REGISTRATION REPORT

Part B

Section 8

Environmental Fate

Detailed summary of the risk assessment

Product code: GLOB182F

Product name: SURRENDER

Chemical active substance:

Fludioxonil, 100 g/L

Interzonal

Zonal Rapporteur Member State: PL

CORE ASSESSMENT

Applicant: Globachem NV

Submission date: January 2021

MS Finalisation date: October 2021 (initial Core Assessment)

March 2022 (final Core Assessment)

Version history

When	What
January 2021	Initial dRR – Globachem NV
October 2021	Initial izRMS assessment The report in the dRR format has been prepared by the Applicant, therefore all comments, additional evaluations and conclusions of the izRMS are presented in grey commenting boxes. Minor changes are introduced directly in the text and highlighted in grey. Not agreed or not relevant information are ~~struck through and shaded for transparency~~.
March 2022	Final report (Core Assessment updated following the commenting period) Additional information/assessments included by the izRMS in the report in response to comments recieved from the cMS and the Applicant are highlighted in yellow. Information no longer relevant ~~is struck through and shaded~~.

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8 Fate and behaviour in the environment (KCP 9)

8.1 Critical GAP and overall conclusions

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

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17
Use-No. *	Member state(s)	Crop and/or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I **	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**					PHI (days)	Min-Max. TGW (thousand grain weight, g/1000 seeds) Min-Max. Sowing density per ha (seeds/ha)	**Conclusion**
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L/ton seeds a) max. rate per appl. b) max. total rate per crop/season	Kg a.s./ton seeds a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Sowing rate (kg seeds/ha) min/ max	Water L/ton seeds min / max			Groundwater
Interzonal uses (use as seed treatment, in greenhouses (or other closed places of plant production), as post-harvest treatment or for treatment of empty storage rooms)																
1 [1)]	izRMS + all cMS*	Maize (forage) ZEAMX	I (treatment seeds) F (sowing)	*Fusarium* sp. (FUSASP) Pythium sp. (PYTHSP)	Seed treatment	BBCH 00	a) 1 b) 1	/	a) 0.5 b) 0.5	a) 0.050 b) 0.050	a) 1.20-2.375 b) 1.20-2.375	24-47.5	4-8 L (incl. product)	N/A	TGW: 240-380 Sowing density: 100,000-125,000 12-23.75 mL product/ha	A
4 [2)]	izRMS + cMS*	Sunflower HELAN	I (treatment seeds) F (sowing)	*Botrytis cinerea* (BOTRCI) Downy mildew (PLASHA) *Fusarium* sp. (FUSASP)	Seed treatment	BBCH 00	a) 1 b) 1	/	a) 1.5 b) 1.5	a) 0.150 b) 0.150	a) 0.525-1.6875 b) 0.525-1.6875	3.5-11.3	4-8 L (incl. product)	N/A	TGW: 20-50 Sowing density: 175,000-225,000 5.25-16.95 ~~16.88~~ mL product/ha	A

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

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

1) Protective also for uses No 2 (maize at 0.96-1.71 g a.s./ha) and No 3 (sweet corn at 0.2925-0.825 g a.s./ha); see Core Assessment, Part B, Section 0 for more details

2) Protective also for uses No 5 (sunflower at 0.4375-1.6875 g a.s./ha) and No 6 (sunflower at 1.15 g a.s./ha); see Core Assessment, Part B, Section 0 for more details

Explanation for column 15 "Conclusion"

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

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

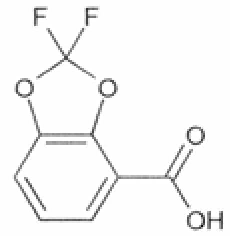
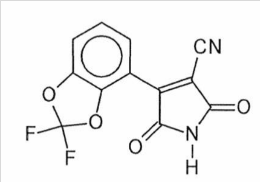
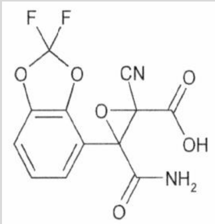
1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. *	Member state(s)	Crop and/or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I **	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			PHI (days)	Remarks: e.g. g safener/ synergist per ha
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		
1	EU, North and South	Wheat	F	*Microdochium nivale* *Fusarium spp.* *Tilletia caries* *Septoria sp.* *Helminthosporium sp.*	Seed treatment	BBCH 00	a) 1 b) 1	/	a) 2 L/ton seeds (0.050 kg a.s./ton seeds) b) 2 L/ton seeds (0.050 kg a.s./ton seeds	a) 0.005 - 0.00875 gkg a.s./ha b) 0.005 - 0.00875 gkg a.s./ha	0 – 15 L/ton seeds	N/A	Sowing rate: 100 – 175 kg/ha

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

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

8.2 Metabolites considered in the assessment

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

Metabolite	Molar mass	Chemical structure	Maximum observed occurrence in compartments	Exposure assessment required due to
CGA192155	202.1		Soil: Max. 11.7% AR in lab soil photolysis study. Max. 13% AR in the field. Water/sediment: 17.3% ~~13.7%~~	PEC_{soil}: not required since route of formation of this metabolite (in presence of light) is not relevant for seed treatment $PEC_{sw/sed}$: not covered by EU assessment
CGA265378	278.2		Soil: Max. 12.3% AR in lab soil photolysis study. Not detected in the field. Water/sediment: 3.8%	PEC_{soil}: not required since route of formation of this metabolite (in presence of light) is not relevant for seed treatment $PEC_{sw/sed}$: not required since formation in water/sediment systems not relevant (<5% AR)
CGA339833	312.2		Soil: Max. 9.1% AR in lab soil photolysis study. Max. 8% AR in the field. Water/sediment: not detected Max. 30.5% in aqueous photolysis study	PEC_{soil}: not required since route of formation of this metabolite (in presence of light) is not relevant for seed treatment $PEC_{sw/sed}$: Not covered by the EU assessment (also in case of seed treatment fludioxonil may migrate to surface water bodies where metabolite CGA339833 will be formed)
CGA344623	not given in the LoEP	Not available	Soil: - Water/sediment: 12.4% in aqueous photolysis study	In the course of the EU review this compound was considered to be minor metabolite since it was detected only in the sterile photolysis study and not in the water/sediment study performed under light conditions
A5	not given in the LoEP	Not available	Soil: - Water/sediment: 11.3% in aqueous photolysis study	In the course of the EU review this compound was considered to be minor metabolite since it was detected only in the sterile photolysis study and not in the water/sediment study performed under light conditions

izRMS comments:

Information regarding fludioxonil metabolite CGA192155 is in general in line with EU agreed data reported in EFSA Scientific Report (2007) 110 with correction regarding the maximum formation in water/sediment study.
It is noted that two other metabolites were formed via photodegradation in soil (CGA265378 and CGA339833). However, due to the type of application (seed treatment) photolysis will not play a major role in degradation of fludioxonil in soil and for this reason metabolites formed exclusively via photolysis in soil may not be taken into account in exposure assessment for the intended uses of GLOB182F. Nevertheless, metabolites formed via photolysis in water (CGA339833, CGA344623 and A5) may be relevant, since fludioxonil applied as a seed treatment may migrate to surface water bodies where it will undergo photodegradation. It is noted that in the course of the EU review photolytic metabolites CGA344623 and A5 were considered to be minor metabolites since they were detected only in the sterile photolysis study and not in the water/sediment study performed under light conditions. Therefore, in addition to CGA192155, also photolytic aquatic metabolite CGA339833 is considered to be relevant for the surface water exposure assessment.

Respective information has been provided by the izRMS in Table 8.2-1 for completeness.

8.3 Rate of degradation in soil (KCP 9.1.1)

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

8.3.1 Aerobic degradation in soil (KCP 9.1.1.1)

The rate of degradation in soil of Fludioxonil was evaluated during the Annex I Inclusion. No additional studies have been performed.

The fate and behaviour of Fludioxonil in soil is discussed in detail in the corresponding document of the EU review dossier where the study references can be found.

Route of degradation

Photolysis plays a major role for the degradation of Fludioxonil in the soil. Major metabolites are formed in light but not in the dark. In laboratory studies in the dark the degradation of Fludioxonil was relatively slow with DT_{50}Lab ranging between 143 days and > 365 days, while DT_{50} in field exposed to sunlight ranged between 7 days and 52 days.
Aerobic degradation in laboratory studies in the dark resulted mainly in the formation of CO_2 and non-extractables. Only few fractions of metabolites in small amounts were detected. The low amounts indicate that potential metabolites were short living intermediates, compared to the half-life of Fludioxonil. The observed mineralisation rate supports this conclusion and demonstrates the importance of microbial processes in the degradation of Fludioxonil and its metabolites.
Sterile and anaerobic conditions resulted in negligible degradation of Fludioxonil demonstrating that the decline of soil incorporated Fludioxonil is strongly mediated by aerobic soil microorganisms.
Photolysis resulted in a fast degradation and was the only process forming major metabolites (after light exposure). The structures and the pathway of degradation for Fludioxonil in light exposed soil are given in Figure 8.3-1.

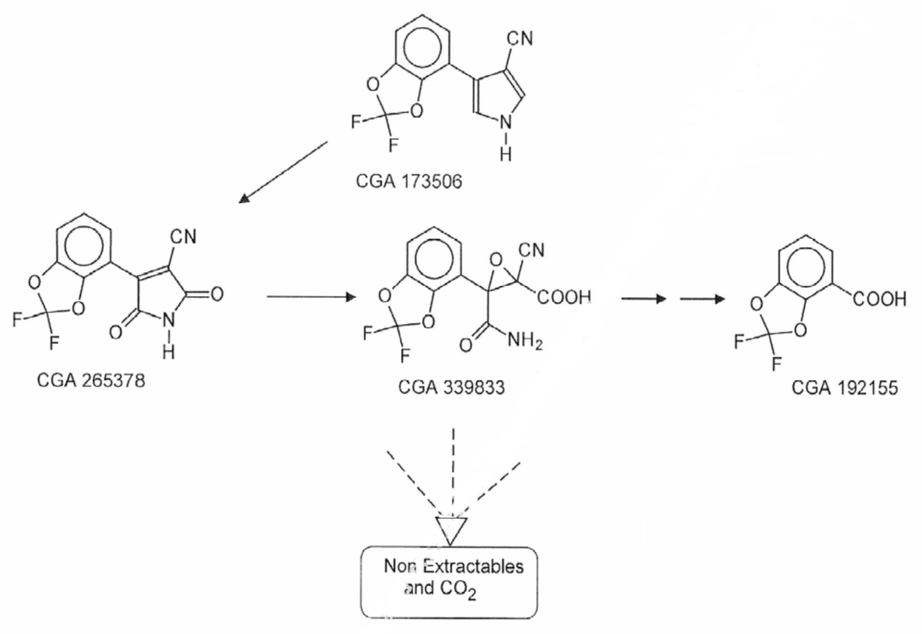


Figure 8.3-1: Proposed metabolic pathway of Fludioxonil in light exposed soil

Rate of degradation

Studies on aerobic degradation in soil with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance. These data are summarised in Tables 8.3-1 to 8.3-3 for respectively Fludioxonil and its metabolites.

Table 8.3-1: Summary of aerobic degradation rates for Fludioxonil - laboratory studies

Fludioxonil, Laboratory studies, aerobic conditions									
Trial no.	**Soil type**	**pH**	**t. ºC**	**MWHC %**	**DT50 (d)**	**DT90 (d)**	**DT50 (d) 20°C pF2/10kPa**	**Chi2 (%)**	**Evaluated on EU level y/n/ Reference**
1	Sandy loam	6.5	25	-	> 365		-		Y EFSA, 2007 DK, 2006
2	Loam	7.9	25	-	> 365		-		
3	Sandy loam	5.4	20	-	> 365		165		
4	Sandy loam	5.4	20	-	> 365		126		
5	Sandy loam	5.4	20	-	> 365		190		
6	Sandy loam	5.4	10	-	>> 365		139 [1]		
Mean (n = 3)							**160**		
7	Sandy loam	7.0	20	40	373	1580	**186**		
8	Sand	6.6	20	40	> 365	-	**569**		
9	Sandy loam	7.0	20	40	151	540	**100**		
10	Sandy loam	7.0	30	40	79	311	123 [2]		
11	Sandy loam	7.0	20	40	313	1159	**169**		
12	Loamy sand	7.2	20	40	350	> 365	**177**		
13	Silt loam	7.3	20	40	342	> 365	**151**		
14	Silt loam	7.0	20	50	143	788	97	1.24	
15	Silt loam	7.0	20	50	220	1732	143	2.79	
16	Silt loam	7.0	20	50	183	855	121	1.59	
Mean (n = 3)							**120**		
17	Silt loam	7.0	20	50	232	770	**164**	8.01006	
Geometric mean/Median(n=9)							**175/164**		
pH-dependency:							No		

[1] Duplication with trial no 3 and not included in the calculation of the mean, median and 90th percentile.
[2] Duplication with trial no 9 and not included in the calculation of the mean, median and 90th percentile.

Table 8.3-2: Summary of aerobic degradation rates for CGA192155 - laboratory studies

CGA192155, Laboratory studies, aerobic conditions										
Soil name	**Soil type**	**pH**	**t. ºC**	**MWHC %**	**DT50 (d)**	**DT90 (d)**	**DT50 (d) 20°C pF2/10kPa**	**r^2**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
Gartenacker, CH	Silt loam	7.18	20	70.14	16	52	8.56	0.95532	SFO	Y EFSA, 2007 DK, 2006
Pappelacker, CH	Loamy sand	7.43	20	39.98	24	79	18.3	0.98503	SFO	
Weide, CH	Sandy loam	7.36	20	49.35	16	54	10.8	0.97197	SFO	
Geometric mean (n=3)							11.9			
pH-dependency:							No			

Table 8.3-3: Summary of aerobic degradation rates for CGA339833 - laboratory studies

CGA339833, Laboratory studies, aerobic conditions										
Soil name	**Soil type**	**pH**	**t. ºC**	**MWHC %**	**DT50 (d)**	**DT90 (d)**	**DT50 (d) 20°C pF2/10kPa**	**r^2**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
Gartenacker, CH	Silt loam	7.18	20	40	9	31	5.66	0.9921	SFO	Y EFSA, 2007 DK, 2006
Pappelacker, CH	Loamy sand	7.43	20	40	16	53	12.4	0.9936	SFO	
Weide, CH	Sandy loam	7.36	20	40	12	40	8.15	0.9926	SFO	
Geometric mean (n=3)							8.3			
pH-dependency:							No			

izRMS comments:

Aerobic soil degradation data for fludioxonil and its metabolites presented in Tables 8.3-1 to 8.3-3 above are in line with EU agreed endpoints reported in EFSA Scientific Report (2007) 110 and DAR (Vol. 3, B.8 of 2005).

The normalised geometric mean DT_{50} values calculated by the Applicant are confirmed to be correct.

8.3.2 Anaerobic degradation in soil (KCP 9.1.1.1)

Studies on anaerobic degradation in soil with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance. In case of Fludioxonil, there is practically no degradation under anaerobic conditions.

izRMS comments:

According to EFSA Scientific Report (2007) 110, fludioxonil is practically not degraded under anaerobic conditions.

8.4 Field studies (KCP 9.1.1.2)

Field studies with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substances.

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

Studies on field dissipation rates with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance.

Studies on field dissipation in soil of Fludioxonil have been reviewed during the EU Review of the active substance.

Triggering endpoints

Field dissipation studies for the use of Fludioxonil were part of the EU review on Fludioxonil and are summarized in the EFSA Scientific Report (2007) 110, 1-85. Results from the field dissipation studies on Fludioxonil are given in Table 8.4-1.

Table 8.4-1: Summary of aerobic degradation rates for Fludioxonil - field studies: Triggering endpoints

Fludioxonil, Field studies – Triggering endpoints								
Soil type	**Location**	**pH**	**Depth (cm)**	**DissT50 (d) actual**	**DT90 (d) actual**	**St. (χ^2)**	**Method of calculation**	**Evaluated on EU level y/n/ Reference**
Silty clay loam	France	8.0	0-20	15	49	0.81	SFO	Y EFSA, 2007 DK, 2006
Silt loam	Italy	7.4	0-20	10	34	0.99	SFO	
Sandy loam	Germany	6.3	0-20	28	104	0.85	SFO	
Sand	Germany	7.0	0-20	9	31	0.78	SFO	
Sand to silt loam	Germany	6.2	0-20	8	28	0.81	SFO	
Loam	Germany	6.4	0-30	43	142	0.78	SFO	
Silt loam	Germany	5.9	0-30	14	48	0.71	SFO	
Silt loam	Germany	6.9	0-30	14	47	0.82	SFO	
Sandy loam	Switzerland	7.3	0-10	16	nd	-	SFO	
Maximum (n=9)				43				

izRMS comments:

Presented above field soil degradation data for fludioxonil are in line with EU agreed endpoints reported in EFSA Scientific Report (2007) 110.

Modelling endpoints

For modelling of the PEC ground water and surface water of Fludioxonil, the geometric mean DT_{50} of the laboratory trials of 175 days is used.
Assessment of the PEC in soil of fludioxonil was done following a tiered approach using the worst case laboratory DT50 value of 569 days reported in the EFSA Scientific Report (2007), as the available EU agreed endpoint list only contains field dissipation trials in which the substance is exposed to sunlight (the DT_{50} of 43 days is not relevant for seed treatment uses as it includes photolytic degradation).

izRMS comments:

The izRMS agrees that degradation data taken from studies performed in the dark will better describe soil metabolism of fludioxonil used as a seed treatment.
Soil DT_{50} of 175 days derived from studies performed in the dark and proposed for use in groundwater modelling is marginally longer than relevant EU agreed endpoint of 164 days and represents thus worst case in parent simulations. As no soil metabolites are formed in the dark, consideration of shorter DT_{50} for metabolite simulations is not necessary.

8.4.2 Soil accumulation testing (KCP 9.1.1.2.2)

Since field DT_{50} < 3 months and field DT_{90} < 1 year were observed for Fludioxonil, soil accumulation is not expected to occur. However, studies with annual applications were provided during the EU review. They confirmed that Fludioxonil does not accumulate continuously after repeated use over 8 years, foliar use in grape vine.

- Plateau reached after 4-6 years with a max concentration of 0.7 and 1.1 mg/kg in 0-10 cm soil layer after application of 2x300 or 2x500 g as/ha/year respectively, declining to 0.23 - 0.37 mg/kg in the following years.
- In two 5 year accumulation studies on grapevine (foliar use 2 x 300 g as/ha/year or 1-2x 500 gas/ha/year), the concentration reached a maximum of 2.0 mg/kg and 0.78 mg/kg in the year 3 and 4 respectively, and was declining to 1.35 mg/kg and 0.63 mg/kg within 5 and 3 years, respectively.

The foliar use scenario is considered as worst case and covers for seed treatment use.

For Fludioxonil and its metabolites CGA192155, CGA339833 and CGA265378, also no accumulation was observed after 8 years of use.

izRMS comments:
Provided above information regarding potential of fludioxonil to accumulate in soil is in line with information presented in EFSA Scientific Report (2007) 110. Potential for accumulation of fludioxonil in soil following application of GLOB182F is addressed in soil exposure estimations in point 8.7 of this document.

8.5 Mobility in soil (KCP 9.1.2)

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

Studies on mobility in soil of Fludioxonil have been reviewed during the EU Review of the active substance.

The mobility in soil of Fludioxonil was evaluated during the Annex I Inclusion. No additional studies have been performed.

A summary of the available studies on adsorption/desorption of Fludioxonil and major metabolites in soil is given in Table 8.5-1 to 8.5-3. The results from available studies indicate that Fludioxonil has a strong sorption and a low potential for mobility in soil, while the metabolites CGA192155 and CGA339833 have a weak sorption and are more likely to leach through the soil profile. Metabolite CGA265378 is unstable in soil. The adsorption coefficients could not be directly determined because CGA265378 was already degraded two hours after equilibration with the soil. Due to instability of CGA265378 in aqueous solution, there is no risk of leaching to ground water.

Table 8.5-1: Summary of soil adsorption/desorption for Fludioxonil

Fludioxonil							
Soil name	**Soil type**	**OC (%)**	**pH (-)**	**Kf (mL/g)**	**Kfoc (mL/g)**	**1/n (-)**	**Evaluated on EU level y/n/ Reference**
Gleadthorpe, Nottingham shire	Sand	1.7	6.4	770	46000	0.95	Y EFSA, 2007 DK, 2006
Somersham, Cambridge shire	Sandy loam	2.4	6.5	290	12000	0.81	
Sandiacre, Nottingham shire	Sandy silt loam	3.5	6.9	7300	210000	1.14	
Gool, Humberside	Sandy silt loam	2.8	7.9	2100	75000	0.92	
Ramsey, Cambridgeshire	Silty clay loam	15.8	6.6	61000	385000 ~~38500~~	1.19	
Arithmetic mean (n=5)					145600	1.00	
Geometric mean (n=5)					**80341**		
pH-dependency					No		

Table 8.5-2: Summary of soil adsorption/desorption for CGA192155

CGA192155							
Soil Name	**Soil Type**	**OC (%)**	**pH (-)**	**Kf (mL/g)**	**Kfoc (mL/g)**	**1/n (-)**	**Evaluated on EU level y/n/ Reference**
Lakeland, USA	Sand	0.58	5.3	0.246	42.4	0.789	Y EFSA, 2007 DK, 2006
Hanford, USA	Sandy loam	0.23	7.4	0.0627	27.3	0.841	
Collamer, USA	Loam	2.15	6.5	0.266	12.4	0.811	
Niagara, USA	Loam	2.38	6.7	0.278	11.7	0.769	
Arithmetic mean (n=4)					23.5	0.803	
Geometric mean (n=4)					**20.2**		
pH-dependency					No		

Table 8.5-3: Summary of soil adsorption/desorption for CGA339833

CGA339833							
Soil Name	**Soil Type**	**OC (%)**	**pH (-)**	**Kf (mL/g)**	**Kfoc (mL/g)**	**1/n (-)**	**Evaluated on EU level y/n/ Reference**
Lakeland, USA	Sand	0.58	5.3	0.057	5.79	0.907	Y EFSA, 2007 DK, 2006
Hanford, USA	Sandy loam	0.23	7.4	0.011	1.94	0.072	
Collamer, USA	Loam	2.15	6.5	0.109	5.23	0.861	
Niagara, USA	Loam	2.38	6.7	0.053	3.16	1.080	
Arithmetic mean (n=4)					4.03	0.730	
Geometric mean (n=4)					3.69		
pH-dependency					No		

izRMS comments:

Soil mobility data for fludioxonil and metabolites CGA191155 and CGA339833 presented in Tables 8.5-1 to 8.5-3 above are in general in line with EU agreed endpoints reported in EFSA Scientific Report (2007) 110 with exception of Koc values for fludioxonil in Ramsey soil. Probably due to the typing error value of 38500 has been reported while in line with EFSA report it should be 385000 mL/g. Correct value has been inserted by the izRMS.

The geometric mean Koc values calculated by the Applicant are confirmed to be correct.

Information regarding metabolite CGA265378 is in line with statement provided in the DAR (Vol. 3, B.8 of 2005). However, in the LoEP rough estimates of Koc in range of 36-111 mL/g are reported, resulting with arithmetic mean of 68.3 mL/g and geometric mean of 62.3 mL/g.

8.5.1 Column leaching (KCP 9.1.2.1)

Since reliable adsorption/desorption data were available for Fludioxonil and metabolites, soil column leaching is not formally required. However, soil column leaching studies with "freshly" applied Fludioxonil were submitted during the EU review and the results support the conclusion of the adsorption/desorption tests.

izRMS comments:

Results of column leaching studies were deemed not necessary to finalise evaluation of GLOB182F since potential leaching of fludioxonil following application of GLOB182F as a seed treatment in maize and sunflower is sufficiently addressed in groundwater modelling presented in point 8.8 of this report.

8.5.2 Lysimeter studies (KCP 9.1.2.2)

Since Fludioxonil is of low mobility to soil as confirmed by the column leaching study, lysimeter studies are not formally required and were therefore not performed. The metabolites of Fludioxonil, CGA192155 and CGA339833, exhibit low soil adsorption and are therefore mobile in the soil. However, no lysimeter studies were performed as there is no indication of pronounced leaching in field degradation studies.

izRMS comments:

Lysimeter studies were not required during the EU review of fludioxonil and are also not required to finalise evaluation of GLOB182F. Potential leaching of fludioxonil following application of GLOB182F as a seed treatment in maize and sunflower is sufficiently addressed in groundwater modelling presented in point 8.8 of this report.

8.5.3 Field leaching studies (KCP 9.1.2.3)

Since Fludioxonil is of low mobility to soil as confirmed by the column leaching study, lysimeter studies are not formally required and were therefore not performed. The metabolites of Fludioxonil, CGA192155 and CGA339833, exhibit low soil adsorption and are therefore mobile in the soil. However, no lysimeter studies were performed as there is no indication of pronounced leaching in field degradation studies.

izRMS comments:

Field leaching studies were not required during the EU review of fludioxonil and are also not required to finalise evaluation of GLOB182F. Potential leaching of fludioxonil following application of GLOB182F as a seed treatment in maize and sunflower is sufficiently addressed in groundwater modelling presented in point 8.8 of this report.

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

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

Studies on degradation in water/sediment systems of Fludioxonil have been reviewed during the EU Review of the active substance.

In absence of light, Fludioxonil rapidly disappeared from the water phase in two laboratory water/sediment systems at 20 ºC (DT50 water = 1-2 days) due to adsorption to the sediment (max 94.5% AR at 30d) but degradation in the whole system was greatly slower, with first order DT50 system = 451-699 days. A few minor metabolite fractions, accounting for 0.1 to 5% of the radioactivity applied were observed in the sediment and water extracts, but they were not identified. 14CO2 accounted for 1.6 and 1.9% AR.

In another study the influence of light (artificial sunlight 290-400 nm, 12 hours per day) on degradation in water/sediment systems was investigated for up to 100 days. Fludioxonil was rapidly partitioned to the sediment in both the irradiated systems (max. 53% AR at 7d) and the dark controls (about 70% AR after 15 days and increasing up to 83.5-85.6% AR at the end of the study). The calculated DT50 water values by 2-compartment first order kinetics for Fludioxonil were 6-7 days in the dark control and less than 2 days in the light exposed systems. As Fludioxonil concentrations in sediment increased during the test, no degradation rates could be calculated. The dissipation of Fludioxonil in the total irradiated system was estimated to be 19-25 days. The only major metabolite was CGA 192155, which amounted to a maximum of 10.2-11.9% AR in the water phase under light/dark conditions.

In an outdoor aquatic microcosm study water and sediment phases were analysed for Fludioxonil residues for up to 112 days after the application. Fludioxonil dissipated with an estimated half-life of 10 days (whole system). Only low sediment residues of Fludioxonil were observed, with estimated first-order DT50 system ranging from 51 to 154 days.

Table 8.6-1: Summary of degradation in water/sediment of Fludioxonil

Fludioxonil										
Water/sediment system	**pH water/ sed.**	**DegT50 whole syst. (d)**	**DegT90 whole syst. (d)**	**Kinetic, Fit**	**DissT50 water (d)**	**DissT90 water (d)**	**Kinetic, Fit**	**DissT50 sed. (d)**	**Kinetic, Fit**	**Evaluated on EU level y/n/ Reference**
Tugbach, pond	8.4/6.9	699	2323	SFO	-	-	-	-	-	Y EFSA, 2007 DK, 2006
Rhine, river	8.4/7.2	451	1499	SFO	-	-	-	-	-	
Geometric mean (n=2)		561	1866							

Table 8.6-2: Summary of degradation in water/sediment of Fludioxonil in light

Fludioxonil										
Water/sediment system	**pH water/ sed.**	**DegT50 whole syst. (d)**	**DegT90 whole syst. (d)**	**Kinetic, Fit**	**DissT50 water (d)**	**DissT90 water (d)**	**Kinetic, Fit**	**DissT50 sed. (d)**	**Kinetic, Fit**	**Evaluated on EU level y/n/ Reference**
Fröschweiher, pond	7.4-9.0/7.2	18.8	133	SFO	1.7	9.8	SFO	57.8	SFO	Y EFSA, 2007 DK, 2006
Rhine, river	8.0-8.9/7.2	25.2	148	SFO	1.8	14.5	SFO	65.4	SFO	
Geometric mean (n=2)		21.8	140		1.7	11.9		61.5		

izRMS comments:

Information on degradation of fludioxonil in water/sediment systems presented in Tables 8.6-1 and 8.6-2 is in line with data reported in EFSA Scientific Report (2007) 110.

The geometric mean DT_{50} values calculated by the Applicant are confirmed to be correct.

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

8.7.1 Justification for new endpoints

No deviations from the EU agreed endpoints was made.

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

The PEC soil calculations were performed with the FOCUS model for a standard soil considering a dry soil bulk density of 1.5 g/cm^3 and 5cm soil depth in agreement with the recommendation of the EU guideline FOCUS (1997) [1]. A crop interception of 0% was considered as GLOB182F is used as a seed treatment. The application rate in g as/ha was calculated based on a sowing rate of 47.5 kg/ha and a dose rate of 50 g as/ton seeds, which equals to 2.375 g as/ha.

Input parameters for the PEC soil calculations related to the application of GLOB182F are summarized in tables 8.7-1 and 8.7-2 below.

Table 8.7-1: Input parameters related to application for PEC_{soil} calculations

Use No.	1
Crop	Maize, sunflower
Application rate (g as/ha)	Fludioxonil: 2.375 g as/ha
Number of applications/interval	1/365 d
Crop interception (%)	0% (seed treatment)
Depth of soil layer (relevant for plateau concentration) (cm)	5 cm

Table 8.7-2: Input parameter for active substance(s) for PEC_{soil} calculation

Compound	**Molecular weight (g/mol)**	**Max. occurrence (%)**	**DT50 [1] (days)**	**Value in accordance to EU endpoint y/n/ Reference**
Fludioxonil	248.2	100	569	Y / EFSA (2007)

PEC_s immediately after sowing treated seeds were calculated using FOCUS guidance[2] (i.e. current guidance) with the following equation:

$$PEC_{S,\,ini} = [A * (1-f_{int})]/(100 * d * bd)$$

where: A = application rate
f_{int} = fraction intercepted by plant cover
d = depth of the soil
bd = bulk soil density (g/cm3)

The actual PEC_S at specific times (t) after the sowing of treated seeds are calculated with the formula:

$$PEC_{S,\,actual} = PEC_{S,ini} * e^{-k.t}$$

where: $k = \ln(2)/DT_{50}$;
t: time period.

[1] FOCUS (1997) Soil persistence models and EU Registration - The Final Report of the Soil Modelling Workgroup of FOCUS (Forum for the Co-ordination of Pesticide Fate Models and their Use) – 29 February 1997.
[2] FOCUS (1997) Soil persistence models and EU Registration - The Final Report of the Soil Modelling Workgroup of FOCUS (Forum for the Co-ordination of Pesticide Fate Models and their Use) – 29 February 1997.

The maximum ('moving window') time weighted average (TWA) PEC values are found by calculating a set of TWA PECs over a time window that is moved along the time axis. The average PEC within a day is calculated by:

$$PEC_{twa} = PEC_{S,ini} \cdot (1 - e^{-k*t})/(k*t)$$

<u>Accumulation PEC_{soil} (mg a.s./kg soil)</u>

Additionally $PEC_{soil\ plateau}$ and $PEC_{soil\ accu}$ were calculated.

$PEC_{soil\ plateau}$ was calculated using the following equation:

$$Average\ PECsoil\ plateau = \frac{\text{Initial PECs for 1 application}}{\text{ki}}$$

$$Maximun\ PECsoil\ plateau = \frac{\text{Initial PECs for 1 application}}{(1 - e^{-ki})}$$

where:
Initial PECs is considering a mixing depth of 20cm
k= degradation rate constant = ln(2)/DT50
i = time interval between 2 applications = 365 days (i.e. 1 year)

$PEC_{soil\ accu}$ was calculated using the following formula:

$$PECsoil\ accu = max\ PECsoil\ plateau + PECs\ ini$$

where max $PEC_{soil\ plateau}$ is considering mixing depth of 20cm and $PEC_{s\ ini}$ is considering 5cm.
A soil layer depth of 20 cm was considered for the calculations as a conservative assumption for mixing by soil cultivation.

Results of the calculations are presented in Table 8.7-3.

Table 8.7-3: PEC_{soil} for Fludioxonil on Maize and sunflower

PEC_{soil} (mg/kg)		**Maize, sunflower**			
		Single application		**Multiple applications**	
		Actual	**TWA**	**Actual**	**TWA**
Initial		0.0032	-	-	-
Short term	24h	0.0032	0.0032	-	-
	2d	0.0032	0.0032	-	-
	4d	0.0032	0.0032	-	-
Long term	7d	0.0031	0.0032	-	-
	14d	0.0031	0.0031	-	-
	21d	0.0031	0.0031	-	-
	28d	0.0031	0.0031	-	-
	50d	0.0030	0.0031	-	-
	100d	0.0028	0.0030	-	-
$PEC_{s,plateau}$ (20 cm) with tillage after year 11		0.00565			
$PEC_{s,accumulation}$ ($PEC_{s,accumulation} = PEC_{s,ini} + PEC_{s,plateau}$)		0.00882			

PEC_{soil} of metabolites

No relevant metabolites in soil have to be considered for Fludioxonil. Following the use of Fludioxonil as a seed treatment product, only the degradation in the dark has to be taken into account as the treated seeds are incorporated into the soil. As the metabolites of Fludioxonil are only formed in the light by photolysis, they are not relevant for the use of Fludioxonil as seed treatment product.

izRMS comments:

Soil exposure has been calculated with consideration of the maximum application rate indicated in the GAP, covering all intended uses of GLOB182F in maize and sunflower.

It is noted that according to EFSA Scientific Report (2007) 110, the maximum field soil DT_{50} of 43 days should be used to calculate the soil exposure to fludioxonil. In case of GLOB182F, the Applicant decided to use the maximum normalised laboratory DT_{50} of 569 days, as being. Value taken into account by the Applicant represents worst case in terms of the soil accumulation potential and is thus agreed by the izRMS, especially it is more relevant for degradation of the active compound in the dark due to use as a seed treatment.

Soil exposure calculated by the Applicant has been independently validated by the izRMS using ESCAPE ver. 2. The same initial, short-term, long-term and TWA values were obtained, while $PEC_{soil,\ accu}$ were lower comparing to those obtained by the Applicant. Taking this into account, PEC_{soil} values provided in table 8.7-3 are agreed and may be used for the risk assessment purposes.

It should be noted that at the EU level photolytic metabolites: CGA 265378, CGA 192155 and CGA 339833 were also considered relevant for soil exposure assessment due to max occurrence >10% AR. However, as GLOB182F is applied as a seed treatment, soil photolysis will only marginally, if at all, contribute to metabolism of fludioxonil in soil and for this reason photolytic metabolites do not have to be considered in soil exposure calculations.

8.7.2.1 PEC_{soil} of GLOB182F

An initial PECsoil value for the formulation has also been calculated for the risk envelope assuming a maximum sowing rate of 47.5 kg per ha and a formulation density of 1.05 g/mL (25.11 g formulation per ha).

Table 8.7-4: PEC_{soil} for GLOB182F on maize, sunflower

Active substance/ reparation	Application rate (g/ha)	PEC_{act} (mg/kg)	PEC_{twa}21 d (mg/kg)	Tillage depth (cm)
GLOB182F	25.113	0.03348	-	5

Time-dependent PEC_{soil} values are not appropriate for the formulation, since it is considered to separate into its constituent components by transport and dissipation processes in the environment.

izRMS comments:

It is noted that the maximum application rate of 23.75 mL product/ha is indicated in the GAP, resulting with 24.94 g product/ha when relative density of 1.05 g/mL is considered. Nevertheless, as for the provided above calculations the Applicant used slightly higher application rate (23.92 mL product/ha), performed calculations represent worst case and are thus agreed by the izRMS.

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

8.8.1 Justification for new endpoints

The following table provides the EU agreed endpoints and the endpoints used in the evaluation for the PEC_{gw} calculations on Fludioxonil. Deviations from the EU agreed endpoints were made in line with the new 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).

Agreed EU End-points used for the PEC_{gw} calculations of Fludioxonil (EFSA Scientific Report 2007;110:1-85)

End-Point	**Fludioxonil**		
	Agreed EU endpoint	**Endpoint used in evaluation**	**Remark**
Molecular weight [g mol^{-1}]	248.2	248.2	-
Water solubility (25°C) [mg L^{-1}]	1.8	1.8	-
Vapour pressure (25°C) [Pa]	3.9 x 10^{-7}	3.9 x 10^{-7}	-
DT_{50} soil [days]	164	**175**	During the EU review, the median of the lab DT_{50} was used. Here the geometric mean was used in accordance with EFSA Journal 2014;12(5):3662.
Kfoc [mL g^{-1}]	145600 ~~145000~~	**80341**	During the EU review, the arithmetic mean of the Kfoc was used. Here the geometric mean was used in accordance with EFSA Journal 2014;12(5):3662.
Freundlich exponent 1/n [-]	1.0	1.0	-
pH dependence, Yes or No	No	No	-

izRMS comments:

According to SANCO/10328/2004 rev. 8 at the zonal level the new active substance data may be considered only in exceptional cases and in general EU agreed endpoints should be used. Nevertheless, the endpoints proposed by the Applicant and deviating from the EU agreed values (geometric mean DT_{50} and Kfoc for fludioxonil) represent worst case in terms of the groundwater modelling and are thus agreed by the zRMS. Both values were derived from the EU agreed individual values for particular soils and are confirmed to be correct.

It is noted that at the EU level average Kfoc of 145000 mL/g has been indicated as relevant for the groundwater modelling, while 145600 mL/g has been calculated based on individual values (see page 55 of the LoEP).

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

The applicant submitted a report in which the PECgw of Fludioxonil was calculated. This report is presented below.

Report:	KCP 9.2.4.1, Fernandez D., 2020a
Title:	GLOB182F - Estimations of the PECgw of Fludioxonil for the intended use as a seed treatment formulation in maize and sunflower.
Document No:	GLOB182F-GW
Guidelines:	"Assessing Potential for Movement of Active Substances and their Metabolites to Ground Water in the EU" Report of the FOCUS Ground Water Work Group, Version 3 of 10 October 2014. EC Document Reference Sanco/13144/2010 version 3, 613 pp. "Focus Groundwater scenarios in the EU review of active substances" - The report of the work of the Groundwater Scenarios Workgroup of FOCUS (FOrum for the Co-ordination of pesticide fate models and their USe), Version 1 of November 2000. EC Document Reference SANCO/321/2000 rev. 2, 202 pp. "Generic Guidance for Tier 1 FOCUS Groundwater Assessments (version 2.2)"
GLP	No

The PEC of Fludioxonil in groundwater has been assessed with standard FOCUS scenarios to obtain outputs from the FOCUS PELMO 5.5.3 and FOCUS PEARL 4.4.4 models and the K_{oc} values established in the EU review. The application rate in g as/ha was calculated based on a sowing rate of 47.5 kg/ha and a dose rate of 50 g as/ton seeds, which equals to 2.375 g as/ha.

Input parameters for the PEC_{gw} calculations related to the application of GLOB182F are summarized in Tables 8.8-1 and 8.8-2 below.

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

Use No.	1 to 4
Crop	Maize, sunflower
Application rate (g as/ha)	Fludioxonil: 2.375 g as/ha (worst case use on Maize)
Number of applications/interval (d)	1/year
Relative application date	7 days before emergence
Crop interception (%)	0%
Frequency of application	Annual
Models used for calculation	FOCUS PEARL v4.4.4 FOCUS PELMO v5.5.3

Table 8.8-2: Input parameters related to active substance Fludioxonil for PEC_{gw} calculations

Parameter	**Fludioxonil**	**Remarks**
PHYSICO-CHEMICAL PARAMETERS		
Molecular weight [g mol^{-1}]	248.2	LoEP Fludioxonil Physical and chemical properties
Water solubility [mg L^{-1}] (25°C)	1.8	LoEP Fludioxonil Physical and chemical properties
Molar enthalpy of dissolution [kJ mol^{-1}]	27	FOCUS recommendation
Vapour pressure [Pa] (25°C)	3.9 x 10^{-7}	LoEP Fludioxonil Physical and chemical properties
Molar enthalpy of vaporization [kJ mol^{-1}]	95	FOCUS recommendation
Diffusion coefficient in water [m² d^{-1}]	4.3 x 10^{-5} (20 °C) (Pearl)	FOCUS recommendation
Diffusion coefficient in gas [m² d^{-1}]	0.43 (20 °C)	FOCUS recommendation
DEGRADATION IN SOIL		
Metabolites formation fraction [-] source $\rightarrow$ sink relation [-]	N/A	LoEP Fludioxonil Fate and behaviour

DT_{50} soil [d]	175 days (n = 9)	LoEP Fludioxonil Fate and behaviour Geometric mean of laboratory studies (normalised to 20°C and pF2) in accordance with EFSA Journal 2014;12(5):3662.
Temperature correction function Reference temperature [°C] MACRO: [K^{-1}] PRZM: Q_{10} [-]	 20 0.095 2.58	 FOCUS recommendation EFSA recommendation DAR
Moisture correction function Reference moisture [-] PRZM / MACRO: moisture exponent [-]	 pF 2 0.7	 FOCUS recommendation
SORPTION TO SOIL		
$K_{f,oc}$ [mL g^{-1}]	80341 (n = 5)	LoEP Fludioxonil Fate and behaviour Geometric mean in accordance with EFSA Journal 2014;12(5):3662.
$K_{f,om}$ [mL g^{-1}]	46601	$K_{f,om} = K_{f,oc}/1.724$
Freundlich exponent 1/n [-]	1.0 (n = 5)	LoEP Fludioxonil Fate and behaviour Arithmetic mean
Method of sorption subroutine description	pH independent	LoEP Fludioxonil
CROP/ MANAGEMENT RELATED PARAMETERS		
Crop uptake factor [-]	0	FOCUS recommendation

The results of the PEC_{gw} for Fludioxonil are presented in the table 8.8-3 for the FOCUS PEARL 4.4.4 and PELMO 5.5.3 models.

Fludioxonil has a biphasic degradation as shown in the degradation pathway below.

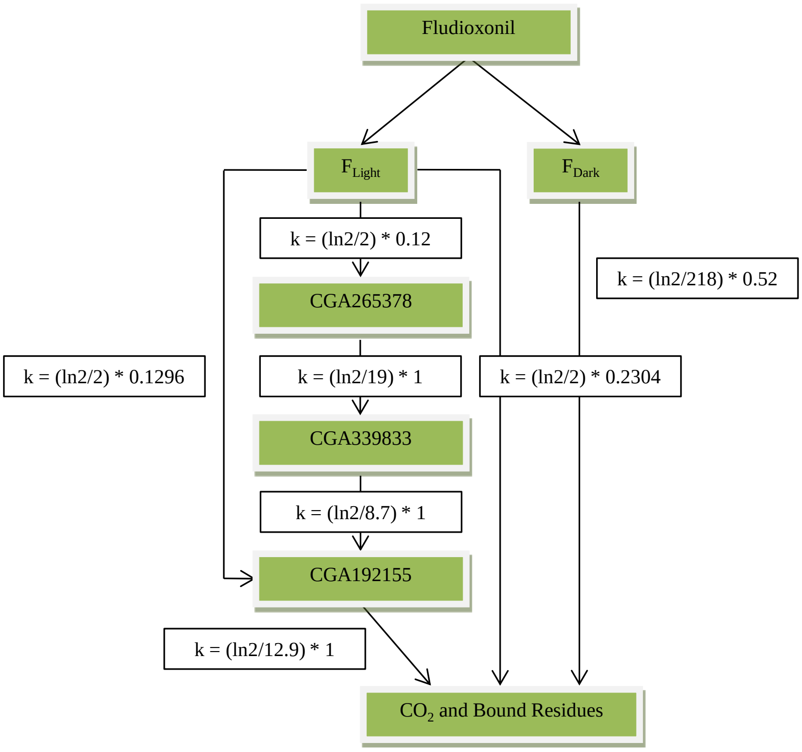


Figure 8.8-1. Degradation pathway of Fludioxonil.

Following the use of Fludioxonil as a seed treatment product, only the degradation in the dark has to be considered as the treated seeds are incorporated into the soil. As the metabolites of Fludioxonil are only formed in the light by photolysis, they are not relevant for the use of Fludioxonil as seed treatment product.

Table 8.8-3: PEC_{gw} for Fludioxonil on maize and sunflower (with FOCUS PEARL 4.4.4/PELMO 5.5.3)

Crop	Scenario	80th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)	
		PEARL 4.4.4	PELMO 5.5.3
Maize	Châteaudun	0.000000	0.000
	Hamburg	0.000000	0.000
	Kremsmünster	0.000000	0.000
	Okehampton	0.000000	0.000
	Piacenza	0.000000	0.000
	Porto	0.000000	0.000
	Sevilla	0.000000	0.000
	Thiva	0.000000	0.000
Sunflower	Piacenza	0.000000	0.000
	Sevilla	0.000000	0.000

Conclusion

The results of the leaching models PEARL 4.4.4 and PELMO 5.5.3 show that when used according to the intended use in maize and sunflower in the EU, Fludioxonil leaches in acceptable amounts to groundwater in every European scenario. Based on these results, it is concluded that Fludioxonil is not expected to exceed the threshold level in groundwater (0.1 µg/L) when GLOB182F is used at the intended GAP in the intended crop.

izRMS comments:

The input parameters presented in Table 8.8-1 related to the application pattern are agreed by the izRMS. The maximum application rate considered in performed simulations covers all intended application rates of GLOB182F.

Input parameters presented in Table 8.8-2 are in general in line with the EU agreed endpoints reported in EFSA Scientific Report (2007) 110 with following exceptions:

1. Geometric mean soil DT_{50} of 175 days was taken into account instead of the median EU agreed value of 164 days.
   As already mentioned in the izRMS comment in point 8.8.1, new active substance data should not be generated at the zonal level, unless critical for the exposure assessment. Recalculation of the geometric mean DT_{50} was not critical for the groundwater simulations, as sufficient data were available from the EU review. Nevertheless, value considered by the Applicant represents worst case comparing to the EU agreed endpoint and is thus agreed by the izRMS for the parent simulations.
2. Geometric mean Kfoc of 80341 mL/g was taken into account instead of the arithmetic mean EU agreed value of 145600 mL/g.
   As already mentioned in the izRMS comment in point 8.8.1, new active substance data should not be generated at the zonal level, unless critical for the exposure assessment. Recalculation of the geometric mean Kfoc was not critical for the groundwater simulations, as sufficient data were available from the EU review. Nevertheless, value considered by the Applicant represents worst case comparing to the EU agreed endpoint and is thus agreed by the izRMS.

No other deviations from the EU agreed endpoints were noted.

The metabolic scheme assumed by the Applicant is agreed by the izRMS. According to the LoEP and in line with Figure 8.8-1 above, when applied as a spray treatment, fludioxonil is expected to undergo bi-phasic degradation pattern with fast phase observed in the light and slow phase observed in the dark. As correctly indicated by the Applicant, seeds treated with GLOB182F will be covered with soil and for this reason only degradation in the dark is considered relevant for fludioxonil used as a seed treatment. Taking this into account, only DT_{50} determined for dark conditions should be assumed in performed simulations, while metabolites are not taken into account as in available regulatory studies they were formed only in presence of light.

Groundwater modelling has been performed using FOCUS PEARL 4.4.4 and PELMO 5.5.3 for all scenarios defined for maize and sunflower. It is noted that for sunflower only one scenario relevant for the Central Zone is defined (Piacenza). However, no additional simulations for the surrogate crop were performed, since maize may be considered as sufficient surrogate for sunflower. As all relevant Central Zone scenarios are defined for maize, modelling performed for this crop is considered sufficiently protective for application to sunflower.

In line with recommendations of the Central Zone guidance document in area of Section 8[3], MACRO simulations were not required, since PEC_{GW} values calculated using FOCUS PEARL and FOCUS PELMO were <0.001 µg/L.

Groundwater exposure was independently validated by the izRMS using Central Zone application pattern and EU agreed endpoints. The same results were obtained, which was expected based on high Kfoc of fludioxonil implying that this substance is not mobile in soil.

Overall, based on the results of the performed groundwater modelling, no unacceptable leaching of fludioxonil at concentrations exceeding 0.1 µg/L is expected when GLOB182F is used according to the Central Zone GAP.

Please note that additional groundwater modelling may be required by the concerned Member States that do not accept simulations performed according to FOCUS recommendations.

[3] Working document of the Central Zone in the authorisation of plant protection products, Section 8, Environmental fate and behaviour. Version 1, rev. 1, June 2018

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

8.9.1 Justification for new endpoints

The following table provides the EU agreed endpoints and the endpoints used in the evaluation for the PEC_{sw} calculations on Fludioxonil and its relevant metabolite CGA192155. Deviations from the EU agreed endpoints were made in line with the new 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).

Agreed EU End-points used for the PEC_{sw} calculations of Fludioxonil and its metabolite CGA192155 (EFSA Scientific Report 2007;110:1-85)

End-Point	Fludioxonil		CGA192155		Remark
	Agreed EU endpoint	**Endpoint used in evaluation**	**Agreed EU endpoint**	**Endpoint used in evaluation**	
Molecular weight [g mol^{-1}]	248.2	248.2	202.1	202.1	-
Molar correction factor	1	1	0.814	0.814	-
DT_{50} soil [days]	164	**175**	12.9	**12**	During the EU review, the median of the lab DT_{50} was used. Here the geometric mean was used in accordance with EFSA Journal 2014;12(5):3662.
K_{foc} [mL g^{-1}]	145000	**80341**	23.5	**20**	During the EU review, the arithmetic mean of the Kfoc was used. Here the geometric mean was used in accordance with EFSA Journal 2014;12(5):3662.
Freundlich exponent 1/n [-]	1.0	1.0	1.0	1.0	-
pH dependence, Yes or No	No	No	No	No	-
Maximum occurrence in soil [%] source -> sink relation [-]	100	100	11.7 Parent → CGA 192155	11.7 Parent → CGA 192155	-
Water/sediment DT_{50} (d)	14	14	1000	1000	-
Water DT_{50} (d)	22	22	1000	1000	-
Sediment DT_{50} (d)	1000	1000	1000	1000	-
Maximum occurrence in water/sediment [%] source -> sink relation [-]	100	100	17.3 Parent → CGA 192155	17.3 Parent → CGA 192155	-

izRMS comments:

According to SANCO/10328/2004 rev. 8 at the zonal level the new active substance data may be considered only in exceptional cases and in general EU agreed endpoints should be used. Nevertheless, the endpoints for fludioxonil proposed by the Applicant and deviating from the EU agreed values (geometric mean DT_{50} and Kfoc) represent worst case and are thus agreed by the zRMS.

It is noted that at the EU level average Kfoc of 145000 mL/g has been indicated as relevant for the groundwater modelling, while 145600 mL/g has been calculated based on individual values (see page 55 of the LoEP).

With regard to metabolite CGA192155, the geometric mean Kfoc of 20 mL/g represents worst case comparing to the EU agreed value of 23.5 mL/g and is thus agreed by the izRMS. The geometric mean DT_{50} of 12 days considered for this compound is slightly shorter than 12.9 days used at the EU level. Nevertheless, difference between both values is minor and is not expected to have significant impact on the obtained results. For this reason recalculated endpoint is accepted by the izRMS.

All geometric mean values were derived from the EU agreed individual values for particular soils and are confirmed to be correct.

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

The applicant submitted a report in which the PEC_{sw} of Fludioxonil was calculated. This report is presented below.

Report:	**KCP 9.2.5, Fernandez D., 2020b**
Title:	GLOB182F - Estimations of the PEC_{sw} and PEC_{sed} of Fludioxonil and relevant metabolites for the intended use as a seed treatment formulation in maize and sunflower.
Document No:	GLOB182F-SW
Guidelines:	FOCUS (1997). “Surface Water Models and EU Registration of Plant Protection Products.” European Commission Document 6476/VI/96. 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. 245 pp “Generic Guidance for Surface Water Scenarios (version 1.4)”, May 2015, Summary of changes made since the official FOCUS Groundwater Scenarios Report (SANCO/4802/2001 rev.2).
GLP	No

PEC surface water calculations are provided for the intended use of GLOB182F in maize and sunflower. The input parameters related to the application are shown in Tables 8.9-1 and 8.9-2 below. The application rate for each crop type used in the calculations is the highest rate in every crop and is taken as worst case.

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

Use No.	1	4
Crop	Maize	Sunflower
Application rate (g as/ha)	2.375 g as/ha	1.6875 g as/ha
Number of applications/interval (d)	1/year	1/year
Application window STEP 1&2	Northern Europe: Mar-May Southern Europe: Mar-May	Northern Europe: Mar-May Southern Europe: Mar-May
Application method	Step 1 & 2: no drift (soil incorporated or seed treatment)	Step 1 & 2: no drift (soil incorporated or seed treatment)
Models used for calculation	FOCUS STEPS 1&2 v3.2	FOCUS STEPS 1&2 v3.2

The PEC of Fludioxonil and relevant metabolite in surface water and sediment has been assessed with standard FOCUS scenarios to obtain outputs from the FOCUS STEP 1 & 2 models. A summary of the input parameters used for the STEP 1 and STEP 2 for Fludioxonil and its metabolite CGA192155 is given in the following Table 8.9-2.

Table 8.9-2: Input parameters related to active substance Fludioxonil and metabolite CGA192155 for $PEC_{sw/sed}$ calculations STEP 1/2

Parameter	**Fludioxonil**	**CGA192155**	**Remarks**
Entry routes into surface water	Runoff Drainage	Runoff Drainage	-
Molecular weight [g mol^{-1}]	248.2	202.1	LoEP Fludioxonil Phys.-chem. Properties
Water solubility [mg L^{-1}] (25°C)	1.8	4900	LoEP Fludioxonil Phys.-chem. Properties
Vapour pressure [Pa] (25°C)	3.9 x 10^{-7}	3.7 x 10^{-5}	LoEP Fludioxonil Phys.-chem. properties Not used in simulations for GLOB182F (only Step 1&2 considered)
Activation Energy [J/mol] MACRO: [K^{-1}] PRZM: Q_{10} [-]	65400 0.0948 2.2	Not used	FOCUS recommendation At the time of EU review Q10 of 2.2, a of 0.079 K^{-1} and activation energy of 54000 J/mol were used; activation energy and “a” given in column 2 are in line with current recommendations. However, neither value was used in simulations for GLOB182F (only Step 1&2 considered)
Reference moisture [-] PRZM/MACRO: moisture exponent [-]	pF2 0.7	Not used	FOCUS recommendation Not used in simulations for GLOB182F (only Step 1&2 considered)
DEGRADATION IN SOIL			
DT_{50} soil [d]	175 days (n = 9)	12 days (n=3)	LoEP Fludioxonil Fate and behaviour Geometric mean of laboratory studies (normalised to 20°C and pF2) in accordance with EFSA Journal 2014;12(5):3662.
Maximum occurrence in soil [%] source -> sink relation [-]	100	11.7	LoEP Fludioxonil Fate and behaviour
SORPTION TO SOIL			
$K_{f,oc}$ [mL g^{-1}]	80341 (n=5)	20 (n=4)	LoEP Fludioxonil Fate and behaviour Geometric mean in accordance with EFSA Journal 2014;12(5):3662.
$K_{f,om}$ [mL g^{-1}]	46601	11.7 ~~7.9~~	$K_{f,om} = K_{f,oc}/1.724$ Not used in simulations for GLOB182F (only Step 1&2 considered)
Freundlich exponent 1/n [-]	1 (n=5)	1 (n=4)	LoEP Fludioxonil Fate and behaviour Arithmetic mean Not used in simulations for GLOB182F (only Step 1&2 considered)
DEGRADATION IN AQUATIC SYSTEMS			

DT_{50} total system [d] (Step 1)	14	1000	LoEP Fludioxonil Fate and behaviour mean DT_{50} whole system default value for CGA192155
DT_{50} water [d] (Step 2, Step 3)	22	1000	LoEP Fludioxonil Fate and behaviour longest DT_{50} whole system default value for CGA192155
DT_{50} sediment [d] (Step 2, Step 3)	1000	1000	Default value
Maximum occurrence in water/sediment [%] source -> sink relation [-]	100	17.3 Parent → CGA192155	LoEP Fludioxonil Fate and behaviour
DEGRADATION IN AQUATIC SYSTEMS			
Crop uptake factor [-]	0	0	FOCUS recommendation Not used in simulations for GLOB182F (only Step 1&2 considered)
Wash off coefficient PRZM: [cm^{-1}] MACRO: [mm^{-1}]	0.5 0.05	20 65 400	FOCUS recommendation Not used in simulations for GLOB182F (only Step 1&2 considered)

$PEC_{sw/sed}$

The predicted environmental concentrations in surface water (PEC_{SW}) and sediment (PEC_{SED}) for Fludioxonil after one application of GLOB182F maize and sunflower were calculated in a first tier approach, using the modelling software STEPS 1-2 in FOCUS 3.2.

The standard assumptions of “STEPS 1-2 in FOCUS” common to both steps 1 and 2 are as follows. The water depth was assumed to be 30 cm overlying sediment of 5 cm depth. The density and the organic carbon content of the sediment were 0.8 g/cm^3 and 5%, respectively. The water body was assumed to have an area equivalent to one tenth of the field from which it receives runoff or drainage water.

A main characteristic of step 1 calculation is that an application leads to inputs via spray drift, runoff, erosion and drainage which are evaluated as a single loading to the water body. All inputs are assumed to occur at the same time. Considering one application, this loading to surface water is based upon the maximum single use rate multiplied by the number of applications.

In contrast to this, at step 2, one application causes a series of individual loadings, i.e. firstly substance inputs entering the water body via drift directly after application, followed by a runoff, erosion and/or drainage event occurring 4 days after the application.

PECsw and PECsed calculations for Fludioxonil maize and sunflower using FOCUS Step 1,2 are shown in Table 8.9-3 and 8.9-4 respectively.

Table 8.9-3: FOCUS Step 1, 2 ~~and 3~~ PEC_{sw} and PEC_{sed} for Fludioxonil following single application of GLOB182F to Maize

Scenario FOCUS	Waterbody	Dominant entry route	Date of max PEC_{sw}	Max PEC_{sw} (µg/L)	21 d- $PEC_{sw,twa}$ (µg/L)	Max PEC_{sed} (µg/kg)
Step 1	---	---	---	0.0073	0.0046	5.8826
Step 2						
Northern Europe	Mar-May	Run-off and drainage	---	0.0014	0.0014	1.1580
Southern Europe	Mar-May	Run-off and drainage	---	0.0029	0.0028	2.3209

Table 8.9-4: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for Fludioxonil following single application of GLOB182F to sunflower

Scenario FOCUS	Waterbody	Dominant entry route	Date of max PEC_{sw}	Max PEC_{sw} (µg/L)	21 d- $PEC_{sw,twa}$ (µg/L)	Max PEC_{sed} (µg/kg)
Step 1	---	---	---	0.0052	0.0032	4.1797
Step 2						
Northern Europe	Mar-May	Run-off and drainage	---	0.0010	0.0010	0.8228
Southern Europe	Mar-May	Run-off and drainage	---	0.0020	0.0020	1.6456

The aquatic risk assessment for Fludioxonil is driven by the chronic toxicity to *Daphnia magna* with a 21d NOEC of 0.005 mg/L for the active substance Fludioxonil (see section B9). Taking into account an Annex VI TER trigger value of 10, PECsw values should be lower than 0.5 µg/L (the regulatory acceptable concentration, RAC). All PECsw calculated with FOCUS STEP 1 & 2 above are below this threshold, therefore no further FOCUS STEP 3 calculations were performed. The maximum PECsw of 0.0073 µg/L (Maize, STEP 1) can be used for risk assessment.

Metabolites of Fludioxonil

PECsw and PECsed were also calculated for the Fludioxonil metabolite CGA192155 using FOCUS SW STEP 1 & 2 model. No PECsw and PECsed was calculated for the other two metabolites of Fludioxonil (CGA265378 and CGA339833) as water/sediment studies in the dark showed no detection of metabolites. However, metabolite CGA192155 was detected in a light-exposed water/sediment study in significant amounts of 17.3% in water/sediment and since it is a soil metabolite, it is considered for PEC_{sw} calculations. The application rate of the “metabolite” was calculated internally by FOCUS SW STEP 1 & 2 based on the maximum percentage found in soil and the difference in molecular weight.

Tables 8.9-5 and 8.9-6 below summarize the PECsw and PECsed for metabolite CGA192155 in the different crops calculated using FOCUS STEPS 1 & 2.

Table 8.9-5: FOCUS Step 1 & 2 PEC_{sw} and PEC_{sed} for metabolite CGA192155 following single application of GLOB182F to maize

Scenario FOCUS	Waterbody	Dominant entry route	Max PEC_{sw} (µg/L)	21 d- $PEC_{sw,twa}$ (µg/L)	Max PEC_{sed} (µg/kg)
Step 1	---	---	0.1825	0.1811	0.0365
Step 2					
Northern Europe	Mar-May	Run-off and drainage	0.0331	0.0329	0.0066
Southern Europe	Mar-May	Run-off and drainage	0.0662	0.0657	0.0132

Table 8.9-6: FOCUS Step 1 & 2 PEC_{sw} and PEC_{sed} for metabolite CGA192155 following single application of GLOB182F to sunflower

Scenario FOCUS	Waterbody	Dominant entry route	Max PEC_{sw} (µg/L)	21 d- $PEC_{sw,twa}$ (µg/L)	Max PEC_{sed} (µg/kg)
Step 1	---	---	0.1296	0.1286	0.0259
Step 2					
Northern Europe	Mar-May	Run-off and drainage	0.0235	0.0233	0.0047
Southern Europe	Mar-May	Run-off and drainage	0.0470	0.0467	0.0094

The aquatic risk assessment for the Fludioxonil metabolite CGA192155 is driven by the acute toxicity to *Rainbow trout (Oncorhynchus mykiss)* and *Daphnia magna* with a 96h LC_{50}/48h EC_{50} of > 100 mg/L (see section B9). Taking into account an Annex VI TER trigger value of 100, PEC_{sw} values should be lower than 1 mg/L (or 1000 µg/L). For each crop all PEC_{sw} for metabolite CGA192155 calculated with FOCUS STEP 1 & 2 are below this threshold, therefore no further FOCUS STEP 3 calculations were performed. The maximum PECsw of 0.1825 µg/L (Maize, STEP 1) can be used for risk assessment.

izRMS comments:

The input parameters presented in Table 8.9-1 related to the application pattern are agreed by the izRMS. The maximum application rates considered in performed simulations cover all intended application rates of GLOB182F in both crops.

Input parameters presented in Table 8.9-2 are in general in line with the EU agreed parameters reported in EFSA Scientific Report (2007) 110 with following exceptions:

1. Geometric mean soil DT_{50} of 175 days was taken into account for fludioxonil instead of the median EU agreed value of 164 days.
   As already mentioned in the izRMS comment in point 8.9.1 above, new active substance data should not be generated at the zonal level, unless critical for the exposure assessment. Recalculation of the geometric mean DT_{50} was not critical for the surface water simulations, as sufficient data were available from the EU review. Nevertheless, value considered by the Applicant represents worst case comparing to the EU agreed endpoint and is thus agreed by the izRMS.
2. Geometric mean soil DT_{50} of 12 days was taken into account for metabolite CGA192155 instead of the EU agreed value of 12.9 days.
   As already mentioned in the izRMS comment in point 8.9.1 above, new active substance data should not be generated at the zonal level, unless critical for the exposure assessment. Recalculation of the geometric mean DT_{50} was not critical for the surface water simulations, as sufficient data were available from the EU review. Nevertheless, difference between DT_{50} considered in calculations and EU agreed endpoint is minimal and is considered to have no significant impact on obtained results. Taking this into account, value used by the Applicant is accepted by the izRMS.
3. Geometric mean Kfoc of 80341 and 20.0 mL/g were taken into account for fludioxonil and metabolite CGA192155, respectively, instead of the arithmetic mean EU agreed values of 145600 and 23.5 mL/g.
   As already mentioned in the izRMS comment in point 8.9.1 above, new active substance data should not be generated at the zonal level, unless critical for the exposure assessment. Recalculation of the geometric mean Kfoc was not critical for the surface water simulations, as sufficient data were available from the EU review. Nevertheless, values considered by the Applicant represent worst case comparing to the EU agreed endpoints and are thus agreed by the izRMS. It is noted that at the EU level average Kfoc of 145000 mL/g has been indicated as relevant for the surface water modelling, while 145600 mL/g has been calculated based on individual values (see page 55 of the LoEP).

It is noted that part of the default input parameters provided in Table 8.9-2 is relevant for FOCUS simulations performed at Step 3. However, as surface water exposure following application of GLOB182 was calculated only with FOCUS Step 1 & 2 $PEC_{SW/SED}$, these default parameters are obsolete. Nevertheless, they were retained in table above with respective information provided by the izRMS.

Calculations performed by the Applicant ~~izRMS~~ were independently validated by the izRMS using the worst case Central Zone GAP and EU agreed endpoints. Obtained PEC_{SW} values were slightly lower while PEC_{SED} were slightly higher comparing to these derived by the Applicant. However, as in the aquatic risk assessment only PEC_{SW} values were considered, no corrections were made by the izRMS and values reported in Tables 8.9-3 to 8.9-6 may be used for purposes of the risk assessment.

As already mentioned in the izRMS comment in point 8.2 of this document, due to the type of application (seed treatment) photolysis will not play a major role in degradation of fludioxonil in soil and for this reason metabolites formed exclusively via photolysis in soil may not be taken into account in exposure assessment for the intended uses of GLOB182F. Nevertheless, metabolites formed via photolysis in water (CGA339833, CGA344623 and A5) may be relevant, since fludioxonil applied as a seed treatment may migrate to surface water bodies where it will undergo photodegradation. It is noted that in the course of the EU review photolytic metabolites CGA344623 and A5 were considered to be minor metabolites since they were detected only in the sterile photolysis study and not in the water/sediment study performed under light conditions. Therefore, in addition to CGA192155, also photolytic aquatic metabolite CGA339833 is considered to be relevant for the surface water exposure assessment and respective Step 1 $PEC_{SW/SED}$ values were calculated by the izRMS for the intended worst case Central Zone GAP, parent input values as used by the Applicant and following EU agreed input parameters for the metabolite:

Compound	CGA339833
Molecular mass [g/mol]	312.2
Water solubility [mg/L]	31000
DT_{50} in soil [days]	8.7
Maximum occurrence in soil [%]	0.00001 (not relevant soil metabolite of fludioxonil used as a seed treatment)
DT_{50} in water/sediment [days]	1000
Maximum occurrence in aquatic systems	30.5 (max from aqueous photolysis study)
Kfoc [mL/g]	4.0

Based on the above assumptions, the maximum Step 1 PEC_{SW} of 0.3027 and 0.2150 µg/L were calculated for uses in maize and sunflower, respectively.

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

Studies on the fate and behaviour in air with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance Fludioxonil.

Table 8.10-1 Summary of atmospheric degradation and behaviour

Compound	Fludioxonil
Direct photolysis in air	Not relevant
Quantum yield of direct phototransformation	Not relevant
Photochemical oxidative degradation in air	DT_{50} (h): 3.6 hours derived by the Atkinson model OH (12h) concentration assumed = 1.5 x 10^6 radicals/cm^3
Volatilisation	Vapour pressure (Pa): 3.9 x 10^{-7} Henry's Law Constant (Pa.m^3/mol): 5.4 x 10^{-5} From plant surfaces: 7% of soil deposit over 24 hours From soil: 1.6% of AR after 24 hours (indirect method) 0.04% of AR after 24 hours (direct method) < 2.6 ng/cm^2/h
Metabolites	No potentially volatile metabolites

The vapour pressure at 20 °C of the active substance Fludioxonil is < 10^{-5} Pa. Hence the active substance Fludioxonil is regarded as non-volatile. Therefore, exposure of adjacent surface waters and terrestrial ecosystems by the active substance Fludioxonil due to volatilization with subsequent deposition should not be considered.

izRMS comments:

Information regarding fate and behaviour in the air presented in Table 8.10-1 is in line with EU agreed data presented in EFSA Scientific Report (2007) 110.

As the vapour pressure of fludioxonil is below the trigger of 10^{-5} Pa, no significant volatilisation from soil and plant surfaces is expected. In addition to that, due to DT_{50} in the air being <2 days, fludioxonil is not expected to be subject to the long- or short-range transport.

Overall, unacceptable contamination of the atmosphere with fludioxonil following application of GLOB182F to maize and sunflower is not expected.

Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Owner
KCP 9.2.4.1	Fernandez, D.	2020a	GLOB182F - Estimations of the PEC_{gw} of Fludioxonil for the intended use as a seed treatment formulation in maize and sunflower. GLOB182F-GW non GLP Unpublished	N	N	Globachem NV
KCP 9.2.5	Fernandez, D.	2020b	GLOB182F - Estimations of the PEC_{sw} and PEC_{sed} of Fludioxonil and relevant metabolites for the intended use as a seed treatment formulation in maize and sunflower. GLOB182F-GW non GLP Unpublished	N	N	Globachem NV

List of data submitted by the applicant and not relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Owner
There were no data submitted by the Applicant and not relied on.						

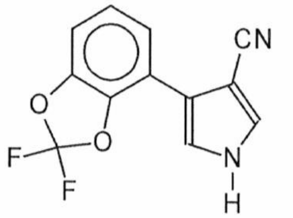
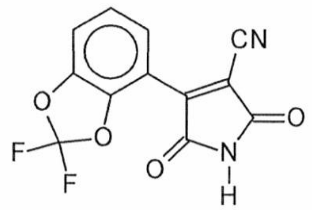
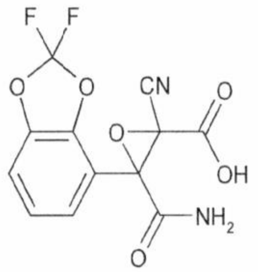
List of data relied on not submitted by the applicant but necessary for evaluation

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Owner
There were no data not submitted by the Applicant and relied on.						

Appendix 2 Detailed evaluation of the new Annex II studies

No new Annex II studies were submitted in support of the evaluation of the fate and behaviour of GLOB182F.

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

CGA173506 (Fludioxonil)	4-(2,2-difluoro-1,3-benzodioxol-4-yl)-1H-pyrrole-3-carbonitrile	Major residue in soil, aquatic environment and air.	
CGA265378	4-(2,2-difluoro-benzo[1,3]dioxol-4-yl)-2,5-dioxo-2,5-dihydro-1H-pyrrole-3-carbonitrile	Max. 12.3% AR in lab soil photolysis study. Not observed in the field (LD not stated).	
CGA339833	3-carbamoyl-2-cyano-3-(2,2-difluoro-benzo[1,3]dioxol-4-yl)-oxirane-2-carbocylic acid	Max. 9.1% AR in lab soil photolysis study. Max. 8% AR in the field.	
CGA192155	2,2-difluoro-benzo[1,3]dioxol-4-carbocylic acid	Max. 11.7% AR in lab soil photolysis study. Max. 13% AR in the field.