PEER REVIEW REPORT ON **PICLORAM** 25 11 2009

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1. Identity, Physical and chemical properties, Details of uses and further information, Methods of analysis

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
	Section 1 Open points: ***16*** Points for clarification: ***5*** Data gaps: ***0***			Section 1 Open points: ***0*** Points for clarification: ***0*** Data gaps: ***3***
	Open point: 0.1 RMS to include the correct GAP table in the list of end points See reporting table 0(1)	DAS: No further comment	RMS: 08.04.09 The endpoints have been updated. Open point addressed.	PRAPeR 66 (21 – 24 April 2009): Open point fulfilled.
	Open point: 0.2 RMS to consider use of picloram rather than the acid equivalent when revising the end points. See reporting table 0(3)	DAS: No further comment	RMS: 08.04.09 Picloram expressed as acid equivalent as formulated and in all the exposure sections, therefore would require substantial changes to the DAR. As long as it's clear how it's being expressed then there is no consequence. Open point addressed. RMS (19 June 2009) The updated tox endpoints have a statement at the start to indicate all dose levels are expressed as picloram even though some studies were done with picloram salts.	PRAPeR 66 (21 – 24 April 2009): Open point still open. RMS to revise the list of end points reflecting that the active substance content should be expressed as picloram rather than acid equivalent. Written procedure: Open point fulfilled. List of endpoints have been updated.
	Open point: 0.3 RMS to provide a comparison table between	DAS: No further comment	RMS: 08.04.09 See Addendum 3 (Confidential information). The proposed technical	PRAPeR 66 (21 – 24 April 2009):

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<tr><td></td><td>the technical specification and the composition of the toxicological batches, including a clear identification of the tested compound and the impurities.

See reporting table 0(4)</td><td></td><td>specification for picloram contains a number of impurities not detected in the batches tested in the toxicity studies, and also a number of impurities present at levels higher than in the tested batches. A study of bacterial mutation (Ames test) using a representative batch of the technical material (as manufactured) in order to address concerns regarding the toxicity of these impurities has been conducted and was found to be negative see Addenda 1.
Open point addressed.</td><td>Open point fulfilled.
Message sent to section 2 (tox) and section 5 (ecotox).</td></tr>
<tr><td></td><td>Open point: 0.4
RMS to provide a summary table of the different toxicological studies performed with the different derivatives of picloram (with doses converted in picloram acid equivalents), in order to compare their toxicity profile.

See reporting table 0(5)</td><td>DAS: No further comment</td><td>RMS: 08.04.09
This is not a useful exercise as most of the package has been conducted with picloram acid, with the exception of the teratology studies which were conducted with either the potassium salt or the triisopropanolamine.
Open point addressed.</td><td>Open point transferred to section 2 (mammalian toxicology).</td></tr>
<tr><td>1.1</td><td>Point of clarification for the notifier:
Notifier to provide the manufacturing dates of the batches analysed in the 7 batch study.</td><td>Report 03-218-E:
<table><tr><th>Technical Lot</th><th>Commercial Batch Number</th><th>Manufacture Date</th></tr><tr><td>TSN104</td><td>RB28162</td><td>28-Feb-</td></tr></table></td><td>RMS: 08.04.09
The information provided by the Notifier indicates that the batches analysed are representative of production. For completeness the information has been presented in Addendum 3 (Confidential information)</td><td>PRAPeR 66 (21 – 24 April 2009):

Point of clarification addressed.</td></tr>
</table>

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<tr><td></td><td>See reporting table 1(1)</td><td>
<table>
<tr><td>168</td><td>951</td><td>2003</td></tr>
<tr><td>TSN104 169</td><td>RB10162 952</td><td>10-Feb-2003</td></tr>
<tr><td>TSN104 170</td><td>RB24162 901</td><td>24-Feb-2003</td></tr>
<tr><td>TSN104 171</td><td>QK07162 951</td><td>07-Nov-2002</td></tr>
<tr><td>TSN104 172</td><td>RB22162 902</td><td>22-Feb-2003</td></tr>
<tr><td>TSN104 173</td><td>QJ011629 65</td><td>01-Oct-2002</td></tr>
<tr><td>TSN104 174</td><td>QL06162 956</td><td>06-Dec-2002</td></tr>
</table>
Report FOR-07-004:
<table>
<tr><th>Technical Lot</th><th>Commercial Batch Number</th><th>Manufacture Date</th></tr>
<tr><td>TSN106 014</td><td>UJ221629 52</td><td>22-Oct-2006</td></tr>
<tr><td>TSN106 015</td><td>UH14162 953</td><td>14-Aug-2006</td></tr>
<tr><td>TSN106 016</td><td>UI011629 01</td><td>01-Sept-2006</td></tr>
<tr><td>TSN106 018</td><td>UI301629 55</td><td>30-Sept-2006</td></tr>
<tr><td>TSN106 020</td><td>UI191629 52</td><td>19-Sept-2006</td></tr>
<tr><td>TSN106</td><td>UJ021629</td><td>02-Oct-</td></tr>
</table>
</td><td>to the DAR.

The RMS considers that this point is addressed.

The RMS notes that Report FOR 07-004 has not been submitted to the RMS therefore this information is surplus to requirements.</td><td></td></tr>
</table>

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
		023 | 01 | 2006 TSN106 248 | VD26162 955 | 26-Apr-2007		
	Open point: 1.1 RMS to present in an addendum the justification based on the QC data for the levels in the technical specification. See reporting table 1(2)	DAS: the notifier has no further comments. A justification letter was provided to the RMS in July 2007.	RMS: 08.04.09 The information has been presented in the Addendum 3 (Confidential information) to the DAR. Open point addressed.	PRAPeR 66 (21 – 24 April 2009): Open point fulfilled.
	Open point: 1.2 RMS to update the LoEP to mention that the minimum purity of the FAO specification is on dry weigh basis. See reporting table 1(13)	DAS: No further comment	RMS: 08.04.09 The LoEP have been updated.	PRAPeR 66 (21 – 24 April 2009): Open point fulfilled.
	Open point: 1.3 RMS to update the end points on vapour pressure. See reporting table 1(15)	DAS: No further comment	RMS: 08.04.09 The LoEP have been updated.	PRAPeR 66 (21 – 24 April 2009): Open point fulfilled.
	Open point: 1.4 RMS to update the end points on temperature for solubility to 20°C. See reporting table 1(16)	DAS: No further comment	RMS: 08.04.09 The LoEP have been updated.	PRAPeR 66 (21 – 24 April 2009): Open point fulfilled.

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
	Open point: 1.5 RMS to update the end points on boiling point. See reporting table 1(17)	DAS: No further comment	RMS: 08.04.09 RMS: 08.04.09 The LoEP have been updated.	PRAPeR 66 (21 – 24 April 2009): Open point fulfilled.
	Open point: 1.6 RMS to update the end points on flammability. See reporting table 1(18)	DAS: No further comment	RMS: 08.04.09 The LoEP have been updated.	PRAPeR 66 (21 – 24 April 2009): Open point fulfilled.
1.2	Point of clarification for the notifier: Notifier to address the possibility of a second pKa due to the structural formula of the active substance (an amino acid like) See reporting table 1(25)	DAS: A supplementary document NAFST-09-27, provides additional information aimed at increasing the robustness of the assessment to support the request for the possibility of a second pKa due to the structural formula of the active substance. A second pKa was calculated to be -3.85. Since the value is a negative number, no additional experimental studies to confirm the pKa are required or have been performed.	RMS: 08.04.09 The information provided by the Notifier has been presented in Addendum 2 to the DAR. The RMS considers that this point is addressed.	PRAPeR 66 (21 – 24 April 2009): Point of clarification addressed. New data gap proposed, see below.
	New data gap 1.1 identified at PRAPeR 66 meeting: Determination of the pKa according to OECD 112 method is required.			PRAPeR 66 (21 – 24 April 2009): Data gap open. Written procedure: Data gap still open. Determination of the pKa according to OECD 112 method is required.

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
	Open point: 1.7 RMS to amend list of tests and studies relied upon concerning pH. See reporting table 1(26)	DAS: No further comment	RMS: 08.04.09 The list of tests and studies will be updated at the end of the peer review process. RMS: 19 June 2009 The list of tests and studies relied upon has been updated (June 2009).	PRAPeR 66 (21 – 24 April 2009): Open point still open. Written procedure: Open point fulfilled. The list of tests and studies relied upon has been updated (June 2009).
	Open point: 1.8 RMS to amend list of tests and studies relied upon concerning relative density. See reporting table 1(27)	DAS: No further comment	RMS: 08.04.09 The list of tests and studies will be updated at the end of the peer review process. RMS: 19 June 2009 The list of tests and studies relied upon has been updated (June 2009).	PRAPeR 66 (21 – 24 April 2009): Open point still open. Written procedure: Open point fulfilled. The list of tests and studies relied upon has been updated (June 2009).
1.3	Point of clarification for the notifier: Notifier to provide justification as to why the determination of relevant impurities after storage is not required. See reporting table 1(29)	DAS: The notifier highlights that if a starting material used in the manufacturing of the technical picloram 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.	RMS: 08.04.09 The Notifier has provided further information as to why they believe that the relevant impurity will not form during storage of the product. This information is presented in Addendum 2 to the DAR. The RMS believes that this justification is acceptable and therefore the determination of relevant impurities in the product after storage is not required.	PRAPeR 66 (21 – 24 April 2009): Point of clarification addressed.

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
		Since no known pathways are present 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. A supplementary document is additional justification aimed at increasing the understanding as to why the determination of relevant impurities after storage is not required.	The RMS considers that this point is addressed.	
1.4	Point of clarification for the notifier: Notifier to provide further information on procedures for cleaning application equipment to address the efficacy of cleaning. See reporting table 1(31)	DAS: The procedure for tank cleaning after using picloram has to follow the Good Field Agricultural practices. 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.	RMS: 08.04.09 The information provided by the Notifier has been presented in Addendum 2 to the DAR for completeness. No data have been submitted to support the effectiveness of the cleaning procedures.	PRAPeR 66 (21 – 24 April 2009): Point of clarification addressed.
	Open point: 1.9	DAS: No further comment	RMS: 08.04.09	PRAPeR 66 (21 – 24 April 2009):

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	RMS to include the information on the method of analysis for the relative impurity in an addendum. See reporting table 1(32)		The information is presented in Addendum 2 to the DAR. The RMS considers that this point is addressed.	Open point fulfilled.
	Open point: 1.10 RMS to amend the LoEP concerning the analytes of the monitoring methods for soil. See reporting table 1(36)	DAS: No further comment	RMS: 08.04.09 The LOEP have been updated.	PRAPeR 66 (21 – 24 April 2009): Open point fulfilled.
	Open point: 1.11 RMS to amend the LoEP concerning the analytes of the monitoring methods for water. See reporting table 1(38)	DAS: No further comment	RMS: 08.04.09 The LOEP have been updated.	PRAPeR 66 (21 – 24 April 2009): Open point fulfilled.
	Open point: 1.12 The acceptability of the residue methods GRM 00.19, GRM 00.18 and GRM 00.17 taking into account the number of fragment-ions used for quantitation and confirmation to be discussed in a meeting of experts	DAS: the notifier believes that sufficient information regarding the fragment ions has been supplied in the tier summaries of the dossier sections submitted and provided in the DAR. The notifier has no additional comments.	RMS: 08.04.09 Methods GRM 00.19, GRM 00.18 and GRM 00.17 all utilise GC/NCI-MS using capillary column HP-5MS for determination of residues of picloram. For method GRM 00.17 Quantitation was conducted using m/z 246, with confirmation at m/z 248 or additional ions m/z = 210,212 and 250. For methods GRM 00.19 & GRM 00.18 quantitation was conducted using m/z	PRAPeR 66 (21 – 24 April 2009): Open point fulfilled. New open point proposed, see below.

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<tr><td></td><td>See reporting table 1(40)</td><td></td><td>246, and it was stated in the DAR that for confirmation m/z 248 could be used. It was not specifically stated for these two methods that any other ions were available, however, given the measurement systems are identical for all 3 methods the RMS is of the opinion that the m/z ratios suggested for method GRM 00.17 can also apply to methods 00.18 & 00.19 and the methods are acceptable.</td><td></td></tr>
<tr><td></td><td>New open point 1.13
EFSA to highlight in the conclusion that the meeting could not agree on the acceptability of the residue methods GRM 00.19, GRM 00.18 and GRM 00.17.</td><td></td><td></td><td>PRAPeR 66 (21 – 24 April 2009):

Open point open.

Written procedure:
Open point fulfilled.</td></tr>
<tr><td>1.5</td><td>Point of clarification for the notifier:
Notifier to provide information on the characteristics of the water used in the method validations.

See reporting table 1(47)</td><td>DAS: The waters used in the method were from different locations within the UK and France and also represented different types/sources.

<table><tr><th>Sample no</th><th>Type</th><th>Source</th></tr><tr><td>R00-999-019</td><td>River Water</td><td>River Odet, Quimper, Brittany, France</td></tr></table></td><td>RMS: 08.04.09
The information provided by the Notifier has been presented in Addendum 2 to the DAR for completeness. The RMS believes that this point is addressed.</td><td>PRAPeR 66 (21 – 24 April 2009):

Point of clarification addressed.</td></tr>
</table>

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		<table><tr><td>R00-999-018</td><td>Lake Water</td><td>Letcombe Lake, Letcombe Regis, Oxfordshire, UK</td></tr><tr><td>R96-000-596</td><td>Ground Water</td><td>Wantage, Oxfordshire, UK</td></tr><tr><td>R96-999-020</td><td>Ground Water</td><td>Bossington, Somerset, UK</td></tr><tr><td>R00-999-020</td><td>Drinking Water</td><td>Letcombe Laboratories, Letcombe Regis, Oxfordshire, UK</td></tr></table> Although no characterisation work was carried out at the time of the validation, the notifier believes the variability's in the water sources offer sufficient robustness for the method to be acceptable and used in determining picloram concentrations in water.		
	New open point 1.14 RMS to update the list of end points according to PRAPeR			PRAPeR 66 (21 – 24 April 2009):

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
	66: In the box of melting point it should be stated ”decomposition occurs during melting” Box of boiling point: “not applicable” pH dependence of water solubility Minimum purity: 920 g/kg on a dry weight basis, minimum/maximum as wet cake should be included as well Representative uses: concentration should be given in the column “g/hl” Analytical method for residues in food of animal origin: matrices should be specified Body fluids and tissues method: it should be stated that the compound is neither toxic nor very toxic.			Open point open. New data gaps 1.2 and 1.3 proposed, see below. Written procedure: Open point fulfilled.
	New data gap 1.2 identified at PRAPeR 66 meeting: Specification for the “wet cake” should be provided.			PRAPeR 66 (21 – 24 April 2009): Data gap open. Written procedure: Data gap closed.

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
				Specification for the "wet cake" was provided (calculation)
	New data gap 1.3 identified at PRAPeR 66 meeting: Water solubility should be determined at pH 5, 7 and 9.			PRAPeR 66 (21 – 24 April 2009): Data gap open. Written procedure: Data gap still open. Water solubility should be determined at pH 5, 7 and 9.
	Message from section 1 to section 2 (mammalian toxicology): Please consider the information on the tox batches presented in Addendum 3 to Vol. 4. The Ames study should not be considered in the peer review (new study).			Answer from section 2: The experts highlighted differences in the impurity profile between the batches used for genotoxicity and carcinogenicity studies and the technical specification agreed at PRAPeR 66. The tested batches generally had lower levels of some impurities and apparently lacked other impurities. It was considered that the structures of the impurities were similar to the parent and no additional structures of clear toxicological concern were observed. Therefore **the proposed levels were considered toxicologically acceptable**. The impurities HCB and sulphuric acid were considered as relevant impurities, but not of concern at the proposed levels

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
				of 0.9% w/w for sulphuric acid and 0.005% w/w for HCB. It was noted that HCB had been tested in the carcinogenic studies up to a level of 0.02% w/w. New open point 2.16 proposed.
	Message from section 1 to section 5 (ecotoxicology): Please consider the information on the ecotox batches presented in Addendum 3 to Vol. 4.			Answer from section 5: There seem to be some inconsistency: information on purity of batches differs between the ecotox DAR/addendum and the addendum 3 to Vol.4. This should be checked by the RMS. New open point 5.8 proposed. The meeting considered that the impurity sulphuric acid (occurring in batch AGR274601 (1989), tested on Daphnia (chronic) and earthworm) is sufficiently addressed.
	Message 1 from section 3 (residues) to section 1: A validated method of analysis for monitoring covering all the standard plant matrices and taking into account the message No 3 to section 1 on picloram conjugates (see open point 3.3) is necessary.			Written procedure: New data gap: Clarification whether the method GRM 00.19 does fully, partially or at all analyse any conjugated picloram.

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
	Message 2 from section 3 (residues) to section 1: A MRL for picloram of 0.2 mg/kg is proposed for kidney. Hence, a validated method of analysis for monitoring covering animal matrices is necessary.			Written procedure: Method is available
	Message 3 from section 3 (residues) to section 1: A decision on a plant residue definition for enforcement (in terms of whether picloram conjugates will have to be included) can currently not be taken, since it is unknown whether the analytical method proposed for monitoring (GRM 00.19) does fully or partially analyse any conjugated picloram.			Written procedure: See message 1 above

2. Mammalian toxicology

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
	Section 2 Open points: ***12*** Points for clarification: ***0*** Data gaps: ***0***			Section 2 Open points: ***0*** Points for clarification: ***0*** Data gaps: ***0***
	Open point: 0.4 RMS to provide a summary table of the different toxicological studies performed with the different derivatives of picloram (with doses converted in picloram acid equivalents), in order to compare their toxicity profile. See reporting table 0(5)	DAS: No further comment	RMS: 08.04.09 This is not a useful exercise as most of the package has been conducted with picloram acid, with the exception of the teratology studies which were conducted with either the potassium salt or the triisopropanolamine. Open point addressed. RMS: 30.10.09 Clarification as to the nature of the tested material in each toxicology study is provided at C.1.2.d in Addendum 5.	PRAPeR 69 (4 – 8 May 2009): Open point closed. See answer to the message from section 1.
	Open point: 2.1 Application of R43 to be discussed by the experts, taking into consideration - the limitations of the available Buehler test - the results of the EPA evaluation: negative for picloram acid, positive for the potassium salt, the isooctyl ester and the TIPA	DAS: The notifier supports the RMS position in the Draft Assessment Report that picloram acid is negative for dermal sensitization.	RMS: 08.04.09 Comment noted.	PRAPeR 69 (4 – 8 May 2009): Open point fulfilled. R43 is proposed for picloram.

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
	salt. See reporting table 2(3)			
	Open point: 2.2 The relevant short-term NOAEL in the rat (13-wk study) has to be confirmed by the experts. (similar findings were observed in the liver in the 2-year rat study) See reporting table 2(4)	DAS: The observations at 300 mg/kg/day include small increases (<10%) in liver and kidney weight and "increased size of hepatocytes often accompanied by altered tinctorial properties" graded as slight to very slight. The notifier supports the RMS conclusion that the findings at this dose-level were non-adverse. The NOAEL is therefore considered to be 300 mg/kg/day	RMS: 08.04.09 Comment noted.	PRAPeR 69 (4 – 8 May 2009): Open point closed. See open point 2.3.
	Open point: 2.3 Based on the relevance of the liver and pancreas findings, the systemic NOAEL of the 2-yr rat study (Landry, 1986) has to be discussed by the experts. (similar liver findings were observed in the 13-wk rat study) See reporting table 2(5)	DAS: The notifier supports the RMS conclusion from the Draft Assessment Report that the histopathological liver and pancreas findings at 60 mg/kg/day were non-adverse (not toxicologically significant). The NOAEL is therefore considered to be 60 mg/kg/day.	RMS: 08.04.09 Comment noted.	PRAPeR 69 (4 – 8 May 2009): Open point fulfilled. The NOAEL in the 2-yr rat study is 60 mg/kg bw/day. The NOAEL in the 13-week rat study is 300 mg/kg bw/day. New open point proposed, see below.
	New open point: 2.12 RMS to provide further information (including			PRAPeR 69 (4 – 8 May 2009): Open point open.

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	historical control range) on the pancreas findings in sub chronic and chronic studies in an addendum to the DAR.			Written procedure: Open point fulfilled. Further information on pancreas findings is included in Addendum 4 (June 2009).
	Open point: 2.4 MS experts to discuss the carcinogenic potential of picloram based on the published article by Reuber Melvin Dwaine (J. of Tox. and Env. Health, 7:207-222, 1981). See reporting table 2(6)	DAS: the notifier highlights that the two guideline GLP rat bioassays were included in the original submission and provide a more robust assessment of the carcinogenic potential of picloram. These two guideline rat bioassays were both negative for carcinogenicity as indicated by the RMS in the Draft assessment report. The following document provides additional information and justification as to why the published article by Reuber Melvin Dwaine (J.of Tox and Env. Health, 7:207-222, 1981) should not be considered under the 91/414 evaluation of picloram.	RMS: 08.04.09 Comment noted. The information provided by the notifier has been presented in Addendum 3 (Confidential information).	PRAPeR 69 (4 – 8 May 2009): Open point fulfilled. The experts agreed that picloram has no carcinogenic potential. New open point proposed, see below.
	New open point: 2.13 RMS to provide further information on why the Reuber evaluation regarding the carcinogenic potential of picloram was rejected (show the inconsistencies in			PRAPeR 69 (4 – 8 May 2009): Open point open. Written procedure: Open point fulfilled.

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
	reporting between Reuber and US EPA/NTP).			Further clarification as to why Reuber's assessment of carcinogenic potential of picloram was rejected (particularly by providing examples of inconsistencies with the official NCI report) is included in Addendum 4 (June 2009).
	Open point: 2.5 The derivation of the developmental NOAEL in rats based on the foetal findings in both studies has to be discussed by the experts. See reporting table 2(7)	DAS: The notifier highlights that there were no treatment-related effects on development evident in either study.	RMS: 08.04.09 Comment noted.	PRAPeR 69 (4 – 8 May 2009): Open point fulfilled. Rat developmental study (K salt): - developmental NOAEL is 860 mg picloram/kg bw/day - maternal NOAEL is 430 mg picloram/kg bw/day based on clinical signs (salivation). Rat developmental study (TIPA salt) - developmental NOAEL is 560 mg picloram/kg bw/day - maternal NOAEL is 280 mg picloram/kg bw/day based on clinical signs (salivation). The experts agreed that the **overall maternal NOAEL in rats** should be **280 mg picloram/kg bw/day** and the **overall developmental NOAEL** should be **560 mg picloram/kg bw/day** (based on the worst case and taking into account the

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				LOAEL of the second study). New open point proposed, see below.
	New open point: 2.14 RMS to provide information regarding the cranial facial malformations in the rat studies in an addendum to the DAR.			PRAPeR 69 (4 – 8 May 2009): Open point open. Written procedure: Open point fulfilled. Information on craniofacial malformations in rat studies is included in Addendum 4 (June 2009).
	Open point: 2.6 The relevant developmental NOAEL in the rabbit developmental studies has to be discussed by the experts, based on the incidence of the foetal findings observed in the different studies at the high dose. See reporting table 2(14)	DAS: For the K-salt study, the Notifier affirms that the NOAEL for developmental effects should be > 400 mg/kg (Picloram Acid Equivalents). The two incidences of forelimb flexure at the top dose were limited to a tendon anomaly and importantly were confined to a single litter. Also supporting that the effects were non-treatment related, similar findings were not observed in the rabbit teratology study with the TIPA salt. For the study on the TIPA salt, the notifier supports the RMS position that	RMS: 08.04.09 Comment noted.	PRAPeR 69 (4 – 8 May 2009): Open point fulfilled. In the rabbit developmental study with the K salt, the developmental NOAEL is 200 mg picloram/kg bw/day. In the rabbit developmental study with the TIPA salt, the developmental NOAEL is 300 mg picloram/kg bw/day based on adverse foetal findings at the highest dose.

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
		there were not treatment-related foetal findings in the study. The developmental NOAEL is therefore considered to be >558 mg/kg/day.		No classification for developmental effects was proposed.
	Open point: 2.7 The relevant maternal NOAEL in the developmental rabbit studies has to be discussed by the experts, based on the changes in body weight (gain). (in the DAR, this NOAEL is proposed as the basis for the ADI). See reporting table 2(17)	DAS: For the K-salt study, the notifier agrees with the RMS supported maternal NOAEL of 40 mg/kg/day. For the TIPA-salt study, the observed effect on body weight gain at 180 mg/kg/day is not considered to be toxicologically meaningful due to the mild nature (<1% change) and transient duration (only observed at one interval) of the observation. The notifier therefore considers the maternal NOAEL to be 180 mg/kg/day (a.e. of 100 mg/kg/day).	RMS: 08.04.09 In the TIPA-salt study there were clear effects on bodyweight gain and even a bodyweight loss at 180 mg/kg/day (a.e. of 100 mg/kg/day) which was observed in both phases of the study.	PRAPeR 69 (4 – 8 May 2009): Open point fulfilled. The overall maternal NOAEL in the rabbit developmental studies is 30 mg picloram/kg bw/day (based on the study with the TIPA salt)
	Open point: 2.8 The derivation of the ADI has to be discussed by the experts. See reporting table 2(20)	DAS: The Notifier supports the proposed ADI of 0.35 mg/kg/day derived from the NOAEL of 35 mg/kg/day in the 1 year dog study. This exposure limit is based on the most suitable toxicological endpoint available and is health protective. The proposed ADI values of 0.3 and 0.2 mg/kg/day are based on endpoints of a transient nature and/or are of questionable toxicological significance.	RMS: 08.04.09 The weight loss and reduced bodyweight gain in the rabbit teratology study must be considered as adverse.	PRAPeR 69 (4 – 8 May 2009): Open point fulfilled. ADI agreed as 0.3 mg/kg bw/day

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
	Open point: 2.9 The need for ARfD has to be discussed by the experts (and the derivation if needed). See reporting table 2(22)	DAS: The Notifier maintains the active substance picloram has low acute hazard potential (LD50 > 4000 mg/kg bw), is not teratogenic, and other toxicological alerts (FAO/WHO, 2000) that would trigger the establishment of an ARfD have not been demonstrated.	RMS: 08.04.09 There are several studies where reduced bodyweight gain is evidence after a few days of dosing. Therefore an ARfD is required.	PRAPeR 69 (4 – 8 May 2009): Open point fulfilled. ARfD agreed as 0.3 mg/kg bw
	Open point: 2.10 The derivation of the systemic AOEL has to be discussed by the experts. See reporting table 2(24)	DAS: The Notifier supports the derivation of the AOEL from the TIPA-salt rabbit developmental study as the salts are considered toxicologically equivalent to picloram. The maternal NOAEL is considered to be 100 mg/kg/day in this study rather than 30 mg/kg/d (discussed in point 2.7) resulting in an AOEL of 1 mg/kg/day.	RMS: 08.04.09 Comment noted.	PRAPeR 69 (4 – 8 May 2009): Open point fulfilled. AOEL agreed as 0.3 mg/kg bw/day
	Open point: 2.11 Dermal absorption values to be discussed by the experts, taking into account the weaknesses of the *in vivo* rat study and the findings in the human volunteer study. See reporting table 2(29)	DAS: The default assumptions associated with the dermal absorption of covalent bounded compounds may not always be applicable to salts of acids as is the case of the olamine salt of picloram. Decrease in %absorption with increased dilution is unusual, but reflects the difference in the disassociation of the active substance at the concentration in the formulation and dilute spray dilution. The human volunteer study (B6.1.1)	RMS: 08.04.09 Comment noted.	PRAPeR 69 (4 – 8 May 2009): Open point fulfilled. The experts agreed 10% (default) for the concentrate and 0.1% for the dilution. New open point proposed, see below.

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
		confirms this point with low absorption of the acid. A recent OECD 428 guideline compliant study on an olamine salt with the structurally related clopyralid –olamine demonstrated again that the absorption from a dilute spray solution was less than that from the neat formulation. Van Burgsteden (2007) In vitro percutaneous absorption of 14C Clopyralid formulated as EF-1136 and field dilutions through human skin membranes using flow through diffusion cells. A copy of this study was provided as supplementary information only to verify the conclusions regarding the validity of the proposed dermal values. DAS: The OECD Guideline 427 specifies that recoveries <90% are acceptable if justified. The OECD guidance 28 recommends wash off at 6 hours , the contact time in the study was24 hours, combined with the high wash off percentages, (ca. 70%) the missing 5% would have no impact on the absorption. The specific activity and conc. of the picloram dictated that a 500 fold dilution was the maximum conc. that could be studied. 2x difference will not impact on % absorption. Neither of these criteria		

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
		warrant part inclusion of the application site. No movement from the application site was observed over 72 hours.		
	New open point: 2.15 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.			PRAPeR 69 (4 – 8 May 2009): Open point open Written procedure: Open point fulfilled. Revised exposure estimates were provided in the addendum 4 (June 2009).
	Message from section 1 (Phys-chem) to section 2: Please consider the information on the toxicological batches presented in Addendum 3 to Vol. 4. The Ames study should not be considered in the peer review (new study).			PRAPeR 69 (4 – 8 May 2009): Answer: The experts highlighted differences in the impurity profile between the batches used for genotoxicity and carcinogenicity studies and the technical specification agreed at PRAPeR 66. The tested batches generally had lower levels of some impurities and apparently lacked other impurities. It was considered that the structures of the impurities were similar to the parent and no additional structures of clear toxicological concern were observed.

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
				Therefore **the proposed levels were considered toxicologically acceptable**. The impurities HCB and sulphuric acid were considered as relevant impurities, but not of concern at the proposed levels of 0.9% w/w for sulphuric acid and 0.005% w/w for HCB. It was noted that HCB had been tested in the carcinogenic studies up to a level of 0.02% w/w. New open point proposed, see below.
	New open point: 2.16 The revised section C.1.2.d 'Purity of test material used in toxicity studies' of Addendum 3 Vol4, including comparison of the batches with the technical specification, has to be presented by the RMS in a confidential addendum.			PRAPeR 69 (4 – 8 May 2009): Open point open. Written procedure: Open point fulfilled. A revised section C.1.2.d is included in Addendum 5 (Confidential information).

3. Residues

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
	Section 3 Open points: ***5*** Points for clarification: ***1*** Data gaps: ***0***			Section 3 Open points: ***1*** Points for clarification: ***0*** Data gaps: ***3***
	Open point: 3.1 RMS should provide the correct data relating to Table B7.2 in an corrigendum/ addendum as appropriate. See reporting table 3(1)	DAS: The ppm values for Day 84 – Stem in Table B.7.2 are correct but the %TRR value for Acetonitrile/water extract should be 4.0% (0.005/0.125 mg/kg), so that the total %TRR is 4.0% + 32.8% = 36.8%. Continuing with the TLC method in Table B.7.2, the picloram conjugates represent 0.051 mg/kg (correctly reported in Table B.7.2.) which would result in 40.8%TRR (91.1% of the extract). Combining the above two, 36.8% + 40.8% = 77.6% TRR identified as free or conjugated picloram. The diethyl ether extract followed acid and base hydrolysis of the post-extracted solids (PES), so these values can be considered to represent conjugated picloram that was released upon hydrolysis. Using the TLC analysis, 0.041 mg/kg was identified as picloram from hydrolysis of the PES, equivalent to 32.8% TRR.	RMS: 08.04.09 A revised table has been presented in Addendum 2 of the DAR. Open point addressed.	PRAPeR 70 (5 – 8 May 2009): Open point fulfilled. A revised table has been presented in Addendum 2 of the DAR.

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
	Open point: 3.2 RMS to present a re-evaluation of the rotational crop study, considering the correct application rate in an addendum. See reporting table 3(3)	DAS: The notifier agrees with the comments made by the RMS in the reporting table that the correct N rate should be 28.2 N and not 285N	RMS: 08.04.09 A re-evaluation of the metabolism study has been presented in Addendum 2 of the DAR. Taking into consideration the revised rates 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. As discussed in the Addendum the Notifier has previously provided justification that the 30 day interval is not relevant to the proposed uses. The RMS is of the opinion that for the proposed use no further data on rotational crops are considered necessary. However, for other uses proposed in the future further data may be necessary.	PRAPeR 70 (5 – 8 May 2009): Open point fulfilled. Rotational crop study was re-evaluated and MRLs for rotational crops were proposed.
	New open point: 3.6 [based on reporting table comment 3(9)]: In an addendum, RMS to provide animal intake calculations [on a dry matter basis] considering residues in rotational crops, and clarify the dose rate in the goat metabolism study [see			PRAPeR 70 (5 – 8 May 2009): Open point open. RMS: 21 July 2009 Revised animal intake calculations taking residues in root crop into account have been conducted and presented in Addendum 6. LOEP (July 2009) have

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
	3(9) in the reporting table]. RMS to re-evaluate the goat metabolism study in order to propose MRLs for animal products.			been updated to reflect this. Written procedure: Addendum has been provided, however the calculations are not peer reviewed. Open point fulfilled.
	New data gap: 3.1 identified at PRAPeR 70 meeting [based on reporting table comment 3(10)]: Notifier to name impurities and to clarify the possible impact of the impurities that showed the same chromatographic behaviour as the non-polar components in the goat metabolism study.			PRAPeR 70 (5 – 8 May 2009): Data gap open. Written procedure: Data gap open.
3.1	Point of clarification for the notifier: Notifier to address the potential for residues in following crops as field trials in rotational crops seem to be triggered. See reporting table 3(3)	DAS: Since the majority of the residue was identified as free or conjugated picloram, another study to confirm these results should not be required. No metabolite was present at levels greater than 0.148 mg/kg after hydrolysis (28.2 N), which would be less than 0.006 mg/kg at a 1N rate. The analytical methods will detect free and conjugated picloram. A field rotational crop study should not be required.	RMS: 08.04.09 RMS notes the comments from the Notifier. See also comments for open point 3.2 above.	PRAPeR 70 (5 – 8 May 2009): Point of clarification turned into a data gap: Field rotational crop study is requested to confirm or if necessary to modify (refine) the proposed MRLs in rotational crops. Written procedure: Data gap open.

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
				Messages 1 and 2 sent to section 1.
	Open point: 3.3 The issue on whether conjugated picloram should be included in the residue definition for risk assessment and whether the available data sufficiently address conjugated residues (primary and rotational crops) should be discussed by experts. See reporting table 3(8)	DAS: Both free and conjugated picloram were expected to be included in the residue definition for monitoring (MRLs) and dietary risk assessment. The analytical method involves hydrolysis of conjugates and measures both free and conjugated picloram, reported as total picloram.	RMS: 08.04.09 Comment noted.	PRAPeR 70 (5 – 8 May 2009): Open point fulfilled. Conjugated picloram should be included in the residue definition for risk assessment, i.e. the residue of concern for RA is defined as picloram, free and conjugated. New open point proposed, see below. Message 3 sent to section 1.
	New open point: 3.7 Decision on residue definition for enforcement pending on confirmation whether or not the analytical method for monitoring does analyse picloram conjugates.			PRAPeR 70 (5 – 8 May 2009): Open point open. RMS: 21 July 2009 This issue depends upon information from the Notifier to confirm that method GRM.00.19, hydrolyzes conjugated picloram. See data gap 3.2 and open point 3.4. Written procedure: Open point still open.
	Open point: 3.4	DAS: The plant metabolism studies	RMS: 08.04.09	PRAPeR 70 (5 – 8 May 2009):

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
	Experts to consider whether the method used in residue trials is suitable to determine conjugated picloram (consider also extraction efficiency in releasing conjugated picloram) or whether further information or data should be required. See reporting table 3(14)	(as submitted in the original dossier) describe the extraction procedures which were used to quantitatively extract and hydrolyze residues of picloram. Very similar procedures (e.g., alkaline extraction with heat) were used in this metabolism study as well as in the residue methods. There is adequate proof in the metabolism reports that the extraction methods which are used in the methods are sufficient to extract the residues from the samples. Analytical method GRM 00.19 uses both basic and acidic conditions (sodium hydroxide and hydrochloric acid), and this is expected to hydrolyze any conjugated picloram present in the sample.	Comment noted.	Open point fulfilled. Refer to open point 3.3 New data gap proposed, see below.
	New data gap: 3.2 identified at PRAPeR 70 meeting: Notifier to provide validation data to demonstrate the efficiency of the analytical method used in the supervised residue trials in terms of the analysis of picloram conjugates.			PRAPeR 70 (5 – 8 May 2009): Data gap open. Written procedure: Data gap open.
	Open point: 3.5 Acceptability of storage stability data in terms of the	DAS: The storage stability data for oil seed rape seed was carried out for a period of 24 months (730 days) and	RMS: 08.04.09 Comment noted. RMS agrees that the only samples stored for longer	PRAPeR 70 (5 – 8 May 2009): Open point fulfilled.

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
	sample storage time in the field trials to be agreed by experts. See reporting table 3(15)	residues were stable over this interval. The maximum period of frozen storage for residue study samples was approximately 810 days. This is only about 10% over the measured storage interval. Since there was no degradation during the 730 day interval, no appreciable degradation would be expected over the period of 80 additional days. Additionally, it is important to point out that the samples stored for about 800 days were whole plant samples, which are not used in the MRL. The seed samples were stored for a maximum period of time that was only within or nearly within the 730 day interval supported by the storage stability study.	than 24 months before analysis were the immature whole plants (i.e. not at harvest maturity)	Storage stability data are acceptable taking into account the overall stability of the active substance.
	New open point: 3.8 RMS to update the LoEP according to the discussions at PRAPeR 70, including a new risk assessment.			PRAPeR 70 (5 – 8 May 2009): Open point open. RMS: 19 June 2009 The list of endpoints has been updated where possible based upon the current risk assessment. RMS: 21 July 2009 A revised risk assessment taking into

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
				account a consideration of potential MRLs in rotational crops and animal products has been conducted and is presented in Addendum 6. The list of endpoints (July 2009) has been updated based upon the revised risk assessment. Written procedure: Open.point fulfilled.
	Message 1 from section 3 to section 1: A validated method of analysis for monitoring covering all the standard plant matrices and taking into account the message No 3 to section 1 on picloram conjugates (see open point 3.3) is necessary.			
	Message 2 from section 3 to section 1: A MRL for picloram of 0.2 mg/kg is proposed for kidney. Hence, a validated method of analysis for monitoring covering animal matrices is necessary.			
	Message 3 from section 3 to			

section 3 – Residues

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
	section 1: A decision on a plant residue definition for enforcement (in terms of whether picloram conjugates will have to be included) can currently not be taken, since it is unknown whether the analytical method proposed for monitoring (GRM 00.19) does fully or partially analyse any conjugated picloram.			

4. Environmental fate and behaviour

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
	Section 4 Open points: ***18*** Points for clarification: ***3*** Data gaps: ***0***			Section 4 Open points: ***1*** Points for clarification: ***0*** Data gaps: ***0***
	Open point: 4.1 RMS to 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, than the normalization should be corrected. Remark: The normalisation procedure used by the RMS is correct. However, the normalisation of the soil from Douglas County, KS could be regarded to be correct only if it was silty clay as indicated in Table B.8.16 of the DAR. If it was silty loam as indicated in Table B.8.23 and in the LoEP than the normalisation still seems to be wrong See reporting table 4(2)	DAS: It does appear a Silt Loam field capacity value (26%) was chosen rather than the Silty clay value (40%) for the Kansas soil in the normalization procedure. However, choosing the correct value will reduce the normalized half-life. The resulting geometric mean is 46.5 day versus the 48.3 day value used in the PECgw assessment. Thus, the existing assessment may be considered conservative.	RMS: 08.04.09 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 should therefore 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. However as the final corrected DT50 value is correct at 5.2 days, then no re-calculation of the geometric mean DT50 value is required. Corrected versions of the relevant tables have been included in Addendum 2 where they are now referred to as B.8.23b and B.8.35b. The Appropriate changes have been made to the LoEP.	PRAPeR 67 (20 – 24 April 2009): Open point fulfilled.

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
			The RMS considers that the open point is closed.	
	Open point: 4.2 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. See reporting table 4(3)	DAS: No further comment	RMS: 08.04.09 The RMS has included the Notifiers original argumentation in full in Addendum 2. The Notifier also submitted a total of 33 chromatograms to assist in the illustration of this argument. The RMS has not reproduced all of these chromatograms in the addendum, but has reproduced chromatograms to which the Notifier specifically refers along with a small number of others. As indicated in the DAR, the RMS considers that the peak unidentified radioactivity at study end of 5.7% AR is likely to be due to an analytical artefact rather than a specific metabolite from picloram.	PRAPeR 67 (20 – 24 April 2009): Open point fulfilled.
	Open point: 4.3 MSs experts to discuss in a meeting that whether the degradation of picloram is dose related and whether it is supported that DT_{50} values from the lowest dose, which are always the shortest ones, are used in the estimation of the exposure	DAS: See notifier's comments in point 4.1 below.	RMS: 08.04.09 The RMS previous comments in Reporting Table are reproduced below for ease of reference. Also see comments in Point of clarification 4.1 below. [RMS 04.02.09: Additional information on mineralisation of another substance, 3,4-dichlorobenzoic acid,	PRAPeR 67 (20 – 24 April 2009): Open point fulfilled. New open points 4.19 and 4.20 proposed see below.

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
	from the study by Cook, W.L., Buehrer, J.T., 1999. MSs experts to discuss the exclusion or inclusion of DT_{50} values from the study by McCall, P.J., Jeffries, T.K., 1978, as well. See reporting table 4(5)		in each soil was provided in the study report, but there were no additional measurements of microbial activity of the soil apart from indirectly via rate of degradation and mineralisation. The study report provides graphical presentation of degradation of picloram at each dose in each soil and the effect of dose on half-life for each soil. The graphs in the CADDY version of the study report are relatively indistinct, and it would be useful to request the Notifier to provide better quality images to include in an addendum.]	
	New open point: 4.19 RMS to include in the LoEP in a separate column (X) the dose rates associated with each endpoint.			PRAPeR 67 (20 – 24 April 2009): Open point open. RMS: [28/05/09] Action completed. Dose rates added to all lab and field soil studies. Written procedure (October-November 2009): Open point fulfilled.
	New open point: 4.20 RMS to ensure that the study by McCall et al 1978 is not present in the List of			PRAPeR 67 (20 – 24 April 2009): Open point open.

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
	studies relied on.			RMS: [28/05/09] Action not completed. The study was used for anaerobic degradation and therefore should be retained in the list of studies relied on, even though it was relied on for aerobic degradation following PRAPeR discussions. Written procedure (October-November 2009): Open point fulfilled.
4.1	Point of clarification for the notifier: Notifier to provide information/argumentation which supports the discussion on the possible dose-related degradation of picloram observed in the study Cook, W.L., Buehrer, J.T., 1999 (e.g by provision better quality images of the graphs in the study report of the mentioned study). See reporting table 4(5)	DAS: Based on simple examination, the rate effect is clear in the Cook & Buehrer study. It is important to highlight that the lowest rate in the Cook & Buehrer study is actually higher than the GAP rate being supported at Annex 1, therefore the existing assessment may be considered conservative. If the concept of the application rate effect is accepted as true, the exclusion of the McCall & Jeffries data is justified because that study employed an application rate of >30 times the GAP being supported at Annex I. Additionally, newly collected field dissipation kinetics which support the findings of the soil dissipation	RMS: 08.04.09 In addition to the Notifiers argumentation the RMS would draw the attention to Table B.8.22. For two soils DT50 increases with increasing application rate. For the remaining two soils the general trend is the same, though it could be said that the effect is no longer observed at the highest two application rates. However, these highest two application rates are ≥ 33x the proposed application rate. The proposed application rate for the Annex I listing use is 23.5 g as/ ha, and the lowest application rate used in the relevant study is equivalent study is 134 g/ ha. Therefore the RMS considers the Notifier is correct in	PRAPeR 67 (20 – 24 April 2009): Point of clarification addressed.

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
		submitted in the Annex I dossier will be used for end-use product submissions for Annex III.	stating that the DT50 values used are conservative.	
	Open point: 4.4 MSs experts to discuss in a meeting whether it is agreed that the degradation endpoints derived from the study by Knowles, S., Swales, S.A., 2002 is excluded. If not, what DT_{50} value should be used. 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. See reporting table 4(6)	DAS: No further comment.	RMS: 08.04.09 Based upon the graphical fit and residual plots presented in the addendum it is considered by the RMS that SFO kinetics is not appropriate for use in modelling. It is noted that the increase of the geometric mean to 51.6 days which would occur compares to the geomean of 48.3 days reported in the DAR. The RMS therefore considers that the use of the revised value in subsequent modelling would have an insignificant impact on PEC values. FOMC kinetics describes the degradation well. Giving a DT90 of 67155 d and a calculated DT50 for use in FOCUS modelling of 20227 d. However, the RMS considers that there is significant uncertainty around these values due to their extrapolation beyond the study duration, and that they are clear anomalies when compared to the rest of the acceptable data set. The RMS therefore considers that the end-points derived from this study should be excluded	PRAPeR 67 (20 – 24 April 2009): Open point fulfilled. New open point proposed, see below.

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
			from the geometric mean DT50 calculation. Full details of the fitting and the RMS considerations are presented in Addendum 2.	
	New open point: 4.21 RMS to include in the LoEP and in the calculation the median of the HS DT50 value derived for the top soil of the lysimeter, and to check the normalisation for moisture (however no impact on median since the DT50 concerned is not the median value).			PRAPeR 67 (20 – 24 April 2009): Open point open. RMS: [28/05/09] Action completed. DFOP fits from soil added to LoEP. Median value reported instead of geamean in soil rate of degradation table. Written procedure (October-November 2009): Open point fulfilled.
	Open point: 4.5 MSs experts to discuss in a meeting the requirement of a new soil photolysis study. See reporting table 4(7)	DAS: It is clear that soil photolysis is not a major route of degradation and therefore support the opinion of the RMS regarding the importance of soil photolysis *"that it is not considered important"* for the representative use. The notifier highlights that a new soil photolysis study is in preparation for Annex III/MS en-use product submissions.	RMS: 08.04.09 Previous comments made by the RMS in the Reporting Table are reproduced below for ease of reference. [RMS 04.02.09: Our opinion regarding the importance of soil photolysis for the representative use is clear, i.e. we do not consider it important. However, the issue as to whether this should subsequently be considered a data	PRAPeR 67 (20 – 24 April 2009): Open point fulfilled. New open points 4.22 and 4.23 are proposed, see below.

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
			gap could be considered by an expert meeting.]	
	New open point: 4.22 EFSA to indicate a data gap in the EFSA conclusion (lack of valid soil photolysis study).			PRAPeR 67 (20 – 24 April 2009): Open point open. Written procedure (October-November 2009): Open point fulfilled.
	New open point: 4.23 RMS to remove all current entries in the box soil photolysis and replace with 'data gap'.			PRAPeR 67 (20 – 24 April 2009): Open point open. RMS: [28/05/09] Action completed. Requested amendments have been made. Written procedure (October-November 2009): The box of soil photolysis was amended by EFSA. Open point fulfilled.
4.2	Point of clarification for the notifier: Notifier to clarify the column	DAS: the notifier highlights that the data in this table shows some intermediate extraction results and	RMS: 08.04.09 The RMS considers that the Notifier has not clarified what the column	PRAPeR 67 (20 – 24 April 2009): Point of clarification regarded as

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
	names and that what the values in the table exactly mean in the study by Knowles, S., Schnöder, F., 2003a (the table of concern is referenced in the DAR as Table B.8.33). It should be noted that pending on the information submitted by the notifier new DT_{50} and PECsoil calculation might be needed. See reporting table 4(12)	shows some of the difficultly in successfully extracting residues at the low levels observed in the study. As the data represents the 0 – 10 cm layer and the DT50 from this study was taken from the combined total radioactivity in the 0 – 20 cm layer (conservative worst case) the actual values in table B8.33 have not been used in the kinetic analysis (DT50 calculation). Subsequently a conservative DT50 value has been used in the PECsoil calculation. New field dissipation data to be considered at Member State level will show that the DT50 value of 49 days is an over estimation of the field dissipation for picloram.	names mean. The RMS did supply some clarification in the reporting table 4(12) on this point but the Notifier was asked to confirm/ clarify. However, the Notifier is correct in stating that the DT50 was based upon total extractable radioactivity in the 0 – 20 cm layer, and is therefore conservative.	addressed.
	Open point: 4.6 MSs experts to discuss in a meeting to cancel the DT_{50} of 14 days derived from the study by Knowles, S., Unsworth, C., 2003 from the LoEP. See reporting table 4(14)	DAS: The notifier agrees with the conservative approach taken by the RMS in using this value to represent the worst case field DT50 value. New field dissipation data can be considered at Member State level. Updated soil dissipation kinetics will therefore be used for MS Annex III submissions.	RMS: 08.04.09 Previous comments made by the RMS in the Reporting Table are reproduced below for ease of reference. [RMS 04.02.09: We included this value in the endpoints principally because, whilst the basis of the calculation is not ideal, it leads to the longest field dissipation DT50 value and thus it's use in PECsoil calculation	PRAPeR 67 (20 – 24 April 2009): Open point fulfilled. New open point proposed, see below.

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
			arguably represents a more precautionary approach.]	
	New open point: 4.24 RMS to remove the 14 d value from the LoEP and delete the geomean field DT50 value (not pertinent to this exposure assessment).			PRAPeR 67 (20 – 24 April 2009): Open point open. RMS: [28/05/09] Action completed. 14 d value and geomean value deleted. Written procedure (October-November 2009): Open point fulfilled.
	Open point: 4.7 MSs experts to discuss in a meeting to include the Koc values (or any of them) from the study Knowles, S., Swales, SA., 2002 in the LoEP. See reporting table 4(17)	DAS: The notifier believes the mean Koc from the guideline study Knowles, S. 2000 which includes 8 representative EU soils provides a representative Koc value for picloram. The additional 3 values in the study Knowles, S., Swales, S.A. 2002 would not significantly impact the overall value.	RMS: 08.04.09 The mean value calculated from the 8 soils and used as input values for FOCUS modelling was 35 mL/ g which compares to a mean Koc of 37 mL/ g had the additional 3 soils been used. Previous comments made by the RMS in the Reporting Table are reproduced below for ease of reference. [RMS 04.02.09: We are not sure why the Koc values from the Knowles and Swales 2002 study were excluded as they appear to have been appropriately derived. Adding the	PRAPeR 67 (20 – 24 April 2009): Open point fulfilled.

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
			three additional Koc values raises the average Koc to 37. Thus there would be no practical impact on the risk assessment.]	
	Open point: 4.8 MSs experts to discuss in a meeting to include in the LoEP and use in the PEC calculations 1 as 1/n instead of 0.9. See reporting table 4(18)	DAS: The approach taken at the time of the original submission utilised the FOCUS default value for 1/n of 0.9 and has been assessed with laboratory DT50 values for the PECgw calculations. This assessment utilising the laboratory DT50 values represents a conservative approach. Using fully compliant field dissipation data from studies included in the original submission along with additional studies clearly demonstrates no issue for the ground water assessment. The new compliant field dissipation studies and associated ground water risk assessments will be used for end-use product Annex III/MS submissions. (Study ref: GHE-P-11865).	RMS: 08.04.09 At the time of the original evaluation the evaluating officer considered that a 1/n value of 1.0 may be more scientifically appropriate, but guidance indicated that a value of 0.9 should be used. However the RMS considers it inappropriate to retrospectively apply new guidance, and considers it even more inappropriate to retrospectively apply relatively new scientific opinion which contradicts previous guidance. The RMS notes that the Notifier has submitted a new study (Ref: GHE-P-11865), detailing revised DT50 calculations from field studies. However, this study has not been assessed in detail by the RMS, as in accordance with Regulation (EC) No 1095/2007, these data cannot be taken into consideration in the peer review. The RMS notes that two of the studies from which DT50 values have been calculated have not been assessed by the RMS. Previous comments made by the RMS	PRAPeR 67 (20 – 24 April 2009): Open point fulfilled.

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
			in the Reporting Table are reproduced below for ease of reference. [RMS 04.02.09: At the time of the assessment, we considered that we should comply with the FOCUS Groundwater guidance in respect of the default 1/n, i.e. 0.9. Use of a 1/n of 1 is considered to be more appropriate by many experts in such circumstances, but is not official guidance, thus it was difficult to argue against the official guidance.]	
	Open point: 4.9 MSs experts to discuss the need of new PECgw and PECsw calculations for picloram. If they are regarded as needed, the proper input parameters to be used should be discussed. See reporting table 4(18)	DAS: The notifier agrees with the comment made by the RMS that at the time of the assessment, to comply with the FOCUS Groundwater guidance, the default 1/n value was 0.9. Also see notifier's comments under open point 4.8 with respect to lab and field DT50 values. With respect to PEC Surface Water a change in 1/n from 0.9 to 1 has minimal impact.	RMS: 08.04.09 Whether or not new modelling is required is dependant upon the outcome of open points 4.1, 4.3 (& point of clarification 4.1), 4.4, 4.8 and 4.11 in this evaluation table. However, the RMS is of the opinion that either no change to input parameters is justified or that any changes to input values are likely to have little impact on any PEC values which would subsequently be calculated. Therefore the RMS considers that new modelling is not required for annex I listing purposes.	PRAPeR 67 (20 – 24 April 2009): Open point fulfilled. New open point proposed, see below.
	New open point: 4.25 RMS to provide new PECgw,			PRAPeR 67 (20 – 24 April 2009):

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
	$PEC_{SW,}$ PEC_{SED} calculations. For PEC gw two models should be used. For the new input parameters refer to Discussion table at open point 4.9.			Open point open. RMS: [28/05/09] Action completed in part. New groundwater modelling has been performed and is reported in Addendum 4. The relevant changes have been made to the LoEP. New FOCUS Step 3 modelling has not been performed. In the original evaluation an acceptable risk was displayed at step 1, and lower concentrations were observed at Step 3 than either step 1 or 2. Step 1 and 2 calculations have been performed with the revised input parameters, which display an acceptable risk with a large 'margin of safety'. These are reported in an addendum and the LoEP has been amended accordingly. Therefore given the large 'margin of safety' based on the step 1 PEC and the time constraints in the current peer-review process we do not view it pertinent to perform Step 3 modelling at this stage. Written procedure (October-November 2009):

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
				Open point fulfilled.
	Open point: 4.10 RMS to include information and results on the series of test solution containing both picloram and sodium benzoate in an addendum. Remark: 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). See reporting table 4(20)	DAS: The notifier agrees with the position of the RMS in the reporting table and has no further comments.	RMS: 08.04.09 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. A statement to this effect has been added to Addendum 2. The RMS apologises for any confusion caused.	PRAPeR 67 (20 – 24 April 2009): Open point fulfilled.
	Open point: 4.11 MSs experts to discuss in a meeting the proper DT_{50} values (for water and sediment) to be used in the PECsw calculations for picloram.	DAS: The notifier supports the comments of the RMS in the reporting table and has nothing further to add.	RMS: 08.04.09 Previous comments made by the RMS in the reporting table are reproduced below for ease of reference. [RMS 04.02.09: The DT50 in water of 135 days is a dissipation DT50, i.e. overall rate of disappearance from the	PRAPeR 67 (20 – 24 April 2009): Open point fulfilled.

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
	See reporting table 4(23)		water phase, not a degradation-only DT50. For FOCUSsw modelling, at the time (pre-FOCUS Kinetics guidance) it was considered better to use a conservative DT50 of 300 days for the water degradation (as there was significant partitioning to sediment) and the geomean whole system DT50 to represent the sediment degradation. It is considered that this is an appropriate approach for an evaluation conducted pre-FOCUS Kinetics.]	
	Open point: 4.12 MSs experts to discuss in a meeting the proper formation fraction (or 'application rate') to be used in the PECsw calculations for the metabolites. See reporting table 4(24)	DAS: see notifiers commnets under previous point (open point 4.11)	RMS: 08.04.09 Previous comments made by the RMS in the reporting table are reproduced below for ease of reference. [RMS 04.02.09: We accept the observation made. However, there was no guidance available at the time of the evaluation (and none now) as to how to treat such instances. It is considered that the approach taken in the DAR is reasonable in the light of available guidance. In addition, given the dynamic water bodies considered at FOCUSsw Step 3, and the relatively slow formation of the metabolites in the water sediment systems, it is considered that in reality, even if higher formations were to be	PRAPeR 67 (20 – 24 April 2009): Open point fulfilled. See new open point 4.26

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
			considered as input parameters, the flow dynamics would prevent significant formation in the simulation if TOXSWA were able to simulate formation of the metabolites.]	
	Open point: 4.13 RMS to include an assessment of the degradation and adsorption in soil of aminopyralid (=3,6-dichloro analogue) in an addendum. See reporting table 4(27)	DAS: No further comment.	RMS: 08.04.09 The requested information from the aminopyralid DAR has been added to Addendum 2 for picloram as requested. However, information for the adsorb/ desorb studies is complicated because additional information was received by the RMS after both the DARs for picloram and aminopyralid were completed. This information 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 is also added to Addendum 2 for picloram for ease of reference. However, the RMS considers that this additional information does not significantly affect the PECsw values calculated for aminopyralid as a result of the	PRAPeR 67 (20 – 24 April 2009): Open point fulfilled.

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
			proposed use of picloram. The RMS considers all other input parameters used for aminopyralid in surface water modelling reported in the DAR for picloram to be appropriate. The RMS considers the open point closed.	
	Open point: 4.14 MSs experts to discuss in a meeting whether the input parameters for the metabolites used in the PECsw calculations are agreed. See reporting table 4(27)	DAS: No further comment.	RMS: 08.04.09 Previous comments made by the RMS in the reporting table are reproduced below for ease of reference. Also See comments in open point 4.13 above. [RMS 04.02.09: The evaluation of the aminopyralid adsorption study can be included in an addendum. Alternatively, EFSA and MS can consult the aminopyralid DAR on CIRCA.]	PRAPeR 67 (20 – 24 April 2009): Open point fulfilled. New open point proposed, see below.
	New open point: 4.26 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			PRAPeR 67 (20 – 24 April 2009): Open point open. RMS: [28/05/09] Action completed. Step 1 and 2 FOCUS SW calculations performed for the metabolites and reported in an

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
	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.			addendum. The LoEP has also been amended appropriately. Written procedure (October-November 2009): Open point fulfilled.
	Open point: 4.15 EFSA to include in EFSA conclusion a recommendation for restriction of timing of application to spring. See reporting table 4(29)	DAS: the notifier highlights that the Spring use is supported by the lab DT50 values and subsequent PEC Groundwater calculation. However, a less restrictive practice (ie: autumn uses) will be likely using the previously submitted and additional field DT50 values and re-calculated PEC Groundwater assessment for end-use product Annex III/MS submissions.	RMS: 08.04.09 The open point relates to an action for EFSA and the RMS therefore has no further comments.	PRAPeR 67 (20 – 24 April 2009): Open point open. EFSA to include in EFSA conclusion a recommendation for restriction of timing of application to spring and not more frequently than once every 3 years. Written procedure (October-November 2009): Open point fulfilled.
4.3	Point of clarification for the notifier: Notifier to submit the information on recalculation of field kinetics for picloram to the RMS. See reporting table 4(30)	DAS: As indicated by the RMS in the reporting table, field kinetics have been submitted as part of the original PEC Groundwater assessment. This initial assessment utilised the data from 4 field dissipation studies. During the evaluation of the dossier, the RMS was not confident of using data from 2 of the 4 field dissipation studies and therefore all subsequent Groundwater kinetic analysis was based on lab data.	RMS: 08.04.09 Previous comments made by the RMS in the reporting table are reproduced below for ease of reference. [RMS 04.02.09: This issue is addressed in the DAR and discussed with the Notifier prior to finalisation of the DAR. The RMS was not confident of using the data from these two sites even following discussion, hence the	PRAPeR 67 (20 – 24 April 2009): Point of clarification addressed.

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
		Recalculation of the already submitted field kinetics but utilising only the 2 field dissipation studies the RMS is confident with would not represent the most conservative assessment. The notifier believes the initial PEC Groundwater assessment can be taken to support the field kinetics in this submission. Using fully compliant field dissipation data from the 2 studies the RMS is confident of using along with additional studies clearly demonstrates no issue for the PEC ground water assessment.	outcome described in the DAR.]	
	Open point: 4.16 If RMS accepts this information on recalculation of field kinetics for picloram from the notifier, RMS to evaluate in an addendum. See reporting table 4(30)	DAS: see notifier's comments under previous point (point 4.2)	RMS: 08.04.09 See previous comments made in reporting table 4(30) and Notifiers comments in point of clarification 4.2 in this evaluation table.	PRAPeR 67 (20 – 24 April 2009): Open point closed.
	Open point: 4.17 RMS to revise LOEP in light of EFSA comments. See reporting table 4(32)	DAS: No further comment.	RMS: 08.04.09 The LoEP has been updated as requested in the reporting table. The RMS notes that the comment made re: the PECsw box actually relates to degradation in water/ sediment.	PRAPeR 67 (20 – 24 April 2009): Open point open. RMS to update the LoEP as indicated in Column 3 of the discussion table.

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
			Re: the comment on quantum yield, the RMS cannot identify where this value has originated from. Notifier to clarify or RMS to amend to make consistent with the value reported in the Phys/ chem. props section.	RMS: [28/05/09] Action completed. LoEP has been amended as requested. Written procedure (October-November 2009): EFSA has deleted the step 3 calculations as these were not updated. The questioned value for quantum yield has already been cancelled by the RMS. Open point fulfilled.
	Open point: 4.18 RMS to amend list of tests and studies relied upon in light of EFSA comments. See reporting table 4(33)	DAS: No further comment.	RMS: 08.04.09 The list of tests and studies relied is to will be updated as appropriate at the end of the peer review process. RMS: 19 June 2009 The list of tests and studies relied upon has been updated (June 2009).	PRAPeR 67 (20 – 24 April 2009): Open point open. Written procedure (October-November 2009): Open point open.
	New open point : 4.27 RMS to amend the residue definition for further assessment in line with the conclusions of PRAPeR 67 meeting. (refer to Discussion table)			PRAPeR 67 (20 – 24 April 2009): Open point open. RMS: [28/05/09] Action completed. LoEP has been amended as requested.

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
				Written procedure (October-November 2009): Open point fulfilled.
	Message from section 1 (phys-chem) to section 4: A new water solubility study is required, it is expected that water solubility will be (even) higher than the value established now.			PRAPeR 67 (20 – 24 April 2009): Answer: Noted.

5. Ecotoxicology

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
	Section 5 Open points: ***6*** Points for clarification: ***0*** Data gaps: ***0***			Section 5 Open points: ***0*** Points for clarification: ***0*** Data gaps: ***0***
	Open point: 5.1 RMS to address in an addendum explanation of conversion factor use to convert the acute endpoint from mallard duck study (Beavers 1986a) from picloram potassium salt (2250 mg picloram potassium salt/kg bw) to picloram acid equivalent (1994 mg ae/kg bw). See reporting table 5(1)	DAS: In the study, 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).	RMS: 08.04.09 An explanation of the conversion factor is provided by the Notifier and is discussed further in DAR Addendum 2. Open point addressed.	PRAPeR 68 (4 – 8 May 2009): Open point fulfilled.
	Open point. 5.2 RMS to address in an addendum explanation of conversion factor of 0.864 use 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.	DAS: As 5 (1).	RMS: 08.04.09 As 5.1 in relation to conversion factor. The body weight and food consumption data mentioned have been added to Addendum 2 to the DAR. Open point addressed.	PRAPeR 68 (4 – 8 May 2009): Open point fulfilled. New open point proposed, see below.

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
	mean body weight and food consumption table included in the reporting table). See reporting table 5(3)			
	New open point: 5.7 RMS to clarify the LoEP (report the short-term endpoints both for ae and salt and add the conversion factor in a footnote).		RMS: 05.06.09 The LoEP have been updated to include avian endpoints in terms of both acid equivalent or salt - and a footnote has been added regarding the conversion factor. Open point addressed.	PRAPeR 68 (4 – 8 May 2009): Open point open. RMS: 05.06.09 See response in Column C and Addendum 4. LoEP now updated. Open point addressed.
	Open point: 5.3 More details on acute and long-term endpoints for mammals used for risk assessment in the German national authorisation would be needed to decide if they are relevant for picloram peer review. Could, please, Germany provide this information? See reporting table 5(4)	DAS: Endpoints align with those given in the Toxicology section	RMS: 08.04.09 This is also a point for the German authority. Currently the mammalian endpoints align with those given in the Mammalian Toxicology section. If these should change as a result of discussions in that area, then further consideration of their relevance to wild mammal risk assessment will be undertaken (see 5.4). No change to these endpoints is proposed at present. RMS: 05.06.09 In light of discussions at the Ecotox and MamTox PRAPeR meetings (68 & 69), a revised mammalian long-term endpoint for use in the Ecotox risk	PRAPeR 68 (4 – 8 May 2009): Open point still open. RMS to crosscheck the endpoints with the mammalian toxicology section and update LoEP if necessary. RMS: 05.06.09 See response in Column C and Addendum 4. LoEP updated. Open point addressed.

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
			assessment is proposed. This is the rabbit developmental NOEL of 300 mg picloram/kg bw/d (from study with TIPA salt). This is considered conservative because of the uncertain ecotoxicological relevance of the foetal effects seen at the highest test doses. However, it was the decision of PRAPeR 68 to use the rabbit developmental endpoint. The long-term wild mammal risk assessment in the DAR has now been revised in Addendum 4 and the LoEP has also been updated. Open point addressed.	
	Open point: 5.4 MSs to discuss in a PRAPeR expert meeting the endpoint to be used for risk assessment to mammals, if necessary. See reporting table 5(4)	DAS: No further comments	RMS: 08.04.09 This is reliant upon point 5.3 above. If necessary, then there could be further consideration at PRAPeR of the endpoints most relevant to wild mammal risk assessment. No change to these endpoints is proposed at present.	PRAPeR 68 (4 – 8 May 2009): Open point closed. See open point 5.3
	Open point: 5.5 RMS to include in an addendum full data on cell count, biomass and growth rate from Desjardins 2001 study, as it was done for metabolite studies on algae in tables B.9.12 to B.9.18 of	DAS: The notifier agrees with the comment.	RMS: 08.04.09 This information has been added to Addendum 2 to the DAR. Open point addressed.	PRAPeR 68 (4 – 8 May 2009): Open point fulfilled.

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
	the DAR. See reporting table 5(5)			
	Open point: 5.6 RMS to address in an addendum explanation of conversion factor use to convert the endpoint from se*lenastrum capricornutum* study (Hughes, 1990) from picloram potassium salt to picloram acid equivalent. See reporting table 5(6)	DAS: In the study, all exposure levels were expressed in terms of measured 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).	RMS: 08.04.09 As 5.1.	PRAPeR 68 (4 – 8 May 2009): Open point fulfilled.
	Message from section 5 to section 2 (mammalian toxicology): What is the developmental NOAEL from the rabbit developmental study with potassium salt (page 115 of the DAR)?		RMS: 05.06.09 See response to Open Point 5.3 above. Point addressed.	Answer from section 2: 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: 05.06.09 See response to Open Point 5.3 above. Point addressed.
	Message from section 1 (phys-chem) to section 5: Please consider the			PRAPeR 68 (4 – 8 May 2009): Answer:

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
	information on the tox and ecotox batches presented in Addendum 3 to Vol. 4.			There seem to be some inconsistency: information on purity of batches differs between the ecotox DAR/addendum and the addendum 3 to Vol.4. This should be checked by the RMS. New open point proposed, see below. The meeting considered that the impurity sulphuric acid (occurring in batch AGR274601 (1989), tested on Daphnia (chronic) and earthworm) is sufficiently addressed.
	New open point: 5.8 RMS to check the purity of all batches; there are differences between Table C.1.6 in addendum 3 of Vol.4 and DAR B.9. To be addressed in a revised DAR.		RMS: 05.06.09 The difference in purity and the levels of impurities between the different batches are low and are not considered to be ecotoxicologically relevant. A similar conclusion was reached in the MamTox meeting (PRAPeR 69) which stated: 'It was considered that the structures of the impurities were similar to the parent and no additional structures of clear toxicological concern were observed. Therefore the proposed levels were considered toxicologically acceptable. The impurities HCB and sulphuric acid were considered as relevant impurities, but not of concern at the proposed levels of 0.9% w/w for sulphuric acid and 0.005% w/w for	PRAPeR 68 (4 – 8 May 2009): Open point open. RMS: 05.06.09 See response in Column C Open point addressed.

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
			HCB'. Overall PRAPeR 69 concluded that the proposed levels of impurities in the technical specification presented in Addendum 3 Vol4 were considered toxicologically acceptable. The same conclusion is proposed regarding ecotoxicological relevance of the impurities. Open point addressed.	
	Message from section 4 (fate and behaviour) to section 5: PECsw have changed.		RMS: 05.06.09 Due to the revised PECsw values for the parent and main metabolites, a revised aquatic risk assessment is provided in DAR Addendum 4. The LoEP have also been updated. Revised acute and chronic TERs for picloram and its main metabolites were relatively small in relation to the numerically high TER values - and these still indicate low risks to all aquatic life. There is no change in the overall risk assessment conclusions. Point addressed.	PRAPeR 68 (4 – 8 May 2009): Answer: 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: 05.06.09 See response in Column C and Addendum 4. LoEP updated. Point addressed.
	Message from section 4 (fate and behaviour) to section 5: A restriction for use has been set for groundwater: picloram can only be applied in spring and only once per three years.			PRAPeR 68 (4 – 8 May 2009): Answer: No action required for ecotox.