Draft Renewal Assessment Report
under Regulation (EC) 1107/2009

CLOPYRALID

Volume 3 – B.8 (PPP) – GF-1374

RMS: Finland
Co-RMS: Poland

May 2017

Version History

When	What
2017/ May	DRAR- First version submitted to EFSA

Table of contents

B.8. ENVIRONMENTAL FATE AND BEHAVIOUR

B.8.0. Introduction

This document summarises the environmental exposure of the formulation GF-1374, and where appropriate, the active substances and potentially relevant metabolites, and evaluates the potential exposure of the environmental compartments soil, groundwater, surface water, sediment and air to the formulation. A risk assessment according to Uniform Principles is provided which demonstrates that the formulation does not give rise to unacceptable risk for groundwater and provides PECs for ecotoxicology risk assessments.

Details of the active substances, the Annex I inclusion Directive and Commission Review Report are provided in Table 8.0.1 below.

Table 8.0.1. Details for the active substances

Active Substance	Annex I Inclusion Directive	SANCO Review Report	EFSA Scientific Report
Fluroxypyr	736/2011	SANCO/11019/2011	*EFSA Scientific Report* (2011) 9, (3), 2091
Clopyralid	06/64/EC	SANCO/10012/2006	*EFSA Scientific Report* (2005) 50, 1–65
Florasulam	02/64/EC	SANCO/1406/2001	*EFSA Scientific Report* (2015) 13(1), 3984

Where appropriate this document refers to the conclusions of the EU review of the active substances fluroxypyr, clopyralid and florasulam. 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.

The 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. Studies which have already been evaluated during the Annex I process are not summarised. New Annex II data is only included if they are considered essential for the evaluation and a full study summary is provided. Furthermore, fluroxypyr and florasulam have recently been granted Annex I inclusion. For fluroxypyr, the conclusions from the peer review process were published in 2011 (EFSA 2011). For florasulam, conclusions from the peer review process were published in 2015 (EFSA 2015). A risk envelope approach is being applied for the exposure assessment of fluroxpyr and florasulam. Within the scope of this assessment, one application of fluroxypyr at 200 g a.s./ha was determined to be a safe use on both cereals and grasslands. Also, one application of flurosulam at 6.25 g a.s./ha was determine to be a safe use on cereals and grasslands. Therefore, for the below assessments, it is justified to refer to fluroxypyr and florasulam data wherever appropriate. Specific exposure assessments for these two active substances are not necessary to defend the Annex I listing of clopyralid since the proposed use rate falls within their safe use. Please refer to the EFSA Scientific reports of florasulam and fluroxypyr to review their associated risk assessments.

GF-1374 was not the representative formulation for Annex I and it has been previously evaluated according to Uniform Principles.

The EFSA Conclusions and/or SANCO Review Reports for fluroxypyr, clopyralid and florasulam listed in Table 8.0.1. above are considered to provide the relevant review information or a reference to where such information can be found. The EU endpoints to be used in the evaluation are summarised at relevant points in this document.

The Annex I Inclusion Directive for fluroxypyr, clopyralid and florasulam provide specific provisions under Part B which need to be considered by the applicant in the preparation of their submission and by the MS prior to granting an authorisation.

For the implementation of the uniform principles of Annex VI, the conclusions of the SANCO Review Reports on fluroxypyr, clopyralid and florasulam and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 17 June 2011 (fluroxypyr), on 4 April 2006 (clopyralid) and 19 April 2002 (florasulam) shall be taken into account.

Specific provisions are indicated under Part B which needs to be considered by the applicant in the preparation of their submission and by the Member States prior to granting an authorisation. In the case of clopyralid, it is indicated that Member States may need to pay particular attention to potential groundwater contamination in vulnerable conditions. These concerns have been addressed within the current submission.

B.8.1. FATE AND BEHAVIOUR IN SOIL

The core environmental fate properties of clopyralid are summarised in Tables 8.1.1- 8.1.3. below.

Table 8.1.1. Summary of Environmental Fate of Clopyralid

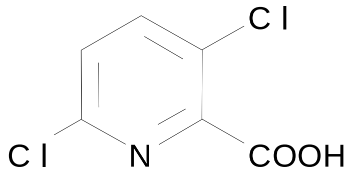
Parent or Metabolite Name	Structure	Key Information
Clopyralid		72.9 – 83.3 % of AR after 374 days at 20ºC, [2,6-pyridinyl-^{14}C]-label (n=5) CO_2: 47.5 – 65.5 % of AR after 92 days 11.2 – 35.1 % of AR after 92 days at 20ºC, [2,6-pyridinyl-^{14}C]-label (n=5) No major metabolites in addition to CO_2 Unidentified minor metabolites max. 7.7 % of AR at 20ºC

Table 8.1.2. Active substance considered in this assessment

Component	Soil (max %)			Water (max %)		Sediment (max %)	Air
	Aerobic	Anaerobic	Photolysis	Photolysis	Surface		
Clopyralid	100	100	100	100	100	30.6	100

Table 8.1.3. Physical-chemical properties of clopyralid (EFSA Scientific Report (2005) 50, 1-65)

Property	Clopyralid
Molar mass (g/mol)	191.96
Solubility in water, 20°C (mg/L)	143,000
Vapour pressure, 20°C (Pa)	1.36 x 10^{-3} Pa at 25°C

Henry's Law Constant, 20°C (Pa m^3/mol)	1.8 x 10^{-11}
Photolytic stability	DT_{50}: 261 days in sterile aqueous pH 7 buffer solution at a concentration of 2.0 ppm clopyralid under natural sunlight at 25°C
Hydrolytic stability, 25°C	pH 4-9: No hydrolysis

The following Table provides a justification for the use of a different study to address fate and behaviour in soil to that evaluated for the Active Approval.

Table 8.1.4. Clopyralid - justification for the use of a different study to address fate and behaviour in soil

Data point/Study	Rationale
CA 7.1.1.1/3 and CA 7.1.2.1.1/3 (Wardrope, 2009; DAS Study ID 29902)	In order to address minor quality issues with one of the studies previously submitted and to investigate the relevance of the unidentified metabolite (7.7% AR) detected in the US soil further (CA 7.1.1.1/2), an additional degradation study on four European soils has been conducted.
CA 7.1.2.1.1/4 (Schubert, 2015; DAS Study ID 151039)	Kinetic (re-)evaluation of all aerobic laboratory degradation data in order to derive persistence and modelling endpoints according to the latest guidance (FOCUS, 2006, 2014).
CA 7.1.2.2.1/3 (Kröger, 2015; DAS Study ID 130673)	Additional data were generated in in order to support the data previously reviewed for Active Approval.
CA 7.1.2.2.1/4 (Kröger, 2016a; DAS Study ID 150672)	Additional data were generated in in order to support the data previously reviewed for Active Approval.
CA 7.1.2.2.1/5 (Kröger, 2016b; DAS Study ID 150673)	Additional data were generated in in order to support the data previously reviewed for Active Approval.
CA 7.1.2.2.1/6 (Robinson, P, 2015; DAS Study ID 150296)	Kinetic (re-)evaluation of all field dissipation data in order to derive persistence and modelling endpoints according to the latest guidance (FOCUS, 2006, 2014).
CA 7.1.2.2.1/7 (Robinson, P, 2016; DAS Study ID 160486)	Kinetic (re-)evaluation of the two new Kröger field dissipation studies (Kröger 2016a, 2016b) in order to derive persistence and modelling endpoints according to the latest guidance (FOCUS, 2006, 2014).
CA 7.1.3.1.1/2 (Buntain & Simmonds, 2015; DAS Study ID 130733)	Additional data were generated in in order to support the data previously reviewed for Active Approval.

RMS comments and evaluation:

The studies on the aerobic degradation of clopyralid were evaluated in the DAR (2003) and the results were used in the risk assessment presented in the EFSA conclusion on clopyralid (EFSA Scientific Report 2005: 50). The outcomes as summarized below are still valid and therefore the studies are not reviewed here again. No other comments, studies are acceptable and adequate for the renewal for the approval of clopyralid.

B.8.1.1. Route and rate of degradation in soil

As summarized by EFSA, (EFSA Scientific Report (2005) 50, 1-65, Conclusion on the peer review of clopyralid, 14 December 2005):

Degradation rate of clopyralid under aerobic and anaerobic conditions was investigated in the same studies used to establish the route of degradation in soil. At an application rate of 0.3 mg / kg (corresponding to 225 g a.s. / ha) and 40 % MWHC clopyralid is moderate to medium persistent ($DT_{50\ 20ºC}$ = 57 d – 215 d). Under anaerobic conditions there is practically no degradation and half-life is estimated to be greater than one year. In the field studies clopyralid dissipated slightly faster being low to moderate persistent ($DT_{50\ field}$ = 2 – 24 d). Half-lives were calculated taking in to account residues found in the 0-10 cm and 10-20 cm soil layers. Residues were not measured at deeper horizons.

B.8.1.1.1. Laboratory studies on the rate of degradation of clopyralid in soil

Studies to determine the rate of degradation in soil are described in CA Point 7.1.2, degradation data as used in the surface water modelling are presented in the table below. Studies with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance.

Table 8.1.5. Clopyralid laboratory degradation in aerobic soils (CA 1.2.1.1/4; Schubert, 2015)

Soil name	Kinetic model	Non-normalised DT_{50} (days)	Normalised DT_{50} (days)	Study
Parabraunerde	SFO	44.4	34.2	Baloch & Grant, 1991 (CA 7.1.1.1/1 / CA 7.1.2.1.1/1)
Marcham	SFO	34.5	32.4	
Castle Rising	SFO	26.3	26.3	
Speyer 2.1	SFO	64.6	64.6	
Speyer 2.2	SFO	16.2	16.2	
Mississippi	SFO	8.6	11.6	Skinner *et al.*, 1995 (CA 7.1.1.1/2 / CA 7.1.2.1.1/2)
A	SFO	16.5	16.5	Wardrope, 2009 (CA 7.1.1.1/3 / CA 7.1.2.1.1/3)
B	SFO	23.0	15.9	
C	SFO	4.9	4.9	
D	SFO	9.8	9.8	
		Geometric mean	**18.4**	

RMS comments and evaluation:

The rate of degradation studies of clopyralid evaluated in the DAR (2003) are still valid and the results were used in the risk assessment presented in the EFSA conclusion on clopyralid (EFSA Scientific Report 2005: 50). Additionally, one new study was included in the data package, which was evaluated in dRAR Part 10 Vol. 3 Chapter 8.

The kinetic calculation of the soil degradation endpoints of clopyralid presented by the Notifier was assessed. The DT_{50} and DT_{90} values were derived from three different studies on ten soils with an adequate variety of properties. The studies are acceptable and all individual values are valid, thus allowing an appropriate risk assessment. The kinetic calculation was performed according to FOCUS guidance, and the outcomes are considered acceptable. Single First-Order kinetics appears to appropriately describe the degradation of clopyralid in soils.

The resulting DT50 values in these ten soils are summarized above. The geometric mean of 18.4 days is appropriate to be used in the risk assessment of clopyralid. No other comments, studies are acceptable and adequate for the renewal for the approval of clopyralid.

B.8.1.1.2. Field studies on the rate of degradation of clopyralid in soil

GF-1374 was not the representative formulation for the Active Approval of clopyralid. Data to address this point were not evaluated as part of the Active Approval therefore all relevant data are provided.

Field dissipation studies with clopyralid formulated as GF-1966 were conducted and are described in CA 7.1.2.2.1. Degradation data as used in the soil and groundwater modelling are presented in Table 8.1.6. below.

Table 8.1.6. Clopyralid field dissipation data – persistence endpoints (CA 7.1.2.2.1/6; Robinson, 2015; CA 7.1.2.2.1/7; Robinson, 2016)

Soil name	Location	Soil type	pH (H_2O)	OC (%)	Soil moisture (field capacity % w/w)	DT_{50} (actual) (days)	Study
Middlefart	Røjleskovvej, Denmark	Sandy clay loam[a]	7.5	1.7	22	23.7	Rawle & Yon, 2002a,b (CA 7.1.2.2.1/1; CA 7.1.2.2.1/2
Ansonville	Loiret, Northern France	Silty clay loam[a]	8.2	1.5	30	0.16	
Mainber-villiers	Seine-et-Marne, Northern France	Clay loam[a]	7.1	1.1	28	6.04	
Oederquart	Lower Saxony, Germany	Silty clay loam[a]	7.5	1.7	30	16.2	
Bargstedt	Northern Germany	Loamy sand[b]	4.3	1.5	14	21.0	Kröger, 2015 (CA 7.1.2.2.1/3)
Wilson	UK	Loam[b]	6.2	1.3	25	16.7	
Sermaises	Northern France	Silty clay loam[b]	7.0	1.3	30	16.3	
Canals	Spain	Clay loam[b]	8.0	0.4	28	13.7	Kröger, 2016a (CA 7.1.2.2.1/4)
Elne	Southern France	Silt loam[b]	6.3	1.1	26	*(49.3)*[c]	Kröger, 2016b (CA 7.1.2.2.1/5)

[a] ADAS classification
[b] USDA classification
[c] Model fit not statistically or visually acceptable (according to FOCUS, 2006, 2014)

RMS comments and evaluation:

The field dissipation studies of clopyralid were partly evaluated in the DAR (2003) and the results were used in the risk assessment presented in the EFSA conclusion on clopyralid (EFSA Scientific Report 2005: 50). Additional new studies were submitted for the AIR3 evaluation, and evaluated in dRAR Part 10 Vol. 3 Chapter 8. The outcomes as summarized are valid. No other comments, studies are acceptable and adequate for the renewal for the approval of clopyralid.

Table 8.1.7. Clopyralid field dissipation data - modelling endpoints (CA 7.1.2.2.1/6; Robinson, 2015; CA 7.1.2.2.1/7; Robinson, 2016)

Soil name	Location	Soil type	pH (H_2O)	OC (%)	Soil moisture (field capacity % w/w)	DT_{50} (normalised)[a] (days)	Study
Middlefart	Røjleskovvej, Denmark	Sandy clay loam[b]	7.5	1.7	22	8.46	Rawle & Yon, 2002a,b (CA 7.1.2.2.1/1; CA 7.1.2.2.1/2
Ansonville	Loiret, Northern France	Silty clay loam[b]	8.2	1.5	30	2.07	
Mainber-villiers	Seine-et-Marne, Northern France	Clay loam[b]	7.1	1.1	28	2.70	
Oederquart	Lower Saxony, Germany	Silty clay loam[b]	7.5	1.7	30	5.69	
Bargstedt	Northern Germany	Loamy sand[c]	4.3	1.5	14	13.0	Kröger, 2015 (CA 7.1.2.2.1/3)
Wilson	UK	Loam[c]	6.2	1.3	25	13.5	
Sermaises	Northern France	Silty clay loam[c]	7.0	1.3	30	7.50	
Canals	Spain	Clay loam[c]	8.0	0.4	28	12.3	Kröger, 2016a (CA 7.1.2.2.1/4)
Elne	Southern France	Silt loam[c]	6.3	1.1	26	-[d]	Kröger, 2016b (CA 7.1.2.2.1/5)
					Geometric mean	**6.76**	

[a] Normalised to pF2, 20 °C; Q_{10} = 2.58
[b] ADAS classification
[c] USDA classification
[d] Model fit not statistically or visually acceptable (according to FOCUS, 2006, 2014)

RMS comments and evaluation:

No field dissipation data with the current representative formulation GF-1374 are available, but field dissipation studies with clopyralid formulated as GF-1966 (earlier formulation representative to support the original Annex I inclusion of clopyralid, containing clopyralid as the only active substance) were conducted as presented above. This is considered acceptable, as the current representative formulation is a mixture of three active substances and thus more complex for assessing the environmental fate of the active substance than the earlier single active formulation.

The kinetic calculation of the field dissipation endpoints of clopyralid in Northern and Central European conditions, as presented by the Notifier was assessed by the RMS in the dRAR Part 10 Vol. 3 Chapter 8. The DT_{50} and DT_{90} values were derived from three different studies on eight locations and address adequate variety of climate and soil conditions in Northern and Central parts of the Europe. The studies are acceptable and all individual values are valid, thus allowing an appropriate risk assessment. The kinetic calculation was performed according to FOCUS guidance, and the outcomes as summarized above are considered acceptable. The recalculated $DT_{50field}$ values are somewhat shorter (with geomean of 6.2 days) than originally obtained during the first evaluation of clopyralid (mean $DT_{50field}$ of 11 days from the studies Rawle & Yon 2002a-b). However, the individual values at different locations remain within the same range in all studies. The data is adequate for the renewal for the approval of clopyralid, and no further data are required.

Because the results of separate field dissipation studies in Southern European conditions were not available when the dossier was prepared, the kinetic evaluation of these studies is performed separately (Robinson 2016). No further data is required.

The soil degradation data available indicate that clopyralid is readily degraded in the field in various conditions throughout the Europe.

B.8.1.1.3. Soil accumulation studies

Field soil accumulation studies are required if the $DT_{90field}$ for the active substance is greater than one year. All $DT_{90field}$ values for clopyralid were less than one year (see CA 7.1.2.2.1). Therefore, soil accumulation studies with the active substance have not been conducted.

RMS comments and evaluation:

The justification presented by the Notifier is acceptable and no further studies are required to support the renewal for the approval of clopyralid.

B.8.1.2. Route of degradation

As summarized by EFSA, (EFSA Scientific Report (2005) 50, 1-65, Conclusion on the peer review of clopyralid, 14 December 2005):

"Clopyralid metabolism in soil under dark aerobic conditions at 20 ºC was investigated in two studies with a total of six different soils. The six soils covered a range of pH (6.0-8.3), clay contents (3%-26%) and organic matter content (1.28%-27.6%). Additionally one of the soils was tested at 10 ºC and at various moisture levels. No degradation product was identified in the first study (five soils), likely due to the limitation of the analytical methodology employed (TLC). In the second study some unidentified radioactive regions were separated by HPLC, none accounting for more than 10 % AR. Non extractable radioactivity increased to a maximum of 35 % AR after 92 d. Volatiles collected in a trap with alkaline solution amounted up to a maximum of 83.3 % AR. No identification of the volatiles was attempted and precipitation with $BaCl_2$ was performed only in the one of the experiments (applicant claim not reported in the DAR but in the reporting table). Based on complementary evidences such the soil volatilization study, it was accepted that most of the radioactivity found in the alkaline volatiles trap should be attributed to CO_2.

Degradation under dark anaerobic conditions at 20 ºC was investigated in a study with a sandy clay loam soil. Analysis of soil and water by HPLC indicated that minimal degradation occurred under anaerobic conditions and no transformation products were found during the anaerobic experiment. Photolysis will not contribute to the dissipation of clopyralid in soil according to the available study. Dissipation of clopyralid under field conditions was investigated in two field dissipation studies in five different sites located in the United Kingdom, Denmark, France (2 Northern sites) and Germany. Clopyralid was applied as formulated LONTREL (EF-1136) however no degradation products or bounded residue were analysed in these field trials.

Over the 90-day aerobic soil incubation period, ^{14}C-Clopyralid mineralised to CO_2 and a minor metabolite which was accounted for <5 % AR. CO_2 accounted for 68.21% to 74.31% at 90 days.

In the laboratory soil photolysis study where ^{14}C-Clopyralid used as a test substance, the irradiated DT_{50} was longer than the DT_{50} for the dark samples indicating that phototransformation is not a significant route of degradation on dry soil.

B.8.1.3. Mobility in soil

A summary of adsorption data on clopyralid in soil as presented in CA 7.1.3.1.1 and used in modelling is presented in Table 8.1.8. below.

Table 8.1.8. Clopyralid adsorption data (CA 7.1.3.1.1)

Soil name	Soil type	OC (%)	pH ($CaCl_2$)	$K_{f,ads}$ (mL/g)	K_{foc} (mL/g)	Modelling 1/n[a] (-)	Study
Merzenhausen	Silt loam[b]	1.00	7.19	0.006	0.57[c]	0.9	Reeves & Middelstaedt, 2002 (CA 7.1.3.1.1/1)
Kaldenkirchen	Loamy sand[b]	0.98	5.34	0.027	2.72[c]	0.9	
Lanna	Clay loam[b]	2.06	6.62	0.005	0.26[c]	0.9	
Overhetfeld	Loamy sand[b]	0.93	6.49	0.013	1.34[c]	0.9	
Calke	Sandy loam[d]	3.15	5.7	0.01	0.5	0.489	Buntain & Simmonds, 2015 (CA 7.1.3.1.1/2)
Longwoods	Sandy loam[d]	3.13	7.4	0.08	2.5	0.9	
LUFA 2.1	Loamy sand[d]	0.68	4.9	0.03	4.1	0.9	
Quilen	Loam[d]	4.02	6.9	0.16	3.9	0.804	
DU-L-PF	Clay loam[d]	6.47	6.3	0.14	2.1	0.829	
				Geometric mean	**1.41**	**-**	
				Arithmetic mean	**-**	**0.836**	

[a] according to reliability criterion presented in the OECD 106 guideline
[b] BBA classification
[c] calculated based on RMS, 2005
[d] USDA classification

RMS comments and evaluation:

The calculation presented by the Notifier is acceptable and the data is appropriate to be used in the modelling of clopyralid. No further data to derive the adsorption and desorption endpoints are required to support the renewal for the approval of clopyralid.

B.8.1.3.1. Laboratory studies

Studies to determine the mobility in soil are described in CA 7.1.4. Studies with the formulation GF-1374 were not performed, since it is possible to extrapolate from data obtained with the active substance.

RMS comments and evaluation:
It is agreed that adsorption/desorption studies with the formulation GF-1374 are not necessary. The study with active substance presented by the Notifier in the AIR3 dossier was new and not evaluated before in the context of the regulation 1107/2009. The study was well conducted according to the current test guideline and the GLP, well reported and overall acceptable. The results are in line with the earlier study, considered as valid and can thus be used in the risk assessment together with the data already available. Therefore the knowledge base available on the sorption of clopyralid in a variety of soils is adequate. The data requirement is fulfilled and no further studies on the adsorption and desorption in soil are required to support the renewal of the approval of clopyralid.

B.8.1.3.2. Lysimeter studies

Studies with the formulation were not performed as it is possible to extrapolate from data obtained with the active substance.

The mobility of clopyralid in soil was assessed with FOCUS groundwater modelling tools using the degradation data described under CA 7.1.2 and the sorption data described in CA 7.1.3.1.1. Therefore, lysimeter studies are not required.

However, lysimeter studies were presented in the dossier submitted in April 2002 for the Active Approval and were deemed acceptable following evaluation and peer review at EU level. These data are still valid as supporting information, although the use patterns supported by data have been changed in AIR3 dossier.

RMS comments and evaluation:
The justification presented by the Notifier is acceptable and no further lysimeter studies are required to support the renewal for the approval of clopyralid. The mobility can be assessed reliably by modelling, for which appropriate mobility endpoints have been submitted according to the data requirement regulation 283/2013.

B.8.1.3.3. Field leaching studies

Studies with the formulation were not performed as it is possible to extrapolate from data obtained with the active substance.

The mobility of clopyralid in soil was assessed with FOCUS groundwater modelling tools using the degradation data described under CA 7.1.2 and the sorption data described in CA 7.1.3.1.1. Therefore, field leaching studies are not required.

RMS comments and evaluation:

The justification presented by the Notifier is acceptable and no further field leaching studies are required to support the renewal for the approval of clopyralid. The mobility can be assessed reliably by modelling, for which appropriate mobility endpoints have been submitted according to the data requirement regulation 283/2013.

B.8.2. PREDICTED ENVIRONMENTAL CONCENTRATIONS IN SOIL (PEC_{SOIL})

Predicted environmental concentrations of clopyralid in soil (PEC_{soil}) were calculated by the Notifier as presented below. Predicted environmental concentrations in soil (PEC_{soil}) were calculated for the herbicide clopyralid according to recommendations by FOCUS (1997)[1] and the EU Commission (2000)[2]. GF-1374 was not the representative formulation for the Active Approval of clopyralid, with a lower exposure, and therefore a new calculation was necessary compared to what was presented in the first evaluation and conclusion on clopyralid in 2005. A single application to winter cereals and grassland at rates of 80 and 120 g a.s./ha, respectively, were considered in the calculations.

Methods

Calculations were carried out according to recommendations from FOCUS (1997) and the EU Commission (2000) using Microsoft® Excel spreadsheets and the following equations:

$$PEC_{soil,ini}\ (mg/kg) = \frac{A\ (g/ha) \times (1 - F)}{100 \times d\ (cm) \times \rho\ (g/cm^3)}$$

Where:
A = Application rate
F = Fraction intercepted by crop
d = Depth of field soil layer (5 cm)
ρ = Dry bulk density (1.5 g/cm^3)

Actual predicted environmental concentrations in soil at time t ($PEC_{soil,act,t}$) were calculated using the following equation:

$$PEC_{soil,act,t}\ (mg/kg) = PEC_{soil,ini} \times e^{-kt}$$

Where:
$PEC_{soil,ini}$ = initial concentration [mg/kg]
k = degradation rate ($\ln(2)/DT_{50}$)
t = time after peak concentration

The Time Weighted Average PEC over time t (TWA $PEC_{soil,t}$) was calculated by:

$$TWA\ PEC_{soil,t}\ (mg/kg) = \frac{PEC_{soil,ini} \times (1-e^{-kt})}{kt}$$

[1] FOCUS (1997): Soil persistence models and EU Registration. The final report of the work of the Soil Modelling Work group of FOCUS. February 1997.
[2] EU (2000): Guidance document on persistence in soil. EU Commission Document 9188/VI/97 rev. 8, 12. July 2000.

The maximum non-normalised field DT_{50} was considered in the calculations. The application patterns considered for the calculations are presented in Table 8.2.1. Foliar spray application of clopyralid to winter cereals and grassland in Europe is considered. An interception rate for each crop was assumed for modelling purposes based on FOCUS groundwater scenarios workgroup guidelines (EC, 2014[3]; 2014[4]).

Table 8.2.1. Application patterns of GF-1374 and clopyralid to winter cereals and grassland used in PEC_{soil} calculations

Compound / formulation	Crop	Appl. rate (g/ha)	No. of appl.	Appl. method	Growth stage	FOCUS crop interception at application (%)	Resulting soil deposit (g/ha)
GF-1374	-	1560[a]	1	Spray	BBCH 13	0	1560
Clopyralid	Winter cereals	80	1	Spray	BBCH 13	0	80
	Grassland	120	1	Spray	Established	90	12

[a] worst case assumption; based on a formulation density of 1.04 g/mL and a maximum application rate of 1.5 L GF-1374/ha

Input parameters for clopyralid used in the calculations are shown in Table 8.2.2.

Table 8.2.2. Input parameters for clopyralid used in PEC_{soil} simulations

Parameter	Unit	Clopyralid
Molecular Mass	g/mol	191.96
DT_{50} soil[a]	days	23.7

[a] worst case, field, non-normalised (n = 8)

Results

Maximum concentrations ($PEC_{soil,ini}$) were assessed for formulation GF-1374 and clopyralid. Results are summarised in Table 8.2.3.

Table 8.2.3. Predicted environmental concentrations of GF-1374 and clopyralid in soil following a single application of GF-1374 to winter cereals and grassland

[3] EC (2014): Assessing Potential for Movement of Active Substances and their Metabolites to Ground Water in the EU. Report of the FOCUS Ground Water Work Group, EC Document Reference Sanco/13144/2010 version 3.

[4] FOCUS (2014): Generic guidance for Tier 1 FOCUS ground water assessments, version 2.2. FOCUS groundwater scenarios working group.

Compound / formulation	Crop	Appl. rate (g/ha)	No. of appl.	FOCUS crop interception at application (%)	$PEC_{soil,ini}$ (mg/kg)
GF-1374	-	1560[a]	1	0	2.08
Clopyralid	Winter cereals	80	1	0	0.107
	Grassland	120	1	90	0.016

[a] calculated based on a formulation density of 1.04 g/ml and a maximum application rate of 1.5 L GF-1374/ha

The actual and time-weighted average concentrations in soil ($PEC_{soil,act}$ and $PEC_{soil,twa}$) are presented in Table 8.2.4 and Table 8.2.5 for winter cereals and grassland, respectively.

Table 8.2.4. Actual and time-weighted average concentrations of clopyralid in soil following single application of GF-1374 to winter cereals

Time (d)	$PEC_{soil,act}$ (mg/kg)	$PEC_{soil,twa}$ (mg/kg)
0	0.107	-
1	0.104	0.105
2	0.101	0.104
4	0.095	0.101
7	0.087	0.096
14	0.071	0.088
21	0.058	0.080
28	0.047	0.073
50	0.025	0.056
100	0.006	0.035

Table 8.2.5. Actual and time-weighted average concentrations of clopyralid in soil following single application of GF-1374 to grassland

Time (d)	$PEC_{soil,act}$ (mg/kg)	$PEC_{soil,twa}$ (mg/kg)
0	0.016	-
1	0.016	0.016
2	0.015	0.016
4	0.014	0.015
7	0.013	0.014
14	0.011	0.013
21	0.009	0.012
28	0.007	0.011
50	0.004	0.008
100	0.001	0.005

Conclusion

Predicted environmental concentrations in soil for clopyralid and formulation GF-1374 were calculated for the use on winter cereals and grassland in Europe in accordance with recommendations by FOCUS (1997) and the EU Commission (2000). The results for PEC in soil for the active substance were used for the ecotoxicological risk assessment.

RMS comments and evaluation:

The calculation presented by the Notifier was conducted according to the guidance and is acceptable with regard to the use of the product CF-1374 on cereals with the highest application rate of 1 Liter of the product corresponding to 80 g a.i./ha. For pasture the Notifier has claimed that the highest application rate of 2 Liters per hectare, corresponding to 160 g a.i./ha, as authorized in certain Member States, is not valid any more. Therefore the worst case use rate on pasture is 1.5 L/ha, corresponding to 120 g a.i./ha. The PECs from pasture use have therefore been calculated only with the application rate of 1.5 Liters of the product or 120 g a.i./ha. Higher use rates are not supported by data appropriately any longer, and so this approach is acceptable for the RMS evaluator.

The Notifier highlights that this is not necessarily the worst case GAP at MS level. Higher use rates of clopyralid than 80 g/ha in cereals and and 120 g/ha in established pasture may be supported with appropriate data at national level depending on agronomic needs, weed pressure, approved endpoints and specific Member States' modelling requirements and risk mitigation measures to be applied, and need to be evaluated separately at MS level. The RMS agrees on this statement.

For the EU AIR3 assessment, a worst case $PEC_{soil,\ ini}$ of 2.08 mg/kg for the representative formulation GF-1374 was calculated considering a maximum application rate of 1.5 L/ha. The maximum concentration of clopyralid ($PEC_{soil,ini}$) of 0.107 mg/kg for winter cereals and 0.016 mg/kg for grassland was obtained resulting from the representative uses of the product GF-1374 according to the GAP. These worst case PECsoil values should be used in the ecotoxicological risk assessment of soil dwelling organisms.

As no degradation products other than CO_2 are formed from clopyralid, it is not relevant to calculate the PEC_{soil} of metabolites.

The calculation is acceptable and provides a reliable basis for the ecotoxicological risk assessment. No further data are required.

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

GF-1374 was not the representative formulation for the Active Approval of clopyralid, with a lower exposure, and therefore a new calculation was necessary compared to what was presented in the first evaluation and conclusion on clopyralid in 2005. Predicted environmental concentrations in groundwater resulting from the use of this new representative formulation were not evaluated during the first Approval of clopyralid, and therefore all relevant information is provided here. A single application to winter cereals and grassland at rates of 80 and 120 g a.s./ha, respectively were considered in the calculations. Following modelling report was presented by the Notifier.

CP 9.2.4.1/1 - Predicted environmental concentrations of clopyralid in ground water

Report	CP 9.2.4.1/1; Robinson, P. 2016a
Report title	Predicted environmental concentrations of clopyralid in groundwater (PEC_{gw}) following the application to winter cereals and grassland - a modelling assessment for Europe using FOCUS PEARL, FOCUS PELMO and FOCUS MACRO
DAS Study number	Dr Knoell Consult Ltd., Cardiff, UK, Report No.: 104115-2 DAS Study ID: 151156 25.2.2016
Guidelines	EC (2014): Assessing potential for movement of active substances and their metabolites to ground water in the EU. Report of the FOCUS Ground Water Work Group, EC Document Reference Sanco/13144/2010 version 3. FOCUS (2000): FOCUS groundwater scenarios in the EU plant protection product review process. Report of the FOCUS Groundwater Scenarios Workgroup, EC Document Reference Sanco/321/2000 rev 2. FOCUS (2014): Generic Guidance for Tier 1 FOCUS Ground Water Assessments, version 2.2.
GLP	No

Methods

Application scenarios

According to ‘Good Agricultural Practice’ (GAP), clopyralid is intended to be used as a herbicide on winter cereals and grassland with a single spray application at a rate of 80 g a.s./ha and 120 g a.s./ha, respectively. These use rates correspond to application rates of 1 L/ha and 1.5 L/ha of the product GF-1374. For winter cereals, a yearly single foliar spray application of 80 g a.s./ha from approximately BBCH 13, between February and June inclusive, was considered, and additionally, a bi-annual or tri-annual application was simulated for some model scenarios. For established grassland, a yearly single foliar spray application of 120 g a.s./ha between February and August was considered.

Based on the development stages of the selected crops at the time of application, the interception rates were estimated to be 0% for winter cereals and 90% for established grassland in accordance with FOCUS guidance (FOCUS, 2014). Therefore 100% for winter cereals, or 10% for grass, of the intended application rate was assumed to reach the soil surface and become available for leaching.

Modelling was conducted in a tiered approach. In the first instance runs were simulated with annual applications, but where results with a specific application date exceeded the trigger value of 0.1 µg/L, bi-annual application and application every third year were also considered.

Application scenarios resulting from the representative uses of the formulation GF-1374 which were considered for the simulations are summarised in Table 8.3.1. Detailed application dates are presented in Table 8.3.2.

Table 8.3.1. Application patterns of clopyralid used in PEC_{gw} calculations

Crop	Appl. rate (g a.s./ha)	No. of appl.	Appl. method	Growth stage (BBCH) (appl. period)	FOCUS crop interception at application (%)	Resulting soil deposit (g a.s./ha)
Winter cereals	80	1	Spray	13 (Feb - Jun)	0	80
Established grassland	120	1	Spray	- (Feb – Aug)	90	12

Table 8.3.2. Application dates used in groundwater modelling

Crop	Scenario	Date
Winter cereals	Châteaudun Hamburg Jokioinen Kremsmünster Okehampton Piacenza Porto Sevilla Thiva	01-Feb (32) or 01-Mar (60) or 01-Apr (91) or 01-May (121) or 01-Jun (152)
Established grassland	Châteaudun Hamburg Jokioinen Kremsmünster Okehampton Piacenza Porto Sevilla Thiva	01-Feb (32) or 01-Mar (60) or 01-Apr (91) or 01-May (121) or 01-Jun (152) or 01-Jul (182) or 01-Aug (213)

Figures in brackets are the respective 'Julian Days' used in the MACRO modelling

Environmental behaviour in soil

Studies on the degradation behaviour of the active substance clopyralid were conducted and are described under Annex Point CP 9.1.1. For the PEC_{gw} simulations, the normalised geometric mean DT_{50} from field studies was used (see Table 8.3.3).

The adsorption behaviour of the active substance clopyralid was examined in several studies, which are described under Annex Point CP 9.1.2. The geometric mean K_{foc}, together with the arithmetic mean Freundlich exponent 1/n were used in the simulations according to the latest guidance (EC, 2014[5]; see Table 8.3.3).

Input parameters

A summary of input parameters used in the simulations is given in Table 8.3.3. Apart from the input parameters explicitly discussed, all variables in the model were left at their default values.

[5] EFSA (2014): EFSA Guidance Document for evaluating laboratory and field dissipation studies to obtain DegT50 values of active substances of plant protection products and transformation products of these active substances in soil. EFSA Journal 2014; 12(5):3662.

The plant uptake factor was set to 0.5. This value was considered as more appropriate since a specific plant uptake factor study had been conducted (CA 6.2.1/4 – Gourlay, 2015). The plant uptake factors determined were 1.07 (CV = 12.3%) for wheat and 0.68 (CV = 18.3%) for oilseed rape.

Independent from crop type, the experiments clearly showed that using a default PUF of 0.5 in pesticide leaching models does not overestimate the plant uptake.

Table 8.3.3. Input parameters for clopyralid used in the groundwater simulations

Parameter	Unit	Clopyralid
Molecular Mass	g/mol	191.96
Water solubility at 20°C	mg/L	1.43×10^5
Vapour pressure at 20°C	Pa	0[a]
DT_{50} soil	days	6.76[b]
K_{foc}	mL/g	1.41[c]
K_{fom} [c]	mL/g	0.82[d]
Freundlich Exponent (1/n)	-	0.836[e]
Plant uptake factor	-	0.5
Q_{10}-value	-	2.58

[a] set to default of 0 (no volatilisation) as worst case
[b] geometric mean, field, normalised, n = 8
[c] geometric mean, n = 9
[d] calculated from K_{foc}; $K_{fom} = K_{foc}/1.724$
[e] arithmetic mean, n = 9

<u>Simulation models</u>
The FOCUS simulation models FOCUS PEARL v 4.4.4, FOCUS PELMO v 5.5.3 and FOCUS MACRO v. 5.5.4 were used in the modelling study. All standard FOCUS locations defined for the respective crops were considered in the simulations.

Results and discussion

The predicted environmental concentration (PEC_{gw}) of clopyralid following its annual application to winter cereals, obtained with FOCUS PEARL 4.4.4 and FOCUS PELMO 5.5.3, is presented in Table8.6.4, and results with FOCUS MACRO 5.5.4 are given in Table 8.3.5. The PEC_{gw} for bi-annual and tri-annual applications to winter cereals is presented in Table 8.3.6.

For grassland, the PEC_{gw} of clopyralid for an annual application is presented in Table 8.3.7 and Table 8.3.8 for FOCUS PEARL / FOCUS PELMO and FOCUS MACRO, respectively. The PEC_{gw} for bi-annual and tri-annual applications to grassland is presented in Table 8.3.9.

As no degradation products of clopyralid than CO_2 were observed in the degradation studies, it was not relevant to calculate the PEC_{gw} for the metabolites.

<u>Winter cereals</u>

The first tier calculation of the PECgw of clopyralid following the annual application of GF-1374 on winter cereals is presented in nine FOCUS scenarios in Table 8.3.4. below.

Table 8.3.4. 80th percentile leachate concentrations of clopyralid in groundwater at 1 m soil depth following the annual application to winter cereals, 1 × 80 g a.s./ha (FOCUS PEARL / FOCUS PELMO)

Application date	**Scenario**	**80th percentile PEC$_{gw}$ (µg/L)**	
		Clopyralid	
		FOCUS PEARL	**FOCUS PELMO**
1-Feb	Châteaudun	0.015	0.010
	Hamburg	**0.199**	**0.726**
	Jokioinen	**0.272**	**2.08**
	Kremsmünster	**0.153**	**0.286**
	Okehampton	**0.312**	**0.630**
	Piacenza	**0.119**	**0.619**
	Porto	**0.309**	**1.64**
	Sevilla	<0.001	0.004
	Thiva	<0.001	0.010
1-Mar	Châteaudun	0.003	0.005
	Hamburg	**0.111**	**0.242**
	Jokioinen	**0.110**	**1.55**
	Kremsmünster	0.062	**0.104**
	Okehampton	**0.125**	**0.367**
	Piacenza	0.054	**0.165**
	Porto	0.037	**0.129**
	Sevilla	<0.001	<0.001
	Thiva	<0.001	<0.001
1-Apr	Châteaudun	0.003	0.002
	Hamburg	0.057	0.056
	Jokioinen	0.074	**0.338**
	Kremsmünster	0.069	0.089
	Okehampton	0.056	0.089
	Piacenza	0.035	**0.126**
	Porto	0.009	0.009
	Sevilla	<0.001	<0.001
	Thiva	<0.001	<0.001
1-May	Châteaudun	0.007	0.003
	Hamburg	**0.114**	0.016
	Jokioinen	0.096	0.074
	Kremsmünster	0.069	0.051
	Okehampton	0.099	0.083
	Piacenza	0.030	0.023
	Porto	0.004	0.004
	Sevilla	<0.001	<0.001
	Thiva	<0.001	<0.001
1-Jun	Châteaudun	0.008	0.002
	Hamburg	**0.303**	0.032
	Jokioinen	**0.194**	**0.123**
	Kremsmünster	0.091	0.068
	Okehampton	**0.138**	**0.124**
	Piacenza	0.007	0.003
	Porto	<0.001	0.001

	Sevilla	<0.001	<0.001
	Thiva	<0.001	<0.001

Because at first tier there were several exceedings of the trigger value of 0.1 µg/L in many scenarios and at different application times, further modellings were conducted. Table 8.3.5. summarizes the outcomes of FOCUS MACRO runs in Châteaudun scenario with macropore flow at different application timings.

Table 8.3.5. 80th percentile leachate concentrations of clopyralid in groundwater at 1 m soil depth following the annual application to winter cereals, 1 × 80 g a.s./ha (FOCUS MACRO)

Application date	**Scenario**	**80th percentile PEC_{gw} (µg/L)**
		Clopyralid
1-Feb	Châteaudun	0.020
1-Mar		0.004
1-Apr		0.001
1-May		0.002
1-Jun		0.001

Next, reducing the application timing to every second or third year was considered, ant the outcomes of these modellings with two separate FOCUS models are presented in Table 8.3.6. below. The data illustrate the consequences of application timing in reducing the environmental load into groundwaters.

Table 8.3.6. 80th percentile leachate concentrations of clopyralid in groundwater at 1 m soil depth following the bi-annual and tri-annual application to winter cereals, 1 × 80 g a.s./ha (FOCUS PEARL / FOCUS PELMO)

Application date	Scenario	80th percentile PEC_{gw} (µg/L)			
		Bi-annual		Tri-annual	
		FOCUS PEARL	FOCUS PELMO	FOCUS PEARL	FOCUS PELMO
1-Feb	Châteaudun	0.006	0.005	0.005	0.003
	Hamburg	**0.109**	**0.460**	0.087	**0.363**
	Jokioinen	**0.170**	**1.21**	**0.118**	**0.930**
	Kremsmünster	0.089	**0.169**	0.060	**0.111**
	Okehampton	**0.125**	**0.283**	0.083	**0.190**
	Piacenza	0.065	**0.213**	0.069	**0.147**
	Porto	**0.209**	**0.916**	**0.161**	**0.730**
	Sevilla	<0.001	0.001	<0.001	<0.001
	Thiva	<0.001	0.006	<0.001	0.007
1-Mar	Châteaudun	0.002	0.002	-	0.002
	Hamburg	0.056	**0.134**	-	0.098
	Jokioinen	0.067	**0.812**	-	**0.663**
	Kremsmünster	0.032	0.051	-	0.035
	Okehampton	0.083	**0.190**	-	**0.147**
	Piacenza	0.025	0.098	-	0.074
	Porto	0.019	0.053	-	0.036
	Sevilla	<0.001	<0.001	-	<0.001
	Thiva	<0.001	<0.001	-	<0.001
1-Apr	Châteaudun	-	0.001	-	0.001
	Hamburg	-	0.023	-	0.013
	Jokioinen	-	**0.206**	-	**0.134**
	Kremsmünster	-	0.050	-	0.037
	Okehampton	-	0.040	-	0.026
	Piacenza	-	0.048	-	0.031
	Porto	-	0.006	-	0.004
	Sevilla	-	<0.001	-	<0.001
	Thiva	-	<0.001	-	<0.001
1-May	Châteaudun	0.003	-	-	-
	Hamburg	0.064	-	-	-
	Jokioinen	0.064	-	-	-
	Kremsmünster	0.037	-	-	-
	Okehampton	0.049	-	-	-
	Piacenza	0.018	-	-	-
	Porto	0.002	-	-	-
	Sevilla	<0.001	-	-	-
	Thiva	<0.001	-	-	-
1-Jun	Châteaudun	0.001	0.001	0.001	-
	Hamburg	**0.148**	0.019	0.095	-
	Jokioinen	**0.116**	0.082	0.092	-
	Kremsmünster	0.055	0.048	0.039	-
	Okehampton	0.075	0.063	0.052	-
	Piacenza	0.004	0.001	0.004	-

	Porto	<0.001	<0.001	<0.001	-
	Sevilla	<0.001	<0.001	<0.001	-
	Thiva	<0.001	<0.001	<0.001	-

Grassland

Table 8.3.7. 80th percentile leachate concentrations of clopyralid in groundwater at 1 m soil depth following the annual application to grassland, 1 × 120 g a.s./ha (FOCUS PEARL / FOCUS PELMO)

Application date	Scenario	80th percentile PEC_{gw} (µg/L)	
		Clopyralid	
		FOCUS PEARL	FOCUS PELMO
1-Feb	Châteaudun	0.006	0.004
	Hamburg	0.014	0.058
	Jokioinen	0.047	**0.249**
	Kremsmünster	0.020	0.024
	Okehampton	0.054	0.081
	Piacenza	0.034	**0.126**
	Porto	0.061	**0.193**
	Sevilla	0.003	0.003
	Thiva	<0.001	<0.001
1-Mar	Châteaudun	0.003	0.001
	Hamburg	0.007	0.015
	Jokioinen	0.030	**0.169**
	Kremsmünster	0.006	0.005
	Okehampton	0.025	0.046
	Piacenza	0.015	0.090
	Porto	0.005	0.034
	Sevilla	<0.001	<0.001
	Thiva	<0.001	<0.001
1-Apr	Châteaudun	0.003	0.001
	Hamburg	0.004	0.004
	Jokioinen	0.018	0.032
	Kremsmünster	0.005	0.005
	Okehampton	0.007	0.007
	Piacenza	0.006	0.050
	Porto	0.001	0.012
	Sevilla	<0.001	<0.001
	Thiva	<0.001	<0.001
1-May	Châteaudun	0.003	0.001
	Hamburg	0.007	0.001
	Jokioinen	0.015	0.011
	Kremsmünster	0.005	0.005
	Okehampton	0.005	0.008
	Piacenza	0.002	0.014
	Porto	<0.001	0.002
	Sevilla	<0.001	<0.001
	Thiva	<0.001	<0.001
1-Jun	Châteaudun	0.001	0.001
	Hamburg	0.012	0.003
	Jokioinen	0.021	0.017
	Kremsmünster	0.004	0.003
	Okehampton	0.010	0.010
	Piacenza	<0.001	0.004
	Porto	<0.001	<0.001

	Sevilla	<0.001	<0.001
	Thiva	<0.001	<0.001
1-Jul	Châteaudun	0.002	0.001
	Hamburg	0.027	0.010
	Jokioinen	0.029	0.023
	Kremsmünster	0.007	0.009
	Okehampton	0.010	0.011
	Piacenza	<0.001	0.002
	Porto	<0.001	0.001
	Sevilla	<0.001	<0.001
	Thiva	<0.001	<0.001
1-Aug	Châteaudun	0.004	0.004
	Hamburg	0.076	0.018
	Jokioinen	0.093	0.076
	Kremsmünster	0.013	0.015
	Okehampton	0.016	0.009
	Piacenza	0.007	0.011
	Porto	0.002	0.002
	Sevilla	<0.001	<0.001
	Thiva	<0.001	<0.001

Table 8.3.8. 80th percentile leachate concentrations of clopyralid in groundwater at 1 m soil depth following the annual application to grassland, 1 × 120 g a.s./ha (FOCUS MACRO)

Application date	Scenario	80th percentile PEC_{gw} (µg/L)
		Clopyralid
1-Feb	Châteaudun	0.007
1-Mar		0.001
1-Apr		<0.001
1-May		<0.001
1-Jun		<0.001
1-Jul		<0.001
1-Aug		0.002

Table 8.3.9. 80th percentile leachate concentrations of clopyralid in groundwater at 1 m soil depth following the bi-annual and tri-annual application to grassland, 1 × 120 g a.s./ha (FOCUS PEARL / FOCUS PELMO)

Application date	**Scenario**	**80th percentile PEC_{gw} (µg/L)**		
		Bi-annual		**Tri-annual**
		FOCUS PEARL	**FOCUS PELMO**	**FOCUS PELMO**
1-Feb	Châteaudun	-	0.002	0.001
	Hamburg	-	0.036	0.028
	Jokioinen	-	**0.140**	**0.105**
	Kremsmünster	-	0.014	0.009
	Okehampton	-	0.035	0.026
	Piacenza	-	0.063	0.044
	Porto	-	**0.111**	0.077
	Sevilla	-	0.001	<0.001
	Thiva	-	<0.001	<0.001
1-Mar	Châteaudun	-	<0.001	-
	Hamburg	-	0.008	-
	Jokioinen	-	0.091	-
	Kremsmünster	-	0.003	-
	Okehampton	-	0.024	-
	Piacenza	-	0.055	-
	Porto	-	0.017	-
	Sevilla	-	<0.001	-
	Thiva	-	<0.001	-

PEC_{gw} of clopyralid was less than 0.1 µg/L for some scenarios with a single annual application at each of the months indicated in the GAP. With a tri-annual application, all scenarios apart from Jokioinen resulted in PEC_{gw} <0.1 µg/L with all models.

Conclusions

Predicted environmental concentrations for clopyralid in groundwater (PEC_{gw}) were calculated using the leaching models FOCUS PEARL (v 4.4.4), FOCUS PELMO (v 5.5.3) and FOCUS MACRO (v. 5.5.4) following a single application of the product GF-1374 on winter cereals and grassland in Europe. The calculation was in accordance with FOCUS guidelines (FOCUS, 2000, 2014; EC, 2014).

PEC_{gw} of clopyralid was less than 0.1 µg/L for at least two scenarios for both use patterns of winter cereals and pasture. For grassland, PEC_{gw} <0.1 µg/L for all model scenarios with an annual application occurring from April was obtained. For applications in February and March, a bi-annual or tri-annual application was required for some scenarios.

Therefore, it can be concluded that save use of clopyralid was sufficiently demonstrated for Annex I renewal of inclusion.

RMS comments and evaluation:

The PEC_{gw} calculation provided by the Notifier was well conducted and clearly reported. The RMS evaluator agrees with the proposed input parameters to be used in the modeling, except with the proposal on using the value of 0.5 for the plant uptake factor (PUF) proposed by the Notifier, which is not a standard procedure. This parameter choice was disagreed by the RMS evaluator.

Transpiration stream concentration factor (TSCF) is required for PEARL and MACRO as surrogate of PUF. Equations produced by Briggs *et al.* (1982, 1983) for non-ionic compounds provide a relationship between TSCF and octanol/water partition coefficient with the maximum value for TSCF given as 0.8. Based on the data in this reference, the default value of 0.5 for systemic compounds and 0 for nonsystemic compounds is recommended in the FOCUS Guidance, if the equation of Briggs & al.

$$TSCF = 0.774 \exp - [(\log Kow - 1.78)^2/2.44]$$

is not utilised.

The experimental method originally published by Briggs & al. (1982, 1983) has not been validated to cover extremely polar compounds with partition coefficient octanol/water (log Kow) less than ca -0.5, which is the case also with clopyralid, having the log Kow of -2.63 at pH 7 and 20 ºC. The authors pointed out that the equation for calculating the transpiration stream concentration factor (TSCF)
is probably inaccurate below Kow = 0, as the empirical curve describing TSCF underestimated the measured TSCF values for polar compounds studied.

According to FOCUS guidelines, 0 should be used as the default of PUF, if there is no indication that the compound is systemic and uptaken by roots. The EFSA has interpreted that if residues of the parent compound are found on the aerial part of the plants cultivated in soil treated with the substance, it is generally accepted that the substance is uptaken by the roots and that a TSCF of 0.5 can be used as plant uptake factor for groundwater modelling.

The choice of a refined PUF based on the systemic nature of distribution of clopyralid in plants was addressed by a new experimental plant metabolism study on clopyralid (CA 6.2.1/4; Gourlay 2015). The study provided by the Notifier was new and not used before in the context of renewal for the approval. The study to define experimental plant uptake factors for clopyralid was clearly reported and performed according to GLP. The study did not follow any commonly agreed guideline, although the methodology was adequately described to understand the procedure. The experimental design was, however, hydroponic instead of soil cultivation. The plant metabolism aspect of the study is evaluated in more detail under Section 6 (Residues), but the acceptability of amending the PUF for groundwater modelling based on this study is considered here.

The study design was intended to mimic the soil pore water that contains the test item and to focus on the gross uptake of this test item with the soil pore water via the root system into the plant. Other processes influencing the concentration of the test item in soil, such as degradation or adsorption to soil particles were intentionally excluded in the test system.

Plants were kept for eight days in the test solutions with known concentration of ^{14}C-clopyralid and volume of the solution. The visual assessment of the plants together with their water consumption ensured that the plants remained healthy over the course of the experiment. There was negligible loss of solution by evaporation, indicating exclusive plant consumption. The resulting water consumption volumes after eight days were sufficient for PUF calculation. Water consumption over 30% of the initial volume was always obtained, with no significant effect of the treatment.

Clopyralid remained stable during the whole experiment. As neither glass adsorption nor volatilisation was detected throughout the study, variation of test item in solution could be used for PUF calculation. The radioactivity measurements in the final compartments (i.e. plant material, test solution, root washing solution) showed that most of the spiked radioactivity was recovered (without plants: 96.3%, wheat: 95.1% (CV = 1.5%), oilseed rape: 94.8% (CV = 4.4%)). This also gave the information that the radioactivity was transferred to the shoots and leaves of the plants (wheat: 87.2% (CV = 1.8%), oilseed rape: 75.8% (CV = 5.3%)).

The calculation of the plant uptake factors with pre-incubation phases of 6 h, one day or two days showed no significant difference with the value over eight days. The values without pre-incubation were nevertheless found slightly lower for wheat plants and, in the context of leaching models, were taken as conservative values. The plant uptake factors determined were 1.07 (CV = 12.3%) for wheat and 0.68 (CV = 18.3%) for oilseed rape.

The EFSA has highlighted that a plant uptake factor derived from hydroponic studies where changes in concentration are measured is not equivalent to the TSCF as measured by Briggs & al (1982, 1983) and therefore not appropriate for GW modelling, as usually such measured values result to fall in a higher range with respect to Briggs equation values. Also, in the case of clopyralid, the log Kow being far below the range the authors recommend, it is overall questionable if a TSCF can be reliably extrapolated using the Briggs equation.

After consultation with the agricultural researchers from the Natural Resources Institute Finland, the evaluator concluded that the experimental design with plants kept in nutrient solution most likely overestimates the uptake of active substance compared to soil cultivation, where adsorption to soil particles probably reduces the availability of the test material to plant roots. Equal conditions for plant uptake in soil would require saturated soil solutions to be available for the plants, which is most unlikely in practice, as the GAPs of any plant protection product would not produce such concentrations in soil pore water. Therefore this study design is inappropriate for confirming the systemic distribution of clopyralid in plants in practical field conditions. Therefore the experimentally derived PUF of 0.5 based on the plant metabolism study of Gourlay (2015; CA 6.2.1/4) is considered as inappropriate to be used in PEC_{gw} modelling to address the systemic nature of clopyralid distribution in plants, as proposed by the Notifier. If a refinement of the default of 0 would be considered, it would require experimental evidence on the systemic nature of clopyralid in plants cultivated in soil instead of nutrient solutions.

Potential risk to the ground waters from the intended uses of the product GF-1374 is a critical property when deciding on the renewal of the active substance clopyralid. Even the tri-annual applications were not able to reduce the PEC_{gw} values below the trigger of 0.1 µg/L on winter cereals in several scenarios, if the application timing was unfavourable. Also on pasture the trigger was exceeded in vulnerable conditions. Adjusting the appropriate application timing during the growth season to less vulnerable weather conditions is of great importance in searching for safe uses of the product GF-1374 and reducing the leaching of clopyralid into the ground waters in European conditions. Although at least some safe uses could be demonstrated, it is obvious that risk mitigation is necessary when plant protection products containing clopyralid are authorized in the Member States.

The input parameters and choice of application rates and timing for the PEC_{gw} calculation of clopyralid as submitted by the Notifier are adequate and acceptable, except the experimentally derived plant uptake factor (PUF) of 0.5 based on the plant metabolism study of Gourlay (2015; CA 6.2.1/4). Although the calculation was assessed as not acceptable, the results are summarized above for transparency reasons. To conclude, the PEC_{gw} should be recalculated using the typical PUF default of 0, as recommended by the FOCUS guidance and the EFSA. All other input parameters are appropriate and do not need to be refined.

As no degradation products other than CO_2 are formed from clopyralid, it is not relevant to calculate the PEC_{gw} of metabolites.

In the renewal decision the potential risk to ground waters should be addressed by appropriate risk mitigation measures.

Following the request of the RMS evaluator, the Notifier submitted a revised PEC_{gw} calculation (Robinson 2016b), where a tiered approach for the plant uptake factor was considered. The revised report is assessed below. Despite obvious repeating, the revision is presented in detail below, in order to ensure adequate transparency. *The changes in the revised PECgw calculation as compared to the original report presented above are highlighted in the text below in italics*.

Furthermore, the Notifier submitted their response to the request of the RMS as a letter which is included below as a supporting data concerning the PECgw calculation.

CP 9.2.4.1/2 - Predicted environmental concentrations of clopyralid in ground water

Report	CP 9.2.4.1/2; Robinson, P. 2016b
Report title	Predicted environmental concentrations of clopyralid in groundwater (PEC_{gw}) following the application to winter cereals and grassland - a modelling assessment for Europe using FOCUS PEARL, FOCUS PELMO and FOCUS MACRO
DAS Study number	Dr Knoell Consult Ltd., Cardiff, UK, Report No.: 104115-7 DAS Study ID: 151156 Revision 04.05.2016
Guidelines	EC (2014): Assessing potential for movement of active substances and their metabolites to ground water in the EU. Report of the FOCUS Ground Water Work Group, EC Document Reference Sanco/13144/2010 version 3. FOCUS (2000): FOCUS groundwater scenarios in the EU plant protection product review process. Report of the FOCUS Groundwater Scenarios Workgroup, EC Document Reference Sanco/321/2000 rev 2. FOCUS (2014): Generic Guidance for Tier 1 FOCUS Ground Water Assessments, version 2.2.
GLP	No

Methods

Environmental behaviour in soil

Studies on the degradation behaviour of the active substance clopyralid were conducted and are described under Annex Point CP 9.1.1. For the PEC_{gw} simulations, the normalised geometric mean DT_{50} from field studies was used (see Table 8.3.12).

The adsorption behaviour of the active substance clopyralid was examined in several studies, which are described under Annex Point CP 9.1.2. The geometric mean K_{foc}, together with the arithmetic mean Freundlich exponent 1/n were used in the simulations according to the latest guidance (EC, 2014[6]; see Table 8.3.12).

Application scenarios

According to ‘Good Agricultural Practice’ (GAP), clopyralid is intended to be used as a herbicide on winter cereals and grassland with a single spray application at a rate of 80 g a.s./ha and 120 g a.s./ha, respectively. Based on the development stages of the selected crops at the time of application, the interception rates were estimated to be 0% for winter cereals and 90% for established grassland in accordance with FOCUS guidance (FOCUS, 2014). Therefore 100% for winter cereals, or 10% for

[6] EFSA (2014): EFSA Guidance Document for evaluating laboratory and field dissipation studies to obtain DegT50 values of active substances of plant protection products and transformation products of these active substances in soil. EFSA Journal 2014; 12(5):3662.

grass, of the intended application rate was assumed to reach the soil surface and become available for leaching.

Modelling was conducted in a tiered approach. In the first instance runs were simulated with annual applications, but where results with a specific application date exceeded the trigger value of 0.1 µg/L, bi-annual application and application every third year were also considered.

Application scenarios which were considered for the simulations are summarised in Table 8.3.10. Detailed application dates are presented in Table 8.3.11.

Table 8.3.10. Application patterns of clopyralid used in PEC_{gw} calculations

Crop	Appl. rate (g a.s./ha)	No. of appl.	Appl. method	Growth stage (BBCH) (appl. period)	FOCUS crop interception at application (%)	Resulting soil deposit (g a.s./ha)
Winter cereals	80	1	Spray	13 (Feb - Jun)	0	80
Established grassland	120	1	Spray	- (Feb – Aug)	90	12

Table 8.3.11. Application dates used in groundwater modelling

Crop	Scenario	Date
Winter cereals	Châteaudun Hamburg Jokioinen Kremsmünster Okehampton Piacenza Porto Sevilla Thiva	01-Feb (32) or 01-Mar (60) or 01-Apr (91) or 01-May (121) or 01-Jun (152)
Established grassland	Châteaudun Hamburg Jokioinen Kremsmünster Okehampton Piacenza Porto Sevilla Thiva	01-Feb (32) or 01-Mar (60) or 01-Apr (91) or 01-May (121) or 01-Jun (152) or 01-Jul (182) or 01-Aug (213)

Figures in brackets are the respective 'Julian Days' used in the MACRO modelling

<u>Input parameters</u>

A summary of input parameters used in the simulations is given in Table 8.6.12. Apart from the input parameters explicitly discussed, all variables in the model were left at their default values.

Two different plant uptake factors were considered in the assessment, 0 (Tier 1), as a worst case, and a refined value of 0.5 (Tier 2) that takes into account the systemic nature of clopyralid. The latter was considered more appropriate since a specific plant uptake factor study had been conducted (CA 6.2.1/4 – Gourlay, 2015), as well as evidence from a 30 day plant-back interval confined rotations crop study (CA 6.6.1/3 – Hall, 2015). Please refer to DAS letter to RMS "DAS Response to RMS position on Plant Uptake Factor" from 09 May 2016.

Table 8.3.12. Input parameters for clopyralid used in the groundwater simulations

Parameter	Unit	Clopyralid
Molecular Mass	g/mol	191.96
Water solubility at 20°C	mg/L	1.43×10^5
Vapour pressure at 20°C	Pa	0[a]
DT_{50} soil	days	6.76[b]
K_{foc}	mL/g	1.41[c]
K_{fom} [c]	mL/g	0.82[d]
Freundlich Exponent (1/n)	-	0.836[e]
Plant uptake factor	-	*0 / 0.5*[f]
Q_{10}-value	-	2.58

[a] set to default of 0 (no volatilisation) as worst case
[b] geometric mean, field, normalised, n = 8
[c] geometric mean, n = 9
[d] calculated from K_{foc}; $K_{fom} = K_{foc}/1.724$
[e] arithmetic mean, n = 9
[f] Tier 1 / Tier 2

<u>Simulation models</u>

The FOCUS simulation models FOCUS PEARL v 4.4.4, FOCUS PELMO v 5.5.3 and FOCUS MACRO v. 5.5.4 were used in the modelling study. All standard FOCUS locations defined for the respective crops were considered in the simulations.

Results and discussion

The predicted environmental concentration (PEC_{gw}) of clopyralid following its annual application to winter cereals, obtained with FOCUS PEARL 4.4.4 and FOCUS PELMO 5.5.3, is presented in Table 8.6.13, and results with FOCUS MACRO 5.5.4 are given in Table 8.3.14. The PEC_{gw} for bi-annual and tri-annual applications to winter cereals is presented in Table 8.3.15 and Table8.3.16.

For grassland, the PEC_{gw} of clopyralid for an annual application is presented in Table 8.3.17 and Table 8.3.18. for FOCUS PEARL / FOCUS PELMO and FOCUS MACRO, respectively. The PEC_{gw} for bi-annual and tri-annual applications to grassland is presented in Table 8.3.19 and Table 8.3.20.

<u>Winter cereals</u>

Table 8.3.13. 80th percentile leachate concentrations of clopyralid in groundwater at 1 m soil depth following the annual application to winter cereals, 1 × 80 g a.s./ha (FOCUS PEARL / FOCUS PELMO)

Application date	**Scenario**	**80th percentile PEC$_{gw}$ (µg/L)**			
		Tier 1 (PUF = 0)		***Tier 2 (PUF = 0.5)***	
		FOCUS PEARL	***FOCUS PELMO***	**FOCUS PEARL**	**FOCUS PELMO**
1-Feb	Châteaudun	*0.018*	*0.013*	0.015	0.010
	Hamburg	***0.312***	***0.916***	**0.199**	**0.726**
	Jokioinen	***0.513***	***3.00***	**0.272**	**2.08**
	Kremsmünster	***0.194***	***0.385***	**0.153**	**0.286**
	Okehampton	***0.341***	***0.775***	**0.312**	**0.630**
	Piacenza	***0.147***	***0.760***	**0.119**	**0.619**
	Porto	***0.351***	***1.77***	**0.309**	**1.64**
	Sevilla	*<0.001*	*0.004*	<0.001	0.004
	Thiva	*0.001*	*0.011*	<0.001	0.010
1-Mar	Châteaudun	*0.005*	*0.007*	0.003	0.005
	Hamburg	***0.176***	***0.459***	**0.111**	**0.242**
	Jokioinen	***0.238***	***2.32***	**0.110**	**1.55**
	Kremsmünster	*0.089*	***0.166***	0.062	**0.104**
	Okehampton	***0.179***	***0.520***	**0.125**	**0.367**
	Piacenza	*0.070*	***0.208***	0.054	**0.165**
	Porto	*0.049*	***0.156***	0.037	**0.129**
	Sevilla	*<0.001*	*<0.001*	<0.001	<0.001
	Thiva	*<0.001*	*<0.001*	<0.001	<0.001
1-Apr	Châteaudun	*0.004*	*0.004*	0.003	0.002
	Hamburg	*0.097*	***0.113***	0.057	0.056
	Jokioinen	***0.152***	***0.697***	0.074	**0.338**
	Kremsmünster	***0.100***	***0.137***	0.069	0.089
	Okehampton	*0.095*	***0.149***	0.056	0.089
	Piacenza	*0.055*	***0.144***	0.035	**0.126**
	Porto	*0.012*	*0.012*	0.009	0.009
	Sevilla	*<0.001*	*<0.001*	<0.001	<0.001
	Thiva	*<0.001*	*<0.001*	<0.001	<0.001
1-May	Châteaudun	*0.010*	*0.004*	0.007	0.003
	Hamburg	***0.178***	*0.041*	**0.114**	0.016
	Jokioinen	***0.162***	***0.191***	0.096	0.074
	Kremsmünster	***0.100***	*0.085*	0.069	0.051
	Okehampton	***0.165***	***0.156***	0.099	0.083
	Piacenza	*0.039*	*0.027*	0.030	0.023
	Porto	*0.005*	*0.005*	0.004	0.004
	Sevilla	*<0.001*	*<0.001*	<0.001	<0.001
	Thiva	*<0.001*	*<0.001*	<0.001	<0.001
1-Jun	Châteaudun	*0.009*	*0.003*	0.008	0.002
	Hamburg	***0.426***	*0.063*	**0.303**	0.032
	Jokioinen	***0.287***	***0.259***	**0.194**	**0.123**
	Kremsmünster	***0.120***	***0.104***	0.091	0.068
	Okehampton	***0.191***	***0.196***	**0.138**	**0.124**
	Piacenza	*0.007*	*0.003*	0.007	0.003

	Porto	*0.001*	*0.001*	<0.001	0.001
	Sevilla	*<0.001*	*<0.001*	<0.001	<0.001
	Thiva	*<0.001*	*<0.001*	<0.001	<0.001

Table 8.3.14. 80th percentile leachate concentrations of clopyralid in groundwater at 1 m soil depth following the annual application to winter cereals, 1 × 80 g a.s./ha (FOCUS MACRO)

Application date	Scenario	80th percentile PEC_{gw} (µg/L)	
		Tier 1 (PUF = 0)	***Tier 2 (PUF = 0.5)***
1-Feb	Châteaudun	*0.021*	0.020
1-Mar		*0.005*	0.004
1-Apr		*0.002*	0.001
1-May		*0.003*	0.002
1-Jun		*0.002*	0.001

Table 8.3.15. 80th percentile leachate concentrations of clopyralid in groundwater at 1 m soil depth following the bi-annual application to winter cereals, 1 × 80 g a.s./ha (FOCUS PEARL / FOCUS PELMO)

Application date	Scenario	80th percentile PEC_{gw} (µg/L)			
		Tier 1 (PUF = 0)		*Tier 2 (PUF = 0.5)*	
		FOCUS PEARL	*FOCUS PELMO*	FOCUS PEARL	FOCUS PELMO
1-Feb	Châteaudun	*0.008*	*0.007*	0.006	0.005
	Hamburg	***0.173***	***0.589***	**0.109**	**0.460**
	Jokioinen	***0.316***	***1.74***	**0.170**	**1.21**
	Kremsmünster	***0.109***	***0.234***	0.089	**0.169**
	Okehampton	***0.141***	***0.367***	**0.125**	**0.283**
	Piacenza	*0.080*	*0.267*	0.065	**0.213**
	Porto	*0.231*	*0.994*	**0.209**	**0.916**
	Sevilla	*<0.001*	*0.001*	<0.001	0.001
	Thiva	*0.001*	*0.007*	<0.001	0.006
1-Mar	Châteaudun	*0.003*	*0.003*	0.002	0.002
	Hamburg	*0.091*	***0.217***	0.056	**0.134**
	Jokioinen	***0.137***	***1.28***	0.067	**0.812**
	Kremsmünster	*0.045*	*0.082*	0.032	0.051
	Okehampton	***0.117***	***0.272***	0.083	**0.190**
	Piacenza	*0.034*	***0.125***	0.025	0.098
	Porto	*0.025*	*0.072*	0.019	0.053
	Sevilla	*<0.001*	*<0.001*	<0.001	<0.001
	Thiva	*<0.001*	*<0.001*	<0.001	<0.001
1-Apr	Châteaudun	*0.002*	*0.002*	-	0.001
	Hamburg	*0.052*	*0.054*	-	0.023
	Jokioinen	*0.091*	***0.402***	-	**0.206**
	Kremsmünster	*0.065*	*0.082*	-	0.050
	Okehampton	*0.049*	*0.063*	-	0.040
	Piacenza	*0.025*	*0.058*	-	0.048
	Porto	*0.006*	*0.008*	-	0.006
	Sevilla	*<0.001*	*<0.001*	-	<0.001
	Thiva	*<0.001*	*<0.001*	-	<0.001
1-May	Châteaudun	*0.005*	*0.002*	0.003	-
	Hamburg	***0.103***	*0.020*	0.064	-
	Jokioinen	***0.109***	***0.123***	0.064	-
	Kremsmünster	*0.054*	*0.040*	0.037	-
	Okehampton	*0.079*	*0.074*	0.049	-
	Piacenza	*0.023*	*0.008*	0.018	-
	Porto	*0.002*	*0.002*	0.002	-
	Sevilla	*<0.001*	*<0.001*	<0.001	-
	Thiva	*<0.001*	*<0.001*	<0.001	-
1-Jun	Châteaudun	*0.002*	*0.001*	0.001	0.001
	Hamburg	***0.209***	*0.037*	**0.148**	0.019
	Jokioinen	***0.175***	***0.172***	**0.116**	0.082
	Kremsmünster	*0.073*	*0.069*	0.055	0.048
	Okehampton	***0.100***	*0.098*	0.075	0.063
	Piacenza	*0.005*	*0.002*	0.004	0.001

	Porto	*<0.001*	*0.001*	<0.001	<0.001
	Sevilla	*<0.001*	*<0.001*	<0.001	<0.001
	Thiva	*<0.001*	*<0.001*	<0.001	<0.001

Table 8.3.16. 80th percentile leachate concentrations of clopyralid in groundwater at 1 m soil depth following the tri-annual application to winter cereals, 1 × 80 g a.s./ha (FOCUS PEARL / FOCUS PELMO)

Application date	**Scenario**	**80th percentile PEC_{gw} (µg/L)**			
		Tier 1 (PUF = 0)		***Tier 2 (PUF = 0.5)***	
		FOCUS PEARL	***FOCUS PELMO***	**FOCUS PEARL**	**FOCUS PELMO**
1-Feb	Châteaudun	*0.006*	*0.004*	0.005	0.003
	Hamburg	***0.134***	***0.463***	0.087	**0.363**
	Jokioinen	***0.219***	***1.33***	**0.118**	**0.930**
	Kremsmünster	*0.075*	***0.160***	0.060	**0.111**
	Okehampton	*0.098*	***0.243***	0.083	**0.190**
	Piacenza	*0.089*	***0.181***	0.069	**0.147**
	Porto	***0.177***	***0.796***	**0.161**	**0.730**
	Sevilla	*<0.001*	*<0.001*	<0.001	<0.001
	Thiva	*<0.001*	*0.008*	<0.001	0.007
1-Mar	Châteaudun	*0.002*	*0.002*	-	0.002
	Hamburg	*0.068*	***0.179***	-	0.098
	Jokioinen	*0.091*	***1.13***	-	**0.663**
	Kremsmünster	*0.037*	*0.054*	-	0.035
	Okehampton	*0.085*	***0.201***	-	**0.147**
	Piacenza	*0.031*	*0.094*	-	0.074
	Porto	*0.017*	*0.049*	-	0.036
	Sevilla	*<0.001*	*<0.001*	-	<0.001
	Thiva	*<0.001*	*<0.001*	-	<0.001
1-Apr	Châteaudun	-	*0.002*	-	0.001
	Hamburg	-	*0.030*	-	0.013
	Jokioinen	-	***0.273***	-	**0.134**
	Kremsmünster	-	*0.057*	-	0.037
	Okehampton	-	*0.047*	-	0.026
	Piacenza	-	*0.036*	-	0.031
	Porto	-	*0.006*	-	0.004
	Sevilla	-	*<0.001*	-	<0.001
	Thiva	-	*<0.001*	-	<0.001
1-May	Châteaudun	*0.004*	*0.002*	-	-
	Hamburg	*0.079*	*0.015*	-	-
	Jokioinen	*0.075*	*0.078*	-	-
	Kremsmünster	*0.046*	*0.031*	-	-
	Okehampton	*0.052*	*0.051*	-	-
	Piacenza	*0.028*	*0.014*	-	-
	Porto	*0.001*	*0.001*	-	-
	Sevilla	*<0.001*	*<0.001*	-	-

	Thiva	*<0.001*	*<0.001*	-	-
1-Jun	Châteaudun	*0.001*	*0.001*	0.001	-
	Hamburg	***0.134***	*0.021*	0.095	-
	Jokioinen	***0.138***	***0.104***	0.092	-
	Kremsmünster	*0.051*	*0.052*	0.039	-
	Okehampton	*0.070*	*0.068*	0.052	-
	Piacenza	*0.004*	*0.001*	0.004	-
	Porto	*<0.001*	*<0.001*	<0.001	-
	Sevilla	*<0.001*	*<0.001*	<0.001	-
	Thiva	*<0.001*	*<0.001*	<0.001	-

Grassland

Table 8.3.17. 80th percentile leachate concentrations of clopyralid in groundwater at 1 m soil depth following the annual application to grassland, 1 × 120 g a.s./ha (FOCUS PEARL / FOCUS PELMO)

Application date	Scenario	80[th] percentile PEC_{gw} (µg/L)			
		Tier 1 (PUF = 0)		*Tier 2 (PUF = 0.5)*	
		FOCUS PEARL	***FOCUS PELMO***	**FOCUS PEARL**	**FOCUS PELMO**
1-Feb	Châteaudun	*0.007*	*0.004*	0.006	0.004
	Hamburg	*0.017*	*0.067*	0.014	0.058
	Jokioinen	***0.112***	***0.339***	0.047	**0.249**
	Kremsmünster	*0.024*	*0.030*	0.020	0.024
	Okehampton	*0.060*	*0.091*	0.054	0.081
	Piacenza	*0.039*	***0.156***	0.034	**0.126**
	Porto	*0.063*	***0.214***	0.061	**0.193**
	Sevilla	*0.003*	*0.004*	0.003	0.003
	Thiva	*<0.001*	*0.001*	<0.001	<0.001
1-Mar	Châteaudun	*0.004*	*0.001*	0.003	0.001
	Hamburg	*0.013*	*0.030*	0.007	0.015
	Jokioinen	*0.060*	***0.244***	0.030	**0.169**
	Kremsmünster	*0.008*	*0.009*	0.006	0.005
	Okehampton	*0.030*	*0.055*	0.025	0.046
	Piacenza	*0.018*	***0.105***	0.015	0.090
	Porto	*0.006*	*0.043*	0.005	0.034
	Sevilla	*<0.001*	*<0.001*	<0.001	<0.001
	Thiva	*<0.001*	*<0.001*	<0.001	<0.001
1-Apr	Châteaudun	*0.004*	*0.001*	0.003	0.001
	Hamburg	*0.008*	*0.008*	0.004	0.004
	Jokioinen	*0.039*	*0.068*	0.018	0.032
	Kremsmünster	*0.007*	*0.008*	0.005	0.005
	Okehampton	*0.008*	*0.012*	0.007	0.007
	Piacenza	*0.008*	*0.063*	0.006	0.050
	Porto	*0.002*	*0.015*	0.001	0.012
	Sevilla	*<0.001*	*<0.001*	<0.001	<0.001
	Thiva	*<0.001*	*<0.001*	<0.001	<0.001
1-May	Châteaudun	*0.003*	*0.002*	0.003	0.001
	Hamburg	*0.014*	*0.003*	0.007	0.001
	Jokioinen	*0.026*	*0.024*	0.015	0.011
	Kremsmünster	*0.007*	*0.007*	0.005	0.005
	Okehampton	*0.008*	*0.014*	0.005	0.008
	Piacenza	*0.003*	*0.018*	0.002	0.014
	Porto	*0.001*	*0.003*	<0.001	0.002
	Sevilla	*<0.001*	*<0.001*	<0.001	<0.001
	Thiva	*<0.001*	*<0.001*	<0.001	<0.001
1-Jun	Châteaudun	*0.002*	*0.002*	0.001	0.001
	Hamburg	*0.023*	*0.006*	0.012	0.003
	Jokioinen	*0.041*	*0.034*	0.021	0.017
	Kremsmünster	*0.005*	*0.005*	0.004	0.003
	Okehampton	*0.013*	*0.017*	0.010	0.010
	Piacenza	*0.001*	*0.005*	<0.001	0.004

	Porto	*<0.001*	*0.001*	<0.001	<0.001
	Sevilla	*<0.001*	*<0.001*	<0.001	<0.001
	Thiva	*<0.001*	*<0.001*	<0.001	<0.001
1-Jul	Châteaudun	*0.003*	*0.003*	0.002	0.001
	Hamburg	*0.046*	*0.016*	0.027	0.010
	Jokioinen	*0.045*	*0.034*	0.029	0.023
	Kremsmünster	*0.009*	*0.013*	0.007	0.009
	Okehampton	*0.013*	*0.017*	0.010	0.011
	Piacenza	*0.001*	*0.003*	<0.001	0.002
	Porto	*0.001*	*0.001*	<0.001	0.001
	Sevilla	*<0.001*	*<0.001*	<0.001	<0.001
	Thiva	*<0.001*	*<0.001*	<0.001	<0.001
1-Aug	Châteaudun	*0.006*	*0.005*	0.004	0.004
	Hamburg	***0.102***	*0.027*	0.076	0.018
	Jokioinen	***0.126***	***0.112***	0.093	0.076
	Kremsmünster	*0.016*	*0.019*	0.013	0.015
	Okehampton	*0.020*	*0.014*	0.016	0.009
	Piacenza	*0.008*	*0.013*	0.007	0.011
	Porto	*0.002*	*0.003*	0.002	0.002
	Sevilla	*<0.001*	*<0.001*	<0.001	<0.001
	Thiva	*<0.001*	*0.001*	<0.001	<0.001

Table 8.3.18. 80th percentile leachate concentrations of clopyralid in groundwater at 1 m soil depth following the annual application to grassland, 1 × 120 g a.s./ha (FOCUS MACRO)

Application date	Scenario	80th percentile PEC_{gw} (µg/L)	
		Tier 1 (PUF = 0)	***Tier 2 (PUF = 0.5)***
1-Feb	Châteaudun	*0.007*	0.007
1-Mar		*0.001*	0.001
1-Apr		*<0.001*	<0.001
1-May		*<0.001*	<0.001
1-Jun		*<0.001*	<0.001
1-Jul		*0.001*	<0.001
1-Aug		*0.004*	0.002

Table 8.3.19. 80th percentile leachate concentrations of clopyralid in groundwater at 1 m soil depth following the bi-annual application to grassland, 1 × 120 g a.s./ha (FOCUS PEARL / FOCUS PELMO)

Application date	Scenario	80th percentile PEC_{gw} (µg/L)			
		Tier 1 (PUF = 0)		***Tier 2 (PUF = 0.5)***	
		FOCUS PEARL	***FOCUS PELMO***	**FOCUS PEARL**	**FOCUS PELMO**
1-Feb	Châteaudun	*0.005*	*0.002*	-	0.002
	Hamburg	*0.011*	*0.043*	-	0.036
	Jokioinen	*0.068*	***0.200***	-	**0.140**

	Kremsmünster	*0.015*	*0.017*	-	0.014
	Okehampton	*0.026*	*0.043*	-	0.035
	Piacenza	*0.021*	*0.076*	-	0.063
	Porto	*0.042*	*0.123*	-	0.111
	Sevilla	*0.001*	*0.001*	-	0.001
	Thiva	*<0.001*	*<0.001*	-	<0.001
1-Mar	Châteaudun	-	*0.001*	-	<0.001
	Hamburg	-	*0.015*	-	0.008
	Jokioinen	-	***0.136***	-	0.091
	Kremsmünster	-	*0.005*	-	0.003
	Okehampton	-	*0.029*	-	0.024
	Piacenza	-	*0.067*	-	0.055
	Porto	-	*0.020*	-	0.017
	Sevilla	-	*<0.001*	-	<0.001
	Thiva	-	*<0.001*	-	<0.001
1-Aug	Châteaudun	*0.003*	*0.002*	-	-
	Hamburg	*0.048*	*0.013*	-	-
	Jokioinen	*0.066*	*0.050*	-	-
	Kremsmünster	*0.009*	*0.012*	-	-
	Okehampton	*0.011*	*0.008*	-	-
	Piacenza	*0.004*	*0.007*	-	-
	Porto	*0.001*	*0.002*	-	-
	Sevilla	*<0.001*	*<0.001*	-	-
	Thiva	*<0.001*	*<0.001*	-	-

Table 8.3.20. 80th percentile leachate concentrations of clopyralid in groundwater at 1 m soil depth following the tri-annual application to grassland, 1 × 120 g a.s./ha (FOCUS PEARL / FOCUS PELMO)

Application date	Scenario	80th percentile PEC_{gw} (µg/L)	
		Tier 1 (PUF = 0)	***Tier 2 (PUF = 0.5)***
		FOCUS PELMO	**FOCUS PELMO**
1-Feb	Châteaudun	*0.001*	0.001
	Hamburg	*0.033*	0.028
	Jokioinen	***0.143***	**0.105**
	Kremsmünster	*0.011*	0.009
	Okehampton	*0.031*	0.026
	Piacenza	*0.053*	0.044
	Porto	*0.084*	0.077
	Sevilla	*0.001*	<0.001
	Thiva	*<0.001*	<0.001
1-Mar	Châteaudun	*0.001*	-
	Hamburg	*0.012*	-
	Jokioinen	***0.113***	-
	Kremsmünster	*0.003*	-
	Okehampton	*0.021*	-
	Piacenza	*0.051*	-

	Porto	*0.013*	-
	Sevilla	*<0.001*	-
	Thiva	*<0.001*	-

PEC_{gw} of clopyralid was less than 0.1 µg/L for some scenarios with a single annual application at each of the months indicated in the GAP at both tiers. With a bi-annual and tri-annual application, more scenarios resulted in PEC_{gw} <0.1 µg/L with all models.

Conclusions

Predicted environmental concentrations for clopyralid in groundwater (PEC_{gw}) were calculated for the use on winter cereals and grassland in Europe in accordance with FOCUS guidelines (FOCUS, 2000, 2014; EC, 2014).

A tiered approach was followed, initially considering a conservative plant uptake factor of 0 (Tier 1) then as a refinement a more realistic value of 0.5 (Tier 2) was used.

For winter cereals with applications from February through to June, a bi-annual or tri-annual application is required for some model scenarios at both tiers.

At Tier 1, for grassland, all PEC_{gw} values are <0.1 µg/L for all model scenarios, for annual applications (from April to July). For applications in February, March and August, bi-annual or tri-annual applications are necessary for some scenarios.

At Tier 2, for grassland, PEC_{gw} is <0.1 µg/L for all model scenarios with an annual application occurring from April. For applications in February and March, a bi-annual or tri-annual application is required for some scenarios.

PEC_{gw} of clopyralid was less than 0.1 µg/L for at least two scenarios for every use pattern using FOCUS PEARL, FOCUS PELMO and FOCUS MACRO. Therefore, it can be concluded that safe use of clopyralid was sufficiently demonstrated for the renewal of EU approval.

RMS comments and evaluation:

The recalculation presented by the Notifier was conducted according to the guidance and is acceptable with regard to the use of the product CF-1374 on cereals with the highest application rates of 1 Liter of the product corresponding to 80 g a.i./ha and 1.5 L/ha on pasture, corresponding to 120 g a.i./ha. Higher use rates are not supported by data appropriately within the EU any longer.

The Notifier highlights that this is not necessarily the worst case GAP at MS level. Higher use rates of clopyralid than 80 g/ha in cereals and and 120 g/ha in established pasture may be supported with appropriate data at national level depending on agronomic needs, weed pressure, approved endpoints and specific Member States’ modelling requirements and risk mitigation measures to be applied, and need to be evaluated separately at MS level. The RMS agrees on this statement.

The tiered approach for recalculating the PEC_{gw} is acceptable for the RMS as presented by the Notifier in the revised report. The revised PUF might be an appropriate higher tier refinement option in specific conditions within the member States. Also the different choices of application timing may provide appropriate risk mitigation options.

It is obvious that risk mitigation may be necessary to protect the groundwaters, when plant protection products containing clopyralid are authorized in the Member States. The case provided by the Notifier, to combine formulations with lower amounts of clopyralid, most favourable timing of application with regard to soil hydrology, and restrictions of use every second or third year, may provide appropriate options for risk mitigation measures to reduce the concentrations of clopyralid in groundwaters to an acceptable level in most EU FOCUS scenarios. Thus it is agreed that safe uses of clopyralid could be sufficiently demonstrated.

The data submitted by the Notifier is acceptable and adequate for the renewal of approval of clopyralid. The data requirement is fulfilled and no futher data is required.

The reasoning for the choices of Plant Uptake Factor was presented by the Notifier in their letter to the RMS. This response is attached below as further information.

CP 9.2.4.1/3: Clopyralid – DAS Response to RMS position on Plant Uptake Factor (letter from Philippe Chatton, 19 May 2016)

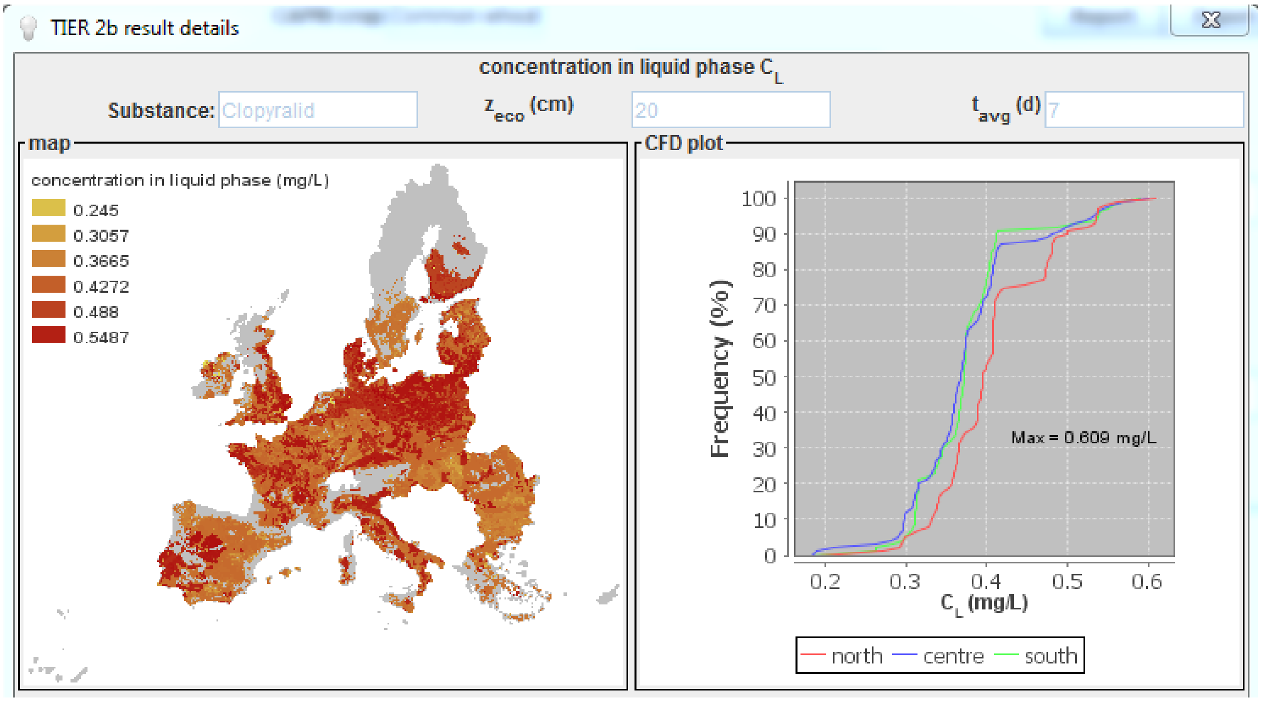
DAS concedes that calculations based on a PUF = 0 should have been provided initially. However, DAS proposes that Tier 2 calculations with a PUF = 0.5 should be considered as a refinement. Below DAS attempts to address the concerns raised by the RMS. In particular the dedicated PUF study Gourlay (2015; CA 6.2.1/4) is compared to the 30 days plant-back interval confined rotational crop study by Hall (2015; CA 6.6.1/3) which was run with soil. DAS also wants to draw the attention to previous EFSA conclusion on Succeeding and Rotational Crops (EFSA Scientific Report, 2005 (50), Conclusion on the peer review of clopyralid):

"Furthermore, metabolism studies indicated that clopyralid is systemically taken into plants and readily translocated in plants. Soil –plant transition factors to estimate the residue situation in rotational crops have been calculated by RMS and presented in the evaluation meeting. The values indicate that there might be good uptake from soil or even accumulation in the plants, and soil residues above 0.001 mg/kg might be present at the time of harvesting rotational crops."

The primary intention for submission of study Gourlay (2015; CA 6.2.1/4) was not to derive a measured PUF value for use in modelling but to demonstrate under controlled conditions that clopyralid will be taken up by roots and transported to the shoots. The observed PUF values were higher than the default PUF = 0.5 for root systemic substances. DAS concedes with the RMS that the study set up may favour root uptake when compared to soil systems. However, the experimental derived PUF value should represent the potential of a crop to take up a substance. Actual uptake is downregulated in the simulation models. In the groundwater simulation models plant uptake is regulated by a) availability of substance in in the pore water, and b) transpiration. This is similar to DegT50 which enters the models determined at (or normalized to) 20°C. Actual degradation rates are adjusted for actual temperature conditions (ignoring soil moisture for the sake of simplicity).

With regards to a potential overestimation of substance availability in hydroponic systems DAS would like to add that clopyralid test solution concentration had been selected to mirror what could be expected in soil pore water in the field. The magnitude of concentration had been estimated with EFSA model PERSAM whose mathematical equations are described in the EFSA Scientific Opinion on the assessment of exposure of organisms to substances in soil (EFSA Journal 2012;10(2):2562). Considering the common wheat scenario, a DegT50 = 18.4 days (geomean lab), Koc = 1.41 (geomean), and a soil loading of 80 g clopyralid per ha the Tier 2 CDF of soil pore water concentrations across Europe can be predicted.

Below, the PECpore,water shown is the 7 day TWA which is considered as more relevant to a study with an exposure duration of similar length. Furthermore, 20 cm soil depths is considered because the root system will be mainly found in this layer.



Predicted 7 day pore water concentrations of clopyralid over 20 cm following a soil load of 80 g/ha yields a range from 300 to 600 µg/L. The average clopyralid test solution concentration was 70 µg/L in Gourlay (2015; CA 6.2.1/4). The reason for selecting a lower concentration than predicted was that pre-tests on plant tolerance had shown that higher concentrations would impair plant health in the test system.

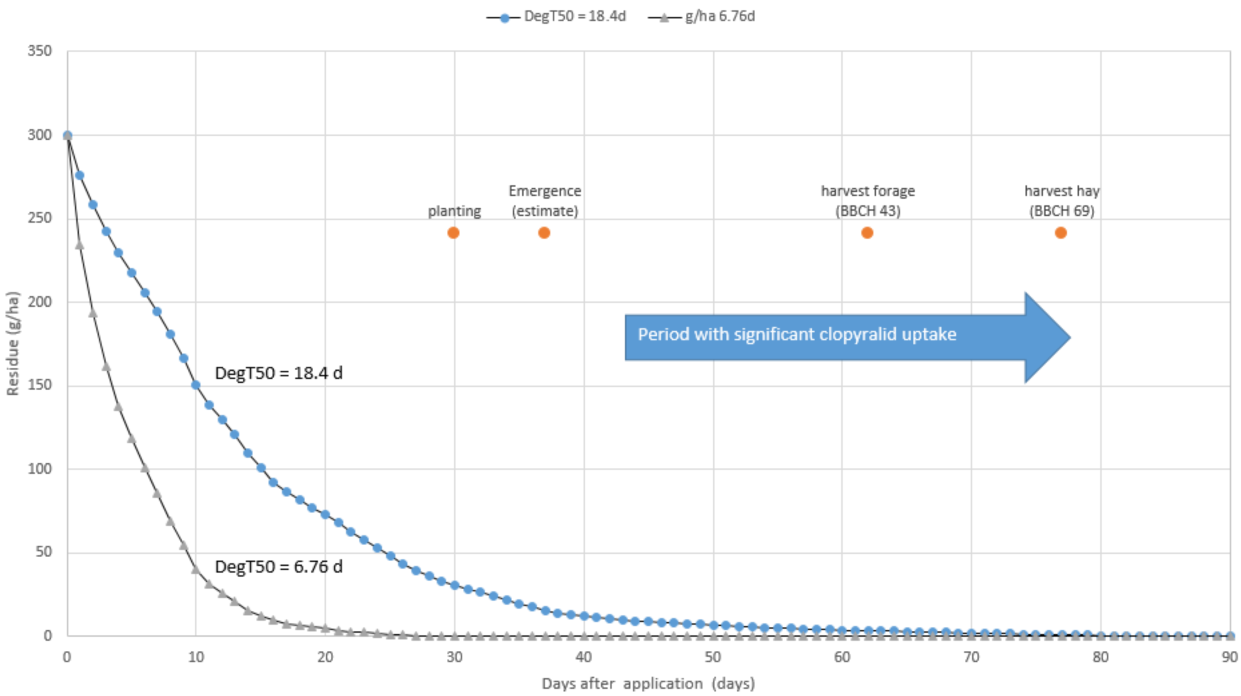
Additionally, DAS would like to point to study Hall (2015; CA 6.6.1/3), a 30 day plant-back interval confined rotational study. One of the primary objectives was to provide an estimate of the total radioactive residues in three rotational crops (wheat, cabbage and radish) following an application of 300 g clopyralid per ha to bare soil 30 days prior to planting. Crops were grown in test plots containing a Missouri sandy loam. Wheat samples were harvested 62 days after treatment (DAT) at BBCH 43, as well as later. The first sampling is closest to the growth stage considered in Gourlay (2015; CA 6.2.1/4), e.g. BBCH 21-31 at application of test item.

At 62 DAT clopyralid residue in wheat shoots amounted to 0.367 mg/kg. At 78 DAT to 0.729 mg/kg. These values are about one magnitude of order lower than observed by Gourlay (2015; CA 6.2.1/4):

Replicate	Clopyralid in stem & leaves observed by Gourlay (2015) (mg/kg)
a	8.19
b	7.84
c	6.75
d	6.96
Average	7.43

Dry matter content of clopyralid had not been reported in the study report but is recorded in the raw data.

The lower contents found by Hall (2015; CA 6.6.1/3) may be explained by a lower exposure to clopyralid in soil. While soil concentrations had not been measure directly, an estimate can be provided. Below clopyralid residue decline is modelled with the geomean laboratory DegT50 (18.4 d) and the geomean field DegT50 (6.75 d). Considering both DegT50 values should show the range of soil residue that could be expected. The decline has been adjusted for observed daily soil temperature, which was always well above 20°C. Furthermore, the plots had been irrigated often. Soil moisture should not have affected degradation greatly.



No date is given for emergence of wheat in the trial. However, given the fairly high temperatures one week after planting can be assumed. With regards to clopyralid uptake it can be assumed that seedlings will not take up significant amounts since their canopy is still too small for higher transpiration rates.

Taking this crop development into account it can be excluded that plants took up significant amounts of clopyralid before 44 DAT. Looking at the modelled residue decline curves 44 DAT corresponds to 0 to 10 g/ha clopyralid residue, depending on the DegT50. This is a very low level and may explain why wheat dry matter residue contents of clopyralid where lower than in Gourlay (2015; CA 6.2.1/4). Especially when considered that real uptake would not have taken place before BBCH 20. Which would correspond to even lower soil residue contents.

Finally, DAS would like to question the appropriateness of estimating plant uptake potential via log Kow as suggested by Briggs. Please note the comment of Member State Germany in the latest update of FOCUS GW Higher Tier, page 2 (Sanco/13144/2010, version 3, 10 October 2014). It is highly questionable if one parameter, log Kow, can predict plant uptake for all substances. Furthermore, it should be noted that Germany accepts the hydroponic test system at national level. Though only to refine the PUF to 0.5 not to the measured value.

RMS comments and evaluation:

The explanations and justification for a PUF value higher than 0 as a higher tier refinement option for PEC_{gw} calculation, as presented by the Notifier, is acceptable. The data may be considered as additional information for authorization of plant protection products containing clopyralid in different conditions within EU Member States. No further data are required and the data requirement is fulfilled.

B.8.4. Fate and behaviour in water and sediment

B.8.4.1. Aerobic mineralisation in surface water

Studies to determine aerobic mineralisation of clopyralid in surface water in water are described in CA 7.2.2.2. The following table provides a justification for the use of a different study to address fate and behaviour in water and sediment to that evaluated for the Active Approval.

Data point/Study	Rationale
CA 7.2.2.2/1	OECD 309 study to meet new data requirement. No degradation of clopyralid was observed.

Aerobic mineralisation studies with the formulation GF-1374 were not performed as it is possible to extrapolate from data obtained with the active substance.

No degradation of clopyralid was observed.

RMS comments and evaluation:

The justification presented by the Notifier is acceptable. The data available is adequate for assessing the aerobic mineralisation of clopyralid in surface water. No further data with the formulation GF-1374 are required and the data requirement is fulfilled.

B.8.4.2. Water/sediment study

Studies to determine the rate of degradation in water/sediment are described in CA 7.2.2.3. Studies with the formulation were not performed as it is possible to extrapolate from data obtained with the active substance.

As summarized by EFSA, (EFSA Scientific Report (2005) 50, 1-65, Conclusion on the peer review of Clopyralid, 14 December 2005):

A study with two water sediment systems is available. Clopyralid partitions slowly from water to the sediment ($DT_{50\ water}$ = 128 d – 167 d) and reaches a maximum of 30.6 % AR after 100 d into the sediment. There is practically no degradation of clopyralid in the water sediment system and up to 91 % AR remains as clopyralid at the end of the experiment after 100 d (extrapolated $DT_{50\ whole\ system}$ >

500 d). Non extractable radioactivity in te sediment amounted at the end of the study (100 d) to 5.85 % AR. The amount of CO_2 formed slowly increased to 2.3 % and 5.3 % AR after 100 d.

For modelling purposes the FOCUS default of 1000 d was used in all compartments.

RMS comments and evaluation:
The justification presented by the Notifier is acceptable. The data available is adequate for assessing the fate and behaviour of clopyralid in surface water. No further data with the formulation GF-1374 are required and the data requirement is fulfilled.

B.8.4.3. Irradiated water/sediment study

The degradation properties of clopyralid do not indicate the need for a study to be conducted with the formulation GF-1374. Studies with the formulation were not performed as it is possible to extrapolate from data obtained with the active substance.

The degradation properties of clopyralid do not indicate the need for a study to be conducted.

RMS comments and evaluation:
The justification presented by the Notifier is acceptable. No further data are required and the data requirement is fulfilled.

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

For the AIR3 dossier, GF-1374 was changed as the representative formulation, containing less clopyralid and causing a lower environmental exposure compared to the previous representative formulation. Therefore a new PEC_{sw} and PEC_{sed} calculation was necessary. Predicted environmental concentrations in surface water and sediment resulting from the uses of GF-1374 were not evaluated as part of the first Active Approval of clopyralid in 2005. Therefore all relevant information is provided here.

For the formulation GF-1374, an initial concentration in surface water *via* spray drift was calculated. As formulations consist of a mixture of components, the spray drift PEC_{sw} cannot be estimated by the FOCUS models; therefore it is considered here according to published spray drift data (Rautmann, 2001)[7].

The initial PEC_{SW} for a single application of the product GF-1374 is calculated as follows:

$$PEC_{SW}\ (\mu g/L) = \frac{\%\ \text{drift}\ (90^{th}\ \text{percentile}) \times \text{application rate [g/ha]}}{\text{water depth (30 cm)} \times 10}$$

[7] D. Rautmann, M. Streloke, M. Winkler (2001). New basic drift values in the authorisation procedure for plant protection products. In: R. Forster, M. Streloke: Workshop on Risk Assessment and Risk Mitigation Measures in the Context of the Authorization of Plant Protection Products (WORMM). Mitt. Biol. Bundesanst. Land-Forstwirtsch, Berlin-Dahlem, Heft 381

Mitigation by implementing no-spray buffers was also considered.

Table 8.5.1. GF-1374 PEC_{SW} from spray drift

Formulation	GF-1374
App. rate & frequency	1 × 1560 g/ha[a]
Scenario / Drift percentile	Arable crops / 90th percentile
Entry pathways considered	Drift: yes Volatilisation: no

[a] assuming a formulation density of 1.04 g/mL and an application rate of 1.5 L GF-1374/ha

Table 8.5.2. Estimates of aquatic concentrations for GF-1374 based on spray drift

Spray drift buffer (m)	Drift (%)	Initial PEC_{SW} (µg/L)			
		0% Drift red.	50% Drift red.	75% Drift red.	90% Drift red.
1	2.77	14.4	7.20	3.60	1.44
5	0.57	2.96	1.48	0.741	0.296
10	0.29	1.51	0.754	0.377	0.151
15	0.2	1.04	0.520	0.260	0.104
20	0.15	0.780	0.390	0.195	0.078

The PEC_{sw} and PEC_{sed} of clopyralid resulting from the use of GF-1374 was not calculated before in the context of EU evaluation for the renewal of approval of clopyralid. Therefore following report was submitted by the Notifier and is evaluated in detail here.

CP 9.2.5/1 - Predicted environmental concentrations of clopyralid in surface water and sediment

Report	CP 9.2.5/1; Robinson, P. 2015
Report title	Predicted environmental concentrations of clopyralid in surface water and sediment (PEC_{sw} and PEC_{sed}) following the application to winter cereals and grassland - a modelling assessment for Europe using the FOCUS surface water scenarios at Steps 1-3
DAS Study number	Dr Knoell Consult Ltd., Cardiff, UK, Report No.: 102664-2 DAS Study ID: 151157
Guidelines	FOCUS (2001): FOCUS Surface Water Scenarios in the EU Evaluation Process under 91/414/EEC. Report of the FOCUS Working Group on Surface Water Scenarios. EC Document Reference SANCO/4802/2001 rev. 2. FOCUS (2015): Generic guidance for FOCUS surface water Scenarios, version 1.4.
GLP	No

Methods

Environmental behaviour in soil and in aquatic system

Studies on soil degradation behaviour of the active substance clopyralid were conducted and are described under Annex Point CP 9.1.1. For the PEC_{sw} simulations, the laboratory normalised geometric mean $DegT_{50}$ was used (see Table 8.5.3).

The adsorption behaviour of the active substance clopyralid was examined in two studies which are described in detail under Annex Point CP 9.1.2. The geometric mean K_{foc} together with the arithmetic mean Freundlich exponent 1/n for clopyralid were used in the simulations according to recommendations by FOCUS (FOCUS, 2015; see Table 8.5.3).

The degradation of clopyralid in surface water was characterised by studies in two laboratory aerobic natural sediment water systems (see Annex Point CP 9.2.2). Clopyralid partitioned slowly from the water to the sediment and there was very little degradation in the total system. Therefore, a default DT_{50} value of 1000 days was used in Step 1 simulations for the total system, and in Steps 2-3 simulations for the water and sediment phases in accordance with FOCUS recommendations (FOCUS, 2015).

Input parameters

Apart from the input parameters explicitly discussed, all variables in the models were left at their default values. A summary of the relevant input parameters is given in Table 8.5.3.

Table 8.5.3. Input parameters for clopyralid used in surface water simulations (FOCUS STEPS 1-2, FOCUS SWASH)

Parameter	Unit	Clopyralid
Molecular Mass	g/mol	191.96
Water solubility at 20°C	mg/L	1.43×10^5
Vapour pressure at 25°C	Pa	1.36×10^{-3}
DT_{50} soil	days	18.4[a]
DT_{50} water	days	1000[b]
DT_{50} sediment	days	1000[b]
DT_{50} total system	days	1000[b]
K_{foc}	mL/g	1.41[c]
Freundlich Exponent (1/n)	-	0.836[d]
Plant uptake factor	-	0.5

[a] geometric mean, laboratory, normalised, n = 10
[b] FOCUS default
[c] geometric mean, n = 9
[d] arithmetic mean, n = 9

Application scenarios

Simulations were carried out considering a single spray application of clopyralid to winter cereals at a rate of 80 g a.s./ha from approximately BBCH 13 and of 120 g a.s./ha to established grassland. A summary of application patterns used in the simulations is presented in Table 8.5.4.

Table 8.5.4. Application patterns used for SW modelling of clopyralid

Crop scenario	Region[a]	Application period	Interception[a]
Winter cereals 1 × 80 g a.s./ha	North / South Europe	Feb – Jun	Minimal crop cover (0%)
Established grassland 1 × 120 g a.s./ha	North / South Europe	Feb – Aug	Full canopy (75%)

[a] Required for STEPS 1-2 simulations

At Step 3, to identify the worst-case environmental concentration possible to occur within the recommended application period for each crop, a single application in each month was simulated individually. Appropriate application windows were chosen based on the recommended GAP for the use of clopyralid. The actual date of application within the windows was determined by the Pesticide Application Timer (PAT) incorporated in FOCUS SWASH v. 5.3. A summary of application dates used for modelling at Step 3 is presented in Table 8.5.5.

Table 8.5.5. PECsw calculation at Step 3: Application windows and dates used in modelling with FOCUS SWASH

Crop	FOCUS Scenario	Application window		
		1st date of application window	Last date of application window	Actual application date[a]
Winter cereals	D1	01-Feb (32)	03-Mar (62)	03-Feb
	D2			22-Feb
	D3			01-Feb
	D4			24-Feb
	D5			10-Feb
	D6			27-Feb
	R1			24-Feb
	R3			19-Feb
	R4			04-Feb
	D1	01-Mar (60)	31-Mar (90)	07-Mar
	D2			12-Mar
	D3			29-Feb
	D4			01-Mar
	D5			07-Mar
	D6			05-Mar
	R1			17-Mar
	R3			01-Mar
	R4			05-Mar
	D1	01-Apr (91)	01-May (121)	01-Apr
	D2			01-Apr
	D3			04-Apr
	D4			18-Apr
	D5			08-Apr
	D6			09-Apr
	R1			26-Apr
	R3			04-Apr
	R4			29-Apr
	D1	01-May (121)	31-May (151)	14-May
	D2			07-May
	D3			04-May
	D4			30-May
	D5			11-May
	D6			03-May
	R1			02-May
	R3			18-May
	R4			04-May
	D1	01-Jun (152)	01-Jul (182)	17-Jun
	D2			02-Jun
	D3			21-Jun
	D4			01-Jun
	D5			09-Jun
	D6			01-Jun
	R1			01-Jun
	R3			02-Jun

	R4			08-Jun
Grassland	D1	01-Feb (32)	03-Mar (62)	03-Feb
	D2			22-Feb
	D3			01-Feb
	D4			24-Feb
	D5			10-Feb
	R2			04-Feb
	R3			19-Feb
	D1	01-Mar (60)	31-Mar (90)	07-Mar
	D2			12-Mar
	D3			29-Feb
	D4			01-Mar
	D5			07-Mar
	R2			01-Mar
	R3			01-Mar
	D1	01-Apr (91)	01-May (121)	01-Apr
	D2			01-Apr
	D3			04-Apr
	D4			18-Apr
	D5			08-Apr
	R2			22-Apr
	R3			04-Apr
	D1	01-May (121)	31-May (151)	14-May
	D2			07-May
	D3			04-May
	D4			30-May
	D5			11-May
	R2			07-May
	R3			18-May
	D1	01-Jun (152)	01-Jul (182)	17-Jun
	D2			02-Jun
	D3			14-Jun
	D4			01-Jun
	D5			09-Jun
	R2			04-Jun
	R3			02-Jun
	D1	01-Jul (182)	31-Jul (212)	02-Jul
	D2			01-Jul
	D3			30-Jun
	D4			04-Jul
	D5			19-Jul
	R2			31-Jul
	R3			31-Jul
	D1	01-Aug (213)	31-Aug (243)	04-Aug
	D2			06-Aug
	D3			31-Jul
	D4			27-Aug
	D5			04-Aug

	R2			05-Aug
	R3			01-Aug

[a] Determined by PAT
Numbers in brackets indicate 'Julian Days'

Simulation models
Calculations were carried out according to FOCUS (FOCUS, 2001, 2015) at Steps 1-3 using the current versions of FOCUS STEPS 1-2 (v 3.2) and FOCUS SWASH (v 5.3), which includes the operational models FOCUS MACRO (v 5.5.4), FOCUS PRZM (v 4.3.1) and FOCUS TOXSWA (v 4.4.3).

Results

Step 1 and 2 simulations
The maximum PEC_{sw} and PEC_{sed} of clopyralid at Step 1 and 2 are shown in Table 8.5.6. and Table 8.5.7 for applications to winter cereals and grassland.

Table 8.5.6. STEPS 1-2: Maximum PEC_{sw} and PEC_{sed} of clopyralid following the application to winter cereals (BBCH 13), 1 × 80 g a.s./ha

FOCUS Step	Appl. scenario	PEC_{sw} (µg/L)	PEC_{sed} (µg/kg)
1	-	27.4	0.385
2	N-Europe, Oct - Feb	12.2	0.172
	N-Europe, Mar - May	5.31	0.075
	N-Europe, Jun - Sep	5.31	0.075
	S-Europe, Oct - Feb	9.89	0.139
	S-Europe, Mar - May	9.89	0.139
	S-Europe, Jun - Sep	7.60	0.107

Table 8.5.7. STEPS 1-2: Maximum PEC_{sw} and PEC_{sed} of clopyralid following the application to established grassland, 1 × 120 g a.s./ha

FOCUS Step	Appl. scenario	PEC_{sw} (µg/L)	PEC_{sed} (µg/kg)
1	-	41.0	0.578
2	N-Europe, Oct - Feb	5.39	0.076
	N-Europe, Mar - May	2.82	0.040
	N-Europe, Jun - Sep	2.82	0.040
	S-Europe, Oct - Feb	4.53	0.064
	S-Europe, Mar - May	4.53	0.064
	S-Europe, Jun - Sep	3.67	0.052

Time-weighted average concentrations (TWA-21d) of clopyralid in surface water for all uses at Step 2 are summarised in Table 8.5.8.

Table 8.5.8. STEP 2: Example time-weighted average concentrations (TWA-21d) for clopyralid in surface water following the application to winter cereals and grassland

Use pattern	Application scenario	$PEC_{sw,}$TWA-21d (µg/L)
Winter cereals BBCH 13 (1 × 80 g a.s./ha)	N-Europe, Oct - Feb	12.1
	N-Europe, Mar - May	5.27
	N-Europe, Jun - Sep	5.27
	S-Europe, Oct - Feb	9.82
	S-Europe, Mar - May	9.82
	S-Europe, Jun - Sep	7.55
Established grassland (1 × 120 g a.s./ha)	N-Europe, Oct - Feb	5.35
	N-Europe, Mar May	2.80
	N-Europe, Jun Sep	2.80
	S-Europe, Oct - Feb	4.50
	S-Europe, Mar May	4.50
	S-Europe, Jun Sep	3.65

Step 3 simulations

Maximum PEC_{sw} and PEC_{sed} of clopyralid at Step 3 are shown in Tables 8.5.9. and 8.5.10. for the application to winter cereals and grassland, respectively.

Table 8.5.9. STEP 3: Maximum PEC_{sw} and PEC_{sed} values of clopyralid following the application to winter cereals (BBCH 13), 1 × 80 g a.s./ha

Appl. period	Scenario	Water body	PEC_{sw} (µg/L)	PEC_{sed} (µg/kg)	Main entry route
February	D1	d	7.69	2.22	Drainage
	D1	s	4.92	1.36	Drainage
	D2	d	9.91	1.60	Drainage
	D2	s	6.65	0.867	Drainage
	D3	d	0.639	0.217	Drift
	D4	p	0.239	0.181	Drainage
	D4	s	0.456	0.073	Drift
	D5	p	0.483	0.310	Drainage
	D5	s	2.71	0.167	Drainage
	D6	d	0.520	0.034	Drift
	R1	p	0.022	0.012	Runoff
	R1	s	0.932	0.047	Runoff
	R3	s	1.12	0.065	Runoff
	R4	s	0.336	0.012	Drift
March	D1	d	10.2	2.77	Drainage
	D1	s	6.40	1.71	Drainage
	D2	d	8.82	1.69	Drainage
	D2	s	5.53	1.03	Drainage
	D3	d	0.629	0.162	Drift
	D4	p	0.225	0.170	Drainage
	D4	s	0.454	0.068	Drift
	D5	p	0.044	0.034	Drift
	D5	s	0.411	0.014	Drift
	D6	d	0.562	0.066	Drift
	R1	p	0.040	0.021	Runoff
	R1	s	1.10	0.068	Runoff
	R3	s	3.28	0.212	Runoff
	R4	s	0.334	0.011	Drift
April	D1	d	11.7	2.78	Drainage
	D1	s	7.34	1.51	Drainage
	D2	d	11.0	1.80	Drainage
	D2	s	7.30	1.03	Drainage
	D3	d	0.618	0.115	Drift
	D4	p	0.164	0.133	Drainage
	D4	s	0.448	0.053	Drift
	D5	p	0.049	0.034	Drift
	D5	s	0.415	0.015	Drift
	D6	d	0.514	0.063	Drift
	R1	p	0.021	0.013	Runoff
	R1	s	0.736	0.043	Runoff
	R3	s	0.877	0.078	Runoff
	R4	s	1.37	0.097	Runoff
May	D1	d	1.05	0.483	Drainage
	D1	s	0.977	0.208	Drainage
	D2	d	19.0	1.94	Drainage
	D2	s	11.9	1.12	Drainage

Appl. period	Scenario	Water body	PEC_{sw} (µg/L)	PEC_{sed} (µg/kg)	Main entry route
	D3	d	0.657	0.149	Drift
	D4	p	0.204	0.159	Drainage
	D4	s	0.467	0.060	Drift
	D5	p	0.051	0.037	Drift
	D5	s	0.473	0.029	Drift
	D6	d	0.512	0.105	Drift
	R1	p	0.025	0.014	Runoff
	R1	s	0.959	0.055	Runoff
	R3	s	3.31	0.198	Runoff
	R4	s	2.33	0.162	Runoff
June	D1	d	0.626	0.305	Drift
	D1	s	0.449	0.121	Drift
	D2	d	7.33	2.71	Drainage
	D2	s	7.99	1.55	Drainage
	D3	d	0.717	0.209	Drift
	D4	p	0.262	0.211	Drainage
	D4	s	0.490	0.083	Drift
	D5	p	0.142	0.107	Drainage
	D5	s	0.473	0.042	Drift
	D6	d	0.512	0.105	Drift
	R1	p	0.086	0.042	Runoff
	R1	s	0.541	0.046	Runoff
	R3	s	1.36	0.122	Runoff
	R4	s	0.336	0.012	Drift

Table 8.5.10. STEP 3: Maximum PEC_{sw} and PEC_{sed} values of clopyralid following the application to established grassland, 1 × 120 g a.s./ha

Appl. period	Scenario	Water body	PEC_{sw} (µg/L)	PEC_{sed} (µg/kg)	Main entry route
February	D1	d	25.9	7.90	Drainage
	D1	s	18.4	4.66	Drainage
	D2	d	30.4	8.22	Drainage
	D2	s	24.7	3.69	Drainage
	D3	d	0.796	0.067	Drift
	D4	p	0.058	0.048	Drainage
	D4	s	0.623	0.036	Drift
	D5	p	1.16	0.711	Drainage
	D5	s	6.75	0.438	Drainage
	R2	s	0.640	0.026	Drift
	R3	s	0.709	0.033	Drift
March	D1	d	30.9	6.73	Drainage
	D1	s	19.3	4.16	Drainage
	D2	d	35.1	4.99	Drainage
	D2	s	25.7	2.65	Drainage
	D3	d	0.808	0.083	Drift
	D4	p	0.056	0.044	Drainage
	D4	s	0.625	0.036	Drift
	D5	p	0.053	0.035	Drift
	D5	s	0.633	0.019	Drift
	R2	s	0.662	0.014	Drift
	R3	s	0.705	0.029	Drift
April	D1	d	26.5	6.12	Drainage
	D1	s	16.7	3.30	Drainage
	D2	d	30.2	6.64	Drainage
	D2	s	26.0	3.51	Drainage
	D3	d	0.809	0.094	Drift
	D4	p	0.046	0.030	Drift
	D4	s	0.602	0.023	Drift
	D5	p	0.069	0.047	Drift
	D5	s	0.644	0.024	Drift
	R2	s	0.663	0.014	Drift
	R3	s	1.27	0.113	Runoff
May	D1	d	0.881	0.376	Drift
	D1	s	0.673	0.104	Drift
	D2	d	50.2	6.10	Drainage
	D2	s	33.5	3.64	Drainage
	D3	d	0.885	0.156	Drift
	D4	p	0.048	0.035	Drift
	D4	s	0.657	0.034	Drift
	D5	p	0.079	0.056	Drift
	D5	s	0.710	0.041	Drift
	R2	s	0.674	0.017	Drift
	R3	s	0.709	0.032	Drift
June	D1	d	0.814	0.362	Drift
	D1	s	0.673	0.150	Drift

Appl. period	Scenario	Water body	PEC$_{sw}$ (µg/L)	PEC$_{sed}$ (µg/kg)	Main entry route
	D2	d	0.854	0.442	Drift
	D2	s	0.767	0.328	Drift
	D3	d	1.12	0.348	Drift
	D4	p	0.104	0.073	Drift
	D4	s	0.662	0.053	Drift
	D5	p	0.299	0.212	Drainage
	D5	s	0.710	0.089	Drift
	R2	s	0.674	0.047	Drift
	R3	s	2.23	0.201	Runoff
July	D1	d	0.795	0.346	Drift
	D1	s	0.673	0.121	Drift
	D2	d	0.843	0.460	Drift
	D2	s	0.736	0.317	Drift
	D3	d	1.69	0.786	Drift
	D4	p	0.154	0.130	Drainage
	D4	s	0.658	0.088	Drift
	D5	p	0.195	0.160	Drainage
	D5	s	0.710	0.044	Drift
	R2	s	0.674	0.017	Drift
	R3	s	0.709	0.051	Drift
August	D1	d	0.781	0.344	Drift
	D1	s	0.673	0.167	Drift
	D2	d	2.76	1.25	Drainage
	D2	s	4.42	1.52	Drainage
	D3	d	2.11	1.27	Drift
	D4	p	0.392	0.313	Drainage
	D4	s	0.658	0.219	Drift
	D5	p	0.818	0.535	Drainage
	D5	s	0.710	0.217	Drift
	R2	s	0.674	0.017	Drift
	R3	s	0.709	0.055	Drift

Conclusions

Predicted environmental concentrations for clopyralid in surface water (PEC$_{sw}$) and sediment (PEC$_{sed}$) were calculated for the use on winter cereals and grassland in Europe in accordance with FOCUS guidelines (FOCUS, 2001, 2015).

Based on the exposure assessment presented in this section, it can be concluded that the single application of clopyralid to winter cereals and grassland is unlikely to result in unacceptable concentrations in surface water if used in compliance with good agricultural practice.

Predicted environmental concentrations in surface water (PEC$_{sw}$) and sediment (PEC$_{sed}$) were calculated for the herbicidal active substance clopyralid following the application to winter cereals and established grassland within Europe. For winter cereals, a single foliar spray application of 80 g a.s./ha from approximately BBCH 13, between February and June inclusive, was considered. For established grassland, a single foliar spray application of 120 g a.s./ha from February through to August was considered.

Calculations were carried out at Steps 1-2 using FOCUS STEPS 1-2 (v 3.2) and at Step 3 using FOCUS SWASH (v 5.3).

The overall maximum PEC_{sw} and PEC_{sed} values of the active substance clopyralid were predicted to be 12.2 µg/L and 0.172 µg/kg and 5.39 µg/L and 0.076 µg/kg following the application to winter cereals (Northern Europe, Oct-Feb) and grassland (Northern Europe, Oct-Feb) at **Step 2,** respectively. At **Step 3**, the application to grassland resulted in an overall maximum PEC_{sw} and PEC_{sed} of 50.2 µg/L and 8.22 µg/kg, while for winter cereals overall maximum PEC_{sw} and PEC_{sed} of 19.0 µg/L and 2.78 µg/kg were determined.

RMS comments and evaluation:

The new PEC_{sw} and PEC_{sed} calculations of clopyralid, resulting from the worst case uses of the representative formulation GF-1374 on winter cereals and established pasture, as submitted by the Notifier, are well performed and clearly reported.The proposed input parameters appropriate for modeling are agreed with the Notifier, except the default value for Plant Uptake Factor as set to 0.5 instead of 0.

Although the calculation was assessed as not acceptable, the results are summarized above for transparency reasons. To conclude, the PEC_{gw} should be recalculated using the typical PUF default of 0, as recommended by the FOCUS guidance and the EFSA. All other input parameters are appropriate and do not need to be refined.

Following the request of the RMS evaluator, the Notifier submitted a revised PECsw and PECsed calculation with a worst case assumption of PUF = 0 (Robinson 2016b). The revised calculation is presented below. Despite obvious repeating, the revision is presented in detail below, in order to ensure adequate transparency. *The changes in the revised PECsw and PECsed calculation as compared to the original report presented above are highlighted in the text below in italics.*

CP 9.2.5/2 - Predicted environmental concentrations of clopyralid in surface water and sediment

Report	CP 9.2.5/2; Robinson, P. 2016c
Report title	Predicted environmental concentrations of clopyralid in surface water and sediment (PEC_{sw} and PEC_{sed}) following the application to winter cereals and grassland - a modelling assessment for Europe using the FOCUS surface water scenarios at Steps 1-3
DAS Study number	Dr Knoell Consult Ltd., Cardiff, UK, Report No.: 104115-8 DAS Study ID: 151157 Revision 04.05.2016
Guidelines	FOCUS (2001): FOCUS Surface Water Scenarios in the EU Evaluation Process under 91/414/EEC. Report of the FOCUS Working Group on Surface Water Scenarios. EC Document Reference SANCO/4802/2001 rev. 2. FOCUS (2015): Generic guidance for FOCUS surface water Scenarios, version 1.4.
GLP	No

Methods

Environmental behaviour in soil and in aquatic system

Studies on soil degradation behaviour of the active substance clopyralid were conducted and are described under Annex Point CP 9.1.1. For the PEC_{sw} simulations, the laboratory normalised geometric mean $DegT_{50}$ was used (see Table 8.5.13).

The adsorption behaviour of the active substance clopyralid was examined in two studies which are described in detail under Annex Point CP 9.1.2. The geometric mean K_{foc} together with the arithmetic mean Freundlich exponent 1/n for clopyralid were used in the simulations according to recommendations by FOCUS (FOCUS, 2015; see Table 8.5.13).

The degradation of clopyralid in surface water was characterised by studies in two laboratory aerobic natural sediment water systems (see Annex Point CP 9.2.2). Clopyralid partitioned slowly from the water to the sediment and there was very little degradation in the total system. Therefore, a default DT_{50} value of 1000 days was used in Step 1 simulations for the total system, and in Steps 2-3 simulations for the water and sediment phases in accordance with FOCUS recommendations (FOCUS, 2015).

Application scenarios

Simulations were carried out considering a single spray application of clopyralid to winter cereals at a rate of 80 g a.s./ha from approximately BBCH 13 and of 120 g a.s./ha to established grassland. A summary of application patterns used in the simulations is presented in Table 8.5.11.

Table 8.5.11. Application patterns used for modelling

Crop scenario	Region[a]	Application period	Interception[a]
Winter cereals 1 × 80 g a.s./ha	North / South Europe	Feb – Jun	Minimal crop cover (0%)
Established grassland 1 × 120 g a.s./ha	North / South Europe	Feb – Aug	Full canopy (75%)

[a] Required for STEPS 1-2 simulations

At Step 3, to identify the worst-case environmental concentration possible to occur within the recommended application period for each crop, a single application in each month was simulated individually. Appropriate application windows were chosen based on the recommended GAP for the use of clopyralid. The actual date of application within the windows was determined by the Pesticide Application Timer (PAT) incorporated in FOCUS SWASH v. 5.3. A summary of application dates used for modelling at Step 3 is presented in Table 8.5.12.

Table 8.5.12. Step 3: Application windows and dates used in modelling with FOCUS SWASH

Crop	FOCUS Scenario	Application window		
		1st date of application window	Last date of application window	Actual application date[a]
Winter cereals	D1	01-Feb (32)	03-Mar (62)	03-Feb
	D2			22-Feb
	D3			01-Feb
	D4			24-Feb
	D5			10-Feb
	D6			27-Feb
	R1			24-Feb
	R3			19-Feb
	R4			04-Feb
	D1	01-Mar (60)	31-Mar (90)	07-Mar
	D2			12-Mar
	D3			29-Feb
	D4			01-Mar
	D5			07-Mar
	D6			05-Mar
	R1			17-Mar
	R3			01-Mar
	R4			05-Mar
	D1	01-Apr (91)	01-May (121)	01-Apr
	D2			01-Apr
	D3			04-Apr
	D4			18-Apr
	D5			08-Apr
	D6			09-Apr
	R1			26-Apr
	R3			04-Apr
	R4			29-Apr
	D1	01-May (121)	31-May (151)	14-May
	D2			07-May
	D3			04-May
	D4			30-May
	D5			11-May
	D6			03-May
	R1			02-May
	R3			18-May
	R4			04-May
	D1	01-Jun (152)	01-Jul (182)	17-Jun
	D2			02-Jun
	D3			21-Jun
	D4			01-Jun
	D5			09-Jun
	D6			01-Jun
	R1			01-Jun
	R3			02-Jun

	R4			08-Jun
Grassland	D1	01-Feb (32)	03-Mar (62)	03-Feb
	D2			22-Feb
	D3			01-Feb
	D4			24-Feb
	D5			10-Feb
	R2			04-Feb
	R3			19-Feb
	D1	01-Mar (60)	31-Mar (90)	07-Mar
	D2			12-Mar
	D3			29-Feb
	D4			01-Mar
	D5			07-Mar
	R2			01-Mar
	R3			01-Mar
	D1	01-Apr (91)	01-May (121)	01-Apr
	D2			01-Apr
	D3			04-Apr
	D4			18-Apr
	D5			08-Apr
	R2			22-Apr
	R3			04-Apr
	D1	01-May (121)	31-May (151)	14-May
	D2			07-May
	D3			04-May
	D4			30-May
	D5			11-May
	R2			07-May
	R3			18-May
	D1	01-Jun (152)	01-Jul (182)	17-Jun
	D2			02-Jun
	D3			14-Jun
	D4			01-Jun
	D5			09-Jun
	R2			04-Jun
	R3			02-Jun
	D1	01-Jul (182)	31-Jul (212)	02-Jul
	D2			01-Jul
	D3			30-Jun
	D4			04-Jul
	D5			19-Jul
	R2			31-Jul
	R3			31-Jul
	D1	01-Aug (213)	31-Aug (243)	04-Aug
	D2			06-Aug
	D3			31-Jul
	D4			27-Aug
	D5			04-Aug

	R2			05-Aug
	R3			01-Aug

[a] Determined by PAT
Numbers in brackets indicate 'Julian Days'

Input parameters
Apart from the input parameters explicitly discussed, all variables in the models were left at their default values. A summary of the relevant input parameters is given in Table 8.5.13.

Table 8.5.13. Input parameters for clopyralid used in surface water simulations (FOCUS STEPS 1-2, FOCUS SWASH)

Parameter	Unit	Clopyralid
Molecular Mass	g/mol	191.96
Water solubility at 20°C	mg/L	1.43×10^{5}
Vapour pressure at 25°C	Pa	1.36×10^{-3}
DT_{50} soil	days	18.4[a]
DT_{50} water	days	1000[b]
DT_{50} sediment	days	1000[b]
DT_{50} total system	days	1000[b]
K_{foc}	mL/g	1.41[c]
Freundlich Exponent (1/n)	-	0.836[d]
Plant uptake factor	-	*0*[e]

[a] geometric mean, laboratory, normalised, n = 10
[b] FOCUS default
[c] geometric mean, n = 9
[d] arithmetic mean, n = 9
[e] *worst case assumption*

Simulation models
Calculations were carried out according to FOCUS (FOCUS, 2001, 2015) at Steps 1-3 using the current versions of FOCUS STEPS 1-2 (v 3.2) and FOCUS SWASH (v 5.3), which includes the operational models FOCUS MACRO (v 5.5.4), FOCUS PRZM (v 4.3.1) and FOCUS TOXSWA (v 4.4.3).

Results

Step 1 and 2 simulations
The maximum PEC_{sw} and PEC_{sed} of clopyralid at Step 1 and 2 are shown in Table 8.5.14. and Table 8.5.15. for applications to winter cereals and grassland.

Table 8.5.14. STEPS 1-2: Maximum PEC_{sw} and PEC_{sed} of clopyralid following the application to winter cereals (BBCH 13), 1 × 80 g a.s./ha

FOCUS Step	Appl. scenario	PEC_{sw} (µg/L)	PEC_{sed} (µg/kg)
1	-	27.4	0.385
2	N-Europe, Oct - Feb	12.2	0.172
	N-Europe, Mar - May	5.31	0.075
	N-Europe, Jun - Sep	5.31	0.075
	S-Europe, Oct - Feb	9.89	0.139
	S-Europe, Mar - May	9.89	0.139
	S-Europe, Jun - Sep	7.60	0.107

Table 8.5.15. STEPS 1-2: Maximum PEC_{sw} and PEC_{sed} of clopyralid following the application to established grassland, 1 × 120 g a.s./ha

FOCUS Step	Appl. scenario	PEC_{sw} (µg/L)	PEC_{sed} (µg/kg)
1	-	41.0	0.578
2	N-Europe, Oct - Feb	5.39	0.076
	N-Europe, Mar - May	2.82	0.040
	N-Europe, Jun - Sep	2.82	0.040
	S-Europe, Oct - Feb	4.53	0.064
	S-Europe, Mar - May	4.53	0.064
	S-Europe, Jun - Sep	3.67	0.052

Time-weighted average concentrations (TWA-21d) of clopyralid in surface water for all uses at Step 2 are summarised in Table 8.5.16.

Table 8.5.16. STEP 2: Example time-weighted average concentrations (TWA-21d) for clopyralid in surface water following the application to winter cereals and grassland

Use pattern	Appl. scenario	$PEC_{sw,}$TWA-21d (µg/L)
Winter cereals BBCH 13 (1 × 80 g a.s./ha)	N-Europe, Oct - Feb	12.1
	N-Europe, Mar - May	5.27
	N-Europe, Jun - Sep	5.27
	S-Europe, Oct - Feb	9.82
	S-Europe, Mar - May	9.82
	S-Europe, Jun - Sep	7.55
Established grassland (1 × 120 g a.s./ha)	N-Europe, Oct - Feb	5.35
	N-Europe, Mar May	2.80
	N-Europe, Jun Sep	2.80
	S-Europe, Oct - Feb	4.50
	S-Europe, Mar May	4.50
	S-Europe, Jun Sep	3.65

Step 3 simulations

Maximum PEC_{sw} and PEC_{sed} of clopyralid at Step 3 are shown in Table 8.5.17. and Table 8.5.18. for the application to winter cereals and grassland, respectively.

Table 8.5.17. STEP 3: Maximum PEC_{sw} and PEC_{sed} values of clopyralid following the application to winter cereals (BBCH 13), 1 × 80 g a.s./ha

Appl. period	Scenario	Water body	PEC_{sw} (µg/L)	PEC_{sed} (µg/kg)	Main entry route
February	D1	d	*7.78*	*2.28*	Drainage
	D1	s	*4.98*	*1.39*	Drainage
	D2	d	*10.4*	*1.70*	Drainage
	D2	s	*6.96*	*0.928*	Drainage
	D3	d	*0.699*	*0.262*	Drift
	D4	p	*0.405*	*0.306*	Drainage
	D4	s	*0.517*	*0.122*	Drift
	D5	p	*0.504*	*0.324*	Drainage
	D5	s	*2.74*	*0.173*	Drainage
	D6	d	*0.522*	*0.034*	Drift
	R1	p	*0.022*	*0.012*	Runoff
	R1	s	*0.968*	*0.048*	Runoff
	R3	s	*1.17*	*0.067*	Runoff
	R4	s	*0.336*	*0.012*	Drift
March	D1	d	*10.3*	*2.83*	Drainage
	D1	s	*6.45*	*1.75*	Drainage
	D2	d	*9.01*	*1.74*	Drainage
	D2	s	*5.65*	*1.06*	Drainage
	D3	d	*0.707*	*0.222*	Drift
	D4	p	*0.394*	*0.298*	Drainage
	D4	s	*0.514*	*0.119*	Drift
	D5	p	*0.064*	*0.053*	Drift
	D5	s	*0.419*	*0.019*	Drift
	D6	d	*0.563*	*0.067*	Drift
	R1	p	*0.042*	*0.022*	Runoff
	R1	s	*1.17*	*0.073*	Runoff
	R3	s	*3.30*	*0.213*	Runoff
	R4	s	*0.334*	*0.011*	Drift
April	D1	d	*12.1*	*2.94*	Drainage
	D1	s	*7.60*	*1.59*	Drainage
	D2	d	*11.2*	*1.86*	Drainage
	D2	s	*7.47*	*1.07*	Drainage
	D3	d	*0.699*	*0.172*	Drift
	D4	p	*0.338*	*0.267*	Drainage
	D4	s	*0.518*	*0.103*	Drift
	D5	p	*0.072*	*0.053*	Drift
	D5	s	*0.423*	*0.021*	Drift
	D6	d	*0.514*	*0.064*	Drift
	R1	p	*0.021*	*0.013*	Runoff
	R1	s	*0.769*	*0.044*	Runoff
	R3	s	*0.932*	*0.082*	Runoff
	R4	s	*1.48*	*0.104*	Runoff
May	D1	d	*1.11*	*0.525*	Drainage
	D1	s	*1.03*	*0.230*	Drainage
	D2	d	*19.5*	*2.01*	Drainage
	D2	s	*12.3*	*1.16*	Drainage

Appl. period	**Scenario**	**Water body**	**PEC$_{sw}$ (µg/L)**	**PEC$_{sed}$ (µg/kg)**	**Main entry route**
	D3	d	*0.763*	*0.226*	Drift
	D4	p	*0.356*	*0.277*	Drainage
	D4	s	*0.508*	*0.105*	Drift
	D5	p	*0.070*	*0.051*	Drift
	D5	s	*0.473*	*0.032*	Drift
	D6	d	*0.512*	*0.105*	Drift
	R1	p	*0.025*	*0.014*	Runoff
	R1	s	*0.985*	*0.057*	Runoff
	R3	s	*3.33*	*0.198*	Runoff
	R4	s	*2.37*	*0.165*	Runoff
June	D1	d	*0.647*	*0.327*	Drift
	D1	s	*0.449*	*0.149*	Drift
	D2	d	*7.55*	*2.79*	Drainage
	D2	s	*8.23*	*1.60*	Drainage
	D3	d	*0.866*	*0.328*	Drift
	D4	p	*0.407*	*0.321*	Drainage
	D4	s	*0.525*	*0.122*	Drift
	D5	p	*0.164*	*0.123*	Drainage
	D5	s	*0.473*	*0.048*	Drift
	D6	d	*0.512*	*0.105*	Drift
	R1	p	*0.089*	*0.043*	Runoff
	R1	s	*0.563*	*0.048*	Runoff
	R3	s	*1.36*	*0.122*	Runoff
	R4	s	*0.336*	*0.012*	Drift

Table 8.5.18. STEP 3: Maximum PEC_{sw} and PEC_{sed} values of clopyralid following the application to established grassland, 1 × 120 g a.s./ha

Appl. period	Scenario	Water body	PEC_{sw} (µg/L)	PEC_{sed} (µg/kg)	Main entry route
February	D1	d	*25.9*	*7.92*	Drainage
	D1	s	*18.5*	*4.67*	Drainage
	D2	d	*30.5*	*8.24*	Drainage
	D2	s	*24.8*	*3.70*	Drainage
	D3	d	*0.899*	*0.134*	Drift
	D4	p	*0.149*	*0.118*	Drainage
	D4	s	*0.667*	*0.089*	Drift
	D5	p	*1.17*	*0.717*	Drainage
	D5	s	*6.76*	*0.441*	Drainage
	R2	s	*0.640*	*0.026*	Drift
	R3	s	*0.709*	*0.033*	Drift
March	D1	d	*31.0*	*6.79*	Drainage
	D1	s	*19.4*	*4.20*	Drainage
	D2	d	*35.2*	*5.02*	Drainage
	D2	s	*25.7*	*2.68*	Drainage
	D3	d	*0.948*	*0.169*	Drift
	D4	p	*0.141*	*0.108*	Drainage
	D4	s	*0.659*	*0.088*	Drift
	D5	p	*0.093*	*0.064*	Drift
	D5	s	*0.650*	*0.031*	Drift
	R2	s	*0.662*	*0.014*	Drift
	R3	s	*0.705*	*0.029*	Drift
April	D1	d	*26.7*	*6.20*	Drainage
	D1	s	*16.8*	*3.35*	Drainage
	D2	d	*30.5*	*6.67*	Drainage
	D2	s	*26.1*	*3.53*	Drainage
	D3	d	*0.959*	*0.196*	Drift
	D4	p	*0.117*	*0.091*	Drainage
	D4	s	*0.658*	*0.063*	Drift
	D5	p	*0.128*	*0.088*	Drift
	D5	s	*0.665*	*0.040*	Drift
	R2	s	*0.663*	*0.014*	Drift
	R3	s	*1.36*	*0.122*	Runoff
May	D1	d	*0.916*	*0.401*	Drift
	D1	s	*0.673*	*0.137*	Drift
	D2	d	*50.3*	*6.18*	Drainage
	D2	s	*33.6*	*3.68*	Drainage
	D3	d	*1.16*	*0.347*	Drift
	D4	p	*0.121*	*0.099*	Drainage
	D4	s	*0.669*	*0.070*	Drift
	D5	p	*0.140*	*0.105*	Drift
	D5	s	*0.710*	*0.049*	Drift
	R2	s	*0.674*	*0.017*	Drift
	R3	s	*0.709*	*0.032*	Drift
June	D1	d	*0.830*	*0.430*	Drift
	D1	s	*0.673*	*0.201*	Drift

Appl. period	Scenario	Water body	PEC_{sw} (µg/L)	PEC_{sed} (µg/kg)	Main entry route
	D2	d	*0.867*	*0.452*	Drift
	D2	s	*0.778*	*0.336*	Drift
	D3	d	*1.49*	*0.645*	Drift
	D4	p	*0.287*	*0.220*	Drift
	D4	s	*0.682*	*0.158*	Drift
	D5	p	*0.416*	*0.286*	Drainage
	D5	s	*0.710*	*0.122*	Drift
	R2	s	*0.674*	*0.050*	Drift
	R3	s	*2.25*	*0.202*	Runoff
July	D1	d	*0.803*	*0.363*	Drift
	D1	s	*0.673*	*0.162*	Drift
	D2	d	*0.925*	*0.530*	Drainage
	D2	s	*0.773*	*0.372*	Drainage
	D3	d	*2.16*	*1.13*	Drift
	D4	p	*0.384*	*0.307*	Drainage
	D4	s	*0.658*	*0.215*	Drift
	D5	p	*0.308*	*0.245*	Drainage
	D5	s	*0.710*	*0.066*	Drift
	R2	s	*0.674*	*0.017*	Drift
	R3	s	*0.709*	*0.053*	Drift
August	D1	d	*0.784*	*0.401*	Drift
	D1	s	*0.673*	*0.214*	Drift
	D2	d	*2.95*	*1.34*	Drainage
	D2	s	*4.80*	*1.64*	Drainage
	D3	d	*2.57*	*1.66*	Drift
	D4	p	*0.712*	*0.550*	Drainage
	D4	s	*0.888*	*0.393*	Drainage
	D5	p	*0.924*	*0.603*	Drainage
	D5	s	*0.710*	*0.243*	Drift
	R2	s	*0.674*	*0.017*	Drift
	R3	s	*0.709*	*0.057*	Drift

Conclusions

Predicted environmental concentrations for clopyralid in surface water (PEC_{sw}) and sediment (PEC_{sed}) were calculated for the use on winter cereals and grassland in Europe in accordance with FOCUS guidelines (FOCUS, 2001, 2015).

Based on the exposure assessment presented in this section, it can be concluded that the single application of clopyralid to winter cereals and grassland is unlikely to result in unacceptable concentrations in surface water if used in compliance with good agricultural practice.

RMS comments and evaluation:

The recalculation presented by the Notifier was conducted according to the guidance and is acceptable with regard to the use of the product CF-1374 on cereals with the highest application rate of 1 Liter of the product corresponding to 80 g a.i./ha, and on pasture 1.5 L/ha, corresponding to 120 g a.i./ha. Higher use rates are not supported by data appropriately any longer.

The Notifier highlights that this is not necessarily the worst case GAP at MS level. Higher use rates of clopyralid than 80 g/ha in cereals and and 120 g/ha in established pasture may be supported with appropriate data at national level depending on agronomic needs, weed pressure, approved endpoints and specific Member States' modelling requirements and risk mitigation measures to be applied, and need to be evaluated separately at MS level. The RMS agrees on this statement.

The revised PEC_{sw} and PEC_{sed} calculations of clopyralid, resulting from the worst case uses of the representative formulation GF-1374 on winter cereals and established pasture, as submitted by the Notifier, are well performed and clearly reported, and acceptable following the default value for Plant Uptake Factor setting to the worst case default of 0. This change did not significantly change the resulting PEC values. Both calculations are presented above for transparency, because the refinement of the default might be considered appropriate for certain conditions within the Member States.

If the PUF=0.5 is considered (Robinson 2015), the overall maximum PEC_{sw} and PEC_{sed} values of the active substance clopyralid were predicted to be 12.2 µg/L and 0.172 µg/kg and 5.39 µg/L and 0.076 µg/kg following the application to winter cereals (Northern Europe, Oct-Feb) and grassland (Northern Europe, Oct-Feb) at **Step 2,** respectively. At **Step 3**, the application to grassland resulted in an overall maximum PEC_{sw} and PEC_{sed} of 50.2 µg/L and 8.22 µg/kg, while for winter cereals overall maximum PEC_{sw} and PEC_{sed} of 19.0 µg/L and 2.78 µg/kg were determined. As this is not the worst case, the revised values should be used in the risk assessment, as summarized below.

If the worst case PUF=0 is considered (Robinson 2016c), the overall maximum PEC_{sw} and PEC_{sed} values of the active substance clopyralid were predicted to be 12.2 µg/L and 0.172 µg/kg and 5.39 µg/L and 0.076 µg/kg following the application to winter cereals (Northern Europe, Oct-Feb) and grassland (Northern Europe, Oct-Feb) at **Step 2,** respectively. At **Step 3**, the application to grassland resulted in an overall maximum PEC_{sw} and PEC_{sed} of 50.3 µg/L and 8.24 µg/kg, while for winter cereals overall maximum PEC_{sw} and PEC_{sed} of 19.5 µg/L and 2.94 µg/kg were determined.

These worst case PEC_{sw} and PEC_{sed} values are appropriate to be used in the ecotoxicological risk assessment to aquatic organisms, as presented in dRAR Part 20 Vol. 3 Chapter 9 in detail.

No PEC_{twa} values are reported, since these values are not needed in the risk assessment. As no degradation products other than CO_2 are formed from clopyralid, it is also not relevant to calculate the PEC_{sw} and PEC_{sed} of metabolites.

The data requirement is fulfilled and no further data on the surface water concentrations are required for supporting the renewal of approval of clopyralid in the EU.

Appropriate risk mitigation measures might be considered at Member State level to address the potential exposure routes via drainage and runoff for protecting aquatic organisms in vulnerable conditions and application timing, when the products containing clopyralid will be authorized.

B.8.6. FATE AND BEHAVIOUR IN AIR

The route and rate of degradation in air is described in CA 7.3.1. Studies with the formulation were not performed as it is possible to extrapolate from data obtained with the active substance.

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

Photochemical oxidative degradation in air for clopyralid was determined to be 19.5 days (Atkinson method, AOPWIN v1.90).

However, it can be concluded that the potential for long-range transport of clopyralid via air might be considered as minimal, due to experimental data on volatilisation.

RMS comments and evaluation: The photochemical oxidative degradation in air for clopyralid is slow, with a calculated half-life of 19.5 days (Atkinson method, AOPWIN v1.90). The calculation was considered valid and adequate for the Annex I inclusion of clopyralid and not repeated here. However, based on volatilization data, the risk for long-range aerial transport of clopyralid was assessed as minimal in the first EU evaluation. The data on the fate and behavior of clopyralid in air is still valid and acceptable, and no further studies are required to support the renewal for the approval of clopyralid.

B.8.6.2. Predicted environmental concentrations from airborne transport

It was concluded that clopyralid is anticipated not to be present in air in significant quantities due to low vapour pressure, low Henry's Law Constant, and experimental data on volatilisation. Due to experimental data on volatilisation of clopyralid, the potential for long-range transport via air might be considered as minimal.

RMS comments and evaluation: The justification of the Notifier is agreed and acceptable, and no further studies are required to support the renewal for the approval of clopyralid.

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

Not required.

RMS comments and evaluation: It is agreed with the Notifier that no further formulation data are required to support the renewal for the approval of clopyralid.

B.8.8. References relied on

Data Point	Author(s)	Year	Title Compagny Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
CP 9.2.4/1	Robinson, P.	2016a	Predicted environmental concentrations of clopyralid in groundwater (PECgw) following the application to winter cereals and grassland - a modelling assessment for Europe using FOCUS PEARL, FOCUS PELMO and FOCUS MACRO DAS Report No. 151156, 25.2.2016. Dr. Knoell Consult Report 104115-2. GLP/GEP (Y/N): No Published (Y/N): No	N	Y	Active substance data submitted with an application under Article 15 of the Regulation (renewal) and with the application for renewal of authorisation of the corresponding product. Applies also to data submitted with applications for authorisation for products containing AIR2 substances (Regulation (EU) No 1141/2010)	DAS	Submitted for the purpose of renewal
CP 9.2.4/2	Robinson, P.	2016b	Predicted environmental concentrations of clopyralid in groundwater (PECgw) following the application to winter cereals and grassland - a modelling assessment for Europe using FOCUS PEARL, FOCUS PELMO and FOCUS MACRO DAS Report No. 151156, revision 04.05.2016 Dr. Knoell Consult Report 104115-7.	N	Y	Active substance data submitted with an application under Article 15 of the Regulation (renewal) and with the	DAS	Submitted for the purpose of renewal

Data Point	Author(s)	Year	Title Compagny Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
			GLP/GEP (Y/N): No Published (Y/N): No			application for renewal of authorisation of the corresponding product. Applies also to data submitted with applications for authorisation for products containing AIR2 substances (Regulation (EU) No 1141/2010)		
CP 9.2.4/3	Chatton, P.	19.5.2016	Letter from DAS to Tukes: DAS Response to RMS position on Plant Uptake Factor	N	N	N/A	DAS	Submitted for the purpose of renewal
CP 9.2.5/1	Robinson, P.	2015	Predicted environmental concentrations of clopyralid in surface water and sediment (PECSW and PECSED) following the application to winter cereals and grassland - a modelling assessment for Europe using the FOCUS surface water scenarios at Steps1-3 DAS Report No. 151157, 16.10.2015. Dr. Knoell Consult Report 02664-2. GLP/GEP (Y/N): No Published (Y/N): No	N	Y	Active substance data submitted with an application under Article 15 of the Regulation (renewal) and with the application for renewal of authorisation of the corresponding product. Applies also to data submitted with	DAS	Submitted for the purpose of renewal

Data Point	Author(s)	Year	Title Compagny Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
						applications for authorisation for products containing AIR2 substances (Regulation (EU) No 1141/2010)		
CP 9.2.5/2	Robinson, P.	2016c	Predicted environmental concentrations of clopyralid in surface water and sediment (PECSW and PECSED) following the application to winter cereals and grassland - a modelling assessment for Europe using the FOCUS surface water scenarios at Steps 1-3 DAS Report No. 151157, revision 04.05.206 Dr. Knoell Consult Report 104115-8. GLP/GEP (Y/N): No Published (Y/N): No	N	Y	Active substance data submitted with an application under Article 15 of the Regulation (renewal) and with the application for renewal of authorisation of the corresponding product. Applies also to data submitted with applications for authorisation for products containing AIR2 substances (Regulation (EU) No 1141/2010)	DAS	Submitted for the purpose of renewal