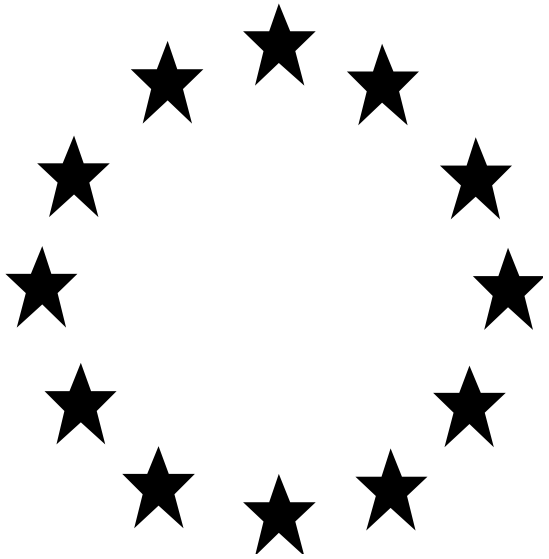

Final addendum to the

Additional Report

- public version -

Additional risk assessment provided by the rapporteur Member State Denmark for the existing active substance

HALOXYFOP-P

according to the Accelerated Resubmission Procedure laid down in Commission Regulation (EC) No. 33/2008

September 2009

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Rapporteur Member State: Denmark

September 2009

Contents

INTRODUCTION

This addendum has been prepared to address open points (not data requirements) for Haloxyfop-P (former Haloxyfop-R) identified at the expert meetings (teleconference) 3 September 2009 (c.f. Evaluation Table, Haloxyfop-P, rev. 1-1 (2009.09.07) and Reporting Table, Haloxyfop-P, rev. 1-1 (17.07.2009).
The List of End Points has been updated according to the Evaluation Table September 2009.

B.5. METHOD OF ANALYSIS

B.5.3.1 Residues in soil

Open point 1.2 in the evaluation table (Haloxyfop-P, rev. 1-1 (07.09.2009)):

"The methods contained in the re-submission dossier for the metabolites in soil and water should be evaluated in an addendum. These are needed to support the residue definitions."

Report: Hastings, M.J., 2007. Method Validation Report for the Determination of Residues of (R)-Haloxyfop and its Metabolites in Soil and Sediment by Liquid Chromatography with tandem Mass Spectrometry detection using Dow AgroSciences method GRM 07.03. Dow AgroScienced LLC, Indiana, USA. Report no. 060155

GLP: Yes

Conclusion: The method for haloxyfop-P and its metabolites DE535 pyridinone, DE 535 phenol and DE535 pyridinole is acceptable, as the method is validated as required. The method is not specific for haloxyfop-P as it cannot separate haloxyfop-P from haloxyfop-M. The LOQ at 2.0 µg/kg for all substances is below the lowest observed NOEC, and is therefore regarded acceptable by RMS.

Haloxyfop--P and its metabolites DE535 pyridinone, DE 535 phenol and DE535 pyridinole are extracted from the soil using methanol followed by methanol/water/10N Naoh (90:5:5). The sample are acidified, diluted and purified on different SPE cartridge and eluted with different solvents depending of the substance. The samples were analysed with positive ESI-LC-MS-MS monitoring two characteristic transitions Haloxyfop-P 362.1/316.0 and 362.1/91.0, DE535 pyridinone 212.0/169.1 and 212.0/74.9, DE 535 phenol 290.0/65.1 and 290.0/39.1 and DE535 pyridinole 198.0/179.9 and 198.0/68.9. The column used is a Phenomenex Gemini C18,; 2.0 x 50 mm, 5 µm.

Linearity: The detector responses are linear for eight reference standards of haloxyfop-P and its metabolites within the concentration range 0.05-0.25 ng/ml. The correlation coefficients are > 0.9985.

Linearity: The detector responses are linear for eight reference standards of tau haloxyfop-P and its metabolites within the concentration range 0.05-0.25 ng/mll. The correlation coefficients are > 0.9992.

Three different soil types, Silt Loam, Sandy Loam and Clay Loam were used in the validation. Two of each types of soil were used for the high and low concentration and one of each for the mid-concentration.

Untreated control soil and sediment samples were obtained from the Dow AgroSciences LLC Control Soil Database. Soil characterization data for the soil and sediment samples used in the validation study are given in the table below.

Sample Number	Matrix (USDA textural classification)	pH	% Organic Carbon
M641	Soil (Silt Loam)	6.2	0.9
M644	Soil (Sandy Loam)	7.7	0.8
M649	Soil (Clay Loam)	7.6	3.8
M693	Sediment (Sand)	6.3	0.4
M694	Sediment (Sandy Loam)	7.8	9.3

Recovery of haloxyfop in soil and sediment:

Matrix	Analyte	Fortification Level (ng/g)	Number of Samples	Recovery (%)	Mean (%)	SD (%)	RSD (%)
Soil	Quantitation Transition	2.0	6	65 - 82	76	5.6	7.4
		20	3	74 - 87	83	7.4	8.9
		200	6	75 - 91	83	6.5	7.8
		2.0 – 200	15	65 - 91	80	6.8	8.5
	Confirmatory Transition	2.0	6	67 - 85	77	6.0	7.8
		20	3	73 - 87	82	7.5	9.2
		200	6	75 - 91	83	7.1	8.5
		2.0 – 200	15	67 - 91	81	6.9	8.6
Sediment	Quantitation Transition	2.0	6	80 - 84	81	1.7	2.1
		20	3	83 - 88	86	2.9	3.3
		200	5	77 - 86	82	3.1	3.8
		2.0 – 200	14	77 - 88	83	3.1	3.8
	Confirmatory Transition	2.0	6	77 - 84	80	2.4	3.0
		20	3	82 - 88	86	3.0	3.5
		200	5	76 - 86	81	3.5	4.3
		2.0 – 200	14	76 - 88	82	3.5	4.3

Recovery of the haloxyfop pyridinol metabolite in soil and sediment:

Matrix	Analyte	Fortification Level (ng/g)	Number of Samples	Recovery (%)	Mean (%)	SD (%)	RSD (%)
Soil	Quantitation Transition	2.0	6	79 - 96	87	5.9	6.7
		20	3	80 - 89	86	5.3	6.1
		200	6	78 - 95	86	6.4	7.5
		2.0 – 200	15	78 - 96	87	5.6	6.5
	Confirmatory Transition	2.0	6	75 - 88	83	5.3	6.3
		20	3	78 - 88	84	5.1	6.1
		200	6	77 - 93	85	6.4	7.5
		2.0 – 200	15	75 - 93	84	5.3	6.4
Sediment	Quantitation Transition	2.0	6	79 - 88	84	3.5	4.1
		20	3	80 - 84	83	2.3	2.8
		200	5	76 - 86	80	3.9	4.9
		2.0 – 200	14	76 - 88	82	3.7	4.5
	Confirmatory Transition	2.0	6	81 - 90	85	3.2	3.8
		20	3	79 - 81	80	1.3	1.7
		200	5	74 - 86	79	4.4	5.6
		2.0 – 200	14	74 - 90	82	4.4	5.3

Recovery of the haloxyfop pyridinone metabolite in soil and sediment:

Matrix	Analyte	Fortification Level (ng/g)	Number of Samples	Recovery (%)	Mean (%)	SD (%)	RSD (%)
Soil	Quantitation Transition	2.0	6	86 - 102	92	5.8	6.3
		20	3	87 - 89	88	1.1	1.3
		200	6	85 - 95	91	3.6	3.9
		2.0 – 200	15	85 - 102	91	4.3	4.7
	Confirmatory Transition	2.0	6	90 - 99	95	4.2	4.4
		20	3	84 - 91	87	3.4	3.9
		200	6	84 - 94	90	3.4	3.7
		2.0 – 200	15	84 - 99	91	4.8	5.3
Sediment	Quantitation Transition	2.0	5	90 - 102	94	4.6	4.9
		20	3	79 - 87	83	4.1	4.9
		200	5	76 - 88	83	4.3	5.3
		2.0 – 200	13	76 - 102	87	6.8	7.9
	Confirmatory Transition	2.0	5	89 - 99	94	4.1	4.3
		20	3	80 - 85	83	2.2	2.6
		200	5	76 - 88	82	4.3	5.2
		2.0 – 200	13	76 - 99	87	6.9	7.9

Recovery of the haloxyfop phenol metabolite in soil and sediment:

Matrix	Analyte	Fortification Level (ng/g)	Number of Samples	Recovery (%)	Mean (%)	SD (%)	RSD (%)
Soil	Quantitation Transition	2.0	6	78 - 87	82	3.5	4.3
		20	3	72 - 80	77	4.1	5.4
		200	6	73 - 88	80	5.3	6.5
		2.0 – 200	15	72 - 88	80	4.5	5.7
	Confirmatory Transition	2.0	6	76 - 85	80	3.7	4.7
		20	3	74 - 77	75	1.7	2.3
		200	6	75 - 86	80	4.1	5.1
		2.0 – 200	15	74 - 86	79	3.9	5.0
Sediment	Quantitation Transition	2.0	5	70 - 84	74	5.8	7.9
		20	3	63 - 76	70	6.5	9.2
		200	5	58 - 79	69	7.7	11.1
		2.0 – 200	13	58 - 84	71	6.7	9.4
	Confirmatory Transition	2.0	5	65 - 87	77	9.2	12.0
		20	3	63 - 80	71	8.3	11.8
		200	5	61 - 75	69	5.6	8.1
		2.0 – 200	13	61 - 87	73	8.0	11.0

B.5.3.2 Residues in water

Open point 1.2 in the evaluation table (Haloxyfop-P, rev. 1-1 (07.09.2009)):

"The methods contained in the re-submission dossier for the metabolites in soil and water should be evaluated in an addendum. These are needed to support the residue definitions."

Report: Hastings, M.J., 2007. Method Validation Report for the Determination of Residues of (R)-Haloxyfop and its Metabolites in Waters by Liquid Chromatography with tandem Mass Spectrometry detection using Dow AgroSciences method GRM 07.02. Dow AgroScienced LLC, Indiana, USA. Report no. 060156
GLP: Yes

Conclusion: The method for haloxyfop-P and its metabolites DE535 pyridinone, DE 535 phenol and DE535 pyridinole is acceptable, as the method is validated as required. The method is not specific for haloxyfop-P as it cannot separate haloxyfop-P from haloxyfop-M. The LOQ at 0.05 µg/L for all substances is below the lowest observed NOEC, and is therefore regarded acceptable by RMS.

Haloxyfop-P and its metabolites DE535 pyridinone, DE 535 phenol and DE535 pyridinole are extracted from an acidified water sample and purified on SPE cartridge. The SPE cartridge is washed with water/methanol (80/20) and eluted with methanol. The eluate is diluted with water and analysed with positive ESI-LC-MS-MS, monitoring two characteristic transitions. Haloxyfop-P 362.1/316.0 and 362.1/91.0, DE535 pyridinone 212.0/169.1 and 212.0/74.9, DE 535 phenol 290.0/65.1 and 290.0/39.1 and DE535 pyridinole 198.0/179.9 and 198.0/68.9. The column used is a Phenomenex Gemini C18,; 2.0 x 50 mm, 5 µm.
Linearity: The detector responses are linear for eight reference standards of haloxyfop-P and its metabolites within the concentration range 0.05-0.25 ng/ml. The correlation coefficients are > 0.9985.

Three types of water (drinking, ground and surface) were used in the validation. Each type was collected from different sites. Three repetitions from each collection site were used for the high and low concentration and two of each for the mid-concentration.

The untreated control drinking water samples were obtained from the drinking water supply within the Dow AgroSciences Research and Development Center, Indianapolis, Indiana, and from a residence in Fishers, Indiana. The untreated control ground water samples were obtained from residential wells in Cicero and Greenfield, Indiana. The surface water samples were obtained from a residential pond in Cicero, Indiana, and from the pond within the Dow AgroSciences Research and Development Center, Indianapolis, Indiana. The chemical and physical properties of the water samples are listed below.

Physical properties of the water samples:

Sample Group Number	Water Type	pH	Hardness (mg equiv. $CaCO_3$/L)	Total Suspended Solids (ppm)	Alkalinity (mg $CaCO_3$/L)	Total Organic Carbon (ppm)	Dissolved Organic Carbon (ppm)
CONTROL-189	Drinking Water	7.9	351	10	252	9.4	9.1
CONTROL-194	Drinking Water	8.2	249	4	202	2.5	2.3
CONTROL-190	Ground Water	7.9	441	6	340	1.6	1.3
CONTROL-193	Ground Water	8.0	324	24	298	7.6	5.3
CONTROL-191	Surface Water	8.3	255	6	137	11.6	7.3
CONTROL-192	Surface Water	7.9	262	10	188	10.6	9.4

Recovery of haloxyfop in water:

Matrix	Analyte	Fortification Level (µg/L)	Number of Samples	Recovery (%)	Mean (%)	SD (%)	RSD (%)
Drinking Water	Quantitation Transition	0.05	6	77 - 98	89	8.0	9.0
		0.50	4	81 - 97	90	7.0	7.8
		5.0	6	87 - 93	91	2.2	2.4
		0.05 – 5.0	16	77 - 98	90	5.8	6.5
	Confirmatory Transition	0.05	6	74 - 96	87	7.8	9.1
		0.50	4	78 - 94	88	7.1	8.0
		5.0	6	86 - 93	89	2.4	2.7
		0.05 – 5.0	16	74 - 96	88	5.8	6.6
Ground Water	Quantitation Transition	0.05	6	73 - 91	86	6.5	7.6
		0.50	4	79 - 96	88	6.7	7.6
		5.0	6	79 - 95	89	6.1	6.9
		0.05 – 5.0	16	73 - 96	88	6.2	7.1
	Confirmatory Transition	0.05	6	73 - 90	84	5.6	6.7
		0.50	4	78 - 91	85	5.4	6.3
		5.0	6	77 - 93	88	6.1	6.9
		0.05 – 5.0	16	73 - 93	86	5.6	6.5
Surface Water	Quantitation Transition	0.05	6	87 - 96	89	3.2	3.5
		0.50	4	89 - 97	93	3.8	4.1
		5.0	6	86 - 97	93	3.7	4.0
		0.05 – 5.0	16	86 - 97	91	3.7	4.0
	Confirmatory Transition	0.05	6	84 - 95	87	3.9	4.4
		0.50	4	85 - 93	89	3.8	4.3
		5.0	6	85 - 95	91	3.6	4.0
		0.05 – 5.0	16	84 - 95	89	4.1	4.5

Recovery of the haloxyfop pyridinol metabolite in water:

Matrix	Analyte	Fortification Level (µg/L)	Number of Samples	Recovery (%)	Mean (%)	SD (%)	RSD (%)
Drinking Water	Quantitation Transition	0.05	6	93 - 102	97	3.1	3.2
		0.50	4	93 - 96	95	1.2	1.3
		5.0	6	87 - 94	90	2.5	2.8
		0.05 – 5.0	16	87 - 102	94	3.9	4.1
	Confirmatory Transition	0.05	6	90 - 105	98	5.4	5.5
		0.50	4	94 - 96	95	1.1	1.2
		5.0	6	86 - 92	89	2.5	2.8
		0.05 – 5.0	16	86 - 105	94	5.4	5.7
Ground Water	Quantitation Transition	0.05	6	92 - 99	95	2.6	2.7
		0.50	4	90 - 99	95	4.0	4.2
		5.0	6	88 - 96	92	3.6	3.9
		0.05 – 5.0	16	88 - 99	94	3.4	3.6
	Confirmatory Transition	0.05	6	91 - 96	94	1.9	2.0
		0.50	4	92 - 99	94	3.4	3.6
		5.0	6	87 - 94	91	2.8	3.1
		0.05 – 5.0	16	87 - 99	93	2.9	3.2
Surface Water	Quantitation Transition	0.05	6	91 - 103	97	5.2	5.3
		0.50	4	92 - 98	95	2.7	2.8
		5.0	6	92 - 96	94	1.4	1.5
		0.05 – 5.0	16	91 - 103	95	3.6	3.8
	Confirmatory Transition	0.05	6	90 - 95	93	2.0	2.1
		0.50	4	91 - 95	93	2.0	2.2
		5.0	6	90 - 93	92	1.5	1.6
		0.05 – 5.0	16	90 - 95	93	1.8	1.9

Recovery of the haloxyfop pyridinone metabolite in water:

Matrix	Analyte	Fortification Level (µg/L)	Number of Samples	Recovery (%)	Mean (%)	SD (%)	RSD (%)
Drinking Water	Quantitation Transition	0.05	6	93 - 101	96	2.9	3.0
		0.50	4	95 - 96	95	0.5	0.6
		5.0	6	88 - 94	91	2.2	2.5
		0.05 – 5.0	16	88 - 101	94	3.2	3.4
	Confirmatory Transition	0.05	6	91 - 103	98	5.1	5.3
		0.50	4	91 - 96	94	2.1	2.3
		5.0	6	88 - 94	91	2.2	2.4
		0.05 – 5.0	16	88 - 103	94	4.5	4.8
Ground Water	Quantitation Transition	0.05	6	94 - 99	97	1.8	1.9
		0.50	4	92 - 97	95	2.3	2.4
		5.0	6	89 - 95	93	2.7	2.9
		0.050 – 5.0	16	89 - 99	95	2.9	3.1
	Confirmatory Transition	0.05	6	93 - 101	98	3.1	3.2
		0.50	4	90 - 97	93	3.3	3.6
		5.0	6	88 - 96	93	3.0	3.3
		0.050 – 5.0	16	88 - 101	95	3.9	4.1
Surface Water	Quantitation Transition	0.05	6	96 - 100	98	1.6	1.6
		0.50	4	91 - 98	94	3.2	3.4
		5.0	6	91 - 96	94	1.7	1.8
		0.050 – 5.0	16	91 - 100	96	3.1	3.2
	Confirmatory Transition	0.05	6	96 - 110	103	5.1	5.0
		0.50	4	91 - 95	93	1.9	2.0
		5.0	6	91 - 96	94	2.0	2.1
		0.050 – 5.0	16	91 - 110	97	5.6	5.7

Recovery of the haloxyfop phenol metabolite in water:

Matrix	Analyte	Fortification Level (µg/L)	Number of Samples	Recovery (%)	Mean (%)	SD (%)	RSD (%)
Drinking Water	Quantitation Transition	0.05	6	78 - 108	90	11.3	12.6
		0.50	4	81 - 94	89	5.2	5.9
		5.0	6	86 - 92	88	2.0	2.3
		0.05 – 5.0	16	78 - 108	89	7.1	8.0
	Confirmatory Transition	0.05	6	77 - 105	89	11.2	12.5
		0.50	4	79 - 90	85	5.3	6.3
		5.0	6	82 - 88	85	2.3	2.7
		0.05 – 5.0	16	77 - 105	86	7.4	8.5
Ground Water	Quantitation Transition	0.05	6	86 - 91	88	1.9	2.2
		0.50	4	84 - 97	91	5.8	6.3
		5.0	6	84 - 92	89	3.0	3.4
		0.05 – 5.0	16	84 - 97	89	3.5	3.9
	Confirmatory Transition	0.05	6	77 - 91	85	5.8	6.8
		0.50	4	84 - 89	87	2.2	2.6
		5.0	6	79 - 88	86	3.3	3.9
		0.05 – 5.0	16	77 - 91	86	4.1	4.8
Surface Water	Quantitation Transition	0.05	6	67 - 91	80	8.2	10.3
		0.50	4	76 - 91	83	7.3	8.8
		5.0	6	76 - 91	83	6.0	7.2
		0.05 – 5.0	16	67 - 91	82	6.8	8.4
	Confirmatory Transition	0.05	6	75 - 92	81	6.3	7.8
		0.50	4	73 - 86	79	6.2	7.9
		5.0	6	74 - 87	81	5.3	6.5
		0.05 – 5.0	16	73 - 92	80	5.6	6.9

B.5.6 References relied on

Annex Point / Reference Number	Author(s)	Year	Title Source Company Report Number GLP Published	Data Protection Claimed	Submitter
IIA, 4.2.2	Hastings, M.J	2007	Method Validation Report for the Determination of Residues of (R)-Haloxyfop and its Metabolites in Soil and Sediment by Liquid Chromatography with tandem Mass Spectrometry detection using Dow AgroSciences method GRM 07.03. Dow AgroScienced LLC, Indiana, USA. Report no. 060155 GLP, Unpublished	Y	Dow
IIA, 4.2.3	Hastings, M.J	2007	Method Validation Report for the Determination of Residues of (R)-Haloxyfop and its Metabolites in Waters by Liquid Chromatography with tandem Mass Spectrometry detection using Dow AgroSciences method GRM 07.02. Dow AgroScienced LLC, Indiana, USA. Report no. 060156 GLP, Unpublished	Y	Dow

Additional Report

Re-assessment for Annex 1 inclusion

Haloxyfop-P

Addendum

Annex B.8 & B.9
Fate and behaviour & Ecotoxicology

Rapporteur Member State: Denmark

September 2009

Contents

INTRODUCTION

This addendum has been prepared to address open points (not data requirements) for Haloxyfop-P (former Haloxyfop-R) identified at the expert meetings (teleconference) 3 September 2009 (c.f. Evaluation Table, Haloxyfop-P, rev. 1-1 (2009.09.07) and Reporting Table, Haloxyfop-P, rev. 1-1 (17.07.2009).
The List of End Points has been updated according to the Evaluation Table September 2009.

B.8 FATE AND BEHAVIOUR

B.8.1.2.1 Rate of degradation in soil, laboratory data

Open point 4.2 in the evaluation table (Haloxyfop-P, rev. 1-1 (07.09.2009)):

"RMS to include the goodness of fit and plots for the residuals of the degradation model without "ghost compartment" (i.e. simple linear degradation route) in an addendum or revised Additional Report."

RMS answer:

Goodness-of-fit for simple model

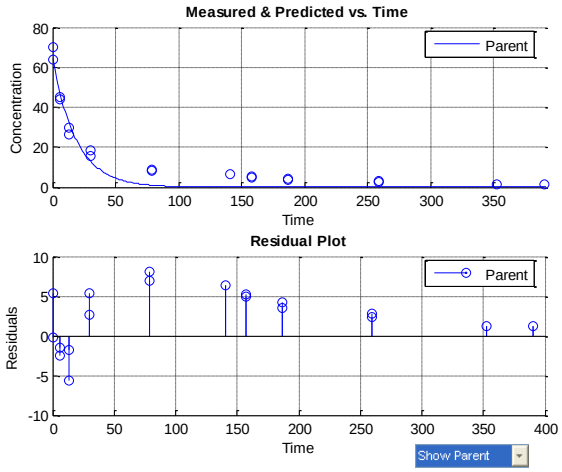
Model: dual SFO, with formation fraction, parent & pyridinol

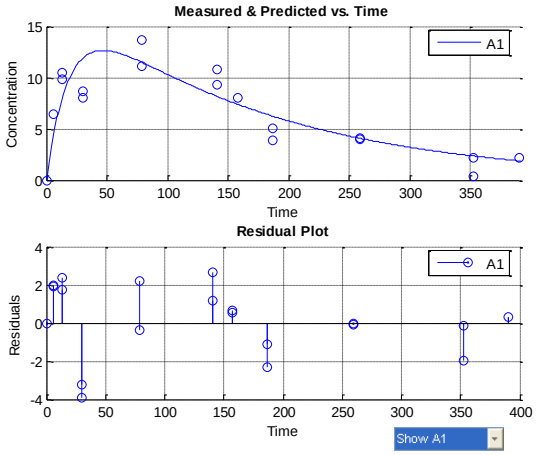
Site	kp, d^{-1}	ffM	km (pyr→ sink), d^{-1}	k1 (parent→ sink), d^{-1}	k2 (parent→pyr), d^{-1}	χ^2error parent	χ^2error pyridinol	DT50 (pyr→ sink), d
Neidersachsen	0.0529	0.2589	0.0059	0.0392	0.0137	19.78%	22.65%	117.48
Bas-Rhin	0.0309	0.2778	0.0120	0.0223	0.0086	18.41%	20.55%	57.76
Baden-Wurttenberg	0.0439	0.3283	0.0209	0.0295	0.0144	27.83%	30.70%	33.16
Champagne	0.045	0.1693	0.0125	0.0374	0.0076	21.68%	33.52%	55.45
-044A	0.0375	0.1684	0.0036	0.0312	0.0063	17.30%	27.67%	192.54
-044B	0.1166	0.2991	0.0372	0.0817	0.0349	30.76%	22.76%	18.63
-044C	0.1266	0.2243	0.0079	0.0982	0.0284	36.49%	11.42%	87.74
	Average ffM	**0.2466**			**Geometric Mean DT50 (d) for pyridinol→sink**			**63.0**
	Geometric Mean DT50 (d) for parent→ sink			**16.40**				
	Geometric Mean DT50 (d) for parent→pyridinol			**51.43**				

Residuals for the simple model

Site: Niedersachsen, Germany

DE-535-pyridinol formation and decline -- Dual SFO, with formation fraction





Parameters:

kp = 0.0529day^{-1}

ffM = 0.2589

k2 (parent -> pyridinol) = (ffM)*kp = 0.0137 day^{-1}

km (pyridinol -> sink) = 0.0059 day^{-1}

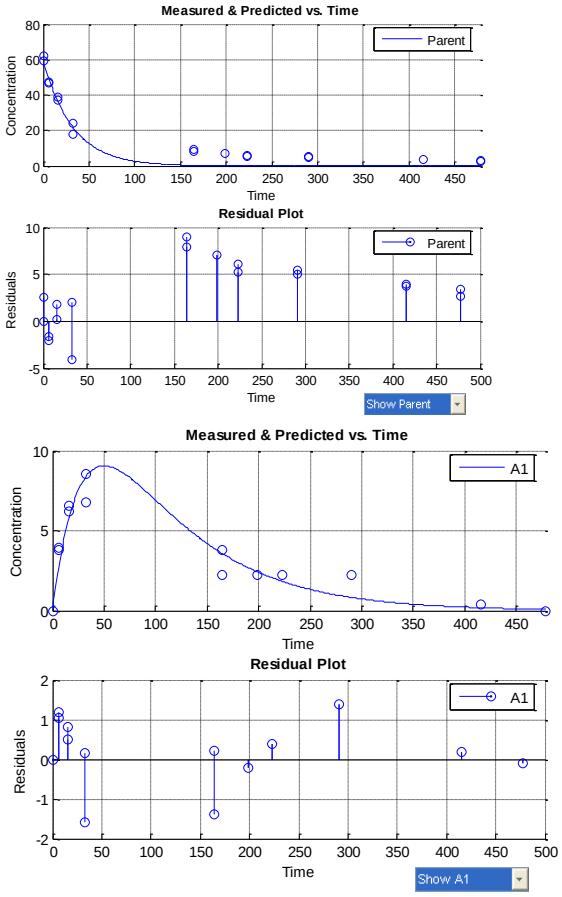
pyridinol DT_{50} = 117.5 d

χ^2 test error level for pyridinol = 22.7%

Observations: Reasonable visual fit for metabolite, with little systematic pattern in residuals. Error somewhat higher than criteria. This schema is usable for PECgw modeling for the metabolite only.

Site: Bas-Rhin, France

DE-535-pyridinol formation and decline -- Dual SFO, with formation fraction



Parameters:

kp = 0.0309day^{-1}

ffM = 0.2778

k2 (parent -> pyridinol) = ffM*kp = 0.0086 day^{-1}

km (pyridinol -> sink) = 0.0120 day^{-1}

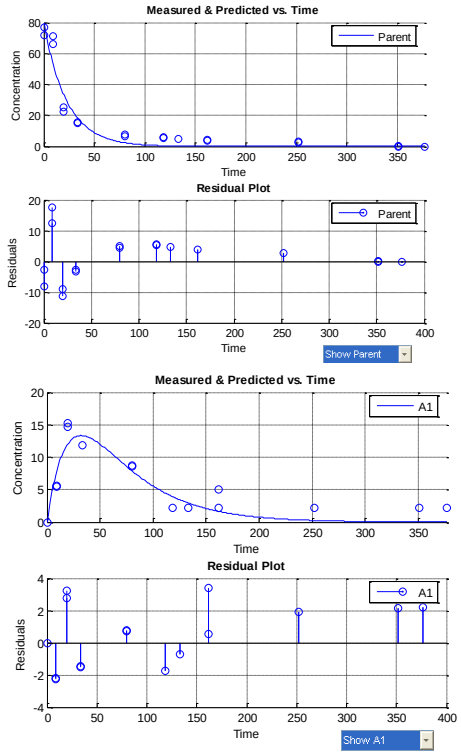
pyridinol DT_{50} = 57.76 d

χ^2 test error level for pyridinol = 20.6%

Observations: Reasonable visual fit for pyridinol, with little systematic pattern in residuals. Error higher than criteria, but this is field data. This schema is usable for PECgw modeling for the metabolite only.

Site: Baden-Wurttemberg, Germany

DE-535-pyridinol formation and decline -- Dual SFO, with formation fraction



Parameters:

kp = 0.0439 day^{-1}

ffM = 0.3283

k2 (parent -> pyridinol) = (ffM)*kp = 0.0144 day^{-1}

km (pyridinol -> sink) = 0.0209 day^{-1}

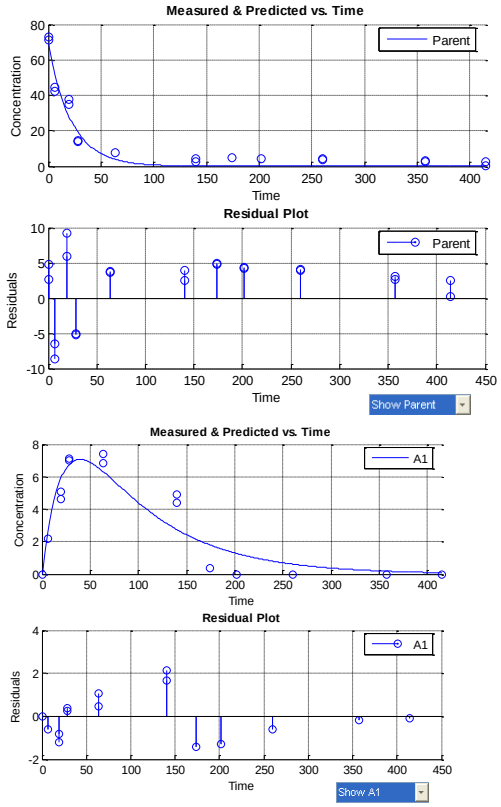
pyridinol DT_{50} = 33.16 d

χ^2 test error level for pyridinol = 30.7%

Observations: Underestimation at later time points, primarily due to <LOQ points set to default of 1.2. Error higher than criteria, but this is field data. This schema is usable for PECgw modeling for the metabolite only.

Site: Champagne, France

DE-535-pyridinol formation and decline -- Dual SFO, with formation fraction



Parameters:

kp = 0.045 day^{-1}

ffM = 0.1693

k2 (parent -> pyridinol) = (ffM)*kp = 0.0076 day^{-1}

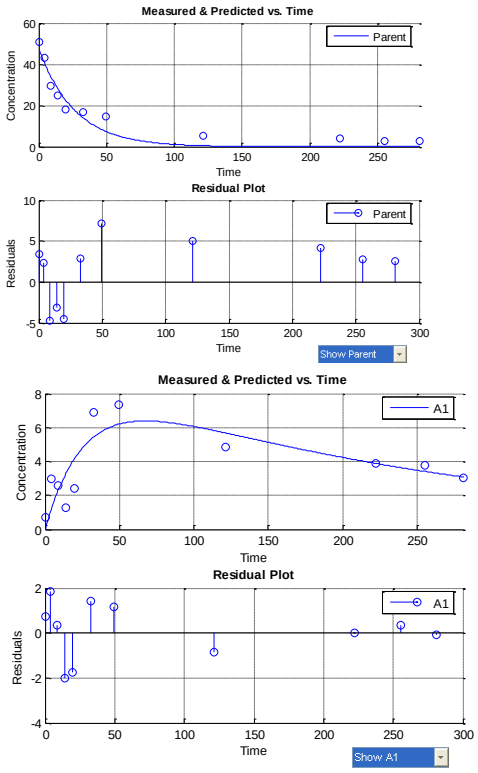
km (pyridinol -> sink) = 0.0125 day^{-1}

pyridinol DT_{50} = 55.45 d

χ^2 test error level for pyridinol = 33.52%

Observations: Reasonable visual fit, with some systematic pattern in residuals. Error somewhat higher than criteria, but this is field data. This schema is usable for PECgw modeling for the metabolite only.

Site: Gross Shenkenberg (044A), Germany
DE-535-pyridinol formation and decline -- Dual SFO, with formation fraction



Parameters:

kp = 0.0375 day^{-1}

ffM = 0.1684

k2 (parent -> pyridinol) = (ffM)*kp = 0.0063 day^{-1}

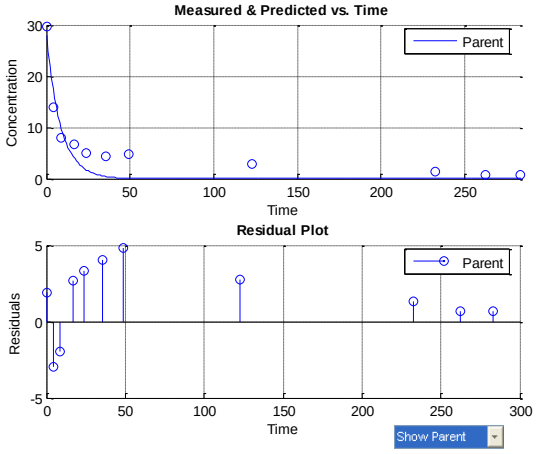
km (pyridinol -> sink) = 0.0036 day^{-1}

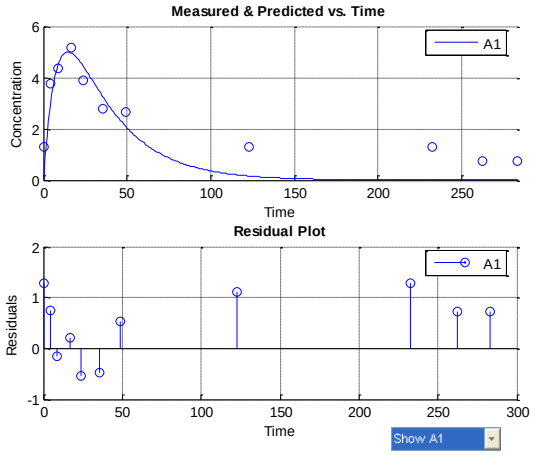
pyridinol DT_{50} = 192.5 d

χ^2 test error level for pyridinol = 17.3%

Observations: Reasonable visual fit, with little systematic pattern in residuals. Error higher than criteria, but this is field data. This schema is usable for PECgw modeling for the metabolite only.

Site: Landsberg (044B), Germany
DE-535-pyridinol formation and decline -- Dual SFO, with formation fraction





Parameters:

kp = 0.1166 day^{-1}

ffM = 0.2991

k2 (parent -> pyridinol) = (ffM)*kp = 0.0349day^{-1}

km (pyridinol -> sink) = 0.0372 day^{-1}

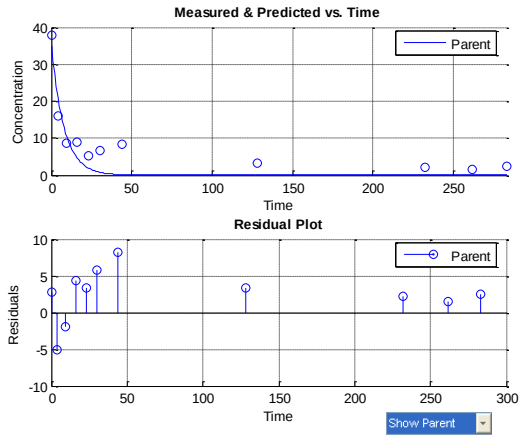
pyridinol DT_{50} = 18.63 d

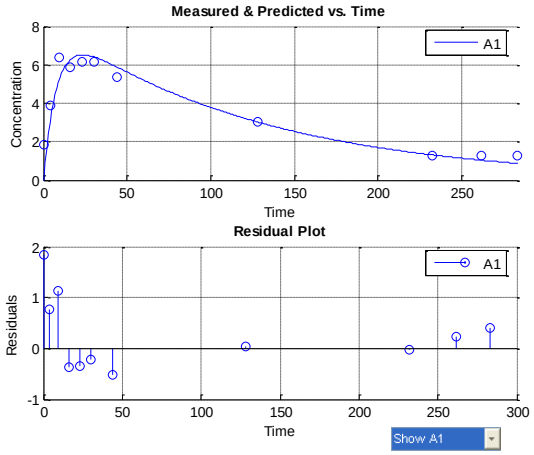
χ^2 test error level for pyridinol = 30.8%

Observations: Reasonable visual fit, underestimation at later time points due to <LOQ rules. Error somewhat higher than criteria, but this is field data. This schema is usable for PECgw modeling for the metabolite only.

Site: Ismanning (044C), Germany

DE-535-pyridinol formation and decline -- Dual SFO, with formation fraction





Parameters:

kp = 0.1254day^{-1}

ffM = 0.2247

k2 (parent -> pyridinol) = (ffM)*kp = 0.0282 day^{-1}

km (pyridinol -> sink) = 0.0080 day^{-1}

pyridinol DT_{50} = 86.64 d

χ^2 test error level for pyridinol = 16.12%

Observations: Reasonable visual fit, with little systematic pattern in residuals. Error just above the criterion. This schema is usable for PECgw modeling for the metabolite only.

B.8.6 PREDICTED ENVIRONMENTAL CONCENTRATIONS IN SURFACE WATER AND IN GROUNDWATER (PEC_{SW}, PEC_{GW}) (ANNEX IIIA.9.2.1; ANNEX IIIA 9.2.3)

B.8.6.1 Predicted environmental concentrations in Groundwater

Open point 4.6 in the evaluation table (Haloxyfop-P, rev. 1-1 (07.09.2009)):

"RMS to report the kinetic parameters (alpha and beta) for the DT50 calculated with a FOMC model (laboratory and field studies) in an addendum or revised Additional Report."

RMS answer:

The kinetic parameters (alpha and beta) are presented in the table below designated a and b, respectively.

compound	Lab (L) Field (F)	report	Soil	parameter	
haloxyfop-P	L	GHE-P-11491	Borstel, PY	2.4025	FOMC, a
				35.4061	FOMC, b
haloxyfop-P	L	GHE-P-11491	Marcham SL, PY	0.8319	FOMC, a
				3.0008	FOMC, b
haloxyfop-P	L	GHE-P-11491	Marcham SL, PH	0.7953	FOMC, a
				2.4995	FOMC, b
haloxyfop-P	L	GHE-P-11491	Highworth, PY	0.5214	FOMC, a
				2.3546	FOMC, b
haloxyfop-P	L	GHE-P-11491	Marcham LS, PY	0.8681	FOMC, a
				8.8541	FOMC, b
Haloxyfop-P	L	GHE-P-11491	Marcham SCL, PY	0.7109	FOMC, a
				2.6659	FOMC, b
haloxyfop-P	L	GHE-P-11491	Speyer 2.2, PY	1.0743	FOMC, a
				14.4114	FOMC, b
haloxyfop-P	F	81098.02	Niedersachsen	0.9764	FOMC, a
				10.2604	FOMC, b
haloxyfop-P	F	81098.02	Bas-Rhin	0.8962	FOMC, a
				18.202	FOMC, b
haloxyfop-P	F	81098.02	Baden-Wurttemberg	4.3008	FOMC, a
				89.5059	FOMC, b
haloxyfop-P	F	81098.02	Champagne	1.161	FOMC, a
				14.4773	FOMC, b
haloxyfop-P	F	81098.02	Gross Shenkenberg	0.8449	FOMC, a
				10.4633	FOMC, b
haloxyfop-P	F	81098.02	Landsberg	0.629	FOMC, a
				1.654	FOMC, b
haloxyfop-P	F	81098.02	Ismanning	0.4729	FOMC, a
				0.6699	FOMC, b

New data gap: 4.2. Identified at PRAPeR TC 18 meeting:

"FOCUS GW modelling with the agreed input parameters (including the agreed 1/n= 1 values associated with the linear partition coefficients (Kd)) is not available."

RMS answer:
A new ground water modelling with the agreed input parameters has been submitted. The study has not been evaluated and peer reviewed:
D YON & P HAVENS, 2009. FOCUSPEARL GROUNDWATER MODELLING OF HALOXYFOP-R AND TWO SOIL METABOLITES – SIMPLIFIED DEGRADATION SCHEME. DOW AGROSCIENCES REGULATORY LABORATORIES. 14 September 2009.

Open point 4.15 in the evaluation table (Haloxyfop-P, rev. 1-1 (07.09.2009)):
"RMS to provide in an addendum or revised Additional Report further details on the adjustments used in PEARL and PELMO to allow the models to run 2 applications every three years."

RMS answer:
An explanation has been giving in the evaluation table (recited below) and a new more exhaustive supplementary explanation can be seen below the recited one below.

Explanation giving in the evaluation table
The adjustments necessary in PELMO and PEARL to allow the models to run two applications in every 3 years (which is a "non-standard" scheme) is explained in GHE-P-11899 (Sections 2.8.1 (p.15) and 2.8.2 (p.16)).

Further clarification is given as follows.

For PELMO, a ".psm" file for a "standard" regime of one application every 3 years was created. The subsequent ".psm" file for each FOCUS scenario was then modified, with an application rate added for year 2 but with no treatment in year 3 which continued in sequence to year 36. Therefore, years 1-6 were for model equilibration, with years 7-36 providing 20 years of applications over a 30 year period.

PELMO was run with the amended ".psm" file and data for years 7-36 were extracted into Excel, from which the 80th percentile annual average leachate concentrations for the modelled period were derived. Appendix II of GHE-P-11899 provides an example.

For PEARL, the application dates for each crop/FOCUS scenario were entered as absolute applications (rather than relative timings), with one application in year 1 and one application in year 2 followed by no treatment in year 3. This continued in sequence through to year 36. As before, years 1-6 were for model equilibration, with years 7-36 providing 20 years of application over a 30 year period. Individual schemes were necessary for each FOCUS scenario to cover the different (in some cases) application dates.

The model wizard was then used to set up a run for each individual FOCUS scenario (since different application dates were set for each). The run was copied to allow the FOCUS run options to be modified, and the following edits were made to the copied run. In Output Control, the report was changed from "FOCUS report" to "No report" which allowed the run dates in Simulation Control to be changed from 1901-1926 to 1901-1936. Then in the Scenario tab, the repeat interval for application events was changed from "1" to "NoRepeat" which allowed 36 years worth of application cycles to be run individually for each FOCUS scenario.

To process the data, the individual ".sum" file for each run was opened from within the PearlDB folder, and the "ConLeaFoc" data extracted into Excel, from which the 80th percentile annual average leachate concentrations were derived. Appendix III of GHE-P-11899 provides an example.

Supplementary explanation to open point 4.15

Modelling Two Annual Applications Every Three Years in FOCUSPELMO

To model the GAP described in Table 1 where single applications are made in two consecutive years followed by no treatment in the third year (which is not a standard option in the model shell), it was necessary to firstly run FOCUSPELMO to model one application every three years. The subsequent ".psm" file for each scenario was then opened and the application details for each FOCUS location modified accordingly, with single applications in each of years 1 and 2 followed by no treatment in year 3. This continued in sequence through to year 36. This allowed years 1-6 to be used for model equilibration, with years 7-36 providing 20 years of application over a 30 year period.

The 80th percentile annual average leachate concentrations for the modelled years 7-36 were extracted into Excel, from which the 80th percentile annual average leachate concentrations for the modelled period were derived.

Modelling Two Annual Applications Every Three Years in FOCUSPEARL

For FOCUSPEARL, two consecutive annual applications every three years could not be incorporated into the model shell, and so the following procedure was carried out to allow this application regime to be modelled.

The application dates in Table 1 for each crop and FOCUS scenario were entered as absolute applications (rather than relative timings) in the FOCUSPEARL application scheme, with applications in years 1 and 2 followed by no treatment in year 3. This continued in sequence through to year 36. This allowed years 1-6 to be used for model equilibration, with years 7-36 providing 20 years of application over a 30 year period. Individual schemes were necessary for each FOCUS scenario to cover the different (in some cases) application dates.

Once the application scheme was created, the FOCUSPEARL wizard was used to set up a run for each individual FOCUS scenario (since different application dates were set for each). The run was then copied to allow the FOCUS run options to be modified, and the following edits were made to the copied run. In the Output Control tab, the report was changed from "FOCUS report" to "No report" which allowed the run dates in the Simulation Control tab to be changed from 1901-1926 to 1901-1936. Then in the Scenario tab, the repeat interval for application events was changed from "1" to "NoRepeat". This then allowed the 36 years worth of application cycles to be run individually for each FOCUS scenario.

In order to process the data the individual ".sum" file for each run was opened from within the FOCUSPEARL file structure (PearlDB folder), and the "ConLeaFoc" data extracted into an Excel spreadsheet, from which the 80th percentile annual average leachate concentrations for the modelled period were derived.

Table 1: Description of GAP Modelled

GAP	Application Date Given by FOCUS Scenarios Corresponding to Post-em Timing
Application to Oilseed Rape (Winter) 52 g ae^{+}/ha (42 d post-em) 40% crop interception (BBCH 10-19) *Effective rate 31 g ae/ha*	CHA = 19 Oct, HAM = 14 Oct, KRE = 14 Oct, OKE = 25 Sep, PIA = 16 Nov, POR = 19 Oct
Application to Sugar Beet 36 g ae^{+}/ha (28 d post-em) 20% crop interception (BBCH 10-19) *Effective rate 29 g ae/ha*	CHA = 14 May, HAM = 13 May, JOK = 22 Jun KRE = 14 May, OKE = 23 May, PIA = 17 Apr POR = 12 Apr, SEV = 8 Dec, THI = 29 May

+ acid equivalent = haloxyfop-R

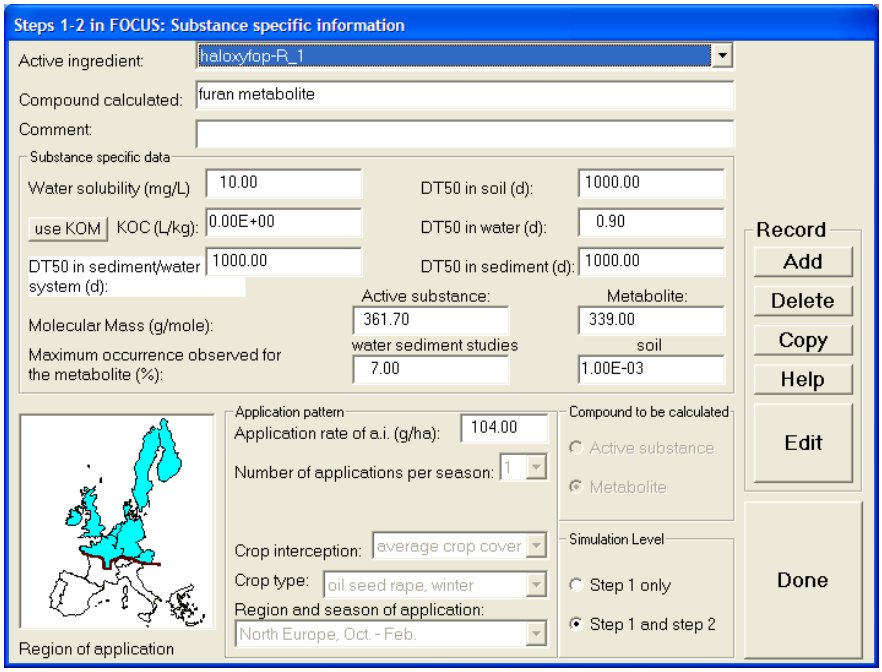
B.8.6.2 Predicted environmental concentrations in Surface Water

Open point 4.16 in the evaluation table (Haloxyfop-P, rev. 1-1 (07.09.2009)):

"RMS to provide specific data for the precursor DE-535 acid used in the FOCUS Steps 1-2 calculations and to clarify for which crop the results presented in Table B.8.6.2.2 on p. 44 of Annex 1 to Addendum are referred to."

RMS answer:

The worst case results for the PECsw of the furan metabolite are given by the autumn use in wOSR, and these are the results presented in Table 1 of the document. This is indicated by the crop type shown in the screen dump (below) from FOCUS Steps 1-2.



B.9 ECOTOXYCOLOGI

B.9.2 Effects on aquatic organisms (Annex IIA 8.2; Annex IIIA 10.2)

B.9.2.1 Acute toxicity to fish (Annex IIA 8.2.1; Annex IIIA 10.2.1)

5.1 Point for clarification in the evaluation table (Haloxyfop-P, rev. 1-1 (07.09.2009)):
"RMS should clarify the units used to give the results of all the tests through the section. The units appear as mg DE-535-pyridinone/L or µg a.i/L instead of mg metabolite /L or µg metabolite /L. This error that should be corrected in an addendum."

RMS answer:
It can be noted that in all cases "DE-535-pyridinone" referred to the compound tested. Moreover, the former name haloxyfop-R has been changed in the text to haloxyfop-P. The corrected sections follow below:

With regard to studies of acute toxicity to fish two new studies were conducted. One with the phenol metabolite (Annex IIA: pt. 8.2.1/05) and one with the pyridinone metabolite (Annex IIA 8.2.1/06). Both studies were with *O. mykiss.*

Annex: IIA section 6 pt. 8.2.1/05

Report: Hicks, Stephen L. (2005). (4-((3-Chloro-5-(trifluoromethyl)2-pyridinyl)oxy)phenol, a phenol metabolite of Haloxyfop: An acute toxicity study with the rainbow trout, *Oncorhynchus mykiss*, Determined under flow through conditions. Dow Chemical Company Study ID: 050227, 49594. Dow AgroSciences, unpublished report No. DECO HET DR-01969-6387-005. Dow AgroSciences.

GLP: Yes

Guidelines: OECD Test Guideline 203, Fish Acute Toxicity Test.
U.S. EPA FIFRA Testing Guideline 72-1.
Deviations: None stated

Material and methods:
The purpose of this study was to determine the acute toxicity of 4-((3-Chloro-5-(trifluoromethyl)-2-pyridinyl)oxy)phenol, a phenol metabolite of Haloxyfop) to *Oncorhyncus mykiss* under flow-through conditions.
Test substance: Batch No. Test Substance Number. TSN102042; Lot No. E0697-9DE-535, Purity 99% (w/w).
Test species: *Oncorhyncus mykiss.* The fish were obtained as eyed embryos from Trout lodge, Summer, Washington. At test start fish were 4.4±0.22 cm length, 0.648-1.263 g weight. They were adapted to test conditions (temperature) before testing.
Test concentrations: Nominal - a dilution water control, Acetone (0.01 ml/L), 0.25, 0.50, 1.0, 2.0, 4.0 mg 4-((3-Chloro-5-(trifluoromethyl)2-pyridinyl)oxy)phenol /L, with mean measured concentrations 0.220, 0.449, 1.01, 1.78 and 3.57 mg DE-535-phenol /L respectively. Test concentrations were measured on a daily basis.
Test design: Two replicates per treatment each containing ten fish. The test media were replaced continually via a proportional diluter.
Sampling: Fish were observed for mortality and sublethal effects at 6, 24, 48, 72 and 96 hours. Dissolved oxygen, pH and temperature were recorded in each test vessel at 0, 24, 48, 72 and 96 hours. Temperature was also recorded continuously in one test vessel.
Statistical analysis: Statistical analysis were performed using a SAS computer program. For LC_{50} with 95% C.L. trimmed Spearman-Karber method was used.
Food: The fish were not fed during the study
Test conditions: Test aquaria were 23 x 31x 32 cm with at test volume of 15 L.

Findings:
Table 8.2.1/05-1. Results

Test substance	4-((3-Chloro-5-(trifluoromethyl)2-pyridinyl)oxy)phenol (Mean measured - mg ts/L)
Test object	*Oncorhyncus mykiss*
24-hour LC_{50} (95% C.L.)	2.83 (2.51 to 3.19)
48-hour LC_{50} (95% C.L.)	2.52 (1.78 to 3.57)
72-hour LC_{50} (95% C.L.)	2.44 (2.30 to 2.60)
96-hour LC_{50} (95% C.L.)	2.37 (2.17 to 2.58)
NOEC 96-hour	1.01

Observations:
Actual concentrations were 0 (control), 0 (vehicle control), 0.220, 0.449, 1.01, 1.78 and 3.57 mg DE-535-phenol/L respectively. After 96 hours mortality was, 0, 0, 0, 0, 0, 10 and 100% in the 0 (control), 0 (vehicle control), 0.220, 0.449, 1.01, 1.78 and 3.57 mg DE-535-phenol/L respectively. The sublethal effects observed in 1.78 and 3.57 DE-535-phenol /L treatments during the exposure consisted of fish lying on the bottom of the test chamber, irregular respiration, and loss of equilibrium. There were no sublethal effects observed in the remaining treatments.

Table 8.2.1/05-2. Mortality and sublethal effects of *Oncorhynchus mykiss* exposed to 4-((3-Chloro-5-(trifluoromethyl)-2-pyridinyl)oxy)phenol under flow through test conditions.

Mean measured concentration (µg/L)	Number of mortalities and sublethal effects			
	24 hours	48 hours	72 hours	96 hours
Control	10N	10N	10N	10N
A	10N	10N	10N	10N
B				
Acetone control	10N	10N	10N	10N
A	10N	10N	10N	10N
B				
0.220	10N	10N	10N	10N
A	10N	10N	10N	10N
B				
0.449	10N	10N	10N	10N
A	10N	10N	10N	10N
B				
1.01	10N	10N	10N	10N
A	10N	10N	10N	10N
B				
1.78	10N	10N	8N; 1B	8N
A	10N	9N; 1B,I	9N; 1LE	9N; 1LE
B				
3.57	2B,I	---	---	---
A	3B,I	---	---	---
B				

10 fish/replicate (20 fish/treatment)
Key: N = Normal, B = on Bottom of test chamber, I = Irregular Respiration, LE =Loss of Equilibrium
"---"indicates that there were no surviving fish

Reviewers comments:
The 96 hours- LC50 was 2.37 mg 4-((3-Chloro-5-(trifluoromethyl)2-pyridinyl)oxy)phenol/L
Some fish in the control were smaller than recommended in OECD 203 Fish Acute Toxicity, the guideline recommendation for trout is 5.0 ± 1.0 cm. The range of the length of the fish was 4.4-5.1 mm. (mean total length). There is a possibility that smaller fish are more sensitive than larger ones.
This deviation from the standard is very small and is not likely to influence the results. The study is acceptable

Annex: IIA section 6 pt. 8.2.1/06

Report: Hicks, Stephen L. (2005). (3-Chloro-N-methyl-5-trifluoromethyl-2-pyridinone) a pyridinone metabolite of Haloxyfop. An acute toxicity study with the rainbow trout, *Oncorhynchus mykiss*, determined under static conditions. Dow Chemical Company Study ID: 050228, 49589. Dow AgroSciences, unpublished report No. DECO HET DR-0238-7066-002. Dow AgroSciences.

GLP: Yes

Guidelines: OECD Test Guideline 203, Fish Acute Toxicity Test and FIFRA EPA FIFRA, Subdivision 72-1.
Deviations: None stated. The report does mention a decrease in oxygen concentration after 24h. An aeration is initiated at this time point, which is in accordance with the OECD guideline.

Material and methods:
The purpose of the study was to determine the acute toxicity of (3-Chloro-N-methyl-5-trifluoromethyl-2-pyridinone) to rainbow trout *Oncorhynchus mykiss.*
Test substance: (3-Chloro-N-methyl-5-trifluoromethyl-2-pyridinone), Batch No. NB-033374-91 TSN104909, Purity 99% (w/w).
Test substance concentrations (based on range finding): Nominal - Water control, Solvent control, 1.9, 3.8, 7.5, 15, 30 mg DE-535-pyridinone /L. Measured 0, 2.10, 3.39, 7.45, 14.0, 29.0 mg DE-535-pyridinone/L. The concentrations were measured on day 0 and day 4.
Test species: Rainbow trout, *Oncorhynchus mykiss*.The fish were obtained as eyed juveniles from Trout Lodge, Summer Washington. The fish used for the test were acclimated (temperature) before the test, without food the last 48 hours before test. Fish mean total length was 44± 2.7mm and mean blotted weight was 0.678 ± 0.128 g.
Test design: Two replicate aquaria each containing ten fish were exposed to each of five target exposure concentrations plus water control and solvent control (0.1 ml/L acetone). The exposure took place under static conditions.
Sampling: Fish were observed for mortality and sublethal effects at 24, 48, 72 and 96 hours.
Statistical analysis: All statistical analysis was performed with SAS software. For LC_{50} with 95% C.L. the trimmed Spearman-Karber method was employed.

Test conditions: Fish were not fed during the study. Dissolved oxygen, pH and temperature were recorded in each test vessel at 0, 24, 48, 72 and 96 hours. Temperature was also recorded continuously in one test vessel. Dissolved oxygen ranged from 5.3 to 9.9 mg O_2/L (55%-102%), temperature 14.8 to 14.9 °C and pH 7.7 to 8.3.

Findings:
Table 8.2.1/06-1. Results

Test substance	3-Chloro-N-methyl-5-trifluoromethyl-2-pyridinone (Mean measured - mg ts/L)
Test object	*Oncorhynchus mykiss*
24-hour LC_{50} (95% C.L.)	22.8 (20.1-25.8)
48-hour LC_{50} (95% C.L.)	20.5 (19.7-21.4)
72-hour LC_{50} (95% C.L.)	20.1 (14.0-29.0)
96-hour LC_{50} (95% C.L.)	20.1 (14.0-29.0)
NOEC	14.0

Observations:
Table 8.2.1/06-2. Mortality and sublethal effects of *Oncorhynchus mykiss* exposed to 3-Chloro-N-methyl-5-trifluoromethyl-2-pyridinone under static test conditions

Mean measured concentration (µg/L)		Number of mortalities and sublethal effects			
		24 hours	48 hours	72 hours	96 hours
Control		10N	10N	10N	10N
A		10N	10N	10N	10N
B					
Acetone control		10N	10N	10N	10N
A		10N	10N	10N	10N
B					
2.10	A	10N	10N	10N	10N
	B	10N	10N	10N	10N
3.39	A	10N	10N	10N	10N
		10N	10N	10N	10N
B					
7.45	A	10N	10N	10N	10N
		10N	10N	10N	10N
B					
14.0	A	10N	10N	10N	10N
		10N	10N	10N	10N
B					
29.0	A	1N, 1B	1N	---	---
		3N	---	---	---
B					

10 fish/replicate (20 fish/treatment)
Key: N = Normal, B = on Bottom of test chamber, "---" indicates that there were no surviving fish

Reviewers comment:
The 96-hours LC50 was 20.1 mg 3-Chloro-N-methyl-5-trifluoromethyl-2-pyridinone/L.
The percentage of oxygen in the test chambers was below the criteria of 80 % of air saturation level after 24 hours. At this time the authors state that a gentle aeration was initiated. There are no reports on dead fish as a result of this oxygen depletion. The study is acceptable.

B.9.2.1.1 The ecotoxicological relevance of the aqueous photolysis metabolite DE-535 furan

In the EFSA conclusion report (EFSA Scientific Report (2006) 87, 1-96, Conclusion on the peer review of Haloxyfop-P) the following data requirement is mentioned in List of studies to be generated: "The ecotoxicological relevance of the photolysis metabolite DE-535 furan needs to be addressed (relevant for all representative uses evaluated; data gap identified in the EPCO meeting; no submission date proposed by the applicant; refer to point 5.2)".

The Notifier has made a recalculation of the TER value based on a recalculation of the predicted environmental concentration (PECsw) of DE-535 furan in surface water. The calculation of (PECsw) is presented in Haloxyfop-P Annex 1 to addendum to Annex B8 March 2009, section B.8.6.2.

REFERENCE: Annex IIA 8.2.1; Annex IIIA 10.2.1

Report:

Dow AgroSciences 2008. Haloxyfop-P. Summary of new information. May 2007, updated March 2008.

The 4 day time weighted average PEC_{SW} for the furan was calculated to be 0.072 µg/L. In the absence of toxicity data, it is assumed that the furan in 10 times more toxic than DE-535. The most sensitive species to DE-535 is the fish, with a 4-day LC50 of 88.4 µg/L. On this basis the resulting TER would be:

88.4 µg/L / 0.072 µg DE-535 furan/L / 10 = **123**

This is greater than trigger TER of 100.

Reviewer's assessment:

According to the Guidance Document on Aquatic Ecotoxicology[1] it is not appropriate to use a time weighted average concentration in a risk assessment of acute effects because it could lead to an underestimation of the risk resulting from the initial period of exposure. In the actual case we have no information about the toxicity e.g. the time of onset of effects. Therefore, an initial PECsw shall be used in stead of a time weighted value.

RMS has calculated the TER value based on the initial PECsw at 0.245 µg/L (this value is equivalent to a FOCUS step 1 PEC) as presented in Haloxyfop-P Annex B8 addendum June 2008, section B.8.6.2.

TER = 88.4 µg DE-535 furan/L / 0.245 µg DE-535 furan/L / 10 = **36**

This value does not meet the trigger value of 100.

As mentioned in Annex B8 Addendum June 2008, the RMS finds that the estimated PEC_{SW} = 0.245 µg/L DE-535 furan is very conservative. The precursor of DE-535 furan - Haloxyfop-P methyl ester (DE-535) - degrades fast in soil ($DT_{50, lab}$: 0.001 – 0.6 days, average: < 0.5 days) and water (DT_{50} 0.19-0.28 days) why a major part may be degraded before reaching the aquatic environment.

Based on the FOCUS surface water step 2 maximum value for run-off/drainage plus spray drift at a distance of 5 meter the RMS has calculated the maximum PEC_{SW} for DE-535 furan to be equal to 0.10 µg/L (Annex B8 Addendum June 2008). The resulting TER value is:

TER = 88.4 µg DE-535 furan/L / 0.10 µg DE-535 furan/L / 10 = **88**.

This value is relatively close to meet the trigger value of 100.

Furthermore, due to the rapid degradation of the precursor a major part of it may be degraded before reaching the aquatic environment and the recommended buffer zone at 5 meter (due to the active substance risk assessment) will give a certain degree of protection against run-off compared with the 1 meter zone used in the calculation of PEC_{SW}. RMS is therefore of the opinion that DE-535 furan does not pose an unacceptable risk to aquatic organisms. However, Member States may require higher tier FOCUS modelling to confirm the assessment.

After the above evaluation and calculation made by the RMS the Notifier 26 March 2009 made a FOCUS surface water step 2 modelling of PEC_{SW} for DE-535 furan. The calculation is presented in Haloxyfop-P Annex 1 to addendum to Annex B8 March 2009, section B.8.6.2 and gave a maximum initial PECsw equal **to 0.0627 µg/L.**

[1] EU Commission Document SANCO /3268/2001 rev. 4 (final), 17 October 2002

Based on this new PEC_{SW} the resulting TER value is:

TER = 88.4 µg DE-535 furan/L / 0.0627 µg DE-535 furan/L / 10 = **141**.

Reviewer's assessment:

The calculated TER value is higher than the trigger value of 100 indicating that no unacceptable effects is expected to occur if the toxicity of the furan metabolite is set to be 10 times higher than the toxicity of haloxyfop-P methyl ester for the most sensitive organism (fish) regarding the ester.

B.9.2.4 Acute toxicity to aquatic invertebrates (Annex IIA 8.2.4; Annex IIIA 10.2.1)

With regard to new studies concerning acute effects on aquatic invertebrates one species, *Daphnia magna*, was tested. The pyridinone and the phenol metabolites were tested.

Annex: IIA, section 6, pt 8.2.4/04

Report: 4-((3-Chloro-5-(trifluoromethyl)-2-pyrindinyl)oxy)phenol, a phenol metabolite of Haloxyfop: Acute Toxicity to the Water Flea, Daphnia magna, Determined Under Static Test Conditions. Hughes, C. (2005). The DOW Chemical Company. Study ID 050229.

GLP: Yes (certified).

Guidelines:
U.S EPA OPPTS 850.1010: Aquatic Invertebrate Acute Toxicity Test, Freshwater Daphnid.
OECD 202: "Daphnia sp. acute immobilisation test and reproduction test, Part I: The 24 hr EC50 acute immobilisation test (Adopted buy the Council on the 4th July 1984). Official Journal of the European Communities. Directive 92/69 EC.2
U.S: EPA – FIFRA Standard Evaluation Procedure 540/9-85-005. Pesticide Assessment Guidelines Subdivision E, Hazard Evaluation: Guideline 72-2.
Deviations: The temperature is supposed to vary only 1°C, in this study the temperature is measured 19-20.5 °C, the deviations is not expected to have influence on the test result.

Material and methods:
This study was carried out to investigate the effect of 4-((3-Chloro-5-(trifluoromethyl)-2-pyrindinyl)oxy)phenol, a Phenol Metabolite of Haloxyfop-P on the 24 and 48- hr immobility for daphnia following laboratory exposure.

Test substance: 4-((3-Chloro-5-(trifluoromethyl)-2-pyrindinyl)oxy)phenol, a Phenol Metabolite of Haloxyfop-P;
Specification: TSN102042; Lot Number: E0697-9; Purity: 99% active ingredient (DE-535-pyridinone)
Test animals: Young (age less than 24 hours) *Daphnia magna* Straus (not first brood).
Test concentrations: Nominal: 0 (control), 0 (vehicle control; 0.10 mL acetone/L), 0.65, 1.3, 2.5, 5.0, and 10 mg DE-535-phenol/L. Measured: 0 (control), 0 (vehicle control; 0.10 mL acetone/L), 0.561, 1.26, 2.35, 4.86, and 9.74 mg DE-535-phenol/L.

Test system: Static system.
Replicates: A glass jar of 250 ml containing 200 ml of test media.
Design: 5 concentrations, a water- and a solvent control. 4 replicates per concentrations with 10 animals in each.
Statistical analysis: Probit analysis, Trimmed Spearman-Karber and Fischers exact test.
Test media: Natural well water blended with demineralised well water to a total hardness of 130 to 160 mg $CaCO_3$/L.
Conditions: pH = 8.3-8.4, Dissolved oxygen >85%, Light (513 Lux)/Dark = 16/8 hr, Temperature = 19-20.5 °C, Hardness: 144 mg $CaCO_3$/L.
Food: None.
Test duration: 48 hr.
Measured: Mortality and mobility
Reference substance: None stated.

Findings:

Table 8.2.4/01- 1: Toxicity of 4-((3-Chloro-5-(trifluoromethyl)-2-pyrindinyl)oxy)phenol to *Daphnia magna*.

Test substance	4-((3-Chloro-5-(trifluoromethyl)-2-pyrindinyl)oxy)phenol, mg DE-535-phenol /L (measured concentrations)
Test object	*Daphnia magna*
Test duration	48 hr
EC50 (Immobility).	4.41
NOEC (Immobility)	2.35*

* Note that a NOEC obtained in an acute study is not valid for risk assessment

Observations:

After 48 hours of exposure, mortality was 0, 5, 0, 0, 5, 60, and 100% in 0 (control), 0 (vehicle control), 0.561, 1.26, 2.35, 4.86, and 9.74 mg DE-535-phenol/L treatments, respectively. Of the 18 surviving daphnids in the 2.35 mg DE-535-phenol/L treatment, one daphnid was observed as quiescent. Of the eight surviving daphnids in the 4.86 mg DE-535-phenol/L treatment, seven daphnids were observed as quiescent. All other daphnids were considered normal.

Analytical confirmation of test solutions was performed at 0 and 48 hours. Mean measured concentrations of the Phenol Metabolite were 0.561, 1.26, 2.35, 4.86, and 9.74 mg DE-535-phenol/L or 86 to 97% of the nominal concentrations.

Table 8.2.4/01-2: Measured concentrations of 4-((3-Chloro-5-(trifluoromethyl)-2-pyrindinyl)oxy)phenol during an acute toxicity test with *Daphnia magna* under static test conditions

Nominal concentration (mg DE-535-phenol/L)	Mean measured concentration of 4-((3-Chloro-5-(trifluoromethyl)-2-pyrindinyl)oxy)phenol (mg DE-535-phenol /L)		
	0 hr	48 hr	Mean
Control	< MQL a	< MQL	a ---
Solvent control	< MQL a	< MQL	a ---
0.65	0.638 (98)	0.483 (74)	0.561 (86)
1.3	1.33 (102)	1.19 (92)	1.26 (97)
2.5	2.63 (105)	2.06 (82)	2.35 (94)
5.0	5.03 (101)	4.68 (94)	4.86 (97)
10	9.57 (96)	9.90 (99)	9.74 (97)
100,000 (stock solution)	96,400 (96)	---	---

[a] Minimum Quantifiable Limit (MQL) = 0.306 mg DE-535-phenol/L.

Reviewers comments:

The study was performed according to the guideline and the study is acceptable. Immobilisation of daphnia of the phenol metabolite of Haloxyfop-P was observed above 2.35 mg DE-535-phenol/L. An EC50 of 4.41 mg DE-535-phenol/L was found.

Annex: IIA, section 6, pt 8.2.4/05

Report: 3-Chloro-N-methyl-5-trifluoromethyl-2-pyridinone, a Pyridinone Metabolite of Haloxyfop; Acute Toxicity to the Water Flea, Daphnia magna, Determined Under Static Test Conditions. Hughes, C. (2005). The DOW Chemical Company. Study ID 050230.

GLP: Yes (certified).

Guidelines:

U.S EPA OPPTS 850.1010: Aquatic Invertebrate Acute Toxicity Test, Freshwater Daphnid.

OECD 202: "Daphnia sp. Acute immobilisation test and reproduction test, Part I: The 24 hr EC50 acute immobilisation test (Adopted buy the Council on the 4th July 1984). Official Journal of the European Communities. Directive 92/69 EC.2
U.S: EPA – FIFRA Standard Evaluation Procedure 540/9-85-005. Pesticide Assessment Guidelines Subdivision E, Hazard Evaluation: Guideline 72-2.

Material and methods:
This study was carried out to investigate the effect of 3-Chloro-N-methyl-5-trifluoromethyl-2-pyridinone, a Pyridinone Metabolite of Haloxyfop-P on the 24 and 48- hr immobility for daphnia following laboratory exposure.

Test substance: 3-Chloro-N-methyl-5-trifluoromethyl-2-pyridinone, a Pyridinone Metabolite of Haloxyfop-P.
Specification: TSN104900; Lot Number: NB-033374-91; Purity: 99% "active ingredient" (DE-535-pyridinone)
Test animals: Young (age less than 24 hours) *Daphnia magna* Straus (not first brood).
Test concentrations: Nominal: 0 (control), 0 (vehicle control; 0.10 mL acetone/L), 1.9, 3.8, 7.5, 15 and 30 mg DE-535-pyridinone/L. Measured: 0 (control), 0 (vehicle control; 0.10 mL acetone/L), 2.06, 4.15, 7.40, 14.8 and 29.1 mg DE-535-pyridinone/L.

Test system: Static system.
Replicates: A glass jar of 250 ml containing 200 ml of test media.
Design: 5 concentrations, a water- and a solvent control. 4 replicates per concentrations with 5 animals in each.
Statistical analysis: Probit analysis, Trimmed Spearman-Karber and Fischers exact test.
Test media: Natural well water blended with demineralised well water to a total hardness of 130 to 160 mg $CaCO_3$/L.
Conditions: pH = 8.2-8.5, Dissolved oxygen >74%, Light (580 Lux)/Dark = 16/8 hr, Temperature = 19.8-20.2 °C, Hardness: 144 mg $CaCO_3$/L.
Food: None.
Test duration: 48 hr.
Measured: Mortality and mobility
Reference substance: None stated.

Findings:
Table 8.2.4/05- 1: Toxicity of 3-Chloro-N-methyl-5-trifluoromethyl-2-pyridinone to *Daphnia magna.*

Test substance	3-Chloro-N-methyl-5-trifluoromethyl-2-pyridinone mg DE-535-pyridinone /L (measured concentrations)
Test object	*Daphnia magna*
Test duration	48 hr
EC50 (Immobility).	$\geq$ 29.1
NOEC (Immobility)	29.1*

* Note that a NOEC obtained in a acute study is not valid for risk assessment

Observations:
At the end of the test (48 h) mortality was 0 % in all controls and test concentrations except for test concentration 7.40 mg DE-535-pyridinone/L in which mortality was 5 %. The 24-h and 48-h EC50 values were estimated to be >29.1 mg DE-535-pyridinone/L. The 48-h NOEC was 29.1 mg DE-535-pyridinone/L based on the lack of statistically significant mortality and sublethal effects in this and lower test substance treatments. Analytical confirmation of test solutions was performed at 0 and 48 hours. Mean measured concentrations of the Pyridinone Metabolite were 97 to 109% of the nominal concentrations.

Table 8.2.4/05-2: Measured concentrations of 3-Chloro-N-methyl-5-trifluoromethyl-2-pyridinone during an acute toxicity test with *Daphnia magna* under static test conditions

Nominal concentration (mg DE-535-pyridinone/L)	Mean measured concentration of 3-Chloro-N-methyl-5-trifluoromethyl-2-pyridinone (mg DE-535-pyridinone /L)		
	0 hr	48 hr	Mean
Control	< MQL [a]	< MQL [a]	a ---
Solvent control	< MQL [a]	< MQL [a]	a ---
1.9	2.09 (110)	2.03 (107)	2.06 (108)
3.8	4.00 (105)	4.29 (113)	4.15 (109)
7.5	7.32 (98)	7.47 (100)	7.4 (99)
15	14.8 (99)	14.7 (98)	14.8 (98)
30	30.6 (102)	27.6 (92)	29.1 (97)
300,000 (stock solution)	332000 (111)	---	---

[a] Minimum Quantifiable Limit (MQL) = 0.306 mg DE-535-pyridinone/L.

Reviewers comments:
The study was performed according to the guideline and the study is acceptable. Toxicity of the pyridinone metabolite of Haloxyfop-P was observed above 29.1 mg/L in the 48 hours test, hence the EC50 is ≥29.1 mg DE-535-pyridinone/L.

B.9.2.6 Effects on algae growth (Annex IIA 8.2.6; Annex IIIA 10.2.1)

With respect to studies of algae growth inhibition the effects of a phenol metabolite (Annex IIA: 8.2.6/06) and a pyridinone metabolite (Annex IIA 8.2.6/07) were studied in algae, *Pseudokirchneriella subcapitata*.

Annex: IIA section 6 pt. 8.2.6/06

Report: Hughes, Chris (2005).
4-((Chloro-5-(trifluoromethyl)-2-pyridinol)oxy)phenol, a phenol metabolite of Haloxyfop: Growth inhibition test with the unicellular green alga, *Pseudokirchneriella subcapitata*. Dow Chemical Company Study ID: 050226, 49592. Dow AgroSciences, unpublished report No. DECO HET DR-0196-6387-004, Dow AgroSciences.

GLP: Yes

Guidelines: OECD Test Guideline No.201, Alga Growth Inhibition Test,
U.S. EPA OPPTS Guideline 850.5400
Deviations: None stated

Material and methods:
The purpose of this study was to assess the 96 hour acute toxicity (NOEC, EC_{50}) of (4-((Chloro-5-(trifluoromethyl)-2-pyridinol)oxy)phenol) on the growth of the green alga *Pseudokirchneriella subcapitata.*
Test substance: (4-((Chloro-5-(trifluoromethyl)-2-pyridinol)oxy)phenol), Batch No. TSN102042, Purity 99% (w/w).
Test species: *Pseudokirchneriella subcapitata,* was obtained from the Department of Botany, Culture collection of algae, University of Texas Austin.
Nominal concentrations: 0 (control), 0 (vehicle control; 0.10 mL acetone/L), 1.9, 3.8, 7.5, 15, and 30 mg DE-535-phenol/L.
Measured concentrations: <MQL (control), <MQL (vehicle control), 1.86, 3.73, 7.73, 15.0, and 26.7 mg DE-535-phenol/L
Test design: Exposure flasks were Erlenmeyer flasks with foam stoppers. For each exposure concentration, algal assay medium control and solvent control treatment (algal assay medium with 100 µL acetone/L) there were four replicates (A; B; C and D) each containing 100 ml of appropriate parent solution. An additional replicate (E) was also prepared of the lowest test substance treatment in order to evaluate incorporation of the test substance into the algal biomass. At test initiation each replicate of the control and vehicle control as well as each A, B, C and

D replicate was inoculated with 1.0 mL of algal concentrate containing approximately 1.0 $*10^6$cells /mL, resulting in a final density of approximately $1.0*10^4$ cells/mL for each flask. Replicate E was not inoculated with algae. Replicate D of the control and test substance treatments was prepared exclusively for water quality measurements at 72 hours. The cultures were incubated in an orbital shaker at approximately 100 rpm throughout the test. Temperature and pH were measured in all parent solutions prior to distribution of the solutions to the test flasks. At 72 and 96 hours, temperature and pH were measured in all treatments.
Statistical analysis: NOEC values were based on area under the curve and growth rate were estimated using a one-way analysis of variance (ANOVA) procedure and a two tailed Dunnett's test. Prior to the Dunnett's test, a Shapiro-Wilks´s test and a Levene´s test were conducted to test for normality and homogeneity of variance respectively over treatments at each time point. EC_{50}, EbC_{50} and ErC_{50} estimates were calculated using a logistic (sigmoid-shaped) model to fit the data with percent inhibition as the dependent variable and concentration as the independent variable.
Test conditions: Continuous temperature recording within the environmental chamber indicated the periodic average temperature within the incubator to be 24.7 ± 0.1°C and ranged from 24.1 to 25.8°C. Continuous light at 4193 to 4381 Lux. Test solution pH ranged from 7.5 to 7.6 at 0 hour. Test solution pH at 72 hours ranged from 7.4 to 8.1 and ranged from 8.6 to 8.9 at 96 hours.

Findings:
Table 8.2.6/06-1. Results

Hour	EC Type	EC Value (95 % confidence interval) [mg DE-535-phenol/L]	NOEC [mg DE-535-phenol/L]
72	EC50	4.70 (4.04-5.36)	2.39
	EbC50	4.43 (4.06-4.81)	2.39
	ErC50	Could not be estimated	2.39
96	EC50	5.75 (5.43-6.97)	2.39
	EbC50	5.16 (4.81-5.51)	2.39
	ErC50	Could not be estimated	2.39

Observations:

Table 8.2.6/06-2. Cell density values for *Pseudokirchneriella subcapitata* during a 96 hour exposure to phenol metabolite.

Mean measured concentration (mg as/L)	Mean cell density (cells/Ml*10^4)				% difference a)	
	24 h	48 h	72 h	96 h	72 h	96 h
Control	2.6	15	51	158	--	--
Solvent control	2.5	13	58	179	--	--
Pooled control	2.6	14	54	169	--	--
0.485	2.3	14	56	195	+4	+15
1.18	2.8	10	58	179	+7	+6
2.39	2.8	10	49	146	-9	-14
4.42	1.9	7.0*	28*	119*	-48	-30
9.75	0.78*	2.2*	8.0*	25*	-85	-85

a) Compared to control
*significant growth enhancement compared to pooled control

Reviewers comments:
The 72-hours EC50 found during this study was 4.70 mg DE-535-phenol/L and for 96 hours EC50 was 5.75 mg DE-535-phenol/L. The NOEC for 72 hours and 96 hours was 2.39 mg DE-535-pyridinone/L.
The light intensity measured during the test (4193 to 4381 lux) was slightly below or in the lower end of the recommended intensity in the OECD guideline (4222-8880 lux). Since the growth in the control increased by more than a factor 16, which is recommended in the guideline this is not regarded as an important factor. The study is acceptable. Toxicity of the phenol metabolite of Haloxyfop-P was observed above 2.39 mg/L (NOEC)

Annex: IIA section 6 pt. 8.2.6/07

Report: Stephen L. Hicks. (2005):
Effects of 3-Chloro-N-Methyl-5-Trifluoromethyl-2-pyridinone on the growth of the freshwater green alga, *Pseudokirchneriella subcapitata*. Dow Chemical Company Study ID: 050225, 49587 September 14, 2005. Dow AgroSciences, unpublished report No. DECO HET DR-0238-7066-003. Dow AgroSciences

GLP: Yes

Guidelines: OECD Test Guideline No.201, Alga Growth Inhibition Test,
U.S. EPA OPPTS Guideline 850.5400
Deviations: None stated

Material and methods:
The purpose of this study was to assess the acute toxicity of 3-Chloro-N-Methyl-5-Trifluoromethyl-2-pyridinone over a 96 hour exposure period on the growth of the fresh water green alga *Pseudokirchneriella subcapitata*.
Test substance: 3-Chloro-N-Methyl-5-Trifluoromethyl-2-pyridinone Batch No. NB-033374-91, TSN 104909, Purity 99% (w/w).
Test species: *Pseudokirchneriella subcapitata*, from the Department of Botany, Culture Collection of Algae, University of Texas Austin.
Nominal concentrations: 1.9, 3.8, 7.5, 15 and 30 mg DE-535-pyridinone /L, plus solvent (acetone) control and negative control.
Analysed concentrations (0 hour, mean) 3-Chloro-N-Methyl-5-Trifluoromethyl-2-pyridinone: 0 for controls, 1.86, 3.73, 7.73, 15.0, 26.7 mg DE-535-pyridinone/L.
Test design: The control and the vehicle control were replicated seven times (A-G) and each test substance treatment were replicated four times. An additional replicate (replicate E of the lowest test substance treatment), containing 100 mL of the appropriate parent solution, was also prepared and used to evaluate incorporation of the test substance in the algal biomass. At initiation each test substance treatment were inoculated with 1.0 mL of an algal concentrate containing approximately $1.0 * 10^6$ cells/mL resulting in a final density of approximately $1.0 * 10^4$ cells/mL for each flask. Density was measured at time 24, 48, 72 and 96 hours. Replicate E of the lowest test substance treatment was not inoculated with algae. Temperature and pH was measured in all treatments at 72 and 96 hours. The prepared cultures were maintained in a temperature controlled environmental chamber under continuous light.
Statistical analysis: Analysis of variance and Dunnett's test. Prior to the Dunnett's test a Shapiro-Wilk´s test and a Levene´s test were conducted to test normality and homogeneity of variance.
Test conditions: The exposure flasks were 250-mL Erlenmeyer flasks with foam stoppers and labeled with study Number, treatment, replicate, and grid position. Prior to test initiation, the flasks were cleaned and autoclaved according to ABC standard operating procedures. At test initiation, all replicates of the control and vehicle control and each A, B, C, and D replicate of each test substance treatment were added 100 mL of the appropriate parent solution and inoculated with 1.0 mL of an algal concentrate containing approximately 1.0 × 106 cells/mL, resulting in a final density of approximately 1.0 × 104 cells/mL for each flask. The temperature was maintained at 24 ± 2 °C, with continuous light at 4222 to 4359 lux.

Findings:
Table 8.2.6/07-1. Results

Test substance	3-Chloro-N-Methyl-5-Trifluoromethyl-2-pyridinone (Mean measured concentration (mg DE-535-pyridinone/L))
Test object	*Pseudokirchneriella subcapitata*
72-hour E_bC_{50} and E_rC_{50} (growth inhibition and growth rate)	> 26.7
96-hour E_bC_{50} and E_rC_{50} (growth inhibition and growth rate)	> 26.7
72 and 96-hour NOEC	26.7

Observations:
The temperature was kept between 23.5 and 25.2 °C. The pH was between 7.5 and 7.6 without alga and between 7.4 and 8.9 with algae. Light was between 4222 and 4359 lux.
The NOEC at 72 and 96 hours was 26.7 mg DE-535-pyridinone/L based on the lack of a statistically significant reduction in the area under the growth curve at this and lower test substance treatments. Based on the area under the growth curve values, the EC50 for 72 and 96 hours is >26.7 mg DE-535-pyridinone /L the highest concentration used.

Reviewers comments:
Both the 72-hour and the 96-hour EC50 value were > 26.7 mg DE-535-pyridinone/L the highest concentration used. The NOEC for 72 hours and 96 hours were 26.7 mg DE-535-pyridinone/L

The measured light intensity (4222-4359) was below the lower range mentioned in the OECD guideline (4440-8880 lux). This might have influence general the growth of the algaes but is not seen as a reason to require a new test. The study is acceptable. NOEC is >26.7 mg DE-535-pyridinone the highest concentration used.

B.9.2.7 Effects on sediment dwelling organisms (Annex IIA 8.2.7)

With regard to sediment testing of aquatic invertebrates one species, *Chironomus riparius*, was tested with the pyridinol metabolite (Annex IIA: 8.2.7/0/) in a 28-day study.

Annex: IIA section 6 pt. 8.2.7/02

Report: John Aufderheide (2001). 3-Chloro-5-(trifluoromethyl)-2pyridinol, a pyridinol metabolite of Haloxyfop: Chronic toxicity in whole sediment to freshwater midge, *Chironomus riparius*. Unpublished report. The Dow Chemical Company.

GLP: Yes

Guidelines:
OECD Guideline 219 (2005)
Deviations: Test organisms were not fed on day 7.

Material and methods:
The effects of 3-Chloro-5-(trifluoromethyl)-2pyridinol on the sediment dwelling phase of the midge *Chironomus riparius* were assessed under laboratory test conditions. The test concentrations were based on a 13 day range finding test. Observations were made on a daily basis and after 13 days of exposure treated animals were not impacted as compared to the control.
Specification: Batch No. ACPR 1-95, Purity = 99.9% (w/w) and TSN: AGR218257.
Test animals: First instar (age 1-4 days) *Chironomus riparius*.
Test concentrations: Nominal: 0, 0.95; 1.9; 3.8; 7.5; 15 and 30 mg DE-535-pyridinol/L. A solvent control was included (acetone, 100µL acetone/L). Maximum concentration of 30 mg/L was selected due to the limited solubility in water at higher concentrations. Actual concentrations 0.910, 1.85, 3.20, 6.25, 12.1 and 23.3 mg DE-535-pyridinol/L.
Test system: 28 days chronic toxicity with *Chironomus riparius* exposed to 3-Chloro-5-(trifluoromethyl)-2-pyridinol within the overlying water. Aeration was provided and only discontinued during the addition of larvae and the resumed within 24 hours.
Objective: The primary objective was to determine the effect of the test substance on adult emergence or development rate.
Replicates: Four replicate test chambers were prepared for the biological parameters. A total of eight replicate Chambers were prepared for the various analyses of the overlying water, pore water, and sediment samples. The biological replicates were covered with an emergence trap that consisted of a polyethylene jar with a screen mesh lid. The analytical replicates were covered with a perforated plastic lid. The test chambers were prepared three days prior to test initiation (i.e. addition of the test organisms).
Design: The test chambers were 1L glass jars that were approximately 17*9.5 cm. Approximately 200 g sediment (2 cm in depth) was added to each replicate and 600 mL volume of dilution water or prepared test solution added. Test chambers were inoculated daily for three days prior to test initiation with concentrated green alga (1.5 to 2.5 mL (*Pseudokirchneriella subcapitata*)) solution in order to provide a food source for the larvae. Measurements of temperature, dissolved oxygen concentration and pH were made at the initiation and weekly in each replicate test chamber. Six concentrations and a water and a solvent control with 20 first instar animals in each.
Statistical analysis: NOEC values for emergence and development rate were determined by using a one way analysis of variance (ANOVA), followed by a Dunnett's test for determination of significance. The Dunnett's test was conducted at a 0.05 level of significance. Prior to the ANOVA and Dunnett's test a Shapiro-Wilk´s test and a Levenes test were conducted to test for normality and homogeneity of variance respectively.
Test media:
Sediment (artificial): 76% fine industrial sand, 20% kaolinite clay, and 4% sphagnum peat. The pH adjusted by $CaCO_3$ to a pH of 7±0.5.
Water: The test water was a moderately hard freshwater prepared by blending naturally hard well water with well water that was de-mineralized by reverse osmosis. These waters were blended to yield a total hardness of 130 to 160 mg/L as CaCO3 and biologically aged (held in a tank containing aquatic organisms).

Conditions: pH = 7.8-8.5, Light/Dark = 16/8 hr, Temperature = 19.4 – 20.6 °C. The lowest dissolved oxygen concentrations for the overlying water, including the controls were 3.37 mg/L (39% of air saturation), which was recorded only on day 7 in one replicate of the vehicle control and 4.84 mg/L (56% of air saturation), which was recorded in one replicate of the control treatment on day 21. Aeration was increased in these test chambers and the dissolved oxygen was maintained above 60% saturation of the remainder of the exposure. All other dissolved oxygen measurements ranged from 5.47 to 8.45 mg/L (63 to 97% of air saturation).
Test duration: 28 days. From day 15, when the first flies emerged, adults were sexed.
Measured: Emergence and development.
Reference substance: The test substance was used to prepare all test solutions for the range-finding and definitive tests as well as quality control samples.

Findings:
Table 8.2.7/02- 1: Toxicity of 3-Chloro-5-(trifluoromethyl)-2pyridinol to *Chironomus riparius.*

Test substance	mg 3-Chloro-5-(trifluoromethyl)-2pyridinol /L	
Test object	*Chironomus riparius*	
Test duration	28 days	
	Emergence	Development rate
EC50	>23.3	>23.3
NOEC	23.3	23.3

Observations:
Percent emergence of adult chironomids in the control and vehicle control were 94 and 96%, respectively, which exceeded the minimum of 70% control emergence specified by the protocol and the OECD guidance document. The majority of control emergence (>90%) occurred between days 12 and 23 days after addition to the test chambers. The mean percent emergence was 98, 90, 88, 89, 94, and 88% for the 0.910, 1.85, 3.20, 6.25, 12.1, and 23.3 mg DE-535-pyridinol/L treatments, respectively.
The gender ratio for the control and vehicle control were both 1.1 males to each female. The male to female gender ratio for the treatments ranged from 0.7 in the 1.85 mg DE-535-pyridinol/L treatment level to 1.3 in the 12.1 mg DE-535-pyridinol/L treatment level. There was not a concentration dependent effect of the test substance on the observed gender ratios. Therefore statistical analysis of the emergence rates was based upon total adult emergence.

Table 8.2.7/02-2: Measured overlying water concentration of 3-Chloro-5-(trifluoromethyl)-2-pyridinol during a 28-day exposure with *Chironomus riparius*.

Nominal water concentration (mg /L)	Measured 3-Chloro-5-(trifluoromethyl)-2-pyridinol concentration as mg/L (Percent of nominal)			
	Day 0	Day 7	Day 28	Mean[b]
Control (0)	<MQL [a]	<MQL [a]	<MQL [a]	<MQL [a]
Vehicle control (0)	<MQL [a]	<MQL [a]	<MQL [a]	<MQL [a]
0.95	0.910 (96)	0.844 (89)	0.619 (65)	0.780 (82)
1.9	1.85 (97)	2.08 (109)	1.27 (67)	1.70 (89)
3.8	3.20 (84)	3.97 (104)	2.26 (59)	3.06 (81)
7.5	6.25 (83)	4.60 (61)	4.58 (61)	5.09 (68)
15	12.1 (81)	9.97 (66)	7.31 (49)	9.59 (64)
30	23.3 (78)	21.4 (71)	14.6 (49)	19.4 (65)
Stock (300,000)	311,000 (104)	---	---	---
	QC Fortifications			
Low spike (0.918)	1.04 (113)	1.10 (120)	1.09 (119)	---
High Spike (30.5)	27.3 (90)	28.7 (94)	31.0 (102)	---

[a] MGL= 0.309 mg/L
[b] Calculated geometric mean of the measured concentrations

No residues of 3-Chloro-5-(trifluoromethyl)-2-pyridinol were detected in the control or vehicle control at or above the MQL of 0.309 mg DE-535-pyridinol/L. Recoveries of 3-Chloro-5-(trifluoromethyl)-2-pyridinol in the QC samples ranged from 90 to 120% of the nominal concentrations during the exposure period.

Table 8.2.7/02-3: Measured interstitial water concentration of 3-Chloro-5-(trifluoromethyl)-2-pyridinol during a 28-day exposure with *Chironomus riparius*.

Nominal water concentration (mg /L)	Measured 3-Chloro-5-(trifluoromethyl)-2-pyridinol concentration as mg/L			
	Day 0	Day 7	Day 28	Mean[b]
Control (0)	<MQL [a]	<MQL [a]	<MQL [a]	<MQL [a]
Vehicle control (0)	<MQL [a]	<MQL [a]	<MQL [a]	<MQL [a]
0.95	<MQL [a]	<MQL [a]	<MQL [a]	<MQL [a]
1.9	<MQL [a]	1.73	1.88	1.36
3.8	<MQL [a]	2.21	2.44	1.61
7.5	2.43	3.59	3.83	3.22
15	3.70	5.73	6.19	5.08
30	7.29	11.3	11.8	9.91

[a] MGL= 1.55 µg/L (mg/kg sediment)
[b] Calculated as the geometric mean of the measured concentrations. If the measured concentration was less than MQL, ½ of the MQL value was used in the mean calculations

The initial measured concentrations of 3-Chloro-5-(trifluoromethyl)-2-pyridinol within the sediment samples were <MQL (control), <MQL (vehicle control), <MQL, <MQL, <MQL, 2.43, 3.70, and 7.29 mg DE-535-pyridinol/kg of sediment. The day 7 sediment concentrations were <MQL (control), <MQL (vehicle control), <MQL, 1.73, 2.21, 3.59, 5.73, and 11.3 mg DE-535-pyridinol/kg of sediment. The day 28 sediment concentrations were <MQL (control), <MQL (vehicle control), <MQL, 1.88, 2.44, 3.83, 6.19, and 11.8 mg DE-535-pyridinol/kg of sediment. Mean measured concentrations of 3-Chloro-5-(trifluoromethyl)-2-pyridinol within the sediment samples were <MQL (control), <MQL (vehicle control), <MQL, 1.36, 1.61, 3.22, 5.08, and 9.91 mg DE-535-pyridinol/kg of sediment. No residues of 3-Chloro-5-(trifluoromethyl)-2-pyridinol were detected in the control or vehicle control at or above the MQL of 1.55 mg DE-535-pyridinol/kg of sediment. The sediment concentrations have not been corrected for dry weight of sediment.

Table 8.2.7/02-4: Measured interstitial water concentrations of 3-Chloro-5-(trifluoromethyl)-2-pyridinol during a 28-day exposure with *Chironomus riparius*.

Nominal water concentration (mg /L)	Measured 3-Chloro-5-(trifluoromethyl)-2-pyridinol concentration expressed as mg/kg sediment			
	Day 0	Day 7	Day 28	Mean[b]
Control (0)	<MQL [a]	<MQL [a]	<MQL [a]	<MQL [a]
Vehicle control (0)	<MQL [a]	<MQL [a]	<MQL [a]	<MQL [a]
0.95	<MQL [a]	0.654	0.621	0.447
1.9	0.563	0.969	1.31	0.894
3.8	0.908	1.95	1.82	1.48
7.5	1.96	4.00	4.27	3.22
15	3.88	7.86	8.98	6.49
30	7.93	15.7	14.8	12.3

The initial measured concentrations of 3-Chloro-5-(trifluoromethyl)-2-pyridinol within the interstitial water samples were <MQL (control), <MQL (vehicle control), <MQL, 0.563, 0.908, 1.96, 3.88, and 7.93 mg DE-535-pyridinol/L. The day 7 interstitial water concentrations were <MQL (control), <MQL (vehicle control), 0.654, 0.969, 1.95, 4.00, 7.86, and 15.7 mg DE-535-pyridinol/L. The day 28 interstitial water concentrations were <MQL (control), <MQL (vehicle control), 0.621, 1.31, 1.82, 4.27, 8.98, and 14.8 mg DE-535-pyridinol/L. Mean measured concentrations of 3-Chloro-5-(trifluoromethyl)-2-pyridinol within the interstitial water samples were <MQL (control), <MQL (vehicle control), 0.447, 0.894, 1.48, 3.22, 6.49, and 12.3 mg DE-535-pyridinol/L. No residues of 3-Chloro-5-(trifluoromethyl)-2-pyridinol were detected in the control or vehicle control at or above the MQL of 0.441 mg DE-535-pyridinol/L.

Reviewers comments:
The EC50 values of the pyridinol metabolite for emergence and developmental rate were both > 23.3 mg/L. The corresponding NOEC values for emergence and developmental rate where 23.3 mg/L.
The lowest dissolved oxygen concentrations for the overlying water, including the controls were 3.37 mg/L (39% of air saturation), which was recorded only on day 7 in one replicate of the vehicle control and 4.84 mg/L (56% of air saturation), which was recorded in one replicate of the control treatment on day 21. According to the OECD standard the oxygen saturation should be above 60%. Since aeration was increased in these test chambers and the dissolved oxygen was maintained above 60% saturation of the remainder of the exposure and since no effects of the decrease in oxygen supply is reported this deviation is not regarded as a reason to repeat the study. The study can be accepted.

B.9.2.8 Effects on aquatic plants (Annex IIA 8.2.8)

With regard to studies of growth inhibition of aquatic plants the effects of the phenol metabolite (Annex: 8.2.8/04) and the pyridinone metabolite (Annex: 8.2.8/05) were studied in *Lemna gibba.*

Annex: IIA section 6 pt. 8.2.8/04

Report: Hughes, C., (2005). 4-((3-Chloro-5-(trifluromethyl-2-pyridinol)oxy)phenol, a phenol metabolite of Haloxyfop: Growth inhibition test with the freshwater aquatic plant, Duckweed, *Lemna gibba*. Test Substance Number TSN102042; Lot no. E0697-9; File number DECO HET DR-0196-6387-002; STUDY ID 050224, 49593; Dow AgroSciences, unpublished report.

GLP: Yes

Guidelines:
OECD Draft Test Guideline 221
Deviations: None stated

Material and methods:

The study was carried out to assess the 7-day median effect concentration (EC_{50}) of the phenol metabolite to *Lemna gibba.* A secondary objective was to determine the No Observable Effect Concentration (NOEC) and the Lowest Observable Effect Concentration (LOEC). Inhibition of growth and biomass were used as toxicological endpoints.
Test substance: 4-((3-Chloro-5-(trifluromethyl-2-pyridinol)oxy)phenol Test Substance Number TSN102042: Lot no. E0697-9. Purity 99%.Test species: *Lemna gibba.* Acclimated laboratory culture originating from specimens obtained from USDA/ARS Beltsville Agricultural Research Center, Beltsville, Maryland (November 27, 2002).
Test concentrations based on range finding study. The nominal concentrations used were: 0 (control), 0 (control, vehicle 0.1 mL acetone/L), 0.65, 1.3, 2.5, 5.0 and 10.0 mg DE-535-phenol/L was established. The definitive tests were conducted in Erlenmeyer flasks with foam stoppers. Before initiation the flasks were cleaned and autoclaved.
Measured concentrations: <MQL (control), <MQL (vehicle control), 0.522, 1.23, 2.57, 4.91, and 9.95 mg DE-535-phenol/L. Test design: Two hundred-milliliter volumes of the resulting solutions were transferred to the exposure flasks. Fresh test solutions were prepared in the same manner on study days 3 and 5, respectively. The flasks were randomly positioned each day and incubated at 25 ± 2º C for seven days in a temperature-controlled environmental chamber under continuous warm-white fluorescent lightning. Intensity 8477-8980 lux. Three replicate vessels in all test and control treatments. Each flask received three plants, for a total of 10 fronds, at test initiation. Aseptic addition of *Lemna gibba* was initiated within one hour after solution preparation was completed. Plant growth was monitored in each flask. Growth was measured by determining the change in the number of fronds during the exposure period. Every frond that visibly projected beyond the edge of the parent frond was counted as a separate frond. Any change in plant development, frond size, appearance, necrosis or chlorosis was noted, if observed. Frond observations and counts were performed on days 3, 5, and 7 for all replicates of the controls and each test substance treatment. The duration of the experiment was 7 days. The control, vehicle control, and all test substance treatments were renewed on days 3 and 5 of the test. Beginning with the controls and continuing up to the highest test substance treatment, plants were aseptically transferred from spent test solutions to fresh test solutions. Test concentrations were verified at day 0, and 5 in the fresh solutions and on day 3 and 7 in the expired media.
Temperature and pH were measured in all fresh parent solutions, prior to distribution of the solutions to the test flasks, on days 0, 3 and 5. On days 3, 5, and 7, temperature and pH were measured in replicate A of all treatment spent solutions. Temperature was between 24.2 and 24.5 (day 3), 23.5 and 23.9 (day 5) and 24.0 and 24.5 (day 7). pH was between 8.8 and 8.9 (day 3), 8.7 and 8.8 (day 5) and 8.8 and 9.1 (day 7).
Statistical analysis: A Shapiro-Wilk´s test and a Levene´s test were conducted to test for normality and homogeneity ($p>0.01$). A one-way analysis of variance (ANOVA) and a Dunnett's comparison to the pooled control were conducted for each time point to determine the NOEC. A one-tailed Dunnett's test was conducted at the level 0.05 of significance. The LOEL was also determined by this analysis.
Test conditions: 200 ml of test or control culture in 500 ml Erlenmeyer flasks in a random blocked design in a controlled environmental chamber (8447-8980 lux, 25±2 °C).

Findings:
Table 8.2.8/04 -1 Results (day 7)

	Parameter Effect Concentration as mg DE-535-phenol/L (95% Confidence Limits)			
Endpoint	Number of fronds	Area under the growth curve	Growth rate	Biomass as dry weight
NOEC	2.57	2.57	2.57	2.57
LOEC	4.91	4.91	4.91	4.91
EC_{50}	7.90 (7.00 to 8.80)	9.21 (8.02 to 10.4)	> 9.95 (---)	7.27 (6.34 to 8.20)

Measured concentrations of phenol metabolite in fresh solutions approximated the nominal concentration (76-106%) indicating that the test solutions were correctly dosed. Therefore endpoints were based on the mean of the day 0 and 5 phenol metabolite concentrations in fresh solutions.

Observations:
Percent change in the number of fronds, as compared to the pooled controls, ranged from -59% at 9.94 mg DE-535-phenol /L to +14% at 0.522 mg DE-535-phenol/L after 7 days of exposure to Phenol Metabolite. One-way analysis of variance showed no significant ($p = 0.05$) reduction in the number of fronds in test substance treatments ≤ 2.57 mg DE-535-phenol/L as compared to the pooled controls at the 7-day time point. The NOEC on day 7 was 2.57 mg DE-535-phenol/L, based on the lack of a statistically significant reduction in the number of fronds at this and lower test substance treatments. The LOEC on day 7 was 4.91 mg DE-535-phenol/L, based

on the statistically significant reduction in the number of fronds at this test substance treatment. Based on the number of fronds, the 7-day EC50, value was estimated to be 7.90 mg DE-535-phenol/L with 95% confidence limits of 7.00 to 8.80 mg DE-535-phenol/L.

Percent change in area under the growth curve, as compared to the pooled controls, ranged from -52% at 9.95 mg DE-535-phenol/L to +12% at 0.522 mg DE-535-phenol/L after 7 days of exposure to Phenol Metabolite. One-way analysis of variance showed no significant ($p = 0.05$) reduction in the area under the growth curve in test substance treatments ≤ 2.57 mg DE-535-phenol/L as compared to the pooled controls. The NOEC on day 7 was 2.57 mg DE-535-phenol/L, based on the lack of a statistically significant reduction in area under the growth curve at this and lower test substance treatments. The LOEC on day 7 was 4.91 mg DE-535-phenol/L, based on the statistically significant reduction in area under the growth curve at this test substance treatment. Based on area under the growth curve, the EC50 value on day 7 was estimated to be 9.21 mg DE-535-phenol/L

Percent change in growth rate, as compared to the pooled controls, ranged from -30% at 9.95 mg DE-535-phenol/L to +5% at 0.522 mg DE-535-phenol/L after 7 days of exposure to Phenol Metabolite. One-way analysis of variance showed no significant ($p = 0.05$) reduction in the growth rate in test substance treatments ≤ 2.57 mg DE-535-phenol/L as compared to the pooled controls. The NOEC on day 7 was 2.57 mg DE-535-phenol/L, based on the lack of a statistically significant reduction in the growth rate at this and lower test substance treatments. The LOEC on day 7 was 4.91 mg DE-535-phenol/L, based on the statistically significant reduction in growth rate at this test substance treatment. Based on growth rate, the EC50 value on day 7 was estimated to be >9.95 mg DE-535-phenol/L, the highest concentration tested.

Percent change in biomass, as compared to the pooled controls, ranged from -63% at 9.95 mg DE-535-phenol/L to +14% at 0.522 mg DE-535-phenol/L. One-way analysis of variance showed no significant ($p = 0.05$) reduction in the biomass in all test substance treatments ≤ 2.57 mg DE-535-phenol/L as compared to the pooled controls. The NOEC on day 7 was 2.57 mg DE-535-phenol/L, based on the lack of a statistically significant reduction in the biomass at this and the lower test substance treatments. The LOEC on day 7 was 4.91 mg DE-535-phenol/L, based on the statistically significant reduction in biomass at this test substance treatment. Based on biomass, the EC50 value on day 7 was estimated to be 7.27 mg DE-535-phenol/L with 95% confidence limits of 6.34 to 8.20 mg DE-535-phenol/L.

Reviewers comments:
The NOEC and LOEC values for the phenol metabolite were 2.57 mg DE-535-phenol/L and 4.91 mg DE-535-phenol /L respectively for all endpoints tested (numbers of fronds, area under the growth curve, growth rate and biomass as dry weight). The lowest LC50 value was found for the endpoint "biomass as dry weight" and was 7.27 mg DE-535-phenol/L. The test followed the procedures and the criterion's described in the OECD Guideline and is accepted.

Annex: IIA section 6 pt. 8.2.8/05

Report: Stephen L. Hicks. (2005). 3-chloro-N-methyl-5-trifluromethyl-2-pyridinone, a pyridinone metabolite of Haloxyfop: Growth inhibition test with the freshwater aquatic plant, Duckweed, *Lemna gibba.* Dow AgroSciences unpublished report Study ID 050223, 49588, DECO HET DR-0238-7066-066.

GLP: Yes

Guidelines:
OECD Draft Test Guideline 221: Lemna sp. Growth inhibition Test.
Deviations: None stated

Material and methods:
Test substance: 3-chloro-N-methyl-5-trifluromethyl-2-pyridinone, purity 99 % (w/w), Batch No. NB-033374-91, Test substance Number TSN104909 Test species: *Lemna gibba* G3 obtained from the USDA/ARS Beltsville Agricultural Research Center, Beltsville Maryland (November 2002).
Test Concentrations: Range finding was carried out at concentrations from 0.1 to 10 mg as/L. Nominal concentrations in exposure media were 0 (control), 0 (vehicle control; 0.10 mL acetone/L), 0.95, 1.9, 3.8, 7.5, 15, and 30 mg DE-535-pyridinone/L. measured mean concentrations were similarly 0.565, 1.79, 3.46, 6.83, 13.8 and 26.4 mg pyridinone/L.

Test design: Each test vessel (500 ml Erlenmeyer flasks with foam stoppers) received 200 ml of the appropriate test solution. Test concentrations were verified by measurement of samples taken on day 0, 3, 5 and 7. A HP 5890 Series II gas chromatograph (GC) equipped with a flame ionization detector (FID). There were three replicate vessels in all test and control treatments. Initially each vessel contained 11 fronds. The duration of the exposure phase was 7 days and on days 3, 5, test media was renewed
Temperature and pH were measured in all fresh media prior to distribution of the solutions to the test flasks on day 0, 3 and 5. On days 3, 5 and 7 temperature and pH were measured in replicate A, B and C respectively of all treatment spent solutions. Temperature and pH were measured with a WTW pH 330i meter.
Statistical analysis: Calculations of the EC values and determination of NOEC and LOEC values were based on growth parameters of number of fronds, area under the growth curve, growth rate, and biomass (dry weight) versus the mean of the fresh solution measured concentrations of Pyridinone Metabolite. A Shapiro-Wilk's test and Levene's test were conducted to test for normality and homogeneity of variance, respectively, over treatments at each time point. A one-way analysis of variance (ANOVA) and a Dunnett's comparison to the pooled control were conducted for each time point to determine the NOEC and LOEC. A two-tailed Dunnett's test was conducted at the 0.05 level of significance with the alternate hypothesis being that the growth parameter analyzed had been reduced or enhanced in comparison to the pooled controls.
Test conditions: Laboratories are maintained under the same conditions (i.e., temperature, growth medium, and light quality) as those for the toxicity test, no acclimation to exposure conditions was necessary. Tests were conducted in a controlled environment chamber under continuous illumination (8164-8721lux) at 24.5-24.7 °C.

Findings:
Table 8.2.8/05 -1 Results (day 7)

	Parameter Effect Concentration as mg DE-535-pyridinone/L			
Endpoint	Number of fronds	Area under the growth curve	Growth rate	Biomass as dry weight
NOEC	13.18	13.8	13.8	26.4
LOEC	26.4	26.4	26.4	>26.4
EC_{50}	>26.4	>26.4	>26.4	>26.4

Observations:
Percent change in the number of fronds, as compared to the pooled controls, ranged from -19% at 26.4 mg DE-535-pyridinone/L to +3% at 6.83 mg DE-535-pyridinone/L after 7 days of exposure to Pyridinone Metabolite. One-way analysis of variance showed no significant (p = 0.05) reduction in the number of fronds in test substance treatments ≤ 13.8 mg DE-535-pyridinone/L as compared to the pooled controls at the 7-day time point. The NOEC on day 7 was 13.8 mg DE-535-pyridinone/L, based on the lack of a statistically significant reduction in the number of fronds at this and lower test substance treatments. The LOEC on day 7 was 26.4 mg DE-535-pyridinone/L, based on the statistically significant reduction in the number of fronds at this test substance treatment. Based on the number of fronds, the 7-day EC50, value was estimated to be >26.4 mg DE-535-pyridinone/L, the highest concentration tested.

Percent change in area under the growth curve, as compared to the pooled controls, ranged from -23% at 26.4 mg DE-535-pyridinone/L to 0% at 6.83 mg DE-535-pyridinone/L after 7 days of exposure to Pyridinone Metabolite. One-way analysis of variance showed no significant (p = 0.05) reduction in the area under the growth curve in test substance treatments ≤13.8 mg DE-535-pyridinone/L as compared to the pooled controls. The NOEC on day 7 was 13.8 mg DE-535-pyridinone/L, based on the lack of a statistically significant reduction in area under the growth curve at this and lower test substance treatments. The LOEC on day 7 was 26.4 mg DE-535-pyridinone/L, based on the statistically significant reduction in area under the growth curve at this test substance treatment. Based on area under the growth curve, the EC50 value on day 7 was estimated to be >26.4 mg DE-535-pyridinone/L, the highest concentration tested.

Percent change in growth rate, as compared to the pooled controls, ranged from -7% at 26.4 mg DE-535-pyridinone/L to 0% at 6.83 mg DE-535-pyridinone/L after 7 days of exposure to Pyridinone Metabolite. One-way analysis of variance showed no significant (p = 0.05) reduction in the growth rate in test substance treatments ≤13.8 mg DE-535-pyridinone/L as compared to the pooled controls. The NOEC on day 7 was 13.8 mg DE-535-pyridinone/L, based on the lack of a statistically significant reduction in the growth rate at this and lower test substance treatments. The LOEC on day 7 was 26.4 mg DE-535-pyridinone/L, based on the statistically significant reduction in growth rate at this test substance treatment. Based on growth rate, the EC50 value on day 7 was estimated to be >26.4 mg DE-535-pyridinone/L, the highest concentration tested.

Percent change in biomass, as compared to the pooled controls, ranged from -22% at 26.4 mg DE-535-pyridinone/L to +2% at 6.83 mg DE-535-pyridinone/L. One-way analysis of variance showed no significant (p = 0.05) reduction in the biomass in all test substance treatments as compared to the pooled controls. The NOEC on day 7 was 26.4 mg DE-535-pyridinone/L, based on the lack of a statistically significant reduction in the biomass at this and the lower test substance treatments. The LOEC on day 7 was >26.4 mg DE-535-pyridinone/L, the highest concentration tested. Based on biomass, the EC50 value on day 7 was estimated to be >26.4 mg DE-535-pyridinone/L, the highest concentration tested.

Reviewers comments:
For the pyridinone metabolite the lowest NOEC =13.18 mg DE-535-pyridinone/L and the lowest LOEC =26.4 mg DE-535-pyridinone/L was found for numbers of fronds, area under the growth curve and growth rate. For all endpoints tested the EC50 was > 26.4 mg DE-535-pyridinone /L.
Looking at the data presented in the report, the results obtained from the test concentration 6.83 mg DE-535-pyridinone/L stands out. I.e. there is an increase in the final biomass compared to the control solutions and the mean growth rate and the numbers of fronds were not negatively affected compared to the remaining test concentrations. There is no explanation for this in the report. The study followed the procedures and criteria's in the OECD Guideline and is accepted.

B.9.2.12 Summary of effects on aquatic organisms

New studies on aquatic ecotoxicology were submitted. Tests included acute toxicity tests on rainbow trout, acute toxicity tests on invertebrate *Daphnia magna*, growth inhibition test with green algae *Pseudokirchneriella subcapitata* and the fresh water plant *Lemna gibba.* All tests were conducted with the phenol metabolite and the pyridinone metabolite of Haloxyfop-P. Chronic toxicity of the pyridinol metabolite of Haloxyfop-P was also tested on the fresh water midge *Chironomus riparius*, this is in accordance with the requirements stated in the "list of studies to be generated" in the ESFA scientific report (2006). All tests were conducted according to GLP and all studies were accepted.

B.9.2.12.1 Summary of acute toxicity to fish

A total of two new studies concerning acute fish toxicity were included. Both of these concerned the acute toxicity (96 hour) to *Oncorhynchus mykiss.* The tested metabolites were phenol and pyridinone.
The study concerning the acute toxicity of the phenol metabolite showed a LC_{50} = 2.37 mg as/L and the acute NOEC was 1.01mg as/L. The study concerning the acute toxicity of the pyridinone metabolite showed a LC_{50} = 20.1 mg as/L and the acute NOEC was 14.0 mg as/L.
The results are summarised in table 9.2-1.

Table 9.2-1. Summary of acute toxicity to fish studies

Reference	Species	Test type	Test substance	NOEC	LC_{50}
8.2.1/05	*Oncorhynchus mykiss*	Acute toxicity (96 h)	Phenol metabolite	1.01 mg/L	2.37 mg/L
8.2.1/06	*Oncorhynchus mykiss*	Acute toxicity (96 h)	Pyridinone metabolite	14 mg/L	20.1 mg/L

B.9.2.12.4 Acute and Chronic toxicity to aquatic invertebrates

When testing *Daphnia magna* in acute (48 hr) toxicity tests the phenol and pyridinone metabolites showed an EC_{50} of 4.41 mg/L and ≥29.1 mg/L respectively.

Table 9.2.12.4-1. Summary of acute toxicity to aquatic invertebrates

Annex (Duration)	Substance (purity)	Species	EC_{50} (Immobility)	NOEC (Immobility)	LOEC (Immobility)
8.2.4/04 (48 hr)	Phenol metabolite of Haloxyfop-P	*Daphnia magna*	4.41 mg/L	2.35 mg/L	-
8.2.4/05 (48 hr)	Pyridinone metabolite of Haloxyfop-P	*Daphnia magna*	≥29.1 mg/L	29.1 mg/L	-

"-": not estimated

B.9.2.12.5 Effects on algae

Two new studies concerning toxic effects towards algae were evaluated.
The phenol and the pyridinone metabolite were tested and the estimated NOEC was 2.39 and 26.7 mg/L respectively, for both 72 h and 96h. E_bC_{50} were 4.43 and 5.16 mg/L for the phenol metabolite after 72 hours and 96 hours and for the pyridinone metabolite the E_bC_{50} and E_rC_{50} were >26.7 mg/L.

Table 9.2.12.5-1. Summary of algae studies

	Test species	Test substance	NOEC mg/L	E_bC_{50} mg/L	E_rC_{50} mg/L
8.2.6/06	*Pseudokirchneriella subcapitata*	Phenol metabolite of Haloxyfop-P	2.39 (72h)	4.43 (72h)	-
			2.39 (96h)	5.16 (96h)	-
8.2.6/07	*Pseudokirchneriella subcapitata*	Pyridinone metabolite of Haloxyfop-P	26.7 (72h)	> 26.7 (72h)	> 26.7 (72h)
			26.7 (96h)	> 26.7 (96h)	> 26.7 (96h)

"-": Not calculated

B.9.2.12.6 Effects on sediment-dwelling organisms

One study was performed for other aquatic invertebrates (*Chironomus riparius*) and this showed reduced emergence at concentrations above 23.3 mg/L for the pyridinol metabolite.

Table 9.2.12.6-1. Summary of effects on sediment dwelling organisms.

Reference	Substance (purity)	Media	Species	EC50	NOEC	LOEC
				(mg DE-535/L, nominal)		
8.2.7/02	Pyridinol metabolite of Haloxyfop-P		*Chironomus riparius*			
			Emergence	>23.3	23.3	-
			Development rate	>23.3	23.3	-

"-": not estimated

B.9.2.12.8 Summary of aquatic macrophytes

Two new studies on growth inhibition were conducted with *Lemna gibba*. The phenol metabolite and the pyridinone metabolite of Haloxyfop-P were tested and metabolites were found to have EC50 values of 7.27 mg/L and > 26.4 mg/L respectively

Table 9.2.12.8-1. Summary of aquatic higher plant studies Table 9.2.12.8-1.

Reference	Species	Study type	Test substance	NOEC mg/L	LOEC mg/L	EC_{50} mg/L
8.2.8/04	*Lemna gibba*	Growth inhibition	Phenol metabolite of Haloxyfop-P	2.57	4.91	EbC_{50} = 7.27 ErC_{50} > 9.95
8.2.8/05	*Lemna gibba*	Growth inhibition	Pyridinone metabolite of Haloxyfop-P	26.4	26.4	> 26.4

B.9.2.13 Risk assessment to aquatic organisms

Calculations of PEC_{sw} and TER

The risk assessment is based on the most sensitive species from the different groups of organisms. The toxicity values used can be found in table 9.2.13-1. PEC_{sw} values for the phenol metabolite were taken from the EFSA

conclusion report[2]; these values were calculated assuming contribution from drainage and runoff plus spray drift.

This can be regarded as a conservative estimate.

As no PECsw values are presented for the phenol and the pyridinone metabolites in the EFSA conclusion report, the PECsw for both metabolites are set equal to the initial PECsw for DE-535. This is a very conservative approach only to be used in a tier 1 risk assessment.
I could be mentioned that no data were obtained during the water/sediment study on disposition of the pyridinone metabolite expressed as % AR (B.8.4.4.2). The phenol metabolite was detected in a max concentration at 1.63 % AR.
The result of the risk assessment is presented in Table B.9.2.13-2 below.

Table B.9.2.13-1. The relevant toxicity data for aquatic organisms.

Test substance	Species	Exposure	EC/LC_{50} (mg/L)	NOEC (mg/L)
Phenol metabolite of Haloxyfop-P	*Oncorhynchus mykiss*	96 hr	2.37	1.01
Pyridinone metabolite of Haloxyfop-P	*Oncorhynchus mykiss*	96 hr	20.1	14.0

Table B.9.2.13-1 (cont.): The relevant toxicity data for aquatic organisms.

Test substance	Species	Exposure	EC/LC_{50} (mg/L)	NOEC (mg/L)
Phenol metabolite of Haloxyfop	*Daphnia magna*	48 hr	4.41	2.35
Pyridinone metabolite of Haloxyfop-P	*Daphnia magna*	48 hr	≥ 29.1	29.1
Pyridinol metabolite of Haloxyfop-P	*Chironomus riparius*			
	Emergence	28 d	>23.3	23.3
	Emer. rate		>23.3	23.3
Phenol metabolite of Haloxyfop-P	*Pseudokirchneriella subcapitata*	72 hr	4. 43	2.39
		96 hr	5.16	2.39
Pyridinone metabolite of Haloxyfop-P	*Pseudokirchneriella subcapitata*	72 hr	>26.7	26.7
		96 hr	>26.7	26.7

[2] EFSA Scientific Report (2006) 87, 1-96, Conclusion on the peer review of haloxyfop-R

Table B.9.2.13-1 (cont.): The relevant toxicity data for aquatic organisms.

Test substance	Species	Exposure	EC/LC_{50} (mg/L)	NOEC (mg/L)
Phenol metabolite of Haloxyfop-P	*Lemna gibba*	14 d	EbC_{50} = 7.27 ErC_{50} > 9.95	2.57
Pyridinone metabolite of Haloxyfop-P	*Lemna gibba*	14 d	>26.4	26.4

Fish
Studies on acute toxicity to fish included a phenol and a pyridinone metabolite. With an LC_{50} of 7.27 mg phenol/L the phenol metabolite was the most toxic giving a TER > 370. The PEC for the phenol and pyridinone metabolites, which are used in the calculations of the TER values in Table B.9.2.13-2 are both based on the initial PECsw value for DE-335. The reason for this is the lack of PEC values for these two metabolites. Setting the PECsw for the phenol and the pyridinone metabolites equal to the parent compound (DE-335) represents conservative scenario. The calculated TER values for the phenol and the pyridinone metabolites both exceed the trigger value when 1 meter spray drift plus 15% run-off were combined (see table B.9.2.13-2). Hence, no acute concern arises for fish.

Invertebrates – water phase
The phenol and the pyridinone metabolite were tested on *Daphnia magna*. Calculations of the TER values for the phenol and the pyridinone metabolites are based on the same assumptions as mentioned in the above section Calculations of PEC_{sw} and TER. The lowest TER value was >689 (for phenol) calculated from 1 meter spray drift plus 15% run-off/drainage flow. Hence, no acute concern arises for free-water-living invertebrates.

Invertebrates - sediment
Nevertheless, with regard to effect studies in the sediment one 28-days study was reported dealing with the toxicity of the pyridinol metabolite to *Chironomus riparius*.
The TER value for *Chironomus riparius* is > 12315 based on spray drift in a distance of 1 meter plus 15% run-off/drainage flow, and therefore well above the trigger of 10 so the pyridinol metabolite does not posses a risk to sediment dwelling organism.

Algae
Acute toxicity on algae was tested with the phenol and the pyridinone metabolite. The lowest toxicity EC_{50}'s was 4.43 mg as/L for the pyridinone metabolite (72 hr) in experiment applying *Pseudokirchneriella subcapitata.* Calculations of the TER values for the phenol and the pyridinone metabolites are based on the same assumptions regarding PEC as mentioned in the above section Calculations of PEC_{sw} and TER. The lowest TER value (at 1 meter spray drift plus 15% run-off/drainage flow) was > 692 indicating no risk to algae.

Aquatic macrophytes
Studies on growth inhibition of aquatic macrophytes were conducted with the phenol and the pyridinone metabolite. Calculations of the TER values for the phenol and the pyridinone metabolites are based on the same assumptions regarding PEC as mentioned in the above section Calculations of PEC_{sw} and TER. The lowest TER value was calculated to >1135 based on 1 meter spray drift plus 15% run-off/drainage flow (Table B9.2.13-2), which is higher than the trigger value of 10 indicating no unacceptable risk.

It can be concluded that all test conducted on aquatic toxicity, followed the respective OECD guideline and the criteria´s listed in the guidelines. As no PECsw values are presented for the phenol and the pyridinone metabolites in the EFSA conclusion report, the PECsw for both metabolites are set equal to the initial PECsw for DE-535. This is a very conservative approach only to be used in a tier 1 risk assessment.
Nevertheless, the tier 1 risk assessment showed that none of the metabolites represent an unacceptable risk to the aquatic environment.

Table B.9.2.13-2. Haloxyfop-P compounds: Summary of toxicity data and TERs for aquatic organisms. Drift at 1 m is 2.77% (field crop) and run-off is 15%.

Annex	Test substance	Test & duration	Species	PECsw (mg/L)	Drift (m)	Toxicity value (mg/L)	TER field crop	Trigger (TER)
Acute effects				**Initial PEC**			**TERacute**	
8.2.1/05	Phenol metabolite of Haloxyfop-P	96 hr	*O. mykiss*	0.0064	1 m + run-off	2.37	>370	100
8.2.1/06	Pyridinone metabolite of Haloxyfop-P	96 hr	*O. mykiss*	0.0064	1 m + run-off	20.1	>3140	100
8.2.4/04	Phenol metabolite of Haloxyfop-P	48 hr. (Static)	*Daphnia magna*	0.0064	1 m + run-off	4.41	>689	100
8.2.4/05	Pyridinone metabolite of Haloxyfop-P	48 hr. (Static)	*Daphnia magna*	0.0064	1 m + run-off	≥29.1	>4546	100
8.2.6/06	Phenol metabolite of Haloxyfop-P	72 hr 96 hr	*Pseudokirchneriella subcapitata*	0.0064	1 m + run-off	4.43 5.16	>692 >806	10 10
8.2.6/07	Pyridinone metabolite of Haloxyfop-P	72 hr 96 hr	*Pseudokirchneriella subcapitata*	0.0064	1 m + run-off	>26.7 >26.7	>4171 >4171	10 10
Long term effects (Tier 1 calculations)				**Initial PEC**			**TERlt**	
8.2.8/04	Phenol metabolite of Haloxyfop-P	14 Growth inhibition	*Lemna gibba*	0.0064	1 m + run-off	7.27	>1135	10
8.2.8/05	Pyridinone metabolite of Haloxyfop-P	14 Growth inhibition	*Lemna gibba*	0.0064	1 m + run-off	>26.4	4125	10
8.2.7/02	Pyridinol metabolite of Haloxyfop-P	28 d Emergence Development rate	*Chironomus riparius*	0.001892	1 m + run-off	>23.3	>12315	10

B.9.11 References relied on

There are no new references. All information and corrections in this addendum are referring to the Additional Report on haloxyfop-P March 2009.