for PCOC

PEC$_{soil}$ (mg/kg dws) for PCOC			
PEC$_{soil}$		**Cereals**	
(mg/kg)		**Single application**	
		Actual	**TWA**
Initial		0.062	-
Short term	24h	0.060	0.061
	2d	0.058	0.060
	4d	0.054	0.058
Long term	7d	0.049	0.055
	14d	0.039	0.049
	21d	0.031	0.044
	28d	0.024	0.040
	50d	0.013	0.031
	100d	0.002	0.018

8.7.2.2 Fluroxypyr and its metabolites

Table 8.7-6: PEC$_{soil}$ for Fluroxypyr-MHE

PEC$_{soil}$ (mg/kg dws) for fluroxypyr MHE			
PEC$_{soil}$		**Cereals**	
(mg/kg)		**Single application**	
		Actual	**TWA**
Initial		0.230	-
Short term	24h	0.157	0.191
	2d	0.107	0.161
	4d	0.049	0.118
Long term	7d	0.016	0.080
	14d	0.001	0.043
	21d	<0.001	0.028
	28d	<0.001	0.021
	50d	<0.001	0.012
	100d	<0.001	0.006

Table 8.7-7: PEC$_{soil}$ for fluroxypyr (acid)

PEC$_{soil}$ (mg/kg dws) for fluroxypyr (acid)			
PEC$_{soil}$		**Cereals**	
(mg/kg)		**Single application**	
		Actual	**TWA**
Initial		0.160	-
Short term	24h	0.157	0.159
	2d	0.154	0.157
	4d	0.149	0.155
Long term	7d	0.142	0.151
	14d	0.125	0.142
	21d	0.111	0.134
	28d	0.098	0.126
	50d	0.069	0.108
	100d	0.028	0.076

Table 8.7-8: PEC$_{soil}$ for pyridinol

PEC$_{soil}$ (mg/kg dws) for pyridinol			
PEC$_{soil}$		**Cereals**	
(mg/kg)		**Single application**	
		Actual	**TWA**
Initial		0.030	-
Short term	24h	0.029	0.029
	2d	0.029	0.029
	4d	0.029	0.029
Long term	7d	0.028	0.029
	14d	0.027	0.028
	21d	0.026	0.028
	28d	0.025	0.027
	50d	0.022	0.025
	100d	0.015	0.022
Plateau concentration after 20 years (5cm)		0.003	-
PEC$_{accu}$		0.032	-

Table 8.7-9: PEC$_{soil}$ for methoxypyridine

PEC$_{soil}$ (mg/kg dws) for methoxypyridine					
PEC$_{soil}$		**Cereals**			
(mg/kg)		**Single application**			
		Standard (HSE PECsoil calculator v1.0)		**Refined (ESCAPE v2.0)**	
		Actual	**TWA**	**Actual**	**TWA**
Initial		0.037	-	0.024	-
Short term	24h	0.037	0.037	0.024	0.024
	2d	0.037	0.037	0.024	0.024
	4d	0.037	0.037	0.024	0.024
Long term	7d	0.037	0.037	0.024	0.024
	14d	0.037	0.037	0.024	0.024
	21d	0.037	0.037	0.024	0.024
	28d	0.037	0.037	0.024	0.024
	50d	0.036	0.037	0.023	0.024
	100d	0.035	0.036	0.023	0.024
Plateau concentration after 28/many* years (5cm)		0.153	-	0.105	-
PEC$_{accu}$		0.190	-	0.128	-

*Escape terminology

8.7.2.3 Clopyralid

Table 8.7-10: PEC$_{soil}$ for clopyralid

PEC$_{soil}$ (mg/kg dws) for clopyralid			
PEC$_{soil}$		**Cereals**	
(mg/kg)		**Single application**	
		Actual	**TWA**
Initial		0.085	-
Short term	24h	0.084	0.085
	2d	0.084	0.084
	4d	0.082	0.084
Long term	7d	0.079	0.082
	14d	0.073	0.079
	21d	0.068	0.076
	28d	0.063	0.074
	50d	0.051	0.067
	100d	0.029	0.052
Plateau concentration after 20 years (5cm)		0.002	-
PEC$_{accu}$		0.087	-

8.7.2.4 PEC_{soil} of formulation

For the calculation of formulation PEC_{soil} the standard FOCUS methodology embedded in the HSE PECsoil calculator tool (version 1.0, 2015) was used. The application rate of 3 L/ha for winter cereals was converted to a mass of 3375 g/ha based on a formulation density of 1.125 g/mL.

Table 8.7-11: PEC_{soil} for formulation on crop

Formulation	Application rate (mL/ha)	Application rate (g/ha)	PEC_{max} (mg/kg)
Kinvara	3000	3375	3.6

8.8 Predicted Environmental Concentrations in groundwater (PEC_{gw}) (KCP 9.2.4)

zRMS Comments:	Calculations of PEC_{GW} for active substances and their relevant metabolites were accepted. The recommended FOCUS models were used: FOCUS PELMO and FOCUS PEARL. Most of used endpoints were agreed at the EU level. Only for clopyralid the recalculated value of Kfoc was used. For winter and spring cereals and grasses the relevant application rates were considered. The proposed application dates were accepted. The plant uptake factor of 0 was used for all active substances and relevant metabolites. **MCPA**. The lowest value of Kfoc (alkaline soils) was used and accepted. Additionally, the metabolite PCOC was considered. The maximum PEC_{GW} values for active substance and its metabolite were below the trigger value of 0.1 µg/L. **Fluroxypyr**. The agreed value of Koc was used (arithmetic mean of 68 mL/g) in PECgw assessment. In accordance with EFSA, 2014, the geometric mean (67 mL/g) should be used; in this case the difference between both means will not effect on results, In case of Fluroxypyr pyridinol, the recommended Kfoc value was used (of 68.5 mL/g) representing a worse case (alkaline soils) which covers the acidic and neutral conditions. The maximum PEC_{GW} values for active substance and its metabolites in all scenarios were below the trigger value of 0.1 µg/L. **Clopyralid**. The recalculated Kfoc values was used in PECgw assessment was used and accepted. The maximum PEC_{GW} values for active substance in all scenarios relevant for Central Zone were below the trigger value of 0.1 µg/L in case of winter and spring cereals and grasslands if formulation is applied from March to August 15th . The PECgw assessment was amended using the EU agreed endpoint for Kfoc = 1.41 mL/g and 1/n =0.836. The results are presented in Table 8.8-10a, 8.8-10b, 8.8-11a, 8.8-11b.

8.8.1 Justification for new endpoints

The soil sorption and degradation values for MCPA have been made more conservative than the values reported in the EFSA peer reviews. The derivations of these values are provided in Sections 8.3 and 8.5 above. They are based on the official EU data but corrected for historic idiosyncrasies.

The soil sorption value for clopyralid has been calculated from the agreed EFSA data and applying current EU best practices for selecting modelling endpoints. The approach is described in Section 8.5 above and more details are provided in Appendix III of this dossier.

8.8.2 Active substance(s) and relevant metabolite(s) (KCP 9.2.4.1)

Table 8.8-1: Input parameters related to application for PEC_{gw} calculations

Use Pattern	Winter Cereals	Spring Cereals	Grassland (all uses)	Grassland (>1 year)
Crop	Winter Cereals	Spring Cereals	Grass, alfalfa	Grass, alfalfa
Application rate (g as/ha)	MCPA 1:700 Fluroxypyr (acid):150 Clopyralid:84	MCPA 1:700 Fluroxypyr (acid):150 Clopyralid:84	MCPA 1:700 Fluroxypyr (acid):150 Clopyralid:84	MCPA 1:700 Fluroxypyr (acid):150 Clopyralid:84
Number of applications/interval (d)	1	1	1	1
Application date	see Table 8.8-2**Błąd! Nie można odnaleźć źródła odwołania.**	see Table 8.8-2	March-15, June-01	August- 15, September-15
Crop interception (%)	20	20	40	90
Frequency of application	annual	annual	annual	annual

Table 8.8-2: Application dates used for groundwater risk assessment

Scenario	**Winter Cereals BBCH 24**	**Spring Cereals BBCH 24**
Châteaudun	Apr-09	Apr-05
Hamburg	Apr-28	Apr-20
Jokioinen	May-08	May-31
Kremsmünster	Apr-18	Apr-20
Okehampton	Apr-15	Apr-16
Piacenza	Mar-13	N/A
Porto	Mar-01	Apr-05
Sevilla	Dec-26	N/A
Thiva	Jan-03	N/A

8.8.2.1 MCPA and PCOC

Table 8.8-3: Input parameters related to active substance active substance MCPA and PCOC for PEC_{gw} calculations

Compound	MCPA	PCOC	Value in Accordance with EU Endpoint	
			MCPA	**PCOC**
Molecular weight (g/mol)	200.6	142.6	Y, EC (2008)	UNEP (1998)
Saturated vapour pressure (Pa)	4.00×10^{-4}	1×10^{-10}	Y, EC (2008)	UNEP (1998)
Water solubility (mg/L)	293900	2300	Y, EC (2008)	UNEP (1998)
Formation fraction in soil	-	1	FOCUS default	FOCUS default
Maximum Occurrence in Soil (%)	100	55	Y, EC (2008)	UNEP (1998)
$DT_{50,soil}$ (d)	26.7*	21 (median)	N, Normalised values from EC (2008)*	UNEP (1998)
Transformation rate	0.03448 to PCOC	0.03300 to CO_2		
K_{foc} (mL/g)	55.5 (alkaline, worst case)	400	Y, Geometric mean of EC (2008) soils with pH >4	UNEP (1998)
1/n	0.71 (alkaline, worst case)	1	Y, EC (2008)	UNEP (1998)
Plant Uptake	0	0	FOCUS default	
Maximum occurrence observed (% molar basis with respect to the parent)	-	55	-	UNEP (1998)
Formation fraction in soil:	-	1	-	FOCUS default

*geometric mean of experimental values in EC (2008), normalized for temperature and moisture, see Section 8.3.1.1 for further details
**value more conservative than EC (2008), see Section 8.6.1 for further details

Table 8.8-4: PEC$_{gw}$ for MCPA and PCOC (with FOCUS PEARL v5.5.5)

80th Percentile PEC$_{gw}$ at 1 m Soil Depth (µg/L)											
Application		Substance	Châteaudun	Hamburg	Jokioinen	Kremsmünster	Okehampton	Piacenza	Porto	Sevilla	Thiva
Winter cereals		MCPA	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
		PCOC	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
Spring cereals		MCPA	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	NP	< 0.001	NP	NP
		PCOC	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001		< 0.001		
Grass	Mar	MCPA	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
		PCOC	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
	Jun	MCPA	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
		PCOC	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
	Sep	MCPA	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
		PCOC	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001

NP = Not parameterised

Table 8.8-5: PEC$_{gw}$ for MCPA and PCOC (with FOCUS PELMO v6.6.4)

80th Percentile PEC$_{gw}$ at 1 m Soil Depth (µg/L)											
Application		Substance	Châteaudun	Hamburg	Jokioinen	Kremsmünster	Okehampton	Piacenza	Porto	Sevilla	Thiva
Winter cereals		MCPA	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
		PCOC	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
Spring cereals		MCPA	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	NP	< 0.001	NP	NP
		PCOC	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001		< 0.001		
Grass	Mar	MCPA	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	0.010	< 0.001	< 0.001	< 0.001
		PCOC	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	0.011	< 0.001	< 0.001	< 0.001
	Jun	MCPA	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
		PCOC	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
	Sep	MCPA	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	0.007	< 0.001	< 0.001	< 0.001
		PCOC	< 0.001	< 0.001	< 0.001	< 0.001	0.001	0.014	0.001	< 0.001	< 0.001

NP = Not parameterised

8.8.2.2 Fluroxypyr and its metabolites

Table 8.8-6: Input parameters related to active substance active substance fluroxypyr and its metabolites for PEC_{gw} calculations

Compound	**Fluroxypyr (acid)**	**Pyridinol**	**Methoxypyridine**	**Value in accordance with EU endpoint**
Molecular weight (g/mol)	255	197	211	y, EFSA (2011)
Water solubility (mg/L):	91	91 (assumed same as parent)	91 (assumed same as parent)	y, EFSA (2011)
Saturated vapour pressure (Pa):	3.8×10^{-9}	0 (worst case assumption)	0 (worst case assumption)	y, EFSA (2011)
DT50 in soil (d)	13.9 (median)	17.6	111.1	y, Ireland (2014)
Formation fraction in soil	1	0.286 from fluroxypyr; 0.723 from methoxypyridine	0.201 from fluroxypyr	y, Ireland (2014)
Maximum occurence in Soil (%)	100	23.9	38.2	y, EFSA (2011)
K_{fOC} (mL/g)	68	68.5	321	y, Ireland (2014)
1/n	0.92	0.72	0.84	y, Ireland (2014)
Plant Uptake	0	0	0	FOCUS default

Table 8.8-7: PEC_{gw} for fluroxypyr and its metabolites (with FOCUS PEARL v5.5.5)

80th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)											
Application		Substance	Châteaudun	Hamburg	Jokioinen	Kremsmünster	Okehampton	Piacenza	Porto	Sevilla	Thiva
Winter cereals		Fluroxypyr	< 0.001	0.002	< 0.001	0.002	0.004	0.001	< 0.001	< 0.001	< 0.001
		Methoxy-pyridine	< 0.001	0.002	< 0.001	0.001	0.005	0.002	< 0.001	< 0.001	< 0.001
		Pyridinol	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
Spring cereals		Fluroxypyr	< 0.001	0.002	< 0.001	0.002	0.003	NP	< 0.001	NP	
		Methoxy-pyridine	< 0.001	0.003	< 0.001	0.001	0.003		< 0.001		
		Pyridinol	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001		< 0.001		
Grass	Mar	Fluroxypyr	< 0.001	0.001	< 0.001	< 0.001	0.002	0.001	< 0.001	< 0.001	< 0.001
		Methoxy-pyridine	< 0.001	0.001	< 0.001	< 0.001	0.002	0.002	< 0.001	< 0.001	< 0.001
		Pyridinol	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
	Jun	Fluroxypyr	< 0.001	0.001	< 0.001	< 0.001	0.002	0.001	< 0.001	< 0.001	< 0.001
		Methoxy-pyridine	< 0.001	0.001	< 0.001	< 0.001	< 0.001	0.001	< 0.001	< 0.001	< 0.001
		Pyridinol	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
	Sep	Fluroxypyr	< 0.001	0.001	< 0.001	< 0.001	0.001	0.001	0.001	< 0.001	< 0.001
		Methoxy-pyridine	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
		Pyridinol	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001

NP = Not parameterised

Table 8.8-8: PEC$_{gw}$ for fluroxypyr and its metabolites (with FOCUS PELMO v6.6.4)

80th Percentile PEC$_{gw}$ at 1 m Soil Depth (µg/L)											
Application		Substance	Châteaudun	Hamburg	Jokioinen	Kremsmünster	Okehampton	Piacenza	Porto	Sevilla	Thiva
Winter cereals		Fluroxypyr	< 0.001	0.001	< 0.001	< 0.001	0.001	< 0.001	< 0.001	< 0.001	<0.001
		Methoxy-pyridine	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
		Pyridinol	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
Spring cereals		Fluroxypyr	< 0.001	0.001	< 0.001	0.001	0.001	NP	< 0.001	NP	
		Methoxy-pyridine	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001		< 0.001		
		Pyridinol	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001		< 0.001		
Grass	Mar	Fluroxypyr	< 0.001	< 0.001	< 0.001	< 0.001	0.002	0.003	< 0.001	< 0.001	< 0.001
		Methoxy-pyridine	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	0.002	< 0.001	< 0.001	< 0.001
		Pyridinol	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
	Jun	Fluroxypyr	< 0.001	0.001	< 0.001	< 0.001	0.001	0.001	< 0.001	< 0.001	< 0.001
		Methoxy-pyridine	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	0.001	< 0.001	< 0.001	< 0.001
		Pyridinol	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
	Sep	Fluroxypyr	< 0.001	0.004	0.003	0.002	0.009	0.019	0.007	< 0.001	< 0.001
		Methoxy-pyridine	< 0.001	0.001	< 0.001	< 0.001	0.002	0.005	0.001	< 0.001	< 0.001
		Pyridinol	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	0.001	< 0.001	< 0.001	< 0.001

NP = Not parameterised

8.8.2.3 Clopyralid

Table 8.8-9: Input parameters related to active substance active substance clopyralid

Parameter	Clopyralid	Comments
Molecular Mass (g/mol)	191.96	EFSA (2018)
Water solubility at 20 °C (mg/L)	143000	EFSA (2018)
Vapour pressure (Pa at 20°C)	1.36E-03	EFSA (2018)
Kfoc (mL/g)	1.41	EFSA (2018)
1/n	0.836	EFSA (2018)
Kfoc (mL/g)	4.05	Refined endpoints See Section 8.5
1/n	0.881	
DegT$_{50}$ Soil(d)	7.05	EFSA (2018)
Crop uptake factor	0	FOCUS default

EFSA (2018) endpoints

Table 8.8-10a: PEC$_{gw}$ for clopyralid (with FOCUS PEARL v5.5.5)

	80th Percentile PEC$_{gw}$ at 1 m Soil Depth (µg/L)					
	Winter Cereals	Spring Cereals	Grassland			
			March	June	August 15th	Sept.
Châteaudun (C)	0.005	0.003	0.022	0.011	0.007	**0.213**
Hamburg (H)	**0.169**	**0.151**	0.052	**0.134**	**0.127**	**1.659**
Jokioinen (J)	**0.136**	**0.191**	**0.345**	**0.194**	**0.196**	**2.899**
Kremsmünster (K)	**0.121**	**0.104**	0.040	0.035	0.022	**0.402**
Okehampton (N)	**0.140**	0.068	0.099	0.072	0.033	**0.661**
Piacenza (P)	0.057	-	0.059	0.008	0.021	**0.467**
Porto (O)	0.043	0.001	0.029	0.002	0.006	**0.343**
Sevilla (S)	<0.001	-	<0.001	<0.001	<0.001	0.020
Thiva (T)	0.009	-	<0.001	<0.001	0.001	0.034

Values in bold exceed the 0.1 µg/L threshold for groundwater

Table 8.8-11a: PEC$_{gw}$ for clopyralid (with FOCUS PELMO v6.6.4)

	80th Percentile PEC$_{gw}$ at 1 m Soil Depth (µg/L)					
	Winter Cereals	Spring Cereals	Grassland			
			March	June	August 15th	Sept.
Châteaudun (C)	0.003	0.001	0.008	0.009	0.006	0.018
Hamburg (H)	0.027	0.023	0.072	0.037	0.045	**0.136**
Jokioinen (J)	**0.173**	**0.226**	**0.546**	**0.200**	**0.188**	**0.447**
Kremsmünster (K)	0.066	0.068	0.039	0.030	0.026	0.079
Okehampton (N)	**0.113**	0.080	**0.169**	0.087	0.028	**0.101**
Piacenza (P)	**0.119**	-	**0.359**	0.019	0.026	0.061
Porto (O)	**0.127**	0.005	**0.164**	0.003	0.006	0.051
Sevilla (S)	**0.127**	-	<0.001	<0.001	<0.001	0.002
Thiva (T)	0.074	-	<0.001	<0.001	0.001	0.007

Values in bold exceed the 0.1 µg/L threshold for groundwater

Refined endpoints (see Table 8.8-9 for details)

Table 8.8-12b: PEC$_{gw}$ for clopyralid (with FOCUS PEARL v5.5.5)

	80[th] Percentile PEC$_{gw}$ at 1 m Soil Depth (µg/L)					
	Winter Cereals	Spring Cereals	Grassland			
			March	June	August 15th	Sept.
Châteaudun (C)	0.004	< 0.001	0.012	0.006	0.004	0.017
Hamburg (H)	0.001	< 0.001	0.031	0.073	0.066	**0.125**
Jokioinen (J)	< 0.001	< 0.001	**0.111**	0.074	0.095	**0.204**
Kremsmünster (K)	0.004	< 0.001	0.022	0.019	0.012	0.031
Okehampton (N)	0.001	< 0.001	0.059	0.046	0.019	0.076
Piacenza (P)	< 0.001	< 0.001	0.034	0.004	0.014	0.042
Porto (O)	0.004	< 0.001	0.011	0.001	0.004	0.022
Sevilla (S)	0.001	< 0.001	<0.001	<0.001	<0.001	0.002
Thiva (T)	< 0.001	< 0.001	<0.001	<0.001	<0.001	0.004

Values in bold exceed the 0.1 µg/L threshold for groundwater

Table 8.8-13b: PEC$_{gw}$ for clopyralid (with FOCUS PELMO v6.6.4)

	80[th] Percentile PEC$_{gw}$ at 1 m Soil Depth (µg/L)					
	Winter Cereals	Spring Cereals	Grassland			
			March	June	August 15th	Sept.
Châteaudun (C)	0.001	0.001	0.004	0.005	0.004	0.01
Hamburg (H)	0.015	0.012	0.039	0.018	0.029	0.093
Jokioinen (J)	0.063	0.093	**0.195**	0.085	0.083	**0.265**
Kremsmünster (K)	0.041	0.043	0.022	0.019	0.016	0.047
Okehampton (N)	0.071	0.051	0.095	0.054	0.017	0.083
Piacenza (P)	0.066	-	**0.230**	0.012	0.017	0.044
Porto (O)	0.050	0.003	0.077	0.001	0.003	0.026
Sevilla (S)	0.061	-	<0.001	<0.001	<0.001	0.001
Thiva (T)	0.038	-	<0.001	<0.001	0.001	0.005

Values in bold exceed the 0.1 µg/L threshold for groundwater

8.9 Predicted Environmental Concentrations in surface water (PEC_{sw}) (KCP 9.2.5)

zRMS Comments:	The submitted calculations were accepted. PEC_{SW} and PEC_{SED} were assessed in accordance with FOCUS Surface Water guidance; Step 1 & 2 and Step 3 (SWASH model) and Step 4 (SWAN) were used. The spring application dates were accepted. **MCPA**. The used endpoints were accepted. **Spring cereals**. The mitigation measures were proposed. At Step 4 the run-off mitigation via vegetated filter strip was calculated for 1 m buffer using the ~~VFS model~~ SWAN model. Additionally, the run-off reduction was considered with a vegetative buffer zone of 10 m

SWAN model. Max. PECsw, (µg/L)

Crop	Application rate g a.s./ha	MCPA 10 m VFS + 10 m NSS
Spring cereals	700	7.443 R4 stream

For winter cereals at spring application and for grass no mitigation measures were proposed, the max PECsw = 6.131 µg a.s./L in D3 ditch scenario and PECsw = 4.782 µg a.s./L, in R2 stream scenario respectively.

Fluroxypyr. The used endpoints were accepted. No mitigation measures were proposed.

Clopyralid. The used endpoints agreed at the EU were accepted. The recalculated endpoints by the applicant could be used at cMS level.
No mitigation measures were proposed in both cases.

Formulation. The submitted by the applicant PECsw assessment for formulation was not accepted.
Drift calculator for formulation PECsw assessment was used. PECsw value recalculated by evaluator, including the buffer zones, are presented in tables below.

Winter/Spring cereals and Grass 1 x 3375 g product/ha

FOCUS buffer zone (m)	Max. PEC_{sw} (µg formulation/L)
1	21.68
3	9.18
5	5.88

National assessment, Poland.
The submitted PECsw assessment was accepted. The winter cereals a surrogate crop for spring cereals and grass was used.
No mitigation measure is required.

The PEC_{SW} values for active substance and its metabolites and formulation will be used for further risk assessment.

8.9.1 Justification for new endpoints

The soil sorption and degradation values for MCPA have been made more conservative than the values reported in the EFSA peer reviews. The derivations of these values are provided in Sections 8.3 and 8.5 above. They are based on the official EU data but corrected for historic idiosyncrasies.

The soil sorption value for clopyralid has been calculated from the agreed EFSA data and applying current EU best practices for selecting modelling endpoints. The approach is described in Section 8.5 above and more details are provided in Appendix III of this dossier.

8.9.2 Active substance(s), relevant metabolite(s) and the formulation (KCP 9.2.5)

The input parameters used to conduct the surface water risk assessment are listed in Table 8.9-1.

Table 8.9-1: Input parameters related to application for $PEC_{SW/SED}$ calculations

Plant protection product	Kinvara		
Crop	Winter Cereals	Spring Cereals	Grassland
Application rate (g as/ha)	MCPA: 700	MCPA: 700	MCPA:700
	Fluroxypyr-MHE: 216.1	Fluroxypyr-MHE: 216.1	Fluroxypyr-MHE: 216.1
	Clopyralid: 84	Clopyralid: 84	Clopyralid: 84
Number of applications/interval (d)	1	1	1
Application window (STEP 1&2)	March-May	March-May	March-May
Crop cover (STEP 1&2)	Average crop cover (20 % crop interception)	Average crop cover (20 % crop interception)	Minimum crop cover (40 % crop interception)
Application Window (Step 3)	See Table 8.9-2		
Application method	Ground Spray	Ground Spray	Ground Spray
CAM (Chemical application method)	2	2	2 (D-scenarios) 1 (R-scenarios)*
Soil depth (cm)	4	4	4
Models used for calculation	Steps 1-2 in FOCUS v3.2, FOCUS SWASH v5.3, FOCUS PRZM v4.3.1, FOCUS MACRO v5.5.3, FOCUS TOXSWA v3.3.1, EVA v3.2 SWAN v5.0		

*The worst-case use of new grass was modelled with 40 % crop interception by reducing the application rate for R-scenarios by 40% and setting crop interception (ZFINT) to 0.4 in FOCUS MACRO.

The application dates (**Table 8.9-2**) used in the assessment are based on the suggested groundwater and surface water dates for BBCH 24 in spring and winter cereals given by the program AppDate v 2.03 (Klein, 2017); they have been maintained for continuity with previous submissions. Developmental stage BBCH 24 in winter cereals is a very good indication of the onset of spring across the EU as it marks the start of spring growth and end of the winter stagnation period. This is the same time period when Kinvara is to be applied to grassland and therefore the winter cereals dates have also been used for the assessment of applications to new ley grass.

Table 8.9-2: FOCUS Step 3 Scenario related input parameters for $PEC_{sw/sed}$ calculations for the application of Kinvara

Scenario	Winter Cereals	Spring Cereals	Grassland		
	Begin Application Window	Begin Application Window	Begin Application Window		
			Spring	Summer	Fall
D1	Apr-19	May-21	Apr-01	Jun-15	Sep-01
D2	Mar-29	N/A	Apr-01	Jun-15	Sep-01
D3	Apr-10	Apr-20	Mar-15	Jun-15	Sep-01
D4	Mar-12	May-12	Mar-15	Jun-15	Sep-01
D5	Mar-09	Apr-06	Mar-15	Jun-15	Sep-01
D6	Feb-10	N/A	N/A	N/A	N/A
R1	Apr-28		N/A	N/A	N/A
R2	N/A		Mar-15	Jun-15	Sep-01
R3	Mar-13		Mar-15	Jun-15	Sep-01
R4	Jan-02	Apr-02	N/A	N/A	N/A

8.9.2.1 MCPA and PCOC

Table 8.9-3: Input parameters related to MCPA and PCOC for $PEC_{sw/sed}$ calculations

Compound	MCPA	PCOC	Value in Accordance with EU Endpoint, Reference	
			MCPA	PCOC
Molecular weight (g/mol)	200.6	142.6	Y, EC (2008)	UNEP (1998)
Saturated vapour pressure (Pa)	4.00×10^{-4}	1×10^{-10}	Y, EC (2008)	UNEP (1998)
Water solubility (mg/L)	293900	2300	Y, EC (2008)	UNEP (1998)
Diffusion coefficient in water (m²/d)	4.3×10^{-5}	4.3×10^{-5}	FOCUS default	FOCUS default
Diffusion coefficient in air (m²/d)	0.43	0.43	FOCUS default	FOCUS default
K_{foc} (mL/g)	55.5	400	Y, Geometric mean of EC (2008) soils with pH >4	UNEP (1998)
1/n	0.71	1	Y, EC (2008)	UNEP (1998)
Plant Uptake	0	0	FOCUS default	FOCUS default
Wash-Off factor from Crop (1/mm)	0.05	0.05	FOCUS default	FOCUS default
$DT_{50,soil}$ (d)	26.7*	21 (median)	N, Normalised values from EC (2008)*	UNEP (1998)
$DT_{50,water}$ (d)**	20.1	21	N, Normalised values from EC (2008)**	UNEP (1998)
$DT_{50,sed}$ (d)	1000	1000	Normalised values from EC (2008)	UNEP (1998)
$DT_{50,whole\ system}$ (d)**	20.1	1000	Normalised values from EC (2008)**	UNEP (1998)
Maximum occurrence observed (% molar basis with respect to the parent)	-	55 (soil) 11.6 (water)	-	UNEP (1998)
Formation fraction in soil:	-	1	-	FOCUS default

*geometric mean of experimental values in EC (2008), see Section 8.3.1.1 for further details normalized for temperature and moisture.
**value more conservative than EC (2008), see section 8.6.1 for further details.

PEC$_{sw/sed}$

MCPA

Table 8.9-4: FOCUS Step 1,2, and 3 PEC$_{sw}$ and PEC$_{sed}$ for MCPA following single application of Kinvara to winter cereals

MCPA PEC$_{SW/SED}$ for applications to winter cereals					
Scenario	**Waterbody**	**Max PEC$_{sw}$ (µg/L)**	**Dominant entry route**	**7 d- PEC$_{sw,twa}$ (µg/L)**	**Max PEC$_{sed}$ (µg/kg)**
Step 1					
---		223.694	Drift	198.383	120.577
Step 2					
Northern Europe	March-May	36.703	Runoff	32.706	20.292
Southern Europe	March-May	68.035	Runoff	60.707	37.670
Step 3					
D1 [A]	ditch	5.656	Drift	4.889	10.76
D1 [A]	stream	4.457	Drainage	1.815	6.367
D2 [A]	ditch	73.61	Drainage	40.74	44.57
D2 [A]	stream	47.02	Drainage	23.35	26.38
D3	ditch	4.431	Drift	0.598	1.231
D4	pond	0.164	Drainage	0.161	0.791
D4	stream	3.279	Drift	0.161	0.32
D5	pond	0.207	Drainage	0.192	0.700
D5	stream	3.578	Drift	0.056	0.334
D6 [A]	ditch	4.438	Drift	0.339	0.994
R1	pond	0.227	Runoff	0.207	0.648
R1	stream	5.759	Runoff	0.371	1.247
R3	stream	6.131	Runoff	0.847	2.118
R4	stream	2.894	Runoff	0.060	0.270

[A)] Scenarios D1, D2 and D6 are not relevant for the Central Zone.

Table 8.9-5: FOCUS Step 1,2, 3 and 4 PEC_{sw} and PEC_{sed} for MCPA following single application of Kinvara to spring cereals

Scenario	Waterbody	Max PEC_{sw} (µg/L)	Dominant entry route	7 d- $PEC_{sw,twa}$ (µg/L)	Max PEC_{sed} (µg/kg)
Step 1					
---		223.694	Drift	198.383	120.577
Step 2					
Northern Europe	March-May	36.703	Runoff	32.706	20.292
Southern Europe	March-May	68.035	Runoff	60.707	37.670
Step 3					
D1	ditch	5.804	Drainage	5.490	15.002
D1	stream	4.961	Drainage	3.440	7.834
D3	ditch	4.435	Drift	0.660	1.293
D4	pond	0.248	Drainage	0.246	1.043
D4	stream	3.633	Drift	0.253	0.497
D5	pond	0.191	Drift	0.176	0.639
D5	stream	3.549	Drift	0.044	0.316
R4	stream	16.490	Runoff	2.128	3.995
Step 4 (volatilization/deposition and 10m drift/runoff VBS)					
D1	ditch	5.802	Drainage	5.487	13.45
D1	stream	4.961	Drainage	3.44	7.786
D3	ditch	0.638	Drift+Deposition	0.116	0.278
D4	pond	0.248	Drainage	0.245	1.011
D4	stream	0.728	Drift+Deposition	0.253	0.490
D5	pond	0.150	Drift+Deposition	0.142	0.563
D5	stream	0.720	Drift+Deposition	0.036	0.242
R4	stream	7.443	Runoff	0.963	1.977

Table 8.9-6: FOCUS Step 1,2 and 3 PEC_{sw} and PEC_{sed} for MCPA following single application of Kinvara to grass

Scenario	Waterbody	Max PEC_{sw} (µg/L)	Dominant entry route	Max PEC_{sed} (µg/kg)
Step 1		233.694	-	120.577
Step 2				
Northern Europe	March-May	28.869	-	15.948
Southern Europe	March-May	52.369	-	28.981
Step 3- Spring Applications				
D1 [A]	Ditch	58.86	Drainage	53.92
D1 [A]	Stream	36.88	Drainage	29.49
D2 [A]	Ditch	95.66	Drainage	60.37
D2 [A]	Stream	62.49	Drainage	33.65
D3	Ditch	4.437	Drift	1.322
D4	Pond	0.153	Drift	0.427
D4	Stream	3.393	Drift	0.118
D5	Pond	0.178	Drift	0.577
D5	Stream	3.676	Drift	0.276
R2 [A]	Stream	2.318	Drift	0.793
R3	Stream	2.965	Runoff	1.172
Step 3- Summer Applications				
D1	Ditch	4.755	Drift	15.30
D1	Stream	3.928	Drift	7.63
D2	Ditch	4.722	Drift	13.66
D2	Stream	7.782	Drainage	11.29
D3	Ditch	4.459	Drift	1.845
D4	Pond	0.153	Drift	0.317
D4	Stream	3.837	Drift	0.577
D5	Pond	0.242	Drainage	1.006
D5	Stream	4.755	Drift	15.30
R2	Stream	4.782	Runoff	1.749
R3	Stream	2.482	Drift	0.456
Step 3- Fall Applications				
D1	Ditch	13.50	Drainage	28.31
D1	Stream	9.435	Drainage	14.83
D2	Ditch	22.57	Drainage	34.67
D2	Stream	27.04	Drainage	26.71
D3	Ditch	4.453	Drift	1.65
D4	Pond	0.153	Drift	0.39
D4	Stream	3.837	Drift	0.578
D5	Pond	0.795	Drainage	2.895
D5	Stream	4.139	Drift	1.234
R2	Stream	2.661	Runoff	1.026
R3	Stream	2.478	Drift	0.437

A) Scenarios D1, D2 and R2 are not relevant for the Central Zone.

PCOC

Table 8.9-7: FOCUS Step 1, 2 and 3 for PCOC following single applications of Kinvara to winter cereals

PCOC $PEC_{SW/SED}$ for applications to winter cereals					
Scenario	**Waterbody**	**Max PEC_{sw} (µg/L)**	**Dominant entry route**	**7 d- $PEC_{sw,twa}$ (µg/L)**	**Max PEC_{sed} (µg/kg)**
Step 1					
---		72.576	Drift	64.651	288.180
Step 2					
Northern Europe	March-May	10.503	Runoff	9.613	41.833
Southern Europe	March-May	20.655	Runoff	18.935	82.412
Step 3					
D1	ditch	2.535	Drainage	2.392	6.417
D1	stream	1.625	Drainage	1.532	3.821
D2	ditch	2.458	Drainage	1.594	5.401
D2	stream	1.561	Drainage	0.862	3.155
D3	ditch	<0.001	Drainage	<0.001	<0.001
D4	pond	0.232	Drainage	0.230	0.612
D4	stream	0.278	Drainage	0.204	0.315
D5	pond	0.096	Drainage	0.095	0.361
D5	stream	0.085	Drainage	0.062	0.222
D6	ditch	0.042	Drainage	0.035	0.145
R1	pond	0.018	Runoff	0.016	0.034
R1	stream	0.260	Runoff	0.029	0.076
R3	stream	0.561	Runoff	0.078	0.215
R4	stream	0.089	Runoff	0.012	0.029

Table 8.9-8: FOCUS Step 1, and 2 for PCOC following single applications of Kinvara to spring cereals

PCOC $PEC_{SW/SED}$ for applications to spring cereals					
Scenario	**Waterbody**	**Max PEC_{sw} (µg/L)**	**Dominant entry route**	**7 d- $PEC_{sw,twa}$ (µg/L)**	**Max PEC_{sed} (µg/kg)**
Step 1					
---		72.575	Drift	64.651	288.180
Step 2					
Northern Europe	March-May	10.503	runoff	9.613	41.833
Southern Europe	March-May	20.655	runoff	18.935	82.412
Step 3					
D1	ditch	2.529	Drainage	2.314	8.879
D1	stream	1.606	Drainage	1.442	5.214
D3	ditch	<0.001	Drainage	<0.001	<0.001
D4	pond	0.327	Drainage	0.324	0.887
D4	stream	0.382	Drainage	0.293	0.476
D5	pond	0.123	Drainage	0.121	0.407
D5	stream	0.116	Drainage	0.071	0.177
R4	stream	0.706	Runoff	0.141	0.214

Table 8.9-9: FOCUS Step 1, and 2 for PCOC following single applications of Kinvara to Grass

Scenario	Waterbody	Max PEC_{sw} (µg/L)	Dominant entry route	Max PEC_{sed} (µg/kg)
Step 1		72.576	-	288.180
Step 2				
Northern Europe	March-May	7.965	-	31.688
Southern Europe	March-May	15.579	-	62.122
Step 3- Spring Applications				
D1	Ditch	2.121	Drainage	4.902
D1	Stream	1.389	Drainage	2.721
D2	Ditch	2.215	Drainage	4.788
D2	Stream	1.418	Drainage	3.309
D3	Ditch	<0.001	Drainage	<0.001
D4	Pond	<0.001	Drainage	<0.001
D4	Stream	<0.001	Drainage	<0.001
D5	Pond	0.108	Drainage	0.364
D5	Stream	0.141	Drainage	0.199
R2	Stream	0.167	Runoff	0.062
R3	Stream	0.493	Runoff	0.192
Step 3- Summer Applications				
D1	Ditch	3.084	Drainage	8.557
D1	Stream	2.173	Drainage	4.752
D2	Ditch	2.854	Drainage	6.508
D2	Stream	1.798	Drainage	3.844
D3	Ditch	<0.001	Drainage	<0.001
D4	Pond	<0.001	Drainage	<0.001
D4	Stream	<0.001	Drainage	<0.001
D5	Pond	0.226	Drainage	0.642
D5	Stream	0.341	Drainage	0.254
R2	Stream	0.099	Runoff	0.039
R3	Stream	0.179	Runoff	0.072
Step 3- Fall Applications				
D1	Ditch	3.657	Drainage	11.00
D1	Stream	2.28	Drainage	5.92
D2	Ditch	4.482	Drainage	10.82
D2	Stream	2.819	Drainage	6.244
D3	Ditch	<0.001	Drainage	<0.001
D4	Pond	<0.001	Drainage	0.001
D4	Stream	0.002	Drainage	0.002
D5	Pond	0.481	Drainage	1.393
D5	Stream	0.68	Drainage	0.558
R2	Stream	0.495	Runoff	0.196
R3	Stream	0.514	Runoff	0.191

8.9.2.2 Fluroxypyr and its metabolites

Table 8.9-10: Input parameters related to fluroxypyr-MHE and its metabolites for $PEC_{sw/sed}$ calculations

Compound	Fluroxypyr-MHE	Fluroxypyr-acid	Pyridinol	Methoxypyridine	3-CP	Reference
Molecular weight (g/mol)	367.3	255	197	211	162	EFSA (2011)
Saturated vapour pressure (Pa)	3.8×10^{-9}	3.8×10^{-9}	0 (worst case assumption)	0 (worst case assumption)		EFSA (2011)
Water solubility (mg/L)	0.009	91	91 (assumed same as parent)	91 (assumed same as parent)		EFSA (2011)
Diffusion coefficient in water (m²/d)	4.3×10^{-5}	4.3×10^{-5}	4.3×10^{-5}	4.3×10^{-5}	4.3×10^{-5}	FOCUS Default
Diffusion coefficient in air (m²/d)	0.43	0.43	0.43	0.43	0.43	FOCUS Default
K_{foc} (mL/g)	19550 (geometric mean, n=5)	67 (geometric mean, n=4)	68 (geometric mean of alkaline soils)	311 (geometric mean, n=4)	0 (default)	EFSA (2011), Confirmatory Data, Ireland (2014)
1/n	1.0 (default)	0.92 (arithmetic mean, n=4)	0.72 (arithmetic mean of alkaline soils)	0.84 (arithemtic mean, n=4)	1.0 (default)	EFSA (2011), Confirmatory Data, Ireland (2014)
Plant Uptake	0	0	0	0	0	FOCUS Default
Wash-Off factor from Crop (1/mm)	0.05	0.05	0.05	0.05	0.05	FOCUS Default
$DT_{50,soil}$ (d)	1.0 (geometric mean, n=12)	13.9 (median, n=14)	17.6 (geomean lab, n=16)	111.11 (Geomean lab, n=16)	not formed	EFSA (2011), Confirmatory Data, Ireland (2014)
$DT_{50,water}$ (d)	1000	38.1	35.5	1000	1000	EFSA (2011)
$DT_{50,sed}$ (d)	38.1	1000	1000	1000	1000	EFSA (2011)
$DT_{50,whole\ system}$ (d)	38.1	38.1	35.5	1000	1000	EFSA (2011)
Maximum occurrence observed (% molar basis with respect to the parent)	-	Soil: 100	Soil: 23.9 Water:55.5	Soil: 38.2 Water: 0.01	Soil: - Water: 24.4	EFSA (2011)
Formation fraction in soil:	-	1 from fluroxypyr-MHE	0.286 from fluroxypyr, 0.723 from methoxypyridine	0.201 from fluroxypyr	not formed	EFSA (2011)

$PEC_{sw/sed}$

Fluroxypyr-MHE

Table 8.9-11: FOCUS Step 1,2, 3 and 4 PEC_{sw} and PEC_{sed} for fluroxypyr-MHE following application of Kinvara to winter cereals

Fluroxypyr MHE $PEC_{SW/SED}$ for applications to winter cereals					
Scenario	**Waterbody**	**Max PEC_{sw} (µg/L)**	**Dominant entry route**	**7 d- $PEC_{sw,twa}$ (µg/L)**	**Max PEC_{sed} (µg/kg)**
Step 1					
---		4.649	Drift	2.865	534.274
Step 2					
Northern Europe	March-May	1.987	Drift	0.366	18.370
Southern Europe	March-May	1.987	Drift	0.379	23.498
Step 3					
D1	ditch	1.363	Drift	0.943	5.359
D1	stream	1.163	Drift	0.043	0.226
D2	ditch	1.359	Drift	0.658	3.093
D2	stream	1.124	Drift	0.02	0.106
D3	ditch	1.348	Drift	0.176	0.882
D4	pond	0.047	Drift	0.041	0.436
D4	stream	0.996	Drift	0.005	0.029
D5	pond	0.047	Drift	0.041	0.439
D5	stream	1.077	Drift	0.006	0.031
D6	ditch	1.333	Drift	0.084	0.438
R1	pond	0.047	Drift	0.041	0.402
R1	stream	0.888	Drift	0.023	0.126
R3	stream	1.248	Drift	0.049	0.263
R4	stream	0.88	Drift	0.018	0.098

Table 8.9-12: FOCUS Step 1,2, and 3 PEC_{sw} and PEC_{sed} for fluroxypyr-MHE following application of Kinvara to spring cereals

Fluroxypyr MHE $PEC_{SW/SED}$ for applications to spring cereals					
Scenario	**Waterbody**	**Max PEC_{sw} (µg/L)**	**Dominant entry route**	**7 d- $PEC_{sw,twa}$ (µg/L)**	**Max PEC_{sed} (µg/kg)**
Step 1					
---		4.645	Drift	2.865	534.274
Step 2					
Northern Europe	March-May	1.987	Drift	0.379	18.370
Southern Europe	March-May	1.987	Drift	0.379	23.498
Step 3					
D1	ditch	1.365	Drift	0.997	6.220
D1	stream	1.194	Drift	0.150	0.759
D3	ditch	1.349	Drift	0.194	0.963
D4	pond	0.047	Drift	0.042	0.399
D4	stream	1.104	Drift	0.014	0.077
D5	pond	0.047	Drift	0.041	0.421
D5	stream	1.072	Drift	0.006	0.030
R4	stream	0.891	Drift	0.025	0.607

Table 8.9-13: FOCUS Step 1,2, and 3 PEC_{sw} and PEC_{sed} for fluroxypyr-MHE following application of Kinvara to grass

Scenario	Waterbody	Max PEC_{sw} (µg/L)	Dominant entry route	Max PEC_{sed} (µg/kg)
Step 1		4.649	-	534.274
Step 2				
Northern Europe	March-May	1.987	-	17.093
Southern Europe	March-May	1.987	-	20.924
Step 3- Spring Applications				
D1	Ditch	1.358	Drift	3.279
D1	Stream	1.109	Drift	0.082
D2	Ditch	1.367	Drift	4.948
D2	Stream	1.216	Drift	4.376
D3	Ditch	1.349	Drift	1.002
D4	Pond	0.047	Drift	0.443
D4	Stream	1.032	Drift	0.038
D5	Pond	0.047	Drift	0.433
D5	Stream	1.113	Drift	0.041
R2	Stream	0.705	Drift	0.045
R3	Stream	0.750	Drift	0.170
Step 3- Summer Applications				
D1	Ditch	1.365	Drift	6.22
D1	Stream	1.194	Drift	0.759
D2	Ditch	1.367	Drift	6.278
D2	Stream	1.216	Drift	5.51
D3	Ditch	1.356	Drift	1.776
D4	Pond	0.047	Drift	0.392
D4	Stream	1.167	Drift	0.254
D5	Pond	0.047	Drift	0.392
D5	Stream	1.259	Drift	0.358
R2	Stream	0.718	Drift	0.059
R3	Stream	0.755	Drift	0.209
Step 3- Fall Applications				
D1	Ditch	1.365	Drift	6.444
D1	Stream	1.194	Drift	0.760
D2	Ditch	1.367	Drift	6.659
D2	Stream	1.216	Drift	5.802
D3	Ditch	1.354	Drift	1.457
D4	Pond	0.047	Drift	0.457
D4	Stream	1.167	Drift	0.254
D5	Pond	0.047	Drift	0.424
D5	Stream	1.259	Drift	0.358
R2	Stream	0.718	Drift	0.059
R3	Stream	0.754	Drift	0.196

Fluroxypyr

Table 8.9-14: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for fluroxypyr (acid) following application of Kinvara to cereals

Crop	Scenario		PEC_{SW} (µg/L)	PEC_{SED} (mg/kg)
Winter Cereals	Step 1		93.197	61.517
	Step 2	N. Europe	7.691	5.128
		S. Europe	14.166	9.464
Spring Cereals	Step 1		93.197	61.379
	Step 2	N. Europe	7.691	5.128
		S. Europe	14.167	9.464

Table 8.9-15: FOCUS Step 1, 2 and 3 PEC_{sw} and PEC_{sed} for fluroxypyr (acid) following application of Kinvara to grass

Scenario	Waterbody	Max PEC_{sw} (µg/L)	Dominant entry route	Max PEC_{sed} (µg/kg)
Step 1		93.197	-	61.517
Step 2				
Northern Europe	March-May	6.072	-	4.044
Southern Europe	March-May	10.929		7.296
Step 3- Spring Applications				
D1	Ditch	8.812	Drainage	6.774
D1	Stream	5.536	Drainage	3.409
D2	Ditch	147.8	Drainage	68.37
D2	Stream	96.8	Drainage	34.76
D3	Ditch	6.339	Drift	1.136
D4	Pond	0.219	Drift	0.295
D4	Stream	4.848	Drift	0.134
D5	Pond	0.235	Drift	0.335
D5	Stream	5.238	Drift	0.172
R2	Stream	0.497	Drift	0.103
R3	Stream	0.624	Runoff	0.153
Step 3- Summer Applications				
D1	Ditch	0.994	Drift	1.233
D1	Stream	0.842	Drift	0.47
D2	Ditch	0.976	Drift	1.319
D2	Stream	0.946	Drift	1.105
D3	Ditch	0.956	Drift	0.256
D4	Pond	0.033	Drift	0.039
D4	Stream	0.822	Drift	0.085
D5	Pond	0.034	Drift	0.047
D5	Stream	0.887	Drift	0.109
R2	Stream	1.037	Runoff	0.253
R3	Stream	0.532	Runoff	0.064
Step 3- Fall Applications				
D1	Ditch	2.515	Drainage	2.668
D1	Stream	1.722	Drainage	1.568
D2	Ditch	4.436	Drainage	4.704
D2	Stream	5.652	Drainage	3.683
D3	Ditch	0.954	Drift	0.228
D4	Pond	0.033	Drift	0.049
D4	Stream	0.822	Drift	0.085
D5	Pond	0.078	Drainage	0.192
D5	Stream	0.887	Drift	0.129
R2	Stream	0.506	Drift	0.101
R3	Stream	0.531	Drift	0.062

Pyridinol

Table 8.9-16: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for pyridinol following application of Kinvara

Crop	Scenario		PEC_{SW} (µg/L)	PEC_{SED} (mg/kg)
Winter Cereals	Step 1		28.695	19.251
	Step 2	N. Europe	4.248	2.899
		S. Europe	7.979	5.452
Spring Cereals	Step 1		28.695	19.251
	Step 2	N. Europe	4.248	2.899
		S. Europe	7.979	5.452
Grass	Step 1		28.695	19.251
	Step 2	N. Europe	3.316	2.260
		S. Europe	6.114	4.176

Methoxypyridine

Table 8.9-17: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for methoxypyridine following application of Kinvara

Crop	Scenario		PEC_{SW} (µg/L)	PEC_{SED} (mg/kg)
Winter Cereals	Step 1		11.085	35.582
	Step 2	N. Europe	1.730	5.553
		S. Europe	3.460	11.105
Spring Cereals	Step 1		11.085	35.582
	Step 2	N. Europe	1.730	5.553
		S. Europe	3.460	11.105
Grass	Step 1		11.085	35.582
	Step 2	N. Europe	1.297	4.165
		S. Europe	2.595	8.329

3-CP

Table 8.9-18: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for 3-CP following application of Kinvara

Crop	Scenario		PEC_{SW} (µg/L)	PEC_{SED} (mg/kg)
Winter Cereals	Step 1		7.965	<0.001
	Step 2	N. Europe	1.207	<0.001
		S. Europe	2.223	<0.001
Spring Cereals	Step 1		7.965	<0.001
	Step 2	N. Europe	1.207	<0.001
		S. Europe	2.223	<0.001
Grassland	Step 1		7.965	<0.001
	Step 2	N. Europe	0.953	<0.001
		S. Europe	1.715	<0.001

8.9.2.3 Clopyralid

Table 8.9-19: Input parameters related to clopyralid for $PEC_{sw/sed}$ calculations

Compound	Clopyralid	Reference
Molecular weight (g/mol)	192	EFSA (2018)
Saturated vapour pressure (Pa)	1.36×10^{-3}	EFSA (2018)
Water solubility (mg/L)	1430000	EFSA (2018)
Diffusion coefficient in water (m²/d)	4.3×10^{-5}	FOCUS Default
Diffusion coefficient in air (m²/d)	0.43	FOCUS Default
K_{foc} (mL/g)	1.41	EFSA (2018)
1/n	0.836	EFSA (2018)
Applicant proposed K_{foc} (mL/g)	4.05	N, see Section 8.5.3
Applicant proposed 1/n	0.881	N, see Section 8.5.3
Plant Uptake	0	FOCUS Default
Wash-Off factor from Crop (1/mm)	0.05	FOCUS Default
$DT_{50,soil}$ (d)	7.05*	EFSA (2018)
$DT_{50,water}$ (d)	1000	EFSA (2018)
$DT_{50,sed}$ (d)	1000	EFSA (2018)
$DT_{50,whole\ system}$ (d)	1000	EFSA (2018)

*Field studies on clopyralid were considered by EFSA (2018) and used to derive the normalized modelling degradation endpoint for the active substance.

Table 8.9-20: FOCUS Step 1, 2 and 3 PEC_{sw} and PEC_{sed} for clopyralid following application of Kinvara to winter cereals

Clopyralid $PEC_{SW/SED}$ for applications to winter cereals					
Scenario	**Waterbody**	**Max PEC_{sw} (µg/L)**	**Dominant entry route**	**7 d-$PEC_{sw,twa}$ (µg/L)**	**Max PEC_{sed} (µg/kg)***
Step 1					
---		28.720	Drift	28.649	0.394
Step 2					
Northern Europe	March-May	3.787	Drainage	3.777	0.053
Southern Europe	March-May	6.805	Drainage	6.788	0.096
Step 3					
D1	ditch	4.225	Drainage	4.081	1.431
D1	stream	2.892	Drainage	2.329	0.592
D2	ditch	11.24	Drainage	6.001	1.723
D2	stream	7.476	Drainage	3.049	0.970
D3	ditch	0.534	Drift	0.075	0.038
D4	pond	0.019	Drift	0.019	0.011
D4	stream	0.394	Drift	0.003	0.006
D5	pond	0.019	Drift	0.018	0.012
D5	stream	0.497	Drift	0.027	0.023
D6	ditch	0.535	Drift	0.044	0.030
R1	pond	0.023	Runoff	0.023	0.014
R1	stream	0.796	Runoff	0.047	0.046
R3	stream	0.493	Runoff	0.043	0.029
R4	stream	0.347	Runoff	0.007	0.010

Table 8.9-21: FOCUS Step 1, 2 and 3 PEC_{sw} and PEC_{sed} for clopyralid following application of Kinvara to spring cereals

Clopyralid $PEC_{SW/SED}$ for applications to spring cereals					
Scenario	**Waterbody**	**Max PEC_{sw} (µg/L)**	**Dominant entry route**	**7 d- $PEC_{sw,twa}$ (µg/L)**	**Max PEC_{sed} (µg/kg)**
Step 1					
---		28.720	Drift	28.649	0.394
Step 2					
Northern Europe	March-May	3.787	Drainage	3.777	0.053
Southern Europe	March-May	6.805	Drainage	6.788	0.096
Step 3					
D1	ditch	7.572	Drift	7.295	3.061
D1	stream	5.611	Drift	1.241	0.773
D3	ditch	6.385	Drift	1.009	0.470
D4	pond	0.261	Drift	0.255	0.144
D4	stream	5.206	Drift	0.088	0.133
D5	pond	0.221	Drift	0.214	0.119
D5	stream	5.036	Drift	0.027	0.067
R4	stream	15.47	Runoff	1.936	1.046

Table 8.9-22: FOCUS Step 1, 2 and 3 PEC_{sw} and PEC_{sed} for clopyralid following application of Kinvara to grass

Clopyralid $PEC_{SW/SED}$ for applications to grass					
Scenario	**Waterbody**	**Max PEC_{SW}**	**Dominant Entry Route**	**7 d $PEC_{sw.twa}$ (µg/L)**	**Max PEC_{SED} (µg/kg)**
Step 1					
-		28.720	Drift	28.649	0.394
Step 2					
Northern Europe	March-May	3.033	Drainage	3.025	0.043
	June-September	3.023	Drainage	3.025	0.043
Southern Europe	March-May	5.260	Drainage	5.283	0.075
	June-September	4.164	Drainage	4.154	0.590
Step 3 – Spring Applications					
D1	Ditch	15.31	Drainage	12.35	3.514
D1	Stream	9.638	Drainage	7.553	1.89
D2	Ditch	17.65	Drainage	11.55	2.655
D2	Stream	12.91	Drainage	5.651	1.394
D3	Ditch	0.534	Drift	0.085	0.040
D4	Pond	0.019	Drift	0.018	0.010
D4	Stream	0.408	Drift	0.003	0.007
D5	Pond	0.019	Drift	0.018	0.012
D5	Stream	0.440	Drift	0.003	0.007
R2	Stream	0.278	Drift	0.003	0.006
R3	Stream	0.296	Drift	0.013	0.012
Step 3 – Summer Applications					
D1	Ditch	0.556	Drift	0.54	0.235
D1	Stream	0.471	Drift	0.139	0.067
D2	Ditch	0.548	Drift	0.534	0.278
D2	Stream	0.488	Drift	0.475	0.197
D3	Ditch	0.552	Drift	0.189	0.070
D4	Pond	0.023	Drift	0.023	0.015
D4	Stream	0.460	Drift	0.019	0.020
D5	Pond	0.019	Drift	0.018	0.012
D5	Stream	0.497	Drift	0.027	0.023
R2	Stream	0.869	Runoff	0.120	0.080
R3	Stream	0.298	Drift	0.016	0.014
Step 3 – Autumn Applications					
D1	Ditch	0.543	Drift	0.529	0.241
D1	Stream	0.471	Drift	0.262	0.121
D2	Ditch	0.702	Drainage	0.682	0.378
D2	Stream	0.667	Drainage	0.588	0.291
D3	Ditch	0.879	Drift	0.484	0.292
D4	Pond	0.113	Drainage	0.113	0.095
D4	Stream	0.460	Drift	0.171	0.073
D5	Pond	0.074	Drainage	0.074	0.055
D5	Stream	0.497	Drift	0.041	0.026
R2	Stream	0.283	Drift	0.004	0.007
R3	Stream	0.297	Drift	0.015	0.014

Applicant proposed clopyralid endpoints

Table 8.9-23: FOCUS Step 3 PEC_{sw} and PEC_{sed} for clopyralid following application of Kinvara to winter cereals – applicant proposed sorption endpoints

Clopyralid $PEC_{SW/SED}$ for applications to winter cereals					
Scenario	**Waterbody**	**Max PEC_{sw} (µg/L)**	**Dominant entry route**	**7 d-$PEC_{sw,twa}$ (µg/L)**	**Max PEC_{sed} (µg/kg)**
Step 3					
D1	ditch	4.113	Drainage	3.970	1.612
D1	stream	2.806	Drainage	2.267	0.653
D2	ditch	11.12	Drainage	5.817	1.948
D2	stream	7.549	Drainage	3.162	1.095
D3	ditch	0.533	Drift	0.074	0.042
D4	pond	0.019	Drift	0.018	0.012
D4	stream	0.394	Drift	0.003	0.007
D5	pond	0.018	Drift	0.018	0.013
D5	stream	0.425	Drift	0.002	0.007
D6	ditch	0.535	Drift	0.044	0.034
R1	pond	0.024	Runoff	0.023	0.016
R1	stream	0.785	Runoff	0.046	0.051
R3	stream	0.493	Runoff	0.045	0.034
R4	stream	0.347	Runoff	0.007	0.012

Table 8.9-24: FOCUS Step 3 PEC_{sw} and PEC_{sed} for clopyralid following application of Kinvara to spring cereals – applicant proposed sorption endpoints

Clopyralid $PEC_{SW/SED}$ for applications to spring cereals					
Scenario	**Waterbody**	**Max PEC_{sw} (µg/L)**	**Dominant entry route**	**7 d- $PEC_{sw,twa}$ (µg/L)**	**Max PEC_{sed} (µg/kg)**
Step 3					
D1	ditch	0.623	Drift	0.599	0.309
D1	stream	0.471	Drift	0.090	0.078
D3	ditch	0.533	Drift	0.082	0.044
D4	pond	0.020	Drift	0.020	0.015
D4	stream	0.436	Drift	0.006	0.012
D5	pond	0.018	Drift	0.018	0.013
D5	stream	0.423	Drift	0.002	0.007
R4	stream	1.322	Runoff	0.166	0.105

Table 8.9-25: FOCUS Step 3 PEC_{sw} and PEC_{sed} for clopyralid following application of Kinvara to grass – applicant proposed sorption endpoints

Clopyralid $PEC_{SW/SED}$ for applications to grass					
Scenario	**Waterbody**	**Max PEC_{SW}**	**Dominant Entry Route**	**7 d $PEC_{sw.twa}$ (µg/L)**	**Max PEC_{SED} (µg/kg)**
Step 3 – Spring Applications					
D1	Ditch	14.74	Drainage	12.05	3.923
D1	Stream	9.297	Drainage	7.365	2.079
D2	Ditch	14.36	Drainage	8.783	2.86
D2	Stream	9.389	Drainage	4.861	1.576
D3	Ditch	0.533	Drift	0.085	0.044
D4	Pond	0.019	Drift	0.018	0.012
D4	Stream	0.407	Drift	0.003	0.008
D5	Pond	0.019	Drift	0.018	0.014
D5	Stream	0.439	Drift	0.003	0.008
R2	Stream	0.278	Drift	0.003	0.007
R3	Stream	0.296	Drift	0.013	0.014
Step 3 – Summer Applications					
D1	Ditch	0.556	Drift	0.539	0.273
D1	Stream	0.471	Drift	0.139	0.081
D2	Ditch	0.547	Drift	0.531	0.329
D2	Stream	0.487	Drift	0.473	0.227
D3	Ditch	0.542	Drift	0.179	0.070
D4	Pond	0.021	Drift	0.021	0.016
D4	Stream	0.460	Drift	0.019	0.022
D5	Pond	0.019	Drift	0.018	0.014
D5	Stream	0.497	Drift	0.027	0.026
R2	Stream	0.847	Runoff	0.117	0.088
R3	Stream	0.298	Drift	0.016	0.016
Step 3 – Autumn Applications					
D1	Ditch	0.557	Drainage	0.543	0.364
D1	Stream	0.471	Drift	0.326	0.166
D2	Ditch	3.575	Drainage	3.279	1.464
D2	Stream	5.783	Drainage	4.902	1.669
D3	Ditch	0.732	Drift	0.328	0.231
D4	Pond	0.112	Drainage	0.112	0.107
D4	Stream	0.460	Drift	0.201	0.079
D5	Pond	0.102	Drainage	0.102	0.086
D5	Stream	0.497	Drift	0.054	0.035
R2	Stream	0.282	Drift	0.004	0.008
R3	Stream	0.297	Drift	0.015	0.015

Safe use in accordance with the GAP can be concluded if a 10 m vegetated filter strip is respected.

8.9.2.4 $PEC_{sw/sed}$ of formulation

Formulation $PEC_{sw/sed}$ were calculated using the drift calculator in SWASH v5.3 according to the standard FOCUS approach (Table 8.9-26). The application rate of 3.0 L/ha was converted to a mass of 3.375 kg/ha based on a formulation density of 1.125 g/mL.

Table 8.9-26: Formulation PEC_{SW} values

PEC_{SW} formulation in FOCUS ditch and stream (µg/L)		
Crop	**Buffer Distance**	
	FOCUS Default	**10 m**
Winter cereals	6.505	0.935
Spring cereals	6.505	0.935
Grass	6.505	0.935

8.10 Fate and behaviour in air (KCP 9.3, KCP 9.3.1)

The fate and behaviour in air of the active substances were evaluated during the applicable Annex I Inclusion. No additional studies have been performed.

Substance: MCPA
MCPA has a vapour pressure of 4×10^{-4} Pa at 32 °C, a Henry's Law constant of 5.5×10^{-5} Pa m^3 mol^{-1} at 25 °C and a solubility in water of 293 g L^{-1} at 25 °C. Due to its physical-chemical properties, MCPA can be classed with low volatility meaning that no significant loss to the atmosphere is expected and atmospheric accumulation is unlikely.

Substance: fluroxypyr and fluroxypyr-MHE
Fluroxypyr has a vapour pressure of 3.8×10^{-9} Pa at 20 °C, a Henry's Law constant of 1.69×10^{-10} Pa m^3 mol^{-1} at 20 °C and a solubility in water of 91 g L^{-1} at 25 °C. Fluroxypyr-MHE has a vapour pressure of 1×10^{-5} Pa at 20 °C, a Henry's Law constant of 2.7×10^{-2} Pa m^3 mol^{-1} at 20 °C and a solubility in water of 9×10^{-6} g L^{-1} at 25 °C. Due to these physical-chemical properties, fluroxypyr and fluroxypyr-MHE can be classed with low volatility meaning that no significant loss to the atmosphere is expected and atmospheric accumulation is unlikely. In addition, these substances are characterised by rapid photochemical oxidation in the atmosphere.

Substance: clopyralid
Clopyralid has a vapour pressure of 1.36×10^{-3} Pa at 25 °C, a Henry's Law constant of 1.8×10^{-11} Pa m^3 mol^{-1} at 20 °C and a solubility in water of 143 g L^{-1} at 20 °C. Due to these physical-chemical properties, clopyralid can be classed with low volatility meaning that no significant loss to the atmosphere is expected and atmospheric accumulation is unlikely.

Appendix 1 Lists of data considered in support of the evaluation

The following lists should include all product data considered in support of the evaluation, even if they may have been evaluated previously, e.g. in the EU peer review of the active substance(s), and thus, are not summarised in this document in detail. New data evaluated for the active substance(s) should be included as well.

Please sort by data points and within one data point by names of authors.

Tables considered not relevant can be deleted as appropriate.

MS to blacken authors of vertebrate studies in the version made available to third parties/public.

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP XX	Author	YYYY	Title Company Report No Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Owner

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

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP XX	Author	YYYY	Title Company Report N Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Owner

The following tables are to be completed by MS

List of data submitted by the applicant and not relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP XX	Author	YYYY	Title Company Report N Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Owner

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

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP XX	Author	YYYY	Title Company Report N Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Owner

Appendix 2 Detailed evaluation of the new Annex II studies

Present the authority's comment on the study in a box above each individual study. If there is more than one fate study available, list each one separately, i.e., A.7.1.1 Study 1, A.7.1.2 Study 2 etc.

A 2.1 Study 1

Comments of zRMS:	Comment on study; acceptable or not; deficiencies, corrections, according to recent guidelines or not, used in evaluation or only as additional information

Reference:	Data point
Report	Title, author(s), year, report No, document No, Authority registration No
Guideline(s):	Yes/No (If yes, give guidelines; If no, give justification, e.g., " no guidelines available" or " methods used comparable to guideline(s) xxx")
Deviations:	Yes/No (If yes, describe deviations from test guidelines)
GLP:	Yes/No (If no, give justification, e.g., state that GLP was not compulsory at the time the study was performed)
Acceptability:	Yes/No/Supplementary

Materials and methods

Results and discussions

Conclusion

Appendix 3 Additional information provided by the applicant (e.g. detailed modelling data)

Comments of zRMS:	The submitted opinion was accepted and could be used in further exposure assessment.

A 3.1 CP 9.1.1/01 Hawley (2021)

Report:	CP 9.1.1/02, Hawley (2021)
Title:	Opinion of the Soil Sorption Value of Clopyralid
Guidelines:	EFSA (2017)-Outcome of the pesticide peer review meeting on the OECD 106 evaluators checklist

Executive Summary

Recently EFSA approved a new guidance document titled 'Outcome of the pesticide peer review meeting on the OECD 106 evaluators checklist' which provides the regulatory framework needed to address quality issues in soil sorption studies. The EFSA 2017 guidance document is to be implemented immediately for plant protection risk assessment because it is not dependent upon the manner in which soil sorption studies are collected. What EFSA (2017) does provide is three independent tests for assessing the quality of soil sorption studies:

Criteria 1: The product of the soil adsorption coefficient and the ratio of soil-to-solution in the experiment should be greater than 0.3: K_d X (g soil/ mL solution) >0.3

Criteria 2: The ratio of measured Freundlich sorption coefficient to the true Freundlich sorption coefficient should be less than or equal to 1.2: $K_{fe}/K_f \leq 1.2$

Criteria 3: The linear regression of the Freundlich sorption isotherm should have a value of R^2>0.975

Failing any single criteria does not automatically invalidate a study, but it indicates the study results have a low reliability. If on balance all three criteria indicate more extensive issues with the study then EFSA does suggest all values of the study should be excluded from further consideration. In summary, a study realistically needs to pass at least one, if not two, of the criteria before it should be considered reliable.

The EFSA (2017) guidance was published for immediate implementation and was to be used for all endpoint assessments following the date of application. The EFSA peer review panel for clopyralid were well aware of this requirement when trying to derive the agreed list of endpoints for clopyralid in what was published as EFSA (2018). The peer review panel was also well aware that soil adsorption data for clopyralid was highly problematic and the selection criteria in EFSA (2017) would significantly affect the final endpoint. However, EFSA (2017) had not actually been finalised or published when the peer review panel was forced to conclude the endpoint assessment, so it was impossible for them to follow the guidance requirements.

As predicted by EFSA (2018), significant deviations exist between the screening criteria they applied and the screening criteria EFSA finalised in EFSA (2017). When the finalised EFSA (2017) criteria are applied the modelling endpoints are **K_{fOC}=4.05 mL/g** and **1/n=0.881** (see **Table A 1**)

Table A 1: Summary of endpoint value for clopyralid.

Study Report	Soil	OC%	pH	K_d	Kfoc	Kdoc	1/n
Reeves and Mittelstaedt (2002)	Merzenhausen	1	7.19	0.051	0.57	5.1	0.9*
	Kaldenkirchen (Ap horizon)	0.98	5.34	0.048	2.72	4.9	0.9*
	Lanna	*2.06*	*6.62*	*0.151*	*0.26*	*7.3*	*0.9**
	Overhetfeld	0.93	6.49	0.032	1.34	3.4	0.9*
Buntain and Simmonds (2015)	*Calke*	*3.15*	*5.7*	*0.139*	*0.5*	*4.4*	*0.9* (0.489)***
	Longwoods	*3.13*	*7.4*	*0.069*	*2.5*	*2.2*	*0.9**
	Lufa 2.1	0.68	4.9	0.04	4.1	5.9	0.9*
	Quilen	4.02	6.9	0.356	3.9	8.9	0.804
	DU-L-PF	6.47	6.3	0.282	2.1	4.4	0.829

Geometric Mean (n=9)	1.41	4.82	-
Geometric mean in accordance with EFSA (2018) Soil Sorption Checklist	**4.05**		-
Arithmetic mean in accordance with EFSA (2018) Soil Sorption Checklist			**0.881**

The values shaded in grey are considered unreliable for endpoint derivation
*EFSA (2013) considered 6 of values invalid and replaced them with default values for endpoint derivation
**EFSA (2018) LoEP value.

EFSA (2017) OECD 106 Screening

K_d x Soil Solution Ratio
The OECD 106 guidelines state that the product of K_d values and the ratio of soil-to-solution in a test can be used to evaluate the statistical reliability of the results of the test. For indirect studies the soil-solution ratio is calculated using the net weight of the soil and the total volume of solution added to the soil. For direct studies the ratio should be calculated 'after centrifugation and is therefore calculated as the ratio between the soil mass divided by the residual moisture volume in the soil pellet.' This later calculation has not been reported for any of the studies, so for the screening step all studies were assumed to be direct studies. However, the cut-off value of 0.3 does not differ between direct and indirect studies.

The principle underpinning this test is that a low value of K_d × Soil solution ratio means nearly all the test substance is in solution. By extension the calculated soil sorption parameters are extremely sensitive to analytic errors in the solution measured concentrations and/or minor issues with mass balance. As the analytic errors are not systematic it is not possible to work out whether resulting values over or underestimate the true values. While this is a general issue in the raw data, it is greatly amplified when converting Kd values to 1/n and Kfoc values. This is due to the assumption made in the conversion causing 1/n value to be extraordinarily sensitive to uncertainty in Kd.

EFSA (2017) quantified how much of a problem analytic uncertainty was as a function of K_d × soil solution ratio and determined a value less than 0.3 had a 5% probability of being reliable while values less than 0.1 had less than a 1% probability of being valid. Validity here referring to the Freundlich isotherm. Therefore EFSA (2017) recommends continued use of the OECD criteria as a screening tool with the understanding that studies with values between 0.1 and 0.3 should still be considered if all other indicators are that the results are reliable.

The K_d × soil solution values for all the soils are provided in the table below. Only two of the experiments have a value above the threshold of 0.3, with a further four soils (shown in light grey) being close enough to the cut-off to not warrant immediate exclusion. The remaining 7 soils have values which indicate it is statistically improbable that the studies are reliable i.e. <1% chance of being accurate. In effect the uncertainty on the Kd measurements is so great that in most cases it is not possible to derive reliable K_{foc} or 1/n values from the dataset.
Results for initial screening of study data reliability. A soil/solution ratio of 1 was assumed for all studies as this was the ratio determined via the indirect method. Buntain and Simmonds (2015) did not measure the parameters required to enable correct calculation of the ratio for direct studies.

Study Report	Soil	K_d	K_{foc}	1/n	Kd*(soil/solution)	Value above the threshold of 0.3?
Reeves and Mittelstaedt (2002)	Merzenhausen	0.051	0.57	0.5577	0.051	No
	Kaldenkirchen (pH 5.34)	0.048	2.72	0.8602	0.048	No
	Lanna (pH 6.62)	0.151	0.26	0.3881	0.151	Near miss
	Overhetfeld	0.032	1.34	0.783	0.032	
Buntain and	Calke	0.139	0.5	0.489	0.139	Near miss
	Longwoods	0.069	2.5	1.047	0.069	No

Simmonds (2015)	Lufa 2.1	0.04	4.1	0.889	0.04	No
	Quilen	0.356	3.9	0.804	0.356	Yes
	DU-L-PF	0.282	2.1	0.829	0.282	Near miss

K_{fe}/K_f

All of the soil in Buntain and Simmonds (2015) attained an acceptable level of mass balance, but EFSA (2017) clearly outlines why mass balance can still be an issue when it comes to deriving accurate sorption and 1/n values, even when studies appear to have attained acceptable mass balance. Specifically, for substances with low sorption it becomes critically important to determine if mass not accounted for in the overall mass balance is sorbed to the soil or not. In these instances, significantly different final results are yielded if it is assumed that all the material not in solution is adsorbed, rather than assuming analytic errors account for mass balance issues. The K_{fe}/K_f test quantifies how uncertain experimental results are due to these small mass balance issues.

EFSA (2017) states a clear cut-off value for the test cannot be provided but values above 1.2 indicate a study needs to be 'treated with caution' as the results are prone to substantial systematic error. The results of the K_{fe}/K_f tests on the clopyralid studies are summarised in **Błąd! Nie można odnaleźć źródła odwołania.** and three values pass the screening.

Reeves and Mittlestaedt (2002) did not measure the required parameters necessary to fully quantify mass balance or conduct the K_{fe}/K_f test but there are concerns with mass balance based on the information which is available. Recoveries were only reported for 3 of the 8 soils, it is ambiguous how recoveries were quantified, and only one of the reported soils had a recovery <88%. The lack of proper mass balance measurements does not immediately eliminate the studies but place additional weight on the K_d and R^2 as indicators of study reliability.

Summary of K_{fe}/K_f results

Study Report	Soil	K_d	K_{foc}	1/n	K_{fe}/K_f	Screening passed?
Buntain and Simmonds (2015)	Calke	0.139	0.5	0.489	7.1	No
	Longwoods	0.069	2.5	1.047	1	Yes
	Lufa 2.1	0.04	4.1	0.889	3.08	No
	Quilen	0.356	3.9	0.804	1.22	Yes
	DU-L-PF	0.282	2.1	0.829	1.21	Yes

R^2

In addition to the K_{fe}/K_f test, the coefficient of determination (R^2) of the Freundlich adsorption plot indicates potential problems with the test. EFSA (2017) does not set a definitive cut-off but states $R^2<0.975$ should be treated as suspect. The R^2 is a good way of detecting substances which simply do not adhere to Freundlich sorption even if the raw data are fine. The R^2 values for all the soils are presented below.

Two of the soils from Buntain and Simmonds (2015) and one soil from Reeves and Mittelstaedt (2002) have values significantly below the 0.975 threshold (shaded in the table below). All these soils also fail the K_d screening and or K_{fe}/K_f screening by a substantial margin.

Results for full reliability screening of clopyralid soil sorption studies

Study Report	Soil	K_d	K_{foc}	1/n	R^2
Reeves and Mittelstaedt (2002)	Merzenhausen	0.051	0.57	0.5577	0.99
	Kaldenkirchen (pH 5.34)	0.048	2.72	0.8602	0.99

	Lanna (pH 6.62)	0.151	0.26	0.3881	0.9
	Overhetfeld	0.032	1.34	0.783	0.99
Buntain and Simmonds (2015)	Calke	0.139	0.5	0.489	0.933
	Longwoods	0.069	2.5	1.047	0.8244
	Lufa 2.1	0.04	4.1	0.889	0.9903
	Quilen	0.356	3.9	0.804	0.9927
	DU-L-PF	0.282	2.1	0.829	0.9919

Using the quality checks in decision making
Section 3 of EFSA (2017) is dedicated to explaining how the three checks presented above should be used when it comes to deriving acceptable endpoints. If a soil passes all of the checks then the experimentally derived K_{foc} and 1/n should be selected for use to derive regulatory endpoints. Even if some of checks fail for a given soil the experimental K_{foc} and 1/n values should accepted as reliable if on balance there is no indication of a systematic error in the study. Where the quality checks are mostly acceptable or if the raw data are considered good but non-Freundlich then then the geometric mean Kdoc values should be accepted with a default 1/n of 0.9. That is endpoints are still derived from the study but the endpoints are based on the actual study measurements rather than derived assuming Freundlich sorption. Only where the quality checks indicate the studies are flawed by systematic error should the result be considered totally unreliable and excluded from further consideration.

Two soils, Quilen and DU-L-PF, studies can be considered fully reliable and so K_{foc} and experimentally derived 1/n values can be used. It is worth nothing these soils were also fully accepted in the EFSA list of endpoints for clopyralid. The 7 remaining studies all have varying degrees of reliability concerns. In the EFSA peer review 6 of soils were considered unreliable for Freundlich sorption while the Calke soil was assessed as fully reliable. It is not clear why the Calke soil was considered reliable as even the absolute value of the 1/n values is outside what is considered theoretically possible for Freundlich isotherms. The Kfe/Kf results for the soil indicate mass balance was a major issue which is a very plausible explanation for the low reported 1/n value. Therefore it should also be considered unreliable.

When the above reliability screening is applied the resulting endpoints are K_{oc}=4.05 and 1/n=0.881. This represents a full implementation of EFSA guidance whereby default 1/n are always coupled to Kdoc values while experimentally reported 1/n values are coupled for experimental Kfoc values. It should be noted that in this case all studies measured Kd at multiple concentrations and the reported Kd values are the geometric mean of those measurements. This is what facilitates the 1/n being set to 0.9. Had K_d only have been measured at a single concentration the default for 1/n gets set to 1.0. The current EFSA peer review does adhere to this same standard principle.

Summary of endpoint value for clopyralid.

Study Report	Soil	OC%	pH	K_d	Kfoc	Kdoc	1/n
Reeves and Mittelstaedt (2002)	Merzenhausen	1	7.19	0.051	0.57	5.1	0.9*
	Kaldenkirchen (Ap horizon)	0.98	5.34	0.048	2.72	4.9	0.9*
	Lanna	2.06	6.62	0.151	0.26	7.3	0.9*
	Overhetfeld	0.93	6.49	0.032	1.34	3.4	0.9*
Buntain and Simmonds (2015)	Calke	3.15	5.7	0.139	0.5	4.4	0.9* (0.489)**
	Longwoods	3.13	7.4	0.069	2.5	2.2	0.9*
	Lufa 2.1	0.68	4.9	0.04	4.1	5.9	0.9*

	Quilen	4.02	6.9	0.356	3.9	8.9	0.804
	DU-L-PF	6.47	6.3	0.282	2.1	4.4	0.829
Geometric Mean (n=9)					1.41	4.82	-
Geometric mean in accordance with EFSA (2018) Soil Sorption Checklist					**4.05**		-
Arithmetic mean in accordance with EFSA (2018) Soil Sorption Checklist							**0.881**

The values shaded in grey are considered unreliable for endpoint derivation
*EFSA (2013) considered 6 of values invalid and replaced them with default values for endpoint derivation
**EFSA (2018) LoEP value.

Conclusion

The correct soil sorption modelling endpoints for clopyralid are Koc=4.05 and 1/n=0.881. This is not because the current EFSA peer review mis-reports or mis calculates K_{foc} values, including the geometric mean Kfoc value, but rather than many of those K_{foc} values are not reliable for modelling endpoints. As Kfoc and 1/n value are derived, and never directly measured, in a way which always links the two it is not scientifically or procedurally correct to throw out one set of values as unreliable but retain the other values. As detailed in EFSA (2017) using Kdoc values coupled with default 1/n values is the accepted solution for deriving endpoints from studies where the Freundlich isotherms are unreliable.