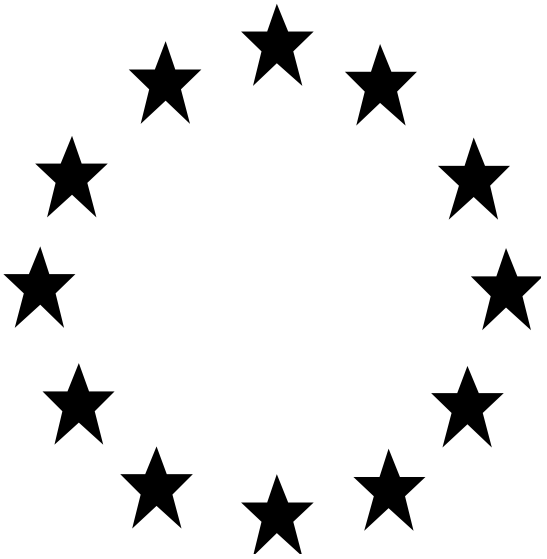

Final addendum to the

Draft Assessment Report (DAR)

- public version -

Initial risk assessment provided by the rapporteur Member State the United Kingdom for the existing active substance

PICLORAM

of the third stage Part B of the review programme referred to in Article 8(2) of Council Directive 91/414/EEC

October 2009

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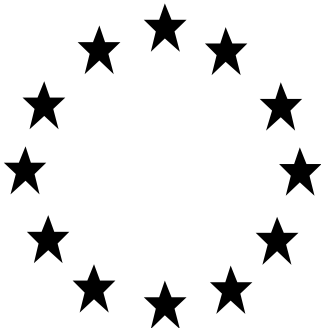
Council Directive 91/414/EEC



Picloram

Draft Assessment Report

Addendum 1
to the Report and Proposed Decision of the United Kingdom made to the European Commission under Article 8(2) of 91/414/EEC

Toxicology

July 2007

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B.6 TOXICOLOGY AND METABOLISM

B.6.4 Genotoxicity studies (IIA 5.4)

The proposed specification of picloram was not considered to be technically equivalent to the material tested in the toxicity studies according to current guidance (Sanco/10597/2003). The Notifier was therefore requested to provide a confirmatory Ames test using a representative batch of the technical material (as manufactured, this is evaluated below.

B.6.4.1 Genotoxicity *in vitro* (IIA 5.4.1)

Study	*Salmonella-Escherichia coli*/Mammalian-Microsome Reverse Mutation Assay Preincubation Method with a Confirmatory assay with Picloram TGAI
Reference	Mecchi MS (2007)
Date performed	18th April-9th July 2007
Test facility	Covance, USA
Report reference	Covance Study No.: 6736-181 Dow Study No.: 070160
Guideline(s)	OECD 471 (1997)
Deviations from the guideline	None
GLP	Yes
Test material	Picloram TGAI; Lot No. RB10162952
Study acceptable	Yes

The mutagenicity of the test material was investigated in an Ames test (pre-incubation method) using *S. typhimurium* strains TA98, TA100, TA1535 and TA1537; and *E. coli* WP2 *uvr*A. Triplicate bacterial cultures were exposed to the test material (dissolved in DMSO) at six concentrations between 33.3-5000 µg/plate in the absence and presence of an exogenous metabolic activation system (Aroclor 1254-induced male Sprague-Dawley rat liver S9 fraction). Concentrations of the test material were based on the results of a preliminary cytotoxicity assay, in which signs of cytotoxicity in strain TA100 (reduced numbers of revertant colonies and reduced background lawn) were apparent at concentrations of ≥3330 µg/plate in the absence of metabolic activation.

In the main assay, evidence of cytotoxicity (reduced numbers of revertant colonies and reduced background lawn) was observed at the two highest concentrations of 2500 and 5000 µg/plate in the absence of metabolic activation only. Exposure to the test material at concentrations up to the limit concentration of 5000 µg/plate of did not result in increased numbers of revertant colonies of any bacterial strain. Results were confirmed in an independently repeated assay. Appropriate positive control compounds (benzo[a]pyrene, 2-nitrofluorene, 2-aminoanthracene, sodium azide, ICR-191 and 4-nitroquinoline-N-oxide) confirmed the sensitivity of the assay.

No evidence of mutagenicity was seen under the conditions of this study.

The study was performed using a batch of picloram (RB10162952) considered as one of the seven representative batches of the manufactured material (Vol. 4 C.1.2). The purity of

the batch (stated to be 93.4%) is the lowest of the seven representative batches (purity range 93.4-96.3%) and contains relatively high levels of impurities. The tested material is therefore considered to be fully representative of picloram, as currently manufactured.

B.6.4.2 Genotoxicity *in vivo* (IIA 5.4.2)

No additional studies have been submitted: none are required.

B.6.4.3 Summary of genotoxicity studies

The clear negative result of in the confirmatory Ames test (Mecchi, 2007) is in line with that of the previously submitted Ames test (Samson & Gollapudi, 1990), which is evaluated in the DAR (Vol. 3, B.6.4.1). No evidence of genotoxicity was seen in this study or *in vitro* in studies of mammalian cell mutagenicity (Linscombe & Gollapudi, 1987) and unscheduled DNA synthesis (McClintock & Gollapudi, 1990). Similarly, no evidence of genotoxicity was seen *in vivo* in a mouse bone marrow micronucleus study (Gollapudi et al, 1985).

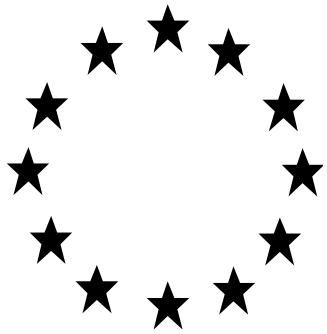
The confirmatory Ames test therefore supports the conclusion in the DAR that picloram is not genotoxic.

B.6.15 References relied on

Active Substance: picloram

Annex point / Ref. No.	**Author**	**Year**	**Title** **Source (where different from company)** **Company, Report No.** **GLP status, published or not**	**Data protection claimed** **Y/N**	**Owner**
II 5.4.1/Ref DAR Vol.1, Level 4, point 4.1.6, Vol 3, section B.6.4.1	Mecchi MS	2007	*Salmonella-Escherichia coli*/Mammalian-Microsome Reverse Mutation Assay Preincubation Method with a Confirmatory assay with Picloram TGAI Covance Study No.: 6736-181 Dow Study No.: 070160 GLP. Unpublished	Y	Dow AgroSciences

Council Directive 91/414/EEC



Picloram

Draft Assessment Report

Addendum 2

to the Report and Proposed Decision of the United Kingdom made to the European Commission under Article 8(2) of 91/414/EEC

April 2009

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B.2 PHYSICAL CHEMICAL PROPERTIES

B.2.1 Physical and chemical properties of the active substance

B.2.1.18 Dissociation contact (pKa) (IIA 2.9)

The Notifier was asked to address the possibility of investigation a second pKa (NH3+/NH2) due to the structural formula of the active substance. The Notifier calculated a second pKa value using computer software and calculated the second value to be -3.18 +/- 0.5. The information provided by the Notifier in support of this estimation is reported below:

A second dissociation constant (pKa) of picloram was calculated using Advanced Chemistry Development Inc. (Toronto, Ontario, Canada) pKa DB software (V 6.0). The software provides the approximated apparent pKa value using algorithms contained in the software. The calculated pKa (H2L/H+HL) of picloram was -3.18 ± 0.50.

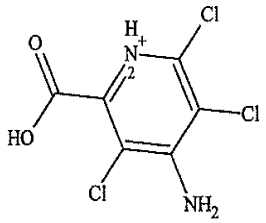
Based on this calculation, no experimental verification was performed.

The structure of the test substance was inputted into the software using the ChemSketch structure drawing program (V 6.0) and the approximated results were calculated. The software presented the prediction as follows:

The calculated pKa (H2L/H+HL) of picloram was -3.18 ± 0.50.

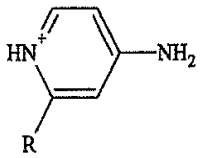
Calculation area summarized below.

Ionic Form: H2L



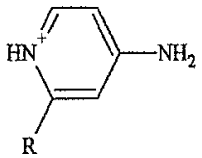
pKa = pKa + Δ(pKa)
calc 0

Calculation of pKa :
0



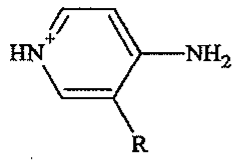
The fragment has been found in the Internal Reaction Centers DataBase with estimated equation

$pKa = 9.138 - 10.58 \cdot \sigma^{Ind} - 2.215 \cdot \sigma^{Res(-)}$ n=3, StD=0.5000



The fragment has been found in the Internal Reaction Centers DataBase with experimental equation

$pKa = 8.976-5.11.\sigma^{ortho(Pyr)}$ n=3, r=0.9952, StD=0.3000



The fragment has been found in the Internal Reaction Centers DataBase with experimental equation

$pKa = 9.256-5.48.\sigma^{Ind}-1.536.\sigma^{Res(-)}$ n=7, r=0.9983, StD=0.1200

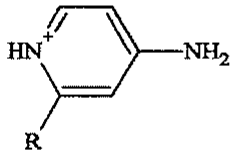
The final value of pKa :

$pKa = \sum pKa^{0i} / n = (9.138+8.976+9.256+9.256) / 4 = 9.156$

Calculation of Δ(pKa):

$\Delta(pKa)^1 = -3.861$ from:

Equation for Reaction Center :



$pKa = 9.138-10.58.\sigma^{Ind}-2.215.\sigma^{Res(-)}$ n=3, StD=0.5000

Substituent has:

$\sigma^{Ind} = 0.30$; $\sigma^{Res} = 0.11$

$\sigma^{Res(-)} = 0.31$

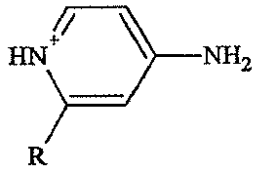
Final equation for $\Delta(pKa)^1$:

$\Delta(pKa)^1 = -10.58.\sigma^{Ind}-2.215.\sigma^{Res(-)}$

$= -3.861$

$\Delta(pKa)^2 = -4.241$ from:

Equation for Reaction Center :



pKa = 8.976-5.11.$\sigma^{ortho(Pyr)}$ n=3, r=0.9952, StD=0.3000

Substituent has:

$\sigma^{ortho(Pyr)}$ = 0.83

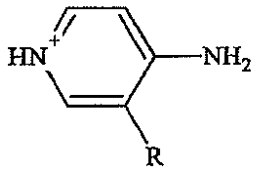
Final equation for $\Delta(pKa)^2$:

$\Delta(pKa)^2 = -5.11.\sigma^{ortho(Pyr)}$

= -4.241

$\Delta(pKa)^3$ = -2.115 from:

Equation for Reaction Center :



pKa = 9.256-5.48.σ^{Ind}-1.536.$\sigma^{Res(-)}$ n=7, r=0.9983, StD=0.1200

Substituent has:

σ^{Ind} = 0.47; σ^{Res} = -0.25

$\sigma^{Res(-)}$ = -0.30

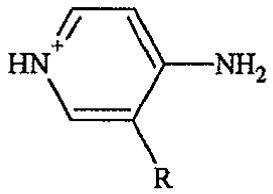
Final equation for $\Delta(pKa)^3$:

$\Delta(pKa)^3 = -5.48.\sigma^{Ind}-1.536.\sigma^{Res(-)}$

= -2.115

$\Delta(pKa)^4$ = -2.115 from:

Equation for Reaction Center :



pKa = 9.256-5.48.σ^{Ind}-1.536.$\sigma^{Res(-)}$ n=7, r=0.9983, StD=0.1200

Substituent has:

σ^{Ind} = 0.47; σ^{Res} = -0.25

$\sigma^{Res(-)}$ = -0.30

Final equation for $\Delta(pKa)^4$:

$\Delta(pKa)^4$ = -5.48.σ^{Ind}-1.536.$\sigma^{Res(-)}$

= -2.115

Total Sum of $\Delta(pKa)$:

$\Delta(pKa) = \Sigma\Delta(pKa)^i$ = -3.861-4.241-2.115-2.115 = -12.332

pKa_{calc} = 9.156-12.332 = -3.175

B.2.2 Physical and chemical properties of the plant protection product

B.2.2.15 Storage Stability
B.2.2.16 Shelf-life

The Notifier was asked to consider the potential for formation of the relevant impurity HCB during storage of the plant protection product. The Notifier stated:

"The source of the toxicologically significant impurity, hexachlorobenzene (HCB), in technical picloram is an impurity in a starting material for the manufacture of the technical. If the starting material does not contain HCB, then HCB is not found in the technical material. No known pathways exist for the formation of HCB in technical picloram after manufacture. Because of this, it is extended to formulations that no known pathways for the formation of HCB exist.

Since no known pathways are known for the formation of this impurity in technical picloram, and the impurity has been identified as an impurity in a starting material, it is proposed that the analysis of this impurity in formulated materials is not required before or after storage since this impurity is monitored in the technical, and is below the limits set for technical picloram at the time of formulation manufacturing.

An estimated maximum HCB content in GF-224 is as follows:

Clopyralid a.e = 22.9% wt (HCB in technical, none)
Picloram a.e. = 5.75% wt (HCB in technical, maximum of 50 ppm (µg/g)

Maximum concentration HCB in formulation:

HCB in GF-224 = 0.0575 g picloram / 1 g GF-224 x 50 µg HCB/g picloram
= 2.88 µg HCB / g GF-224 = 2.88 ppm HCB"

The justification provided by the Notifier is considered acceptable. The determination of relevant impurities in the product after storage is not required.

B.3 DATA ON APPLICATION AND FURTHER INFORMATION

B.3.5 Further information on the plant protection product (IIIA 4)

B.3.5.2 Procedures for cleaning application equipment (IIIA 4.2)

The Notifier was asked to provide further information on procedures for cleaning application equipment to address the efficacy of cleaning. The Notifier stated:

"The following procedure should be followed up: Wash out spray equipment thoroughly with water and detergent immediately after use. Spray out, fill with clean water. Spray out again before storing or using another product. Traces of picloram could cause harm to susceptible crops sprayed later."

No data have been submitted to support the effectiveness of the cleaning procedures

B.5 METHODS OF ANALYSIS

B.5.1 Analytical methods for formulation analysis (IIA 4.1, IIIA 5.1)

B.5.1.2 Impurities (IIA 4.1)

The Method of analysis for the relevant impurity HCB was included in the confidential section of the original DAR. As this impurity is considered relevant the method should not be considered confidential. It is presented below for completeness.

Relevant impurities: Hexachlorobenzene

Samples of technical material were dissolved in dimethylformamide and analysed by reversed phase HPLC/UV at 210 nm (gradient elution using Novapak C18 column and mobile phase: acetonitrile/aqueous phosphate buffer solution). Quantification was carried out with external standardisation.

Validation data are presented in Table B.5.1.

Anon, 1990

Table B.5.1 Summary of method validation (picloram)

	linearity (linear between)	precision – repeatability	accuracy (%)	interference
HCB in technical active substance	1 – 200 mg/L	6.8 @ 6.6 ppm level 5.47@ 56 ppm level	102-120	none

B.5.3 Analytical methods (residue) in soil water and air (IIA 4.2.2 to 4.2.4, IIIA 5.2)

B.5.3.2 Residues in water (IIA 4.2.3)

Information on the waters used in the method validation was provided by the Notifier on request:

Sample no	Type	Source
R00-999-019	River Water	River Odet, Quimper, Brittany, France
R00-999-018	Lake Water	Letcombe Lake, Letcombe Regis, Oxfordshire, UK
R96-000-596	Ground Water	Wantage, Oxfordshire, UK
R96-999-020	Ground Water	Bossington, Somerset, UK
R00-999-020	Drinking Water	Letcombe Laboratories, Letcombe Regis, Oxfordshire, UK

The Notifier has also stated that although no characterisation work was carried out at the time of the validation, the notifier believes the variability in the water sources offers sufficient robustness for the method to be acceptable.

The RMS agrees that the information provided is acceptable.

B.6 TOXICOLOGY AND METABOLISM

B.6.3 Short-term toxicity studies (IIA 5.3)

B.6.3.1 Oral short-term toxicity in the rat (IIA 5.3.1, 5.3.2)

No. 2(4) Vol.3, B.6.3.1, Oral 13-week study in rats, p.78. EFSA: Considering the histopathological findings described in the table B.6.11, the NOAEL might be 150 instead of 300 mg/kg bw/day (at least for the females). Further details on the histopathological observations in the liver might be helpful to conclude on the NOAEL.

Table 6.1 Histopathological changes in the livers of male and female rats in the 13 week dietary study with picloram.

SEX	MALES					
DOSE IN MG/KG/DAY	0	15	50	150	300	500
NUMBER OF RATS EXAMINED	10	10	10	10	10	10
LIVER (NO. OF TISSUES EXAMINED)	10	10	10	10	10	10
NO LESIONS RECOGNIZED:	2	2	3	0	0	0
INCREASED SIZE OF HEPATOCYTES OFTEN ACCOMPANIED BY ALTERED TINCTORIAL PROPERTIES, CENTRILOBULAR: - VERY SLIGHT	2	1	3	4	3	1
- SLIGHT	0	0	0	3	7	9
AGGREGATE(S) OF MONONUCLEAR (PREDOMINATELY LYMPHOID) CELLS, PERIPORTAL OR PERIVASCULAR, FOCAL OR MULTIFOCAL: - VERY SLIGHT	2	3	0	0	1	0
AGGREGATE(S) OF RETICULOENDOTHELIAL CELLS, MULTIFOCAL: - VERY SLIGHT OR SLIGHT	7	3	7	10	8	9
ARCHITECTURE ALTERED SECONDARY TO DIAPHRAGMATIC HERNIA:	1	0	0	0	0	0
HYPERPLASIA, BILE DUCTS: - VERY SLIGHT	1	3	0	0	0	0
INFARCT, FOCAL: - MODERATE	0	0	0	0	1	0
INFARCT, PAPILLARY LOBE:	1	0	0	0	0	0

SEX	FEMALES					
DOSE IN MG/KG/DAY	0	15	50	150	300	500
NUMBER OF RATS EXAMINED	10	10	10	10	10	10
LIVER (NO. OF TISSUES EXAMINED)	10	10	10	10	10	10
NO LESIONS RECOGNIZED:	1	1	2	0	0	0
INCREASED SIZE OF HEPATOCYTES OFTEN ACCOMPANIED BY ALTERED TINCTORIAL PROPERTIES, CENTRILOBULAR: - VERY SLIGHT	0	0	0	1	8	10
AGGREGATE(S) OF MONONUCLEAR (PREDOMINATELY LYMPHOID) CELLS, PERIPORTAL OR PERIVASCULAR, FOCAL OR MULTIFOCAL: - VERY SLIGHT	5	4	2	5	2	2
AGGREGATE(S) OF RETICULOENDOTHELIAL CELLS, MULTIFOCAL: - VERY SLIGHT OR SLIGHT	5	7	7	9	7	8
ARCHITECTURE ALTERED SECONDARY TO DIAPHRAGMATIC HERNIA:	0	1	0	0	1	0
HYPERPLASIA, BILE DUCTS: - VERY SLIGHT	1	0	0	0	1	1
NECROSIS WITH ACCOMPANYING INFLAMMATION, FOCAL: - VERY SLIGHT	0	0	0	1	0	0

B.7 RESIDUES

B.7.1 Metabolism, distribution and expression of residues in plants

B.7.1.1 Oil seed rape.

A revised version of Table B.7.2 is presented below to take account of some incorrect values present in the original DAR. The revised values are highlighted in yellow for clarity.

Table B.7.2 Characterisation of radioactive residues in spring oil seed rape treated with [^{14}C] - labelled picloram

	TRR	HPLC				TLC			
		Picloram		Conjugates		Picloram		Conjugates	
	mg/kg	mg/kg	% TRR	mg/kg	% TRR	mg/kg	% TRR	mg/kg	% TRR
Day 0 – Whole plant	**1.211**								
Water wash	0.978	0.971	80.2	0.008	0.7	0.952	78.6	0.026	2.1
DCM wash	0.004	NA	NA	NA	NA	0.004	0.3	0.0001	<0.1
Acetonitrile extract	0.169	0.160	13.2	0.009	0.7	0.169	14.0	ND	ND
Acetonitrile/water extract	0.051	0.050	4.1	0.002	0.2	0.044	3.6	0.007	0.6
TOTAL		1.181	97.5	0.019	1.6	1.169	96.5	0.033	2.7
Day 30 - Leaves	**0.553**								
Water wash	0.013	NA	NA	NA	NA	0.01	1.8	0.003	0.5
DCM wash	0.005	NA	NA	NA	NA	NA	NA	NA	NA
Acetonitrile extract	0.232	ND	ND	0.232	42.0	0.036	6.5	0.196	35.4
Acetonitrile/water extract	0.244	ND	ND	0.244	44.1	ND	ND	0.244	44.1
TOTAL				0.476	86.1	0.046	8.3	0.443	80.1
Day 30 - Stem	**0.052**								
Water wash	0.001	NA	NA	NA	NA	0.0003	0.6	0.0002	0.4
DCM wash	<0.001	NA	NA	NA	NA	NA	NA	NA	NA
Acetonitrile extract	0.016	0.004	7.7	0.012	23.1	0.001	1.9	0.014	26.9
Acetonitrile/water extract	0.011	0.003	5.8	0.008	15.4	0.0004	0.8	0.010	19.2
TOTAL		0.007	13.5	0.02	38.5	0.0017	3.3	0.024	46.5
Day 30 – Flower buds	**0.07**								
Water wash	0.001	NA	NA	NA	NA	0.0008	1.1	0.0006	0.9
DCM wash	<0.001	NA	NA	NA	NA	NA	NA	NA	NA
Acetonitrile extract	0.027	0.015	21.4	0.012	17.1	0.011	15.7	0.016	22.8
Acetonitrile/water extract	0.021	0.010	14.3	0.011	15.7	0.005	7.1	0.016	22.8
TOTAL		0.025	35.7	0.023	32.9	0.017	24.0	0.033	46.6
Day 50 - Leaves	**0.706**								
Water wash	0.003	NA	NA	NA	NA	NA	NA	NA	NA
DCM wash	0.001	NA	NA	NA	NA	NA	NA	NA	NA
Acetonitrile extract	0.216	ND	ND	0.216	30.6	0.048	6.7	0.168	23.8
Acetonitrile/water extract	0.445	0.037	5.2	0.409	57.9	0.013	1.8	0.433	61.3
TOTAL		0.037	5.2	0.625	88.5	0.061	8.6	0.601	85.1
Day 50 - Stem	**0.065**								
Water wash	<0.001	NA	NA	NA	NA	NA	NA	NA	NA
DCM wash	<0.001	NA	NA	NA	NA	NA	NA	NA	NA
Acetonitrile extract	0.017	0.005	7.7	0.012	18.5	0.004	6.2	0.013	20.0
Acetonitrile/water extract	0.018	0.003	4.6	0.015	23.0	0.001	1.5	0.016	24.6
TOTAL		0.008	12.3	0.027	41.5	0.005	7.7	0.029	44.6

Table B.7.2 cont'd Characterisation of radioactive residues in spring oil seed rape treated with [^{14}C] - labelled picloram

	TRR	HPLC				TLC			
		Picloram		Conjugates		Picloram		Conjugates	
	mg/kg	mg/kg	% TRR	mg/kg	% TRR	mg/kg	% TRR	mg/kg	% TRR
Day 50 – Pods	**0.029**								
Water wash	<0.001	NA	NA	NA	NA	NA	NA	NA	NA
DCM wash	<0.001	NA	NA	NA	NA	NA	NA	NA	NA
Acetonitrile extract	0.014	0.003	10.3	0.011	37.9	0.003	10.3	0.011	37.9
Acetonitrile/water extract	0.0006	0.002	6.9	0.004	13.8	0.001	3.4	0.005	17.2
TOTAL		0.005	17.2	0.015	51.7	0.004	13.8	0.016	55.2
Day 84 - Stem	**0.125**								
Acetonitrile extract	0.004	NA	NA	NA	NA	*	*	*	*
Acetonitrile/water extract	0.056	0.027	21.6	0.029	23.2	0.005	4.0	0.051	40.8
Diethyl ether (acid & basic hydrolysis of PES combined)	0.041	0.040	32.0	0.001	0.8	0.041	32.8	-	-
TOTAL		0.067	53.6	0.030	24.0	0.046	36.8	0.051	91.1
Day 84 - Chaff	**0.137**								
Acetonitrile extract	0.006	NA	NA	NA	NA	*	*	*	*
Acetonitrile/water extract	0.083	0.035	25.5	0.048	35.0	0.007	5.1	0.077	56.2
Diethyl ether (acid & basic hydrolysis of PES combined)	0.031	0.030	21.9	0.001	0.7	0.031	22.6	-	-
TOTAL		0.065	47.4	0.049	35.8	0.038	27.7	0.077	56.2
Day 84 - Seed	**0.006**								
Hexane extract	0.001	NA	NA	NA	NA	*	*	*	*
Acetonitrile extract	<0.001	NA	NA	NA	NA	*	*	*	*
Acetonitrile/water extract	0.001	NA	NA	NA	NA	*	*	*	*

NA = not analysed
ND = not detected
* Chromatogram could not be interpreted due to interference from co-extractives.

B.7.1.3 Metabolism, distribution and expression of the residue in rotational crops

In the original DAR the dose rates in relation to the proposed uses were miscalculated for the rotational crop metabolism study. A revised version of the section of the DAR relating to rotational crops is presented below. Changes are highlighted in yellow for clarity

No data were submitted. The notifier has stated that the relevant DT90 in soils is 46-129 days and that the earliest a succeeding crop would be planted is 4.5 – 5 months (140 – 150 days) for an autumn planted crop following treatment of a spring crop; therefore rotational crop data are not required.

The earliest replant interval of 140 days is considered reasonable and it is also considered unlikely that crop failure would occur, leading to a more critical replanting interval, as the proposed application would take place when the crop was well established.

However the longest relevant DT90 in soil was found to be 163 days (See Section B.8, Table B.8.34). It is possible therefore that > 10% of the applied active substance as its

relevant metabolites or degradation products could still remain in the soil after 140 days.

To address this issue a study investigating the metabolism in rotational crops was submitted by the notifier.

In a GLP study conducted in 1991, radio-labelled picloram labelled in the 2, 6 position of the ring (radiochemical purity 99.7%) was applied as a spray to confined plots containing sandy loam soil at a rate of 0.583 kg/ha (ca 25N). The soil was allowed to age for 30, 120 and 365 days and was lightly cultivated prior to planting. Crops of wheat (*var.* Len), corn/maize (*var.* Hybrid 3751), mustard green (*var.* Southern Giant Curled Long Standing) and turnip (*var.* Seven Top) were planted for each plant back interval. After planting the plots were placed in a screened enclosure equipped with ventilation fans and windows so that cross airflow was promoted. During the winter months the enclosures were covered with plastic and heated to maintain crop growth.

Samples of wheat and were taken at the immature (forage) stage and at harvest maturity. Samples of mature wheat were separated into grain, straw and chaff. Samples of maize were taken at the immature (forage) stage and at harvest maturity. Samples of mature maize were separated into fodder (leaves, stalks and husks), grain and cobs. Samples of mustard greens and turnips were taken at harvest maturity; the turnip samples were separated into roots and tops. Samples of soil were taken at application, planting and at harvest maturity of the crops.

TRR were determined in all samples by combustion LSC and are presented in Tables B.7.4 and B.7.5.

Table B.7.4 Radioactive residues in following crops grown in soil treated with [^{14}C] - labelled picloram at a rate of 0.58 kg ai/ha.

Sample	Days after application	TRR	Basic extraction				Organic extraction			
			Extracted		Non extracted residue		Extracted		Non extracted residue	
		mg/kg	mg/kg	% TRR	mg/kg	% TRR	mg/kg	% TRR	mg/kg	% TRR
30 Day Plantback interval										
Wheat forage (Immature)	87	1.012	1.106	109	0.171	16.9	0.711	70.3	0.072	7.1
Wheat Chaff	174	10.33	9.465	91.6	1.498	14.5	2.594	25.1	4.595	73.5
Wheat Straw	174	3.202	2.562	80.0	0.669	20.9	1.262	39.4	1.755	54.8
Wheat Grain	174	0.419	0.210	50.0	0.175	41.8	0.395	5.7	0.419	94.2
Maize forage (Immature)	160	1.355	0.974	71.9	0.248	18.3	1.012	74.7	0.496	36.6
Maize Cob	178	0.035	0.024	69.3	0.010	29.9	0.020	57.9	0.021	59.5
Maize Fodder	178	1.399	1.053	75.3	0.326	23.3	0.648	46.3	0.761	54.4
Maize Grain	178	0.093	0.070	75.6	0.017	17.9	0.057	61.4	0.040	43.2
Mustard greens	76	0.796	0.686	86.2	0.070	8.8	0.789	99.1	0.097	12.2
Turnip tops	148	1.344	1.054	79.0	0.148	11.1	1.071	80.3	0.187	14.0
Turnip roots	148	0.101	0.066	65.8	0.055	54.8	0.073	72.5	0.053	52.4
120 Day Plantback interval										
Wheat forage (Immature)	180	0.488	0.400	81.9	0.075	15.3	0.44	91.0	0.139	28.5
Wheat Chaff	372	5.733	5.372	93.7	0.178	3.1	1.915	33.4	3.612	63.0
Wheat Straw	372	1.951	1.824	93.5	0.390	20.0	0.788	40.4	0.991	50.8
Wheat Grain	372	0.550	0.626	114	0.021	3.8	0.070	12.7	0.449	81.6
Maize forage (Immature)	253	1.670	1.670	69.3	0.215	12.9	1.069	64.0	0.297	17.8
Maize Cob	267	0.075	0.051	68.1	0.022	29.7	0.036	48.5	0.068	51.3
Maize Fodder	267	0.916	0.941	103	0.181	19.8	0.703	76.7	0.253	27.6
Maize Grain	267	0.384	0.266	69.2	0.073	19.1	0.226	58.9	0.158	41.1
Mustard greens	156	0.089	0.070	78.8	0.019	21.7	0.080	90.2	0.013	14.6
Turnip tops	198	2.180	1.685	77.3	0.157	7.2	1.724	79.1	0.227	10.4
Turnip roots	198	0.101	0.073	72.4	0.027	27.2	0.079	78.0	0.034	33.7
365 Day Plantback interval										
Wheat forage (Immature)	425	0.596	0.592	99.4	0.028	4.7	0.516	86.5	0.108	18.2
Wheat Chaff	491	4.007	4.368	109	0.260	6.5	1.583	39.5	2.128	53.1
Wheat Straw	491	1.241	1.142	92.0	0.110	8.9	0.591	47.6	0.653	52.6
Wheat Grain	491	0.304	0.337	111	0.020	6.6	0.040	13.0	0.253	83.3
Maize forage (Immature)	479	0.449	0.469	104	0.014	3.2	0.265	59.0	0.154	34.2
Maize Cob	495	0.015	0.015	100	0.001	9.5	0.008	56.3	0.004	28.2
Maize Fodder	495	0.516	0.498	96.5	0.019	3.6	0.295	57.2	0.180	34.9
Maize Grain	495	0.022	0.023	104	0.002	10.7	0.018	80.3	0.010	46.7
Mustard greens	433	1.162	1.034	89.0	0.065	5.6	0.854	73.5	0.342	29.4
Turnip tops	503	0.423	0.434	103	0.013	3.1	0.387	91.6	0.070	16.6
Turnip roots	503	0.119	0.110	92.3	0.012	10.3	0.071	59.6	0.042	35.2

Table B.7.5 Radioactive residues in soil treated with [^{14}C] - labelled picloram at a rate of 0.58 kg ai/ha.

Soil segment	TRR (mg/kg)									
	Application	Wheat planted	Corn/ Maize planted	Mustard & turnip planted	Harvest immature wheat	Harvest immature corn	Harvest wheat	Harvest corn	Harvest mustard greens	Harvest turnip
30 day plant back interval										
0 – 3 "	0.651	0.531	0.512	0.384	0.290	0.082	0.169	0.077	0.194	0.114
3 – 6 "	nd	0.047	0.018	0.024	0.015	0.023	0.026	0.017	0.030	0.028
6 – 9"	nd	0.005	nd	0.002	nd	0.003	0.009	0.001	0.003	0.012
9 – 12"	n/a	nd	nd	0.003	0.008	0.003	0.013	0.003	nd	0.024
12 – 15"	n/a	nd	nd	nd	n/a	n/a	0.009	n/a	0.002	0.062
120 day plant back interval										
0 – 3 "	0.603	0.469	0.656	0.507	0.274	0.118	0.134	0.108	0.331	0.146
3 – 6 "	nd	0.019	0.045	0.012	0.105	0.058	0.031	0.031	0.043	0.128
6 – 9"	nd	nd	0.116	0.026	0.015	0.018	0.005	0.005	0.002	0.018
9 – 12"	n/a	nd	n/a	n/a	0.022	0.017	0.001	0.007	Nd	0.017
12 – 15"	n/a	0.032	n/a	n/a	n/a	0.020	0.002	0.013	n/a	0.021
365 day plant back interval										
0 – 3 "	0.525	0.270	0.169	0.192	0.165	0.091	0.168	0.092	0.169	0.067
3 – 6 "	nd	0.036	0.020	0.025	0.081	0.014	0.033	0.024	0.041	0.010
6 – 9"	nd	0.009	0.004	0.010	0.014	0.003	0.004	0.007	0.012	0.004
9 – 12"	n/a	0.009	0.010	0.013	0.019	0.005	0.002	0.002	0.006	0.005
12 – 15"	n/a	0.026	0.001	0.022	0.094	0.002	0.005	0.001	n/a	n/a

TRR were 0.49 – 1.01 mg/kg in wheat forage, 1.24 – 3.20 mg/kg in wheat straw, 0.30 – 0.55 mg/kg in wheat grain, 0.45 – 1.67 mg/kg in maize forage, 0.516 – 1.40 in maize fodder, 0.02 – 0.39 in maize grain, 0.09 – 1.17 in mustard greens, 0.42 – 2.18 in turnip tops and 0.10 - 0.12 mg/kg in turnip roots. TRR were generally seen to decline with longer plant back intervals, however TRR in turnip roots remained relatively stable across all plant back intervals. TRR for maize grain and turnip tops for the for the 120 day plant back interval were significantly higher than those found at the other plant back intervals. No explanation was provided.

All samples were subjected to two extraction procedures – "basic" and "organic" methods.

Basic extraction

Samples of crops were shaken twice with 0.25N NaOH and centrifuged. Soil samples were shaken twice with 0.5N KOH containing 10% KCl after heating for 10 minutes in a boiling water bath and centrifuged. The supernatants from each extraction were combined, refluxed with 6N HCL and partitioned with ethyl ether and sodium chloride. The resulting organic and aqueous phases were concentrated by rotary evaporation.

Organic extraction

Samples of crops and soils were shaken with three successive aliquots of acetonitrile: water (9:1, v/v) and centrifuged. The supernatants were combined and concentrated by rotary evaporation.

Post extraction solids from selected samples were refluxed with 0.25N NaOH (0.5N KOH for soil samples) for 2 hours and centrifuged. The supernatant was acidified with 6N HCl, refluxed for 2 hours and partitioned with ethyl ether and sodium chloride. The resulting organic and aqueous phases were concentrated by rotary evaporation.

Extracts were analysed by HPLC with UV detection at 254 nm against reference standards. Fractions of the post column eluate were collected and the radioactivity in determined by LSC. The identity of picloram in selected extracts was confirmed by GC-MS.

Selected extracts were subjected to acid hydrolysis in order to release conjugated picloram.

Table B.7.7 shows the characterisation of the major metabolites found in the various commodities analysed.

Extractability by the 'basic' extraction procedure was high (> 70%) for most samples, with the exception of wheat grain for the 30 day plant back interval where only 50% of TRR were extracted. Generally extractability using the organic method was lower than for the basic method.

Table B.7.6 Partitioning of "basic" extractable residues in following crops grown in soil treated with [^{14}C] - labelled picloram

Sample	**TRR**	**Total extracted**		**Ether partition**		**Aqueous partition**	
	mg/kg	**mg/kg**	**% TRR**	**mg/kg**	**% TRR**	**mg/kg**	**% TRR**
30 day plant back interval							
Wheat forage (Immature)	1.012	1.106	109	0.993	98.1	0.040	4.0
Wheat Chaff	10.33	9.465	91.6	6.682	64.7	0.388	3.8
Wheat Straw	3.202	2.562	80.0	1.588	49.6	0.389	12.1
Wheat Grain	0.419	0.210	50.1	0.123	29.4	0.050	11.9
Maize forage (Immature)	1.355	0.974	71.9	0.840	62.0	0.156	11.5
Maize Cob	0.035	0.024	68.6	0.019	54.3	0.004	11.4
Maize Fodder	1.399	1.053	75.3	0.867	62.0	0.104	7.4
Maize Grain	0.093	0.070	75.3	0.042	45.2	0.028	30.1
Mustard greens	0.796	0.686	86.2	0.674	84.7	0.027	3.4
Turnip tops	1.344	1.054	78.4	0.704	52.4	0.077	5.7
Turnip roots	0.101	0.066	65.3	0.043	42.6	0.009	8.9
120 day plant back interval							
Wheat forage (Immature)	0.488	0.400	82.0	0.399	81.8	0.031	6.4
Wheat Chaff	5.733	5.372	93.7	3.680	64.2	0.328	5.7
Wheat Straw	1.951	1.824	93.5	1.246	63.9	0.181	9.3
Wheat Grain	0.550	0.626	113.8	0.379	68.9	0.104	18.9
Maize forage (Immature)	1.670	1.670	100.0	0.648	38.8	0.558	33.4
Maize Cob	0.075	0.051	68.0	0.033	44.0	0.016	21.3
Maize Fodder	0.916	0.941	102.7	0.806	88.0	0.111	12.1
Maize Grain	0.384	0.266	69.3	0.200	52.1	0.108	28.1
Mustard greens	0.089	0.070	78.7	0.064	71.9	0.006	6.7
Turnip tops	2.180	1.685	77.3	1.705	78.2	0.290	13.3
Turnip roots	0.101	0.073	72.3	0.059	58.4	0.007	6.9
365 day plant back interval							
Wheat forage (Immature)	0.596	0.592	99.3	0.446	74.8	0.094	15.8
Wheat Chaff	4.007	4.368	109.0	4.185	104.4	0.315	7.9
Wheat Straw	1.241	1.142	92.0	0.952	76.7	0.036	2.9
Wheat Grain	0.304	0.337	110.9	0.324	106.6	0.038	12.5
Maize forage (Immature)	0.449	0.469	104.5	0.366	81.5	0.050	11.1
Maize Cob	0.015	0.015	100	0.012	80.0	0.003	20.0
Maize Fodder	0.516	0.498	96.5	0.446	86.4	0.127	24.6
Maize Grain	0.022	0.023	104.5	0.023	104.5	<0.0001	<1
Mustard greens	1.162	1.034	89.0	0.916	78.8	0.108	9.3
Turnip tops	0.423	0.434	102.6	0.358	84.6	0.048	11.3
Turnip roots	0.119	0.110	92.4	0.087	73.1	0.021	17.6

Table B.7.7 Characterisation of radioactive residues in following crops grown in soil treated with [^{14}C]-labelled picloram - "basic" extraction, ether partition

Sample	Wheat Forage		Wheat Straw		Wheat grain		Maize forage		Maize fodder		Maize grain		Mustard greens		Turnip tops		Turnip roots	
	mg/kg	% TRR	mg/kg	% TRR	mg/kg	% TRR	mg/kg	% TRR	mg/kg	% TRR	mg/kg	% TRR	mg/kg	% TRR	mg/kg	% TRR	mg/kg	% TRR
30 day plant back interval																		
TRR	**1.012**	**-**	**3.202**	**-**	**0.419**	**-**	**1.355**	**-**	**1.399**	**-**	**0.093**	**-**	**0.796**	**-**	**1.334**	**-**	**0.101**	**-**
Ether partition	0.993	98.1	1.588	49.6	0.123	31.0	0.840	62.0	0.867	62.0	0.042	45.2	0.674	84.7	0.704	52.8	0.043	42.6
Picloram	0.993	98.1	1.442	45.0	0.056	13.4	0.808	59.6	0.532	38.0	0.040	43.0	0.648	81.4	0.662	49.6	0.038	37.6
Metab A	N/D	N/D	0.028	0.9	0.001	0.2	0.002	0.1	0.067	4.8	N/D	N/D	N/D	N/D	0.001	0.1	0.001	0.1
Metab B	N/D	N/D	N/D	N/D	0.001	0.2	N/D	N/D	N/D	N/D	N/D	N/D	N/D	N/D	N/D	N/D	N/D	N/D
Metab C	N/D	N/D	0.080	2.5	N/D	N/D	0.001	0.1	0.025	1.8	N/D	N/D	0.020	2.5	0.023	1.7	0.003	3.0
K - 041160	N/D	N/D	N/D	N/D	0.001	0.2	N/D	N/D	0.001	0.1	N/D	N/D	N/D	N/D	N/D	N/D	N/D	N/D
120 day plant back interval																		
TRR	**0.488**	**-**	**1.951**	**-**	**0.550**	**-**	**1.670**	**-**	**0.916**	**-**	**0.384**	**-**	**0.089**	**-**	**2.180**	**-**	**0.101**	**-**
Ether partition	0.399	81.8	1.246	63.9	0.379	68.9	0.648	40.6	0.806	88.0	0.200	52.1	0.064	71.9	1.705	78.2	0.059	58.4
Picloram	0.262	53.7	1.153	59.1	0.379	68.9	0.482	28.9	0.002	0.2	0.139	36.2	0.044	49.4	1.072	49.2	0.039	38.6
Metab A	0.047	9.6	N/D	N/D	N/D	N/D	N/D	N/D	0.722	78.8	0.019	4.9	<0.001	<1.1	0.003	0.1	0.015	14.9
Metab B	N/D	N/D	N/D	N/D	N/D	N/D	0.001	<0.1	N/D	N/D	N/D	N/D	N/D	N/D	N/D	N/D	N/D	N/D
Metab C	0.007	1.4	0.082	4.2	N/D	N/D	0.009	0.5	0.007	0.8	N/D	N/D	0.001	1.1	0.044	2.0	0.001	1.0
K - 041160	N/D	N/D	N/D	N/D	N/D	N/D	N/D	N/D	N/D	N/D	N/D	N/D	<0.001	<1.1	N/D	N/D	N/D	N/D
365 day plant back interval																		
TRR	**0.596**	**-**	**1.241**	**-**	**0.304**	**-**	**0.449**	**-**	**0.516**	**-**	**0.022**	**-**	**1.162**	**-**	**0.423**	**-**	**0.119**	**-**
Ether partition	0.446	74.8	0.952	76.7	0.324	107	0.366	81.5	0.446	86.4	0.023	105	0.916	78.9	0.358	84.6	0.087	73.1
Picloram	0.433	72.7	0.026	2.1	0.312	103	0.324	72.2	0.425	82.4	0.019	86.4	0.716	61.6	0.335	79.2	0.081	68.1
Metab A	N/D	N/D	0.915	73.7	N/D	N/D	N/D	N/D	N/D	N/D	N/D	N/D	N/D	N/D	N/D	N/D	N/D	N/D
Metab B	N/D	N/D	N/D	N/D	N/D	N/D	N/D	N/D	N/D	N/D	N/D	N/D	N/D	N/D	N/D	N/D	0.001	0.8
Metab C	0.002	0.3	N/D	N/D	0.003	1.0	N/D	N/D	0.012	2.3	N/D	N/D	0.172	14.8	0.012	2.8	0.001	0.8
K - 041160	N/D	N/D	N/D	N/D	N/D	N/D	N/D	N/D	0.007	1.4	N/D	N/D	N/D	N/D	0.008	1.9	0.001	0.8

N/D = not detected

Table B.7.8 Characterisation of radioactive residues from "basic" extraction, ether partition before and after acid hydrolyis

Sample	TRR (mg/kg)	Ether partition	Before Hydrolysis					After Hydrolysis				
			Picloram	Metabolite A	Metabolite B	Metabolite C	K-041160	Picloram	Metabolite A	Metabolite B	Metabolite C	K-041160
		mg/kg (%TRR)	mg/kg (% TRR)	mg/kg (% TRR)	mg/kg (% TRR)	mg/kg (% TRR)	mg/kg (% TRR)	mg/kg (% TRR)	mg/kg (% TRR)	mg/kg (% TRR)	mg/kg (% TRR)	mg/kg (% TRR)
30 day plant back interval												
Wheat grain	0.419	0.123 (29.4)	0.056 (13.4)	0.001 (0.2)	0.001 (0.2)	ND	0.001 (0.2)	0.122 (29.1)	ND	ND	ND	ND
Maize fodder	1.399	0.867 (62.0)	0.532 (38.0)	0.067 (4.8)	ND	0.025 (1.8)	0.001 (0.07)	0.789 (56.4)	ND	ND	0.019 (1.4)	0.025 (1.8)
120 day plant back interval												
Wheat forage	0.488	0.399 (81.8)	0.262 (53.7)	0.047 (9.6)	ND	0.007 (1.4)	ND	0.355 (72.7)	0.004 (0.8)	ND	0.002 (0.4)	0.038 (7.8)
Maize forage	1.670	0.648 (38.8)	0.482 (28.9)	ND	0.001 (0.06)	0.009 (0.54)	ND	0.640 (38.3)	ND	ND	0.005 (0.3)	ND
Maize fodder	0.916	0.806 (88.0)	0.002 (0.2)	0.722 (78.8)	ND	0.007 (0.8)	ND	0.755 (82.4)	ND	ND	ND	0.026 (2.8)
Maize grain	0.384	0.200 (52.1)	0.139 (36.2)	0.019 (4.9)	ND	ND	ND	0.197 (51.3)	ND	ND	ND	0.001 (0.3)
Mustard greens	0.089	0.064 (71.9)	0.044 (49.4)	<0.001 (<1.1)	ND	0.001 (1.1)	<0.001 (<1.1)	0.053 (59.6)	ND	ND	0.003 (3.3)	ND
Turnip foliage	2.180	1.705 (78.2)	1.072 (49.2)	0.003 (0.1)	ND	0.044 (2.0)	ND	1.532 (70.3)	ND	ND	0.057 (2.6)	0.017 (0.8)
Turnip roots	0.101	0.059 (58.4)	0.039 (38.6)	0.015 (14.9)	ND	0.001 (1.0)	ND	0.046 (45.5)	ND	ND	0.002 (2.0)	0.003 (2.9)
365 day plant back interval												
Wheat straw	1.241	0.952 (76.7)	0.026 (2.1)	0.915 (73.7)	ND	ND	ND	0.854 (68.8)	ND	ND	0.010 (0.8)	0.023 (1.9)

Generally the metabolite profile was similar across all crops for both extraction methods. In most cases parent picloram was the major metabolite found. Four other metabolites were found; Metabolites A to C were not identified however acid hydrolysis of extracts where these metabolites were found showed conversion of the metabolites to parent picloram indicating that the metabolites were probably conjugates of picloram. Table B.7.8 shows the results of acid hydrolysis of selected extracts for the basic extraction methods. Metabolite K-041160 was identified as 4-amino-3, 5, 6-trichloropridine. This metabolite was found in wheat, maize and turnip samples but in all cases was present at low levels.

Basic reflux of the un-extracted material for wheat grain, wheat straw, maize fodder and turnip roots for the 30 day plant back interval released a further ca 30% TRR for each crop when partitioned into ethyl ether. Analysis by HPLC of the ether extracts revealed that over 70% of the radioactivity extracted was parent picloram.

The notifier has concluded that picloram and possibly any conjugates formed in the soil are readily transported into succeeding crops. Analysis of succeeding crops indicates the radioactivity is present mainly as picloram or conjugates of picloram and it is concluded that the metabolism is similar to that seen in primary crops.

The notifier's conclusions are considered acceptable. A residues definition in following crops of parent picloram only is considered appropriate.

(Kimmel, E; 1993)

The treatment rate used in this study is exaggerated (25 N) compared to the notified uses. Taking into consideration the higher rates in the study in relation to the notified uses it is noted that there is the potential for significant residues in leafy following crops at the shortest harvest interval studied. I.e. for mustard greens 30 day plantback interval TRR = 0.796 m/kg of which 81% (0.648 mg/kg) was identified as picloram. Assuming a linear response between dose and residue level indicates that residues at 1N would be approximately TRR 0.03 mg/kg with 0.026 mg/kg as picloram. At the later plantback intervals residues in following crops are not expected to be significant.

The Notifier has previously stated that for the notified uses the earliest a succeeding crop would be planted is 4.5 – 5 months (140 – 150 days) for an autumn planted crop following treatment of a spring crop and that it is unlikely that crop failure would occur, leading to a more critical replanting interval, as the proposed application would take place when the crop was well established. The Notifer's case is considered reasonable in the light of the notified use on oilseed rape in Northern/Central EU MS however this case may not be acceptable for other crops or for oilseed rape grown in other EU MS.

The RMS considers that for the proposed use **only** further data on rotational crops is not required however for other uses proposed in the future further data may be necessary.

B.7.1.4 Summary/assessment

The metabolism and distribution of picloram was investigated in oil seed rape and wheat. Both studies are considered acceptable. Crops were treated with picloram labelled in the 2, 6 position of the ring at exaggerated dose rates.

Oil seed rape plants were treated once at a rate of 40g ai/ha (1.7 N rate) at growth stage BBCH 33 (stem elongation, three visibly extended internodes). TRR in plants sampled at harvest were 0.103 mg/kg, with TRR in seeds at harvest accounting for 0.006 mg/kg. The majority of TRR were extracted from whole plants and leaves (>89%). Extractability of residues was lower for plant stems and seeds (33 – 54%).

In stem and chaff samples taken at maturity the main component identified was a conjugate which released unchanged picloram when the extracts were subjected to basic or acidic hydrolysis. Acidic and basic hydrolysis of the non-extractable residues released further radioactivity (32.8% TRR, 0.041 mg/kg for the stem and 22.6% TRR, 0.031 mg/kg for chaff). Ca 97% of this released radioactivity was identified as unchanged picloram. The postulated metabolite 4-amino-3, 5-dichloro-6-hydroxypicolinic acid (6-OH) was not detected in any samples. Evidence of the presence of the metabolite 4-amino-2, 3, 5-trichloropyridine (PYR) was found in stem and chaff samples taken at maturity but not at levels considered of significance (<0.005 mg/kg).

Wheat plants were treated at rates of 26g as/ha and ca 53 g as/ha at growth stages BBCH 13 - 22 (3 to 5 leaf/ two tiller). TRR in grain at harvest were 0.048 mg/kg for the lower dose rate and 0.093 mg/kg for the higher dose rate. TRR in straw at harvest were 0.338 mg/kg and 0.520 mg/kg for the low and high dose rates respectively. The majority of TRR were extracted from whole plants and grain 80-90%). Extractability of residues was lower for straw (*ca* 75%).

HPLC analysis of extracts showed the majority of radioactivity was found in a band eluting over 20 – 30 minutes for all samples. No distinct peaks of picloram or the metabolite 4-amino-2, 3, 5-trichloropyridine (PYR) were found however significant proportions of the radioactivity were found to elute within the retention time range for picloram (56% TRR for forage, 45 % TRR for straw and 19% TRR for grain). Hydrolysis of extracts using acid, alkali or β-glucosidase released parent picloram with the alkali hydrolysis releasing the most radioactivity.

Direct hydrolysis of samples of straw, grain and forage revealed the major component found in all samples to be parent picloram. The metabolites 4-amino-3, 5-dichloro-6-hydroxypicolinic acid (6-OH) and 4-amino-2, 3, 5-trichloropyridine (PYR) were not found at levels above 0.002 mg/kg in any samples.

Picloram quickly forms conjugates in plant material that are released after hydrolysis with either acid or alkali. Alkali hydrolysis was found to be the most effective at releasing radioactivity. Hydrolysis of conjugates releases parent picloram.

A proposed metabolic pathway is shown in Figure B.7.1

The metabolism and distribution of radio-labelled tri-isopropanol amine (TIPA) formulated as part of the amine salt of picloram was investigated. TIPA was metabolized completely in wheat, adding to the carbon pool used by normal synthetic routes of the plant, resulting in radioactivity being incorporated into natural plant constituents such as glucose and amino acids. The proposed formulation contains picloram formulated as the monoethanol amine salt and the notifier stated that it is expected that monoethanol amine would be metabolised in the same manner as tri-isopropanol amine.

The longest relevant DT90 in soil was found to be 163 days (See Section B.8, Table B.8.34). It is possible therefore that > 10% of the applied active substance as its relevant metabolites or degradation products could still remain in the soil at replanting of succeeding crops.

In a GLP study conducted in 1991, radio-labelled picloram was applied confined plots containing sandy loam soil at a rate of 0.583 kg/ha (ca 25N). The soil was allowed to age for 30, 120 and 365 days and was lightly cultivated prior to planting. Crops of wheat, corn/maize, mustard green and turnip were planted for each plant back interval.

TRR were 0.49 – 1.01 mg/kg in wheat forage, 1.24 – 3.20 mg/kg in wheat straw, 0.30 – 0.55 mg/kg in wheat grain, 0.45 – 1.67 mg/kg in maize forage, 0.516 – 1.40 in maize fodder, 0.02 – 0.39 in maize grain, 0.09 – 1.17 in mustard greens, 0.42 – 2.18 in turnip tops and 0.10 - 0.12 mg/kg in turnip roots. TRR were generally seen to decline with longer plant back intervals, however TRR in turnip roots remained relatively stable across all plant back intervals. TRR for maize grain and turnip tops for the for the 120 day plant back interval were significantly higher than those found at the other plant back intervals.

Generally the metabolite profile was similar across all crops. In most cases parent picloram was the major metabolite found. Four other metabolites were found; Metabolites A to C were not identified however acid hydrolysis of extracts where these metabolites were found showed conversion of the metabolites to parent picloram indicating that the metabolites were probably conjugates of picloram. Metabolite K-041160 was identified as 4-amino-3, 5, 6-trichloropridine. This metabolite was found in wheat, maize and turnip samples but in all cases was present at low levels.

The notifier has concluded that picloram and possibly any conjugates formed in the soil are readily transported into succeeding crops. Analysis of succeeding crops indicates the radioactivity is present mainly as picloram or conjugates of picloram and it is concluded that the metabolism is similar to that seen in primary crops.

The notifier's conclusions are considered acceptable. A residues definition in following crops of parent picloram only is considered appropriate.

The treatment rate used in this study is exaggerated (25 N) compared to the notified uses. Taking into consideration the higher rates in the study in relation to the notified uses it is noted that there is the potential for significant residues in leafy following crops at the shortest harvest interval studied. At the later plantback intervals residues in following crops are not expected to be significant.

The Notifier has previously stated that for the notified uses the earliest a succeeding crop would be planted is 4.5 – 5 months (140 – 150 days) for an autumn planted crop following treatment of a spring crop and that it is unlikely that crop failure would occur, leading to a more critical replanting interval, as the proposed application would take place when the crop was well established. The Notifer's case is considered reasonable in the light of the notified use on oilseed rape in Northern/Central EU MS however this case may not be acceptable for other crops or for oilseed rape grown in other EU MS.

The RMS considers that for the proposed use **only** further data on rotational crops is not required however for other uses proposed in the future further data may be necessary.

B.8 ENVIRONMENTAL FATE AND BEHAVIOUR

Some of the information provided in the following section relates to aminopyralid, a water metabolite of picloram, which was taken from the EU DAR or addenda for aminopyralid. In order to distinguish this from information specifically relating to picloram any information taken from the aminopyralid assessment is presented in italics. In addition some of the information supplied is a case provided by the Notifier to the RMS. This case was assessed by the RMS in the DAR, but is provided below in full as this was requested in the Evaluation Table. Again to distinguish it is presented in italics.

B.8.1 Route and rate of degradation in soil (IIA 7.1.1, IIIA 9.1.1)

B.8.1.1 Aerobic and anaerobic studies (II 7.1.1, IIIA 9.1.1)

B.8.1.1.1 Soil microbial studies

The following is in response to **Open point 4.13** in the Evaluation Table for picloram and relates to previous discussion in the **reporting table comment 4(27)**. In this point it was requested that the RMS 'RMS to include an assessment of the degradation and adsorption in soil of aminopyralid (=3,6-dichloro analogue) in an addendum.' The RMS assessments of soil degradation studies assessed in the DAR for aminopyralid are therefore reproduced below. Further information is included in the rate of degradation section of this addendum (B.8.1.2), field study section (B.8.1.3) and the summary and assessment section of this addendum (B.8.1.5).

Study a); Yoder, R.N. and Smith, K.P., 2003a

An aerobic soil degradation study was conducted according to SETAC-Europe (1995) guidelines.

The route of aerobic degradation of ^{14}C-phenyl-labelled aminopyralid was investigated in four European soils under laboratory conditions in the dark at 20°C. Additional samples of one soil type (Parabraun Erde) were also incubated at 10°C and 30°C. The soils were sieved to 2 mm prior to use, and included a Thessaloniki clay loam (Greece), a Cuckney sand (UK), a Charentilly clay loam (France) and a Parabraun Erde sandy loam (Germany). The soil characteristics are summarised in Table B.8.1.

Table B.8.1 Characterisation of soils used to investigate the aerobic degradation of aminopyralid

Soil name	***Thessaloniki***	***Cuckney***	***Charentilly***	***Parabraun Erde***
Reference	***M625***	***M626***	***M630***	***M631***
Country of origin	***Greece***	***UK***	***France***	***Germany***
Textural analysis				
Sand (%)	*41*	*91*	*42*	*26*
Silt (%)	*36*	*6*	*32*	*60*

Clay (%)	*23*	*3*	*26*	*14*
Classification				
ADAS (UK)	*Clay loam*	*Sand*	*Clay loam*	*Sandy silt loam*
International	*Clay loam*	*Sand*	*Light clay*	*Loam*
Soil density (g/cm^3)	*0.88*	*1.28*	*1.08*	*1.18*
pH	*7.7*	*5.6*	*5.8*	*7.7*
Organic matter (%)	*2.5*	*2.4*	*1.9*	*2.0*
Organic carbon (%)	*1.5*	*1.5*	*1.0*	*1.0*
CEC (mEq/100 g)	*14.4*	*6.8*	*15.1*	*10.0*
MHC (% dry wt.)	*86.9*	*43.7*	*68.4*	*56.0*
Soil biomass				
(µg C/g soil) Initial	*216.1*	*111.4*	*54.7*	*40.6*
Final	*94.1*	*39.5*	*50.8*	*72.0*

^{14}C-phenyl-aminopyralid (specific activity 27.4 mCi/mmole, radiochemical purity of 99.6%) was dissolved in acetone, and aliquots (1.0 ml) added to portions of each moist soil (50 g dry weight equivalent) at a nominal concentration of 0.16 µg a.s./g. This is equivalent to the rate of 120 g a.s./ha, assuming incorporation to 5 cm depth and a soil density of 1.5 g/ml. The samples were then incubated in the dark at 20°C (with further portions of Parabraun Erde soil incubated at 10°C and 30°C) and 40% moisture holding capacity (MHC) for up to 123 days after treatment. Additional samples of Parabraun Erde soil (5 g dry weight equivalent) were sterilised by gamma-irradiation to investigate microbial and abiotic degradation processes at 20ºC.

Samples were incubated aerobically, with the CO_2 evolved trapped in NaOH. Duplicate samples (or in a limited number of cases, single replicates) were analysed at zero-time and at intervals up to 123 days after treatment. The caustic trap solution was removed and a portion assayed for total radioactivity by LSC. The soil was extracted using acetone:1N HCl (90:10 v/v). Extracts were combined and assayed by LSC. A portion of the extract was then concentrated for reverse-phase HPLC analysis. Soil non-extractable residues (NER) were quantified by combustion of sub-samples of extracted, air-dried soil followed by LSC analysis. The distribution of the soil NER between the fulvic, humic and humin pools was investigated using a standard technique.

The recovery and distribution of radioactivity (as the mean of the duplicate determinations) from the samples incubated at 20°C are summarised in Tables B.8.2 to B.8.5, whilst that for Parabraun Erde soil incubated at 10°C and 30°C are shown in Tables B.8.7 and B.8.8.

Table B.8.2 *Recovery and distribution of radioactivity from Thessaloniki soil treated with aminopyralid and incubated under aerobic conditions at 20°C*

Sampling time (days)	***CO_2 (%AR)***	***Soil extracts (% AR)***	***Soil NER (% AR)***	***Mass balance (% AR)***
0	-	*95.6*	*0.9*	*96.4*
4	*2.2*	*92.4*	*3.1*	*97.6*
7	*3.8*	*88.5*	*4.2*	*96.6*
14	*7.7*	*80.0*	*6.2*	*93.8*
28	*20.3*	*59.1*	*12.3*	*91.7*
61	*56.2*	*8.8*	*22.6*	*87.6*
92	*68.3*	*1.5*	*21.6*	*91.4*
123	*64.8*	*2.4*	*19.6*	*86.8*

Table B.8.3 *Recovery and distribution of radioactivity from Cuckney soil treated with aminopyralid and incubated under aerobic conditions at 20°C*

Sampling time (days)	***CO_2 (% AR)***	***Soil extracts (% AR)***	***Soil NER (% AR)***	***Mass balance (% AR)***
0	-	*92.1*	*1*	*93.05*
4	*1.2*	*94.1*	*1.1*	*96.35*
7	*1.5*	*91.6*	*1.3*	*94.3*
14	*3.3*	*88.0*	*1.3*	*92.55*
28	*6.0*	*84.3*	*1.7*	*91.85*
61	*13.9*	*73.0*	*3.0*	*89.8*
92	*24.1*	*60.2*	*10.3*	*94.6*
123	*28.6*	*51.6*	*8.6*	*88.7*

- no sample available

Table B.8.4 *Recovery and distribution of radioactivity from Charentilly soil treated with aminopyralid and incubated under aerobic conditions at 20°C*

Sampling time (days)	***CO_2 (%AR)***	***Soil extracts (% AR)***	***Soil NER (% AR)***	***Mass balance (% AR)***
0	-	*91.9*	*2.2*	*94.1*
4	*3.3*	*92.0*	*2.2*	*97.5*
7	*5.4*	*86.3*	*2.3*	*93.9*
14	*10.7*	*78.4*	*3.1*	*92.2*
28	*23.6*	*56.8*	*13.6*	*94.0*
61	*54.1*	*16.0*	*20.7*	*90.9*
92	*69.3*	*4.2*	*16.6*	*90.1*

- no sample available

Table B.8.5 *Recovery and distribution of radioactivity from Parabraun Erde soil treated with aminopyralid and incubated under aerobic conditions at 20°C*

Sampling time (days)	***CO_2 (%AR)***	***Soil extracts (% AR)***	***Soil NER (% AR)***	***Mass balance (% AR)***
0	-	*92.8*	*2.4*	*95.3*
4	*1.3*	*94.6*	*2.1*	*98.0*
7	*2.3*	*90.5*	*2.4*	*95.1*
14	*3.3*	*84.8*	*2.7*	*90.8*
28	*9.6*	*78.1*	*3.5*	*91.1*
61	*22.9*	*59.0*	*5.5*	*87.4*
92	*34.6*	*45.8*	*13.8*	*94.2*
123	*41.3*	*34.1*	*14.8*	*90.1*

- no sample available

Table B.8.6 *Recovery and distribution of radioactivity from sterile Parabraun Erde soil treated*

with aminopyralid and incubated under aerobic conditions at 20°C

Sampling time (days)	***CO_2 (%AR)***	***Soil extracts (% AR)***	***Soil NER (% AR)***	***Mass balance (% AR)***
0	-	*98.3*	*0.5*	*98.7*
7	***0.1***	*95.5*	*0.8*	*96.4*
14	*0.7*	*94.7*	*1.1*	*96.5*
28	*0.8*	*98.2*	*1.7*	*100.7*
61	*1.5*	*97.3*	*1.6*	*100.3*
92	*2.3*	*97.9*	*2.1*	*102.3*
122	*3.2*	*100.5*	*2.3*	*105.9*

- no sample available

Table B.8.7 Recovery and distribution of radioactivity from Parabraun Erde soil treated with aminopyralid and incubated under aerobic conditions at 10°C

Sampling time (days)	***CO_2 (% AR)***	***Soil extracts (% AR)***	***Soil NER (% AR)***	***Mass balance (% AR)***
0	-	*97.3*	*1.3*	*98.6*
7	*0.7*	*96.5*	*1.4*	*98.6*
14	*1.4*	*91.6*	*1.7*	*94.7*
28	*2.4*	*90.8*	*2*	*95.2*
61	*6.8*	*85.5*	*5.9*	*98.0*
92	*8.5*	*82.4*	*5.9*	*96.8*
123	*10.4*	*78.3*	*7.1*	*95.8*

- no sample available

Table B.8.8 Recovery and distribution of radioactivity from Parabraun Erde soil treated with aminopyralid and incubated under aerobic conditions at 30°C

Sampling time (days)	***CO_2 (%AR)***	***Soil extracts (% AR)***	***Soil NER (% AR)***	***Mass balance (% AR)***
0	-	*97.4*	*1.2*	*98.6*
7	*4*	*88.6*	*2.4*	*94.9*
14	*7.1*	*82.7*	*3.3*	*93.0*
28	*13.2*	*73.3*	*4.5*	*91.0*
61	*27. 1*	*59.2*	*10.7*	*97.0*
92	*32.5*	*51.5*	*9.4*	*93.3*
123	*36.2*	*45.6*	*12.0*	*93.8*

- no sample available

In 92 day samples 5.1-7.5% AR that was unextractable was associated with the fulvic acid fraction. This range was 1.2-3.2%AR for the humic fraction and 2.3-15.5%AR for the humin fraction. In sterile soil at all time points the radioactivity was unextractable and remained as parent aminopyralid (93.9-100.7%AR).

The results from the HPLC analysis of the extractable radioactivity from each soil showed that aminopyralid was the only radioactive component present at all time points. No degradation products (other than CO_2 and NER) were observed at any time.

(Yoder, R.N. and Smith, K.P., 2003a)

Study b); Rutherford, L.A. and Meitl, T.J., 2004

An anaerobic soil degradation study was conducted according to SETAC-Europe (1995) guidelines, US EPA Pesticide Registration Guidelines, Subdivision N, Section

162-3 and Canada PMRA DACO Number 8.2.3.5.6 – Biotransformation in Aquatic System-Anaerobic Sediment/Water.

The route and rate of anaerobic degradation of ^{14}C-phenyl-aminopyralid has been investigated in a flooded (with HPLC grade water) soil from Europe for up to 120 days in the dark at 20°C. The degradation was also studied in a US pond sediment/associated surface water system for up to 363 days in the dark at 25°C. The European test system and incubation conditions meet the guideline requirement. Therefore, the US test system and incubation conditions are included only as supplementary information.

The characterization details of the test systems used are shown in Tables B.8.10 and B.8.11 for the sediment/soil and water phases, respectively.

Table B.8.10 Characterisation of test systems used to investigate the anaerobic degradation of aminopyralid (sediment and soil)

Test system name		***Cuckney soil***	***North Dakota sediment***
Reference		*M626*	*M635*
Country of origin		*England*	*US*
Textural analysis			
Sand (%)		*89*	*57*
Silt (%)		*8*	*36*
Clay (%)		*3*	*7*
Classification	*ADAS (UK)*	*Sand*	*Sandy loam*
	International	*Sand*	*Sandy loam*
Bulk density (g/cm3)		*1.28*	*0.67*
pH		*6.0*	*8.1*
Organic matter (%)		*2.4*	*6.0*
Organic carbon (%)		*1.3*	*4.9*
CEC (mEq/100 g)		*5.2*	*22.9*
Redox potential (mV)	*Initial*	*-469*	*-431*
	Final	*-410*	*-262*
Biomass (µg C/g)	*Initial*	*111.4*	*42.7*
	Final	*39.5*	*54.3*

Table B.8.11 Characterisation of test systems used to investigate the anaerobic degradation of aminopyralid (water)

Test system name	***Cuckney water***	***North Dakota pond water***
Reference	*HPLC grade water* *No data provided*	*M635*
Country of origin		*US*
pH		*7.9*
Dissolved organic carbon (ppm)		*37.2*
Hardness ($CaCO_3$, ppm)		*669*
Electrical conductivity (mmhos/cm)		*1.71*
Redox potential (mV) *Initial* *Final*		*-355* *-126*
Dissolved O_2 (ppm) *Initial* *Final*		*0.10* *-0.21*

^{14}C-phenyl-aminopyralid (specific activity 27.4 mCi/mmole, radiochemical purity >99%) was dissolved in acetonitrile, and aliquots (83-100 µl) applied to the water layer in each flask at the rate of 0.084 mg a.s./l. The samples were purged with N_2 during dosing to maintain anaerobic conditions.

The trap solution was removed and analysed by LSC. Aliquots of the water were directly analysed by LSC and HPLC. The Cuckney soil samples were extracted on a horizontal shaker at low speed using acetone/1N HCl (90:10 v/v). The North Dakota sediment samples were extracted on a horizontal shaker at low speed using methanol/1N NaOH (90:10 v/v). The extracted residues were then analyzed by LSC and, after preparation, by HPLC. The soil and sediment non-extractable radioactivity was finally determined using a combustion technique to demonstrate an overall mass balance.

The recovery and distribution of radioactivity (as % AR) from the anaerobic samples are summarised in Tables B.8.12 and B.8.13 for the flooded Cuckney and North Dakota sediment/water samples, respectively. The tables also show the HPLC profile of the radioactivity. The results are presented as the mean of the duplicate determinations.

Table B.8.12 Recovery and distribution of radioactivity from flooded Cuckney soil treated with aminopyralid and incubated under anaerobic conditions at 20°C

Sampling time (days)	CO_2 (%AR)	Sample type	Aminopyralid (% AR)	Unknown (% AR)	Soil NER (% AR)	Mass balance (% AR)
0	-	Water	69.2	ND	0.9	100.1
		Soil	29.9	0.1		
3	0.1	Water	59.8	0.2	0.7	93.1
		Soil	32.3	ND		
10	0.2	Water	61.7	ND	0.8	94.5
		Soil	31.8	ND		
20	0.2	Water	63.4	0.2	1.0	94.3
		Soil	29.2	0.2		
30	0.3	Water	67.0	0.1	1.3	96.9
		Soil	28.2	ND		
59	0.3	Water	68.4	0.6	0.6	95.5
		Soil	25.5	ND		
120	0.4	Water	71.7	ND	0.7	94.2
		Soil	21.5	ND		

- no sample available ND = not detected

Table B.8.13 Recovery and distribution of radioactivity from North Dakota sediment/water treated with aminopyralid and incubated under anaerobic conditions at 25°C

Sampling time (days)	CO_2 (%AR)	Sample type	Aminopyralid (% AR)	Unknown (% AR)	Soil NER (% AR)	Mass balance (% AR)
0	-	Water	**69.5**	1.1	**0.9**	**98.8**
		Sediment	**27.3**	0.1		
10	0.2	Water	**62.1**	ND	**1.8**	**94.6**
		Sediment	**29.9**	0.5		
20	0.3	Water	**65.5**	ND	**1.7**	**98.0**
		Sediment	**30.4**	ND		
30	0.4	Water	**65.5**	ND	**1.8**	**98.2**
		Sediment	**30.5**	0.1		
90	0.6	Water	**62.5**	ND	**1.9**	**98.3**
		Sediment	**33.1**	0.1		
181	0.7	Water	**63.5**	0.4	**2.4**	**97.9**
		Sediment	**30.9**	0.1		
268	0.7	Water	**62.0**	0.4	**2.0**	**97.1**
		Sediment	**31.5**	0.6		
363	0.6	Water	**61.4**	0.4	**1.2**	**100.5**
		Sediment	**36.7**	0.2		

- no sample available ND = not detected

HPLC analysis of both the water and soil/sediment extractable radioactivity throughout the incubation periods, showed that aminopyralid was essentially stable, and so DT_{50} and DT_{90} values were not calculated.

There was no significant degradation, with only very low levels of an unknown component detected (<1% AR).

(Rutherford, L.A. and Meitl, T.J., 2004)

B.8.1.2 Soil rate of degradation studies - laboratory

Study b); Knowles, S., Swales, S.A., 2002

The following is in response to **Open point 4.2 in the Evaluation Table** for picloram and relates to previous discussion in the **reporting table comment 4(3)**. In this point it was requested that 'MSs experts to discuss in a meeting the need for further identification of the compound called as 'Largest Unknown' in the study by Knowles, S., Swales, S.A., 2002, and/or the explanation (to be included in an addendum by RMS with the anomalies of the unknowns) which supports that this unknown fraction is an artefact.' The RMS therefore considers it appropriate to reproduce the explanation provided to the RMS by the Notifier. This explanation follows below. The Notifiers explanation was assessed in the DAR and the RMS opinion of it is documented there. A number of rejected chromatograms (11) were also supplied to the RMS by the Notifier. In addition all the acceptable chromatograms from the 0-30 cm and 60-100 cm layers were supplied by the Notifier. The RMS has not reproduced all of these chromatograms here due to issues with the size of the document and for reasons of brevity. However the rejected and accepted chromatograms to which the Notifier refers in the following argumentation are reproduced along with a small selection of other illustrative examples.

'In response to the question raised regarding the unknown >5% in Covance Study No. 295/136, the chromatographic data and peak integration presented in the final report was re-evaluated. From examination of all of the study raw data, whilst the picloram retention time was stable, the retention times of the "largest unknown" component within the traces are variable suggesting that either these are different compounds or just "artefact" noise peaks. There is some variability in the appearance of peaks throughout a series of soil degradation samples (unknown present in soil extract at 58 DAT, absent in 90 DAT, present in 120 DAT). The presentation of the results in Table 8-3 of the final report is misleading as the "largest unknown" occurs at different retention times. A table has been attached to this document in an attempt to clarify the occurrence of peaks within each of the chromatograms.

The poor signal-to-noise ratio for picloram and the "unknowns" is the result of the low application rate of picloram and the solvent extraction from a complex soil matrix. The variation in the noise levels has created problems for accurate quantitative integration as most of these small "peaks" are close to the noise background levels. The inclusion or exclusion of the noisy "peaks", has a significant effect for the overall

quantitation. This is particularly important for HAN 0-10cm soil extracts at 120 DAT as the inclusion of all of the "noise peaks" above background levels could lead to a quantitation of < 5% for the unknown in question.

Furthermore, the type of radioactivity detection cell used also needs to be considered. A solid scintillation cell was initially used but it appears that liquid scintillation cell was also tried at some timepoints to increase detector sensitivity. Also a number of chromatograms from the liquid cell have been rejected by the Study Director due to an "artefact" peaks appearing at the same retention time as the solvent front in the chromatographic trace (~2-3 minutes). There is one chromatogram with only this "artefact peak" at 2.9 minutes within the rejected raw data (CHR066.01). This has been documented by the Study Director as due to the liquid scintillant. These appear at the same retention time as the "unknown" in question in soil extract HAN 0-10cm 120 DAT. Finally in the HAN 60-100 cm the samples, a peak was seen at the same time as the "unknown" (at 2.9 minutes) in the 0 DAT sample, so therefore could not be a degradate.

In summary, the accurate quantitation of these low level "peaks" is extremely difficult given the poor signal-to-noise ratio seen in many of the chromatographic traces. This is more pronounced at the later timepoints following picloram degradation and generation of NERs and CO_2. The "artefact peaks" at the solvent front caused by the liquid scintillant are at the same retention time as the "peak" at 5.7% AR so an overestimation of unknowns is likely. Also the presentation of data in the final report (Table 8-3) creates a false impression of the trends within the soil degradation studies. Therefore DAS believes that even if this "unknown" is "real", the level is likely to be below the 5% trigger value and therefore not a groundwater concern. Furthermore it should be realised the all radioactivity was monitored in lysimeter study and no radioactivity leached at levels >0.1ug/L .

Summary of raw data to show retention times of integrated peaks in the chromatograms.

Soil	*Time (DAT)*	*(2.9 mins)*	*(3.6 mins)*	*(4.3 mins)*	*(5.0 mins)*	*Picloram (19.5 mins)*	*(20.5 mins)*	*(22.4 mins)*	*(24.8 mins)*	*(25.7 mins)*
HAN 1	*0**	-	-	-	-	*101.4*	-	-	-	-
0-30cm	*1*	-	-	-	-	*103.4*	-	-	-	-
	3	-	-	-	-	*96.1*	-	-	-	-
	7	-	-	-	-	*88.0*	*0.71*	-	-	-
	14	-	*0.75*	*0.75*	-	*64.7*	-	-	-	-
	30	-	-	-	-	*60.7*	-	*2.17*	-	-
	58	-	-	-	-	*57.6*	-	-	*3.20*	-
	90	-	*2.80*	*1.81*	*1.84*	*52.9*	*0.49*	-	-	*1.22*
	*120**	*5.67*	*0.87*	-	-	*47.1*	-	-	-	-
HAN 1	*0**	-	-	-	-	*102.3*	-	-	-	-
30-60cm	*1*	-	-	-	-	*99.9*	-	-	-	-
	3	-	-	-	-	*100.3*	*1.57*	-	-	-
	7	-	-	-	-	*90.5*	-	-	-	-

	14	-	-	-	-	*89.1*	-	-	-	-
	30	-	-	-	-	*74.8*	-	-	-	-
	*58**	**	-	-	-	*60.5*	-	-	-	-
	*90**	*2.53*	-	-	-	*38.7*	-	-	-	-
	*120**	*2.40*	-	-	-	*26.0*	-	-	-	-
HAN 1	*0**	**	-	-	-	*101.9*	-	-	-	-
60-100cm	*1**	-	-	-	-	*95.9*	-	-	-	-
	*3**	**	-	-	-	*97.5*	-	-	-	-
	7	-	-	-	-	*95.3*	-	-	-	-
	*14**	*2.91*	-	-	-	*91.0*	-	-	-	-
	*30**	**	-	-	-	*80.2*	-	-	*1.63*	-
	*58**	*1.76*	-	-	-	*74.9*	*0.75*	-	-	-
	*90**	-	-	-	-	*71.8*	-	-	-	-
	*120**	*2.21*	-	-	-	*56.9*	-	-	-	-

* *liquid scintillation cell used*

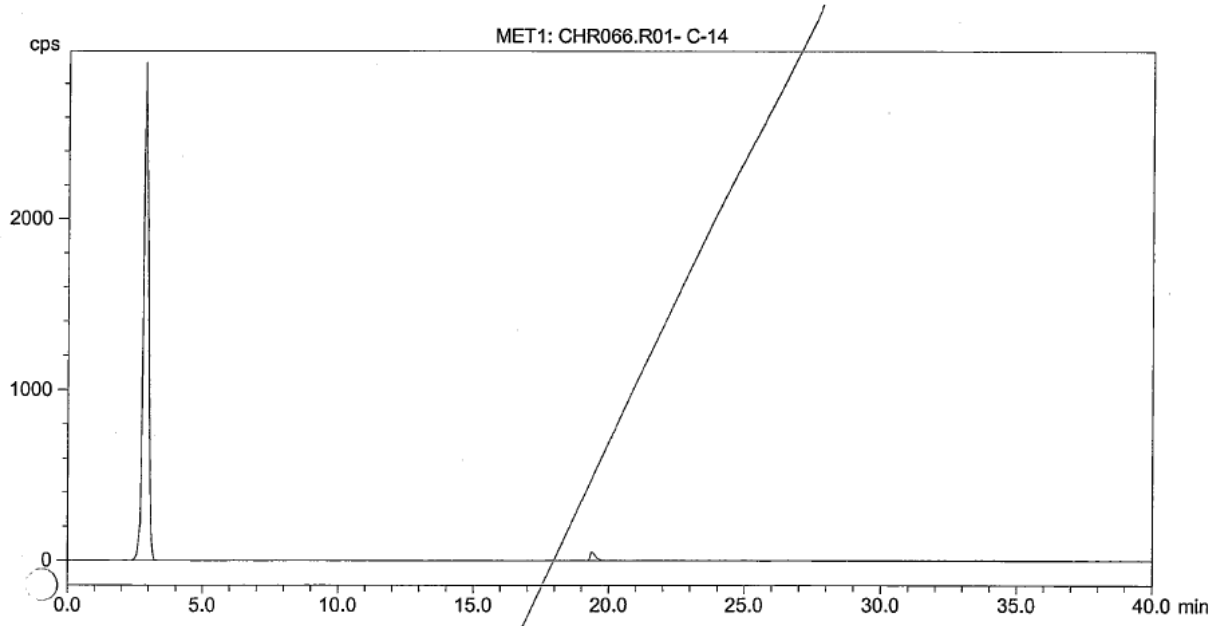
** *signal at solvent front (2.9 minutes) not integrated but likely caused by liquid scintillant.*

Assessment for GW/leaching :

Knowles, S., Schnoder, F. (2003)
[^{14}C]Picloram: Leaching In Outdoor Lysimeters Following Spring Application To Oil Seed Rape, Dow AgroSciences, unpublished report No. GHE-P-10408
Dow AgroSciences, Study ID: 000267, 19 May 2003
Ref. K59

The leaching behaviour of picloram has been assessed in a lysimeter study. During the first year, 0.09% AR and 0.05% AR were recovered in the leachate from lysimeter 11 and 12 and 0.09% AR and 0.06% AR in the second year. Due to the fact that the annual average of ai equivalents was clearly below 0.10 µg/L in all lysimeters and in both years, HPLC analysis was not performed. However, since the ai equivalent annual average concentrations did not exceed 0.10 µg/L in any lysimeter, the annual average concentration of Picloram would have clearly been below 0.10 µg/L.

The lysimeter results provide further evidence that leaching of potential "unknowns" to groundwater is not significant.'



Integrals: CHR066.R01

Channel: C-14 Detector:

Name	Start - End (m)	RT (m)	Height (cps)	Area (Counts)	%Total (%)	%TRR
No ROIs allocated						
0 Peaks				N/A	N/A	N/A

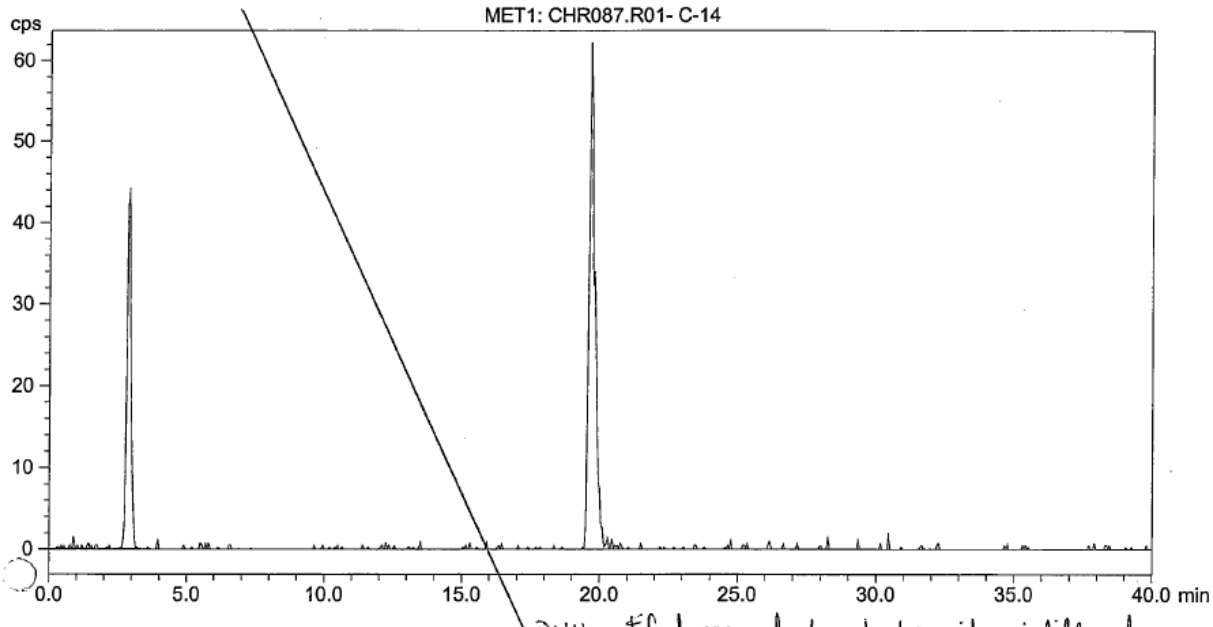
Total Area = 39571.0 Counts
Bkg Area = 0.0 Counts
Unallocated = 39571.0 Counts (100.00%)

Trace Parameters: CHR066.R01 C-14

ce Display Smoothing: 0.0 s
Trace Display Shift: 0.0 s
Trace Display Factor: 1.000
Channel Shift: 0.0 s
Channel Factor: 1.000

DNU, liquid scintillant Monoflow™3 replaced with Monoflow™4. Artifact still present. SES 26/2/02.

Figure B.8.1b: Rejected Chromatogram CHR066.R01



ntegrals: CHR087.R01

Channel: C-14 Detector:

Name	Start - End (m)	RT (m)	Height (cps)	Area (Counts)	%Total (%)	%TRR
No ROIs allocated						
0 Peaks				N/A	N/A	N/A

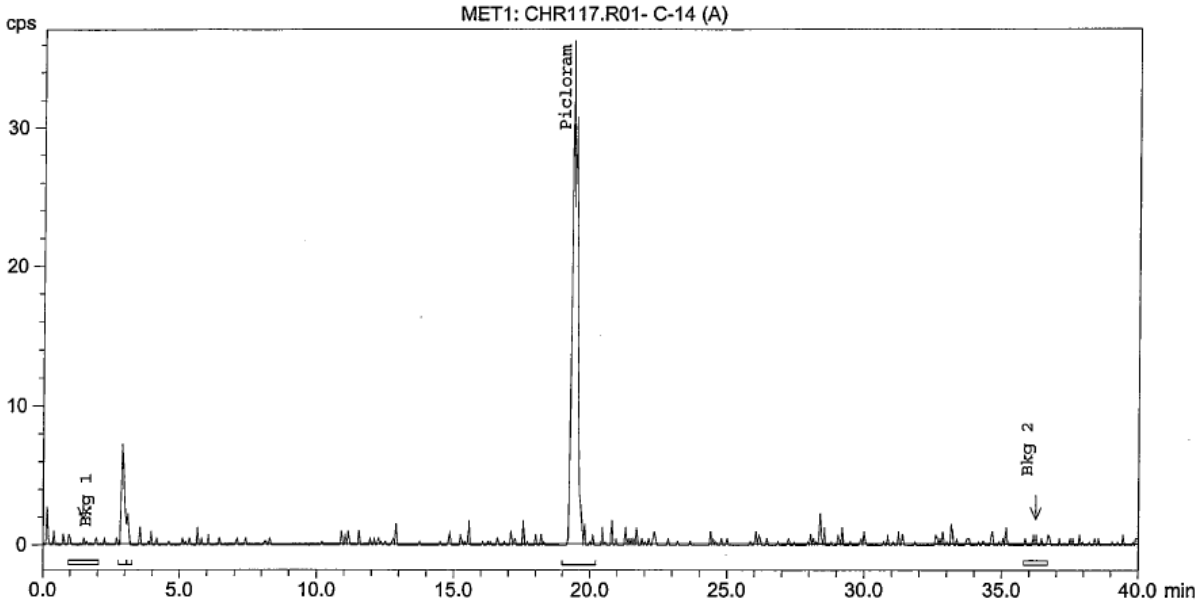
Total Area = 1568.0 Counts
Bkg Area = 0.0 Counts
Unallocated = 1568.0 Counts (100.00%)

race Parameters: CHR087.R01 C-14

7 Day A4 Ext 3

ce Display Smoothing: 0.0 s
Trace Display Shift: 0.0 s
Trace Display Factor: 1.000
Channel Shift: 0.0 s
Channel Factor: 1.000

Figure B.8.2b: Rejected Chromatogram CHR087.R01 (7 days; 0 – 30 cm layer)



Integrals: CHR117.R01

Channel: C-14 Detector:

Name	Start - End (m)	RT (m)	Height (cps)	Area (Counts)	%Total (%)	%TRR
Bkg 1	0.9- 2.0	1.5	0.1			
	2.8- 3.1	2.9	11.9	57.1	10.41	5.67
	3.1- 3.3	3.1	2.9	8.7	1.59	0.87
Picloram	19.0- 20.2	19.3	37.9	474.3	86.47	47.13
Bkg 2	35.8- 36.7	36.2	0.1			
3 Peaks				540.1	98.47	53.67

Total Area = 548.4 Counts
Bkg Area = 287.6 Counts
Unallocated = 8.4 Counts (1.53%)
Sample TRR: 54.5% ✓

Full filepath:
I:\D2142\APPS\LAURA\295_136.PRJ\MET1\CHR117.R01

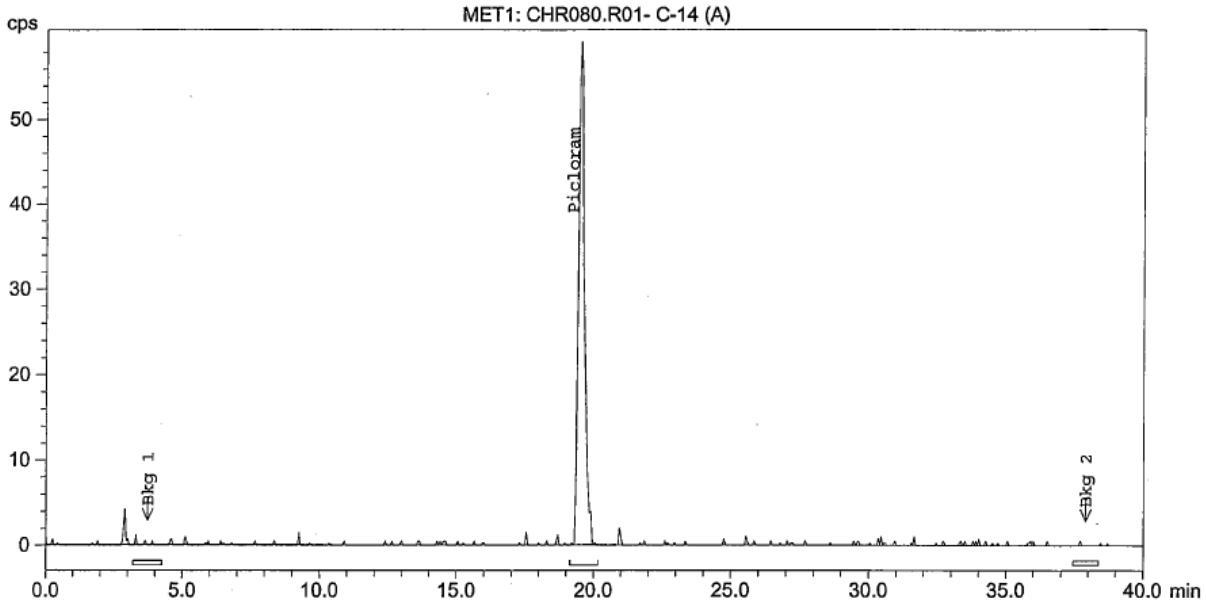
Run Length: 40.0 m
Dwell Time: 1.0 s
Analysed on: 14:11 Wed, 03 Apr 2002
Method by: K.Dixon 13:48 Wed, 03 Apr 2002
Evaluation by: S.Swales 10:29 Tue, 09 Apr 2002

120 Day A9 Ext 3.

SES 9/4/02

KRx 22.5.02.

Figure B.8.3b: Accepted Chromatogram CHR117.R01 (120 days; 0 – 30 cm layer)



Integrals: CHR080.R01

Channel: C-14 Detector:

Name	Start - End (m)	RT (m)	Height (cps)	Area (Counts)	%Total (%)	%TRR
Bkg 1	3.2- 4.3	3.7	0.1			
Picloram	19.1- 20.2	19.5	66.9	876.8	99.22	101.90
Bkg 2	37.4- 38.4	37.9	0.0			
1 Peak				876.8	99.22	101.90

Total Area = 883.7 Counts
Bkg Area = 159.3 Counts
Unallocated = 6.9 Counts (0.78%)
Sample TRR: 102.7% ✓

Trace Parameters: CHR080.R01 C-14

Trace Display Smoothing:	0.0 s
Trace Display Shift:	0.0 s
Trace Display Factor:	1.000
Channel Shift:	0.0 s
Channel Factor:	1.000

Regions were added manually.

C1 Ext 3 0 Day.

SES 26/2/02

KRMC. 22.5.02.

Figure B.8.2b: Accepted Chromatogram CHR080.R01 (0 day; 60 – 100 cm layer)

Study c); Cook, W.L., Buehrer, J.T., 1999

The following is in response to **Open point 4.1 in the Evaluation Table** for picloram and relates to previous discussion in the **reporting table comment 4(2)**. In these points it was requested that the RMS 'clarify the soil classification of the soil from Douglas County, KS in a corrigendum and correct the soil classification of this soil in the LoEP if this was wrong. If this is correct, then the normalisation should be corrected.'

By the RMS calculation the corrected DT50 value of 5.2 days is correct for a silty clay and a field capacity of 40 % moisture. The tables B.8.23 and B.8.35 have therefore been updated to read 'silty clay' in the soil texture and soil type column for Tables B.8.23 and B.8.35 respectively. The Focus default moisture should read 40 not 26 in both Tables. The tables are now referred to as B.8.23b and B.8.35b to avoid confusion and are presented below and in section B.8.1.5 respectively. As the final corrected DT50 value is correct at 5.2 days, and is the same as previously reported, no re-calculation of the geometric mean DT50 value is required.

Table B.8.23b Normalisation of degradation rates at application rate of 134 g/ha (25ºC)

Soil texture	**DT50 (first order, days)**	**Actual soil moisture (%)**	**FOCUS default FC % moisture**	**DT50 Normalised to FC and 20 ºC**
Sandy loam	24.5	9.34	19	21.7
Clay loam	19.3	25.9	28	26.5
Clay	18.3	36.3	48	22.0
Silty clay	5.0	24.6	40	5.2
Geometric mean				**16.0**

Aerobic, 20ºC (and at 10ºC and 30ºC)

The following is in response to **Open point 4.13** in the Evaluation Table for picloram and relates to previous discussion in the **reporting table comment 4(27)**. In this point it was requested that the 'RMS to include an assessment of the degradation and adsorption in soil of aminopyralid (=3,6-dichloro analogue) in an addendum.' Soil degradation studies assessed in the DAR for aminopyralid therefore follow. Further information is included in the route of degradation section of this addendum (B.8.1.1), the field study section (B.8.1.3) and the summary and assessment section of this addendum (B.8.1.5).

Study a); Yoder, R.N. and Smith, K.P., 2003a

The rate of degradation of aminopyralid in soil under aerobic conditions at 20°C (and at 10°C and 30°C) was determined from one study using radiolabelled test substance, which was also used to investigate the route of degradation described under Point B.8.1.1.1 a). The study was conducted according to SETAC-Europe (1995) guidelines.

Therefore, the recovery data for the soil extracts in Tables B.8.2 to B.8.5(20°C), Table B.8.7 (10°C) and Table B.8.8 (30°C) represents the amount of aminopyralid (as mean of duplicate determinations, % AR) present at each time point.

The $DT_{50(lab)}$ and $DT_{90(lab)}$ in each soil was calculated by the Notifier from these values assuming first order kinetics, and using linear regression analysis on the log-transformed data. The rate constant, k ($days^{-1}$), was then used to determine the $DT_{50(lab)}$ (from LN(2)/k) and $DT_{90(lab)}$ (from LN(10)/k) values, DT_{50} was then normalised to field capacity. The Rapporteur repeated this process but estimated the

rate constants using non-linear regression and the results from this assessment are contained in Table B.8.14.

Table B.8.14 Rates of degradation of aminopyralid in aerobic soils under laboratory conditions

Soil name	***Soil type***	***Temp.***	***DT_{50} (first order, days)***	***DT_{90} (first order,days)***	***r^2***	***% moisture 40% MWHC***	***FOCUS default FC % moisture***	***DT50 Normalised to field capacity***
Thessaloniki	*Clay loam*	*20ºC*	*26.4*	*87.6*	*0.959*	*34.8*	*28*	*26.4*
Cuckney	*Sand*	*20ºC*	*146.9*	*488*	*0.988*	*17.5*	*12*	*146.9*
Charentilly	*Clay loam*	*20ºC*	*28.8*	*95.8*	*0.969*	*27.4*	*28*	*28.4*
Parabraun Erde	*Sandy loam*	*20ºC*	*86.2*	*286.3*	*0.994*	*22.4*	*19*	*86.2*
Geometric mean of normalised DT50 (days)								*55.5*
Arithmetic mean of normalised DT50 (days)								*72*
Parabraun Erde	*Sandy loam*	*10ºC*	*401.8*	*1335*	*0.948*	*-*	*-*	*-*
Parabraun Erde	*Sandy loam*	*30ºC*	*106.9*	*355*	*0.970*	*-*	*-*	*-*

(Yoder, R.N. and Smith, K.P., 2003a)

Study b); Rutherford, L.A. and Meitl, T.J., 2004

An anaerobic soil degradation study was conducted according to SETAC-Europe (1995) guidelines, Procedures for Assessing the Environmental Fate and Ecotoxicity of Pesticides (Part 1, Section 1.2), US EPA Pesticide Registration Guidelines, Subdivision N, Section 162-3 and Canada PMRA DACO Number 8.2.3.5.6 – Biotransformation in Aquatic System-Anaerobic Sediment/Water.

This study was summarised under Point B.8.1.1.1 b). Details on the study design can be found there.

Aminopyralid was essentially stable under anaerobic conditions in flooded soil and sediment/water test systems. Therefore, anaerobic degradation will not be a significant degradation route for aminopyralid, and so DT_{50} and DT_{90} values were not calculated.

(Rutherford, L.A. and Meitl, T.J., 2004)

B.8.1.3 Field studies

Field dissipation

The following is in response to **Open point 4.13** in the Evaluation Table for picloram and relates to previous discussion in the **reporting table comment 4(27)**. In this point it was requested that the 'RMS to include an assessment of the degradation and adsorption in soil of aminopyralid (=3,6-dichloro analogue) in an addendum.' The RMS assessments of Soil field degradation studies assessed in the DAR for

aminopyralid are therefore reproduced below. Further information is included in the route and rate of degradation sections of this addendum (B.8.1.1 and B.8.1.2), and the summary and assessment section of this addendum (B.8.1.5).

Study a); Unsworth, C., Scrimshaw, O., Balluff, M., Lagrasse, S., Morgan, A.J. and Schelle, G., 2003;

Field soil dissipation study of aminopyralid was conducted according to SETAC-Europe guidelines, Procedures for Assessing the Environmental Fate and Ecotoxicity of Pesticides (Part 1, Section 3.1), in substantive accordance with BBA Guideline (Part IV, 4-1) and IVA Guidelines – Residue Studies, Part V: Studies on degradation in soil (1993).

Dissipation of aminopyralid was investigated at four different locations in Europe. The properties of the soil at each site are shown in Table B.8.21. Aminopyralid, formulated as GF-819, which is a 30 g a.s./l ME formulation also containing 240 g a.s./l triclopyr BEE, was applied using conventional small plot application equipment to a bare soil plot at each trial (4) location. Only the dissipation of aminopyralid was investigated as part of this study. Details of the four trials are as follows.

UK *– The overall plot size was 3 m x 83 m, which was divided into four subplots. The application was made on 8 May 2002, and the rate achieved was 60.0 g a.s./ha (spray volume 300 l/ha). Soil cores (4.25 cm i.d.) were collected to a depth of 30 cm pre-treatment and at regular intervals through to 1 year after application (May 2003). Soil cores (20 in total, i.e. five cores from each of four subplots) were taken at each time point and these were divided into 0-10 and 10-20 cm horizons. The twenty samples from each respective horizon were combined for analysis, and any soil below 20 cm depth was discarded. The soil was stored frozen prior to analysis.*

Germany *– The overall plot size was 3 m x 72 m, which was divided into four subplots. The application was made on 26 April 2002, and the rate achieved was 56.7 g a.s./ha (spray volume 283 l/ha). Soil cores (5 cm i.d.) were collected to a depth of 30 cm pre-treatment and at regular intervals through to 1 year after application (April 2003). Soil cores (20 in total, i.e. five cores from each of four subplots) were taken at each time point and these were divided into 0-10 and 10-20 cm horizons. The twenty samples from each respective horizon were combined for analysis, and any soil below 20 cm depth was discarded. The soil was stored frozen prior to analysis.*

Northern France *– The overall plot size was 3 m x 72 m, which was divided into four subplots. The application was made on 28 May 2002, and the rate achieved was 61.2 g a.s./ha (spray volume 307 l/ha). Soil cores (5 cm i.d.) were collected to a depth of 25 cm pre-treatment and at regular intervals through to 1 year after application (June 2003). Soil cores (20 in total, i.e. five cores from each of four subplots) were taken at each time point and these were divided into 0-10 and 10-20 cm horizons. The twenty samples from each respective horizon were combined for analysis, and any soil below 20 cm depth was discarded. The soil was stored frozen prior to analysis.*

Southern France *– The overall plot size was 3 m x 72 m, which was divided into four subplots. The application was made on 26 April 2002, and the rate achieved was 61.8 g a.s./ha (spray volume 309 l/ha). Soil cores (5 cm i.d.) were collected to a depth of 25*

cm pre-treatment and at regular intervals through to 1 year after application (April 2003). Soil cores (20 in total, i.e. five cores from each of four subplots) were taken at each time point and these were divided into 0-10 and 10-20 cm horizons. The twenty samples from each respective horizon were combined for analysis, and any soil below 20 cm depth was discarded. The soil was stored frozen prior to analysis.

Analysis *- Soil samples were extracted twice with 90% acetonitrile/10% 1 N hydrochloric acid (HCl) solution. Due to suspected extraction problems with the soils from Southern France, the soils were extracted using 90/10 acetonitrile/9N HCl. The samples were analysed by high performance liquid chromatography with positive ion electrospray (ESI) tandem mass spectrometry (LC/MS/MS). The method has a lowest validated level (LVL) of 1.5 µg/kg. All residues equivalent to <20% of the LVL (i.e. <0.3 µg/kg) are classified as not detected (ND).*

Note: Whilst sampling continued through to 1 year after application for all four trials, the residue analysis was performed only on the samples through to 4-5 months (nominally). This was because it became clear during analysis that the field DT_{90} in each trial had been reached by this time, and so further analysis of the later time point samples was not considered necessary.

The dissipation in each trial was calculated from the aminopyralid residue concentrations (µg/kg dry weight equivalent) in the combined 0-20 cm soil horizon using the first order rate equation:

$$C_T = C_0 \times exp^{-kT}$$

Where C_T is the concentration at time T, C_0 is the initial concentration, and k is the first-order rate constant ($days^{-1}$). The first-order rate constant (k) was determined by non-linear regression by minimising the sum of the squared residuals of the difference between the predicted and actual data. The y-intercept (C_0) was also optimised in this calculation and not fixed to the zero-time results. The concentration of aminopyralid (µg/kg dry weight equivalent) in the 0-10 cm and 10-20 cm soil horizons at each sampling time, together with the total residue at 0-20 cm depth (upon which the dissipation kinetics were derived), the $DT_{50(field)}$ and $DT_{90(field)}$ values and regression parameters calculated for aminopyralid are summarised in Table B.8.21.

The $DT_{50(field)}$ values ranged from 8 to 35 days (mean 25 days), whilst the $DT_{90(field)}$ values ranged from 26 to 116 days (mean 84 days). The r^2 values ranged from 0.777 to 0.944 indicating a reasonable fit of the data to first-order kinetics.

(Unsworth, C., Scrimshaw, O., Balluff, M., Lagrasse, S., Morgan, A.J. and Schelle, G., 2003)

Table B.8.21 Summary of field studies, soil dissipation

Location/ soil properties/ plot size	***Application rate per treatment***			***Applic-ation dates***	***DAA***	***Aminopyralid conc.***			***DT_{50}/DT_{90} (days)***
	Method kind	***No.***	***kg as/ha***		***(Days)***	***(µg/kg dry weight equivalent)***			***data fit used in estimation***
						0-10 cm depth	*10-20 cm depth*	*0-20 cm depth*	***soil layer 0-20cm was used in calculation***
Melbourne, Derbyshire, UK *clay loam* *pH 6.6* *OC 1.5 %* *CEC 10.8 meq/100g* *Air temp. at appl. 10.5ºC* *3m x 83m*	*spray to bare soil*	*1*	*0.060*	*8 May 2002*	*Pre-appn.* *0* *3* *7* *14* *28* *61* *119*	*ND* *43.98* *52.49* *53.64* *40.23* *30.57* *13.41* *1.95*	*ND* *ND* *ND* *ND* *ND* *(0.43)* *(0.44)* *ND*	*ND* *21.99* *26.25* *26.82* *20.11* *15.50* *6.92* *(1.05)*	*35/116* *first order non-linear regression* r^2*=0.932* c_0 *= 26.51*
Dollern, Germany, *sandy loam* *pH 6.2* *OC 3.6 %* *CEC 11.2 meq/100g* *Air temp. at appl. 15ºC* *3m x 72m*	*spray to bare soil*	*1*	*0.0567*	*26 April 2002*	*Pre-appn.* *0* *3* *7* *14* *28* *55* *158*	*ND* *50.43* *45.83* *29.72* *18.50* *12.53* *8.77* *(0.88)*	*ND* *(1.28)* *ND* *2.84* *14.18* *12.94* *8.68* *(0.73)*	*ND* *25.86* *22.99* *16.28* *16.34* *12.74* *8.72* *(0.80)*	*32/105* *first order non-linear regression* r^2*=0.941* c_0 *= 23.44*

Location/ soil properties/ plot size	***Application rate per treatment***			***Applic-ation dates***	***DAA***	***Aminopyralid conc.***			***DT_{50}/DT_{90} (days)***
	Method kind	***No.***	***kg as/ha***		***(Days)***	***(µg/kg dry weight equivalent)***			***data fit used in estimation***
						0-10 cm depth	*10-20 cm depth*	*0-20 cm depth*	***soil layer 0-20cm was used in calculation***
Chalons le Verger, Northern France *sandy loam* *pH 7.5* *OC 0.9 %* *CEC 10.5 meq/100g* *Air temp. at appl. 20ºC* *3m x 72m*	*spray to bare soil*	*1*	*0.0612*	*28 May 2002*	*Pre-appn.* *0* *3* *7* *14* *28* *59* *127*	*ND* *34.58* *21.15* *15.37* *19.88* *15.74* *4.54* *2.17*	*ND* *0.71* *1.22* *ND* *ND* *(0.58)* *(0.36)* *2.56*	*ND* *17.65* *11.19* *7.76* *10.02* *8.16* *2.45* *2.37*	*26/87* *first order non-linear regression* *r^2=0.777* *c_0 = 13.92*
Sorgues, Southern France *clay* *pH 8.0* *OC 3.0 %* *CEC 38.7 meq/100g* *Air temp. at appl. 23ºC* *3m x 72m*	*spray to bare soil*	*1*	*0.0618*	*26 April 2002*	*Pre-appn.* *0* *3* *7* *14* *28* *61* *125*	*ND* *43.94* *23.29* *14.88* *11.83* *4.60* *(0.77)* *(0.35)*	*ND* *3.67* *2.79* *6.46* *4.86* *(1.02)* *ND* *ND*	*ND* *23.80* *13.04* *10.67* *8.34* *2.81* *0.46* *0.25*	*8/26* *first order non-linear regression* *r^2=0.944* *c_0 = 21.43*

ND = not detected (<0.3 µg/kg). For calculation of the concentration at 0-20 cm depth, a value of half the LOD, i.e. 0.15 µg/kg was used when the value was reported as ND. Residue values in brackets are >LOD but <LVL, i.e. >0. µg/kg but <1.5 µg/kg

Study b); Havens,P., 2004, Anon., 2004 a and b; The normalisation procedure

For input into modelling, a re-evaluation of the field dissipation kinetics has been done by normalising the kinetics to standard conditions using the adjusted day length approach (Hardy, 2003) with additional details taken from the FOCUS Degradation Kinetics Workgroup report. The normalisation is done by reducing or increasing day lengths depending on soil temperature and moisture by means of correction factors identical to those used in the regulatory leaching models.

The procedure uses a Q_{10} approach for temperature correction as follows.

$$D_{Norm} = D \cdot f_{Temp}$$

$$f_{Temp} = Q_{10}^{(T-T0)/10}$$

Where:

D_{Norm} = *Normalised day length*
D = *1 day*
f_{temp} = *Correction factor for soil temperature*
Q10 = 2.2 (FOCUS default)
T = *Actual soil temperature*
T_0 = *Reference soil temperature (e.g. 20°C)*

A similar procedure is then done for soil moisture normalisation, employing the Walker equation for moisture correction.

$$D_{Norm} = D \cdot f_{Moisture}$$

$$f_{Moisture} = \left(\frac{theta_{actual}}{theta_{reference}} \right)^{0.7}$$

Where:

D_{Norm} = *Normalised day length*
D = *1 day*
$f_{moisture}$ = *Correction factor for soil moisture*
$theta_{actual}$ = *Actual soil moisture (v/v or w/w)*
$theta_{reference}$ = *Reference soil moisture (=v/v or w/w at field capacity)*

The two corrections are then applied together to yield corrected day lengths for the field data set:

$$D_{Norm} = D \cdot f_{Temp} \cdot f_{Moisture}$$

For three of the four sites (UK, Northern France, Southern France), only air temperatures are available, so the PERSIST model (Walker A & Barnes A., 1981) was used to estimate the soil temperatures. The PERSIST model requires inputs to daily minimum and maximum temperatures, precipitation, latitude, elevation and soil bulk density. The model actually calculates degradation of a pesticide and soil moistures, but these were not used because actual data were available. For the site in Germany, soil temperatures at 10 cm depth were recorded on-site and used directly in the day-length estimation procedure (some values between dates were interpolated), so estimation with PERSIST was not needed (Table B.8.22). Temperatures, precipitation amounts and site information were extracted from the field study report, and input into PERSIST. The input values are summarised in the Table B.8.23. The resulting soil temperatures are shown in the Figure B.8.2.

Table B.8.22 Soil temperatures for Germany site

DAT	***Average soil temperature***	f_{temp}
0	*9.925*	*0*
3	*9.1*	*0.45*
7	*12.1*	*0.42*
14	*15.8*	*0.54*
28	*17.75*	*0.72*
55	*17.7*	*0.84*
158	*9.925*	*0.83*

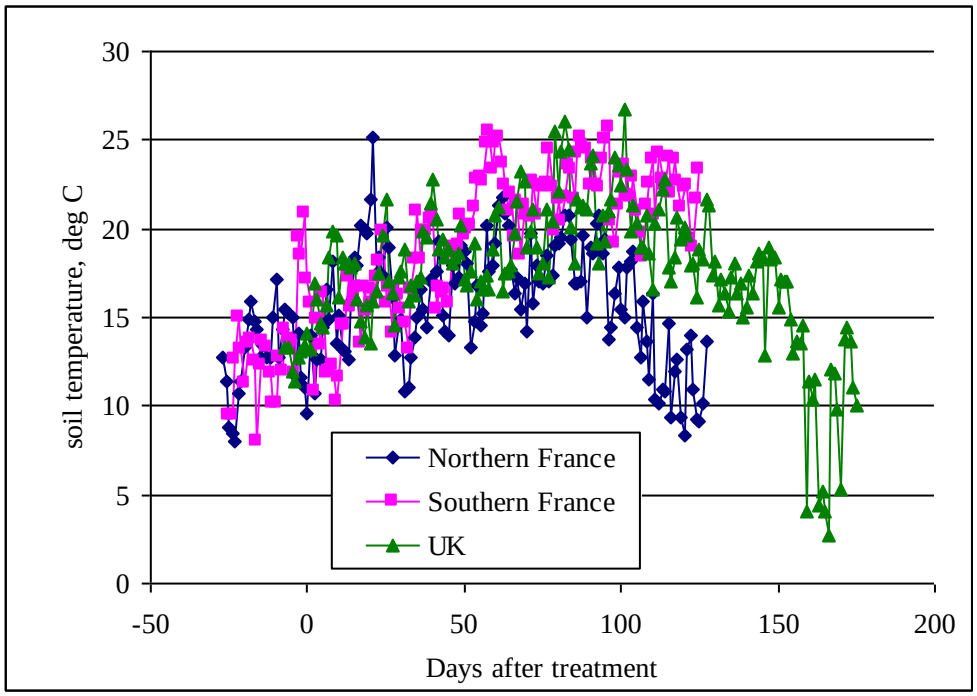
DAT – days after treatment

Table B.8.23 Input values used in PERSIST model

Site	***Soil moisture at FC*, %***	***Soil bulk density, g/ml***	***Elevation, m***	***Latitude, degrees***
UK	*32.9*	*1.2*	*77*	*43 N*
Northern France	*31.4*	*1.1*	*112*	*49 N*
Southern France	*47.3*	*0.9*	*30*	*44 N*

** determined at 5 kPa tension*

Figure B.8.2 The resulting soil temperatures



The results were then used to estimate soil temperature day-length correction factors (f_{Temp}) as shown in the equations above. Soil moistures were extracted directly from the analytical section of the report, as they were determined for each soil sample before analysis. Because the soil moisture values were not continuous (they were measured only at sampling points), average values of $f_{Moisture}$ over the interval between samples was used. The resulting adjusted time points and corresponding concentrations are summarised in the Tables B.8.24 – B.8.27.

Table B.8.24 Day-length adjustment calculation results – UK site

Sampling time, DAT	***Soil temp.***	***avg moisture 0-20***	***$f_{Moisture}$***	***average $f_{Moisture}$***	***Dnorm***	***average residue (ppb), 0-20 cm core depth***
0	*14.1*	*21.775*	*0.749*		*0.000*	*21.99*
3	*16.0*	*19.92*	*0.704*	*0.726*	*1.523*	*26.25*
7	*18.4*	*22.525*	*0.767*	*0.735*	*3.653*	*26.82*
14	*17.8*	*24.055*	*0.803*	*0.785*	*8.463*	*20.11*
28	*14.6*	*20.735*	*0.724*	*0.764*	*16.700*	*15.50*
61	*21.2*	*20.755*	*0.724*	*0.724*	*37.674*	*6.92*
119	*19.4*	*17.44*	*0.641*	*0.683*	*80.204*	*1.05*
mean	*19.1*					

Table B.8.25 Day-length adjustment calculation results – Northern France site

Sampling time, DAT	***Soil temp.***	***avg moisture 0-20***	$f_{Moisture}$	***average*** $f_{Moisture}$	***Dnorm***	***average residue (ppb), 0-20 cm core depth***
0	*9.6*	*17.095*	*0.653*		*0.000*	*17.648*
3	*12.6*	*16.865*	*0.647*	*0.650*	*1.080*	*11.186*
7	*14.9*	*17.3*	*0.659*	*0.653*	*2.801*	*7.758*
14	*15.9*	*17.78*	*0.672*	*0.665*	*5.857*	*10.018*
28	*12.9*	*16.475*	*0.637*	*0.654*	*14.438*	*8.161*
59	*17.9*	*14.54*	*0.583*	*0.610*	*28.311*	*2.453*
127	*13.7*	*16.985*	*0.650*	*0.617*	*59.908*	*2.3655*
mean	*16.0*					

Table B.8.26 Day-length adjustment calculation results – Southern France site

Sampling time, DAT	***Soil temp.***	***avg moisture 0-20***	$f_{Moisture}$	***average*** $f_{Moisture}$	***Dnorm***	***average residue (ppb), 0-20 cm core depth***
0	*17.1*	*30.275*	*0.732*		*0.000*	*23.804*
3	*14.9*	*32.18*	*0.764*	*0.748*	*1.399*	*13.043*
7	*12.0*	*32.49*	*0.769*	*0.766*	*3.241*	*10.671*
14	*15.6*	*34.815*	*0.807*	*0.788*	*6.657*	*8.343*
28	*16.7*	*33.715*	*0.789*	*0.798*	*15.108*	*2.810*
61	*25.1*	*26.765*	*0.671*	*0.730*	*39.167*	*0.463*
125	*23.4*	*32.65*	*0.771*	*0.721*	*94.411*	*0.250*
mean	*19.9*					

Table B.8.27 Day-length adjustment calculation results – Germany site

Sampling time, DAT	***avg moisture 0-20***	$f_{Moisture}$	***average*** $f_{Moisture}$	***Dnorm***	***average residue (ppb), 0-20 cm core depth***
0	*21.775*	*0.749*		*0.000*	*25.86*
3	*19.920*	*0.704*	*0.726*	*0.989*	*22.99*
7	*22.525*	*0.767*	*0.735*	*2.299*	*16.28*
14	*24.055*	*0.803*	*0.785*	*5.553*	*16.34*
28	*20.735*	*0.724*	*0.764*	*14.897*	*12.74*
55	*20.755*	*0.724*	*0.724*	*32.751*	*8.72*
158	*17.440*	*0.641*	*0.683*	*86.882*	*0.8*

These results were curve fit to first-order decline curves with the non-linear regression routines using the Microsoft Excel solver function, yielding the kinetics shown in the following Table B.8.28.

Table B.8.28 Field DT_{50} and DT_{90} at standard conditions

Site	*Normalised DT_{50} (first order, non-linear curve fit), days*	*Normalised DT_{90} (first order, non-linear curve fit), days*	*r^2 statistic for fit*
UK	*21.6*	*71.8*	*0.94*
Germany	*19.2*	*63.8*	*0.91*
Northern France	*13.78*	*45.8*	*0.75*
Southern France	*3.75*	*12.5*	*0.94*
Arithmetic mean	*14.6*	*48.4*	-
Geometric mean	*12.1*	*40.2*	-

In the original submission from the Notifier the Rapporteur observed a routine calculation error in the results proposed for the UK, Northern France and Southern France sites. As a result of this error the original geometric mean proposed by the Notifier was only 9.2 d (compared with the corrected geometric mean value of 12.1 above). The exposure assessments for the environmental compartments of soil, groundwater and surface water were erroneously performed by the Notifier with the original, shorter value of 9.2 d. The effect that this error has on the surface water assessment is discussed in more detail in B.8.6.

(Havens,P., 2004, Anon., 2004 a and b)

B.8.1.5 Summary and assessment

The following is in response to **Open point 4.1 in the Evaluation Table** for picloram and relates to previous discussion in the **reporting table comment 4(2)**. Full details of the response to these open points are detailed in section B.8.1.2 above. However, a corrected version of B.8.35, now referred to as B.8.35b is reproduced below.

Table B.8.35b Rates of degradation of picloram in aerobic soils under laboratory conditions (EU soils) and US soils with application rate of 134 g/ha, normalised DT_{50} to field capacity and 20ºC

Soil name	**Soil type**	**Temp.**	**DT_{50} (first order, days)**	**DT_{90} (first order, days)**	**r^2**	**Actual soil moisture (%)**	**FOCUS default FC % moisture**	**DT50 Normalised to field capacity**
Marcham	Sandy clay loam	20ºC	82.8	274.9	0.950	27.6	22	82.8
Charentilly	Clay loam	20ºC	100.7	334.4	0.899	26.5	28	96.4
Cuckney	Sand	20ºC	220.6	732.7	0.897	9.92	12	193.2
Parabraun Erde	Silty loam	20ºC	295.6	982.1	0.855	25.5	26	292.2
Waller County, TX	Sandy loam	25ºC	24.5	81.6	0.986	9.34	19	21.7
Grand Forks County, ND	Clay loam	25ºC	19.3	64.1	0.993	25.9	28	26.5
Bell County, TX	Clay	25ºC	18.3	60.7	0.984	36.3	48	22.0
Douglas County, KS	Silty clay	25ºC	5.0	16.7	0.970	24.6	40	5.2
Geometric mean of normalised DT50 (days)								48.3
Arithmetic mean of normalised DT50 (days)								92.5
Parabraun Erde	Silty loam	10ºC	1451.2	4820.9	0.706	-	-	-
Parabraun Erde sterile	Silty loam	20ºC	1446.2	4804.3	0.989	-	-	-

The following is in response to **Open point 4.4 in the Evaluation Table** for picloram and relates to previous discussion in the **reporting table comment 4(6)**. In this point it was requested that 'To support the discussion RMS to provide the kinetic fit (e.g SFO and FOMC) of the upper layer of HAN soil in an addendum.'.

The RMS considers that it is inappropriate to retrospectively apply evaluation guidance. In this instance the original submission was made to the RMS prior to FOCUS Degradation Kinetics guidance being available for use.

However, in order to fulfil the open point the RMS has performed the fitting for the upper layer (0 – 30 cm) of the HAN 1 soil using the ModelMaker 4.0 software package. Fitting was performed for both SFO and FOMC degradation kinetics and assumed that picloram degraded to a sink compartment only. Chi-squared and t-test statistics were calculated using the FOCUS DEGKIN V.2 spreadsheet tool. A comparison of the fitting statistics is shown below in Table B.8.36b, while graphs of the fits and residual plots are shown in Figures B.8.1b and B.8.2b for the SFO and FOMC fits respectively.

Based upon the graphs presented in Figure B.8.1b the RMS considers that the SFO fit is unacceptable for providing end-points for use in modelling, due to the large residuals and systematic deviations observed. FOMC kinetics display a good fit with the chi-squared error being 5.3 % and the graphical fits and residual plots also displaying a good fit with small and non-systematic deviations. However, the RMS considers that there is significant uncertainty around the DT90 value which is extrapolated to a value well beyond the study duration.

If FOCUS kinetics is to be followed strictly FOMC kinetics should be used and a pseudo DT50 should be calculated from the calculated DT90 by dividing the calculated DT90 by 3.32. This would result in a pseudo DT50 of 20227 days. However as indicated in the previous paragraph there is significant uncertainty around the DT90 value from this study due to its extrapolation to a point significantly beyond the study termination. The RMS also notes that all of the eight laboratory soils studies considered acceptable were well represented by SFO kinetics (see Table B.8.35b above), and that even the lower layers from the same soil displayed a good SFO kinetic fit (see Table B.8.36 in Volume 3 of the DAR). Further, the DT50 which would be calculated for use in modelling is two orders of magnitude higher than the next longest DT50. In addition the RMS also notes that it is inappropriate to use the values from lower horizons as leaching models generally assume rate constants to be derived from top soils, with correction factors applied to slow the degradation in lower soil horizons. However the DT50 values calculated for those lower horizons using SFO kinetics returned acceptable DT50 values which were significantly shorter than those calculated for the top horizon. The values calculated of 66.6 d and 161.7 d for the 30-60 cm and 60 – 100 cm soil horizons respectively were consistent with the range of values from the studies considered acceptable.

The RMS therefore considers that the degradation of picloram in the upper layer of the HAN1 soil is an anomaly and should not be used to inform the geometric mean laboratory soil DT50 for use in subsequent modelling. From examination of the study report, it is not clear why this should be the case. The reports authors postulated that this may be due to the higher organic matter content of the upper layer resulting in higher adsorption and thus lowering the bioavailability of picloram. However, this effect is not borne out when comparison to soils from the other studies is made. For example the Marcham soil from the study of Knowles, S., Draisey, R., 2001 has a higher % OC than the HAN1 upper layer (1.9 % for Marcham compared to 1.3 % for HAN1) while its DT50 is well represented by SFO degradation kinetics and the normalised DT50 value is in the middle of the range of 8 acceptable DT50 values calculated (82.8 days). While the soil with longest acceptable calculated DT50 (Parabraun Erde from the ; Knowles, S., Draisey, R., 2001 study; 292.5 days; also by SFO kinetics) has a relatively low % OC being 0.8 %.

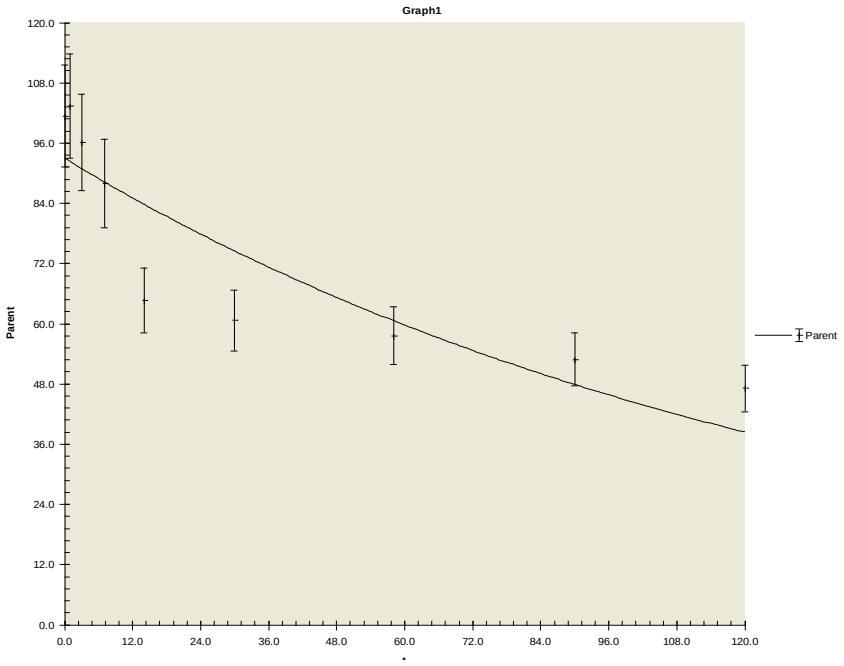
Table B.36b Comparison of kinetic modelling parameters for picloram for SFO and FOMC fitting for the HAN 1 soil upper layer (0-30 cm)

Method of calculation	picloram	
	SFO	**FOMC**
Pini (mg/ kg)	92.98 ± 5.38	105.4 ± 4.44
k (d^{-1})	0.00736 ± 0.00174	-
α	-	0.2376 ± 0.0536
β	-	4.152 ± 2.899
Visual fit	Poor; systematic deviation displayed with large residuals	Generally good. No systematic deviation and small residuals
χ^2 error	10.7	5.3
t-test	Sig. different from zero at p = 0.05	-
DT50 (d)	94.2	72.6 (20227 for use in modelling)*
DT90 (d)	313	67155

* Value in brackets is the DT50 value calculated from the DT90/3.32.

Figure B.8.1b: a) A graphical output for the SFO kinetic fit for picloram in the upper layer (0 – 30 cm) of the HAN1 soil and b) associated plot of residuals

a)



b)

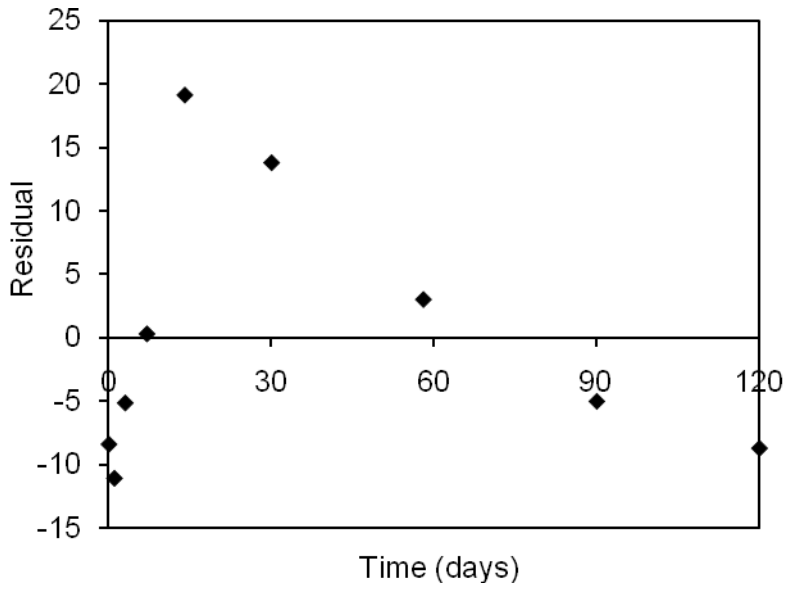
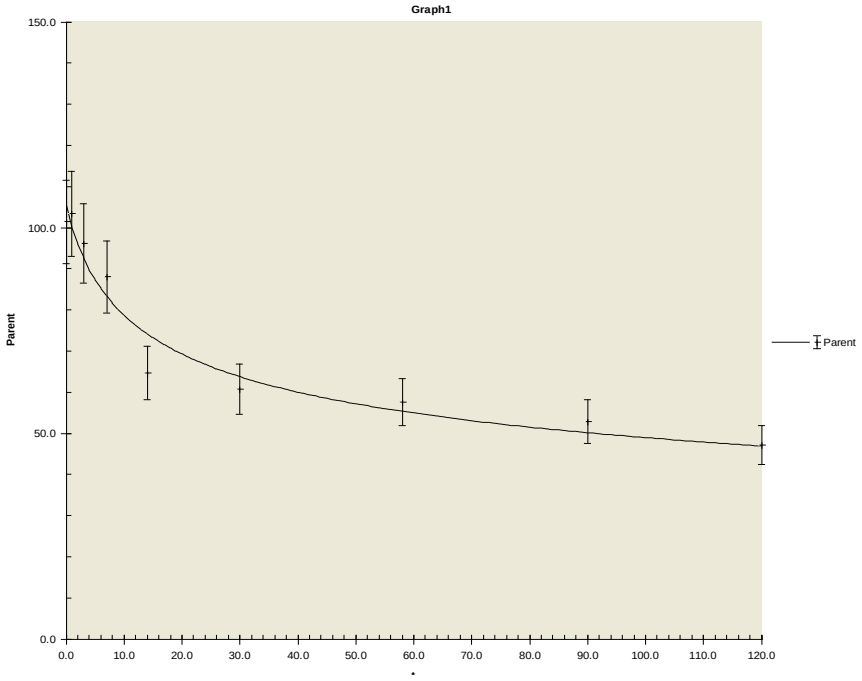
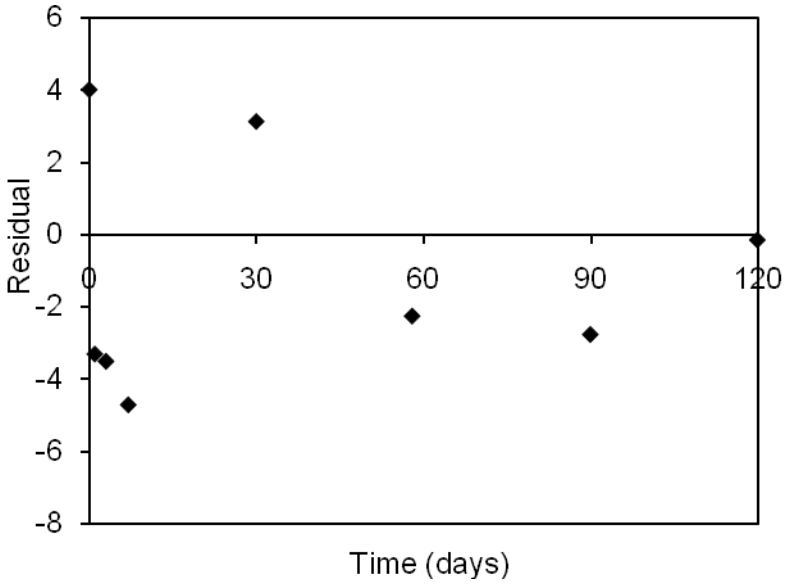


Figure B.8.2b: **a) A graphical output for the FOMC kinetic fit for picloram in the upper layer (0 – 30 cm) of the HAN1 soil and b) associated plot of residuals**

a)



b)



The following is in response to **Open point 4.13** in the Evaluation Table for picloram and relates to previous discussion in the **reporting table comment 4(27)**. In this point it was requested that the 'RMS to include an assessment of the degradation and adsorption in soil of aminopyralid (=3,6-dichloro analogue) in an addendum.' The RMS Summary and Assessment section in the DAR for aminopyralid is therefore reproduced below. Further information is included in the route and rate of degradation sections of this addendum (B.8.1.1 and B.8.1.2), and the field soil degradation section of this addendum (B.8.1.3).

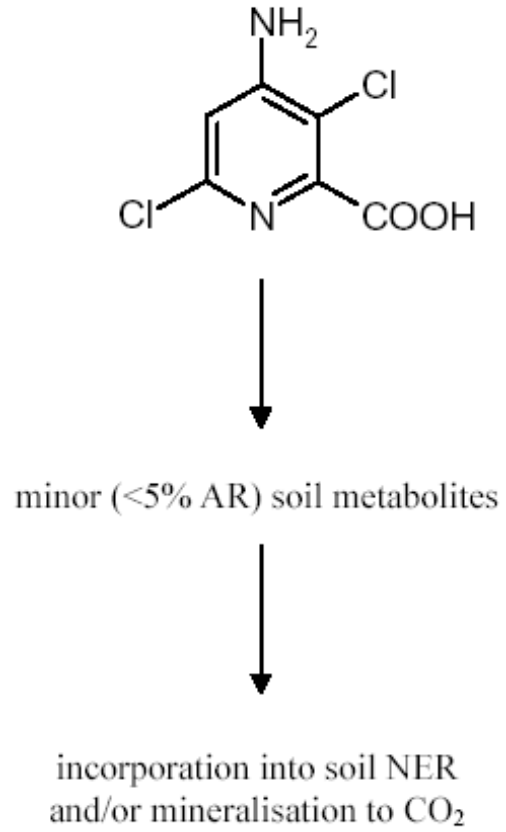
The route and rate of aerobic degradation of aminopyralid has been determined in four European soils under laboratory conditions in the dark at 20ºC (for one soil also at 10ºC and 30ºC) and 40% moisture holding capacity. Aminopyralid was steadily degraded in soil under aerobic conditions. The only metabolite observed was CO_2 indicating that the phenyl ring of aminopyralid is mineralised. No other degradation products were detected. Little or no mineralisation was observed under sterile conditions, demonstrating that the degradation was microbial. After 92 days at 20°C, the CO_2 accounted for 24.1-69.3% AR, whilst the unextracted radioactivity was accounted for 10.3-21.6% AR.

An anaerobic study was performed in a flooded soil from Europe for up to 120 days at 20ºC. The degradation was also studied in a US pond sediment/associated surface water system for up 363 days in the dark at 25ºC. Aminopyralid was essentially stable under anaerobic conditions in flooded soil and sediment/water test systems. Only a single, minor unidentified component (<1% AR) was detected. Therefore, anaerobic degradation will not be a significant degradation route for aminopyralid.

A photolysis study of aminopyralid was carried out at 25ºC and 75% of 1/3 bar moisture holding capacity. Aminopyralid was degraded, one minor photoproduct was seen, but this only reached 4.6% AR after 44 days, and was not identified. Therefore the soil photolysis study did not identify any degradation products not formed in the dark laboratory studies.

Based on these findings, the route of degradation in soil is proposed in Figure B.8.3.

Figure B.8.3 Proposed route of degradation of aminopyralid in soil



Aminopyralid was steadily degraded in soil under laboratory aerobic conditions in the dark with the rate of degradation fitted to first order kinetics (using non linear regression). The $DT_{50/90(lab)}$ values at 20°C were as outlined in Table B.8.31. The $DT_{50(lab)}$ at 10°C was greater than at 20°C in the same soil (401.8 vs. 86.2 days), but less predictably the $DT_{50(lab)}$ at 30°C was also greater than at 20°C (106.9 vs. 86.2 days). See Tables B.8.31 and B.8.32.

Aminopyralid was essentially stable under anaerobic conditions in flooded soil and sediment/water test systems. Therefore, it was not considered meaningful to calculate $DT_{50(lab)}$ and $DT_{90(lab)}$ values.

Table B.8.31 Rate of aerobic degradation of aminopyralid in four European soils under laboratory conditions at 20ºC, 40% MHC and DT_{50} normalised to field capacity

Soil name	***Soil type***	***Soil parametres***	***DT_{50} (first order,days)***	***DT_{90} (first order,days)***	***r^2***	***DT50 Normalised to field capacity***
Thessaloniki	*Clay loam*	*pH 7.7, OC 1.5%*	*26.4*	*87.6*	*0.959*	*26.4*
Cuckney	*Sand*	*pH 5.6, OC 1.5%*	*146.9*	*488*	*0.988*	*146.9*
Charentilly	*Clay loam*	*pH 5.8, OC 1.0%*	*28.8*	*95.8*	*0.969*	*28.4*
Parabraun Erde	*Sandy loam*	*pH 7.7, OC 1.0%*	*86.2*	*286.3*	*0.994*	*86.2*
Geometric mean of normalised DT50 (days)						*55.5*
Arithmetic mean of normalised DT50 (days)						*72*

Table B.8.32 *Rate of aerobic degradation of aminopyralid under laboratory conditions at 10ºC and 30ºC*

Soil name	***Soil type***	***Soil parametres***	***Temp.***	***DT_{50} days***	***DT_{90} days***	***r^2***
Parabraun Erde	*Sandy loam*	*pH 7.7, OC 1.0%*	*10ºC*	*401.8*	*1335*	*0.948*
Parabraun Erde	*Sandy loam*	*pH 7.7, OC 1.0%*	*30ºC*	*106.9*	*355*	*0.970*

Aminopyralid was degraded on the surface of soil by photolysis at a faster rate than in the dark control. The estimated $DT_{50(lab)}$ and $DT_{90(lab)}$ values, after correction for the minimal degradation which occurred in the dark controls, were 40 and 132 days at 25°C and 40ºN summer sunlight assuming 12 hour day lengths, respectively.

The only major soil metabolite was CO_2. In some cases, other metabolites were seen in anaerobic and soil photolysis studies, but these were minor (<5% AR) and not identified. Therefore, the rate of degradation of any soil metabolites is not required. The Rapporteur considers that photolysis on the soil surface is unlikely to be a major route of dissipation for aminopyralid since the presence of crop cover at application will reduce the amount of light reaching the soil. In addition the high mobility of the active substance (see Section B.8.2) is likely to result in movement of aminopyralid to deeper soil layers where photolysis will not occur.

Field soil dissipation study of aminopyralid was performed in the four trials in Northern and Southern Europe following spring application of GF-819. The dissipation of aminopyralid fitted reasonably well to first order kinetics (non-linear regression), as shown by r^2 values of 0.777-0.944. This gave $DT_{50(field)}$ values of 8 to 35 days (mean 25 days), and $DT_{90(field)}$ values of 26 to 116 days (mean 84 days). See Table B.8.33. Since the $DT_{90(field)}$ values were clearly <1 year, then aminopyralid is not expected to accumulate in soil. For input into modelling, a re-evaluation of the field dissipation kinetics has been done by normalising the kinetics to standard conditions (20ºC and soil moisture at field capacity). Kinetics data at standard conditions are in Table B.8.34.

A study of the storage stability of aminopyralid in soil is being conducted and soil stability data are available for up to 194 days. Aminopyralid was stable in soil in the dark for up

to 6 months of frozen storage. This period of storage did not encompass the storage durations of the samples taken in the field dissipation studies.

Table B.8.33 Calculated dissipation rates for aminopyralid in field studies

Trial	***Soil type***	***pH***	***OC (%)***	***Air temp. at appl. (ºC)***	***DT_{50}***	***DT_{90}***	***Regression parameters***	
					(days, first order, depth used 0-20 cm)		***C_0***	***R^2***
UK	*Clay loam*	*6.6*	*1.5*	*10.5*	*35*	*116*	*26.51*	*0.932*
Germany	*Sandy loam*	*6.2*	*3.6*	*15*	*32*	*105*	*23.44*	*0.941*
N France	*Sandy loam*	*7.5*	*0.9*	*20*	*26*	*87*	*13.92*	*0.777*
S France	*Clay*	*8.0*	*3.0*	*23*	*8*	*26*	*21.43*	*0.944*

Table B.8.34 Normalised dissipation rates (20ºC, field capacity)

Site	***Mean soil temp. (ºC)***	***Normalised DT_{50} (first order, non-linear curve fit), days***	***Normalised DT_{90} (first order, non-linear curve fit), days***	***R^2 statistic for fit***
UK	*19.1*	*21.6*	*71.8*	*0.94*
Germany	*13.2*	*19.2*	*63.8*	*0.91*
Northern France	*16*	*13.78*	*45.8*	*0.75*
Southern France	*19.9*	*3.75*	*12.5*	*0.94*
Arithmetic mean	-	*14.6*	*48.4*	-
Geometric mean	-	*12.1*	*40.2*	-

For calculation PEC in soil for parent aminopyralid the Rapporteur proposes the longest field dissipation rate is used. However as the field dissipation trials used spring applications and the intended use encompasses autumn use, it is proposed to use a first order DT50 of 47.5 days (longest first order DT50 of 21.6 days at a reference temperature of 20ºC recalculated to an autumn soil temperature of 10ºC using a Q10 of 2.2). The associated DT90 in soil, of pertinence to consideration of the potential for residues in following crops is therefore 158 days.

For use in calculating PEC in surface water, sediment and groundwater using FOCUS approaches, the geometric mean soil field DT50 after normalisation to reference conditions (field capacity and 20ºC) of 12.1 days is appropriate.

B.8.2 Adsorption, desorption and mobility in soil (IIA 7.1.2, 7.1.3, IIIA 9.1.2)

B.8.2.1 Adsorption and desorption

The following is in response to **Open point 4.13 in the Evaluation Table** for picloram and relates to previous discussion in the **reporting table comment 4(27).** In this point it was requested that the 'RMS to include an assessment of the degradation and adsorption in soil of aminopyralid (=3,6-dichloro analogue) in an addendum.' The summary of the RMS evaluation of the adsorb/ desorb study assessed in the DAR for aminopyralid follows (Rutherford 2002; study a). However additional information was received by the RMS after both the DARs for picloram and aminopyralid were completed, which resulted in a change to the Kfoc and 1/n input parameters for aminopyralid. This information was summarised in an addendum to the aminopyralid DAR, and that study is therefore also reported in this addendum (Laughlin, 2006; study b). The additional study submitted amended the conclusions of the aminopyralid DAR and therefore the average Kfoc and 1/n values were also amended (to 5.19 mL/ g and 0.78). The summary and assessment section of the aminopyralid addendum is therefore included below and not that in the original DAR. The result is that revised Kfoc and 1/n values should be used as input parameters in FOCUS modelling; however these values are comparable to those used in the FOCUS SW modelling reported in the picloram DAR (Kfoc 4.07 mL/ g; 1/n not required at step 1 and 2) and no significant change in PECsw values are anticipated by the RMS.

Study a); Rutherford 2002

A batch equilibrium adsorption/desorption study was conducted in eight soils for aminopyralid according to OECD 106 (2000), SETAC (1995) and US EPA guidelines (Pesticide Assessment Guidelines Subdivision N, Paragraph 163-1, 1982).

The sorption of ^{14}C-phenyl-aminopyralid (specific activity 27.4 mCi/mmol, radiochemical purity >99%) was investigated in eight soils (four North American, four European) using the batch equilibrium technique. Three of the European soils, i.e. Thessaloniki, Cuckney and Charentilly, were used in the aerobic route of degradation study described under Point B.8.1.1.1.
The soils were air-dried and sieved (2 mm) prior to use. The soil characterisation data are shown in Tables B.8.35 and B.8.36 for the North American and European soils, respectively.

Table B.8.35 *Characterisation data for North American soils used to investigate the sorption of aminopyralid using the batch equilibrium technique*

Location	***Dowling, MS***	***Norfolk, NC***	***Barnes, ND***	***Ryerson, Canada***
Textural analysis (%)				
Sand	*8*	*86*	*34*	*17*
Silt	*24*	*10*	*34*	*46*
Clay	*68*	*4*	*32*	*37*
Classification	*Clay*	*Loamy sand*	*Clay loam*	*Silty clay*

pH	*6.9*	*4.5*	*4.8*	*7.8*
Bulk density (g/cm3)	*1.2*	*1.5*	*1.0*	*1.2*
Organic carbon (%)	*1.5*	*0.6*	*3.6*	*3.9*
CEC (mEq/100 g)	*36.9*	*3.6*	*32.3*	*24.6*

Table B.8.36 ***Characterisation data for European soils used to investigate the sorption of aminopyralid using the batch equilibrium technique***

Location	***Thessaloniki,Greece***	***Cuckney, UK***	***Charentilly, France***	***Faringdon, UK***
Textural analysis (%)				
Sand	*37*	*90*	*27*	*25*
Silt	*46*	*6*	*46*	*29*
Clay	*17*	*4*	*27*	*46*
Classification				
ADAS (UK)	*Sandy silt loam Loam*	*Sand*	*Clay loam*	*Clay*
International		*Sand*	*Loam*	*Clay*
pH	*7.8*	*6.6*	*6.1*	*7.5*
Bulk density (g/cm3)	*1.1*	*1.3*	*1.2*	*1.2*
Organic carbon (%)	*1.0*	*1.6*	*1.0*	*3.2*
CEC (mEq/100 g)	*9.9*	*7.1*	*13.5*	*32.7*

For the adsorption phase, duplicate samples of each soil (5.0 g dry weight equivalent) for each concentration were placed into Teflon-capped 24 m glass vials (deemed appropriate from preliminary work where <1% ^{14}C-phenyl-aminopyralid was sorbed from aqueous solution (no soil). Blank 0.01M calcium chloride solution was added to the soils and the samples were shaken using a horizontal shaker in an incubator at 25ºC to equilibrate overnight. The samples were then fortified with the appropriate amount of ^{14}C-phenyl-aminopyralid in 0.01M calcium chloride to achieve the correct test concentration, and give a soil:solution ratio of 1:2 (deemed most appropriate from a range-finding test). The test material was applied to achieve nominal test concentrations of 0.05, 0.1, 0.5, 1 and 5 µg/ml. The actual concentrations were confirmed by LSC. The samples were returned to the shaker and shaken for 48 hours in the dark at 25ºC. After equilibration, the samples were separated by centrifugation and the adsorption supernatant decanted. Triplicate aliquots were analysed by LSC.

Following adsorption, fresh 0.01M calcium chloride (amount approximately equal to the adsorption supernatant removed) was added to each sample. The samples were returned to the shaker and shaken for 2 hours desorption in the dark at 25ºC. The samples were separated and the desorption supernatant was decanted and triplicate aliquots analyzed by LSC. The samples were desorbed for one cycle only.

Following desorption, the soil samples were extracted three times with 90:10 acetone:1N HCl. The extracts were pooled and triplicate aliquots analyzed by LSC. The extracted soils were air-dried and aliquots were taken for combustion analysis to determine the non-extractable residue (NER), and to show a radiochemical balance.

The adsorption and desorption parameters were calculated using the Freundlich isotherms. HPLC analyses of the adsorption and desorption supernatants and the concentrated soil extracts was used to demonstrate stability of ^{14}C-phenyl-aminopyralid under the experimental conditions. The results are summarised in Tables B.8.37 and B.8.38 for the adsorption and desorption phases, respectively.

Table B.8.37 Soil adsorption parameters for aminopyralid in eight soils

Soil name	***Soil type (UK)***	***%O.C.***	***pH***	***K_F***	***Freundlich exponent (1/n)***	***r^2***	***Mean Kfoc (ml/g)***
Dowling, MS	*Clay*	*1.5*	*6.9*	*0.05*	*1.52*	*0.893*	*3.3*
Norfolk, NC	*Loamy sand*	*0.6*	*4.5*	*0.13*	*0.85*	*0.988*	*21.7*
Barnes, ND	*Clay loam*	*3.6*	*4.8*	*0.73*	*0.90*	*0.999*	*20.3*
Ryerson, Canada	*Silty clay*	*3.9*	*7.8*	*0.26*	*0.87*	*0.999*	*6.7*
Thessaloniki, Greece	*Silty clay loam*	*1.0*	*7.8*	*0.04*	*0.81*	*0.948*	*4.0*
Cuckney, UK	*Sand*	*1.6*	*6.6*	*0.05*	*0.74*	*0.942*	*3.13*
Charentilly, France	*Clay loam*	*1.0*	*6.1*	*0.07*	*0.81*	*0.959*	*7.0*
Faringdon, UK	*Clay*	*3.2*	*7.5*	*0.01*	*0.32*	*0.967*	*0.31*

Table B.8.38 Soil desorption parameters for aminopyralid in eight soils

Soil name	***Soil type (UK)***	***pH***	***K_F***	***Freundlich exponent (1/n)***	***r^2***	***Mean Koc (ml/g)***
Dowling, MS	*Clay*	*6.9*	*Parameters not calculated due to no measurable desorption form this soil*			
Norfolk, NC	*Loamy sand*	*4.5*	*2.12*	*0.94*	*0.996*	*353*
Barnes, ND	*Clay loam*	*4.8*	*2.88*	*0.94*	*1.000*	*80*

Ryerson, Canada	*Silty clay*	*7.8*	*3.09*	*1.00*	*0.986*	*79*
Thessaloniki, Greece	*Silty clay loam*	*7.8*	*1.97*	*0.87*	*0.888*	*197*
Cuckney, UK	*Sand*	*6.6*	*1.72*	*0.94*	*0.991*	*107*
Charentilly, France	*Clay loam*	*6.1*	*1.24*	*0.61*	*0.833*	*124*
Faringdon, UK	*Clay*	*7.5*	*Parameters not calculated due to no measurable desorption form this soil*			

(Rutherford, L., 2002)

Study b); Laughlin 2006

A batch equilibrium adsorption/ desorption study was conducted for aminopyralid according to OECD guideline 106: Adsorption /desorption using a batch equilibrium method; January 21, 2000. The study was conducted according to the principles of GLP.

The study was conducted as a supplemental study to the definitive adsorption/ desorption study already performed and reported in Volume 3 of the DAR (Rutherford 2002). Therefore the usual tier 1 and tier 2 tests were not performed, and results from the definitive study were used to determine the experimental conditions used. As a result a soil: solution ratio of 1: 2 and an equilibration time of 48 hours were selected. Based on the study of Rutherford 2002 the RMS considers that these are appropriate parameters. The study also deviated from OECD 106 in that no desorption experiments were performed. Since the purpose of the study was to provide additional adsorption parameters, and the earlier study of Rutherford (2002) assessed in the DAR was fully acceptable, the absence of the desorption step is not considered a significant deficiency in this case by the RMS.

[2, 6-^{14}C]-aminopyralid was dissolved in acetonitrile. An aliquot of this solution was removed and analysed by LSC in order to determine the amount of ^{14}C present. The acetonitrile was then evaporated from the stock solution and the solution was reconstituted in 0.01 M $CaCl_2$ solution to give a stock concentration of 100 µg/ mL. Aliquots of this stock solution were further diluted with 0.01 M $CaCl_2$ solution in order to prepare dose solutions of 20, 10, 2 and 1 µg/ mL.

Soils of around neutral pH were selected in order to be representative of a range of soils in pasture regions of Europe. Neutral soils were selected as Volume 3 of the DAR for aminopyralid reports that soils of pH < 5 display higher Kfoc values. Soil characteristics are shown in Table B.8.35a below. Soils were passed through a 2 mm sieve and an amount of soil was placed in a centrifuge tube in order that 5 g dry weight equivalent of soil were added. Duplicate test samples, controls (test material but no soil) and blanks (soil but no test material) were set up for each test concentration. Prior to the addition of

the ^{14}C-aminopyralid solution, 9.5 mL of 0.01 M $CaCl_2$ solution was added to the soil sample. Test samples and blanks were placed on a horizontal shaker in order to pre-equilibriate overnight. 0.5 mL of the appropriate dosing solution was added to the centrifuge tubes to give solution concentrations of 5.0, 1.0, 0.5, 0.1 and 0.05 µg/ L. Thus a soil: solution ratio of 1: 2 was set-up (based on weight: volume). All experiments were performed at 25 ^oC ± 2 ^oC, which is the same temperature as the original study of Rutherford 2002 which was assessed in Volume 3 of the DAR. The pH of $CaCl_2$ solution for the soil blanks and samples was tested after equilibration.

Following the addition of ^{14}C aminopyralid solution, all samples were mechanically shaken in the dark for 48 hours, following which, soils were centrifuged and the aqueous phases decanted and analysed by LSC. Adsorption solutions were filtered and analysed by HPLC to prove the stability of aminopyralid during the test. The remaining soils were extracted three times in acetonitrile: 1.0 N HCl (90: 10). The extracts were pooled and the amount of radioactivity present in the extracts determined by LSC. Soil extracts were also filtered, concentrated and analysed by HPLC (the pH of solutions were checked with pH paper and solution pH altered to between 6 and 8 if necessary). Dried extracted soil pellets were combusted for radioactive mass balance determination. Where HPLC analysis was performed, UV detection at 270 nm and a RAM flow through detector was used to quantify the ^{14}C aminopyralid in the water / soil samples.

The mass balances, calculated as the sum of the radioactivity recovered from the adsorption supernatant, the soil organic extract and combustion of the extracted soil pellet ranged from 94.8 % to 103.0 %, and are therefore acceptable. In general control samples displayed aminopyralid recoveries from the aqueous solution of > 96 %, indicating that little or no aminopyralid was sorbed to the container walls. One control sample fortified at 0.05 µg/ mL had a recovery of 90.1 % AR, indicating some adsorption to the container. However this is not considered to be a significant level by the UK RMS. The pH of the aqueous portion of the measured controls, blanks and samples were between 6.5 and 7.5.

Freundlich adsorption isotherms were calculated from the sample results for solution concentration versus sorbed concentrations; the results are shown in Table B.8.36b. The Freundlich isotherm calculations were checked by the UK RMS using an internal Excel spreadsheet; similar values were obtained. It is noted by the UK RMS that several of the reported 1/n values are quite low, in particular the 1/n value for the Hertfordshire soil is low with a value of 0.44. However the r^2 value for this soil is 0.622, which is unacceptable. All of the remaining soil Freundlich isotherms display an acceptable fit based on their r^2 values and they and their associated 1/n values are therefore considered to be acceptable by the UK RMS. The mean values in Table B.8.36a are reported for all 6 soils by the applicant. Because the UK RMS did not consider the Hertfordshire soil results acceptable (based on very low 1/n and poor r^2), mean values for the remaining five soils were calculated and are reported in brackets.

For the remaining five soils, although the highest Kf value is associated with the soil with the highest organic carbon content, generally, comparison of the organic carbon content

to the Kf values does not display a strong relationship. Comparison of the Kfoc values to pH displays no obvious relationship, while comparison of Kf to the clay content of the soils also displays no obvious correlation.

In general the study is considered to be acceptable by the UK RMS, though the results for the Hertfordshire soil are not considered to be appropriate for use in modelling due to the poor correlation.

Table B.8.35a Soils used for the adsorption experiments with ^{14}C-aminopyralid

Soil designation	*Altlußheim, Baden-Württemberg, Germany*	*Barrow-On-Trent, Derbyshire, UK*	*Herts., UK*
Soil type (USDA)	*Loam*	*Sandy loam*	*Clay Loam*
% sand (2000 – 50 µm)	*42*	*65*	*35*
% silt (50 - 2 µm)	*37*	*22*	*32*
% clay (< 2 µm)	*21*	*13*	*33*
pH value ($CaCl_2$)	*7.5*	*6.3*	*7.6*
Organic matter (%)			
Organic carbon (%)	*1.7*	*4.6*	*2.2*
Cation exchange capacity (meq/100 g)	*13.3*	*20.9*	*7.2*
Soil designation	*Römenberg/ Rheinland-Pfalz, Germany*	*Languedoc, France*	*Empingham, Rutland, UK*
Soil type (USDA)	*Sandy Loam*	*Loam*	*Clay Loam*
% sand (2000 – 50 µm)	*57*	*31*	*38*
% silt (50 - 2 µm)	*30*	*44*	*33*
% clay (< 2 µm)	*13*	*25*	*29*
pH value ($CaCl_2$)	*7.4*	*7.6*	*7.5*
Organic matter (%)			
Organic carbon (%)	*0.7*	*3.2*	*2.1*
Cation exchange capacity (meq/100 g)	*8.3*	*13.0*	*18.7*

Table B.8.36a Adsorption of ^{14}C-aminopyralid on a range of soils

Soil	*Soil Type*	*pH*	*Org. C (%)*	*K_F (mL/g)*	*1/n*	*r^2*	*Kfoc (mL/g)*
Altlußheim, Germany	*Loam*	*7.5*	*1.7*	*0.09*	*0.63*	*0.895*	*5.3*
Barrow-On-Trent, UK	*Sandy loam*	*6.3*	*4.6*	*0.20*	*0.80*	*0.985*	*4.4*
Hertfordshire, UK.	*Clay loam*	*7.6*	*2.2*	*0.05*	*0.44*	*0.622*	*2.1*
Römenberg, Germany	*Sandy Loam*	*7.4*	*0.7*	*0.11*	*0.78*	*0.922*	*15.2*
Languedoc, France	*Loam*	*7.6*	*3.2*	*0.09*	*0.68*	*0.942*	*2.7*
Empingham, UK	*Clay Loam*	*7.5*	*2.1*	*0.11*	*0.67*	*0.908*	*5.0*
Mean		*-*	*-*	***0.11 (0.12)***	***0.67 (0.71)***	***0.879 (0.930)***	***5.8 (6.5)***

Values in brackets represent the mean values for soils of $r^2 > 0.7$ calculated by the UK RMS (i.e. the Hertforshire soil is excluded).

(Laughlin, 2006)

B.8.2.4 Summary and assessment

Volume 3 of the original DAR concluded that the adsorption characteristics of aminopyralid change with soil pH. Based on the study of Rutherford 2002 which was assessed in the original DAR, it was concluded that there is clear evidence from the data that at low pH (acid soils) the soil Kf_{OC} values are higher (stronger sorption). A mean Kf_{OC} for acid soils (pH 4.5-4.8) is 21 ml/g (n=2), for pH 6.1-7.8 a mean Kf_{OC} is 4.07 ml/g (n=6). For FOCUS modelling inputs it was concluded that in general the appropriate adsorption values were the arithmetic mean Kfoc of 4.07 ml/g and 1/n 0.85 from the 6 soils with pH>6.0. For the Porto groundwater scenario and R2 surface water scenario it was concluded that it would be appropriate to use a Kfoc of 20.3ml/g and 1/n 0.9 (n = 2, therefore the worst case value was selected).

In the study of Laughlin 2006 an additional six European soils were tested all with pH values > 6. The six new kfoc values confirmed the pH dependence of sorption when compared with the study of Rutherford 2002. A summary of all soil adsorption studies is presented in Table B.8.37a. The applicant re-calculated the mean Kfoc and 1/n values based on data from both studies but excluding data from soils with pH values < 5. New FOCUS modelling input parameters of 4.93 mL/ g and 0.76 were calculated for the Kfoc and 1/n respectively, for all scenarios except the Porto groundwater scenario and R2 surface water scenario. However, as indicated in the assessment of the study of Laughlin 2006 (see above), the Hertfordshire soil does not give a freundlich isotherm which is appropriate to support groundwater modelling. The RMS therefore recalculated mean Kfoc and 1/n values excluding this data. Values of 5.19 mL/ g and 0.78 for Kfoc and 1/n respectively were calculated.

Table B.8.37a Adsorption of ^{14}C-aminopyralid on a range of soils

Soil	*Soil Type*	*pH*	*Org. C (%)*	*K_F (mL/g)*	*1/n*	*r^2*	*Kfoc (mL/g)*
Dowling, MS, USA	*Clay*	*6.9*	*1.5*	*0.05*	*1.52*	*0.893*	*3.3*
Norfolk, NC, USA	*Loamy sand*	*4.5*	*0.6*	*0.13*	*0.85*	*0.988*	*21.7*
Barnes, ND, USA	*Clay loam*	*4.8*	*3.6*	*0.73*	*0.90*	*0.999*	*20.3*
Ryerson, Canada	*Silty clay*	*7.8*	*3.9*	*0.26*	*0.87*	*0.999*	*6.7*
Thessaloniki, Greece	*Silty clay loam*	*7.8*	*1.0*	*0.04*	*0.81*	*0.948*	*4.0*
Cuckney, UK	*Sand*	*6.6*	*1.6*	*0.05*	*0.74*	*0.942*	*3.13*
Charentilly, France	*Clay loam*	*6.1*	*1.0*	*0.07*	*0.81*	*0.959*	*7.0*
Faringdon, UK	*Clay*	*7.5*	*3.2*	*0.01*	*0.32*	*0.967*	*0.31*
Altlußheim, Germany	*Loam*	*7.5*	*1.7*	*0.09*	*0.63*	*0.895*	*5.3*
Barrow-On-Trent, UK	*Sandy loam*	*6.3*	*4.6*	*0.20*	*0.80*	*0.985*	*4.4*
Hertfordshire, UK.	*Clay loam*	*7.6*	*2.2*	*0.05*	*0.44*	*0.622*	*2.1*
Römenberg, Germany	*Sandy Loam*	*7.4*	*0.7*	*0.11*	*0.78*	*0.922*	*15.2*
Languedoc, France	*Loam*	*7.6*	*3.2*	*0.09*	*0.68*	*0.942*	*2.7*
Empingham, UK	*Clay Loam*	*7.5*	*2.1*	*0.11*	*0.67*	*0.908*	*5.0*
Mean		***-***	***-***	***0.14***	***0.77***	***0.926***	***7.22***
Mean of soils pH > 5		***-***	***-***	***0.09 (0.10)***	***0.76 (0.78)***	***0.915 (0.942)***	***4.93 (5.19)***

Values in brackets represent the mean values for soils of $r^2 > 0.7$ calculated by the UK RMS (i.e. the Hertforshire soil is excluded).

B.8.4 Fate and behaviour in water (IIA 7.2.1, IIIA 9.2.1, 9.2.3)

B.8.4.3 Ready biodegradation

Heim, D., Heim, L., 2002

The following is in response to **Open point 4.10 in the Evaluation Table** for picloram and relates to previous discussion in the **reporting table comment 4(20)**. In this point it was requested that the 'RMS to include information and results on the series of test solution containing both picloram and sodium benzoate in an addendum.' An additional remark was also made which stated 'Based on the study description there were test vessels, which contained both items together. This information can be valuable to decide whether picloram is toxic to microorganisms (note that soil DT_{50} values with high doses were originally excluded without information on biomass of the soils).'

From further examination of the study report, tests performed with vessels containing both picloram and sodium benzoate were not performed in this study. The confusion appears to have arisen because a study protocol is attached as an appendix to the report which indicates that a toxicity control could be performed. However, this protocol also indicates

that it is an optional requirement. There is no mention of a toxicity control in the core study report and no results are reported for it.

B.9 ECOTOXICOLOGY

General Evaluation Table Open points 5.1, 5.2 and 5.6:
RMS to address in an addendum an explanation of the conversion factor used to convert various ecotoxicology endpoints from picloram potassium salt to picloram acid equivalent (avian acute and dietary toxicity and algal toxicity).

RMS response:
The Notifier has answered this question as follows:
In these studies, all doses were adjusted to 100% active ingredient, picloram potassium salt. In order to convert to acid equivalents, the conversion factor of 0.864 was applied to the values quoted in the report (M.W. of picloram 241.5 / M.W. of picloram K salt 279.6).

This is discussed further by the RMS in the Physical and Chemical Properties Section B.2. of the DAR.

B.9.1 Effects on birds

B.9.1.2.1 Acute oral toxicity to birds

Re: Evaluation Table Open point 5.2
RMS to address in an addendum explanation of conversion factor of 0.864 used to convert the short-term endpoint from bobwhite quail study (Beavers 1986b) from picloram potassium salt to picloram acid equivalent.
RMS to also report in an addendum the raw data (i.e. mean body weight and food consumption table included in the reporting table).
See reporting table 5(3).

RMS response:
In relation to the conversion factor used - please see the General Points discussion above.
In relation to the body weight and food consumption data mentioned: No effects were seen at the top dietary concentration of 5620 ppm and thus the LC50 and NOEC were greater than this - and only the data for this concentration have been added in a Table below:

Nominal Picloram K^+ salt content (mg/kg diet)	Mean bodyweight (g)			Mean food consumption (g/bird/day)	
	day 0	day 5	day 8	days 1 to 5	days 6 to 8
5620	20	31	41	10	14

B.9.2 Effects on aquatic organisms

B.9.2.1.1 Acute toxicity to aquatic organisms

Re: Evaluation Table Open point 5.5
RMS to include in an addendum full data on cell count, biomass and growth rate from Desjardins 2001 study (B.9.2.1.1(iv)), as it was done for metabolite studies on algae in Tables B.9.12 to B.9.18 of the DAR. See reporting table 5(5)

RMS response:
Full data on cell count, biomass and growth rate from the 96h study on the alga *Pseudokirchneriella subcapitata* (syn. *Selenastrum capricornutum*) are available in Tables 8.2.6-2 to 8.2.6-4 in the Dossier Doc. MII, Section 6. These Tables have been copied below:

Table 8.2.6-2 Cell Count Data

Mean measured concentration (mg/L)	Mean cell count (10^4 cells/mL)				
	24 Hours	48 Hours	72 Hours	96-Hours	Percent Inhibition at 72 Hours
Control	6.27	39.6	228	605	---
3.1	6.60	45.9	213	587	6.5
6.0	6.66	43.1	227	607	0.32
12	6.23	41.5	205	588	10
24	5.45	35.1	207	577	9.2
49	5.30	38.4	190 *	518 *	17
98	2.70	14.9	81.4 *	145 *	64

*Significantly less than the control (Dunnett's test, $p \leq 0.05$).

Table 8.2.6-3 Area Under the Growth Curve Data

Mean measured concentration (mg/L)	Biomass (mean area)				
	0-24 Hours	0-48 Hours	0-72 Hours	0-96 Hours	Percent Inhibition at 72 hours
Control	63.3	590	3773	13734	---
3.1	67.2	673	3755	13329	0.47
6.0	67.9	641	3857	13835	-2.2
12	62.8	612	3542	13034	6.1
24	53.4	516	3393	12772	10
49	51.5	552	3266 *	11736 *	13
98	20.3	207	1338 *	4028 *	65

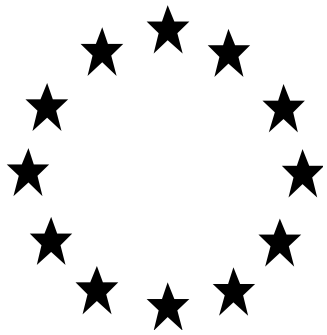
*Significantly less than the control (Dunnett's test, $p \leq 0.05$).

Table 8.2.6-4 Growth Rate Data

Mean measured concentration (mg ae/L)	Growth Rate (cells/mL/hr)				
	0-24 Hours	0-48 Hours	0-72 Hours	0-96 Hours	Percent Inhibition at 72-hours
Control	0.0763	0.0767	0.0754	0.0667	---
3.1	0.0786	0.0796	0.0744	0.0664	1.3
6.0	0.0789	0.0784	0.0753	0.0667	0.040
12	0.0762	0.0775	0.0739	0.0664	1.9
24	0.0706	0.0740	0.0740	0.0662	1.8
49	0.0694	0.0760	0.0728 *	0.0651 *	3.4
98	0.0412	0.0562	0.0611 *	0.0518 *	19

* Significantly less than the control (Dunnett's test, $p \leq 0.05$).

Council Directive 91/414/EEC



Picloram

Addendum 3
to
Volume 4

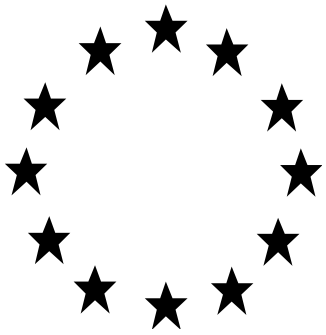
Annex C
to the Report and Proposed Decision of the United Kingdom made to the European Commission under Article 8 of 91/414/EEC

Confidential Information

April 2009

Confidential information available at MS level

Council Directive 91/414/EEC



Picloram

Draft Assessment Report

Addendum 4

to the Report and Proposed Decision of the United Kingdom made to the European Commission under Article 8(2) of 91/414/EEC

June 2009

(Mammalian toxicology, Environmental Fate and Behaviour, Ecotoxicology)

CONTENTS

B.6 TOXICOLOGY AND METABOLISM

1) Pancreas findings in subchronic and chronic rat studies with picloram

Open point 2.12 in evaluation table: RMS to provide further information (including historical control range) on the pancreas findings in sub chronic and chronic studies in an addendum to the DAR

The following information on pancreas histopathology was presented by the RMS at PRAPeR 69 in order to address the relevance of the pancreas findings in these rat studies (as required under open point 2.3 of the evaluation table). The RMS noted that there is no information on pancreas weight from these studies.

90-day rat study (full study summary at B.6.3.1 in DAR)

Pancreas only examined at 0 and 500 mg/kg bw/d.

Male F344:

Atrophy, acini, focal	**Control**	**500 mg/kg bw/d**
v slight or slight	0/10	0/10

Female F344:

Atrophy, acini, focal	**Control**	**500 mg/kg bw/d**
v slight or slight	0/10	2/10

First 2-year chronic toxicity and carcinogenicity study in rat (full study summary at B.6.5.1a in DAR)

Findings at terminal necropsy, plus moribund/dead rats

Male F344:

Atrophy, acini,	**0**	**20**	**60**	**200 mg/kg bw/d**
V slight	15	12	11	12
Slight	8	7	8	7
Moderate	1	2	7*	6 T
Severe	0	1	1	2
Total	24/50	22/50	27/50	27/50
Distended ducts	11/50	7/50	4/50*	3/50* T

Female F334:

Atrophy, acini,	**0**	**20**	**60**	**200 mg/kg bw/d**
V slight	6	12	7	11
Slight	5	4	5	5
Moderate	2	0	0	2
Severe	0	1	0	1
Total	13/50	17/50	12/50	19/50
Distended ducts	2/50	1/50	1/50	3/50

*: Statistical difference from control group, Yates Chi-square test, alpha = 0.05
T: Linear trend by Cochran-Armitage test, alpha = 0.02 (two sided)

Study author notes a similar incidence of moderate and severe pancreatic acinar atrophy for males in a control group of F334 rats in a recent study at their laboratory evaluated by the same pathologist (Johnson 1985). Hence the study author considered this observation to represent normal variability in aged male rats.

The applicant has now provided the following **historical control data** for the pancreas from the 1985 Johnson study and three other studies.

	Johnson 1985		**1982**		**1987**		**1984**	
Atrophy, acini	M	F	M	F	M	F	M	F
slight	22/60	20/60	33/86	4/86	9/50	12/50	20/50	16/50
moderate	4/60	2/60	5/86	-	3/50	3/50	4/50	4/50
severe	3/60	0/60	-	-	1/50	1/50	0/50	0/50

Second 2-year chronic toxicity and carcinogenicity study in rat (full study summary at B.6.5.1b in DAR)

1 year interim kill (pancreas only examined at 0 and 500 mg/kg bw/d)

Male F344:

Atrophy, acini, focal	**Control**	**500 mg/kg bw/d**
slight	1/10	4/10

Female F344:

Atrophy, acini, focal	**Control**	**500 mg/kg bw/d**
slight	3/10	1/10

RMS notes similar incidence for males at 500 mg/kg bw/d and female controls.

Terminal necropsy, plus moribund/dead rats

Male F344:

Atrophy, acini	**0**	**250**	**500 mg/kg bw/d**
Slight	15	4	9
Moderate	1	2	5
Severe	1	1	0
Total	17/50	7/17	14/50
Distended ducts	0/50	0/17	0/50

Female F344:

Atrophy, acini	**0**	**250**	**500 mg/kg bw/d**
Slight	16	4	18
Moderate	4	0	8
Severe	0	0	0
Total	20/50	4/13	26/50
Distended ducts	0/50	0/13	0/50

RMS notes similar incidence of moderate findings for males at 500 mg/kg bw/d and female controls.

Study authors conclude that there were no substance-related effects on the pancreas in this second 2-year rat study.

RMS proposals regarding pancreatic effects in the 2-year rat studies: the increased severity of atrophy of pancreatic acini in male rats at 60 and 200 mg/kg bw/d is not considered to be a substance related effect because:

- It was a common finding in concurrent control male rats
- There was no increase in the incidence of the finding at 60 or 200 mg/kg bw/d (with a substance-related response some increase in incidence might be expected in treated groups, especially as it was not seen in the majority of concurrent controls)
- A similar incidence of moderate and severe pancreatic acinar atrophy was seen in control rats in another study
- There was no convincing evidence for a substance-related effect at a much higher dose level (500 mg/kg bw/d) in the second 2-year rat study (or in the 90-day rat study).

To conclude, the experts at PRAPeR 69 agreed that there were no substance-related adverse effects on the pancreas at the doses of 60 and 200 mg/kg bw/day investigated in the first 2-year rat study. Following further consideration of the liver findings in these studies, PRAPeR 69 agreed:

NOAEL of 60 mg/kg bw/day for the 2-year rat studies (based on liver findings at 200 mg/kg bw/day)*

NOAEL of 300 mg/kg bw/day for the 90- day rat study (based on liver effects at 500 mg/kg bw/day).

[* at 200 mg/kg bw /day, RMS also notes some indications of renal toxicity and mild macrocytic anaemia]

2) Carcinogenicity: further consideration of the NCI bioassays with picloram

Open point 2.13 in evaluation table: RMS to provide further information on why the Reuber evaluation regarding the carcinogenic potential of picloram was rejected (show the inconsistencies in reporting between Reuber and US EPA/NTP).

The carcinogenicity of picloram has been investigated in two rat studies and one mouse study submitted by the Notifier. These studies are evaluated in detail in the DAR (see B.6.5.1 and B.6.5.2). In addition, two NCI (US National Cancer Institute) bioassays with picloram (one in rats, one in mice) are mentioned briefly in the DAR (B.6.5.3). These studies were conducted as part of the US National Toxicology Program (NTP) and reported by the NCI in 1978. The NCI concluded that there was a slightly increased incidence of benign liver tumours in female rats at the top dose of 1000 mg/kg bw/day (an increase in thyroid adenoma was not considered to be substance related based on statistical analysis) and that there was no evidence of substance-related tumours in the mouse bioassay.

This NCI study has also been evaluated in a published paper by Reuber (Carcinogenicity of picloram, Journal of Toxicology and Environmental Health, 7:207-222, 1981), which is not mentioned in the DAR. Reuber conducted his own evaluation of the histological sections from the two NCI bioassays. Reuber concluded that:

- Rats: neoplasms at "all sites", including malignant neoplasms, were increased in male and females given both low and high doses of picloram. Increased neoplasms were reported for endocrine organs, liver and female reproductive organs.
- Mice: males and females developed neoplasms of the spleen.

In response to open point 2.4 in the evaluation table, the notifier provided additional information and justification as to why the article by Reuber should not be considered under the 91/414 evaluation of picloram (C.1.4.2 in Addendum 5). The notifier noted that

Reuber's interpretation of the NCI study was very different to that of the authors of the official NCI study report. The notifier also drew attention to limitations of the NCI study, ie only 2 dose levels plus control for each species, some limitations to the control groups (10 matched controls plus 40 pooled controls), and dosing with picloram that did not continue for the whole duration of the study (notably in rats dosing with picloram was for only 80 weeks following by 33 weeks without exposure to picloram).

At PRAPeR 69 the RMS highlighted a number of differences in interpretation of the NCI study (NCI study report vs Reuber). Examples of these differences are tabulated below. Some notable differences are highlighted.

Male Rat Liver Tumours

NCI study report (1978):

	Matched Control	**Pooled control**	**Low Dose** c.372 mg/kg bw/d	**High Dose** c.747 mg/kg bw/d
Undifferentiated carcinoma metas	0/10		0/49	1/49
Neoplastic nodule	0/10	0/38	3/49	0/49
Hepatocellular carcinoma	0/10		1/49	0/49
Fibrosarcoma	0/10		1/49	0/49

Reuber (1981):

	Matched Control	**Pooled control**	**Low Dose**	**High Dose**
Neoplastic nodule	0/10	1/40	9/45	6/48
Carcinomas	0/10	0/40	5/45	1/48
Total	0/10	1/40	14/45	7/48

Female Rat Liver Tumours

NCI study report (1978):

	Matched Control	**Pooled control**	**Low Dose** c.372 mg/kg bw/d	**High Dose** c.747 mg/kg bw/d
Neoplastic nodule	0/10	0/39	5/50	7/49
Hepatocellular carcinoma	0/10		0/50	1/49

Reuber (1981):

	Matched Control	**Pooled control**	**Low Dose**	**High Dose**
Neoplastic nodule	1/10	2/40	4/50	13/46
Carcinomas	0/10	0/40	7/50	10/46
Total	1/10	2/40	11/50	23/46

Male Rat Thyroid Tumours

NCI study report (1978):

	Matched Control	**Pooled control**	**Low Dose** 372 mg/kg bw/d	**High Dose** c.747 mg/kg bw/d
C cell adenoma	0/9	1/36	6/47	1/49
C-cell carcinoma	0/9		0/47	1/49

Reuber (1981):

	Matched Control	**Pooled control**	**Low Dose**	**High Dose**
Adenomas	1/10	4/40	5/45	6/48
Carcinomas	0/10	2/40	9/45	5/48
Total	1/10	6/40	14/45	11/48

Female Rat Thyroid

NCI study report (1978):

	Matched Control	**Pooled control**	**Low Dose** 372 mg/kg bw/d	**High Dose** c.747 mg/kg bw/d
C cell adenoma	0/9	1/38	3/46	7/46
C-cell carcinoma	0/9		0/46	0/46

Reuber (1981):

	Matched Control	**Pooled control**	**Low Dose**	**High Dose**
Adenomas	0/10	2/40	9/50	3/46
Carcinomas	0/10	0/40	3/50	9/46
Total	0/10	2/40	12/50	12/46

Male Mouse Spleen

NCI study report (1978): all lesions

	Matched Control	**Low Dose** c.357 mg/kg bw/d	**High Dose** c.714 mg/kg bw/d
Neoplasm	0/c.10	0/c.50	0/c.50†
Non-neoplastic lesion	0/c.10	0/c.50	0/c.50

† One mouse with malignant lymphoma and one mouse with lymphocytic leukaemia in multiple organs of the haematopoietic system

Reuber (1981):

	Matched Control	**Low Dose**	**High Dose**
Neoplasm#	3/10	7/44	40/43

Called neoplasm in text but just lesion in table 25

Female Mouse Spleen

NCI study report (1978): all lesions

	Matched Control	**Low Dose** c.357 mg/kg bw/d	**High Dose** c.714 mg/kg bw/d
Neoplasm	0/9	0/48†	0/50
Congestion	0/9	0/48	1/50
Lymphoid hyperplasia	0/9	1/48	1/50

† Two mice with malignant lymphoma in multiple organs of the haematopoietic system

Reuber (1981):

	Matched Control	**Low Dose**	**High Dose**
Neoplasm#	1/10	19/47	34/49

Called neoplasm in text but just lesion in table 25

To conclude, the experts at PRAPeR 69, noting inconsistencies in reporting of the NCI study and limitations in its design, agreed that conclusions in the DAR relating to the more recent carcinogenicity studies by the notifier should be used. Based on the data reported in the DAR, the PRAPeR experts agreed that picloram has no carcinogenic potential

[Note: the EPA Reregistration Eligibility Decision (RED) for picloram (dated 1995) indicates that the NCI bioassays were considered to be deficient and makes no mention of Reuber's evaluation of the study. The EPA also evaluated the more recent carcinogenicity studies conducted by the notifier and classified picloram as a "Group E - Evidence of non-

Carcinogenicity for humans." The notifier has commented that Reuber has published papers on other pesticides and that the EPA is likely to have been aware of his evaluation of picloram.]

3. Developmental toxicity in the rat: craniofacial malformations

Open point 2.14: RMS to provide information regarding the cranial facial malformations in the rat studies in an addendum to the DAR.

Two developmental toxicity studies in the rat are reported in the DAR:

- study with potassium salt of picloram (Schroeder 1990a, see B.6.6.2a).
- study with TIPA salt of picloram (Schroeder 1990b, see B.6.6.2b).

To aid evaluation of the craniofacial malformations reported in these two studies, information additional to that in the DAR was presented by the RMS to PRAPeR 69. This additional information (together with some further clarification) is indicated below.

Study with potassium salt of picloram (Schroeder 1990a, see B.6.6.2a).

In the DAR it is stated:

A single foetus with external malformations (cleft palate and medial facial cleft) was seen at 500 mg*/kg bw/d; this is not considered to be related to treatment as findings occur sporadically in historical controls, and in the absence of similar findings at the top dose level.

[* 500 mg potassium salt of picloram= the mid dose in the study and is equivalent to 430 mg picloram]

Additional clarification

RMS considers that the single mid dose fetus (dose level = 430 mg picloram/kg bw/d) with cleft palate and medial facial cleft on external examination (with associated skull bone malformations on skeletal examination) is not substance related because:

- one concurrent control fetus was found to have a cleft palate on visceral examination (not noted on external examination)
- cleft lip/palate is reported to occur sporadically based on historical control data (1982-1987) for this rat strain at the test laboratory (<0.1% fetuses had cleft lip or cleft palate)
- no such effect was seen at the top dose (860 mg picloram/kg bw/d) in this rat study with the potassium salt

- no such effect was seen at 560 mg picloram/kg bw/d in the rat study with the TIPA salt

Study with TIPA salt of picloram (Schroeder 1990b, see B.6.6.2b).

In the DAR it is stated

A single top dose level foetus with multiple craniofacial malformations (exencephaly, astomia, agnathia and ablepharia) is not considered to be clearly treatment-related; the total incidence of external malformations in this group is less than that of the controls.

Additional clarification

In addition to one top dose fetus with severe craniofacial malformations (but no cleft palate or facial cleft) in this study, similar findings were recorded on external examination of one control fetus. Associated multiple cranial bone malformations were also noted in these two fetuses on skeletal examination. The occurrence of similar externally detected craniofacial malformations in one top dose fetus and one control fetus indicates that occurrence at the top dose was not substance related.

The following table shows the similarity of the craniofacial defects detected externally in one high dose and one control fetus.

One high dose fetus	**One control fetus**
Exencephaly (brain tissue protruding)	-
-	Elongated snout
Absence of mouth (astomia)	Absence of mouth (astomia)
Absence of lower jaw (agnathia)	Absence of lower jaw (agnathia)
Protruding eye (open eye-absence of eyelid)	Ocular malformations (absence of eye bulge(s), ectopic eye(s))

In the DAR it is also noted that two high dose fetuses had distended lateral ventricles of the brain which were not considered to be treatment related. These two fetuses were from different litters but the distension was slight; one of the fetuses also showed slight distension of the third ventricle. It is noteworthy that one control fetus also showed slight distension of the third ventricle of the brain. Overall it is considered that there was not a substance related effect on the brain ventricles.

To conclude, at PRAPeR 69 it was agreed that there were no substance-related adverse developmental effects in the two developmental rat studies with picloram salts (potassium salt and TIPA salt).

4) Revised operator and worker exposure estimates

New open point 2.15 in evaluation table: RMS to provide an addendum to the DAR with revised operator and worker exposure estimates taking into account the revised dermal absorption value agreed for the concentrate.

'Galera' is a soluble concentrate containing 67 g/l of the active substance picloram and 267 g/l clopyralid. Usage information pertinent to operator exposure is summarised in Table B.6.40. The product is to be packaged in 0.25 litres to 5 litre PET bottles and 5 litre HDPE bottles. The 0.25, 0.5, 1 and 2 litre PET bottles will have 45mm screw caps with an induction seal. The 3 and 5 litre PET bottles and 5 litre HDPE bottles will have 63mm screw caps with an induction seal (B.4.1.4). Application of 'Galera' will be achieved via conventional field crop (boom) sprayer. Water will be the diluent/carrier in all situations.

Table B.6.40 Application parameters for 'Galera'

Crop	Maximum individual dose (l product/ha)	Maximum individual dose (kg a.s./ha)	Maximum total dose (kg a.s. /ha/crop)	Spray volume (litres/ha)
Winter oilseed rape	0.35	0.02345	0.02345	100 - 400
Spring oilseed rape	0.35	0.02345	0.02345	100 - 400

AOEL/Dermal absorption

Estimates of operator exposure to picloram arising from the supported use of 'Galera' are made using the German BBA Model[1] and UK Predictive Operator Exposure Model (POEM)[2] . When predicting systemic exposure dermal absorption values of 10% for the concentrate and 0.1% for the spray solution have been used.

'Galera' is likely to be used by farmers for several days per year and by contractors for several weeks per year. Hence, the short-term systemic AOEL for picloram (based on a rabbit developmental study with a safety factor of 100) has been set at 0.3 mg/kg bw/day (B.6.10.3).

'Galera' is unclassified.

B.6.14.1 Operator exposure (IIIA 7.2.1)

Operator exposure estimates using standard assumptions and based on the parameters are presented summarised below.

B.6.14.1.1 Estimation of operator exposure (boom sprayer) – German Model

For vehicle mounted hydraulic boom sprayers a work rate of 20 ha/day is assumed (default value for the German Model).

Table B.6.41 Exposure estimates for boom sprayer application of 'Galera' (picloram): German Model

Dermal exposure mg/person/day		Inhalation exposure mg/person/day		Total systemic exposure *	
Mix/loading	**Application**	**Mix/loading**	**Application**	**mg/kg bw/day****	**% of AOEL**
No PPE					
1.1256	0.9568	0.0003	0.0005	0.00163	0.5%
Gloves when handling the concentrate					
0.0113	0.9568	0.0003	0.0005	0.00004	0.01%
*	assuming dermal absorption values for picloram of 10% for the concentrate and 0.1% for the spray solution				
**	assuming a body weight of 70 kg (default German Model value)				
AOEL	evaluator's proposed systemic AOEL of 0.3 mg/kg bw/day				

B.6.14.1.2 Estimation of operator exposure (boom sprayer) - UK POEM

For vehicle mounted hydraulic boom sprayers a work rate of 50 ha/day is assumed. A total of 17.5 litres of product is required to treat 50 ha at the proposed rate of use of 0.35 litres per hectare. Use of the 5 litre pack has therefore been assumed.

Table B.6.42 Exposure estimates for boom sprayer application of 'Galera' (picloram): UK POEM for 5 litre container size

Dermal exposure mg/person/day		Inhalation exposure mg/person/day		Total systemic exposure *	
Mix/loading	**Application**	**Mix/loading**	**Application**	**mg/kg bw/day****	**% of AOEL**
No PPE					
2.68	9.74	Negligible	0.014	0.0048	2%
Gloves when handling the concentrate					
0.134	9.74	Negligible	0.014	0.0006	0.2%
*	assuming dermal absorption values for picloram of 10% for the concentrate and 0.1% for the spray solution and 100% via the inhalation route				
**	assuming a body weight of 60 kg (default UK POEM value)				
AOEL	evaluator's proposed systemic AOEL of 0.3 mg/kg bw/day				

B.6.14.3 Worker exposure (IIIA 7.2.3)

Workers may enter crops treated with 'Galera' to perform activities such as crop inspection. The oilseed rape crops will be sprayed during growth stages BBCH 14-31, at which point the plants will normally be below knee height. Following spraying, worker re-entry activities would be minimal. It is expected that workers will not re-enter treated crops until spray deposits are dry on the crop foliage, hence exposure will occur through contact with the dry deposit.

Exposure for workers has been predicted using the EUROPOEM re-entry model[8]. The dislodgeable foliar residue (DFR) and transfer coefficient (TC) values assumed are a DFR of 3µg/cm^2 per kg as/ha and a TC of 5,000cm^2/hour[9]. The TC value is for hand harvesting ornamental flowers, however hand harvesting a crop such as carnations in terms of morphology, leaf area index and work task may be considered as a suitable surrogate for inspection activities in oilseed rape crops. For this exposure scenario a work period of 2 hours/day is considered appropriate and a worker bodyweight of 60kg. The maximum application rate has been set at 0.02345 kg a.s./ha/crop.

Parameters used to predict exposure are:

DFR	Dislodgeable foliar residues:	3µg/cm^2 per kg as/ha
TC	Transfer Coefficient:	5,000cm^2/h
A	Working period:	2 hours
P	Clothing penetration:	1 (100% assumes no protection from clothing)
R	Application rate:	0.02345 kg a.s./ha/crop
W	Bodyweight:	60kg
DA	Dermal absorption factor:	0.1 (10%)

DFR×TC×A×R = 3 × 5,000 × 2 × 0.02345 ÷ 60 × 0.03 = 0.0012 mg/kg bw/day
As percentage of AOEL (0.3 mg/kg bw/day) = 0.4%

On the basis of this estimate the level of exposure for unprotected workers entering and handling crops treated with 'Galera' are within the AOEL.

B.6.14.4 Conclusions

'Galera' is unclassified.

The German Model predicted operator exposure for application to winter and spring oilseed rape, based on work rates of 20ha per day, to be within acceptable levels without the use of PPE. UK POEM predicted operator exposure for application to winter and spring oilseed rape, based on work rates of 50 ha per day, to be within acceptable levels without the use of PPE.

Predicted levels of systemic exposure for bystanders are within the AOEL.

Predicted levels of systemic exposure for re-entry workers are within the AOEL.

OPERATOR AND BYSTANDER ESTIMATES

The following exposure estimates were calculated using the German Model and the UK Predictive Operator Exposure Model (POEM).

Estimate	Model	Use	Application method	Operator protection	
				Mix/load	Apply
1	German model	Oilseed Rape	Field crop boom sprayer	None	None
2				Gloves	None
3	UK POEM	Oilseed Rape	Field crop boom sprayer	None	None
4				Gloves	None

The following assumptions were used:

i) a work rate of 20 ha *per* day for use *via* boom sprayers in the German Model and a work rate of 50 ha *per* 6 hour day for use *via* boom sprayers in the UK POEM;

ii) dermal absorption values for picloram of 10% for the concentrate and 0.1% for the spray solution;

iii) an operator body weight of 70 kg in the German Model and 60 kg in the UK POEM;

iv) any assumptions not detailed above will be as given in document SC 8001 (POEM) or the published German model.

Although some values in the exposure estimates are expressed as unrounded figures, this level of precision is not generally justified when considering the various assumptions on which the calculations are based.

Exposure values for German Model estimates 1 and 2

The German Model (Geometric mean values)										
Tractor-mounted/trailed field crop sprayers							Liquid formulations			
Application rate (product)	0.35	l/ha			Dermal absorption:	% absorption				
a.s. content	67	g/l			concentrate	10				
Work rate	20	ha/day			spray solution	0.1				
Amount of a.s. handled/applied	0.469	kg/day								
	Component		kg a.s. handled		Exposure mg/kg a.s.	Reduction coefficient	% absorption		mg/person/day	
No PPE	Im	=	0.469	x	0.0006	1	100	=	0.0002814	
	Dm	=	0.469	x	2.4	1	10	=	0.11256	
	Ia	=	0.469	x	0.001	1	100	=	0.000469	
	Da(c)	=	0.469	x	0.06	1	0.1	=	0.00002814	
	Da(h)	=	0.469	x	0.38	1	0.1	=	0.00017822	
	Da(b)	=	0.469	x	1.6	1	0.1	=	0.0007504	
								Total	**0.11426716**	
With PPE	Im	=	0.469	x	0.0006	1	100	=	0.0002814	
	Dm	=	0.469	x	2.4	0.01	10	=	0.0011256	
	Ia	=	0.469	x	0.001	1	100	=	0.000469	
	Da(c)	=	0.469	x	0.06	1	0.1	=	0.00002814	
	Da(h)	=	0.469	x	0.38	1	0.1	=	0.00017822	
	Da(b)	=	0.469	x	1.6	1	0.1	=	0.0007504	
								Total	**0.00283276**	
	Im	Inhalation exposure (mixing)				**PPE**		**Exposure reduction coefficients**		
	Dm	Hand exposure (mixing)						Dermal	Component	Inhalation
	Ia	Inhalation exposure (application)				Gloves		0.01	hands	
	Da(c)	Head exposure (application)				Coverall + sturdy footwear		0.05	body	
	Da(h)	Hand exposure (application)				Broad-brimmed headwear		0.5	head	
	Da(b)	Body exposure (application)				Hood and visor		0.05	head	
						Filtering facepiece respirator		0.8	head	0.08
						Half-mask with filter		0.8	head	0.02

Estimate 1: German Model - boom spraying (no PPE)

Application method	Tractor-mounted/trailed boom sprayer: hydraulic nozzles				
Product	**Galera**		Active substance	**Picloram**	
Formulation type	Liquid		a.s. concentration	**67**	g/l
Dermal absorption from product	**10**	%	Dermal absorption from spray	**0.1**	%
RPE during mix/loading	None		RPE during application	None	
PPE during mix/loading	None				
PPE during application: Head	None	Hands	None	Body	None
Dose	**0.35**	l product/ha	Work rate/day	**20**	ha

DERMAL EXPOSURE DURING MIXING AND LOADING

Hand contamination/kg a.s.	2.4	mg/kg a.s.
Hand contamination/day	1.1256	mg/day
Protective clothing	none	
Transmission to skin	100	%
Dermal exposure to a.s.	1.1256	mg/day

INHALATION EXPOSURE DURING MIXING AND LOADING

Inhalation exposure/kg a.s.	0.0006	mg/kg a.s.
Inhalation exposure/day	0.0002814	mg/day
RPE	none	
Transmission through RPE	100	%
Inhalation exposure to a.s.	0.0002814	mg/day

DERMAL EXPOSURE DURING SPRAY APPLICATION

Application technique: Tractor-mounted/trailed boom sprayer: hydraulic nozzles

	Head	Hands	Rest of body	
Dermal contamination/kg a.s.	0.06	0.38	1.6	
Dermal contamination/day	0.02814	0.17822	0.7504	
Protective clothing	none	none	none	
Transmission to skin	100	100	100	%
Total dermal exposure to a.s.	0.95676	mg/day		

INHALATION EXPOSURE DURING SPRAYING

Inhalation exposure/kg a.s.	0.001	mg/kg a.s.
Inhalation exposure/day	0.000469	mg/day
RPE	none	
Transmission through RPE	100	%
Inhalation exposure to a.s.	0.000469	mg/day

ABSORBED DOSE

	Mix/load		Application		
Dermal exposure to a.s.	1.1256	mg/day	0.95676	mg/day	
Percent absorbed	10	%	0.1	%	
Absorbed dose (dermal route)	0.11256	mg/day	0.00095676	mg/day	
Inhalation exposure to a.s.	0.0002814	mg/day	0.000469	mg/day	
Total systemic exposure	0.1128414	mg/day	0.00142576	mg/day	

PREDICTED EXPOSURE

Total systemic exposure	0.11426716	mg/day
Operator body weight	70	kg
Operator exposure	0.001632388	mg/kg bw/day

Estimate 2: German Model - boom spraying (gloves mixing)

Application method	Tractor-mounted/trailed boom sprayer: hydraulic nozzles				
Product	**Galera**		Active substance	**Picloram**	
Formulation type	Liquid		a.s. concentration	**67**	g/l
Dermal absorption from product	**10**	%	Dermal absorption from spray	**0.1**	%
RPE during mix/loading	None		RPE during application	None	
PPE during mix/loading	Gloves				
PPE during application: Head	None	Hands	None	Body	None
Dose	**0.35**	l product/ha	Work rate/day	**20**	ha

DERMAL EXPOSURE DURING MIXING AND LOADING

Hand contamination/kg a.s.	2.4	mg/kg a.s.
Hand contamination/day	1.1256	mg/day
Protective clothing	gloves	
Transmission to skin	1	%
Dermal exposure to a.s.	0.011256	mg/day

INHALATION EXPOSURE DURING MIXING AND LOADING

Inhalation exposure/kg a.s.	0.0006	mg/kg a.s.
Inhalation exposure/day	0.0002814	mg/day
RPE	none	
Transmission through RPE	100	%
Inhalation exposure to a.s.	0.0002814	mg/day

DERMAL EXPOSURE DURING SPRAY APPLICATION

Application technique: Tractor-mounted/trailed boom sprayer: hydraulic nozzles

	Head	Hands	Rest of body	
Dermal contamination/kg a.s.	0.06	0.38	1.6	
Dermal contamination/day	0.02814	0.17822	0.7504	
Protective clothing	none	none	none	
Transmission to skin	100	100	100	%
Total dermal exposure to a.s.	0.95676	mg/day		

INHALATION EXPOSURE DURING SPRAYING

Inhalation exposure/kg a.s.	0.001	mg/kg a.s.
Inhalation exposure/day	0.000469	mg/day
RPE	none	
Transmission through RPE	100	%
Inhalation exposure to a.s.	0.000469	mg/day

ABSORBED DOSE

	Mix/load		Application		
Dermal exposure to a.s.	0.011256	mg/day		0.95676	mg/day
Percent absorbed	10	%		0.1	%
Absorbed dose (dermal route)	0.0011256	mg/day		0.00095676	mg/day
Inhalation exposure to a.s.	0.0002814	mg/day		0.000469	mg/day
Total systemic exposure	0.001407	mg/day		0.00142576	mg/day

PREDICTED EXPOSURE

Total systemic exposure	0.00283276	mg/day
Operator body weight	70	kg
Operator exposure	0.000040468	mg/kg bw/day

Estimate 3: UK POEM - boom spraying (no PPE)

Application method	Tractor-mounted/trailed boom sprayer: hydraulic nozzles				
Product	**Galeria**		Active substance	**Picloram**	
Formulation type	water-based		a.s. concentration	**67**	mg/ml
Dermal absorption from product	**10**	%	Dermal absorption from spray	**0.1**	%
Container	5 litres 45 or 63 mm closure				
PPE during mix/loading	None		PPE during application	None	
Dose	**0.35**	l/ha	Work rate/day	**50**	ha
Application volume	**100**	l/ha	Duration of spraying	**6**	h

EXPOSURE DURING MIXING AND LOADING

Container size	5	litres
Hand contamination/operation	0.01	ml
Application dose	0.35	litres product/ha
Work rate	50	ha/day
Number of operations	4	/day
Hand contamination	0.04	ml/day
Protective clothing	None	
Transmission to skin	100	%
Dermal exposure to formulation	0.04	ml/day

DERMAL EXPOSURE DURING SPRAY APPLICATION

Application technique	Tractor-mounted/trailed boom sprayer: hydraulic nozzles			
Application volume	100	spray/ha		
Volume of surface contamination	10	ml/h		
Distribution	Hands	Trunk	Legs	
	65%	10%	25%	
Clothing	None	Permeable	Permeable	
Penetration	100%	5%	15%	
Dermal exposure	6.5	0.05	0.375	ml/h
Duration of exposure	6	h		
Total dermal exposure to spray	41.55	ml/day		

ABSORBED DERMAL DOSE

	Mix/load		Application	
Dermal exposure	0.04	ml/day	41.55	ml/day
Concen. of a.s. product or spray	67	mg/ml	0.2345	mg/ml
Dermal exposure to a.s.	2.68	mg/day	9.743475	mg/day
Percent absorbed	10	%	0.1	%
Absorbed dose	0.268	mg/day	0.009743475	mg/day

INHALATION EXPOSURE DURING SPRAYING

Inhalation exposure	0.01	ml/h
Duration of exposure	6	h
Concentration of a.s. in spray	0.2345	mg/ml
Inhalation exposure to a.s.	0.01407	mg/day
Percent absorbed	100	%
Absorbed dose	0.01407	mg/day

PREDICTED EXPOSURE

Total absorbed dose	0.291813475	mg/day
Operator body weight	60	kg
Operator exposure	0.004863558	mg/kg bw/day

Estimate 4: UK POEM - boom spraying (gloves mixing)

Application method	Tractor-mounted/trailed boom sprayer: hydraulic nozzles				
Product	**Galeria**		Active substance	**Picloram**	
Formulation type	water-based		a.s. concentration	**67**	mg/ml
Dermal absorption from product	**10**	%	Dermal absorption from spray	**0.1**	%
Container	5 litres 45 or 63 mm closure				
PPE during mix/loading	Gloves		PPE during application	None	
Dose	**0.35**	l/ha	Work rate/day	**50**	ha
Application volume	**100**	l/ha	Duration of spraying	**6**	h

EXPOSURE DURING MIXING AND LOADING

Container size	5	litres
Hand contamination/operation	0.01	ml
Application dose	0.35	litres product/ha
Work rate	50	ha/day
Number of operations	4	/day
Hand contamination	0.04	ml/day
Protective clothing	Gloves	
Transmission to skin	5	%
Dermal exposure to formulation	0.002	ml/day

DERMAL EXPOSURE DURING SPRAY APPLICATION

Application technique	Tractor-mounted/trailed boom sprayer: hydraulic nozzles			
Application volume	100	spray/ha		
Volume of surface contamination	10	ml/h		
Distribution	Hands	Trunk	Legs	
	65%	10%	25%	
Clothing	None	Permeable	Permeable	
Penetration	100%	5%	15%	
Dermal exposure	6.5	0.05	0.375	ml/h
Duration of exposure	6	h		
Total dermal exposure to spray	41.55	ml/day		

ABSORBED DERMAL DOSE

	Mix/load		Application	
Dermal exposure	0.002	ml/day	41.55	ml/day
Concen. of a.s. product or spray	67	mg/ml	0.2345	mg/ml
Dermal exposure to a.s.	0.134	mg/day	9.743475	mg/day
Percent absorbed	10	%	0.1	%
Absorbed dose	0.0134	mg/day	0.009743475	mg/day

INHALATION EXPOSURE DURING SPRAYING

Inhalation exposure	0.01	ml/h
Duration of exposure	6	h
Concentration of a.s. in spray	0.2345	mg/ml
Inhalation exposure to a.s.	0.01407	mg/day
Percent absorbed	100	%
Absorbed dose	0.01407	mg/day

PREDICTED EXPOSURE

Total absorbed dose	0.037213475	mg/day
Operator body weight	60	kg
Operator exposure	0.000620225	mg/kg bw/day

B.8 ENVIRONMENTAL FATE AND BEHAVIOUR

B.8.6 Predicted environmental concentrations in surface water and groundwater (PECsw and PECgw) (IIIA 9.2.1, 9.2.3)

Surface Water and Sediment

The following additional information is presented in response to open points 4.25 and 4.26 in the Evaluation Table and Discussion Table for picloram, which were identified following the PRAPeR 67 meeting of experts. Open point 4.25 requested the following in relation to parent picloram:

'*RMS to provide new PECgw, $PEC_{SW,}$ PEC_{SED} calculations. For PEC gw two models should be used. For the new input parameters refer to open point 4.9.'*

while open point 4.26 requested:

'RMS to recalculate PECsw/sed STEP 1 and 2 for the two metabolites (aminopyralid and 5,6-analogue), taking into account that formation in soil should be set to a low value (e.g., 0.001, currently not clear from the DAR or addendum) and a Koc value of 4.07 L/kg for both metabolites, and a formation fraction of 1 for water system as indicated in open point 4.12.'.

The RMS has **not** re-calculated FOCUS Step 3 PEC values for surface water and sediment using the revised input parameters as requested. In the original assessment reported in the DAR PEC values for picloram were calculated up to Step 3 for the proposed use, however acceptable concentrations at Step 1 were displayed. Though some proposed uses of oilseed rape can show higher concentrations for some Step 3 scenarios than at Step 2, this was not the case in the original modelling reported in the DAR. Therefore since no GAP related parameters have been amended, it is not anticipated to be the case here. In addition the Ecotox assessment based upon the Step 1 PECs displays a large 'margin of safety' (see Section B.9.2 of this Addendum). Therefore given the time constraints which the RMS is under for the revised post PRAPeR procedure the RMS has not considered it pertinent to perform FOCUS Step 3 modelling in this instance. Instead the RMS has reported FOCUS Step 1 and Step 2 modelling with the revised input parameters, for parent and both metabolites, which also indicates an acceptable risk from the proposed use.

Modelling was performed in the same manner as reported in section B.8.6 of the DAR using the 'STEPS 1-2 in FOCUS', 'FOCUS surface water tool version 1.1'. The key revised chemical input parameters used for picloram and picloram metabolites in the simulations are shown in Table B.8.61b below along with the remaining input parameters. The following GAPs were considered for Steps 1 and 2:

1) Application to winter oilseed rape: 1 x 23.45 g a.e./ha, October-February, no crop interception

2) Application to spring oilseed rape: 1 x 23.45 g a.e./ha, March-May, no crop interception

The results are outlined in Tables B.8.62b – B.8.64b (Step 1) and in Tables B.8.65b – B.8.67b (Step 2) which are revised versions of Tables B.8.62 – B.8.67 in the original DAR.

Table B.8.61b Chemical specific input parameters for Step 1 and 2

Input parameter	**Unit**	**value**
Picloram		
Molecular mass	$g.mol^{-1}$	241.5
Water solubility	$mg.l^{-1}$	560 (20ºC)
Koc	$ml.g^{-1}$	35
Half-life soil, normalised lab values	days	82.8 (median)
Half-life sed/water	days	196.1
Half-life water	days	1000
Half-life sediment	days	196.1
Input parameter	**Unit**	**value**
Metabolite 3,6-dichloro analogue (aminopyralid)[1]		
Molecular mass	$g.mol^{-1}$	207
Water solubility	$mg.l^{-1}$	2480
Koc	$ml.g^{-1}$	4.07
Half-life soil, field values, normalised	days	12.1 (geometric mean)
Half-life sed/water	days	1001
Half-life water	days	1001
Half-life sediment	days	1001
Maximum observed in water/sed studies	%	100
Maximum observed in soil	%	0.0001
Metabolite 5,6-dichloro analogue[2]		
Molecular mass	$g.mol^{-1}$	207
Water solubility	$mg.l^{-1}$	2480
Koc	$ml.g^{-1}$	4.07
Half-life soil, field values, normalised	days	12.1 (geometric mean)
Half-life sed/water	days	1001
Half-life water	days	1001
Half-life sediment	days	1001
Maximum observed in water/sed studies	%	100
Maximum observed in soil	%	0.0001

[1] these values are taken from aminopyralid DAR

[2] assumed same as 3,6-dichloro as no measured data for 5,6-dichloro

Table B.8.62b Step 1 PECsw and PECsed values for picloram

Day after overall maximum	PEC_{SW} (µg/l)		PEC_{SED} (µg/kg)	
	Actual	TWA	Actual	TWA
0 h	7.7002	-	2.6194	-
24 h	7.6634	7.6818	2.6822	2.6508
2 d	7.6364	7.6659	2.6727	2.6641
4 d	7.5826	7.6377	2.6539	2.6637
7 d	7.5026	7.5969	2.6259	2.6535
14 d	7.3193	7.5037	2.5617	2.6236
21 d	7.1404	7.4123	2.4991	2.5925
28 d	6.9659	7.3224	2.4381	2.5615
42 d	6.6296	7.1471	2.3203	2.5006

Table B.8.63b Step 1 PECsw and PECsed values for metabolite 3,6-dichloro analogue (aminopyralid)

Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
	Actual	TWA	Actual	TWA
0 h	0.1853	-	0	-
24 h	0.1841	0.1847	0.0075	0.0037
2 d	0.184	0.1844	0.0075	0.0056
4 d	0.1837	0.1841	0.0075	0.0066
7 d	0.1834	0.1839	0.0075	0.0069
14 d	0.1825	0.1834	0.0074	0.0072
21 d	0.1816	0.1829	0.0074	0.0073
28 d	0.1807	0.1825	0.0074	0.0073
42 d	0.179	0.1816	0.0073	0.0073

Table B.8.64b Step 1 PECsw and PECsed values for metabolite 5,6-dichloro analogue

Day after overall maximum	PEC_{SW} (µg/l)		PEC_{SED} (µg/kg)	
	Actual	TWA	Actual	TWA
0 h	0.1853	-	0	-
24 h	0.1841	0.1847	0.0075	0.0037
2 d	0.184	0.1844	0.0075	0.0056
4 d	0.1837	0.1841	0.0075	0.0066
7 d	0.1834	0.1839	0.0075	0.0069
14 d	0.1825	0.1834	0.0074	0.0072
21 d	0.1816	0.1829	0.0074	0.0073
28 d	0.1807	0.1825	0.0074	0.0073
42 d	0.179	0.1816	0.0073	0.0073

Table B.8.65b Step 2: PECsw and PECsed values for picloram – winter oilseed rape

	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Northern EU	0 h	3.8278	---	1.3339	---
	24 h	3.822	3.8249	1.3328	1.3334
	2 d	3.8189	3.8227	1.3317	1.3328
	4 d	3.8126	3.8192	1.3295	1.3317
	7 d	3.8033	3.8144	1.3263	1.3301
	14 d	3.7815	3.8034	1.3187	1.3263
	21 d	3.7599	3.7925	1.3111	1.3225
	28 d	3.7383	3.7816	1.3036	1.3187
	42 d	3.6957	3.7601	1.2888	1.3112
Southern EU	0 h	3.104	---	1.0815	---
	24 h	3.0987	3.1014	1.0806	1.081
	2 d	3.0962	3.0994	1.0797	1.0806
	4 d	3.0911	3.0965	1.0779	1.0797
	7 d	3.0835	3.0926	1.0753	1.0784
	14 d	3.0659	3.0837	1.0691	1.0753
	21 d	3.0484	3.0748	1.063	1.0722
	28 d	3.0309	3.066	1.0569	1.0692
	42 d	2.9963	3.0485	1.0449	1.0631

Table B.8.66b Step 2: PECsw and PECsed values for picloram – spring oilseed rape

	Day after overall maximum	**PEC_{SW} (µg/L)**		**PEC_{SED} (µg/kg)**	
		Actual	**TWA**	**Actual**	**TWA**
Northern EU	0 h	1.6565	---	0.5766	---
	24 h	1.6522	1.6544	0.5762	0.5764
	2 d	1.6509	1.653	0.5757	0.5762
	4 d	1.6482	1.6512	0.5747	0.5757
	7 d	1.6441	1.6491	0.5733	0.575
	14 d	1.6347	1.6442	0.5701	0.5733
	21 d	1.6254	1.6395	0.5668	0.5717
	28 d	1.6161	1.6348	0.5636	0.5701
	42 d	1.5976	1.6255	0.5571	0.5668
Southern EU	0 h	3.104	---	1.0815	---
	24 h	3.0987	3.1014	1.0806	1.081
	2 d	3.0962	3.0994	1.0797	1.0806
	4 d	3.0911	3.0965	1.0779	1.0797
	7 d	3.0835	3.0926	1.0753	1.0784
	14 d	3.0659	3.0837	1.0691	1.0753
	21 d	3.0484	3.0748	1.063	1.0722
	28 d	3.0309	3.066	1.0569	1.0692
	42 d	2.9963	3.0485	1.0449	1.0631

Table B.8.67b Step 2: PECsw and PECsed values for metabolites of picloram

	Max. PECsw (µg/l)	TWA PECsw 7 day	TWA PECsw 21 day	Max. PECsed (µg/kg dry)	TWA PECsed 7 day	TWA PECsed 21 day
3,6-dichloro analogue (aminopyralid) of picloram						
Spring oilseed rape North Europe	0.1852	0.1841	0.1830	0.0075	0.0075	0.0074
Winter oilseed rape North Europe	0.1852	0.1841	0.1830	0.0075	0.0075	0.0074
Spring oilseed rape South Europe	0.1852	0.1841	0.1830	0.0075	0.0075	0.0074
Winter oilseed rape South Europe	0.1852	0.1841	0.1830	0.0075	0.0075	0.0074
5,6-dichloro analogue of picloram						
Spring oilseed rape North Europe	0.1852	0.1841	0.1830	0.0075	0.0075	0.0074
Winter oilseed rape North Europe	0.1852	0.1841	0.1830	0.0075	0.0075	0.0074
Spring oilseed rape South Europe	0.1852	0.1841	0.1830	0.0075	0.0075	0.0074
Winter oilseed rape South Europe	0.1852	0.1841	0.1830	0.0075	0.0075	0.0074

Groundwater

The following additional information is presented in response to open point 4.25 in the Evaluation Table and Discussion Table for picloram, which was identified following the PRAPeR 67 meeting of experts. Open point 4.25 requested the following in relation to parent picloram:

'*RMS to provide new PECgw, $PEC_{SW,}$ PEC_{SED} calculations. For PEC gw two models should be used. For the new input parameters refer to open point 4.9.'*

The RMS performed modelling using the FOCUS groundwater scenarios and the models FOCUS PELMO v. 3.3.2 and FOCUS PEARL v.3.3.3. Modelling was performed in the same manner as reported in the original PELMO modelling reported in the DAR. With the exception that amendments were made to the soil DT50 (median lab value of 82.8 d compared to a geomean of 48.3 d in the previous DAR assessment) and 1/n values (default 1.0 compared to 0.9 previously used) for picloram as summarised in Open point 4.9 of the discussion table from the PRAPeR 67 meeting of experts.

The changes to the input parameters which arose following consideration of the PRAPeR 67 meeting of experts are discussed in detail in open points 4.8 and 4.4 of the discussion table. However, to summarise, experts considered that an additional soil DT50 from the aerobic rate of degradation study of Knowles, S. and Swales, S.A., 2002 should be added to the dataset for picloram laboratory aerobic soil degradation, as DFOP kinetics provided a good fit for the degradation observed. The result was that 9 DT50 values were available rather than the 8 previously available, with the additional value being the second longest

DT50 value of the set of 9. Because 9 values were available rather than 8 the meeting considered that a median value was more appropriate than the geometric mean. The median value was 82.8 d, whereas the revised geometric mean was 58 days; both values are longer than the geometric mean value used in the original modelling of 48.3 d.

A default 1/n value of 1.0 was agreed by the meeting of experts in place of the default value of 0.9 used in the original modelling. A default value had to be selected for use in FOCUS modelling since only Kd (rather than Kf) values were available. In the original modelling a 1/n of 0.9 was selected because it was understood that FOCUS Groundwater guidance indicated that where a 1/n value was not available 0.9 should be selected as the 1/n input parameter. However, during the meeting of experts it was considered that this guidance only relates to Kf values, and does not apply to Kd values. It was further considered that there is no guidance on default 1/n values for Kd values. See FOCUS groundwater scenarios in the EU review of active substances; SANCO/321/2000 rev. 2 and Generic guidance for FOCUS groundwater scenarios, Vers 1.1, April 2002.

The meeting of experts considered that as Kd sorption assumes linear adsorption, a 1/n of 1 was appropriate. A default value of 1 has already been agreed in several peer reviews during (at least) stage 3 of the peer review program.

Full substance specific input parameters for picloram used in the groundwater modelling are reported in Table B.8.74b below. There are no soil metabolites which require groundwater modelling.

The following GAPs were assumed:

Spring application of GF-224 to winter oilseed rape
1 x 23.5 g a.s./ha (15 Feb), crop interception 40 %, with application every third year

Spring application of GF-224 to spring oilseed rape
1 x 23.5 g a.s./ha (2 weeks after emergence), crop interception 40 %, with application every third year

In total, 6 scenarios runs were modelled for winter oilseed rape and 3 scenarios were modelled for spring oilseed rape to take into account the use patterns of GF-224 described in combination with the locations relevant to the particular crops, as recommended by FOCUS.

Results are as outlined in Table B.8.75b. The two models display good agreement with many of the PECgw values from individual scenarios showing similar concentrations. However, modelling with the revised input parameters, which were selected by the PRAPeR 67 meeting of experts, indicates that there may be an unacceptable risk to groundwater for areas represented by the majority of the FOCUS groundwater scenarios, with the majority of scenarios displaying picloram PECgw values of > 0.1 µg/ L for both models. Only the Porto scenario displays PECgw values < 0.1 µg/ L trigger value.

Table B.8.74b Summary of chemical property parameters input for PEC_{GW} simulations

Input parameter	Unit	picloram
Physical-chemical parameters		
Molecular mass	$g.mol^{-1}$	241.5
Vapour pressure	Pa	$8x10^{-8}$ (25ºC)
Water solubility	$mg.l^{-1}$	560
Plant uptake factor		0.5
Degradation parameters		
Half-life soil, normalised lab values	days	82.8 (median)
Q10 factor		2.2
Sorption parameters		
Koc	$ml.g^{-1}$	35
Freundlich exponent		1.0

Table B.8.75b 80^{th} Percentile annual average leachate concentration at 1 m depth (µg/l)

Scenario	PEC_{GW} (µg/l) PELMO	PEC_{GW} (µg/l) PEARL
Winter oilseed rape		
Châteaudun	0.241	0.305
Hamburg	0.338	0.345
Kremsmünster	0.287	0.272
Okehampton	0.279	0.270
Piacenza	0.249	0.228
Porto	0.076	0.079
Spring oilseed rape		
Jokionen	0.321	0.352
Okehampton	0.312	0.275
Porto	0.056	0.066

RMS consideration of the revised groundwater input parameters and their possible refinement.

As presented above, the modelling, based on the parameters agreed during the PRAPeR 67 meeting of experts, now indicates the potential for picloram to exceed 0.1 µg/ L in all of the modelled scenarios with the exception of Porto. In the context of the currently agreed risk assessment for picloram, the values agreed at PRAPeR 67 and the consequence modelling are fully presented in the review endpoints and this Addendum.

However, it is the opinion of the rapporteur that there is the potential for further data to allow the refinement of the groundwater modelling for this active substance and that such data has the potential to confirm the acceptability of the supported uses across all EU scenarios.

It is the view of the rapporteur that, on the basis of the acceptability of the Porto scenario, the existing inclusion of picloram could be maintained with the identification of the additional data which would allow a refined risk assessment to be conducted. The RMS considers the additional data, which it should be noted are available for submission in a short time period, would provide confirmation of acceptable exposure in relation to modelled EU groundwater scenarios beyond that represented by Porto.

In order to allow Member States and others to understand the potential for further refinement, the areas and possible refinement steps are outlined below.

Refinement of the Freundlich value of 1/n

In the original assessment the RMS used a default value of 0.9. This has been used by Member States in groundwater assessments as a default value given its acceptance as the default parameter set within the associated FOCUS PEARL and PELMO models and the understanding of FOCUS groundwater guidance at the time. More recently within the PRAPeR expert meeting process it has become the norm to apply a value of 1.0 as the default when only Kd values are available. Experimental data from a batch adsorption/ desorption study which reported freundlich sorption parameters (Kf and 1/n) would allow a refinement of this default 1/n input parameter with measured data.

The Notifier has currently two studies available which have not been considered admissible in the review process:

- a publicly available paper from a peer reviewed journal - *Lu. J et al, Journal of Environmental Quality Vol. 31 pp.123,0 (2002)*
- a batch adsorption/ desorption study conducted on 4 soils study (*Racke, K.D. (1989)*

The Notifier indicates these studies support a revised 1/n value of 0.76 and 0.73 respectively. These studies have not been evaluated by the rapporteur in full other than to determine that the values cited are consistent with an initial reading of the data. If further reassurance were necessary, given one study is a published peer-reviewed journal paper and the other dates from 1989, a new study could be identified as a requirement and could be generated within 2-3 months.

If confirmed on full evaluation, the refinement of this value alone, irrespective of any further consideration of the DT50, to a value of 0.76, in line with the indicative conclusions of the studies, would result in nearly all modelled scenarios being acceptable using FOCUS PEARL and FOCUS PELMO even using the median DT50 of 82.8 days agreed in the PRAPeR expert meeting.

Refinement of the DT50 value

In the original dossier the notifier performed groundwater modelling using field data. However, two of the four field studies in the original assessment were judged not to be acceptable by the RMS due to potential leaching from the lowest soil layer which was analysed.

Consequently a laboratory DT50 value was used in modelling. In this context the experts at PRAPeR 67 considered that there was an acceptable basis for adding an additional laboratory derived soil DT50 to the dataset. This increased the dataset to 9 values, with the additional value being the second longest DT50 value of the set. Given the availability of 9 values it was then agreed that a median rather than geometric mean would be appropriate. This resulted in the median value of 82.8 d being used for the revised modelling that is presented in this Addendum rather than the revised geometric mean which, based on the dataset of 9 values, would be 58 days (both values being longer than the geometric mean value used in the original modelling of 48.3 d). The selection of the median value as an input parameter is regarded by the rapporteur as conservative when compared to the geometric mean given there is no formal guidance on when a median or geometric mean value should be selected. The RMS therefore considers that the selection of a median or geometric mean DT50 value for use as an input parameter is somewhat arbitrary and that the use of the revised geometric mean value could also have been supported.

As stated earlier, two of the field dissipation trials submitted in the original dossier were considered acceptable in the original RMS assessment, and the acceptability of these two field trials was confirmed by the peer review process. The two peer-reviewed field DT50 values were 4.0 d and 4.8 d for sites in the UK and N. France respectively (normalised DT50 values using a Q10 of 2.2). The RMS considers that taken in isolation these values may support the selection of the lower laboratory geometric mean DT50 value (58 d) rather than the median (83 d) DT50 value. It should be noted that both laboratory derived values are significantly higher than the two values obtained in the field.

However, in addition to the two accepted and peer reviewed studies, the notifer has conducted a further field dissipation study to complete the data set for this substance. A new study report is available (Kennedy S.H., 2008) which reports field dissipation conducted at two sites in Northern and Central Germany. These studies report normalised DT50 values of 19.4 days and 6.82 days based on a Q10 of 2.58. These DT50 values are also calculated and reported in a new Kinetic evaluation study of Knowles (2008) which additionally presents the re-calculated normalised field DT50 values for the two studies considered acceptable in the EFSA peer review process using the new Q10 value of 2.58 (3.56 d UK and 4.30 d N. France). Again, in accordance with the interpretation of amended review regulation, these data cannot be taken into consideration to refine the current assessment and the RMS has not evaluated the studies of Kennedy (2008) and Knowles (2008). However the RMS can confirm that following normalisation DT50 values of 19.4 d and 6.82 d are reported in the study of Knowles (2008) for the two sites.

In addition a further re-calculation of the field DT50 values for the two studies considered unacceptable in the original DAR has been conducted by the notifier. This assumes a pseudo soil layer under the lowest layer analysed and an amount of active substance associated with it. The RMS has not considered or evaluated this approach and calculation, but considers that if on evaluation it is considered appropriate, it would additionally support the use of a field DT50 value.

If confirmed on full evaluation, the refinement of the DT50 value alone, irrespective of any further consideration of the Freundlich value, in line with the indicative conclusions of the field studies, would result in nearly all modelled scenarios being acceptable using FOCUS PEARL and FOCUS PELMO even using the 1/n value of 1.0 agreed in the PRAPeR expert meeting.

Overall rapporteur opinion

In conclusion the rapporteur considers that the current risk assessment identifies a single acceptable modelled groundwater scenario. This is based on modelling using a realistic worst case default value of 1/n coupled with a conservative median DT50 value derived from laboratory studies. It is the opinion of the rapporteur that further data will allow refinement of both these input values and that such refinements have a significant and substantial potential to allow a robust risk assessment to be conducted to confirm acceptable risk to groundwater beyond the currently demonstrated acceptable use in the Porto scenario.

References:

Lu. J et al, Journal of Environmental Quality Vol. 31 pp.1230 (2002)

Racke, K.D., An adsorption/ desorption study of picloram; (1989)

Kennedy S.H., Dissipation of picloram in soil following a single application of GF-224 to bare soil, Northern Europe – 2007; (2008)

Knowles, S., Calculation of field kinetics for picloram from two additional field dissipation studies using FOCUS kinetics methodology and Q10 value = 2.58; (2008)

B.9 ECOTOXICOLOGY

B.9.1 Effects on birds

Evaluation Table New Open point 5.7 (PRAPeR 68, 4-8th May 2009)**:**
RMS to clarify in the LoEP (report the short-term endpoints both for ae and salt and add the conversion factor in a footnote).

RMS response:
See also Addendum 2 for background to clarification regarding how the endpoints are expressed in terms of acid equivalent or potassium salt. The LoEP has now been updated to include endpoints in terms of both acid equivalent or salt - and a footnote has been added regarding the conversion factor.

B.9.2 Effects on aquatic organisms

Re: Evaluation Table - Message from Section 4 (fate and behaviour) to Section 5:
'PECsw have changed'.

- and answer from PRAPeR 68 (4-8th May 2009):
The risk assessment to aquatic organisms has to be revised based on the new PECsw for metabolites (however, no risk is expected since the TER-values are >10000 based on the old PECs).

RMS response:
FOCUS Step 1 and Step 2 PECsw values for the picloram active substance and the metabolites 3,6-dichloro analogue (also known as aminopyralid or XDE-750) and 5,6-dichloro analogue, have now changed in the Env. Fate and Behaviour Section (see Section B.8 above and revised LoEP).

The original risk assessment for aquatic organisms can be neatly summarised in Tables B.9.29 (acute a.s.), B.9.32 (acute XDE-750), B.9.33 (chronic a.s.) and B.9.34 (chronic XDE-750), a scientifically reasoned QSAR case is also provided for the 5,6-dichloro analogue metabolite.

Rather than re-write the whole aquatic risk assessment, it is proposed to simply update these TER tables in this Addendum 4 (as well as the LoEP). See below:

B.9.2.1 Risk to aquatic organisms (originally B.9.2.4 in DAR)

Active substance and main metabolites

The original aquatic risk assessment is updated below to take account of recent changes to the PECsw values. This reassessment uses the same acute effects endpoints as originally proposed and simply amends the relevant TER tables as follows:

Table B.9.29 (revised): Acute TERs for picloram based on the FOCUS Step 1 PEC

Test organisms (most sensitive species where more than one tested)	**Scenario**	**Picloram**			**Annex VI trigger**
		LC/EC50 (mg a.e./L)	**PEC at 1 m (mg a.s./L)**	**TER for a.s. at 1 m**	
Oncorhynchus mykiss	Spring/winter oilseed rape	8.8	0.0077	1143	100
Daphnia magna	Spring/winter oilseed rape	44.2	0.0077	5740	100
Anabaena flos-aque	Spring/winter oilseed rape	38.2	0.0077	4961	10
Lemna gibba	Spring/winter oilseed rape	102	0.0077	13247	10

Table B.9.32 (revised): Acute TERs for the metabolite XDE-750 (= aminopyralid or 3,6-dichloro analogue) based on the FOCUS Step 1 PEC

Test organisms (most sensitive species where more than one tested)	**XDE-750**			**Annex VI trigger**
	LC/EC50 (mg XDE 750./l)	**FOCUS Step 1 PEC at 1 m (mg XDE 750/l)**	**TER at 1 m**	
Oncorhynchus mykiss	>100	0.000185	>540541	100
Daphnia magna	>100	0.000185	>540541	100
Navicula pelliculosa	18	0.000185	97297	10
Lemna gibba	>88	0.000185	>475676	10

Table B.9.33 (revised): Long-term TERs for picloram based on FOCUS Step 1 initial maximum PEC in surface water

Test organism	**NOEC (mg a.e./l)**	**$PEC_{max\ ini}$ (mg a.s./l)**	**TER for a.s. at 1 m**	**Annex VI trigger**
Oncorhynchus mykiss	0.55[1]	0.0077	71.4	10
Daphnia magna	6.791	0.0077	882	10
Chironomus riparius	100[2] (spiked water phase)	0.0077	12987	10

[1] Based on mean measured concentrations
[2] Based on nominal concentrations

Table B.9.34 (revised): Long-term TERs for the picloram metabolites XDE-750 (= aminopyralid or 3,6 dichloro analogue) and 5,6-dichloro analogue based on FOCUS Step1 initial maximum PECs in water and sediment

Test organism	NOEC (mg/l)	$PEC_{max\ ini}$ (mg/l or /kg)	TER at 1 m	Annex VI trigger
metabolite XDE-750				
Pimephales promelas	1.3	0.000185	7027	10
Daphnia magna	100	0.000185	540541	10
Chironomus riparius	130 mg/l (water phase)	0.000185	702703	10
	46.7 mg/kg (sediment)	0.0000075 mg/kg	6226667	10
5,6-dichloro metabolite				
Chironomus riparius	50 mg/l (water phase)	0.000185	270270	10

The PECsw values and acute spray-drift risk assessment for the formulated product (originally provided in Table B.9.30) are not considered to be affected by the changes in Env.Fate endpoints and so this has not been amended.

The TERs presented in the tables above are based on revised maximum FOCUS Step 1 PECsw and PECsed values. Each of the revised TERs are still greater than the respective Annex VI triggers and so indicate a low acute and chronic risk from picloram or it main metabolites in the water phase. The scientifically-reasoned (QSAR-based) case originally presented in the DAR for the 5,6-dichloro analogue metabolite still applies and this metabolite is still considered to pose a low risk to all aquatic life.

A revised maximum FOCUS Step 2 PECsw value for picloram has also been provided and this is 3.8278 µg/L (0.00383 mg a.s./L) from the Northern Europe winter OSR use. The revised maximum FOCUS Step 2 PECsw values for XDE-750 (3,6-dichloro analogue or aminopyralid) and the 5,6-dichloro analogue metabolite are virtually identical to Step 1 - both being 0.1852 µg/L or 0.000185 mg/L (PECsw) and 0.0075 µg/kg or 0.0000075 mg/kg (PECsed). Each of these higher-tier FOCUS PECsw values are the same or lower than the Step 1 values and the RMS therefore considers that the Step 1 assessment presented is sufficient to demonstrate a low risk to aquatic life from the proposed uses of picloram**.** Revised global maxima Step 3 PECsw values have not been produced but Section B.8 considers that these will be lower again than the Step 2 values for picloram and its metabolites - and so no further assessment is required.

B.9.3 Effects on other terrestrial vertebrates

Re: Evaluation Table Open point 5.3: (PRAPeR 68, 4-8th May 2009)
RMS to crosscheck the endpoints with the mammalian toxicology section and update LoEP if necessary.

- and answer from Section 2 (mammalian toxicology):
The mammalian toxicology meeting has decided that the relevant developmental endpoint for picloram is 300 mg/kg bw/d, however this is based on another study with the TIPA salt. From the rabbit developmental study with the K-salt they set the endpoint at ≥400 mg/kg bw/d (this was mistakenly reported as 200 in the original DAR).

RMS response:
The mammalian long-term risk assessment (originally DAR Section B.9.3.2) was based on a reproductive NOEL toxicity endpoint of 1000 mg a.e./kg bw from a 2-generation rat feeding study (Breslin et al., 1991) and no effects being observed on fertility, neonatal development or offspring at any dose level (up to 1000 mg a.s./kg bw/day).

Discussions have taken place at PRAPeR 68 and 69 (and since within the RMS) which confirm that this rat reproductive endpoint remains at 1000 mg a.s./kg bw - **however** there has been further discussion over the rabbit developmental endpoint.

As mentioned above, the mammalian toxicology PRAPeR meeting has decided that the lowest developmental NOEL is 300 mg picloram/kg bw/day based on results from two rabbit studies. This resulted from concerns over adverse structural foetal abnormalities (malformations) at the developmental LOELs of 400 mg picloram/kg bw/d in the potassium salt study (B.6.6.3a in DAR) and 558 mg picloram/kg bw/d in the TIPA salt study (B.6.6.3b).

These foetal effects were at low levels and were not statistically significant. Their relevance for setting endpoints for human health assessment was debatable, however a precautionary stance was taken. It is still unclear to the RMS that these effects would translate into survival- or population-relevant effects in wild mammals and we maintain that the original rat multigeneration endpoint is probably more ecotoxicologically relevant (as is standard practice). However, it was the decision of PRAPeR 68 that the rabbit developmental NOEL should be used and therefore the mammalian long-term endpoint is changed to 300 mg picloram/kg bw/day. This should however, be viewed as a conservative value.
A revised mammalian risk assessment is presented below using the original TER table in the DAR. Amendments have also been made to the LoEP.

B.9.3.1 Revised long-term mammalian risk assessment (originally B.9.3.2 in DAR)

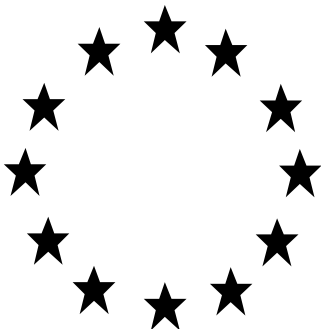
The exposure assumptions and calculated ETE values for wild mammals remain as in Table B.9.35 of the original DAR. The TER Table B.9.36 from the DAR has been revised below to include the new conservative NOEL endpoint of 300 mg a.s./kg bw/day (a.s. = acid equivalent (ae) in the MamTox endpoints). The acute endpoint is unchanged but it is retained here for completeness:

Table B.9.36 (revised): Acute and long-term toxicity:exposure ratios for herbivorous mammals from the consumption of picloram (based on standard SANCO 4145 first tier assumptions)

Time scale	**Indicator species**	**Toxicity end point (mg picloram/kg bw)**	**ETE**	**TER**	**Annex VI trigger**
Acute	Medium herbivorous mammal	Rat (F) acute oral LD_{50}: 4012	0.57	7039	10
Long-term reproductive	Medium herbivorous mammal	Rabbit developmental NOEL: 300	0.14	2143	5

The revised long-term TER value, which is based on a conservative NOEL, passes the respective Annex VI trigger of 5 and so indicates a low long-term risk to wild mammals from the proposed uses of picloram. Similarly the drinking-water TERlt based on the original exposure assumptions in the DAR would be revised to 89.3, this also indicates a low risk from this route of exposure.

Council Directive 91/414/EEC



Picloram

Volume 4

Addendum 5

Annex C

to the Report and Proposed Decision of the United Kingdom made to the European Commission under Article 8(2) of 91/414/EEC

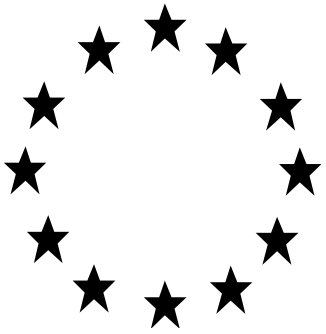
Confidential Information

June 2009

Volume 4 has been revised in response to the comments received on the DAR for picloram. Changes to the version prepared in April 2007 are highlighted in yellow. Changes to the version prepared in April 2009 are highlighted in green.

CONFIDENTIAL INFORMATION AVAILABLE AT RMS

Council Directive 91/414/EEC



Picloram

Draft Assessment Report

Addendum 6

to the Report and Proposed Decision of the United Kingdom made to the European Commission under Article 8(2) of 91/414/EEC

July 2009

(Residues)

CONTENTS

B.7 Residues

B.7.10 Residues in succeeding or rotational crops (IIA 6.6, IIIA 8.5)

A metabolism study for rotational crops conducted at an exaggerated dose rate relative to the notified uses was evaluated in the original DAR dated April 2007 (Section B.7.1.3) and then revised in Addendum 2 to the DAR dated April 2009 to correct the dose factor (25N). Using this factor of 25 residues above LOQ would be expected in rotational crops.

The PRAPeR 70 residues meeting of experts discussed if additional rotational field studies should be requested or if default MRLs could be derived from the submitted rotational crop metabolism study. The majority of the experts were of the opinion that using the available study, a way forward for the moment would be to conduct a risk assessment and to propose MRLs for certain rotational crops. Nevertheless, the meeting agreed that rotational field crop studies should be submitted for national authorisations to either confirm the proposed MRLs or to modify the proposed MRLs if necessary. On the basis of the TRR observed in the ether partition fraction [worst case assumption for the residues of picloram free and conjugated] in the rotational crop study [table B.7.7, Addendum 2], the following provisional MRLs were proposed:

0.07 mg/kg for fruiting vegetables, brassica vegetables, leafy vegetables, stem vegetables, herbal infusion and spices.
0.02 mg/kg for legume vegetables, pulses, cereal grains
0.01* mg/kg for root vegetables and oilseeds.

These values have been used to revise the risk assessments as necessary.

B.7.16 Estimates of potential and actual dietary exposure through diet and other means (IIA 6.9, IIIA 8.8)

B.7.16.1 Intakes by domestic animals

An assessment of the theoretical maximum daily intakes by domestic animals from the consumption of oilseed rape and following crops which may contain residues of picloram has been made. The following assumptions have been made:

(i) the highest likely inclusion rate of all crops which may have been treated has been used with the proviso that the aggregate does not exceed 100% diet.

(ii) all crops which may have been treated, have been treated and contains residues at the following levels:

Crop	Residue	Justification
Oilseed rape seed	0.01 mg/kg	Primary crop
Cereal grain	0.02 mg/kg	Rotational crop MRL proposal – cereal grains
Cereal straw	0.13 mg/kg	Estimated from TRR in rotational crop study – same approach as used in PRAPeR meeting
Legumes/Pulses	0.02 mg/kg	Rotational crop MRL proposal - pulses
Root crops root	0.01 mg/kg	Rotational crop MRL proposal – root veg.
Root crops tops	0.07 g/kg	Rotational crop MRL proposal – leafy veg.
Kale	0.07 mg/kg	Rotational crop MRL proposal – leafy veg.

(iii) there is no loss of residue during transport, storage, processing or preparation of feed prior to consumption.

Table B.7.1 Theoretical maximum daily intakes of picloram by domestic animals

	mg/kg diet (DM)	mg/kg diet (AR)	mg/ animal/ day	mg/kg bw/day
Dairy	0.2157	0.0663	4.3183	0.00784
Beef	0.2541	0.0780	3.8136	0.01094
Sheep	0.2943	0.0794	0.8830	0.01176
Goat	0.2157	0.0662	0.6471	0.00928
Pig	0.1983	0.0595	0.5950	0.00794
Chicken	0.0470	0.0322	0.0056	0.00302
Turkey	0.0233	0.0200	0.0047	0.00066

Based on the intakes calculated in Table B.7.1 above, residues in poultry products are not expected to be significant (intakes below the relevant "trigger value" of 0.1 gm/kg diet).

Based on the animal intake calculations above the "N rates" described in the metabolism studies in Section B.7.2.2 of the DAR dated April 2007 are incorrect and need clarification. The dose rate as described in the study report for the ruminant metabolism study was given as 1g/animal/day or 1200 mg/kg in the diet (food consumption given as 0.823 kg/day). This would be equivalent to >4000 N based on the intake calculations above. Therefore residues of picloram in products of animal origin are unlikely to be significant.

B.7.16.2 Intakes by humans

B.7.16.2.1 Long term intakes – WHO European Cluster diets

The TMDIs for picloram from the consumption of a number of crops have been calculated using the WHO European diet. The commodities considered cover both the use on primary crop (oilseeds) as well as potential residues arising in following crops. The following assumptions have been made:

(i) All produce eaten which may have been treated, has been treated and contains residues at the Highest level (HR) found in the trials considered to support GAP, or at the proposed MRL proposed as detailed below:

Crop	Residue	Justification
Oilseed rape seed	0.01 mg/kg	STMR - Primary crop
Root and tuber vegetables	-	Residues in rotational crops not expected above the LOQ
Bulb vegetables	-	Residues in rotational crops not expected above the LOQ
Fruiting vegetables	0.07 mg/kg	Rotational crop MRL proposal
Brassica vegetables	0.07 mg/kg	Rotational crop MRL proposal
Leaf vegetables/ fresh herbs	0.07 mg/kg	Rotational crop MRL proposal
Legume vegetables	0.02 mg/kg	Rotational crop MRL proposal
Stem vegetables	0.07 mg/kg	Rotational crop MRL proposal
Pulses	0.02 mg/kg	Rotational crop MRL proposal
Cereals	0.02 mg/kg	Rotational crop MRL proposal
Products of animal origin	-	Residues not expected

(ii) There is no loss of residue during transport, processing or storage of foods prior to consumption.

(iii) A body weight of 76 kg was used.

Full definitions of the commodities used can be found on the WHO GEMS website: http://www.who.int/entity/foodsafety/chem/ClusterDietsAug06.xls

The results of the chronic dietary intake estimates together with consumption data for individual commodities are presented in Table B.7.2.

Table B.7.2 Intakes of picloram from treated foodstuffs, using relevant WHO European "cluster" Diets.

Commodity	consumption (kg/person/day)				residue (mg/kg)	Cluster B		Cluster D		Cluster E		Cluster F	
	B	D	E	F		TMDI (mg/kg bw/day)	% ADI	TMDI (mg/kg bw/day)	% ADI	TMDI (mg/kg bw/day)	% ADI	TMDI (mg/kg bw/day)	% ADI
Cereals (total)	0.7139	0.5045	0.3652	0.3287	0.02	0.00018787	0.06	0.00013276	0.04	0.00009611	0.03	0.00008650	0.03
Pulses (total)	0.0629	0.0368	0.0494	0.0479	0.02	0.00001655	0.06	0.00000968	<0.01	0.00001300	<0.01	0.00001261	<0.01
Oilseed (except groundnuts)	0.0621	0.0513	0.0581	0.0380	0.01	0.00000817	0.03	0.00000675	<0.01	0.00000764	<0.01	0.00000500	<0.01
Asparagus	0.0011	0.0002	0.0012	0.0001	0.07	0.00000101	<0.01	0.00000018	<0.01	0.00000111	<0.01	0.00000009	<0.01
Cucumbers	0.0127	0.0115	0.0061	0.0071	0.07	0.00001170	<0.01	0.00001059	<0.01	0.00000562	<0.01	0.00000654	<0.01
Gherkin	0.0127	0.0115	0.0061	0.0071	0.07	0.00001170	<0.01	0.00001059	<0.01	0.00000562	<0.01	0.00000654	<0.01
Squash pumpkins gourds	0.0123	0.0219	0.0032	0.0010	0.07	0.00001133	<0.01	0.00002017	0.01	0.00000295	<0.01	0.00000092	<0.01
Egg plant	0.0175	0.0017	0.0008	0.0004	0.07	0.00001612	<0.01	0.00000157	<0.01	0.00000074	<0.01	0.00000037	<0.01
Mushrooms	0.0015	0.0002	0.0053	0.0014	0.07	0.00000138	<0.01	0.00000018	<0.01	0.00000488	<0.01	0.00000129	<0.01
Okra	0.0010	0.0001	0.0000	0.0000	0.07	0.00000092	<0.01	0.00000009	<0.01	0	0	0	0
Peppers	0.0299	0.0063	0.0062	0.0040	0.07	0.00002754	<0.01	0.00000580	<0.01	0.00000571	<0.01	0.00000368	<0.01
Tomato	0.1850	0.0607	0.0316	0.0409	0.07	0.00017039	0.06	0.00005591	0.0186	0.00002911	0.01	0.00003767	0.01
Spinach	0.0050	0.0001	0.0026	0.0001	0.07	0.00000461	<0.01	0.00000009	<0.01	0.00000239	<0.01	0.00000009	<0.01
Turnip greens	0	0.0001	0	0.0001	0.07	0	0	0.00000009	<0.01	0	0	0.00000009	0.0000
Lettuce, head	0.0238	0.0006	0.0119	0.0180	0.07	0.00002192	<0.01	0.00000055	<0.01	0.00001096	<0.01	0.00001658	0.01
Celery	0.0009	0.0020	0.0015	0.0000	0.07	0.00000083	<0.01	0.00000184	<0.01	0.00000138	<0.01	0	0
Rhubarb	0	0.0020	0.0002	0	0.07	0	0	0.00000184	<0.01	0.00000018	<0.01	0	0
Watercress	0	0.0020	0.0001	0	0.07	0	0	0.00000184	<0.01	0.00000009	<0.01	0	0
Brussels sprouts	0.0001	0.0055	0.0015	0.0019	0.07	0.00000009	<0.01	0.00000507	<0.01	0.00000138	<0.01	0.00000175	<0.01
Cabbage, savoy	0.0117	0.0055	0.0032	0.0150	0.07	0.00001078	<0.01	0.00000507	<0.01	0.00000295	<0.01	0.00001382	<0.01
Chinese cabbage (pak-choi)	0.0026	0.0055	0.0001	0.0019	0.07	0.00000239	<0.01	0.00000507	<0.01	0.00000009	<0.01	0.00000175	<0.01
Chinese cabbage (pe-tsai)	0.0026	0.0055	0	0.0019	0.07	0.00000239	<0.01	0.00000507	<0.01	0	0	0.00000175	<0.01
Kale	0	0.0055	0.0006	0.0019	0.07	0.00000000	0	0.00000507	<0.01	0.00000055	<0.01	0.00000175	<0.01
Kohlrabi	0.0001	0.0055	0.0123	0.0019	0.07	0.00000009	<0.01	0.00000507	<0.01	0.00001133	<0.01	0.00000175	<0.01
Mustard greens	0.0003	0.0055	0.0000	0.0019	0.07	0.00000028	<0.01	0.00000507	<0.01	0.00000000	<0.01	0.00000175	<0.01

Commodity	consumption (kg/person/day)				residue (mg/kg)	Cluster B		Cluster D		Cluster E		Cluster F	
	B	D	E	F		TMDI (mg/kg bw/day)	% ADI	TMDI (mg/kg bw/day)	% ADI	TMDI (mg/kg bw/day)	% ADI	TMDI (mg/kg bw/day)	% ADI
Cauliflower	0.0052	0.0001	0.0017	0.0001	0.07	0.00000479	<0.01	0.00000009	<0.01	0.00000157	<0.01	0.00000009	<0.01
Broccoli	0.0007	0.0001	0.0042	0.0040	0.07	0.00000064	<0.01	0.00000009	<0.01	0.00000387	<0.01	0.00000368	<0.01
Legume vegetables	0.0230	0.0128	0.0269	0.0053	0.02	0.00000605	<0.01	0.00000337	<0.01	0.00000708	<0.01	0.00000139	<0.01
TOTAL						**0.0005196**	**0.17**	**0.0002996**	**0.10**	**0.0002163**	**0.07**	**0.0002075**	**0.07**

Based on chronic exposure estimates for long term dietary exposure, TMDIs for the cluster diets are all below the ADI of 0.3 mg/kg bw/day.

B.7.16.2.2 Long term intakes - National Estimate of Dietary Intake (NEDI)

The long term dietary intakes (NEDIs) for residues of picloram from the consumption of a number of crops individually have been calculated for adults, young people, toddlers, infants, vegetarians and elderly adults. The commodities considered cover both the use on primary crop (oilseeds) as well as potential residues arising in following crops. In addition total dietary intakes (total NEDIs for all crops combined) were calculated for each consumer group using the following formula:

Total NEDI = $\sum$ (Two highest 97.5th % ile intakes + Mean population intakes from other foods)

The following assumptions have been made:

(i) all produce eaten which may have been treated, has been treated and contains residues at the median level (STMR) found in the trials considered to support GAP, or at the proposed MRL as detailed below.

Crop	**Residue**	**Justification**
Oilseed rape seed	0.01 mg/kg	STMR - Primary crop
Root and tuber vegetables	-	Residues in rotational crops not expected above the LOQ
Bulb vegetables	-	Residues in rotational crops not expected above the LOQ
Fruiting vegetables	0.07 mg/kg	Rotational crop MRL proposal
Brassica vegetables	0.07 mg/kg	Rotational crop MRL proposal
Leaf vegetables/ fresh herbs	0.07 mg/kg	Rotational crop MRL proposal
Legume vegetables	0.02 mg/kg	Rotational crop MRL proposal
Stem vegetables	0.07 mg/kg	Rotational crop MRL proposal
Pulses	0.02 mg/kg	Rotational crop MRL proposal
Cereals	0.02 mg/kg	Rotational crop MRL proposal
Products of animal origin	-	Residues not expected

(ii) There is no loss of residue during transport, processing or storage of foods prior to consumption.

The results of the chronic total dietary intake estimates (total NEDIs) are presented in Table B.7.3, together with NEDIs for individual commodities. The mean and 97.5th percentile consumption data are presented in Table B.7.4.

Based on chronic exposure estimates for long term dietary exposure, intakes are all below the ADI of 0.3 mg/kg bw/day. Although the total NEDIs vary according to different consumer groups, all the total intakes are < 1% of the ADI for all consumer groups considered.

B.7.16.2.3 Short term intakes - National Estimate of Short Term Intake (NESTI)

The UK NESTIs for residues of picloram from the consumption of a number of crops have been calculated for adults, young people, toddlers, infants, vegetarians and elderly adults. The commodities considered cover both the use on primary crop (oilseeds) as well as potential residues arising in following crops. The following assumptions have been made:

(i) upper range of normal (97.5th percentile) consumption of each individual crop which may have been treated.

(ii) all produce eaten which may have been treated, has been treated and contains residues at the highest residue level (HR) found in the trials considered to support GAP, or at the proposed MRL as detailed below,:

Crop	**Residue**	**Justification**
Oilseed rape seed	0.01 mg/kg	HR - Primary crop
Root and tuber vegetables	-	Residues in rotational crops not expected above the LOQ
Bulb vegetables	-	Residues in rotational crops not expected above the LOQ
Fruiting vegetables	0.07 mg/kg	Rotational crop MRL proposal
Brassica vegetables	0.07 mg/kg	Rotational crop MRL proposal
Leaf vegetables/ fresh herbs	0.07 mg/kg	Rotational crop MRL proposal
Legume vegetables	0.02 mg/kg	Rotational crop MRL proposal
Stem vegetables	0.07 mg/kg	Rotational crop MRL proposal
Pulses	0.02 mg/kg	Rotational crop MRL proposal
Cereals	0.02 mg/kg	Rotational crop MRL proposal
Products of animal origin	-	Residues not expected

(iii) There is no loss of residue during transport, processing or storage of foods prior to consumption.

The relevant consumption data and acute intake estimates are presented in Table B.7.5. Based on acute exposure estimates for short term dietary exposure, intakes are all below the ARfD of 0.3 mg/kg bw/day. The individual NESTIs vary according to different commodities/consumer groups, although the values range from <0.1% (several consumer groups for several crops) to 1.4% (infants, NESTI of 0.0041 mg/kg bw/day for cauliflower) of the ARfD.

Table B.7.3 UK Intakes (NEDIs) in mg/kg bw/day of residues of picloram from treated foodstuffs [proposed ADI is 0.3 mg/kg bw/day]

			ADULT	INFANT	TODDLER	4-6 YEARS	7-10 YEARS	11-14 YEARS	15-18 YEARS	VEGETARIAN	ELDERLY (OWN HOME)	ELDERLY (RESIDENTIAL)
			0.00037	**0.00062**	**0.00074**	**0.00059**	**0.00048**	**0.00035**	**0.00040**	**0.00045**	**0.00040**	**0.00022**
			<1%	**<1%**	**<1%**	**<1%**	**<1%**	**<1%**	**<1%**	**<1%**	**<1%**	**<1%**
	STMR											
Commodity	**(mg/kg)**	**P**										
Tomatoes	0.07		0.00010	0.00013	0.00018	0.00013	0.00013	0.00008	0.00009	0.00012	0.00010	0.00009
Peppers	0.07		0.00003	L/C	0.00006	0.00003	0.00005	0.00002	0.00002	0.00004	0.00004	0.00001
Aubergines	0.07		0.00002	L/C	0.00011	0.00005	0.00002	0.00004	0.00003	0.00004	0.00003	L/C
Marrows	0.07		0.00004	L/C	0.00011	0.00003	0.00004	0.00004	0.00002	0.00004	0.00010	0.00005
Cucumbers	0.07		0.00003	0.00002	0.00017	0.00011	0.00007	0.00004	0.00003	0.00004	0.00003	0.00001
Gourd	0.07		0.00004	L/C	L/C	L/C	L/C	0.00002	L/C	0.00001	L/C	L/C
Courgettes	0.07		0.00003	0.00010	0.00017	0.00009	0.00005	0.00003	0.00003	0.00004	0.00004	0.00003
Sweet corn	0.07		0.00004	0.00007	0.00016	0.00008	0.00008	0.00003	0.00004	0.00004	0.00006	0.00002
Broccoli	0.07		0.00005	0.00008	0.00012	0.00009	0.00007	0.00005	0.00004	0.00005	0.00007	0.00002
Cauliflower	0.07		0.00006	0.00022	0.00015	0.00012	0.00006	0.00005	0.00006	0.00009	0.00008	0.00005
Brussels sprouts	0.07		0.00004	0.00016	0.00013	0.00010	0.00005	0.00006	0.00004	0.00006	0.00007	0.00003
Head cabbage	0.07		0.00004	0.00012	0.00012	0.00009	0.00005	0.00005	0.00004	0.00005	0.00008	0.00005
Chinese cabbage	0.07		0.00003	L/C	L/C	L/C	L/C	L/C	L/C	0.00004	0.00002	L/C
Cress	0.07		0.00000	L/C	0.00000	0.00000	0.00000	0.00000	0.00000	0.00001	0.00001	0.00000
Lettuce	0.07		0.00004	0.00002	0.00006	0.00005	0.00005	0.00003	0.00003	0.00005	0.00004	0.00002
Spinach	0.07		0.00004	0.00007	0.00011	0.00006	0.00006	0.00004	0.00002	0.00005	0.00004	0.00002
Watercress	0.07		0.00001	L/C	L/C	0.00000	0.00000	0.00001	L/C	0.00002	0.00002	L/C
Parsley	0.07		0.00001	L/C	0.00001	L/C	0.00001	0.00000	0.00000	0.00001	0.00001	0.00003
Beans with pods	0.02		0.00001	0.00002	0.00004	0.00003	0.00001	0.00001	0.00001	0.00001	0.00001	0.00001

Table B.7.3 cont'd UK Intakes (NEDIs) in mg/kg bw/day of residues of picloram from treated foodstuffs [proposed ADI is 0.3 mg/kg bw/day]

			ADULT	INFANT	TODDLER	4-6 YEARS	7-10 YEARS	11-14 YEARS	15-18 YEARS	VEGETARIAN	ELDERLY (OWN HOME)	ELDERLY (RESIDENTIAL)
	STMR											
Commodity	**(mg/kg)**	**P**										
Runner Beans	0.02		0.00001	L/C	0.00003	0.00001	0.00001	0.00001	0.00001	0.00003	0.00002	0.00001
Beans without pods	0.02		0.00001	0.00001	0.00005	0.00001	0.00002	0.00001	0.00001	0.00001	0.00002	0.00001
Peas with pods	0.02		0.00001	L/C	0.00001	0.00003	0.00000	0.00001	0.00000	0.00001	0.00001	L/C
Peas without pods	0.02		0.00002	0.00005	0.00004	0.00003	0.00002	0.00001	0.00002	0.00002	0.00002	0.00001
Asparagus	0.07		0.00003	L/C	L/C	L/C	L/C	L/C	0.00002	0.00006	0.00003	L/C
Celery	0.07		0.00002	0.00003	0.00003	0.00002	0.00001	0.00002	0.00001	0.00003	0.00003	0.00001
Fennel	0.07		0.00003	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C
Leeks	0.07		0.00003	L/C	0.00004	0.00003	0.00002	0.00002	0.00002	0.00003	0.00004	0.00003
Rhubarb	0.07		0.00003	0.00005	0.00008	0.00002	0.00004	0.00001	0.00001	0.00002	0.00005	0.00003
Beans	0.02		0.00003	0.00012	0.00009	0.00007	0.00006	0.00004	0.00004	0.00004	0.00003	0.00002
Lentils	0.02		0.00001	0.00003	0.00004	0.00004	0.00001	0.00002	0.00001	0.00001	0.00001	0.00000
dried Peas	0.02		0.00001	L/C	0.00003	0.00001	0.00001	0.00002	0.00001	0.00001	0.00002	0.00001
Oilseeds	0.01		0.00003	0.00006	0.00007	0.00007	0.00006	0.00004	0.00004	0.00005	0.00003	0.00004
Oats	0.02		0.00001	0.00004	0.00002	0.00002	0.00001	0.00001	0.00001	0.00001	0.00001	0.00001
Barley	0.02		0.00000	L/C	0.00001	0.00001	0.00002	0.00000	0.00000	0.00001	0.00001	0.00000
Maize	0.02		0.00000	0.00009	0.00001	0.00001	0.00000	0.00000	0.00000	0.00001	0.00000	0.00000
Wheat	0.02		0.00007	0.00006	0.00017	0.00018	0.00013	0.00010	0.00008	0.00009	0.00007	0.00007
Rye	0.02		0.00001	0.00003	0.00001	0.00001	0.00001	0.00001	0.00000	0.00001	0.00001	0.00000

* 0.00000 corresponds to <0.000005 mg/kg bw/day (any value ≥0.000005 is rounded to 0.00001
L/C Low consumption (<0.1 g/day) or low number of consumers (<4)

Table B.7.4 Consumption in kg/day of relevant foods.

Mean values are population means, and 97.5th %le are calculated on the basis of those consuming only.

Commodity	ADULT		INFANT		TODDLER		4-6 YEARS		7-10 YEARS		11-14 YEARS		15-18 YEARS		VEGETARIAN		ELDERLY (own home)		ELDERLY (residential)	
	mean	97.5%	mean	97.5%	mean	97.5%	mean	97.5%	mean	97.5%	mean	97.5%	mean	97.5%	mean	97.5%	mean	97.5%	mean	97.5%
Tomatoes	0.033	0.105	0.003	0.016	0.009	0.038	0.013	0.039	0.015	0.057	0.017	0.052	0.026	0.085	0.042	0.118	0.025	0.103	0.016	0.083
Peppers	0.003	0.028	L/C	L/C	0.000	0.012	0.001	0.008	0.001	0.021	0.001	0.015	0.002	0.018	0.005	0.040	0.001	0.040	L/C	0.012
Aubergines	0.000	0.024	L/C	L/C	0.000	0.022	0.000	0.016	0.000	0.008	0.000	0.025	0.000	0.025	0.002	0.041	0.000	0.029	L/C	L/C
Marrows	0.001	0.038	L/C	L/C	0.001	0.023	0.000	0.008	0.001	0.019	0.001	0.031	0.001	0.016	0.001	0.035	0.001	0.097	0.001	0.040
Cucumbers	0.005	0.031	L/C	0.002	0.002	0.035	0.003	0.032	0.003	0.032	0.003	0.025	0.004	0.029	0.007	0.036	0.003	0.034	0.001	0.011
Gourd	0.000	0.041	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	0.000	0.013	L/C	L/C	0.000	0.014	L/C	L/C	L/C	L/C
Courgettes	0.001	0.032	0.000	0.013	0.000	0.034	0.000	0.026	0.000	0.024	0.000	0.020	0.000	0.024	0.003	0.037	0.001	0.037	0.000	0.028
Sweet corn	0.002	0.039	0.000	0.009	0.001	0.033	0.002	0.022	0.002	0.037	0.002	0.024	0.002	0.039	0.004	0.038	0.001	0.059	0.001	0.021
Broccoli	0.006	0.049	0.000	0.010	0.001	0.025	0.002	0.025	0.003	0.032	0.002	0.035	0.003	0.040	0.006	0.046	0.004	0.068	0.002	0.021
Cauliflower	0.005	0.066	0.002	0.027	0.002	0.032	0.002	0.034	0.002	0.026	0.002	0.036	0.004	0.055	0.008	0.081	0.007	0.080	0.008	0.041
Brussels sprouts	0.002	0.046	0.002	0.020	0.001	0.026	0.001	0.030	0.001	0.023	0.001	0.044	0.001	0.040	0.001	0.053	0.005	0.068	0.004	0.029
Head cabbage	0.006	0.041	0.001	0.015	0.001	0.025	0.003	0.026	0.002	0.023	0.003	0.034	0.004	0.034	0.007	0.051	0.009	0.082	0.009	0.045
Chinese cabbage	0.000	0.038	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	0.000	0.033	0.000	0.025	L/C	L/C
Cress	0.000	0.003	L/C	L/C	L/C	0.001	L/C	0.001	L/C	0.001	L/C	0.002	L/C	0.002	0.000	0.005	L/C	0.007	0.000	0.003
Lettuce	0.009	0.047	L/C	0.003	0.000	0.012	0.001	0.014	0.002	0.022	0.003	0.019	0.004	0.028	0.009	0.047	0.005	0.038	0.002	0.017
Spinach	0.001	0.040	0.000	0.009	0.000	0.023	0.001	0.018	0.001	0.027	0.001	0.030	0.001	0.022	0.002	0.046	0.001	0.040	0.000	0.022
Watercress	0.000	0.012	L/C	L/C	L/C	L/C	L/C	0.001	L/C	0.002	0.000	0.009	L/C	L/C	0.001	0.015	0.000	0.021	L/C	L/C
Parsley	0.000	0.013	L/C	L/C	L/C	0.002	L/C	L/C	L/C	0.005	L/C	0.002	L/C	0.001	0.000	0.011	L/C	0.013	0.000	0.023
Beans with pods	0.001	0.040	0.000	0.011	0.000	0.028	0.000	0.027	0.000	0.021	0.000	0.017	0.001	0.045	0.001	0.027	0.001	0.051	0.000	0.019
Runner Beans	0.002	0.047	L/C	L/C	0.000	0.022	0.001	0.010	0.001	0.023	0.001	0.028	0.002	0.032	0.003	0.101	0.004	0.069	0.004	0.035
Beans without pods	0.000	0.033	L/C	0.005	0.000	0.035	L/C	0.008	0.000	0.033	L/C	0.018	0.000	0.027	0.001	0.042	0.001	0.057	0.000	0.033
Peas with pods	0.001	0.022	L/C	L/C	L/C	0.007	0.000	0.026	0.000	0.007	0.000	0.014	0.000	0.011	0.001	0.017	0.000	0.036	L/C	L/C

Table B.7.4 cont'd Consumption in kg/day of relevant foods.

Mean values are population means, and 97.5th %le are calculated on the basis of those consuming only.

Commodity	ADULT		INFANT		TODDLER		4-6 YEARS		7-10 YEARS		11-14 YEARS		15-18 YEARS		VEGETARIAN		ELDERLY (own home)		ELDERLY (residential)	
	mean	97.5%	mean	97.5%	mean	97.5%	mean	97.5%	mean	97.5%	mean	97.5%	mean	97.5%	mean	97.5%	mean	97.5%	mean	97.5%
Peas without pods	0.010	0.059	0.005	0.021	0.004	0.030	0.005	0.029	0.006	0.032	0.007	0.035	0.008	0.059	0.009	0.058	0.011	0.071	0.011	0.045
Asparagus	0.000	0.031	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	0.000	0.014	0.001	0.053	0.000	0.031	L/C	L/C
Celery	0.001	0.025	0.000	0.004	0.001	0.006	0.001	0.006	0.001	0.005	0.001	0.012	0.001	0.012	0.002	0.031	0.002	0.034	0.001	0.007
Fennel	0.000	0.029	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C
Leeks	0.001	0.038	L/C	L/C	0.000	0.009	0.000	0.008	0.000	0.009	0.001	0.017	0.001	0.015	0.002	0.032	0.002	0.041	0.001	0.022
Rhubarb	0.000	0.030	0.000	0.006	0.000	0.016	0.000	0.005	0.000	0.016	0.000	0.007	0.000	0.010	0.001	0.023	0.001	0.048	0.002	0.025
Beans	0.017	0.119	0.004	0.051	0.011	0.068	0.016	0.069	0.017	0.088	0.020	0.100	0.024	0.136	0.024	0.117	0.009	0.100	0.006	0.060
Lentils	0.001	0.055	L/C	0.013	0.000	0.027	0.000	0.040	0.000	0.020	0.001	0.059	0.001	0.032	0.003	0.047	0.001	0.036	0.000	0.015
dried Peas	0.001	0.052	L/C	L/C	0.000	0.025	0.000	0.010	0.001	0.023	0.001	0.057	0.001	0.041	0.002	0.038	0.001	0.076	0.000	0.044
Oilseeds	0.092	0.242	0.012	0.055	0.041	0.105	0.064	0.147	0.080	0.173	0.089	0.194	0.099	0.225	0.117	0.312	0.008	0.227	0.090	0.238
Oats	0.001	0.027	0.002	0.019	0.001	0.018	0.001	0.016	0.001	0.014	0.001	0.017	0.001	0.041	0.003	0.043	0.003	0.037	0.004	0.035
Barley	0.002	0.019	L/C	L/C	0.000	0.005	0.000	0.007	0.000	0.025	0.000	0.009	0.001	0.015	0.001	0.017	0.001	0.018	0.000	0.009
Maize	0.000	0.005	0.009	0.040	0.000	0.011	0.000	0.010	0.000	0.006	0.000	0.008	0.000	0.011	0.001	0.022	0.000	0.010	0.000	0.005
Wheat	0.127	0.274	0.023	0.024	0.057	0.123	0.086	0.182	0.106	0.208	0.117	0.240	0.133	0.258	0.137	0.284	0.112	0.231	0.106	0.213
Rye	0.001	0.039	L/C	0.012	0.000	0.006	0.000	0.009	0.000	0.015	0.000	0.012	0.000	0.007	0.001	0.040	0.001	0.032	0.000	0.010

*<60 consumers in one or more groups. L/C Low consumption (<0.1 g/day) or low number of consumers (<4).

Please note that values specified as 0.000 in the table are in the range of 0.1g/day to 0.4g/day. Values between 0.4g/day and 0.14g/day will be rounded to 0.1g/day [0.001 in the table].

Table B.7.5 UK Intakes (NESTIs) in mg/kg bw/day of residues of picloram from treated foodstuffs [proposed ARfD is 0.3 mg/kg bw/day]

				Adult			Infant			Toddler			4-6 year old child		
commodity	**HR (mg/kg)**	**V**	**P**	**NESTI (mg/kg bw/day)**	**% ARfD**	**acute consumption (kg/day)**	**NESTI (mg/kg bw/day)**	**% ARfD**	**acute consumption (kg/day)**	**NESTI (mg/kg bw/day)**	**% ARfD**	**acute consumption (kg/day)**	**NESTI (mg/kg bw/day)**	**% ARfD**	**acute consumption (kg/day)**
Oilseeds	0.01	1		0.00006	0.02	0.455	0.00012	0.04	0.101	0.00013	0.04	0.196	0.00014	0.05	0.294
Tomatoes	0.07	7		0.00073	0.24	0.283	0.00338	1.13	0.060	0.00290	0.97	0.091	0.00218	0.73	0.127
Peppers	0.07	7		0.00092	0.31	0.143	0.00000	0.00	0.000	0.00114	0.38	0.034	0.00082	0.27	0.034
Aubergines	0.07	5		0.00068	0.23	0.149	0.00000	0.00	0.000	0.00150	0.50	0.062	0.00175	0.58	0.103
Marrows	0.07	5		0.00091	0.30	0.198	0.00000	0.00	0.000	0.00149	0.50	0.062	0.00076	0.25	0.045
Cucumbers	0.07	5		0.00050	0.17	0.108	0.00052	0.17	0.013	0.00207	0.69	0.086	0.00165	0.55	0.096
Gourd	0.07	5		0.00103	0.34	0.224	0.00000	0.00	0.000	0.00000	0.00	0.000	0.00089	0.30	0.052
Courgettes	0.07	7		0.00077	0.26	0.157	0.00222	0.74	0.039	0.00325	1.08	0.096	0.00280	0.93	0.136
Sweet corn	0.07	7		0.00126	0.42	0.195	0.00209	0.70	0.037	0.00304	1.01	0.090	0.00246	0.82	0.103
Broccoli	0.07	5		0.00090	0.30	0.196	0.00144	0.48	0.036	0.00147	0.49	0.061	0.00173	0.58	0.101
Cauliflower	0.07	5		0.00108	0.36	0.235	0.00406	1.35	0.101	0.00232	0.77	0.096	0.00243	0.81	0.143
Brussels sprouts	0.07	1		0.00018	0.06	0.190	0.00051	0.17	0.064	0.00033	0.11	0.067	0.00049	0.16	0.144
Head cabbage	0.07	5		0.00085	0.28	0.184	0.00301	1.00	0.075	0.00178	0.59	0.074	0.00225	0.75	0.132
Chinese cabbage	0.07	5		0.00108	0.36	0.235	0.00000	0.00	0.000	0.00075	0.25	0.031	0.00000	0.00	0.000
Cress	0.07	1		0.00001	0.00	0.013	0.00000	0.00	0.000	0.00002	0.01	0.004	0.00002	0.01	0.006
Lettuce	0.07	5		0.00069	0.23	0.150	0.00089	0.30	0.022	0.00084	0.28	0.035	0.00125	0.42	0.073
Spinach	0.07	1		0.00018	0.06	0.192	0.00037	0.12	0.046	0.00028	0.09	0.058	0.00040	0.13	0.116
Watercress	0.07	1		0.00004	0.01	0.040	0.00000	0.00	0.000	0.00002	0.01	0.004	0.00003	0.01	0.009
Parsley	0.07	1		0.00005	0.02	0.050	0.00000	0.00	0.000	0.00002	0.01	0.005	0.00002	0.01	0.006
Beans with pods	0.02	1		0.00005	0.02	0.175	0.00010	0.03	0.044	0.00010	0.03	0.073	0.00007	0.02	0.077
Runner Beans	0.02	1		0.00004	0.01	0.160	0.00000	0.00	0.000	0.00008	0.03	0.060	0.00007	0.02	0.071
Peas with pods	0.02	1		0.00003	0.01	0.123	0.00000	0.00	0.000	0.00004	0.01	0.033	0.00007	0.02	0.071
Peas without pods	0.02	1		0.00005	0.02	0.200	0.00016	0.05	0.071	0.00010	0.03	0.075	0.00011	0.04	0.117
Beans without pods	0.02	1		0.00004	0.01	0.147	0.00008	0.03	0.035	0.00014	0.05	0.101	0.00005	0.02	0.055

Table B.7.5 UK Intakes (NESTIs) in mg/kg bw/day of residues of picloram from treated foodstuffs [proposed ARfD is 0.3 mg/kg bw/day]

				Adult			Infant			Toddler			4-6 year old child		
commodity	**HR (mg/kg)**	**V**	**P**	**NESTI (mg/kg bw/day)**	**% ARfD**	**acute consumption (kg/day)**	**NESTI (mg/kg bw/day)**	**% ARfD**	**acute consumption (kg/day)**	**NESTI (mg/kg bw/day)**	**% ARfD**	**acute consumption (kg/day)**	**NESTI (mg/kg bw/day)**	**% ARfD**	**acute consumption (kg/day)**
Asparagus	0.07	1		0.00017	0.06	0.186	0.00000	0.00	0.000	0.00032	0.11	0.066	0.00011	0.04	0.033
Celery	0.07	5		0.00041	0.14	0.088	0.00047	0.16	0.012	0.00042	0.14	0.017	0.00037	0.12	0.022
Fennel	0.07	7		0.00100	0.33	0.156	0.00000	0.00	0.000	0.00000	0.00	0.000	0.00000	0.00	0.000
Leeks	0.07	7		0.00091	0.30	0.150	0.00000	0.00	0.000	0.00141	0.47	0.042	0.00111	0.37	0.046
Rhubarb	0.07	7		0.00055	0.18	0.138	0.00238	0.79	0.042	0.00260	0.87	0.083	0.00082	0.27	0.035
Beans	0.02	1		0.00011	0.04	0.420	0.00037	0.12	0.159	0.00025	0.08	0.180	0.00023	0.08	0.238
Lentils	0.02	1		0.00005	0.02	0.186	0.00012	0.04	0.054	0.00010	0.03	0.074	0.00012	0.04	0.123
dried Peas	0.02	1		0.00006	0.02	0.229	0.00000	0.00	0.000	0.00008	0.03	0.061	0.00006	0.02	0.066
Oats	0.02	1		0.00002	0.01	0.070	0.00006	0.02	0.028	0.00006	0.02	0.045	0.00004	0.01	0.038
Barley	0.02	1		0.00001	0.00	0.052	0.00000	0.00	0.000	0.00001	0.00	0.011	0.00004	0.01	0.036
Millet	0.02	1		0.00000	0.00	0.000	0.00000	0.00	0.000	0.00002	0.01	0.012	0.00000	0.00	0.000
Buckwheat	0.02	1		0.00000	0.00	0.000	0.00000	0.00	0.000	0.00000	0.00	0.000	0.00000	0.00	0.000
Maize	0.02	1		0.00001	0.00	0.034	0.00013	0.04	0.059	0.00008	0.03	0.055	0.00003	0.01	0.032
Wheat	0.02	1		0.00012	0.04	0.459	0.00026	0.09	0.112	0.00026	0.09	0.191	0.00029	0.10	0.296
Rye	0.02	1		0.00003	0.01	0.098	0.00013	0.04	0.055	0.00002	0.01	0.017	0.00004	0.01	0.041

Table B.7.5 cont'd UK Intakes (NESTIs) in mg/kg bw/day of residues of picloram from treated foodstuffs [proposed ARfD is 0.3 mg/kg bw/day]

				7-10 year old child			11-14 year old child			15-18 year old child			Vegetarian		
commodity	**HR (mg/kg)**	**V**	**P**	**NESTI (mg/kg bw/day)**	**% ARfD**	**acute consumption (kg/day)**	**NESTI (mg/kg bw/day)**	**% ARfD**	**acute consumption (kg/day)**	**NESTI (mg/kg bw/day)**	**% ARfD**	**acute consumption (kg/day)**	**NESTI (mg/kg bw/day)**	**% ARfD**	**acute consumption (kg/day)**
Oilseeds	0.01	1		0.00011	0.04	0.338	0.00008	0.03	0.391	0.00007	0.02	0.448	0.00010	0.03	0.641
Tomatoes	0.07	7		0.00155	0.52	0.174	0.00099	0.33	0.168	0.00084	0.28	0.251	0.00095	0.32	0.397
Peppers	0.07	7		0.00115	0.38	0.073	0.00074	0.25	0.072	0.00070	0.23	0.091	0.00114	0.38	0.156
Aubergines	0.07	5		0.00066	0.22	0.058	0.00087	0.29	0.119	0.00056	0.19	0.102	0.00124	0.41	0.236
Marrows	0.07	5		0.00100	0.33	0.088	0.00122	0.41	0.167	0.00054	0.18	0.098	0.00129	0.43	0.245
Cucumbers	0.07	5		0.00124	0.41	0.109	0.00068	0.23	0.093	0.00064	0.21	0.117	0.00061	0.20	0.115
Gourd	0.07	5		0.00000	0.00	0.000	0.00057	0.19	0.078	0.00031	0.10	0.057	0.00041	0.14	0.079
Courgettes	0.07	7		0.00181	0.60	0.115	0.00080	0.27	0.079	0.00068	0.23	0.088	0.00094	0.31	0.211
Sweet corn	0.07	7		0.00296	0.99	0.186	0.00129	0.43	0.126	0.00171	0.57	0.267	0.00153	0.51	0.208
Broccoli	0.07	5		0.00157	0.52	0.139	0.00109	0.36	0.150	0.00098	0.33	0.178	0.00117	0.39	0.223
Cauliflower	0.07	5		0.00137	0.46	0.121	0.00117	0.39	0.160	0.00107	0.36	0.195	0.00162	0.54	0.309
Brussels sprouts	0.07	1		0.00026	0.09	0.115	0.00020	0.07	0.140	0.00022	0.07	0.198	0.00027	0.09	0.259
Head cabbage	0.07	5		0.00123	0.41	0.109	0.00117	0.39	0.160	0.00084	0.28	0.153	0.00119	0.40	0.227
Chinese cabbage	0.07	5		0.00156	0.52	0.137	0.00014	0.05	0.020	0.00177	0.59	0.323	0.00062	0.21	0.118
Cress	0.07	1		0.00001	0.00	0.005	0.00001	0.00	0.007	0.00001	0.00	0.008	0.00003	0.01	0.025
Lettuce	0.07	5		0.00094	0.31	0.083	0.00058	0.19	0.080	0.00056	0.19	0.102	0.00077	0.26	0.147
Spinach	0.07	1		0.00023	0.08	0.100	0.00021	0.07	0.147	0.00011	0.04	0.104	0.00025	0.08	0.239
Watercress	0.07	1		0.00003	0.01	0.014	0.00003	0.01	0.019	0.00002	0.01	0.020	0.00008	0.03	0.072
Parsley	0.07	1		0.00008	0.03	0.034	0.00002	0.01	0.014	0.00001	0.00	0.006	0.00008	0.03	0.080
Beans with pods	0.02	1		0.00004	0.01	0.063	0.00004	0.01	0.094	0.00005	0.02	0.175	0.00006	0.02	0.185
Runner Beans	0.02	1		0.00007	0.02	0.102	0.00005	0.02	0.130	0.00006	0.02	0.206	0.00008	0.03	0.260
Peas with pods	0.02	1		0.00003	0.01	0.049	0.00003	0.01	0.065	0.00002	0.01	0.074	0.00003	0.01	0.084
Peas without pods	0.02	1		0.00008	0.03	0.123	0.00007	0.02	0.158	0.00005	0.02	0.163	0.00007	0.02	0.217
Beans without pods	0.02	1		0.00015	0.05	0.228	0.00003	0.01	0.069	0.00006	0.02	0.177	0.00008	0.03	0.262

Table B.7.5 cont'd UK Intakes (NESTIs) in mg/kg bw/day of residues of picloram from treated foodstuffs [proposed ARfD is 0.3 mg/kg bw/day]

				7-10 year old child			11-14 year old child			15-18 year old child			Vegetarian		
commodity	**HR (mg/kg)**	**V**	**P**	**NESTI (mg/kg bw/day)**	**% ARfD**	**acute consumption (kg/day)**	**NESTI (mg/kg bw/day)**	**% ARfD**	**acute consumption (kg/day)**	**NESTI (mg/kg bw/day)**	**% ARfD**	**acute consumption (kg/day)**	**NESTI (mg/kg bw/day)**	**% ARfD**	**acute consumption (kg/day)**
Asparagus	0.07	1		0.00005	0.02	0.023	0.00004	0.01	0.025	0.00011	0.04	0.097	0.00026	0.09	0.248
Celery	0.07	5		0.00029	0.10	0.026	0.00039	0.13	0.054	0.00029	0.10	0.053	0.00058	0.19	0.111
Fennel	0.07	7		0.00000	0.00	0.000	0.00000	0.00	0.000	0.00000	0.00	0.000	0.00130	0.43	0.178
Leeks	0.07	7		0.00077	0.26	0.049	0.00095	0.32	0.093	0.00075	0.25	0.098	0.00106	0.35	0.174
Rhubarb	0.07	7		0.00119	0.40	0.075	0.00043	0.14	0.042	0.00056	0.19	0.073	0.00065	0.22	0.163
Beans	0.02	1		0.00016	0.05	0.255	0.00015	0.05	0.360	0.00013	0.04	0.420	0.00013	0.04	0.420
Lentils	0.02	1		0.00008	0.03	0.129	0.00013	0.04	0.322	0.00005	0.02	0.166	0.00006	0.02	0.205
dried Peas	0.02	1		0.00007	0.02	0.102	0.00013	0.04	0.315	0.00005	0.02	0.145	0.00007	0.02	0.222
Oats	0.02	1		0.00004	0.01	0.064	0.00002	0.01	0.044	0.00003	0.01	0.093	0.00002	0.01	0.080
Barley	0.02	1		0.00011	0.04	0.173	0.00001	0.00	0.021	0.00001	0.00	0.039	0.00001	0.00	0.049
Millet	0.02	1		0.00000	0.00	0.000	0.00000	0.00	0.000	0.00000	0.00	0.000	0.00000	0.00	0.009
Buckwheat	0.02	1		0.00000	0.00	0.000	0.00000	0.00	0.000	0.00000	0.00	0.000	0.00000	0.00	0.000
Maize	0.02	1		0.00002	0.01	0.024	0.00001	0.00	0.035	0.00002	0.01	0.069	0.00004	0.01	0.140
Wheat	0.02	1		0.00022	0.07	0.338	0.00018	0.06	0.426	0.00017	0.06	0.536	0.00016	0.05	0.522
Rye	0.02	1		0.00003	0.01	0.044	0.00001	0.00	0.035	0.00002	0.01	0.051	0.00003	0.01	0.108

Table B.7.5 cont'd UK Intakes (NESTIs) in mg/kg bw/day of residues of picloram from treated foodstuffs [proposed ARfD is 0.3 mg/kg bw/day]

				Elderly – own home			Elderly - residential		
commodity	**HR (mg/kg)**	**V**	**P**	**NESTI (mg/kg bw/day)**	**% ARfD**	**acute consumption (kg/day)**	**NESTI (mg/kg bw/day)**	**% ARfD**	**acute consumption (kg/day)**
Oilseeds	0.01	1		0.00005	0.02	0.336	0.00005	0.02	0.338
Tomatoes	0.07	7		0.00070	0.23	0.200	0.00083	0.28	0.218
Peppers	0.07	7		0.00067	0.22	0.097	0.00037	0.12	0.046
Aubergines	0.07	5		0.00047	0.16	0.095	0.00000	0.00	0.000
Marrows	0.07	5		0.00111	0.37	0.226	0.00043	0.14	0.076
Cucumbers	0.07	5		0.00045	0.15	0.092	0.00020	0.07	0.035
Gourd	0.07	5		0.00049	0.16	0.100	0.00000	0.00	0.000
Courgettes	0.07	7		0.00079	0.26	0.117	0.00088	0.29	0.111
Sweet corn	0.07	7		0.00100	0.33	0.144	0.00068	0.23	0.085
Broccoli	0.07	5		0.00089	0.30	0.181	0.00048	0.16	0.085
Cauliflower	0.07	5		0.00106	0.35	0.215	0.00071	0.24	0.125
Brussels sprouts	0.07	1		0.00017	0.06	0.169	0.00012	0.04	0.107
Head cabbage	0.07	5		0.00093	0.31	0.187	0.00069	0.23	0.122
Chinese cabbage	0.07	5		0.00026	0.09	0.053	0.00000	0.00	0.000
Cress	0.07	1		0.00002	0.01	0.017	0.00001	0.00	0.010
Lettuce	0.07	5		0.00049	0.16	0.100	0.00028	0.09	0.049
Spinach	0.07	1		0.00015	0.05	0.151	0.00010	0.03	0.087
Watercress	0.07	1		0.00005	0.02	0.053	0.00000	0.00	0.002
Parsley	0.07	1		0.00003	0.01	0.031	0.00003	0.01	0.026
Beans with pods	0.02	1		0.00004	0.01	0.154	0.00002	0.01	0.067
Runner Beans	0.02	1		0.00005	0.02	0.165	0.00004	0.01	0.111
Peas with pods	0.02	1		0.00002	0.01	0.074	0.00000	0.00	0.006
Peas without pods	0.02	1		0.00004	0.01	0.155	0.00004	0.01	0.125
Beans without pods	0.02	1		0.00005	0.02	0.179	0.00004	0.01	0.120

Table B.7.5 cont'd UK Intakes (NESTIs) in mg/kg bw/day of residues of picloram from treated foodstuffs [proposed ARfD is 0.3 mg/kg bw/day]

				Elderly – own home			**Elderly - residential**		
commodity	**HR (mg/kg)**	**V**	**P**	**NESTI (mg/kg bw/day)**	**% ARfD**	**acute consumption (kg/day)**	**NESTI (mg/kg bw/day)**	**% ARfD**	**acute consumption (kg/day)**
Asparagus	0.07	1		0.00012	0.04	0.125	0.00007	0.02	0.061
Celery	0.07	5		0.00044	0.15	0.090	0.00015	0.05	0.026
Fennel	0.07	7		0.00073	0.24	0.105	0.00000	0.00	0.000
Leeks	0.07	7		0.00098	0.33	0.153	0.00051	0.17	0.065
Rhubarb	0.07	7		0.00056	0.19	0.108	0.00061	0.20	0.085
Beans	0.02	1		0.00006	0.02	0.229	0.00006	0.02	0.183
Lentils	0.02	1		0.00004	0.01	0.142	0.00001	0.00	0.043
dried Peas	0.02	1		0.00005	0.02	0.185	0.00003	0.01	0.086
Oats	0.02	1		0.00001	0.00	0.051	0.00001	0.00	0.041
Barley	0.02	1		0.00001	0.00	0.034	0.00001	0.00	0.020
Millet	0.02	1		0.00000	0.00	0.000	0.00000	0.00	0.000
Buckwheat	0.02	1		0.00001	0.00	0.027	0.00000	0.00	0.000
Maize	0.02	1		0.00001	0.00	0.032	0.00000	0.00	0.015
Wheat	0.02	1		0.00009	0.03	0.325	0.00009	0.03	0.281
Rye	0.02	1		0.00002	0.01	0.060	0.00001	0.00	0.020