Document Title

Tier 2 Summary of the Fate and Behaviour in the Environment of the Plant Protection Product Sivanto (BYI 02960, Flupyradifurone) SL 200

Specification number

102000021884

Data Requirements

Regulation (EC) No 1107/2009

Annex IIIA
Section 5, Point 9
Document M

According to OECD format guidance for industry data submissions on plant protection products and their active substances

Date

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Author(s)

[redacted]

Bayer CropScience

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IIIA1 9 Fate and Behaviour in the Environment of the Plant Protection Product

In this chapter, estimates of Predicted Environmental Concentrations (PECs) of the insecticide BYI 02960 (Flupyradifurone) and the major metabolites are given. All relevant data concerning the behaviour of the active ingredient in the environment have been summarized in Section 5, Point 7 of the respective Annex IIA dossier. The data are summarized also briefly for the various compartments of the environment in this document.

The PECs were determined for representative uses of the formulation on hops and lettuce in the EU.

The formulants of a preparation would not be expected to influence the environmental behaviour of an active substance (except in special formulation types such as slow release formulations). The effects of the formulants are limited to short term processes such as the formation of stable spray dispersions, sprayability and permeation into target organisms, while the impact on long-term processes such as degradation and distribution is negligible. As this formulation is not a slow release formulation the results of environmental fate studies performed with the active substance are thus valid also for the formulation.
Authors of study reports sometimes used different names or short codes for the active ingredient and its transformation products. In this summary, a single names are always used for the active substance BYI 02960 and its metabolites and degradates DFA, 6-CNA, BYI 02960 succinamide and BYI 02960 azabicyclosuccinamide.
The chemical structures of the metabolites and report names are given in the List of Metabolites which is an attachment to Document N. A list containing the metabolites identified in environmental matrices only and addressed in exposure assessments is included at the end of this document.

Intended application pattern

The formulation is intended for use as an insecticide for hop and lettuce. The intended representative uses pattern for this formulation are summarised as follows.

Table 9- 1 Intended use patterns

Crop	F or G*	Timing of application (BBCH)	Maximum number of applications	Application interval [days]	Maximum dose rate formulation [L/ha]	Maximum application rate, individual treatment [g BYI 02960/ha]
Hops	F	31 - 75	1	-	0.75	150
Lettuce	F	12 - 49	1	-	0.625	125
Lettuce	G	12 - 49	2	10	0.625	125

* F = Field use; G = Glasshouse use

IIIA1 9.1 Rate of degradation in soil

Specific studies on the preparation have not been performed. The results of laboratory studies performed with the active substance as provided in Annex IIA in the context of Section 5, Point 7 are also applicable for the preparation.

IIIA1 9.1.1 Aerobic degradation of the preparation in soil

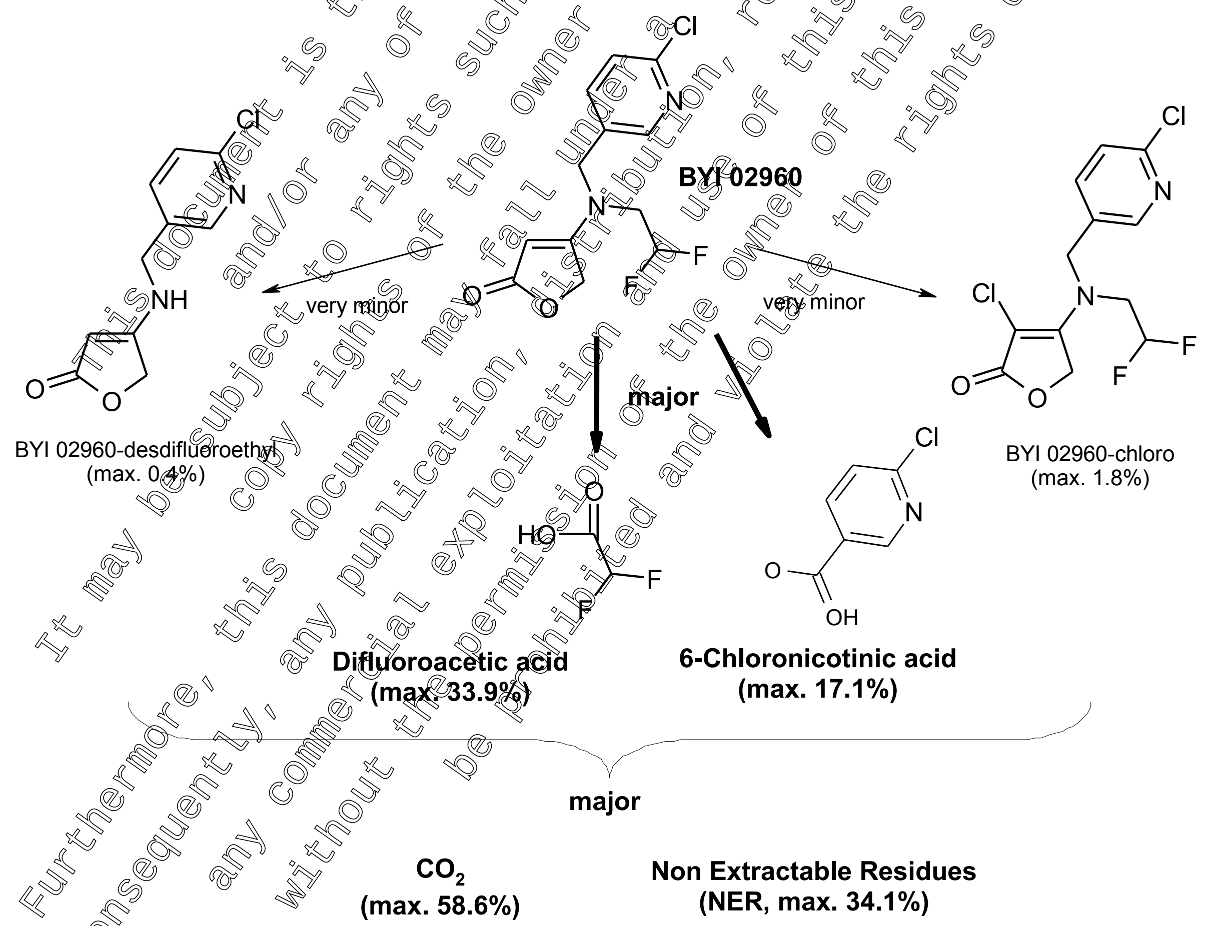
Investigations into the fate and behaviour of BYI 02960 in the environment have been performed in a comprehensive series of laboratory studies and additionally in field studies. Laboratory studies were conducted with ^{14}C-radiolabeled active substance with labelling in four positions to elucidate the complete metabolic pathway in soil.

Route of degradation in soil

The route of degradation of BYI 02960 in soil has been determined in European and American soils with four different label positions under standard laboratory conditions at 20°C for 120 days. Under aerobic conditions two major metabolites were observed, DFA (maximum 33.9%) and 6-CNA (maximum 17.1%) and two very minor metabolites. In all label positions there was significant mineralization to $^{14}CO_2$ (maximum ca. 59%) with relatively low formation of non-extractable residues (max. ca. 34%). The results indicate that BYI 02960 is readily degraded in aerobic soil by microbial activity.

Under anaerobic soil conditions BYI 02960 was stable and it was concluded that photolysis on the soil surface would not be a significant route of degradation. The proposed degradation pathway in soil is given in Figure 9.1- 1.

Figure 9.1.1- 1: Proposed Degradation Pathway for BYI 02960 in Soil



Rate of degradation in soil

Summaries of the European trigger endpoints in soil are given in the Table 9.1.1- 1 for BYI 02960 and in Table 9.1.1- 2 for the major metabolites. For BYI 02960, the DT_{50} values ranged from 33 to 120 days in the European soils and from 56 days to 242 days in the American soils.

Table 9.1.1- 1: Trigger "best-fit" DT_{50} values for BYI 02960

Soil	Label	Model	DT_{50} [days]	Reference
[redacted] (AX)	PYM	DFOP	63.4	KIIA 7.2.1/01 M-414615-01-2
	FUR	DFOP	62.2	KIIA 7.2.1/02 M-411625-01-2
	ETH	DFOP	62.0	KIIA 7.2.1/04 M-414981-01-1
[redacted] (HF)	PYM	DFOP	52.4	KIIA 7.2.1/01 M-414615-01-2
	FUR	DFOP	33.2	KIIA 7.2.1/02 M-411625-01-2
	ETH	DFOP	34.1	KIIA 7.2.1/04 M-414981-01-1
	PYR	DFOP	33.0	KIIA 7.2.1/05 M-411693-01-1
[redacted], Plot 611 (HN)	PYM	DFOP	120.0	KIIA 7.2.1/01 M-414615-01-2
	FUR	DFOP	98.3	KIIA 7.2.1/02 M-411625-01-2
[redacted] II (DD)	PYM	DFOP	56.1	KIIA 7.2.1/01 M-414615-01-2
	FUR	DFOP	49.3	KIIA 7.2.1/02 M-411625-01-2
	ETH	DFOP	33.9	KIIA 7.2.1/04 M-414981-01-1
[redacted] NE	FUR	SFO	228	KIIA 7.2.1/03 M-405497-03-1
	PYM	FOMC	242	KIIA 7.2.1/06 M-413425-02-1
[redacted] CA	FUR	DFOP	58.3	KIIA 7.1.2/03 M-405497-03-1
	PYM	FOMC	56.3	KIIA 7.2.1/06 M-413425-02-1
Overall mean			**73 days**	

Table 9.1.1- 2: Trigger "best-fit" DT_{50} values for BYI 02960 metabolites

Metabolite	Soil	Model	DT_{50}	Reference
DFA	[redacted] II	SFO	44.9	KIIA 7.2.3/05 M-422874-01-1
	[redacted]	SFO	73.6	KIIA 7.2.3/05 M-422874-01-1
	[redacted] 4a	SFO	67.4	KIIA 7.2.3/05 M-422874-01-1
6-CNA	[redacted]	SFO	2.9	KIIA 7.2.3/02 M-422843-01-1
	[redacted]	SFO	2.2	KIIA 7.2.3/02 M-422843-01-1
	[redacted]	SFO	5.3	KIIA 7.2.3/02 M-422843-01-1
	[redacted] 4a	SFO	3.1	KIIA 7.2.3/03 M-422853-01-1
	[redacted]	SFO	36.6	KIIA 7.2.3/04 M-422853-01-1

IIIA1 9.1.2 Anaerobic degradation of the preparation in soil

The anaerobic soil studies showed that the amounts of BYI 02960 remain stable under flooded anaerobic conditions in soil. Degradation would be expected to continue according to the proposed kinetics of degradation of BYI 02960 when aerobic conditions were re-established. No anaerobic metabolites were detected.

IIIA1 9.2 Field studies

IIIA1 9.2.1 Soil dissipation testing on a range of representative soils

The dissipation of BYI 02960 under field conditions has been studied at 6 sites in Europe. The study, performed with the representative formulation BYI 02960 SL200, was described in the Annex IIA, of Section 5, Point 7.3.1. A brief overview of the results is presented in the Annex III document.

Based on the results of the dissipation study it can be concluded that BYI 02960 shows biphasic degradation behaviour under field conditions. BYI 02960 residues remained in the upper 0-20 cm soil layer, small amounts below the LOQ could be detected to a maximum depth of 30 cm. At study completion, i.e. 540 days post-application, the remaining BYI 02960 residues in soil corresponded to between 2.9 to 29.8% of the applied amount. The calculated DT_{50} of BYI 02960 ranged between 8.3 and 251 days.

In general the field dissipation behaviour observed for BYI 02960 residues, i.e. for BYI 02960 and its main soil metabolite DFA, was comparable to that found within the standardized laboratory studies.

Table 9.2.1- 1: Dissipation DT_{50} values of BYI 02960 under field conditions

Location and Trial No.	BYI 02960 Kinetic model	DT_{50} [d]	Reference
[redacted], Germany 09-2702-01	DFOP	41.0	KIIA 7.3.1/01 M-414245-01-1
[redacted], United Kingdom 09-2702-02	DFOP	251	KIIA 7.3.1/01 M-414245-01-1
[redacted], Germany 09-2702-03	DFOP	42.8	KIIA 7.3.1/01 M-414245-01-1
[redacted], Italy 09-2702-05	DFOP	8.3	KIIA 7.3.1/01 M-414245-01-1
[redacted], Spain 09-2702-06	DFOP	22.6	KIIA 7.3.1/01 M-414245-01-1
[redacted], Germany 09-2702-07	DFOP	39.0	KIIA 7.3.1/01 M-414245-01-1

IIIA1 9.2.2 Soil residue testing

Not required under regulation (EC) 1107/2009.

IIIA1 9.2.3 Soil accumulation testing

No study has been performed as the potential accumulation can be determined from the existing studies and calculated accumulation plateaus are summarized in the soil PEC calculations under point IIIA1 9.4.

IIIA1 9.2.4 Aquatic (sediment) field dissipation

Not required under Regulation (EC) 1107/2009.

IIIA1 9.2.5 Forestry field dissipation

Not required under Regulation (EC) 1107/2009.

IIIA1 9.3 Mobility of the plant protection product in soil

Specific studies on the mobility of the formulation BYI 02960 SL200 G have not been performed; data generated for the active substance and major metabolites is also valid for the formulation. All studies are summarized in KIIA Section 5 and only a brief outline of the results is presented below.

For BYI 02960 in standard batch equilibrium studies on 6 soils the adsorption K_{oc} ranged from 74.9 to 132.2 mL/g, desorption K_{doc} were higher indicating significant stronger sorption. In time dependent sorption studies the sorption of BYI 02960 was shown to increase over time with an ageing factor of 2.4 to 4.4.

The K_{oc} of the major metabolite 6-CNA was determined in four soils (excluding one soil with very low organic carbon content and the sediment) ranged from 70 to 129 indicating medium mobility.

The $K_{oc\ ads}$ for the metabolite DFA determined in five soils ranged from 1.7 to 9.5 indicating high mobility in soil.

IIIA1 9.3.1 Column leaching

Not required under Regulation (EC) 1107/2009.

IIIA1 9.3.2 Lysimeter studies

As the concentration in groundwater can be predicted by environmental modelling lysimeter studies have not been performed and are not required.

IIIA1 9.3.3 Field leaching studies

As the concentration in groundwater can be predicted by environmental modelling field leaching studies have not been performed and are not required.

IIIA1 9.3.4 Volatility - laboratory studies

Volatility studies for the formulation have not been performed and are not required under Regulation (EC) 1107/2009.

IIIA1 9.3.5 Volatility - field studies

Not required under Regulation (EC) 1107/2009.

IIIA1 9.4 Predicted environmental concentrations in soil, active substance

PEC_{soil} modelling approach

Calculations were based on a simple first tier approach (Excel sheet) assuming even distribution of the compound in upper 0-5 cm soil layer. A standard soil density of 1.5 g/cm^3 was assumed.
Crop interception data which correspond to the intended growth stages were taken from the FOCUS groundwater guidance paper (FOCUS 2010).
Crop interception will reduce the amount of a compound reaching the soil and therefore this has been taken into account depending on the growth stage at application. The interception rates follow the recommendations of the FOCUS groundwater guidance paper (FOCUS 2010) provided in Table 9.6-1. As hop and lettuce have not been defined in the FOCUS groundwater guidance paper, vines and cabbage were chosen as surrogate crops. As there is currently no guidance on calculation of PECsoil for greenhouse crops no specific calculation was performed and it is assumed that the glasshouse use is covered by the outdoor use on lettuce.

PEC_{soil} for BYI 02960

Report:	**KIIIA1 9.4/01, [redacted].; 2012**
Title:	FPF PECsoil EU: Predicted environmental concentrations in soil (PECsoil) of Flupyradifurone and its metabolites – use in hops and lettuce in Europe
Report no.:	EnSa-12-0117
Document No:	M-428042-01-1
Guidelines:	**Soil Persistence Models and EU registration: Report of the FOCUS Soil Modelling Work Group, 1996** **EC Document Reference 7617VI/96**
GLP:	**No (calculation)**

Methods and Materials: The predicted environmental concentrations in soil (PEC_{soil}) of BYI 02960 were estimated using a simple first tier approach (Excel sheet). Detailed application data used for simulation of PEC_{soil} are compiled in Table 9.4- 1.

Substance Specific Parameters: PEC_{soil} calculations were based on the DT_{50} of 0.2 days for the fast and 462 days for the slowly degrading compartments (DFOP, worst case of field dissipation studies).

Table 9.4- 1: Application pattern used for PEC_{soil} calculations of BYI 02960

Individual Crop	FOCUS Crop Used for Interception	Application				Amount Reaching the Soil per Season application [g a.s. /ha]
		Rate per Season [g a.s. /ha]	Interval [days]	Plant Interception [%]	BBCH Stage	
Hops, GAP – identical with simulation	Vines	1 x 150	-	60	31-75	1 x 60
Lettuce (F), GAP – identical with simulation[1)]	Cabbage	1 x 125	-	25	12-49	1 x 94

[1)] First <u>or</u> second cropping per year
F = field use

To account for potential accumulation of BYI 02960 in soil (worst-case non-normalised DFOP DT_{90} > 365 days), long-term soil concentrations were calculated.

Findings: The PEC_{soil} and the time weighted average values (TWA_{soil}) of BYI 02960 are summarised in Table 9.4- 2 for hops and in Table 9.4- 3 for lettuce.

Table 9.4- 2: PEC_{soil} (actual) and TWA of BYI 02960 in hops in the upper 5 cm, DFOP decay

	Time [days]	BYI 02960 Hops, 1 x 150 g/ha	
		PEC_{soil} [mg/kg]	TWA_{soil} [mg/kg]
Initial	0	0.080	-
Short term	1	0.058	0.069
	2	0.058	0.066
	4	0.058	0.063
Long term	7	0.058	0.061
	14	0.057	0.059
	21	0.057	0.058
	28	0.056	0.058
	50	0.054	0.057
	100	0.050	0.054

Table 9.4- 3: PEC$_{soil}$ (actual) and TWA of BYI 02960 in lettuce in the upper 5 cm, DFOP decay (1st or 2nd cropping per year)

	Time [days]	BYI 02960 Lettuce, 1 x 125 g/ha (field use) PEC$_{soil}$ [mg/kg]	TWA$_{soil}$ [mg/kg]
Initial	0	0.125	-
Short term	1	0.091	0.108
	2	0.091	0.102
	4	0.091	0.098
Long term	7	0.090	0.095
	14	0.089	0.093
	21	0.088	0.091
	28	0.087	0.091
	50	0.085	0.089
	100	0.079	0.085

Accumulation in soil

The potential accumulation of BYI 02960 in soil was calculated considering the following approaches:

- Maximum soil residue in first year: maximum soil residue calculated for one season.
- Long-term plateau concentration C_{min}: maximum of the lower saw tooth curve, which can be considered as background concentration after multiple year use.
- Long-term maximum concentration C_{max}: maximum of the upper saw tooth curve after multiple year use.
- Background C_{min} + maximum of one year in 5 cm depth: to the long-term background concentration C_{min} in a certain depth (e.g. 5, 10 or 20 cm), the maximum residue of one year (distributed in 5 cm) will be added, to take into account a conservative shallow distribution just after an annual application.

Table 9.4- 4: Long-term soil concentrations of BYI 02960 following multi-year use

	Residues distributed over … [cm]	Seasonal PEC$_{s, max}$, max. soil residue in 1st year [mg/kg]	Long-term plateau / background conc. C_{min} [mg/kg]	Long-term maximum conc. C_{max} [mg/kg]	Background C_{min} + max. of 1 year in 5 cm [mg/kg]
Hops 1 x 150 g/ha	**5**	0.080	0.080	**0.160**	
	10	0.040	0.040	0.080	0.120
	20	0.020	0.020	0.040	0.100
Lettuce 1 x 125 g/ha	5	0.125	0.125	0.250	
	10	0.063	0.063	0.125	0.188
	20	0.031	0.031	0.063	**0.156**

In bold: Generally, for long-term assessments the substance distribution in soil for annual crops with tillage should be assumed over a depth of 20 cm (lettuce) and for perennial crops without tillage over a depth of 5 – 10 cm (e.g. hops).

IIIA1 9.4.1 Initial PECs value

Please refer to point IIIA 9.4.

IIIA1 9.4.2 Short-term PECs values - 24hours, 2 and 4 days after last application

Please refer to point IIIA 9.4.

IIIA1 9.4.3 Long-term PECs values - 7, 28, 50 and 100 days after last application

Please refer to point IIIA 9.4.

IIIA1 9.5 Predicted environmental concentrations in soil, for rel. metabolites

Predicted environmental concentrations in soil were calculated for the major soil metabolites DFA and 6-CNA. These metabolites are not automatically "relevant" with regard to their environmental, biological, eco-toxicological or toxicological properties.

Report:	**KIIIA1 9.5/01, [redacted]., 2012**
Title:	FPF PECsoil EU: Predicted environmental concentrations in soil (PECsoil) of Flupyradifurone and its metabolites – use in hops and lettuce in Europe
Report no.	EnSa-12-0117
Document No:	M-428042-01-1
Guidelines:	**Soil Persistence Models and EU registration: Report of the FOCUS Soil Modelling Work Group, 1996** **EC Document Reference 7617VI/96**
GLP:	**No (calculation)**

Methods and Materials: PEC_{soil} for the metabolites were calculated using the approach, scenarios and application rates described for the calculations for the parent compound in Point 9.4.
Compound specific parameters are summarised in Table 9.5- 1.

Table 9.5- 1: Input parameters for PEC_{soil} for metabolites of BYI 02960

Compound	Max. DT_{50} [days]	Max. occurrence in soil [%]	Molar mass [g/mol]	Molar mass correction factor
Difluoroacetic acid	73.6	33.9	96.03	0.333
6-Chloronicotinic acid	36.6	17.1	157.56	0.546

Findings: The maximum PEC_{soil} values of metabolites of BYI 02960 are summarised in Table 9.5- 2.

Table 9.5- 2: Hops and Lettuce: PEC_{soil} (max) of BYI 02960 metabolites

Crop	DFA $PEC_{soil, max}$ [mg/kg]	6-CNA $PEC_{soil, max}$ [mg/kg]
Hops 1 x 150 g/ha of parent	0.009	0.007
Lettuce 1 x 125 g/ha of parent	0.014	0.012

IIIA1 9.5.1 Initial PECs value

Please refer to point IIIA 9.5.

IIIA1 9.5.2 Short-term PECs values - 24hours, 2 and 4 days after last application

Please refer to point IIIA 9.5.

IIIA1 9.5.3 Long-term PECs values - 7, 28, 50 and 100 days after last application

Please refer to point IIIA 9.5.

IIIA1 9.6 Predicted environmental concentrations in ground water (PECgw)

PEC_{gw} modelling approach

The predicted environmental concentrations in groundwater (PEC_{gw}) for the active substance were calculated in a stepwise approach Tier 1 standard calculations, Tier 2a using DFOP and Tier 2a using time-dependent sorption (TDS), based on the simulation models PEARL and PELMO following the recommendations of the FOCUS working group on groundwater scenarios (FOCUS 2009),.

The leaching calculations were run over 26 years, as proposed for pesticides which may be applied every year. The simulation length increases to 46 and 66 years for pesticides which are applied only every second and third year, respectively. The first six years are a 'warm up' period; only the last 20 years were considered for the assessment of the leaching potential. The 80th percentile of the average annual groundwater concentrations in the percolate at 1 m depth under a treated plantation were evaluated and were taken as the relevant PEC_{GW} values. In respect to the assessment of a potential groundwater contamination this shallow depth reflects a worst case. The effective long-term groundwater concentrations will be even lower due to dilution in the groundwater layer.
According to FOCUS, the calculations were conducted based on mean soil half-lives, referenced to standard temperature and moisture conditions. Crop interception will reduce the amount of a compound reaching the soil and therefore this has been taken into account depending on the growth stage at application. The interception rates follow the FOCUS recommendations (Table 9.6- 1 and Table 9.6- 2).
As hop and lettuce have not been defined in the FOCUS groundwater guidance paper, vines and cabbage were chosen as surrogate crops.

Note: There are currently no European guidelines for the assessment of exposure of groundwater water from the use in glasshouses, therefore the simulation was performed, as a worst-case, using the outdoor use scenarios.

Tier 1: standard calculations following the recommendations of FOCUS (2000) with the DT_{50} values derived from SFO at the laboratory soil moisture standardised to DT_{50} values at 100% field capacity (FC)/pF 2

Tier 2a (DFOP): according to FOCUS (2009), DFOP degradation kinetics was considered in leaching modelling based on the procedure described in FOCUS (2006).

Tier 2a (TDS): following the model of [redacted] et al. (1989) implemented in PEARL and PELMO FOCUS (2009), time-dependent sorption (TDS) was evaluated using the TDS parameters determined according to [redacted] et al. (2010)[1].

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[1] [redacted] (2010): Proposed guidance on how aged sorption studies for pesticides should be conducted, analysed and used in regulatory assessments. The Food and Environment research Agency, York, UK and Alterra, Wageningen, The Netherlands

Table 9.6- 1: FOCUS groundwater crop interception values (Hops)

Crop	Crop Stage interception [%]				
Vines (surrogate for hop)	without leaves 40	first leaves 50	leaf development 60	flowering 70	ripening 85

Table 9.6- 2: FOCUS groundwater crop interception values (lettuce)

Crop	Crop stage Interception [%]				
BBCH #	Bare – emergence 00 - 09	Leaf development 10 - 19	Stem elongation 20 - 39	Flowering 40 - 89	Senescence Ripening 90 - 99
Cabbage (surrogate for lettuce)	0	25	40	70	90

IIIA1 9.6.1 Active substance PECgw value

PEC_{gw} for BYI 02960

Use in Hops:

Tier-1:

Report: **KIIIA1 9.6.1/01, [redacted].; 2012**
Title: FPF PECgw EUR: Predicted environmental concentrations in groundwater recharge based on models FOCUS PEARL and FOCUS PELMO – Use in Hops in Europe
Report no. EnSa-12-0089
Document No M-427737-01-1
Guidelines: **FOCUS 2000, SANCO/321/2000, rev. 2**
FOCUS 2006, SANCO/10058/2005, rev. 2
FOCUS 2009, SANCO/13144/2010, version 1
FOCUS 2010, version 2.0
GLP No (calculation)

Tier-2a (DFOP):

Report: **KIIIA1 9.6.1/02, [redacted]; 2012**
Title: Tier 2a (DFOP) FPF PECgw EU: Predicted environmental concentrations in groundwater recharge based on models Focus Pearl and Focus Pelmo - Use in hops in Europe - Flupyradifurone (BYI 02960) - Difluoroacetic acid (DFA) - 6-Chloronicotinic acid (6-CNA)
Report no. EnSa-12-0090
Document No M-427991-01-1
Guidelines: **FOCUS 2000, SANCO/321/2000, rev. 2**
FOCUS 2006, SANCO/10058/2005, rev. 2
FOCUS 2009, SANCO/13144/2010, version 1
FOCUS 2010, version 2.0
GLP **No (calculation)**

Tier-2a (TDS):

Report:	**KIIIA1 9.6.1/03, [redacted].; 2012**
Title:	Tier-2a (TDS) - FPF PECgw EUR: Predicted environmental concentrations in groundwater recharge based on models FOCUS PEARL and FOCUS PELMO – Use in Hops in Europe
Report no.	EnSa-12-0091
Document No	M-427980-01-1
Guidelines:	**FOCUS 2000, SANCO/321/2000, rev. 2** **FOCUS 2006, SANCO/10058/2005, rev. 2** **FOCUS 2009, SANCO/13144/2010, version 1** **FOCUS 2010, version 2.0**
GLP	**No (calculation)**

Materials and Methods: The predicted environmental concentrations in groundwater (PEC_{gw}) for BYI 02960 and its metabolites were calculated using the simulation model FOCUS PEARL (version 4.4.4) and FOCUS PELMO (4.4.3). Detailed application data used for simulation of PEC_{gw} are compiled in Table 9.6.1- 1. Simulations were conducted for annual applications as well as applications performed every second year.

Table 9.6.1- 1: Comparison of simulated and actual use pattern

Individual Crop	FOCUS Crop Used for Interception	Application: Rate per Season [g a.s. /ha]	Application: Interval [days]	Application: Plant Interception [%]	Application: BBCH Stage	Amount Reaching the Soil per Season application [g a.s. /ha]
Hops, GAP	-	1 × 150	-	60	31 - 75	1 × 60.00
Tier 1, Tier 2a (TDS)						
Hops (every year), Simulation 1	Vines	1 × 150	-	60	31 - 75	1 × 60.00
Hops (every 2nd year), Simulation 2	Vines	1 × 150	-	60	31 - 75	1 × 60.00
Tier 2a (DFOP)						
Hops (every year), Simulation 1	Vines	1 × 150	-	60	31 - 75	171 [s] / 129 [f]
Hops (every 2nd year), Simulation 2	Vines	1 × 150	-	60	31 - 75	171 [s] / 129 [f]

[f] used for fast compartment
[s] used for slow compartment

Application dates for the simulation runs were defined following the crop event dates of the respective crop and scenario as given by FOCUS (2009).

Table 9.6.1- 2: First application dates and related information for BYI 02960 as used for the simulation runs (offset is relevant only for relative application dates, two sets of data are provided for crops with two seasons)

Individual crop	Hops	Hops
Repeat Interval for App. Events	Every Year	Every 2nd Year
Application Technique	Spray	Spray
Absolute / Relative to	Emergence	Emergence
Scenario	1st App. Date (Julian day) Offset to crop event	
[redacted]	06 May (126) 35	06 May (126) 35
[redacted]	05 Jun (156) 35	05 Jun (156) 35
[redacted]	- - -	- - -
[redacted]	05 Jun (156) 35	05 Jun (156) 35
[redacted]	- - -	- - -
[redacted]	06 May (126) 35	06 May (126) 35
[redacted]	19 Apr (109) 35	19 Apr (109) 35
[redacted]	05 May (125) 35	05 May (125) 35
[redacted]	19 Apr (109) 35	19 Apr (109) 35

Further input parameters for PEC_{gw} modelling of BYI 02960 are summarised in Table 9.6.1- 3 for BYI 02960 and in Table 9.6.1- 4 for the metabolites. Parameters used for degradation pathway in PEARL and PELMO are depicted in Table 9.6.1- 5.

For Tier 1, a geometric mean of half-lives derived from SFO and from the slow compartment of the DFOP model was used to obtain a conservative model input.

For Tier 2a (DFOP) according to FOCUS (2009), DFOP degradation kinetics was considered in leaching modelling based on the procedure described in FOCUS (2006).
To obtain common DFOP parameters over all soils the following procedure was applied: Firstly, all degradation curves following SFO kinetics on Tier-1 were converted to an equivalent DFOP model where the Tier-1 SFO-DT_{50} was assigned equally (g=0.5) to the slow and fast degrading compartment.

For those soils where the slow compartment of DFOP was already used for modelling at Tier-1, the corresponding shorter DT_{50} of the fast compartment and g (fraction of total amount applied to the compartment) of the DFOP fit were additionally considered. Finally, the DFOP parameters were calculated as mean over all soils.

For leaching modelling the application rate was doubled and assigned to both compartments according to g of 0.43. Then, two separate leaching simulations were performed: one for the fast compartment using DT_{50fast} of 33 days and one using DT_{50slow} of 95 days. Both PEC_{gw} values were summed up and divided by two to get the final result.

<u>Tier 2a (TDS):</u> Time-dependent sorption (TDS) data of BYI 02960 on four soils were derived via curve fitting (see [redacted] 2012; KIIA 7.4.1/04, M-422824-01-1). These parameters constitute the prerequisite to adequately address TDS processes in regulatory exposure modelling.[2]. Experimental soil data were re-calculated to fit the TDS model, resulting in a geomean DT_{50} of 58 days, a K_{OM} of 46.5 L/kg and a Freundlich exponent of 0.860.

Table 9.6.1- 3: Substance specific and model related input parameters for PEC_{gw} calculation of BYI 02960

Parameter	Unit	BYI 02960 Tier 1	Tier 2a (DFOP)	Tier 2a (TDS)
Common				
Molar Mass	[g/mol]	288.7	288.7	288.7
Solubility	[mg/L]	3200	3200	3200
Vapour Pressure	[Pa]	9.10E-07	9.10E-07	9.10E-07
Freundlich Exponent		0.866	0.866	0.86
Plant Uptake Factor		0.5	0.5	0.5
Walker Exponent		0.7	0.7	0.7
PEARL Parameters				
Substance Code		BUTn	BUTf[f] / BUTs[s]	BUTk
DT_{50}	[days]	94.8	33.4[f] / 94.8[s]	58
Molar Activ. Energy	[kJ/mol]	65.4	65.4	65.4
K_{om}	[mL/g]	57.1	57.1	46.5
Desorp. Rate Coeff.	[1/days]	-	-	0.031
Equ. Factor		-	-	0.58
PELMO Parameters				
Substance Code		AS	AS	AS
Rate Constant	[1/day]	0.00730	0.0207[f] / 0.0073[s]	0.01195
Q_{10}		2.58	2.58	2.58
K_{oc}	[mL/g]	98.4	98.4	80.2

[f] DT_{50} used for the fast compartment
[s] DT_{50} used for the slow compartment

2 [redacted]. (2010): Proposed guidance on how aged sorption studies for pesticides should be conducted, analysed and used in regulatory assessments. The Food and Environment research Agency, York, UK and Alterra, Wageningen, The Netherlands

Table 9.6.1- 4: Substance specific and model related input parameters for PEC_{gw} calculation of BYI 02960 metabolites

Parameter	Unit	Difluoroacetic acid	6-Chloronicotinic acid
Common			
Molar Mass	[g/mol]	96	157.6 [a)]
Solubility	[mg/L]	500000	1430
Vapour Pressure	[Pa]	1.00E-10	1.00E-10
Freundlich Exponent		0.835	0.95
Plant Uptake Factor		0.5	0.5
Walker Exponent		0.7	0.7
PEARL Parameters			
Substance Code		DFA	CNA
DT_{50}	[days]	44.7	4.7
Molar Activ. Energy	[kJ/mol]	65.4	65.4
K_{om}	[mL/g]	3.9	51
Desorp. Rate Coeff.	[1/days]	0	0
Equ. Factor		0	0
PELMO Parameters			
Substance Code		A1	B1
Rate Constant	[1/day]	0.01551	0.14748
Q_{10}		2.58	2.58
K_{oc}	[mL/g]	6.8	88

a) The sum of formation fractions of both metabolites is > 1. In order to run the modeling with PELMO, the molar mass of 6-CNA was set to 451 g/mol, resulting from $M_{auxiliary}$ (6-CNA) = M (6-CNA) × 0.478 / (1-0.833) = 451 g/mol

Table 9.6.1- 5: Degradation pathway related parameters for BYI 02960 and its metabolites

Tier 1, Tier 2a (DFOP), Tier 2a (TDS)	Degradation fraction from → to (FOCUS PEARL)	0.83 BUT -> DFA 0.48 BUT -> CNA
Tier 1, Tier 2a (DFOP, slow compartment)	Degradation rate from → to (FOCUS PELMO)	0.0060780 Active Substance → A1 0.0012180 Active Substance → B1 0.0155070 A1 → <BR/CO2 0.1474780 B1 → <BR/CO2
Tier 2a (DFOP, fast compartment)	Degradation rate from → to (FOCUS PELMO)	0.017287 Active Substance → A1 0.003466 Active Substance → B1 0.015507 A1 → <BR/CO2 0.147478 B1 → <BR/CO2
Tier 2a (TDS)	Degradation rate from → to (FOCUS PELMO)	0.0099550 Active Substance → A1 0.0019960 Active Substance → B1 0.0155070 A1 → <BR/CO2 0.1474780 B1 → <BR/CO2

Findings:

The 80th percentile groundwater concentrations of BYI 02960 in hops are given in Table 9.6.1- 6 (Tier 1), Table 9.6.1- 7 (Tier 2a; DFOP) and Table 9.6.1- 8 (Tier 2a; TDS).

Table 9.6.1- 6: Tier 1 - PEC_{gw} of BYI 02960 – Use in Hops

Scenario	BYI 02960			
	Hops (every year), 1 x 150 g/ha, 60 % interception		Hops (every 2nd year), 1 x 150 g/ha, 60 % interception	
	PEARL PEC_{gw} [µg/L]	PELMO PEC_{gw} [µg/L]	PEARL PEC_{gw} [µg/L]	PELMO PEC_{gw} [µg/L]
[redacted]	0.453	0.415	0.193	0.168
[redacted]	0.579	0.634	0.283	0.249
[redacted]	0.430	0.481	0.172	0.196
[redacted]	0.359	0.442	0.154	0.211
[redacted]	0.220	0.286	***0.093***	0.122
[redacted]	0.223	***0.063***	***0.091***	***0.022***
[redacted]	0.183	0.155	***0.073***	***0.059***

In italics: values pass the trigger of 0.1 µg/L

Considering the Tier 1 simulations predicted concentrations of BYI 02960 in groundwater are below the trigger of 0.1 µg/L in the scenario [redacted] (model PELMO) when applied every year and in scenarios [redacted] and [redacted] (both PEARL and PELMO) and [redacted] (PEARL), when applied every second year.

Higher tier calculations have additionally been performed at Tier 2a using DFOP simulations and TDS.

Table 9.6.1- 7: Tier 2a (DFOP) - PEC_{gw} of BYI 02960 – Use in Hops

Scenario	BYI 02960			
	Hops (every year), 1 x 150 g/ha		Hops (every 2nd year), 1 x 150 g/ha	
	PEARL PEC_{gw} [µg/L]	PELMO PEC_{gw} [µg/L]	PEARL PEC_{gw} [µg/L]	PELMO PEC_{gw} [µg/L]
[redacted]	0.272	0.251	0.116	0.102
[redacted]	0.346	0.380	0.172	0.151
[redacted]	0.257	0.287	0.103	0.118
[redacted]	0.213	0.263	***0.093***	0.127
[redacted]	0.133	0.171	***0.056***	***0.073***
[redacted]	0.137	***0.039***	***0.056***	***0.015***
[redacted]	0.111	***0.095***	***0.045***	***0.037***

In italics: values pass the trigger of 0.1 µg/L

When considering the use of DFOP kinetics predicted concentrations of BYI 02960 in groundwater are below the trigger of 0.1 µg/L in the scenario [redacted] and [redacted] (model PELMO) when applied every year and in scenarios [redacted], [redacted] and [redacted] (both PEARL and PELMO) and [redacted] (PEARL), when applied every second year.

Table 9.6.1- 8: Tier 2a (TDS) - PEC_{gw} of BYI 02960 – Use in Hops

Scenario	BYI 02960			
	Hops (every year), 1 x 150 g/ha, 60 % interception		Hops (every 2nd year), 1 x 150 g/ha, 60 % interception	
	PEARL PEC_{gw} [µg/L]	PELMO PEC_{gw} [µg/L]	PEARL PEC_{gw} [µg/L]	PELMO PEC_{gw} [µg/L]
[redacted]	0.116	0.100	*0.044*	*0.035*
[redacted]	0.175	0.175	*0.069*	*0.065*
[redacted]	0.135	0.157	*0.049*	*0.056*
[redacted]	0.118	0.157	*0.041*	*0.065*
[redacted]	*0.056*	*0.087*	*0.020*	*0.030*
[redacted]	*0.042*	*0.007*	*0.014*	*0.002*
[redacted]	*0.030*	*0.023*	*0.010*	*0.006*

In italics: values pass the trigger of 0.1µg/L

When considering TDS behaviour the predicted concentrations of BYI 02960 in groundwater are below the trigger of 0.1 µg/L in the scenario [redacted], [redacted] and [redacted] (models PEARL and PELMO) when applied every year and in all scenarios (both PEARL and PELMO), when applied every second year.

Conclusion: A safe use has been demonstrated as the trigger of 0.1 µg/L is met at tier 1, considering application every year, for the scenario [redacted] (PELMO). For the higher tier calculations applying DFOP the trigger was met in [redacted] and [redacted] for annual applications. When considering higher tier calculations with TDS the trigger was also met in several scenarios for annual uses and all scenarios for use every second year.

Use in Lettuce:

Tier-1:

Report:	**KIIIA1 9.6.1/04, [redacted].; 2012**
Title:	FPF PECgw EUR: Predicted environmental concentrations in groundwater recharge based on models FOCUS PEARL and FOCUS PELMO – Use in Lettuce in Europe
Report no.	EnSa-12-0097
Document No	M-427736-01-1
Guidelines:	**FOCUS 2000, SANCO/321/2000, rev. 2** **FOCUS 2006, SANCO/10058/2005, rev. 2** **FOCUS 2009, SANCO/13144/2010, version 1** **FOCUS 2010, version 2.0**
GLP	**No (calculation)**

Tier-2a (DFOP):

Report:	**KIIIA1 9.6.1/05, [redacted].; 2012**
Title:	Tier-2a (DFOP) - FPF PECgw EUR: Predicted environmental concentrations in groundwater recharge based on models FOCUS PEARL and FOCUS PELMO – Use in Lettuce in Europe - Flupyradifurone (BYI 02960) - Difluoroacetic acid (DFA) - 6-Chloronicotinic acid (6-CNA)
Report no.	EnSa-12-0098
Document No	M-427987-01-1
Guidelines:	**FOCUS 2000, SANCO/321/2000, rev. 2** **FOCUS 2006, SANCO/10058/2005, rev. 2** **FOCUS 2009, SANCO/13144/2010, version 1** **FOCUS 2010, version 2.0**
GLP	**No (calculation)**

Tier-2a (TDS):

Report:	**KIIIA1 9.6.1/06, [redacted].; 2012**
Title:	Tier-2a (TDS) - FPF PECgw EUR: Predicted environmental concentrations in groundwater recharge based on models FOCUS PEARL and FOCUS PELMO – Use in Lettuce in Europe
Report no.	EnSa-12-0099
Document No	M-427981-01-1
Guidelines:	**FOCUS 2000, SANCO/321/2000, rev. 2** **FOCUS 2006, SANCO/10058/2005, rev. 2** **FOCUS 2009, SANCO/13144/2010, version 1** **FOCUS 2010, version 2.0**
GLP	**No (calculation)**

Materials and Methods: The predicted environmental concentrations in groundwater (PEC_{gw}) for BYI 02960 were calculated using the simulation model FOCUS PEARL (version 4.4.4) and FOCUS PELMO (4.4.3). Detailed application data used for simulation of PEC_{gw} are compiled in Table 9.6.1-9.

Although there is no currently agreed model for simulating groundwater concentrations following the use in greenhouses as a conservative approach the simulation was performed as an outdoor application considering two applications in accordance with the GAP.

Table 9.6.1- 9: Comparison of simulated and actual use pattern (outdoor use)

Individual Crop	F or G	FOCUS Crop Used for Interception	Application Rate per Season [g a.s. /ha]	Interval [days]	Plant Interception [%]	BBCH Stage	Amount Reaching the Soil per Season application [g a.s. /ha]
Lettuce 1 (GAP)	F	-	1 × 125	-	25	12 - 49	1 × 93.75
		Tier 1, Tier 2a (TDS)					
Lettuce 1 (every year), Simulation 1		Cabbage	1 × 125	-	25	12 - 49	1 × 93.75
Lettuce 1 (every 2nd year), Simulation 2		Cabbage	1 × 125	-	25	12 - 49	1 × 93.75
		Tier 2a (DFOP)					
Lettuce 1 (every year), Simulation 1		Cabbage	1 × 125	-	25	12 - 49	142.5^{s} / 107.5^{f}

Lettuce 1 (every 2nd year), Simulation 2		Cabbage	1 × 125	-	25	12 - 49	142.5^{s} / 107.5^{f}

F = Field use (GAP: "Lettuce 1" = 1 x 125 g/ha

^{f} used for the fast compartment

^{s} used for the slow compartment

Table 9.6.1- 10: Comparison of simulated and actual use pattern (glasshouse use)

Individual Crop	F or G	FOCUS Crop Used for Interception	Application Rate per Season [g a.s. /ha]	Interval [days]	Plant Interception [%]	BBCH Stage	Amount Reaching the Soil per Season application [g a.s. /ha]
Lettuce 2 (every year), GAP	G	-	2 × 125	10	2 x 25	12 - 49	2 × 93.75
		Tier 1, Tier 2a (TDS)					
Lettuce 2 (every year), Simulation 1		Cabbage	2 × 125	10	2 x 25	12 - 49	2 × 93.75
Lettuce 2 (every 2nd year), Simulation 2		Cabbage	2 × 125	10	2 x 25	12 - 49	2 × 93.75
		Tier 2a (DFOP)					
Lettuce 2 (every year), Simulation 1		Cabbage	2 × 125	10	2 x 25	12 - 49	2×142.5^{s} / 2× 107.5^{f}
Lettuce 2 (every 2nd year), Simulation 2		Cabbage	2 × 125	10	2 x 25	12 - 49	2×142.5^{s} / 2× 107.5^{f}

G = Glasshouse use (GAP: "Lettuce 2" = 2 x 125 g/ha)

^{f} used for the fast compartment

^{s} used for the slow compartment

Application dates for the simulation runs were defined following the crop event dates of the respective crop and scenario as given by FOCUS (2009). In this assessment the first and the second cropping per year of lettuce were calculated separately.

Table 9.6.1- 11: First application dates and related information for BYI 02960 as used for the simulation runs (offset is relevant only for relative application dates, two sets of data are provided for crops with two seasons)

Individual crop	**lettuce, 1st cropping**	**lettuce, 2nd cropping**	**lettuce, 1st cropping**	**lettuce, 2nd cropping**
Repeat Interval for App. Events	Every Year	Every Year	Every 2nd Year	Every 2nd Year
Application Technique	Spray	Spray	Spray	Spray
Absolute / Relative to	Emergence	Emergence	Emergence	Emergence
Scenario	1st App. Date (Julian day) Offset to crop event	1st App. Date (Julian day) Offset to crop event	1st App. Date (Julian day) Offset to crop event	1st App. Date (Julian day) Offset to crop event
[redacted]	25 Apr (115) 5	05 Aug (217) 5	25 Apr (115) 5	05 Aug (217) 5
[redacted]	25 Apr (115) 5	05 Aug (217) 5	25 Apr (115) 5	05 Aug (217) 5
[redacted]	25 May (145) 5	- - -	25 May (145) 5	- - -
[redacted]	25 Apr (115) 5	05 Aug (217) 5	25 Apr (115) 5	05 Aug (217) 5
[redacted]	- - -	- - -	- - -	- - -
[redacted]	- - -	- - -	- - -	- - -
[redacted]	05 Mar (64) 5	05 Aug (217) 5	05 Mar (64) 5	05 Aug (217) 5
[redacted]	06 Mar (65) 5	20 Jun (171) 5	06 Mar (65) 5	20 Jun (171) 5
[redacted]	20 Aug (232) 5	- - -	20 Aug (232) 5	- - -

Further input parameters for PEC_{gw} modelling of BYI 02960 are summarised above in Table 9.6.1- 3 for BYI 02960 and in Table 9.6.1- 4 for the metabolites. Parameters used for degradation pathway in PEARL and PELMO are depicted in Table 9.6.1- 5.

Findings: The 80th percentile concentrations of BYI 02960 for the field and glasshouse uses in lettuce are given in the following tables.

Tier 1: Field Uses (single application)

Table 9.6.1- 12: Tier 1 PEC_{gw} of BYI 02960 – Use in Lettuce, single application (field use), every year

Scenario	BYI 02960 (field use / every year) Lettuce, 1st cropping, every year, 1 x 125 g/ha		Lettuce, 2nd cropping, every year, 1 x 125 g/ha	
	PEARL PEC_{gw} [µg/L]	PELMO PEC_{gw} [µg/L]	PEARL PEC_{gw} [µg/L]	PELMO PEC_{gw} [µg/L]
[redacted]	0.413	0.298	0.556	0.396
[redacted]	0.809	0.724	1.081	0.983
[redacted]	0.325	0.269	-	-
[redacted]	0.595	0.517	0.698	0.637
[redacted]	0.327	0.413	0.643	0.713
[redacted]	*0.018*	*0.005*	*0.025*	*0.006*
[redacted]	0.313	0.221	-	-

In italics: values pass the trigger of 0.1µg/L

Table 9.6.1- 13: Tier 1 PEC_{gw} of BYI 02960 – Use in Lettuce, single application (field use), every 2nd year

Scenario	BYI 02960 (field use / every 2nd year) Lettuce, 1st cropping, every 2nd year, 1 x 125 g/ha		Lettuce, 2nd cropping, every 2nd year, 1 x 125 g/ha	
	PEARL PEC_{gw} [µg/L]	PELMO PEC_{gw} [µg/L]	PEARL PEC_{gw} [µg/L]	PELMO PEC_{gw} [µg/L]
[redacted]	0.154	0.111	0.207	0.142
[redacted]	0.379	0.298	0.443	0.401
[redacted]	0.109	*0.088*	-	-
[redacted]	0.242	0.210	0.291	0.255
[redacted]	0.137	0.177	0.253	0.305
[redacted]	*0.006*	*0.002*	*0.009*	*0.002*
[redacted]	0.109	*0.069*	-	-

In italics: values pass the trigger of 0.1µg/L

For the field use, considering the tier 1 approach the trigger value of 0. 1µg/L is met for the scenario [redacted] for both seasons and models for annual and uses every second year.

Tier 2a (DFOP): Single application (field use)

Table 9.6.1- 14: Tier 2a (DFOP) PEC_{gw} of BYI 02960 – Use in Lettuce, single application (field use), every year

Scenario	BYI 02960 (field use / every year / DFOP) Lettuce, 1st cropping, every year, 1 x 125 g/ha		Lettuce, 2nd cropping, every year, 1 x 125 g/ha	
	PEARL PEC_{gw} [µg/L]	PELMO PEC_{gw} [µg/L]	PEARL PEC_{gw} [µg/L]	PELMO PEC_{gw} [µg/L]
[redacted]	0.269	0.194	0.355	0.257
[redacted]	0.630	0.462	0.751	0.708
[redacted]	0.213	0.175	-	-
[redacted]	0.382	0.347	0.451	0.417
[redacted]	0.216	0.255	0.431	0.461
[redacted]	***0.016***	***0.005***	***0.025***	***0.006***
[redacted]	0.224	0.149	-	-

In italics: values pass the trigger of 0.1µg/L

Table 9.6.1- 15: Tier 2a (DFOP) PEC_{gw} of BYI 02960 – Use in Lettuce, single application (field use), every 2nd year

Scenario	BYI 02960 (field use / every 2nd year / DFOP) Lettuce, 1st cropping, every 2nd year, 1 x 125 g/ha		Lettuce, 2nd cropping, every 2nd year, 1 x 125 g/ha	
	PEARL PEC_{gw} [µg/L]	PELMO PEC_{gw} [µg/L]	PEARL PEC_{gw} [µg/L]	PELMO PEC_{gw} [µg/L]
[redacted]	***0.095***	***0.068***	0.126	***0.087***
[redacted]	0.230	0.179	0.270	0.244
[redacted]	***0.068***	***0.055***	-	-
[redacted]	0.146	0.128	0.177	0.155
[redacted]	***0.082***	0.105	0.153	0.182
[redacted]	***0.004***	***0.001***	***0.006***	***0.002***
[redacted]	***0.067***	***0.043***	-	-

In italics: values pass the trigger of 0.1µg/L

For the outdoor use in lettuce, using the Tier 2 approach (DFOP) the trigger is met for the scenario [redacted] for annual applications and the scenarios [redacted], [redacted], [redacted], [redacted] and [redacted] considering applications every second year.

Tier-2a (TDS): Single application (field use)

Table 9.6.1- 16: Tier-2a (TDS) PEC_{gw} of BYI 02960 – Use in Lettuce, single application (field use), every year (TDS)

Scenario	BYI 02960 (field use / every year / TDS) Lettuce, 1st cropping, every year, 1 x 125 g/ha		BYI 02960 (field use / every year / TDS) Lettuce, 2nd cropping, every year, 1 x 125 g/ha	
	PEARL PEC_{gw} [µg/L]	**PELMO PEC_{gw} [µg/L]**	**PEARL PEC_{gw} [µg/L]**	**PELMO PEC_{gw} [µg/L]**
[redacted]	*0.085*	*0.053*	0.111	*0.070*
[redacted]	0.263	0.194	0.329	0.272
[redacted]	*0.055*	*0.046*	-	-
[redacted]	0.181	0.157	0.216	0.198
[redacted]	*0.090*	0.133	0.176	0.247
[redacted]	*0.001*	*<0.001*	*0.001*	*<0.001*
[redacted]	*0.047*	*0.036*	-	-

In italics: values pass the trigger of 0.1µg/L

Table 9.6.1- 17: Tier-2a (TDS) PEC_{gw} of BYI 02960 – Use in Lettuce, single application (field use), every 2nd year (TDS)

Scenario	BYI 02960 (field use / every 2nd year / TDS) Lettuce, 1st cropping, every 2nd year, 1 x 125 g/ha		BYI 02960 (field use / every 2nd year / TDS) Lettuce, 2nd cropping, every 2nd year, 1 x 125 g/ha	
	PEARL PEC_{gw} [µg/L]	**PELMO PEC_{gw} [µg/L]**	**PEARL PEC_{gw} [µg/L]**	**PELMO PEC_{gw} [µg/L]**
[redacted]	*0.025*	*0.015*	*0.034*	*0.020*
[redacted]	*0.099*	*0.075*	0.132	0.107
[redacted]	*0.014*	*0.011*	-	-
[redacted]	*0.064*	*0.052*	*0.075*	*0.067*
[redacted]	*0.032*	*0.052*	*0.061*	*0.086*
[redacted]	*<0.001*	*<0.001*	*<0.001*	*<0.001*
[redacted]	*0.014*	*0.009*	-	-

In italics: values pass the trigger of 0.1µg/L

For the outdoor use in lettuce, using the Tier 2 approach (TDS) the trigger is met for the scenarios [redacted], [redacted], [redacted], [redacted] and [redacted] considering annual applications and for all scenarios except [redacted] late season for the application every second year.

Tier 1: Glasshouse Uses (multiple Applications)

Table 9.6.1- 18: Tier 1 PEC$_{gw}$ of BYI 02960 – Use in Lettuce, multiple applications (glasshouse use), every year

Scenario	BYI 02960 (glasshouse use / every year) Lettuce, 1st cropping, every year, 2 x 125 g/ha		Lettuce, 2nd cropping, every year, 2 x 125 g/ha	
	PEARL PEC$_{gw}$ [µg/L]	PELMO PEC$_{gw}$ [µg/L]	PEARL PEC$_{gw}$ [µg/L]	PELMO PEC$_{gw}$ [µg/L]
[redacted]	1.131	0.820	1.543	1.122
[redacted]	2.178	1.937	2.843	2.618
[redacted]	0.982	0.796	-	-
[redacted]	1.502	1.372	1.818	1.707
[redacted]	0.873	1.004	1.691	1.836
[redacted]	*0.078*	*0.019*	0.116	*0.025*
[redacted]	0.986	0.749	-	-

In italics: values pass the trigger of 0.1µg/L

Table 9.6.1- 19: Tier 1 PEC$_{gw}$ of BYI 02960 – Use in Lettuce, multiple applications (glasshouse use), every 2nd year

Scenario	BYI 02960 (glasshouse use / every 2nd year) Lettuce, 1st cropping, every 2nd year, 2 x 125 g/ha		Lettuce, 2nd cropping, every 2nd year, 2 x 125 g/ha	
	PEARL PEC$_{gw}$ [µg/L]	PELMO PEC$_{gw}$ [µg/L]	PEARL PEC$_{gw}$ [µg/L]	PELMO PEC$_{gw}$ [µg/L]
[redacted]	0.444	0.319	0.586	0.422
[redacted]	1.042	0.773	1.231	1.170
[redacted]	0.349	0.283	-	-
[redacted]	0.636	0.576	0.755	0.696
[redacted]	0.362	0.428	0.719	0.771
[redacted]	*0.025*	*0.008*	*0.038*	*0.009*
[redacted]	0.363	0.240	-	-

In italics: values pass the trigger of 0.1µg/L

For the greenhouse uses, considering the tier 1 approach the trigger value of 0. 1µg/L is met for the scenario [redacted] for both seasons and models even considering the conservative approach for the greenhouse uses.

Tier 2a (DFOP): Multiple Applications (glasshouse use)

Table 9.6.1- 20: Tier 2a (DFOP) PEC_{gw} of BYI 02960 – Use in Lettuce, multiple applications (glasshouse use), every year

Scenario	BYI 02960 (glasshouse use / every year / DFOP) Lettuce, 1st cropping, every year, 2 x 125 g/ha		Lettuce, 2nd cropping, every year, 2 x 125 g/ha	
	PEARL PEC_{gw} [µg/L]	PELMO PEC_{gw} [µg/L]	PEARL PEC_{gw} [µg/L]	PELMO PEC_{gw} [µg/L]
[redacted]	0.682	0.494	0.927	0.678
[redacted]	1.310	1.159	1.706	1.582
[redacted]	0.597	0.488	-	-
[redacted]	0.898	0.822	1.089	1.023
[redacted]	0.520	0.592	1.008	1.100
[redacted]	*0.050*	*0.013*	*0.076*	*0.017*
[redacted]	0.600	0.458	-	-

In italics: values pass the trigger of 0.1µg/L

Table 9.6.1- 21: Tier 2a (DFOP) PEC_{gw} of BYI 02960 – Use in Lettuce, multiple applications (glasshouse use), every 2nd year

Scenario	BYI 02960 (glasshouse use / every 2nd year / DFOP) Lettuce, 1st cropping, every 2nd year, 2 x 125 g/ha		Lettuce, 2nd cropping, every 2nd year, 2 x 125 g/ha	
	PEARL PEC_{gw} [µg/L]	PELMO PEC_{gw} [µg/L]	PEARL PEC_{gw} [µg/L]	PELMO PEC_{gw} [µg/L]
[redacted]	0.251	0.180	0.338	0.241
[redacted]	0.489	0.438	0.656	0.592
[redacted]	0.200	0.165	-	-
[redacted]	0.354	0.311	0.421	0.387
[redacted]	0.198	0.245	0.387	0.426
[redacted]	*0.012*	*0.003*	*0.017*	*0.004*
[redacted]	0.192	0.138	-	-

In italics: values pass the trigger of 0.1µg/L

For the greenhouse use in lettuce, using the Tier 2 approach (DFOP) the trigger is met for the scenario [redacted] for annual and bi-annual applications even considering the conservative use of the outdoor model.

Tier-2a (TDS): Multiple Applications (glasshouse use)

Table 9.6.1- 22: Tier-2a (TDS) PEC_{gw} of BYI 02960 – Use in Lettuce, multiple applications (glasshouse use), every year (TDS)

Scenario	BYI 02960 (glasshouse use / every year / TDS) Lettuce, 1st cropping, every year, 2 x 125 g/ha		Lettuce, 2nd cropping, every year, 2 x 125 g/ha	
	PEARL PEC_{gw} [µg/L]	PELMO PEC_{gw} [µg/L]	PEARL PEC_{gw} [µg/L]	PELMO PEC_{gw} [µg/L]
[redacted]	0.267	0.182	0.368	0.254
[redacted]	0.726	0.597	0.973	0.845
[redacted]	0.208	0.171	-	-
[redacted]	0.509	0.451	0.609	0.562
[redacted]	0.276	0.387	0.544	0.698
[redacted]	*0.007*	*0.002*	*0.009*	*0.002*
[redacted]	0.199	0.145	-	-

In italics: values pass the trigger of 0.1µg/L

Table 9.6.1- 23: Tier-2a (TDS) PEC_{gw} of BYI 02960 – Use in Lettuce, multiple applications (glasshouse use), every 2nd year (TDS)

Scenario	BYI 02960 (glasshouse use / every 2nd year / TDS) Lettuce, 1st cropping, every 2nd year, 2 x 125 g/ha		Lettuce, 2nd cropping, every 2nd year, 2 x 125 g/ha	
	PEARL PEC_{gw} [µg/L]	PELMO PEC_{gw} [µg/L]	PEARL PEC_{gw} [µg/L]	PELMO PEC_{gw} [µg/L]
[redacted]	*0.085*	*0.055*	0.123	*0.079*
[redacted]	0.296	0.226	0.389	0.339
[redacted]	*0.058*	*0.045*	-	-
[redacted]	0.187	0.156	0.222	0.198
[redacted]	0.102	0.152	0.199	0.271
[redacted]	*0.002*	*0.001*	*0.003*	*0.001*
[redacted]	*0.061*	*0.037*	-	-

In italics: values pass the trigger of 0.1µg/L

For the greenhouse use in lettuce, using the Tier 2 approach (TDS) the trigger is met for the scenario [redacted] for annual applications and for the scenarios [redacted], [redacted], [redacted], [redacted] and [redacted] for the early season uses every second year, even considering the conservative use of the outdoor model.

Conclusion

For all the uses considered safe use can be demonstrated in at least 1 scenario even considering tier 1 calculations. When higher tier (Tier 2) simulations are considered the calculated PEC_{gw} is less than the trigger in several scenarios.

IIIA1 9.6.2 Relevant metabolites, degradation and reaction products PECgw values

PEC_{gw} for BYI 02960 metabolites

For BYI 02960, the metabolites difluoroacetic acid (DFA) and 6-chloronicotinic acid (6-CNA) were assessed.

Use in Hops:

Tier-1:

Report:	**KIIIA1 9.6.2/01, [redacted].; 2012**
Title:	FPF PECgw EUR: Predicted environmental concentrations in groundwater recharge based on models FOCUS PEARL and FOCUS PELMO – Use in Hops in Europe
Report no.	EnSa-12-0089
Document No	M-427737-01-1
Guidelines:	**FOCUS 2000, SANCO/321/2000, rev. 2** **FOCUS 2006, SANCO/10058/2005, rev. 2** **FOCUS 2009, SANCO/13144/2010, version 1** **FOCUS 2010, version 2.0**
GLP:	**No (calculation)**

Tier-2a (DFOP):

Report:	**KIIIA1 9.6.2/02, [redacted].; 2012**
Title:	Tier 2a (DFOP) FPF PECgw EU: Predicted environmental concentrations in groundwater recharge based on models Focus Pearl and Focus Pelmo - Use in hops in Europe - Flupyradifurone (BYI 02960) - Difluoroacetic acid (DFA) - 6-Chloronicotinic acid (6-CNA)
Report no.	EnSa-12-0090
Document No	M-427991-01-1
Guidelines:	**FOCUS 2000, SANCO/321/2000, rev. 2** **FOCUS 2006, SANCO/10058/2005, rev. 2** **FOCUS 2009, SANCO/13144/2010, version 1** **FOCUS 2010, version 2.0**
GLP:	**No (calculation)**

Tier-2a (TDS):

Report:	**KIIIA1 9.6.2/03, [redacted].; 2012**
Title:	Tier-2a (TDS) - FPF PECgw EUR: Predicted environmental concentrations in groundwater recharge based on models FOCUS PEARL and FOCUS PELMO – Use in Hops in Europe
Report no.	EnSa-12-0091
Document No	M-427980-01-1
Guidelines:	**FOCUS 2000, SANCO/321/2000, rev. 2** **FOCUS 2006, SANCO/10058/2005, rev. 2** **FOCUS 2009, SANCO/13144/2010, version 1** **FOCUS 2010, version 2.0**
GLP:	**No (calculation)**

Materials and Methods: PEC_{gw} for the metabolites were calculated using the approach, scenarios and application described for the calculations for the parent compound in Point 9.6.1.

Compound specific input data for the metabolites are summarised together with the data of the parent compound in Table 9.6.1- 4.

Findings: The 80th percentile concentrations for BYI 02960 metabolites for the different EU scenarios are presented in Table 9.6.2- 1 for Tier 1.

Tier 1:

Table 9.6.2- 1: Tier 1 PEC_{gw} of BYI 02960 metabolites (after application of 150 g BYI 02960/ha) in hops

Scenario	Difluoroacetic acid (DFA) PEC_{gw} [µg/L]				6-Chloronicotinic acid (6-CNA) PEC_{gw} [µg/L]			
	every year		every 2nd year		every year		every 2nd year	
	PEARL	PELMO	PEARL	PELMO	PEARL	PELMO	PEARL	PELMO
[redacted]	1.074	0.939	0.553	0.489	*0.010*	*0.009*	*0.004*	*0.004*
[redacted]	1.423	1.395	0.678	0.669	*0.011*	*0.013*	*0.006*	*0.006*
[redacted]	0.941	0.953	0.467	0.467	*0.009*	*0.010*	*0.004*	*0.004*
[redacted]	0.753	0.709	0.393	0.360	*0.007*	*0.009*	*0.003*	*0.005*
[redacted]	0.597	0.581	0.290	0.288	*0.006*	*0.007*	*0.003*	*0.003*
[redacted]	0.635	0.477	0.334	0.266	*0.005*	*0.002*	*0.002*	*0.001*
[redacted]	0.596	0.602	0.300	0.271	*0.004*	*0.004*	*0.002*	*0.002*

In italics: values pass the trigger of 0.1 µg/L

PEC_{gw} values for the metabolite DFA are above 0.1 µg/L for all scenarios (both PEARL and PELMO), and for applications taking place every year or every 2nd year, respectively.

PEC_{gw} values for the metabolite 6-CNA are below 0.1 µg/L for all scenarios (both PEARL and PELMO) for applications taking place every year or every 2nd year, respectively. There are no concerns for groundwater for this metabolite.

Additionally, for difluoroacetic acid (DFA), higher tier have been performed, the results are summarized below.

Tier 2a (DFOP):

Table 9.6.2- 2: Tier 2a (DFOP): PEC_{gw} of difluoroacetic acid (DFA) in hops (1 x 150 g/ha of parent)

Scenario	Difluoroacetic acid (DFA) PEC_{gw} [µg/L]			
	every year		every 2nd year	
	PEARL	PELMO	PEARL	PELMO
[redacted]	1.008	0.875	0.528	0.464
[redacted]	1.386	1.335	0.667	0.656
[redacted]	0.903	0.931	0.458	0.473
[redacted]	0.667	0.655	0.360	0.329
[redacted]	0.513	0.500	0.248	0.248
[redacted]	0.565	0.407	0.302	0.241
[redacted]	0.523	0.504	0.272	0.235

Tier 2a (TDS):

Table 9.6.2- 3: Tier 2a (TDS): PEC_{gw} of difluoroacetic acid (DFA) in hops (1 x 150 g/ha of parent)

Scenario	Difluoroacetic acid (DFA) PEC_{gw} [µg/L] every year		every 2nd year	
	PEARL	PELMO	PEARL	PELMO
[redacted]	1.007	0.895	**0.516**	**0.450**
[redacted]	1.388	1.335	**0.656**	**0.647**
[redacted]	0.912	0.933	**0.439**	**0.448**
[redacted]	**0.701**	**0.671**	**0.364**	**0.343**
[redacted]	**0.541**	**0.538**	**0.261**	**0.263**
[redacted]	**0.572**	**0.420**	**0.296**	**0.234**
[redacted]	**0.514**	**0.525**	**0.254**	**0.230**

In italics: values pass the trigger of 0.1µg/L

In bold: values pass the trigger of 0.75 µg/L

Conclusion:

The groundwater concentration of the metabolite 6-CNA did not exceed the trigger in any scenario at Tier 1.

The PEC in groundwater for the metabolite DFA may exceed the 0.1 µg/L and also the 0.75 µg/L trigger, the concentration was < 10 µg/L in all scenarios. The relevance of the metabolite has been assessed in accordance with Sanco/221/2000 –rev.10 (2003): "Guidance Document on the Assessment of the Relevance of Metabolites in Groundwater", and the metabolite was not relevant in terms of efficacy (see KIIA 8.14.1, M-386333-01-1), genotoxicity and toxicity (see KIIA 5.8/01 - 05) and has also been considered in the dietary risk assessment (see KIIA 6.9).

Please note: DFA was considered in the dietary risk assessment since it is a constituent of the plant residue definition.

Use in Lettuce:

Tier-1:

Report:	**KIIA1 9.6.2/04; [redacted]; 2012**
Title:	FPF PECgw EUR: Predicted environmental concentrations in groundwater recharge based on models FOCUS PEARL and FOCUS PELMO – Use in Lettuce in Europe
Report no.	EnSa-12-0097
Document No	M-427736-01-1
Guidelines:	**FOCUS 2000, SANCO/321/2000, rev. 2** **FOCUS 2006, SANCO/10058/2005, rev. 2** **FOCUS 2009, SANCO/13144/2010, version 1** **FOCUS 2010, version 2.0**
GLP:	**No (calculation)**

Tier-2a (DFOP):

Report:	**KIIIA1 9.6.2/05, [redacted]; 2012**
Title:	Tier-2a (DFOP) - FPF PECgw EUR: Predicted environmental concentrations in groundwater recharge based on models FOCUS PEARL and FOCUS PELMO – Use in Lettuce in Europe - Flupyradifurone (BYI 02960) - Difluoroacetic acid (DFA) - 6-Chloronicotinic acid (6-CNA)
Report no.	EnSa-12-0098
Document No	M-427987-01-1
Guidelines:	**FOCUS 2000, SANCO/321/2000, rev. 2** **FOCUS 2006, SANCO/10058/2005, rev. 2** **FOCUS 2009, SANCO/13144/2010, version 1** **FOCUS 2010, version 2.0**
GLP	**No (calculation)**

Tier-2a (TDS):

Report:	**KIIIA1 9.6.2/06, [redacted].; 2012**
Title:	Tier-2a (TDS) - FPF PECgw EUR: Predicted environmental concentrations in groundwater recharge based on models FOCUS PEARL and FOCUS PELMO – Use in Lettuce in Europe
Report no.	EnSa-12-0099
Document No	M-427981-01-1
Guidelines:	**FOCUS 2000, SANCO/321/2000, rev. 2** **FOCUS 2006, SANCO/10058/2005, rev. 2** **FOCUS 2009, SANCO/13144/2010, version 1** **FOCUS 2010, version 2.0**
GLP	**No (calculation)**

Materials and Methods: PEC_{gw} for the metabolites were calculated using the approach, scenarios and application described for the calculations for the parent compound in Point 9.6.1.
Compound specific input data for the metabolites are summarised together with the data of the parent compound in Point 9.6.1.

Findings: The PEC_{gw} values for the metabolites for the different EU scenarios are presented for field and glasshouse uses in the following tables.

Tier 1: Single Application (field use)

Table 9.6.2- 4: Tier 1 PEC_{gw} of BYI 02960 metabolites (field use in lettuce, 1st cropping)

Scenario	Field use Lettuce, 1st cropping, 1 x 125 g/ha of parent Difluoroacetic acid (DFA) PEC_{gw} [µg/L]				6-chloronicotinic acid (6-CNA) PEC_{gw} [µg/L]			
	every year		every 2nd year		every year		every 2nd year	
	PEARL	PELMO	PEARL	PELMO	PEARL	PELMO	PEARL	PELMO
[redacted]	1.476	1.085	0.687	0.515	*0.009*	*0.006*	*0.004*	*0.003*
[redacted]	2.382	1.815	1.110	0.901	*0.015*	*0.015*	*0.008*	*0.006*
[redacted]	2.373	2.013	1.106	0.954	*0.008*	*0.007*	*0.003*	*0.003*
[redacted]	1.461	1.261	0.712	0.611	*0.012*	*0.011*	*0.005*	*0.005*
[redacted]	0.760	0.715	0.361	0.315	*0.008*	*0.010*	*0.004*	*0.005*
[redacted]	0.383	0.289	0.193	0.134	*<0.001*	*<0.001*	*<0.001*	*<0.001*
[redacted]	1.056	0.875	0.519	0.412	*0.007*	*0.005*	*0.003*	*0.002*

In italics: values pass the trigger of 0.1 µg/L

Table 9.6.2- 5: Tier 1 PEC_{gw} of BYI 02960 metabolites (field use in lettuce, 2nd cropping)

Scenario	Field use Lettuce, 2nd cropping, 1 x 125 g/ha of parent Difluoroacetic acid (DFA) PEC_{gw} [µg/L]				6-chloronicotinic acid (6-CNA) PEC_{gw} [µg/L]			
	every year		every 2nd year		every year		every 2nd year	
	PEARL	PELMO	PEARL	PELMO	PEARL	PELMO	PEARL	PELMO
[redacted]	1.701	1.325	0.793	0.607	*0.012*	*0.008*	*0.005*	*0.003*
[redacted]	2.632	2.322	1.254	1.120	*0.020*	*0.019*	*0.009*	*0.008*
[redacted]	1.583	1.445	0.750	0.713	*0.014*	*0.013*	*0.006*	*0.006*
[redacted]	1.155	1.105	0.589	0.556	*0.015*	*0.016*	*0.006*	*0.007*
[redacted]	0.577	0.410	0.273	0.187	*<0.001*	*<0.001*	*<0.001*	*<0.001*

In italics: values pass the trigger of 0.1 µg/L

Tier-2a (DFOP):

Single Application (field use):

Table 9.6.2- 6: Tier 2a (DFOP) PEC_{gw} of difluoroacetic acid (DFA) (field use in lettuce)

Scenario	Difluoroacetic acid (DFA) PEC_{gw} [µg/L] Field use Lettuce, 1st cropping, 1 x 125 g/ha of parent (DFOP)				Field use Lettuce, 2nd cropping, 1 x 125 g/ha of parent (DFOP)			
	every year		every 2nd year		every year		every 2nd year	
	PEARL	PELMO	PEARL	PELMO	PEARL	PELMO	PEARL	PELMO
[redacted]	1.377	1.025	**0.633**	**0.473**	1.761	1.369	0.807	**0.616**
[redacted]	2.305	1.769	1.075	0.828	2.728	2.473	1.282	1.127
[redacted]	2.448	2.014	1.098	0.935	-	-	-	-
[redacted]	1.493	1.245	**0.687**	**0.581**	1.658	1.573	0.761	**0.724**
[redacted]	**0.620**	**0.590**	**0.296**	**0.276**	1.298	1.212	**0.598**	**0.564**
[redacted]	**0.336**	**0.240**	**0.150**	**0.108**	**0.567**	**0.373**	**0.241**	**0.164**
[redacted]	1.219	0.955	**0.537**	**0.414**	-	-	-	-

In italics: values pass the trigger of 0.1 µg/L
In bold: values pass the trigger of 0.75 µg/L

Tier-2a (TDS): Single Application (field use)

Table 9.6.2- 7: Tier 2a (TDS): PEC_{gw} of BYI 02960 metabolites (field use in lettuce)

Scenario	Difluoroacetic acid (DFA) PEC_{gw} [µg/L] Field use Lettuce, 1st cropping, 1 x 125 g/ha of parent (TDS)				Field use Lettuce, 2nd cropping, 1 x 125 g/ha of parent (TDS)			
	every year		every 2nd year		every year		every 2nd year	
	PEARL	PELMO	PEARL	PELMO	PEARL	PELMO	PEARL	PELMO
[redacted]	1.363	0.994	**0.628**	**0.469**	1.603	1.236	**0.723**	**0.561**
[redacted]	2.289	1.744	1.067	0.865	2.572	2.202	1.221	1.072
[redacted]	2.278	1.930	1.049	0.926	1.542	1.417	**0.721**	**0.676**
[redacted]	1.377	1.208	**0.675**	**0.574**	-	-	-	-
[redacted]	**0.698**	**0.668**	**0.330**	**0.306**	1.083	1.038	**0.544**	**0.515**
[redacted]	**0.351**	**0.257**	**0.171**	**0.119**	**0.517**	**0.353**	**0.246**	**0.164**
[redacted]	0.957	0.808	**0.449**	**0.347**	**-**	**-**	**-**	**-**

In italics: values pass the trigger of 0.1 µg/L
In bold: values pass the trigger of 0.75 µg/L

Considering the use in the field PEC_{gw} values for the metabolite DFA are above 0.1 µg/L for all scenarios (both PEARL and PELMO), and for applications taking place every year or every 2nd year, at Tier 1 and Tier 2.

PEC_{gw} values for the metabolite 6-CNA are below 0.1 µg/L for all scenarios (both PEARL and PELMO) at tier 1, for applications taking place every year or every 2nd year, respectively. There are no concerns for groundwater for this metabolite.

Tier 1: Multiple Applications (glasshouse use):

Table 9.6.2- 8: Tier 1 PEC$_{gw}$ of BYI 02960 metabolites (glasshouse use in lettuce, 1st cropping)

Scenario	Glasshouse use Lettuce, 1st cropping, 2 x 125 g/ha of parent Difluoroacetic acid (DFA) PEC$_{gw}$ [µg/L]				6-chloronicotinic acid (6-CNA) PEC$_{gw}$ [µg/L]			
	every year		every 2nd year		every year		every 2nd year	
	PEARL	PELMO	PEARL	PELMO	PEARL	PELMO	PEARL	PELMO
[redacted]	3.155	2.326	1.496	1.116	*0.022*	*0.016*	*0.009*	*0.007*
[redacted]	5.048	3.857	2.375	1.923	*0.038*	*0.037*	*0.019*	*0.015*
[redacted]	5.179	4.370	2.496	2.043	*0.021*	*0.018*	*0.008*	*0.007*
[redacted]	3.144	2.673	1.560	1.313	*0.028*	*0.027*	*0.013*	*0.012*
[redacted]	1.609	1.481	0.753	0.673	*0.020*	*0.022*	*0.009*	*0.010*
[redacted]	0.832	0.637	0.438	0.302	*0.002*	*0.001*	*<0.001*	*<0.001*
[redacted]	2.355	1.921	1.181	0.948	*0.019*	*0.015*	*0.008*	*0.006*

In italics: values pass the trigger of 0.1 µg/L

Table 9.6.2- 9: Tier 1 PEC$_{gw}$ of BYI 02960 metabolites (glasshouse use in lettuce, 2nd cropping)

Scenario	Glasshouse use Lettuce, 2nd cropping, 2 x 125 g/ha of parent Difluoroacetic acid (DFA) PEC$_{gw}$ [µg/L]				6-chloronicotinic acid (6-CNA) PEC$_{gw}$ [µg/L]			
	every year		every 2nd year		every year		every 2nd year	
	PEARL	PELMO	PEARL	PELMO	PEARL	PELMO	PEARL	PELMO
[redacted]	3.625	2.864	1.726	1.332	*0.030*	*0.023*	*0.012*	*0.009*
[redacted]	5.568	5.020	2.653	2.409	*0.050*	*0.049*	*0.023*	*0.023*
[redacted]	3.377	3.043	1.619	1.536	*0.034*	*0.032*	*0.015*	*0.014*
[redacted]	2.493	2.353	1.269	1.191	*0.035*	*0.039*	*0.016*	*0.017*
[redacted]	1.297	0.911	0.637	0.428	*0.003*	*0.001*	*0.001*	*<0.001*

In italics: values pass the trigger of 0.1 µg/L

Tier 2 a (DFOP): Multiple Applications (glasshouse use)

Table 9.6.2- 10: Tier 2a (DFOP) PEC$_{gw}$ of difluoroacetic acid (DFA) (glasshouse use in lettuce)

Scenario	Difluoroacetic acid (DFA) PEC$_{gw}$ [µg/L] Glasshouse use Lettuce, 1st cropping, 2 x 125 g/ha of parent (DFOP)				Glasshouse use Lettuce, 2nd cropping, 2 x 125 g/ha of parent (DFOP)			
	every year		every 2nd year		every year		every 2nd year	
	PEARL	PELMO	PEARL	PELMO	PEARL	PELMO	PEARL	PELMO
[redacted]	2.832	2.087	1.320	0.973	3.592	2.865	1.676	1.319
[redacted]	4.797	3.492	2.218	1.632	5.602	5.007	2.615	2.312
[redacted]	4.977	4.180	2.270	1.921	-	-		-
[redacted]	2.961	2.492	1.371	1.170	3.360	3.076	1.569	1.440
[redacted]	1.318	1.246	**0.618**	**0.606**	2.487	2.348	1.143	1.086
[redacted]	**0.630**	**0.469**	**0.290**	**0.214**	1.138	**0.748**	**0.500**	**0.341**
[redacted]	2.427	2.007	1.084	0.903	-	-		-

In italics: values pass the trigger of 0.1 µg/L

In bold: values pass the trigger of 0.75 µg/L

Tier-2a (TDS): Multiple Applications (glasshouse use)

Table 9.6.2- 11: Tier 2a (TDS): PEC_{gw} of BYI 02960 metabolites (glasshouse use in lettuce)

Scenario	Difluoroacetic acid (DFA) PEC_{gw} [µg/L]							
	Glasshouse use Lettuce, 1st cropping, 2 x 125 g/ha of parent (TDS)				Glasshouse use Lettuce, 2nd cropping, 2 x 125 g/ha of parent (TDS)			
	every year		every 2nd year		every year		every 2nd year	
	PEARL	PELMO	PEARL	PELMO	PEARL	PELMO	PEARL	PELMO
[redacted]	2.944	2.143	1.370	1.023	3.454	2.711	1.594	1.261
[redacted]	4.936	3.736	2.287	1.846	5.524	4.828	2.612	2.335
[redacted]	4.968	4.194	2.383	1.980	-	-	-	-
[redacted]	3.001	2.581	1.473	1.240	3.288	3.030	1.560	1.476
[redacted]	1.479	1.393	**0.687**	**0.639**	2.369	2.241	1.196	1.115
[redacted]	0.764	**0.561**	**0.392**	**0.270**	1.140	0.766	**0.571**	**0.371**
[redacted]	2.172	1.819	1.034	0.806	-	-	-	-

In italics: values pass the trigger of 0.1 µg/L
In bold: values pass the trigger of 0.75 µg/L

Considering the use in the glasshouses the PEC_{gw} values for the metabolite DFA are above 0.1 µg/L for all scenarios (both PEARL and PELMO), and for applications taking place every year or every 2nd year, at Tier 1 and Tier 2.

PEC_{gw} values for the metabolite 6-CNA are below 0.1 µg/L for all scenarios (both PEARL and PELMO) at tier 1, and for applications taking place every year or every 2nd year, respectively. There are no concerns for groundwater for this metabolite.

Conclusion:
The groundwater concentration of the metabolite 6-CNA did not exceed the trigger in any scenario.
The PEC in groundwater for the metabolite DFA may exceed the 0.1 µg/L and also the 0.75 µg/L trigger, the concentration was < 10 µg/L in all scenarios. The relevance of the metabolite has been assessed in accordance with Sanco/221/2000 –rev.10 (2003): "Guidance Document on the Assessment of the Relevance of Metabolites in Groundwater", and the metabolite was not relevant in terms of efficacy (see KIIA 8.14.1, M-386333-01-1), genotoxicity and toxicity (see KIIA 5.8/01 - 05) and has also been considered in the dietary risk assessment (see KIIA 6.9).
Please note: DFA was considered in the dietary risk assessment since it is a constituent of the plant residue definition.

IIIA1 9.6.3 Additional field testing

No additional field testing was required.

IIIA1 9.6.4 Information on impact on water treatment procedure

The compound would not be expected to reach water treatment plants in sufficient concentrations to have any impact on water treatment procedure.

IIIA1 9.7 Predicted environmental concentrations in surface water (PECsw)

No specific information is available for the preparation, however the information on the active substance submitted in the relevant Annex II, Section 7 documents is also applicable. A summary of this information is presented below.

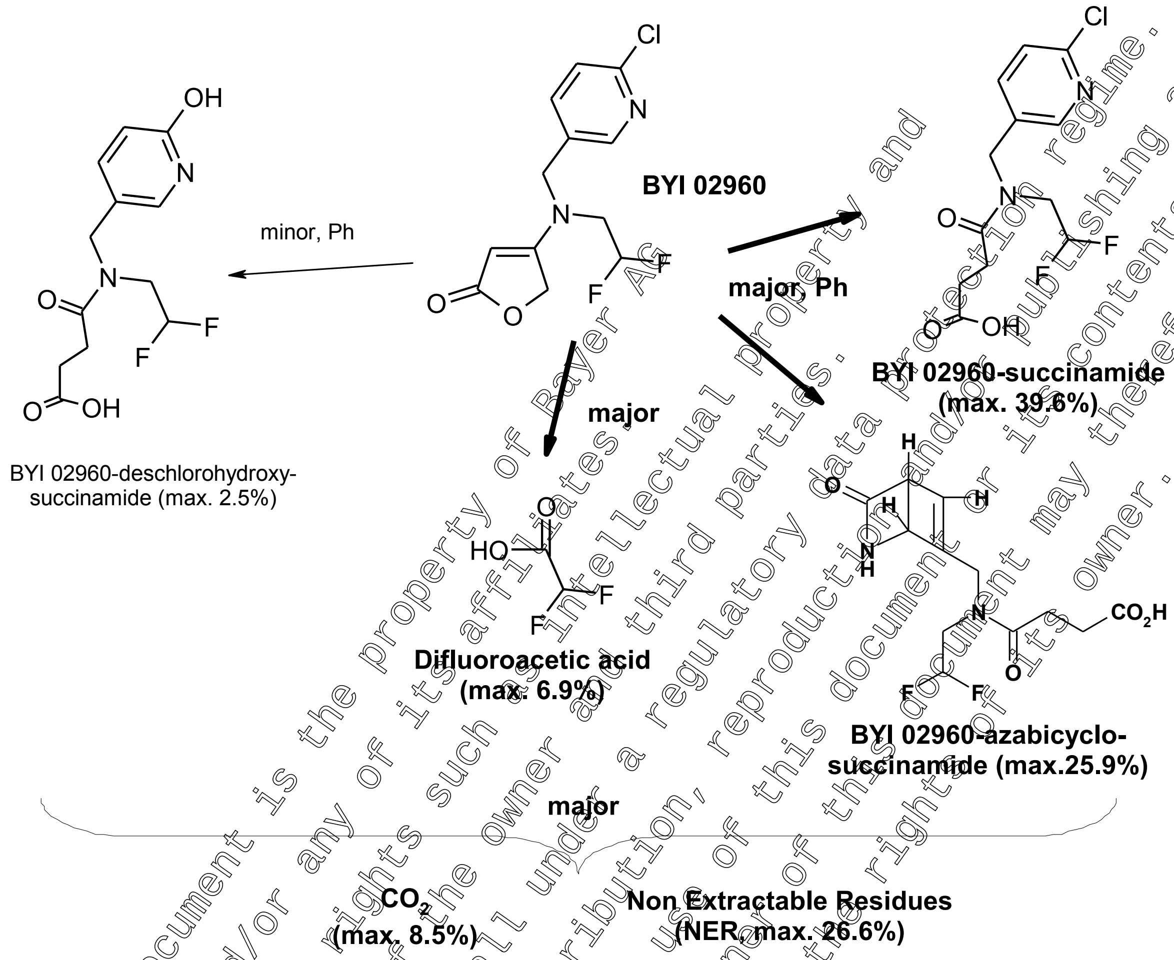
Summary of fate and behaviour of BYI 02960 in water

BYI 02960 was stable to hydrolysis at all pHs but was very rapidly degraded under the influence of photolysis (buffer and sterile natural water) to produce two major transformation products BYI 02960-succinamide and BYI 02960-azabicyclosuccinamide. The half-life was calculated to be equivalent to 2.7 days calculated for [redacted], Greece.

In aerobic water/sediment systems it was concluded that BYI 02960 dissipated rapidly from the water phase and was slowly degraded, the half-life in the total system ranged from 190 to 250 days. DFA was formed at a maximum of ca. 6% in one water system, mineralisation to $^{14}CO_2$ was also significant (maximum 8.5% after 120 days). Non-extractable residues remained at relatively low levels throughout the studies increasing to a maximum of 25% in one sediment system with the PYR label. An additional study showed that if present in water the metabolite DFA would be more slowly degraded systems with the formation of CO_2 (max. 25%) and low levels of non-extractable residues (max.. 16%)..

A proposed degradation pathway is given in Figure 9.7- 1

Figure 9.7- 1: Proposed degradation pathway in aquatic systems



Note: The degradates to be observed as well as the given maximum values are highly dependent on radiolabel and kind of study considered; Ph = photo-transformation

PEC$_{sw}$ modelling approach

Calculation of PEC values for the active substance and metabolites according to FOCUS

FOCUS$_{sw}$ is a four step tiered approach:

Step 1: In this, the most conservative step, all inputs are considered as a single loading to the water body and a worst-case PEC$_{sw}$ and PEC$_{sed}$ is calculated.

Step 2: A refinement is made whereby individual loadings into the water body from different entry routes are considered. Scenarios are also considered for Northern and Southern Europe separately but no specific crop scenarios are defined.

Step 3: An exposure assessment using realistic worst-case scenarios is made. The scenarios are representative of agricultural conditions in Europe and consider weather, soil, crop and different water-bodies. Simulations use the models PRZM, MACRO and TOXSWA.

Step 4: PEC values are refined by considering mitigation measures or specific scenario descriptions on a case-by-case basis.

Note: There are currently no European guidelines for the assessment of exposure of surface water from the use in glasshouses, therefore it was assumed that the use in glasshouses on lettuce is covered by the outdoor field use even considering the different use pattern.

PEC_{sw} for BYI 02960

Report:	**KIIIA1 9.7/01, [redacted].; 2012**
Title:	FPF PECsw FOCUS EU: Predicted environmental concentrations in surface water and sediment - Use in Hops and Lettuce in Europe
Report no.	EnSa-12-0071
Document No	M-427646-01-1
Guidelines:	**FOCUS 2000, SANCO/321/2000-rev.2** **FOCUS 2003, SANCO/4802/2001-rev.2** **FOCUS 2006, SANCO/10058/2005 version 2.0** **FOCUS 2007, SANCO 10422/2005 version 2.0**
GLP:	**No (calculation)**

Materials and Methods: Predicted environmental concentrations in surface water and sediment (PEC_{sw} and PEC_{sed}) of BYI 02960 have been calculated for the use in hop and lettuce in Europe employing the tiered FOCUS Surface Water approach. All relevant entry routes of a compound into surface water (principally a combination of spray drift and runoff/erosion or drain flow) were considered in these calculations.
Details of the parameters used in the calculations are summarised in Table 9.7- 1.

As there is currently no established model for the assessment of exposure of surface water following application in greenhouses the use is assumed to be covered by the field application even considering the higher use rate in greenhouses as the route of entry into surface water would be expected to be much lower following the use in greenhouses.

Table 9.7- 1 Comparison of actual and calculated use pattern (for FOCUS step 1&2)

Individual Crop	FOCUS Crop Used for Interception	Application: Rate per Season [g a.i. /ha]	Application: Interval [days]	Application: Plant Interception [%]	Growth Stage	Amount Reaching the Soil per Season application [g a.i. /ha]
Hops, GAP	hops	1×150	-	-	31-75	-
Hops, simulation		1× 150	-	50 (average crop cover)	31-75	1 x 75
Lettuce (F), GAP	leafy vegetables	1 x 125	-	-	12-49	-
Lettuce (F), simulation [1)]		1 x 125	-	25 (minimal crop cover)	12-49	1 x 93.75

[1)] First or second cropping per year
F = field use

At FOCUS step 3 actual application dates were determined by the PAT (pesticide application timer) included within SWASH. Details on application timing are summarised in Table 9.7- 2.

Table 9.7- 2 Application dates of BYI 02960 (FOCUS Step 3)

Parameter	**Hops**		**Lettuce**	
PAT start date rel./absolute Appl. method (appl. type) No of appl. PAT window range Appl. interval	 Absolute ground spray (CAM 2) 1 98 1		 Absolute ground spray (CAM 2) 2 var. Range 10	
Application Details	PAT Start Date (Julian Day)	Appl. Date	PAT Start Date (Julian Day)	Appl. Date
D1 (1st)	- -	-	- -	-
D2 (1st)	- -	-	- -	-
D3 (1st)	- -	-	30-Apr (121)	04-May 14-May
D3 (2nd)	- -	-	09-Aug (222)	17-Sep 30-Sep
D4 (1st)	- -	-	18-May (139)	18-May 29-May
D5 (1st)	- -	-	- -	
D6 (1st)	- -	-	21-Aug (234)	25-Aug 07-Sep
D6 (2nd)	- -	-	- -	-
R1 (1st)	01-May (122)	02-May	25-Apr (116)	26-Apr 09-May
R1 (2nd)	- -	-	04-Aug (217)	20-Aug 19-Sep
R2 (1st)	- -	-	07-Mar (67)	22-Mar 22-Apr
R2 (2nd)	- -	-	06-Aug (219)	06-Aug 09-Oct
R3 (1st)	- -	-	06-Mar (66)	10-Mar 28-Mar
R3 (2nd)	- -	-	20-Jun (172)	25-Jun 06-Jul
R4 (1st)	- -	-	06-Mar (66)	06-Mar 03-Apr
R4 (2nd)	- -	-	20-Jun (172)	23-Jun 12-Jul

Compound specific input data are summarised in Table 9.7- 3.

Table 9.7- 3 Substance specific and model related input parameter for PEC_{sw} calculation of BYI 02960

Parameter	Unit	BYI 02960
Molar Mass	g/mol	288.7
Water Solubility	mg/L	3200
Vapour pressure	Pa	9.1×10^{-7}
K_{oc}	mL/g	98.4
Freundlich Exponent		0.866
Degradation		
Soil	days	94.8
Total System	days	228
Water	days	228
Sediment	days	228
Max Occurrence		
Water / Sediment	%	100
Soil	%	100

Findings:

Step 1 and 2: The maximum PEC values for Steps 1 and 2 are given in Table 9.7- 4.

Table 9.7- 4 Maximum PEC_{sw} and PEC_{sed} values for BYI 02960 at Step 1 & 2

Crop Appl. rate	FOCUS Step	$PEC_{sw, max}$ [µg/L]	$PEC_{sed, max}$ [µg/kg]
Hops 1 x 150 g/ha	1	53.86	43.49
	2 (N-EU)	13.07	12.49
	2 (S-EU)	17.36	16.70
Lettuce 1 x 125 g/ha (F)	2 (N-EU)	6.410	6.249
	2 (S-EU)	11.78	11.51

Step 3: The maximum PEC_{sw} and PEC_{sed} values for relevant FOCUS Step 3 scenarios are given in Table 9.7- 5. Time dependent PEC values or time-weighted average concentrations are not included in this summary, because they were not used in the risk assessment. However, all values are given in the report.

Table 9.7- 5 Maximum PEC_{sw} and PEC_{sed} of BYI 02960 for relevant scenarios at Step 3 following application to hops

Step 3 Scenario	Entry route	BYI 02960: Hops, 1 x 150 g/ha $PEC_{sw, max}$ [µg/L]	$PEC_{sed, max}$ [µg/kg]
R1, pond	Spray drift	0.394	0.795
R1, stream	Spray drift	5.531	0.362

Table 9.7- 6 Maximum PECsw and PEC_{sed} values of BYI 02960 for relevant scenarios at Step 3 following application to lettuce, field applications

Step 3 Scenario	BYI 02960: Lettuce, 1 x 125 g/ha (F)		
	Entry route *	$PEC_{sw, max}$ [µg/L]	$PEC_{sed, max}$ [µg/kg]
D3 (ditch, 1st)	S	0.830	0.380
D3 (ditch, 2nd)	S	0.840	0.460
D4 (pond, 1st)	D	1.035	4.545
D4 (stream, 1st)	S	0.794	1.772
D6 (ditch, 1st)	D	1.268	1.766
R1 (pond, 1st)	R	0.060	0.162
R1 (stream, 1st)	R	0.858	0.211
R1 (pond, 2nd)	R	0.097	0.254
R1 (stream, 2nd)	R	1.186	0.334
R2 (stream, 1st)	R	1.586	0.521
R2 (stream, 2nd)	R	0.940	0.342
R3 (stream, 1st)	R	2.226	0.469
R3 (stream, 2nd)	R	3.570	1.011
R4 (stream, 1st)	S	0.522	0.054
R4 (stream, 2nd)	R	4.808	1.255

* S = spray drift, R = run-off, D = drainage
F = Field use

Step 4: The maximum PEC_{sw} and PEC_{sed} values for relevant FOCUS Step 4 scenarios with mitigation options are given in the following tables.

Table 9.7- 7: Maximum PEC_{sw} and PEC_{sed} values of BYI 02960 at Step 4 including drift reduction (without buffer) – Hops (1 x 150 g/ha)

Step 4 Buffer Width & Type	FOCUS Scenario	BYI 02960: Hops, 1 x 150 g/ha							
		PECsw [µg/L] Drift Reduction				PECsed [µg/kg] Drift Reduction			
		25%	50%	75%	90%	25%	50%	75%	90%
0m (drift)	R1 (pond, 1st)	0.296	0.197	0.099	0.039	0.607	0.415	0.218	0.094
	R1 (stream, 1st)	4.149	2.766	1.383	0.553	0.273	0.184	0.093	0.072

Table 9.7- 8: Maximum PEC_{sw} and PEC_{sed} values of BYI 02960 at Step 4 including buffer zones and drift reduction – Hops (1 x 150 g/ha)

Step 4		BYI 02960: Hops, 1 x 150 g/ha							
Buffer Width & Type	FOCUS Scenario	PEC_{sw} [µg/L] Drift Reduction				PEC_{sed} [µg/kg] Drift Reduction			
		0%	50%	75%	90%	0%	50%	75%	90%
5m (drift)	R1 (pond, 1st)	0.445	0.223	0.111	0.045	0.891	0.465	0.244	0.105
	R1 (stream, 1st)	4.515	2.258	1.129	0.452	0.297	0.151	0.076	0.071
10m (drift & run-off)	R1 (pond, 1st)	0.253	0.126	0.063	0.025	0.522	0.273	0.142	0.061
	R1 (stream, 1st)	2.354	1.177	0.589	0.235	0.157	0.080	0.04	0.031
15m (drift & run-off)	R1 (pond, 1st)	0.141	0.071	0.035	0.014	0.302	0.158	0.083	0.036
	R1 (stream, 1st)	1.554	0.777	0.388	0.155	0.104	0.053	0.032	0.03
20m (drift & run-off)	R1 (pond, 1st)	0.078	0.039	0.02	0.008	0.174	0.091	0.048	0.021
	R1 (stream, 1st)	0.708	0.354	0.177	0.071	0.048	0.025	0.017	0.016

The mitigation from 10 m onwards includes spray drift and concurrent run-off buffer. However, as can be seen from the linear decrease of PECsw values with increasing drift reduction, the PECsw is always drift dominated and the run-off buffer does not drive the PECsw.
The step 4 PECsw for the pond scenario with 5 m buffer and 0% drift reduction is higher compared to the step 3 value. This is due to the default buffer width of 6 m already included in step 3 calculations resulting in a lower drift percentage of 2.63% compared to 2.97% in step 4.

Table 9.7- 9: Maximum PEC_{sw} and PEC_{sed} values of BYI 02960 at Step 4 including drift reduction (without buffer) – Lettuce (1 x 125 g/ha, field use)

Step 4		BYI 02960: Lettuce, 1 x 125 g/ha (field use)							
Buffer Width & Type	FOCUS Scenario	PECsw [µg/L] Drift Reduction				PECsed [µg/kg] Drift Reduction			
		25%	50%	75%	90%	25%	50%	75%	90%
0m (drift)	D3 (ditch, 1st)	0.632	0.434	0.235	0.117	0.335	0.334	0.333	0.332
	D3 (ditch, 2nd)	0.643	0.446	0.249	0.130	0.419	0.399	0.398	0.397
	D4 (pond, 1st)	1.034	1.034	1.033	1.033	4.538	4.531	4.524	4.520
	D4 (stream, 1st)	0.721	0.721	0.721	0.721	1.771	1.771	1.771	1.771
	D6 (ditch, 1st)	1.268	1.268	1.268	1.268	1.766	1.765	1.765	1.764
	R1 (pond, 1st)	0.055	0.050	0.045	0.043	0.148	0.134	0.119	0.111
	R1 (stream, 1st)	0.858	0.858	0.858	0.858	0.210	0.208	0.207	0.206
	R1 (pond, 2nd)	0.092	0.087	0.082	0.079	0.240	0.225	0.210	0.201
	R1 (stream, 2nd)	1.186	1.186	1.186	1.186	0.333	0.332	0.330	0.330
	R2 (stream, 1st)	1.586	1.586	1.586	1.586	0.520	0.520	0.519	0.518
	R2 (stream, 2nd)	0.940	0.940	0.940	0.940	0.342	0.341	0.341	0.340
	R3 (stream, 1st)	2.226	2.226	2.226	2.226	0.466	0.462	0.459	0.456
	R3 (stream, 2nd)	3.570	3.570	3.570	3.570	1.006	1.000	0.995	0.991
	R4 (stream, 1st)	0.392	0.261	0.131	0.074	0.041	0.027	0.025	0.024
	R4 (stream, 2nd)	4.808	4.808	4.808	4.808	1.253	1.251	1.249	1.248

Table 9.7- 10: Maximum PEC_{sw} and PEC_{sed} values of BYI 02960 at Step 4 including buffer zones and drift reduction – Lettuce (1 x 125 g/ha, field use, 5 and 10m buffer zones

Step 4 Buffer Width & Type	FOCUS Scenario	BYI 02960: Lettuce, 1 x 125 g/ha (field use)							
		PEC_{sw} [µg/L] Drift Reduction				PEC_{sed} [µg/kg] Drift Reduction			
		0%	50%	75%	90%	0%	50%	75%	90%
5m (drift)	D3 (ditch, 1st)	0.252	0.145	0.091	0.059	0.333	0.332	0.332	0.332
	D3 (ditch, 2nd)	0.265	0.158	0.105	0.073	0.398	0.397	0.397	0.396
	D4 (pond, 1st)	1.035	1.034	1.033	1.033	4.541	4.529	4.523	4.520
	D4 (stream, 1st)	0.721	0.721	0.721	0.721	1.771	1.771	1.771	1.771
	D6 (ditch, 1st)	1.268	1.268	1.268	1.268	1.765	1.764	1.764	1.764
	R1 (pond, 1st)	0.057	0.049	0.045	0.042	0.154	0.130	0.117	0.11
	R1 (stream, 1st)	0.858	0.858	0.858	0.858	0.208	0.207	0.206	0.206
	R1 (pond, 2nd)	0.094	0.086	0.082	0.079	0.247	0.221	0.208	0.201
	R1 (stream, 2nd)	1.186	1.186	1.186	1.186	0.331	0.330	0.33	0.329
	R2 (stream, 1st)	1.586	1.586	1.586	1.586	0.519	0.518	0.518	0.518
	R2 (stream, 2nd)	0.940	0.940	0.940	0.940	0.341	0.341	0.34	0.34
	R3 (stream, 1st)	2.226	2.226	2.226	2.226	0.460	0.458	0.456	0.455
	R3 (stream, 2nd)	3.570	3.570	3.570	3.570	0.997	0.993	0.991	0.99
	R4 (stream, 1st)	0.191	0.095	0.074	0.074	0.025	0.025	0.024	0.024
	R4 (stream, 2nd)	4.808	4.808	4.808	4.808	1.250	1.248	1.247	1.247
10m (drift and run-off)	D3 (ditch, 1st)	0.151	0.094	0.066	0.049	0.332	0.332	0.332	0.332
	D3 (ditch, 2nd)	0.165	0.108	0.080	0.063	0.397	0.397	0.396	0.396
	D4 (pond, 1st)	1.034	1.033	1.033	1.033	4.534	4.526	4.522	4.519
	D4 (stream, 1st)	0.721	0.721	0.721	0.721	1.771	1.771	1.771	1.771
	D6 (ditch, 1st)	1.268	1.268	1.268	1.268	1.764	1.764	1.764	1.764
	R1 (pond, 1st)	0.029	0.022	0.019	0.018	0.083	0.064	0.055	0.049
	R1 (stream, 1st)	0.389	0.389	0.389	0.389	0.097	0.097	0.097	0.096
	R1 (pond, 2nd)	0.043	0.037	0.034	0.032	0.122	0.103	0.094	0.088
	R1 (stream, 2nd)	0.540	0.540	0.540	0.540	0.157	0.157	0.157	0.156
	R2 (stream, 1st)	0.716	0.716	0.716	0.716	0.228	0.228	0.228	0.228
	R2 (stream, 2nd)	0.422	0.422	0.422	0.422	0.151	0.151	0.151	0.151
	R3 (stream, 1st)	1.009	1.009	1.009	1.009	0.219	0.217	0.216	0.216
	R3 (stream, 2nd)	1.630	1.630	1.630	1.630	0.452	0.450	0.449	0.448
	R4 (stream, 1st)	0.101	0.051	0.034	0.034	0.012	0.012	0.012	0.011
	R4 (stream, 2nd)	2.184	2.184	2.184	2.184	0.585	0.584	0.584	0.584

Table 9.7- 11: Maximum PEC_{sw} and PEC_{sed} values of BYI 02960 at Step 4 including buffer zones and drift reduction – Lettuce (1 x 125 g/ha, field use, 15 and 20m buffer zones

Step 4 Buffer Width & Type	FOCUS Scenario	BYI 02960: Lettuce, 1 x 125 g/ha (field use)							
		PEC_{sw} [µg/L] Drift Reduction				PEC_{sed} [µg/kg] Drift Reduction			
		0%	50%	75%	90%	0%	50%	75%	90%
15m (drift and run-off)	D3 (ditch, 1st)	0.115	0.076	0.057	0.045	0.332	0.332	0.332	0.332
	D3 (ditch, 2nd)	0.129	0.090	0.071	0.059	0.397	0.396	0.396	0.396
	D4 (pond, 1st)	1.034	1.033	1.033	1.033	4.531	4.524	4.521	4.519
	D4 (stream, 1st)	0.721	0.721	0.721	0.721	1.771	1.771	1.771	1.771
	D6 (ditch, 1st)	1.268	1.268	1.268	1.268	1.764	1.764	1.764	1.764
	R1 (pond, 1st)	0.018	0.013	0.011	0.009	0.055	0.039	0.032	0.027
	R1 (stream, 1st)	0.204	0.204	0.204	0.204	0.053	0.052	0.052	0.052
	R1 (pond, 2nd)	0.025	0.021	0.018	0.017	0.076	0.060	0.052	0.047
	R1 (stream, 2nd)	0.283	0.283	0.283	0.283	0.086	0.085	0.085	0.085
	R2 (stream, 1st)	0.375	0.375	0.375	0.375	0.122	0.122	0.122	0.122
	R2 (stream, 2nd)	0.220	0.220	0.220	0.220	0.081	0.081	0.081	0.081
	R3 (stream, 1st)	0.528	0.528	0.528	0.528	0.119	0.118	0.117	0.117
	R3 (stream, 2nd)	0.856	0.856	0.856	0.856	0.245	0.243	0.242	0.242
	R4 (stream, 1st)	0.069	0.035	0.018	0.018	0.008	0.006	0.006	0.006
	R4 (stream, 2nd)	1.144	1.144	1.144	1.144	0.318	0.317	0.317	0.316
20m (drift and run-off)	D3 (ditch, 1st)	0.097	0.067	0.052	0.045	0.332	0.332	0.332	0.332
	D3 (ditch, 2nd)	0.110	0.081	0.066	0.057	0.397	0.396	0.396	0.396
	D4 (pond, 1st)	1.033	1.033	1.033	1.033	4.529	4.523	4.520	4.518
	D4 (stream, 1st)	0.721	0.721	0.721	0.721	1.771	1.771	1.771	1.771
	D6 (ditch, 1st)	1.268	1.268	1.268	1.268	1.764	1.764	1.764	1.764
	R1 (pond, 1st)	0.016	0.012	0.010	0.009	0.050	0.037	0.03	0.026
	R1 (stream, 1st)	0.204	0.204	0.204	0.204	0.052	0.052	0.052	0.052
	R1 (pond, 2nd)	0.024	0.020	0.018	0.016	0.071	0.057	0.05	0.046
	R1 (stream, 2nd)	0.283	0.283	0.283	0.283	0.086	0.085	0.085	0.085
	R2 (stream, 1st)	0.375	0.375	0.375	0.375	0.122	0.122	0.122	0.122
	R2 (stream, 2nd)	0.220	0.220	0.220	0.220	0.081	0.081	0.081	0.081
	R3 (stream, 1st)	0.528	0.528	0.528	0.528	0.118	0.117	0.117	0.117
	R3 (stream, 2nd)	0.856	0.856	0.856	0.856	0.244	0.243	0.242	0.242
	R4 (stream, 1st)	0.053	0.026	0.018	0.018	0.007	0.006	0.006	0.006
	R4 (stream, 2nd)	1.144	1.144	1.144	1.144	0.317	0.317	0.317	0.316

IIIA1 9.7.1 Initial PECsw value for static water bodies

Please refer to point IIIA 9.7.

IIIA1 9.7.2 Initial PECsw value for slow moving water bodies

Please refer to point IIIA 9.7.

IIIA1 9.7.3 Short-term PECsw values for static water bodies

Please refer to point IIIA 9.7.

IIIA1 9.7.4 Short-term PECsw values for slow moving water bodies

Please refer to point IIIA 9.7.

IIIA1 9.7.5 Long-term PECsw values for static water bodies

Please refer to point IIIA 9.7.

IIIA1 9.7.6 Long-term PECsw values for slow moving water bodies

Please refer to point IIIA 9.7.

IIIA1 9.8 PECsw for relevant metabolites

PEC_{sw} for BYI 02960 metabolites

For BYI 02960, the metabolites difluoracetic acid (DFA), 6-chloronicotinic acid (6-CNA) and BYI 02960-succinamide and BYI 02960-azabicyclosuccinamide were assessed.

Report:	**KIIIA1 9.8/01, [redacted].; 2012**
Title:	FPF PECsw FOCUS EU: Predicted environmental concentrations in surface water and sediment - Use in Hops and Lettuce in Europe
Report no.	EnSa-12-0071
Document No	M-427646-01-1
Guidelines:	**FOCUS 2000, SANCO/321/2000-rev.2** **FOCUS 2003, SANCO/4802/2001-rev.2** **FOCUS 2006, SANCO/10058/2005 version 2.0** **FOCUS 2007, SANCO 10422/2005 version 2.0**
GLP	**No (calculation)**

Materials and Methods: PEC_{sw} for the metabolites were calculated using the approach, scenarios and application rates described for the calculations for the parent compound in Point 9.7. Input parameters for the metabolites are described in Table 9.8- 1.

Table 9.8- 1: Substance specific and model related input parameters for PEC_{sw} calculation

Parameter	Unit	DFA	6-CNA	BYI 02960-succinamide	BYI 02960-azabicyclo-succinamide
Molar Mass	g/mol	96.03	157.6	306.7	288.3
Water Solubility	mg/L	500000	1450	120000	180000
K_{oc}	mL/g	6.8	88	0	0
Degradation					
Soil	days	44.7	4.7	0.1*	0.1*
Total System	days	249	1000	1000	1000
Water	days	249	1000	1000	1000
Sediment	days	249	1000	1000	1000
Max Occurrence					
Water / Sediment	%	6.9	0	39.6	25.9
Soil	%	33.9	17.1	0	0

* The DT_{50} soil was set to 0.1 d as the model STEP2 does not accept 0 d.

Findings:

Step 1 and 2: The maximum PEC values for the metabolites of BYI 02960 at Step 1 and Step 2are given in Table 9.8- 2. Time dependent PEC values or time-weighted average concentrations are not included in this summary, because they were not used in the risk assessment. However, all values are given in the report.

Table 9.8- 2: Maximum PEC_{sw} and PEC_{sed} values for metabolites of BYI 02960

Crop	FOCUS	Difluoroacetic acid		6-Chloronicotinic acid		BYI 02960-succinamide		BYI 02960-azabicyclo-succinamide	
		PEC_{sw} [µg/L]	PEC_{sed} [µg/kg]	PEC_{sw} [µg/L]	PEC_{sed} [µg/kg]	PEC_{sw} [µg/L]	PEC_{sed} [µg/kg]	PEC_{sw} [µg/L]	PEC_{sed} [µg/kg]
Hops 1 x 150 g/ha	Step 1	5.810	0.380	4.177	3.675	4.065	<0.001	2.499	<0.001
	Step 2 N-EU	0.743	0.050	0.232	0.204	4.065	<0.001	2.499	<0.001
	Step 2 S-EU	1.268	0.086	0.463	0.408	4.065	<0.001	2.499	<0.001
Lettuce 1 x 125 g/ha (F)	Step 2 N-EU	0.682	0.046	0.289	0.255	0.484	<0.001	0.297	<0.001
	Step 2 S-EU	1.339	0.091	0.579	0.509	0.484	<0.001	0.297	<0.001

F = Field use

IIIA1 9.8.1 Initial PECsw value for static water bodies

Please refer to point IIIA 9.8.

IIIA1 9.8.2 Initial PECsw value for slow moving water bodies

Please refer to point IIIA 9.8.

IIIA1 9.8.3 Short-term PECsw values for static water bodies

Please refer to point IIIA 9.8.

IIIA1 9.8.4 Short-term PECsw values for slow moving water bodies

Please refer to point IIIA 9.8.

IIIA1 9.8.5 Long-term PECsw values for static water bodies

Please refer to point IIIA 9.8.

IIIA1 9.8.6 Long-term PECsw values for slow moving water bodies

Please refer to point IIIA 9.8.

IIIA1 9.8.7 Additional field studies

Please refer to point IIIA 9.8.

IIIA1 9.9 Fate and behaviour in air

Based on the results of vapour pressure and Henry's law constant determination it is concluded that significant volatilization of BYI 02960 in the environment is not expected. If BYI 02960 enters the atmosphere it would be rapidly degraded with a half-life of 13.1 hours (long-term scenario).

IIIA1 9.9.1 Spray droplet size spectrum - laboratory studies

Not required by current regulations.

IIIA1 9.9.2 Drift - field evaluation

Not required by current regulations.

IIIA1 9.10 Other/special studies

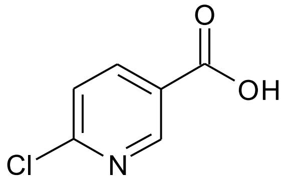
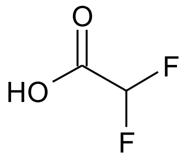
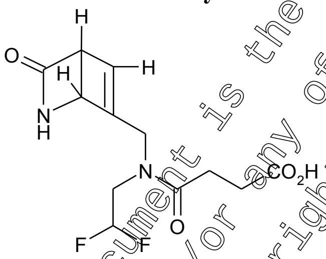
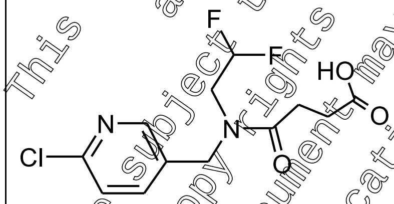
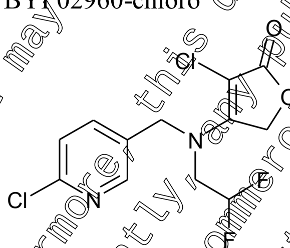
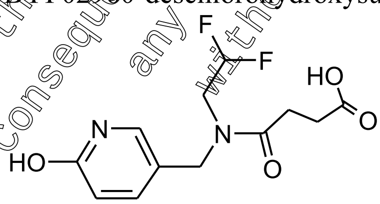
IIIA1 9.10.1 Other/special studies - laboratory studies

Not required by current regulations.

IIIA1 9.10.2 Other/special studies - field studies

Not required by current regulations.

List of BYI 02960 metabolites mentioned in this Section

No.#	Name used in current Section name, Structure	Molecular formula molar mass Other names / codes	Occurrence / considered in
M27	**6-CNA** 	$C_6 H_4 Cl N O_2$ 157.56 g/mol 6-chloronicotinic acid IC-0 (in reports of Nippon Soda Co. Ltd) BYI 02960-6-CNA BCS-AA35572	Aerobic soil (major) Included in PEC_{soil}, PEC_{gw}, PEC_{sw}
M44	**DFA** 	$C_2 H_2 F_2 O_2$ 96.03 g/mol difluoroacetic acid BYI 02960 - DFA BCS-AA56716	Aerobic Soil (major) Aerobic Water /Sediment (major) Included in PEC_{soil}, PEC_{gw}, PEC_{sw}
M47	**BYI 02960-azabicyclosuccinamide** 	$C_{12}H_{14}F_2N_2O_4$ 288.25 g/mol BCS-CS64875	Environment Water – aquatic photolysis (major) Included in PEC_{sw}
M48	**BYI 02960-succinamide** 	$C_{12}H_{13}ClF_2N_2O_3$ 306.69 g/mol BCS-CR74729	Environment Water – Aquatic photolysis (major) Included in PEC_{sw}
The following are minor metabolites in environmental matrices and are not considered in PEC calculations			
M01	BYI 02960-chloro 	$C_{12} H_{10} Cl_2 F_2 N_2 O_2$ 323.13 g/mol BCS-CD27046	Environment Aerobic Soil (minor) Not considered in PEC calculations
M49	BYI 02960-deschlorohydroxysuccinamide 	$C_{12}H_{14} F_2N_2O_4$ 288.25 g/mol DCHS	Environment Water – Aquatic Photolysis (minor) Not considered in PEC calculations

refers to number in Document N