TABLE OF CONTENTS

0. General

General				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
0(1)	Vol. 1, GAP table, p.10, Vol.3, GAP table, p.35, Vol.3, B.3.2.5 Conc. of a.s in material used, p.39, Vol.1, 1.5.3.3 p.12 Vol.1, LoEP, p.53	EFSA: clarification is needed concerning the values and/or units for the concentration of the active in the diluted spray is 0.02345 kg/L and the ones in the GAP tables. The unit in Vol. 3 is g/ha, while in Vol. 1 kg/ha. Taking the value of 23.45 g picloram/ha and 100L/ha water, the used concentration would be 0.2345 g/L	RMS 04.02.09 The correct table will be included in the revised end points.	Open point: RMS to include the correct GAP table in the list of end points
0(2)	Vol. 1 lev1 1.5.3.1 LoEP summary of representive uses Vol.3 B3.2.4 application rate Vol.3 B3.2.5 Concentration of active usage	FR: Unit of the application rate is different in the different tables (g/ha or kg/ha) Please RMS correct.	RMS 04.02.09 The correct table will be included in the revised end points.	See open point in comment 0(1)
0(3)	Vol. 1, GAP table, p.10, Vol.3, GAP table, p.35, Vol.3, B.3.2.5 Conc. of a.s in material used, p.39, Vol.1, 1.5.3.3 p.12 Vol.1, LoEP, p.53, Vol. 1, 3.1 Background information, p.91	EFSA: the expression of the active substance used in a.e. might be correct in the practice, however theoretically it may contain any impurities of the technical which have the COOH group. We think the use of picloram would be more appropriate, as the name defines the acid.	RMS 04.02.09 This point will be considered when the end points are revised.	Open point: RMS to consider use of picloram rather than a.e. when revising the end points.

section 0 – General comments

General				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
0(4)	Vol. 1 and Vol.4, Technical specification and toxicological batches	EFSA: RMS could provide a comparison table (purity and impurities) between the technical specification and the toxicological batches (using the same unit to express the content, i.e. %(wet weight basis) or % (dry basis) or g/kg (wet weight basis) or g/kg (dry basis) to ease the comparison).	RMS 04.02.09: This will be provided in an Adddendum.	Open point: RMS to provide a comparison table between the technical specification and the composition of the toxicological batches, including a clear identification of the tested compound and the impurities.

General				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
0(5)	Vol. 1, Active substance Vol. 3, B.6, Toxicological tests	EFSA: The representative technical material (see section 1) is picloram acid. The formulation contains the monoethanolamine salt of picloram. It should be confirmed that this has been adequately addressed in the toxicological studies (no observed adverse effect levels should also be given in picloram acid equivalents). As far as possible for all the toxicological studies, it should be stated which compound/salt has been used and what was the purity. Furthermore, the bridging approach used for the different salts should be discussed in a meeting of experts, taking into account the EPA evaluation (results mentioned in Vol.3 p.92).	RMS 04.02.09:The core toxicological package has been performed with picloram acid with the exception of the developmental studies which were conducted using potassium and TIPA-salts of picloram due to difficulties encountered in gavage dosing with the acid. References have been made in other parts of the DAR to the US-EPA RED for picloram for the purposes of comparison. Comparable acute toxicity was seen for picloram acid, its salts and ester, however the salts and ester were found to be more irritant and were skin sensitisers. The results of 90-day rat studies using picloram acid and the tri-isopropanolamine salt indicate comparable toxicity. The results of 21-day rabbit dermal toxicity studies indicate comparable toxicity for the potassium and tri-isopropanolamine salts, but slightly greater toxicity for the ester possibly due to enhanced dermal penetration. No evidence of genotoxicity was seen in a range of studies performed with the isooctyl ester or tri-isopropanolamine salts of picloram	Open point: 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.

1. Physical/Chemical Properties; Details of Uses and Further Information; Methods of Analysis

Identity (B.1, Annex C)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
1(1)	Vol. 4, Table C.1.3. Analytical profile of batches p.8	EFSA: the manufacturing date of the 7 batches is missing	RMS 04.02.09: This information has not been provided by the Notifier. The Notifier should be asked to supply this information as a point of clarification.	Point of clarification for the applicant: Applicant to provide the manufacturing dates of the batches analysed in the 7 batch study.
1(2)	Vol. 4, Table C.1. Technical specification for impurities p.4 and Table C.1.3. Analytical profile of batches p.8	EFSA: the specification of the impurities not entirely supported by the batch data, it is not clear what was the basis of the specification for impurity 6 Isomer or the impurities found below 0.1 % in all batches (Guanidine, 4DCT, 4-aminate, 4-aminotet, amide, tet acid, 6-OH). If a justification was provided and the specification set based on QC data, EFSA would welcome a summary of the information presented as it was agreed on PRAPeR 21	RMS 04.02.09: RMS will prepare and addendum to address the justification of the specification levels.	Open point: RMS to present in an addendum the justification based on the QC data for the levels in the technical specification.
1(3)	Vol. 4, Table C.1. Technical specification for impurities p.4 and Table C.1.3. Analytical profile of batches p.8	EFSA: RMS clarified what happens with batches out of specification in case of impurity sulfuric acid, we assume that the same is valid for the relevant impurity HCB too, which also exceeds the specification in one of the batches (QK07162951)	RMS 04.02.09: We do not believe that the HCB content exceeds the specification in any of the batches. The specification level is set at 0.05 g/kg (0.005% w/w) The level found in batch QK07162951 is 0.00345% w/w which is < 0.005% w/w. There is a typing error in table C.1 which incorrectly gives the HCB content as 0.0005% instead of 0.005%.	Addressed: RMS to correct the typing error in table C.1 of Vol.4 concerning the HCB content See also 1(12)

Identity (B.1, Annex C)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
1(4)	Vol. 4, Table C.1.3. Analytical profile of batches p.9	EFSA: can we assume that quantification by internal or external standardisation means that the quantification was done using the analytical standards of the individual impurities, meeting at least the agreement during PRAPeR 36 meeting: *"Specificity of the analytical method for the determination of the impurities in the active substance as manufactured (requirement 4.1) can be suitably addressed by retention time match with reference standards.* *Confirmation of identity of impurities should be addressed under section 1.10/1.11"* No information is available about this confirmation.	RMS 04.02.09: Samples were quantified against analytical standards of the individual impurities. Information on the purity and structural identity of these standards (MS & MS/MS spectra) was included as an appendix to the study report and is considered acceptable.	Addressed. See also comments 1(9), 1(10)

Identity (B.1, Annex C)				
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1(5)	Vol. 4, C.1.2 c) analytical profile of batches	AT: The justification of the notifier accepted by RMS for higher specification of the impurity or impurities (?) should be presented in an addendum. In addition to impurity *4-Aminotet* the specification of the impurities *6 Isomer* and *6-OH TA* has to be clarified. For the impurities *Guanidine*, *4 DCT, Amide* and *tet acid* a justification for specification should be presented as it is not supported by batch analyses (all are <1g/kg).	RMS 04.02.09: See response to point 1 (2) above	See open point in comment 1(2)
1(6)	Vol. 4 C.1.2 c) analytical profile of batches	FR: The given certified values are not relied on with batches but RMS explained that a justification was given in the form of statistical analysis over a long period. Could a Summary of those statistical analyses be reported in volume 4. For transparency, could RMS precise the year of fabrication of the 7 batches used for batch analysis.	RMS 04.02.09: See responses to points 1 (1) and 1 (2) above	See open points in comments 1 (1) and 1 (2)
1(7)	Vol. 4, C.1.4.1 Methods of analysis for impurities p.11	EFSA: the LOD for the HCB method is not mentioned	RMS 04.02.09: The LOD was stated to be 1 ppm.	Addressed: RMS to report the LOD for HCB in a corrigendum
1(8)	Vol. 4, C.1.4.1 Methods of analysis for impurities p.11	EFSA: it is not clear which was the method used for the a.s. determination in the 5 batch analysis, was it the method used for the determination of the impurities?	RMS 04.02.09: The method used was *Method 1* as described in section B.5.1.1. This was not made clear in the DAR.	Addressed.

Identity (B.1, Annex C)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
1(9)	Vol. 4, C.1.4.1 analytical method - impurities	AT: Since no information concerning initial identification of the impurities is given in 1.10 confirmatory techniques are required.	RMS 04.02.09: See response to point 1(4) above	Addressed: See comment 1(4)
1(10)	Vol. 4 C.1.4.1 a) organic impurities	FR: The method used for determination of impurities in technical material is a HPLC-DAD with detection at 225 nm. This method cannot be considered specific as detection is only performed at one wavelength and not on full scan. Could RMS clarify.	RMS 04.02.09: Specificity is addressed by the fact that measurements were made against reference standards. Please see point 1(4) above.	Addressed: See comment 1(4), 1(9)
1(11)	Vol. 4, C.1.3 composition of the PPP	AT: The contents of the active substances should be expressed as the corresponding salts.	RMS 04.02.09: This information is provided in the footnote to the table describing the composition of the PPP.	Addressed.
1(12)	Vol. 4, Table C.1. Technical specification for impurities p.4 and Table C.1.2. Identity of impurities p.7	EFSA: in the case of the relevant impurity HCB there is a discrepancy between the values presented in the tables C.1 and C.1.2	RMS 04.02.09: There is a typo in table C.1 See response to point 1(3).	Addressed: See comment 1(3)
1(13)	Vol. 1, LoEP, FAO specification, p.50	EFSA: to avoid further misinterpretation probably it would be helpful to mention that the minimum purity of the FAO specification is on dry weigh basis	RMS 04.02.09: LOEP will be updated.	Open point: RMS to update LoEP to mention that the minimum purity of the FAO specification is on dry weigh basis

Identity (B.1, Annex C)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
1(14)	Vol. 1, LOE minimum purity	AT: The upper and lower limit of the TK should be inserted.	RMS 04.02.09: It is not clear what is meant by this comment. The technical material considered in the DAR is a TC and not TK. The FAO specification is for a TK, however only the minimum picloram content is given – there is no range supplied. RMS hopes that by providing clarification as requested in point 1 (13), this should address the concern.	Addressed: See also comment 1(13)
1(15)	Vol. 1, Appendix 3, Listing of End points, page 51, Vapour Pressure	DAS: Vapor pressure should be 8 x 10^{-8} Pa at 25°C (99.4%), not 8.00 x 10^{-8} Pa at 25°C (99.4%), Additional comment Significant figures should be 1	RMS 04.02.09: LOEP will be updated	Open point: RMS to update end points on vapour pressure
1(16)	Vol. 1, Appendix 3, Listing of End points, page 51, Solubility in water	DAS: Temperature should be 20°C, not 25°C	RMS 04.02.09: Agreed. LOEP will be updated	Open point: RMS to update end points on temperature for solubility to 20°C

Physical and chemical properties of the active substance (B.2.1)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
1(17)	Vol. 1, LoEP, Boiling point, p.51, Vol.3 B.2.1.2 p.8	EFSA: probably would be better to state that is decomposing at a given temperature	RMS 04.02.09: LOEP will be updated	Open point: RMS to update end points on boiling point.
1(18)	Vol. 1, LoEP, Flammability, p.52	EFSA: not highly flammable	RMS 04.02.09: Agreed. LOEP will be updated	Open point: RMS to update end points on flammability.

Physical and chemical properties of the active substance (B.2.1)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
1(19)	Vol. 3, B.2.1.1 boiling point	DE: Just for clarification, the given justification in the column "comment" is incorrect and not in compliance with the Directive 94/37/EC. However, there is no need to require any additional data.	RMS 04.02.09: Noted.	Addressed: RMS to update the justification given for boiling point in a corrigendum
1(20)	Vol. 3, B.2.1.5, vapour pressure	DAS: Vapor pressure should be 8×10^{-8} Pa at 25°C (99.4%), not 8.0×10^{-8} Pa at 25°C (99.4%), Significant figures should be 1	RMS 04.02.09: Noted	See open point in comment 1(15)
1(21)	Vol. 3, B.2.1.6, Volatility, Henry's law constant	DAS: spelling error - should be /mol at, not /molat	RMS 04.02.09: Noted	Addressed.
1(22)	Vol. 3, B.2.1.11 solubility in water and B.2.1.13 partition coefficient	AT: Was the effect on pH decreasing observed for log Pow determination as well?	RMS 04.02.09: No effect on pH was noted. This may be due to the higher concentrations of picloram in the solubility in water tests (by the nature of the test to determine water solubility) affecting the pH as commented in the DAR	Addressed: RMS to transfer the information from the col. 3 of the reporting table in a corrigendum.
1(23)	Vol.3 B.2.1.11	FR: The explanation given for the non-determination of solubility in water at pH 5,7 and 9 was not clear. Could RMS clarify.	RMS 04.02.09: Picloram is a strong acid and this affected the pH values of the buffer solutions when the sample was added during the test. In the study report it was noted that the use of stronger buffers did not solve the problem. The Notifier concluded that the concentration of buffer ions needed to maintain a correct pH during the solubility test would adversely affect the test therefore no further work was conducted.	Addressed: RMS to transfer the information from the col. 3 of the reporting table in a corrigendum
1(24)	Vol. 3, B.2.1.13, Partition co-efficient	DAS: pH buffer $\log_{10}P_{OW}$ should = 0.057 to 0.248, not -0.057 to 0.248	RMS 04.02.09: Noted.This is a typing error.	Addressed: RMS to correct the typing error in a corrigendum

Physical and chemical properties of the active substance (B.2.1)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
1(25)	Vol.3 B.2.1.18	FR: Due to the structural formula of the active substance (an amino acid like) FR is of the opinion that another pKa (NH3+/NH2) should be investigated.	RMS 04.02.09: We believe that the data requirement is addressed however will ask the notifier to consider this issue	Point of clarification for the applicant: To address the possibility of a second pKa due to the structural formula of the active substance (an amino acid like)

Physical, chemical and technical properties of the formulation (B.2.2)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
1(26)	Vol. 3, B.2.2.9, Acidity / alkalinity	DAS: Add to reference Author of Comb, A.L. 2004 for reference to pH (neat): 7.3 at 20°C Roulin, S. references the pH of the neat formulation as 7.24.	RMS 04.02.09: Noted – data list to be amended.	Open point: RMS to amend list of tests and studies relied upon concerning pH
1(27)	Vol. 3, B.2.2.13, Relative Density	DAS: Reference should be changed to Comb, A.L. 2004, not Roulin, S. 2001 Roulin, S. references the relative density to be 1.1688.	RMS 04.02.09: Noted – data list to be amended.	Open point: RMS to amend list of tests and studies relied upon concerning relative density
1(28)	Vol.3, B.2.2.18 Persistent foam, p.24	EFSA: the foam after 1 minute should be reported	RMS 04.02.09: The foam after 1 minute = 0ml.	Addressed: RMS to include the information of the col. 3 of the reporting concerning the foam after 1 minute in a corrigendum See also comment 1(30)

Physical, chemical and technical properties of the formulation (B.2.2)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
1(29)	Vol.3 B.2.2.15 Vol.3 B.2.2.16	FR: The determination of relevant impurities after storage was not reported. FR is of the opinion that this data is required.	RMS 04.02.09: Determination of relevant impurities in the product are required if it is considered that the formation of the impurity during storage is likely. The Notifier should provide a justification as to why these data are not required.	Point of clarification for the applicant: Applicant to provide justification as to why the determination of relevant impurities after storage is not required See also comment 1(34)
1(30)	Vol.3 B.2.2.18 persistent foaming	FR: Only level of foam after 12 minutes was reported. FR is of the opinion that level of foam after other time should be reported.	RMS 04.02.09: See comment for point 1(28)	Addressed: See comment in point 1(28)

Further information (B.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
1(31)	Vol. 3, B.3.5.2 Procedures for cleaning application equipment	AT: The efficacy should be demonstrated.	RMS 04.02.09: Point of clarification for the notifier	Point of clarification for the applicant: Applicant to provide further information on procedures for cleaning application equipment to address the efficacy of cleaning

Classification and labelling (B.4)

For comments on classification and labelling see the relevant sections.

Methods of analysis (B.5)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
1(32)	Vol. 3, B.5.1.2. Analytical method for impurities, p.50,	EFSA: the method for relevant impurity is not confidential	RMS 04.02.09: Agreed. The information will be provided in an addendum	Open point: RMS to include the information on the method of analysis for the relative impurity in an addendum. See also comment 1(33)
1(33)	Vol.3 B.5.1.2 impurities	FR: FR is of the opinion that the method of determination of relevant impurity Hexachlorobenzen in technical material must not be classified as confidential and should be reported in B5 part.	RMS 04.02.09: See comments for point 1(32)	See open point in comment 1(32)
1(34)	Vol.3 B.5.1.3 Plant protection product	FR: FR is of the opinion that the method of determination of relevant impurity Hexachlorobenzen in PPP must be submitted.	RMS 04.02.09: Disagree. A method of analysis for relative impurities in PPPs is only required if the levels of the impurity are likely to increase during storage. Please also see comments for point 1 (29).	See point of clarification in comment 1(29)
1(35)	Vol. 1, LOE analytical methods-plant matrices	AT: The matrix grass should be deleted as no MRLs are proposed.	RMS 04.02.09: Disagree. If the method was fully validated for this matrix then the information should remain – we would usually report validation data/LOQ for all crop matrices for monitoring methods regardless of the proposed uses.	Addressed.
1(36)	Vol. 1, LoEP Monitoring methods for soil, p.50,	EFSA: the analytes should be indicated, as the GC-MS method is measuring picloram, while the LC/MS/MS the metabolite XDE-750	RMS 04.02.09: Agree. LOEP will be updated.	Open point: RMS to amend the LoEP concerning the analytes of the monitoring methods for soil See also comment 1(38)

Methods of analysis (B.5)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
1(37)	Vol. 1, LOE analytical methods-soil	AT: It should be indicated that the GC-MS method refers to the active substance and the LC-MS/MS method to the metabolite.	RMS 04.02.09: See point 1(37) above	See open point in comment 1(37)
1(38)	Vol. 1, LoEP Monitoring methods for water, p.50,	EFSA: the analytes should be indicated, as the GC-MS method is measuring picloram, while the LC/MS/MS the metabolite XDE-750	RMS 04.02.09: See point 1(37) above	Open point: RMS to amend the LoEP concerning the analytes of the monitoring methods for water See also comment 1(39)
1(39)	Vol. 1, LOE analytical methods-water	AT: It should be indicated that the GC-MS method refers to the active substance and the LC-MS/MS method to the metabolite.	RMS 04.02.09: See point 1(37) above	See open point in comment 1(38)
1(40)	Vol. 3, B.5.2, method 2 (GRM 00.19) plants, p.52, B.5.3.1 method 1 (GRM 00.18) soil, p.53, B.5.3.2 method 1 (GRM 00.17) water, p. 53	EFSA: Is there any information available in the residue methods about the assignment of the fragment-ions used for quantitation and confirmation, to be able to judge the acceptability of the number of fragment-ions used?	RMS 04.02.09: The information about the fragment ions taken from the study reports is already provided in the DAR for each of the methods; however the notifier provided additional information in the tier summaries of the dossier submission. Please also see responses to points 1 (41), 1 (42), 1 (43), 1 (45), 1(46), 1 (47) & 1 (48)	Open point: 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 See also comments in 1 (41), 1 (42), 1 (43), 1 (45), 1(46), 1 (47) and 1 (48)

Methods of analysis (B.5)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
1(41)	Vol. 3, B.5.2 method 2 (GRM 00.19) plants	AT: A confirmatory technique is required since only 2 fragmentations > m/z 100 are used for quantification and confirmation.	RMS 04.02.09: Noted. The Notifier has recommended that further confirmation can be obtained by re-analysing the samples using a different method. This method was not presented in the DAR. Alternatively the RMS suggest that the same approach for confirmation of other monitoring methods is used and another fragment ion is selected (m/z 220)	See open point in comment 1(40) See also comment 1 (42), 1 (43)
1(42)	Volume 3, B 5.2, Volume 3, B 5.3.1, Volume 3, B 5.3.2	DE: It should be discussed in a meeting of experts, if confirmation by one additional GC-MS ion (isotopic peak of [M-HCl]) is sufficient.	RMS 04.02.09: Please see responses to points 1 (40), 1 (41), 1 (43), 1 (45), 1(46), 1 (47) & 1 (48)	See open point in comment 1(40) See also comments in 1 (40), 1 (41), 1 (43), 1 (45), 1(46), 1 (47) and 1 (48)
1(43)	Volume 3, B 5.2	DE: Recovery and precision data of the confirmatory method (Hastings, 2003 a) should be presented in an addendum. Justification: "GC-MS is considered to be highly specific provided … fragment ions … were used for …quantification" (SANCO 825).	RMS 04.02.09: Disagree. Confirmation is by the use of a different fragment ion from the same measurement as the quantification ion. The guidance states that the ions should be reported however there is no mention of the need to provide validation data in this instance.	See open point in comment 1(40) See also comments in 1 (41), 1 (42)
1(44)	Volume 3, B.5.3.1, Volume 3, B.5.3.2	DE: Just for clarification, validation data are presented in table B.5.2 (and not in B.5.3 as written).	RMS 04.02.09: Noted.	Addressed.
1(45)	Vol. 3, B.5.3.1 method 1 (GRM 00.18) soil	AT: A confirmatory technique is required since only 2 fragmentations > m/z 100 are used for quantification and confirmation.	RMS 04.02.09: The Notifier has stated that additional ions that can be used for confirmation for this method include m/z 210, 212 and 250.	See open point in comment 1(40) See also comments in 1 (42), 1 (46)

Methods of analysis (B.5)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
1(46)	Volume 3, B.5.3.1	DE: Recovery and precision data of the confirmatory method (Hastings and Scheuermann, 2001 a) should be presented in an addendum. Justification: "GC-MS is considered to be highly specific provided … fragment ions … were used for …quantification" (SANCO 825).	RMS 04.02.09: Disagree. Confirmation is by the use of a different fragment ion from the same measurement as the quantification ion. There would therefore seem little point in providing recovery or precision data. The guidance states that the confirmatory ions should be *reported* however there is no mention of the need to provide validation data in this instance. Additional fragment ions to use for confirmation are discussed in point 1 (45).	See open point in comment 1(40) See also comments in 1 (42), 1 (45)
1(47)	Vol. 3, B.5.3.2 method 1 (GRM 00.17) water	AT: - A confirmatory technique is required since only 2 fragmentations > m/z 100 are used for quantification and confirmation. - The reported linearity range does not cover the range of fortifications unless dilutions of the samples have been performed. Clarification is requested. - The characteristics of surface water are missing.	RMS 04.02.09: a) The Notifier has stated that additional ions that can be used for confirmation for this method include m/z 210, 212 and 250. b) The method states that for sample solutions containing concentrations greater than 0.05 ug/ml dilution with internal standard solution is required to bring the samples into the linearity range. c) Information on surface water characteristics is not available in the study reports. The notifier will be asked to provide clarification.	a) See open point in comment 1(40) See also comments in 1 (42), 1(48) b) Addressed. c) Point of clarification for the applicant: Applicant to provide information on the characteristics of the water used in the method validations.

Methods of analysis (B.5)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
1(48)	Volume 3, B.5.3.2	DE: Recovery and Precision data of the confirmatory method (Hastings and Scheuermann, 2001 b) should be presented in an addendum. Justification: "GC-MS is considered to be highly specific provided … fragment ions … were used for …quantification" (SANCO 825).	RMS 04.02.09: Disagree. Confirmation is by the use of a different fragment ion from the same measurement as the quantification ion. There would therefore seem little point in providing recovery or precision data. The guidance states that the confirmatory ions should be *reported* however there is no mention of the need to provide validation data in this instance. Additional fragment ions to use for confirmation are discussed in point 1 (47).	See open point in comment 1(40) See also comments in 1 (42), 1(47)
1(49)	Vol. 3, B.5.3.3 method 1 (GRM 02.29) air	AT: The reported linearity range does not cover the range of fortifications unless dilutions of the samples have been performed. Clarification is requested.	RMS 04.02.09: The method states that for sample solutions containing concentrations greater than 2.0 ug/ml dilution is required to bring the samples into the linearity range.	Addressed.

2. Mammalian toxicology

Acute toxicity (B.6.2)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
2(1)	Vol. 3, B.6.2.3, Acute inhalation toxicity; Vol. 1, List of endpoints	DE: Only one study with the active substance is reported in which the maximum attainable concentration was extremely low. A further inhalation study with the potassium salt of picloram is mentioned elsewhere in the DAR suggesting that the LC_{50} was at least above 1.63 mg/L. For giving a more comprehensive picture, this value should be included in the endpoint list.	RMS 04.02.09: Noted	Addressed. RMS to consider in a revised list of end points.
2(2)	Vol. 3, Table B.6.2.5; Eye irritancy. P76, Table B.6.8	DAS: The mean score for corneal opacity presented in Table B.6.8 should be 0.11, not 0.33	RMS 04.02.09: Noted	Addressed. RMS to consider in a revised DAR or corrigendum.
2(3)	Vol. 3, B.6.2.6, Skin sensitisation; Vol. 1, 2.1.4, Classification and labelling	DE: It should be considered and discussed on the PRAPeR meeting to allocate the risk phrase R43 and classify picloram accordingly as "irritant". Justification: The current assessment is based solely on a (negative) Buehler test with 3 inductions that is usually regarded not sufficient to exclude a skin sensitising potential. Furthermore, evidence of sensitisation was found for the potassium and the TIPA salts and the isooctyl ester of picloram. For the proposed ARfD, e.g., studies with the salts have been taken into account.	RMS 04.02.09: Three inductions is the OECD agreed guidelines. However the Buehler test has other clear deficiences. In light of the results of the results provided in the EPA RED (1995) R43 should be considered at the PRAPeR meeting.	Open point: 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 salt.

Short-term toxicity (B.6.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
2(4)	Vol.3, B.6.3.1, Oral 13-week study in rats, p.78	EFSA: Considering the histopathological findings described in the table B.6.11, the NOAEL might be 150 instead of 300 mg/kg bw/day (at least for the females). Further details on the histopathological observations in the liver might be helpful to conclude on the NOAEL.	RMS 04.02.09: Based on the tables provided in the Addenda it could clearly be argued that the NOAEL is 150 mg/kg bw/day although this has no influence on the overall endpoints.	Open point: 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-yr rat study)

Long-term toxicity and carcinogenicity (B.6.5)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
2(5)	Vol. 3, B.6.5.1, Chronic toxicity and carcino-genicity in the rat	DE: In the elder study (Landry et al., 1986), the NOAEL is rather seen at the lowest dose of 20 mg/kg bw/day than at the mid dose level of 60 mg/kg bw/day. At this latter dose level, there were still significant increases in various histopathological findings in liver and pancreas.	RMS 04.02.09: In the case of pancreatic acinar atrophy the overall incidence in each of the treatment groups did not increase. However it would be more consistent with the 90 day study given the mechanism There is an increase in the incidence/severity of Hepatocyte hypertrophy (accompanied by 'altered tinctorial properties') at doses >60 mg/kg bw/day, it would be more consistent with the 90 day rat study to regard this as potentially adverse in the absence of mechanistic data demonstrating that this is an adaptive responce. This should be considered at the PRAPeR meeting as this has an impact on the ADI.	Open point: 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)

Long-term toxicity and carcinogenicity (B.6.5)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
2(6)	Vol.3, B.6.5.3, Summary of chronic toxicity, p.105-106	EFSA: According to Reuber, 1981(*), neoplasms at all sites, as well as malignant neoplasms, were increased in both low- and high-dose picloram-treated male and female rats. The malignant neoplasms were both carcinomas and sarcomas.This should be further considered in the evaluation of the carcinogenic properties of picloram. (*) Carcinogenicity of picloram, by Reuber Melvin Dwaine, Journal of Toxicology and Environmental Health, 7:207-222, 1981 → the rat study evaluated in this article is presumed to be one of the NTP studies referred to in the DAR Vol.3, B.6, p.106.	RMS 04.02.09: Noted	Open point 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 also comment 2(11).

Reproductive toxicity (B.6.6)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
2(7)	Vol. 3, B.6.6.2. Developmental toxicity in the rat, p.110	EFSA: Foetal findings are observed in both rat teratogenicity studies (at 430 and 560 mg/kg bw/d), in presence of a low maternal toxicity (430 was the maternal NOAEL in the first study and 560 was the maternal LOAEL in the second one with reduced BWG and salivation). These findings might be considered relevant for the derivation of the developmental NOAEL.	RMS 04.02.09: There are no findings which appear treatment related.	Open point The derivation of the developmental NOAEL in rats based on the foetal findings in both studies has to be discussed by the experts.
2(8)	Vol. 3, B.6.6.3a; 28-day dog study: summary of findings. p. 84, Table B.6.13	DAS: In Table B.6.13, liver weight for control females should correctly be 211.7, not 311.7	RMS 04.02.09: Noted	Addressed. RMS to consider in a revised DAR or corrigendum.
2(9)	Vol. 3, B.6.3.3b; Oral Short-term toxicity in the dog. P. 85	DAS: Last line under "Bodyweights and food consumption" should read "lower in <u>these</u> groups" not "lower in theses groups"	RMS 04.02.09: Noted	Addressed. RMS to consider in a revised DAR or corrigendum.
2(10)	Vol.3, B.6.4.1b Genotoxicity in vitro: CHO/HGPRT assay. P. 94	DAS: Line 5 should read "five concentrations between 250-<u>1250</u> µg/mL", not "five concentrations between 250-1000 µg/mL".	RMS 04.02.09: Noted	Addressed. RMS to consider in a revised DAR or corrigendum.

Reproductive toxicity (B.6.6)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
2(11)	Vol.3, B.6.5.1b Chronic toxicity and carcinogenicity in the rat. P. 100-101.	DAS: The submitted studies show that Picloram is not carcinogenic in rats or mice. The DAR notes '*some evidence of carcinogenicity…with a slightly increased incidence of hepatocellular adenoma in top dose females*' (500 mkd; Cosse et al., 1992). However, incidences were 2%, 2% and 6% in control, low and high dose groups, not statistically significant, within historical control range for the lab (0 to 8%) and without any pre-neoplastic liver lesions. This is normal variation, unrelated to treatment.. See also additional Dow comments	RMS 04.02.09: Given that the liver is a target it is not possible to say definitively these tumours are not treatment related.	See open point in 2(6).
2(12)	Vol.3, B.6.6.1 Multi-generation study in the rat. P. 109, Table B.6.25	DAS: Values for conception index for F0 males and females were switched in Table B.6.25. Male values should be: 89.7, 96.6, 86.2, 92.3; Female values should be: 86.7, 96.6, 83.3, 90.0.	RMS 04.02.09: Noted	Addressed. RMS to consider in a revised DAR or corrigendum.

Reproductive toxicity (B.6.6)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
2(13)	Vol.3, B.6.6.2a Developmental toxicity in the rat (K-salt), P. 111	DAS: The Notifier supports the proposed NOAEL of 1000mg/kg/d (Acid Equivalent of 860 mg/kg/d) and maintains that the increased incidence of excessive salivation was not toxicologically meaningful. Excessive salivation was observed only in developmental studies where Picloram was administered by gavage. The lack of similar observations in dietary studies with comparable or higher doses indicates that the effect can be attributed to gavage administration and is not the result of Picloram-mediated toxicity. See also additional Dow comments	RMS 04.02.09: Noted	Addressed. The relevant maternal NOAEL in the rat developmental studies is 280 mg picloram acid equivalents/kg bw/day (study with TIPA salt) based on decreased body weight gain and food consumption.

Reproductive toxicity (B.6.6)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
2(14)	Vol.3, B.6.6.3a Developmental toxicity in the rabbit (K-salt), p. 115	DAS: The Notifier affirms that the NOAEL for developmental effects should be set at 400 mg/kg (Picloram Acid Equivalents). The foetal alterations observed at the top dose of this study did not differ statistically from control. The two incidences of forelimb flexure were limited to a tendon anomaly and importantly were confined to a single litter. The high-dose findings were not observed in the rabbit teratology study with the bioequivalent TIPA salt or in any other developmental study with Picloram. See also additional Dow comments	RMS 04.02.09: Noted	Open point 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 also comment in 2(15).
2(15)	Vol. 3, B.6.6.3 Developmental toxicity in the rabbit (with TIPA salt), p.116	EFSA: In the second part of the study (Table B.6.30, p.120), the foetal findings observed at high dose might be taken into account for the derivation of developmental NOAEL of 300 mg/kg bw/day in the rabbit studies.	RMS 04.02.09: The incidences of external, visceral and skeletal malformations and variations were not affected by treatment. Although the incidences of a small number of findings were higher at the top dose level, they are sporadic in nature or marginally increased and lie within the laboratory's historical control range. In addition, there is no consistency with findings in the additional study phase.	See open point in 2(14).
2(16)	Vol. 3, B.6.6.3b Developmental toxicity in the rabbit (TIPA salt), p. 118, Table B.6.29	DAS: Table B.6.29 indicates 2 total resorptions each at 538 mg/kg/d and 1000 mg/kg/d; there were no litters totally resorbed in this study.	RMS 04.02.09: Noted	Addressed. RMS to consider in a revised DAR or corrigendum.

Reproductive toxicity (B.6.6)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
2(17)	Vol. 3, B.6.6.3b Developmental toxicity in the rabbit (TIPA salt), p. 120	DAS: A maternal NOAEL of 180 mg/kg/d (Acid Equivalent of 100 mg/kg/d) is supported by only limited effects on maternal body weight gain at this dose. A modest decrease in body weight was observed only at the day 7-10 interval and was due to decreased food consumption. The effect was minimal, corresponding to less than a 1% change in body weight. This minor effect was also transient with no overall negative impact on body weight or weight gain at study termination. No clinical or other findings indicative of toxicity were reported for animals treated with 180 mg/kg Picloram TIPA-salt. See also additional Dow comments	RMS 04.02.09: Noted	Open point 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).

Summary of mammalian toxicology and setting of ADI, AOEL and ARfD (B.6.10)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
2(18)	Vol. 3, B.6.10 Summary of mammalian toxicology and proposed ADI, AOEL, ARfD and MAC, p. 125	DAS: First line under Short-term toxicity: add comma after the word “rat”.	RMS 04.02.09: Noted	Addressed. RMS to consider in a revised DAR or corrigendum.

Summary of mammalian toxicology and setting of ADI, AOEL and ARfD (B.6.10)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
2(19)	Vol. 3, B.6.10 Summary of mammalian toxicology, p.127, Assessment of the impurity hexachlorobenzene (HCB)	EFSA: We agree that HCB is a toxicologically relevant impurity in the technical specification (see Vol.4). Since a level of 0.2 g/kg has been tested in some of the main tox studies, the proposed level of 0.05 g/kg in the technical specification seems to be covered.	RMS 04.02.09: Noted	Addressed.
2(20)	Vol. 3, B.6.10.1, ADI	DE: A slightly lower ADI of 0.2 mg/kg bw instead of 0.3 mg/kg bw is proposed. Justification: Usually, an ADI should be based on a long-term study. In case of picloram, the first study in rats employing rather low dose levels is considered the most suitable basis. Since the NOAEL in this study is seen at 20 mg/kg bw/day (see comment above), a numeric value of 0.2 mg/kg bw/day would result.	RMS 04.02.09: This is a result of the dose spacing in the two studies LOELs must also be considered.	Open point The derivation of the ADI has to be discussed by the experts. See also comment in 2(21).

Summary of mammalian toxicology and setting of ADI, AOEL and ARfD (B.6.10)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
2(21)	Vol. 3, B.6.10.1 Acceptable Daily Intake (ADI), p. 130	DAS: The Notifier supports the proposed ADI of 0.35 mg/kg 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 Notifier does not agree with using the rabbit developmental study and its corresponding NOAEL to set the ADI: 1.) A transient reduction in weight gain at an early time-point is not justifiable rationale for setting an ADI. 2.) The Notifier supports a maternal NOAEL of 100 mg/kg in the rabbit developmental toxicity study (point #10); therefore 35 mg/kg is the lowest NOAEL and should be used to derive the ADI. See also additional Dow comments	RMS 04.02.09: Noted	See open point in 2(20).
2(22)	Vol. 3, B.6.10.2, ARfD	DE: The need of and, if needed, the most appropriate basis for setting an ARfD should be discussed on the PRAPeR meeting.	RMS 04.02.09: Noted	Open point: The need for ARfD has to be discussed by the experts (and the derivation if needed). See also comment in 2(23).

Summary of mammalian toxicology and setting of ADI, AOEL and ARfD (B.6.10)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
2(23)	Vol. 3, B.6.10.2 Acute Reference Dose (ARfD), p. 130	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. See also additional Dow comments	RMS 04.02.09: Noted	See open point in 2(22).
2(24)	Vol. 3, B.6.10.3, AOEL	DE: Based on the NOAELs of 35 mg/kg bw/day in the 6-month and 1-year dog studies, a slightly higher value of 0.35 mg/kg bw/day instead of 0.3 mg/kg bw/day is proposed. Justification: If available (and, thus, the situation is different from ARfD setting), it is preferred to use studies that were performed with picloram itself and not with its salts as basis for setting reference values.	RMS 04.02.09: Based on the available data there are no differences in toxicity between the various forms of picloram. Picloram itself will be formulated as a salt.	Open point The derivation of the systemic AOEL has to be discussed by the experts. See also comments in 2(25), 2(26), 2(27).
2(25)	Vol. 3, B.6.10.3, AOEL	DE: A need for setting an additional dermal AOEL is not seen.	RMS 04.02.09: If a dermal AOEL can be set it is useful to set one and agree it at PRAPeR.	See open point in 2(24).
2(26)	Vol. 3, B.6.10.3a Admissible Operator Exposure Level (AOEL), P. 131	DAS: The Notifier maintains that the systemic AOEL is appropriately based on the maternal NOAEL for the rabbit developmental study (TIPA salt). However, the Notifier does not agree with the NOAEL of 30 mg/kg/d and maintains that the NOAEL was clearly and firmly established at 100 mg/kg/d (point #10) resulting in an AOEL of 1 mg/kg/day. See also additional Dow comments	RMS 04.02.09: Noted	See open point in 2(24).

Summary of mammalian toxicology and setting of ADI, AOEL and ARfD (B.6.10)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
2(27)	Vol. 3, B.6.10.3b Admissible Operator Exposure Level (AOEL), P. 131	DAS: The Notifier does not support the establishment of a dermal AOEL since the systemic AOEL is intended to account for, and address, all routes of exposure	RMS 04.02.09: Noted	See open point in 2(24).
2(28)	Vol. 3, B.6.10.4 Maximum Allowable Concentration, P. 131	DAS: The Notifier accepts the default MAC of 0.1 µg/l	RMS 04.02.09: Noted	Addressed.
2(29)	Vol. 3, B.6.10.12, Dermal absorption	DE: It is very unlikely that dermal absorption of the dilution was in fact by 30 times lower than that of the concentrate. Taking into account the human volunteer study, it is suggested to use a 3% estimate for both the concentrate and the formulation. This approach might cover a worst-case assumption but should be subject to PRAPeR meeting discussion.	RMS 04.02.09: discuss at expert meeting	Open point: 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 also comment in 2(30).

Dermal absorption (B.6.12)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
2(30)	Vol. 3, B.6.12.2. Dermal absorption, p.137, in vivo study with rats	EFSA: Several weaknesses are present in this study: a low recovery has been obtained with the concentrate (~85%), a 500-fold dilution has been tested whereas the highest dilution is ~1100-fold. Therefore it could be considered that a part of the amount located in the skin should be included as being absorbed. Has any tape stripping of the skin been performed during this study ?	RMS 04.02.09: The recoveries in the undiluted material were on the low side but very consistent. No tape stripping of the skin was performed.	See open point in comment 2(29).

Exposure data (B.6.14)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
2(31)	Vol. 3, B.6.14.1. Operator exposure, p.140	EFSA: It should be noted that since the application rate is only 0.35L of formulated product by hectare, the use of 1L pack might not be excluded as a worst-case approach.	RMS 04.02.09: The use of the1 litre container would require 18 separate mixing/loading operations. Whilst not being improbable, it is expected that a grower treating 50 ha would more typically use the larger 5 litre container. Either scenario gives an exposure within the AOEL for a operator wearing no PPE.	Addressed.

Exposure data (B.6.14)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
2(32)	Vol. 3, B.6.14.1, B.6.14.2 and B.6.14.3, operator exposure, bystander exposure and worker exposure	DE: On the basis of the proposed AOEL [c. f. comment (6)] as well as on the basis of the suggested dermal absorption (if applicable) the data should be re-calculated.	RMS 04.02.09: Should either of these values be revised an Addendum will be provided for the operator, bystander and re-entry exposure assessment.	Addressed. The need of revising the exposure calculations is pending the agreement of the AOEL and dermal absorption values by the experts.

3. Residues

Metabolism in plants (B.7.1)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
3(1)	Vol. 3, B.7.1.1, p. 155 Metabolism, distribution and expression of residues in plants – Oil seed rape	FR: Table B7.2: plotting %TRR 8.9 and 32.8, the sum is not 36.8 but 41.8 ; are these values correct? Also, only in the acetonitrile/water extract with the TLC mehod, the sum of %TRR is 100% (picloram + conjugates); how can we explain 32.8% TRR in the diethyl ester extract after hydrolysis?	RMS 04.02.09: The comment refers to the values for Day 84 stem samples. The % TRR values for the acetonitrile/water analysis for the TLC analysis are not correct. They are expressed as a % of the TRR in the extract rather than the overall TRR in the stem. The correct values for the acetonitrile/water extract TLC analysis should be: Picloram: 0.005 mg/kg (4% TRR), Conjugates: 0.051 mg/kg (40.8% TRR). This would then explain the 32% TRR in the diethyl ether extract.	Open point: RMS should provide the correct data relating to Table B7.2 in an corrigendum/ addendum as appropriate
3(2)	Vol. 3, B.7.1.1, p. 155 Metabolism, distribution and expression of residues in plants – Oil seed rape	FR: Could RMS please clarify “Ca 97% of this released radioactivity was identified as unchanged picloram.” (text following table B7.2)	RMS 04.02.09: This sentence means that when the additional radioactivity released by acid and basic hydrolysis of non-extracted residues (0.041 mg/kg for the stem and 0.0311 mg/kg for the chaff) was analysed, the major component found was parent picloram (97% of the released radioactivity = 0.040 mg/kg for the stem and 0.030 mg/kg for the chaff). The RMS hopes this clarifies the meaning	Addressed.

Metabolism in plants (B.7.1)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
3(3)	Vol.3, B.7.1.3 Rotational crop metabolism and B.7.1. Summary assessment	EFSA: It is not clear how the overdosing factor of 285 N was calculated. The application rate in the study was 0.583 kg ai/ha while the notified use is 0.02345 kg ai/ha. Not considering interception the overdosing factor is 25 N. Even if interception were considered (40% at GS 14) this would not result in an overdosing factor of 285 N. Clarification is necessary, since at N rate residues in food and feed possibly exceed the established trigger values. Re-evaluation of rotational crops residues is required.	RMS 04.02.09: Agree that the N rate is incorrect and should be 25N instead of 285N. A re-evaluation of the study will be presented in addendum/corrigenda to the DAR. The RMS believes that the proposal of a residue definition of parent only for following crops as proposed in the DAR is still applicable. When the correct N rate is considered the data indicate that residues in root crops and cereal crops would not be expected at significant levels (0.01mg/kg for commodities for human consumption, 0.05 mg/kg for animal feed items); however the potential for residues in leafy following crops is indicated.	Open point: RMS to present a re-evaluation of the rotational crop study, considering the correct application rate in an addendum See also comment in 3(4) Point of clarification for the applicant: To address the potential for residues in following crops as field trials in rotational crops seem to be triggered See also comment in 3(7)
3(4)	Vol. 3, B.7.1.3, p.159 Metabolism, distribution and expression of the residue in rotational crops	FR: the rate applied of 0.583 kg/ha does not correspond to 285N as the GAP states 0.02345 kg/ha. This rate corresponds to about 25N.	RMS 04.02.09: See point 3 (3) above	See open point in comment 3 (3)
3(5)	Vol. 3, B.7.1.4, p.166 Metabolism in plant – Summary/assessment	FR: "Crops were treated with picloram labelled in the 2,6 position of the ring at exaggerated dose rates". 1.7N is not really an exaggerated dose rate for oilseed rape; moreover no rate (GAP) was determined on wheat so this dose is not exaggerated.	RMS 04.02.09: The degree by which the study is described as "exaggerated" can be open to interpretation. We note this and will be more careful in our use of language in the future.	Addressed.

Metabolism in plants (B.7.1)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
3(6)	Vol. 3, B.7.1.4, Metabolism in plant – Summary/assessment	FR : see remark 3(1) above.	RMS 04.02.09: It's not clear what is meant by this comment as remark 3(1) refers to a table of results; however the RMS believes that the points above have been addressed.	Addressed.
3(7)	Vol. 3, B.7.1.4, p.168 Summary, assessment	FR: the treatment rate used in this study is of 25N and not of 285N. Further comment (Column 3) as the treatment rate used in this study is 25N instead of 285N and considering the results of analysis could be linear, the maximum rates found in samples and re-calculated at the 1N dose, are at detectable levels (>0.01 mg/kg). Thus, detectable residue levels could occur in rotational crops. A field study should be submitted.	RMS 04.02.09: See point 3 (3) above	See point of clarification for the applicant in comment 3(3)

Metabolism in plants (B.7.1)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
3(8)	Vol.3, B.7.1. Summary assessment and B.7.3 Residue definition	EFSA: It has been elaborated by the RMS that in plant material picloram is quickly conjugated but also easily released from conjugates after hydrolysis. The presence of significant amounts of conjugated picloram in plants was demonstrated in both the primary and rotational crop metabolism studies. However, only (free) picloram was proposed as the residue definition for oilseeds and cereals. For risk assessment purposes it should be considered whether conjugated picloram has to be included in the residue definition, taking also the residue picture in rotational crops into account.	RMS 04.02.09: The residue picture in rotational crops is similar to that in primary crops in that the metabolites found were considered by the Notifier to be conjugates that released unchanged picloram after hydrolysis. As discussed in point 3 (14) it is likely that the methods of analysis used are determining both free and conjugated picloram together as a hydrolysis step is involved, therefore this would have no impact on the risk assessment (as the results for the residue trials could be assumed to include free and conjugated picloram) .	Open point: 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 also comment in 3(14)

Metabolism in livestock (B.7.2)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
3(9)	Vol.3, B.7.2.2 Goat metabolism	EFSA: For future reference, to enable accurate comparison with the estimated livestock burden the administered dose in the study should be specified and expressed on a dry matter basis or mg/kg bw basis, respectively. If expressed on an 'as received' basis, the composition of the diet/ dry matter content of the diet used in the study needs to be reported for further conclusions.	RMS 04.02.09: Noted.	Refer to comment 3(11)

Metabolism in livestock (B.7.2)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
3(10)	Vol.3, B.7.2.2 Goat metabolism	EFSA: For future reference, can the impurities of the active substance that showed the same chromatographic behaviour as the non-polar components in the goat studies be named? The increased ratio of impurities to picloram in the fat residue (47:45) could be an indication for preferential accumulation of those impurities in fatty matrices.	RMS 04.02.09: Noted.	Not addressed. The point might be of relevance for future uses but can currently not be followed up further when not addressed by RMS.
3(11)	Vol. 3, B.7.2.2, p.169 Goats	FR: please explain how RMS obtained the 1N dose of 0.003 mg/kg diet for goats	RMS 04.02.09: The 1N dose rate was calculated using current EU guidance (SANCO 7031/VI/95 rev 4) based on the highest residues of 0.01 mg/kg in oilseed rape seed. The dietary burden calculation for domestic animals is presented in section B.7.16.1 of the DAR. As the study report indicated that the dose rate was on an "as received" basis the dietary burdens calculated as received were used for comparison. Even if the dose rate was calculated on a dry matter basis this would not significantly alter the risk assessment (burden = 0.0035 mg/kg diet DM, therefore the dose rate was 342N)	Addressed. See also comment in 3(9) and 3(12)
3(12)	Vol. 3, B.7.2.3, p.173 Poultry	FR: please explain how RMS obtained the 1N dose of 0.001 mg/kg diet for poultry	RMS 04.02.09: Please see the comments for point 3 (11) above	Refer to comment 3(11)
3(13)	Vol. 3, B.7.2.10, p.189 Residues in succeeding or rotational crops	FR : see remark 3(4) and 3 (7)	RMS 04.02.09: See point 3 (3) above	See open point in comment 3(3)

Use pattern, critical GAP, residues trials (B.7.4 to B.7.6)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
3(14)	Vol.3, B.7.6.1 Residue trials	EFSA: In most of the submitted radiolabel studies a hydrolysis step had already been included in the extraction procedure to determine free and conjugated picloram. In the field studies method GRM00.19 was used. Is the extraction procedure in this method suitable to cover also picloram in conjugated form?	RMS 04.02.09: Method GRM 0019 was evaluated in Section B.5.2 of the DAR as a potential monitoring method. Extraction is with basic methanol solution so there is indeed a hydrolysis step involved. However the extraction efficiency of the methods in releasing conjugated picloram is not known and it would therefore be an assumption that the methods are also covering conjugated picloram. Given the notified use on oilseed rape indicates an LOQ residues situation and the metabolism study on oilseed rape indicates that levels of both conjugates and free picloram will be < LOQ it is questionable whether it is necessary to ask for further information at this stage. This may need to be considered further in light of the revision of the rotational crop metabolism study	Open point: 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

Processing (B.7.7)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
3(15)	Vol.3, B.7.7 Storage stability	EFSA: It is noted that the storage period studied is shorted than the time that samples from the residue trials were stored for. Acceptability should be agreed by MS' experts.	RMS 04.02.09: We concluded in the DAR that although samples from the residue trials were stored for up to 27 months and storage data only covered 24 months, very little degradation occurred over 24 months and it was unlikely that residues will degrade significantly in the additional 3 months. Furthermore on closer inspetion of the field sampling ans extraction dates given tin the study reports the samples that were stored for longer then 24 months were the immature plant samples from the trials in Hungary. All samples taken at harvest maturity were storef for less than 24 month prior to anaylsis.	Open point: Acceptability of storage stability data in terms of the sample storage time in the field trials to be agreed by experts

MRLs related issues and Consumer Risk Assessment (B.7.10 to B.7.15)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
3(16)	Vol. 1, 2.4, Residues, Estimates of potential and actual exposures	DAS: As no Acute Reference Dose (ARfD) is required for picloram, the sentence 'The short term dietary intakes (NESTIs) for residues of picloram from the consumption of oilseed rape have been calculated for 10 consumer groups (UK diet). Based on acute exposure estimates for short term dietary exposure, intakes for all consumer groups are less than 1% of the ARfD of 0.3 mg/kg bw/day' should be removed.	RMS 04.02.09: We have concluded that an Acute Reference Dose (ARfD) is necessary therefore the acute consumer risk assessment should remain in the DAR.	Addressed. In case the toxicology experts agreed that no ARfD is necessary the acute assessment would become redundant. See also comments in 3(17) to 3(19)
3(17)	Vol. 1, Appendix 3, Listing of Endpoints	DAS: The entry for NESTI under Consumer Risk Assessment should be removed and replaced with 'n/a'.	RMS 04.02.09: We concluded that an Acute Reference Dose (ARfD) is necessary therefore the acute consumer risk assessment should remain in the LOEP	See comment in 3(16)
3(18)	Vol 3 B.7.16.2.2, Short term intakes - National Estimate of Short Term Intake (NESTI)	DAS: As no Acute Reference Dose (ARfD) is required for picloram, the section B.7.16.2.2 should be deleted and replaced with the sentence: 'As no ARfD is set for picloram, an acute dietary risk assessment is not required and has not been performed'.	RMS 04.02.09: We concluded that an Acute Reference Dose (ARfD) is necessary therefore the acute consumer risk assessment should remain in the DAR.	See comment in 3(16)

MRLs related issues and Consumer Risk Assessment (B.7.10 to B.7.15)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
3(19)	Vol. 3, B.7.17, Summary and evaluation of residue behaviour	DAS: The sentence 'The short term dietary intakes (NESTIs) for residues of picloram from the consumption of oilseed rape have been calculated for 10 consumer groups (UK diet). Based on acute exposure estimates for short term dietary exposure, intakes for all consumer groups are less than 1% of the ARfD of 0.3 mg/kg bw/day' should be removed.	RMS 04.02.09: We concluded that an Acute Reference Dose (ARfD) is necessary therefore the acute consumer risk assessment should remain in the DAR.	See comment in 3(16)

4. Environmental fate and behaviour

Route and rate of degradation in soil (B.8.1)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(1)	Vol. 3, B.8.1.1, Route and rate of degradation, Route study a), Knowles, S., Draisey, R., 2001	EFSA: the sampling times of the soils indicated in the text and in the tables (B.8.2 and B.8.3) are slightly different. RMS please check the time of soil sampling and whether the correct days were used in the kinetic calculations.	RMS 04.02.09: The original study report has been checked. The sample times in Tables B.8.2 and B.8.3 are correct. The text of the study report states that the incorrect sample times were used as nominal values in spreadsheet tables. Kinetic calculations were performed after the study and were performed with the correct sample time values.	Addressed
4(2)	Vol. 3, B.8.1.2, Route and rate of degradation Rate study a) and c), Knowles, S., Draisey, R., 2001; Knowles, 2004a and Cook, W.L., Buehrer, J.T., 1999	EFSA: If using the values in the relevant tables in the Walker equation (and temp. factor of 1.483 in the study c) from 20°C to 25°C) the normalised DT_{50} values would be slightly different. In the case of study c) all the DT_{50} values would be longer than the reported values.	RMS 04.02.09: We have rechecked the calculations for study a). The differences to the values in Table B.8.7 are at maximum 0.6 day and may be the result of rounding of results. This will make no practical difference to the risk assessment. We have checked the values in Table B.8.23. We confirm the results of our calculations as presented. Our method of calculation employs the activation energy and gas constant to calculate the correction factor, rather than being based on the Q10 of 2.2, thus it is possible that rounding of values may result in slightly different correction factors being produced. Nevertheless, we consider that the calculations conducted are valid. It may be worth noting that a similar comment in relation to temperature correction was received for the UK RMS evaluation of chlormequat, and our calculations subsequently accepted.	Open point: 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.

Route and rate of degradation in soil (B.8.1)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(3)	Vol. 3, B.8.1.2, Route and rate of degradation Rate study b), Knowles, S., Swales, S.A., 2002 Page 215, 4th paragraph & Tables B.8.12 and B.8.14	EFSA: The largest unknown compound is increasing at the study end (at least in 0-30 cm layer and might be also in 60-100 cm layer) reaching 5.7%AR on day 120. The argumentation supporting that these signals were artefacts is not satisfying (in general the paragraph is not clear). All peaks with radioactivity should come from the parent compound. Could RMS please further clarify the method of detection of this false fluorescence (luminescence?/UV absorption?)? Moreover is it correct that the amounts of Total unknowns are less than the Largest unknown in some cases?	RMS 04.02.09: The full explanation of this issue submitted by the applicant, including additional C-14 detector chromatograms, will be presented in an addendum to the DAR. It should be noted that the 'false fluorescence' indicated in the DAR actually refer to detections of radioactivity rather than UV absorption. The largest unknowns are at times equal to total unknowns, but are not greater than total unknowns. The anomalies highlighted in the comment will be corrected in the addendum.	Open point: 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.

Route and rate of degradation in soil (B.8.1)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(4)	Vol. 3, B.8.1.2, Route and rate of degradation Rate study c), Cook, W.L., Buehrer, J.T., 1999 Page 281 bottom and Table B.8.22	EFSA: The application rates used in the study as indicated are not equal with 134, 235, 504, 773 and 1052 g/ha (assuming even distribution in the top 5 cm layer of soil), they are much less, however still higher than the expected soil concentration resulted by the application of picloram according to the GAP. RMS pls check what were the application rates in the study (and compare with application rate according to the GAP/PECsoil) or clarify this calculation and that still only the DT50s from the experiments with the smallest dose should be used in the exposure calculations.	RMS 04.02.09: We have checked the study report. The g/ha application doses cited appear to have been calculated from doses calculated in lb/acre (study conducted in America). We have recalculated the g/ha doses from the nominal dose concentrations on the basis of 1.5 g/cm^3 bulk density and equal mixing in 5cm depth soil. Resulting g/ha doses are 0.07 µg/g – 52.5 g/ha 0.11 µg/g – 82.5 g/ha 0.25 µg/g – 187.5 g/ha 0.38 µg/g – 285 g/ha 0.52 µg/g – 390 g/ha Given that the dose in the representative use GAP is 23.5 g a.e./ha, it is considered that use of DT50s from the lowest dose is still appropriate.	Addressed RMS to include the correct doses (in terms of g/ha) applied in the study by Cook, W.L., Buehrer, J.T., 1999 in a corrigendum. See also 4(5) below.

Route and rate of degradation in soil (B.8.1)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(5)	Vol. 3, B.8.1.2, Route and rate of degradation Rate study c), Cook, W.L., Buehrer, J.T., 1999	EFSA: RMS please add data if there were information about microbiological activity of the soils during the study. Please give more argumentations which support the exclusion of the DT_{50} values calculated from the higher dose experiments. Moreover it would be nice to see the correlation between the dose and the degradation (please see also EFSA comment 4 above). Note: The inclusion/exclusion of the results of the study by McCall, P.J., Jeffries, T.K., 1978 (route b), rate d)) might depend on the acceptability of the argumentation as (in the DAR) these results are excluded for the same reason.	RMS 04.02.09: Additional information on mineralisation of another substance, 3,4-dichlorobenzoic acid, 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.	Open point: 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 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. Point of clarification for the applicant: Applicant 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).

Route and rate of degradation in soil (B.8.1)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(6)	Vol. 3, B.8.1.5, Summary and assessment	EFSA: The DT50 values from the Rate study b), Knowles, S., Swales, S.A., 2002 were reported (calculated by the RMS) in Annex B (not in the LoEP), but not used further in the exposure assessment without any argumentation. RMS please clarify why the DT50 values are not used further from this study.	RMS 04.02.09: Given the biphasic nature of the degradation in the top soil, and that at the time of evaluation the FOCUS Kinetics guidance was not available, we considered that the separate Hockey Stick DT50 values were not suitable for inclusion into the range of values for consideration of modelling. In addition, we considered it inappropriate to use the values from lower horizons as leaching models generally assume rate constants to be derived from top soils, with correction factors applied to slow the degradation in lower soil horizons. In response to this comment, we have investigated SFO kinetics for HAN 1 0-30cm soil using the FOCUS DEGKIN V.1 spreadsheet tool. SFO DT50 under study conditions is 94 days, chi^2 is 10.7 but with poor visual and residual fits (note that the r^2 value associated with this DT50, i.e. applying statistical criteria associated with pre-FOCUS Kinetics evaluations, is 0.777). Correcting this value for moisture (study was conducted at 20ºC and 40% of MWHC) gives an SFO DT50 of 87 days. Adding this value to the database of soils in Table B.8.35 of the DAR would increase the geomean DT50 to 51.6 days.	Open point: 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.

Route and rate of degradation in soil (B.8.1)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(7)	Vol. 3, B.8.1.3, Photolysis in soil Fontaine, D.D., Woodburn, K. B., 1986, & Vol. 1	EFSA: The light source used in the soil photolysis study was not accepted by the Rapporteur, however the results (no photodegradation) appear in the Volume 1 (page 29 and LoEP) hence the opinion of the RMS about the acceptability of any result or the study itself is not clear. In Level 4 of Volume 1 (under the point 4.2.8) RMS suggests to address the requirement of proper soil photolysis at MS level, however soil photolysis is an Annex II requirement and the potential metabolism via soil photolysis should be clarified for Annex I listing.	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 gap could be considered by an expert meeting.	Open point: MSs experts to discuss in a meeting the requirement of a new soil photolysis study.

Route and rate of degradation in soil (B.8.1)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(8)	Vol. 3, B.8.1. 3, Photolysis in soil Fontaine, D.D., Woodburn, K. B., 1986, Table B.8.26	EFSA: The recovery of this study can not be reproduced by the values reported in this Table. RMS please clarify this. Moreover it is not clear whether the values referring to picloram are the percentaged values of the organic extracts (i.e. 99.7 or 100% of the organic extracts were picloram).	RMS 04.02.09: Unfortunately, the tabulated results did not include the % AR as unextracted residue, and this accounts for the discrepancy. Across the study, unextracted residues accounted for 4.1 – 5.0% AR in light exposed samples with a minor trend for increasing unextracted residue over the course of the study. Unextracted residues in dark control samples accounted for 3.1 – 4.4% AR. The text below Table B.8.26 of the DAR states that maximum unextracted residue was 3% AR, although this should read 5% AR. The % amounts of picloram in the table are the percentage of the organic extract that was identified as picloram. The aqueous extract was only quantified for the gross radioactivity present and was not analysed further. However, at least 90% of radioactivity was found in the organic extract, the aqueous extract accounting for maximum 6.5% AR in irradiated samples.	Addressed
4(9)	Vol. 3, B.8.1.3 Photolysis in soil (Fontaine, D.D., Woodburn, K.B., 1986)	FR: The RMS judged that the light source was not acceptable in the photolysis soil study because as it is referred in the OCDE guidelines a xenon lamp must be used. A photolysis study with a xenon lamp should be done.	RMS 04.02.09: Please see response to comment 4(7).	See open point for comment 4(7).

Route and rate of degradation in soil (B.8.1)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(10)	Vol. 3, B.8.1.3, Field studies b), Knowles, S., Brice, A., 2003 Table B.8.30	EFSA: To use the half of the LOQ and the 20% of the LOQ for all the not detected (ND) values are not in line with the FOCUS degradation kinetic guidance (FOCUS 2005). RMS please clarify what were the actual measured residue values at least for cases where they were above the LOD and please recalculate the DT_{50}/DT_{90} values as recommended by FOCUS Kinetic guideline if necessary. The note below the table marked with '*' is not clear.	RMS 04.02.09: Please note that FOCUS Kinetics guidance was not in place at the time of evaluation, and we consider the approach taken was in line with a number of other evaluations of this era. We consider no further evaluation to be necessary at this time. The note marked with '*' refers to the sample time for the Polish trial site.	Addressed
4(11)	Vol. 3, B.8.1.3, Field studies c), Knowles, S., Schnöder, F., 2003a Page 235 & Table B.8.32	EFSA: Could RMS please clarify what exactly mean that for calculating the total extractable radioactivity (TRR) similar (to the top layer) extractability was assumed? What were the exact values in this calculation? The value of 1.54% AR means that this amount of radioactivity (assumed extractable + non extractable) was measured in the soil layer below 10 cm immediately after the application? No changes in the values referring to the 0-10 and 0-20 cm up to 7 days in the Table B.8.32.	RMS 04.02.09: This refers to the treatment of the 10-20 cm soil layer. Gross radioactivity in each sample was only measured by combustion. It was assumed that extractability of radioactivity in this horizon would be the same as in the 0-10cm layer, and thus the amount of radioactivity assumed to be extractable radioactivity at each time point was calculated on this basis. The value of 1.54% AR in 10-20cm was found at 14 DAT and is the gross radioactivity in this soil sample. Prior to this, i.e. up to and including 7 DAT, no radioactivity was found in the 10-20 cm soil horizon explaining no change in the values for 0-7 DAT.	Addressed

Route and rate of degradation in soil (B.8.1)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(12)	Vol. 3, B.8.1.3, Field studies c), Knowles, S., Schnöder, F., 2003a Table B.8.33	EFSA: Could RMS please clarify what the column 'Total incl. procedural recovery' mean and how procedural recovery was determined. If the procedural recovery was around 100% at each day why the values for picloram were not accepted for kinetic analysis? Is it correct that at two cases there is more picloram, than the total AR (2nd column incl. procedural recovery)? All the values in the table refer to %AR? In general it is not easy to understand this table and the study description.	RMS 04.02.09: According to the study report, the procedural recovery for the analysis was: (radioactivity in sample prior to HPLC ÷ radioactivity in aliquot removed for preparation) x 100 Thus the values in the column 'Total incl. procedural recovery' are the total amount of radioactivity in the ethyl acetate extractions. It appears that some diffuse radioactivity was also present in some extracts. Thus when procedural recovery is taken into account, apparently correcting the total radioactivity figure, it appears that the level of picloram exceeds the values in the 'Total incl procedural recovery' column. Thus, we consider that the naming of the columns may actually be slightly misleading. Notifier will be asked to clarify.	Point of clarification for the applicant: Applicant to clarify the column 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 applicant new DT_{50} and PECsoil calculation might be needed.

Route and rate of degradation in soil (B.8.1)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(13)	Vol. 3, B.8.1.3, Field studies c), Knowles, S., Schnöder, F., 2003a	EFSA: RMS please check the full study description as some data is not correct or not clear comparing with the original study report (e.g. description of the soil, whether unextracted residue is 0.59 or 0.39 %AR as indicated in the Summary and Conclusion of the report).	RMS 04.02.09: There appear to be some small differences in the DAR description and the study report. Soil parameters are correct in comparison with Appendix 8 of the study, although the details in the table on page 15 of the report may be from a previous analysis of a soil sample from the same site. The unextracted residue value of 0.59% AR reported in the DAR is confirmed by Table 1 (page 27) of the study report, thus the value reported in the summary and conclusion is presumed to be incorrect. However, this has no bearing on the overall validity of the study and is considered a minor mistake. Overall, we consider that the study description in the DAR is accurate compared to the study report itself.	Addressed
4(14)	Vol. 3, B.8.1.4 Field studies Field dissipation a) (Knowles, S., Unsworth, C., 2003)	FR: The RMS judged that the regression used by the notifier to estimate the DT50 is not reliable. However, the DT50 founded is reported in the endpoints. Please clarify why a DT50 calculated with an unreliable regression is accepted?	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 arguably represents a more precautionary approach.	Open point: 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.
4(15)	Vol 3, B 8.1.4b, Field dissipation – Polish study	DAS: Add line in Table B.8.30 to note 0-90cm showed no soil residues in any horizon after 271 days (Polish trial site). This supports that there is little/no significant leaching to depth. The kinetics calculated from the Polish field study are therefore representative of the degradation of picloram under field conditions.	RMS 04.02.09: This information is already present in the text of the fourth paragraph of the study description. No amendment is considered to be required by the RMS.	Addressed

Route and rate of degradation in soil (B.8.1)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(16)	Vol 3, B 8.1.4c, Field dissipation – German study	DAS: For this ^{14}C study add to DAR that at the bottom of these outdoor soil cores (20cm), all leachate was collected on a weekly basis. 111.5L was collected in total and no radioactivity was detected in the water on any occasion (see conclusion of report GHE-P-10611, ref K60). This clearly demonstrates that there was no leaching of picloram or any other ^{14}C material and therefore the kinetic analysis of the total radioactivity in soil represents a conservative estimate of the DT50. DT50 = 48.9 days	RMS 04.02.09: Whilst we agree that no radioactivity was detected in leachate, we still consider that there was some movement of radioactivity and that use of this field study for modelling purposes is inappropriate. We agree that the consequent dissipation DT50 is the longest and is precautionary for use in PECsoil calculations compared to the other field dissipation DT50 value. No amendment is required.	Addressed

Adsorption,desroptionand mobility in soil (B.8.2)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(17)	Vol. 3, B.8.2.4, Summary and assessment	EFSA: Please add argumentation why the results from the study by Knowles, S., Swales, SA., 2002 were not used further in the exposure assessment.	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 three additional Koc values raises the average Koc to 37. Thus there would be no practical impact on the risk assessment.	Open point: 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.

Adsorption,desroptionand mobility in soil (B.8.2)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(18)	Vol. 3, B.8.2.4, Summary and assessment & PECgw and PECsw	EFSA: As no Freundlich isotherm was established for 1/n 1 should have been used instead of 0.9 in the PEC calculations.	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: 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. Open point: 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 also comments 4(2), 4(5), 4(6), 4(17) and 4(23).
4(19)	Vol. 3, B.8.2.3, Lysimeter studies or field leaching studies	EFSA: RMS please clarify whether there was or not another lysimeter study with picloram on 'HAN' soils (see B.8.1.2 b), and B.8.2.1 b)). If this lysimeter had been performed with picloram could RMS pls. give details about the study?	RMS 04.02.09: The 'HAN' series of soils referred to in soil degradation and adsorption studies relate to the Munster-Handorf lysimeter soil; this is the lysimeter study described in section B.8.2.3 of the DAR.	Addressed

Fate and behaviour in water and impact on water treatment procedures (B.8.4-B.8.5)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(20)	Vol. 3, B.8.4.3 Ready biodegradation (Heim, D., Heim, L;, 2002)	FR: It seems that results with picloram and sodium benzoate are not indicated.	RMS 04.02.09: We are uncertain of this comment because Tables B.8.53 and B.8.54 specifically refer to picloram and sodium benzoate. Picloram is clearly 'not readily biodegradable', and sodium benzoate is clearly 'readily biodegradable'.	Open point: 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).
4(21)	Vol. 3, B.8.4.4, Water/sediment studies Table B.8.58	EFSA: RMS please confirm that from the French system duplicate samples were taken on day 31 and single sample on day 21 and in the Italian system the opposite. Please see also EFSA comment (21) on the LoEP and consider the possible effects of these on the kinetic evaluation.	RMS: For the French system, single samples were taken on days 0, 7 and 21. For the Italian system, single samples were taken on day 21. Scrutiny of the study report indicates that the study authors used all available data points for the linear regression with log transformed data. For the RMS re-evaluation, a similar approach was taken but non-linear regression on un-transformed data was performed. Please take into consideration that at the time of evaluation that the FOCUS Kinetics guidance was not available. Calculations for picloram are not affected by values <LOQ.	Addressed

Fate and behaviour in water and impact on water treatment procedures (B.8.4-B.8.5)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(22)	Vol. 3, B.8.4.4 Water/sediment studies (Yoder R.N., Meilt, T.J., 2004)	FR : Can you clarify the values used in the paragraph just before the table B.8.56 which begin with : "The aerobic aquatic degradation of Picloram led to the formation of two degradates >10%. …". Indeed, in the first sentence, the RMS is talking about %AR in the whole system whereas in the second sentence, he is talking about %AR in water and in sediment. What's more the concentration in water and in sediment refer to average values of the table B.8.58 which is not clear at first sight.	RMS 04.02.09: The comment is correct.	Addressed
4(23)	Vol. 3, B.8.4.4 Water/sediment studies (Yoder R.N., Meilt, T.J., 2004)	FR: Can you please clarify why do you use a DT50 water of 300 d and a DT50 sediment of 196.1 d whereas in the table B.8.59 the maximal value for the DT50 water is 135 and the maximal value of DT50 sediment is 256.6.	RMS 04.02.09: The DT50 in water of 135 days is a dissipation DT50, i.e. overall rate of disappearance from the 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: 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.

PEC in surface water and in ground water (B.8.6)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(24)	Vol. 3, B.8.6, Predicted environmental concentrations in surface water and groundwater (PECsw and PECgw)	EFSA: In the PECsw calculations for the metabolites the maximum observed values were used. As the maximum amounts were observed at the study end when still there were significant amount of parent (>50%), it cannot be excluded that the maximum occurred of these metabolites in w/s systems would be more (theoretically about twice that assumed in current calculations).	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 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: MSs experts to discuss in a meeting the proper formation fraction (or 'application rate') to be used in the PECsw calculations for the metabolites.
4(25)	Vol. 3, B.8.6, Predicted environmental concentrations in surface water and groundwater (PECsw and PECgw)	EFSA: Please clarify whether are there any scientific reason/fact/argumentation to support that the 5,6-dichloro analogue is expected to have comparable adsorption properties to the 3,6-dichloro analogue.	RMS 04.02.09: No additional support is available, however, we considered that given the only structural difference was the relative positions of the two Cl atoms, it was a reasonable assumption to make that the properties of the two substances would be similar.	See open point for comment 4(27).

PEC in surface water and in ground water (B.8.6)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(26)	Vol. 3, B.8.6 Predicted environmental concentrations in surface water and groundwater (PECsw and PECgw)	FR: Can you clarify why the DT50 soil of 3,6-dichloro analogue and 5,6-dichloro analogue is 12.1d?	RMS 04.02.09: The 3,6-dichloro analogue of picloram is also known as aminopyralid. The DT50 value is taken from the DAR for aminopyralid. Aminopyralid is a new a.s. with UK as RMS. The DAR was delivered into the European system before picloram, and it was expected that peer review of aminopyralid would have occurred. As described in our answer to comment 4(25), we considered it reasonable to assume the same substance properties for the 5,6-dichloro analogue as for aminopyralid.	See open point for comment 4(27).
4(27)	Vol. 3, B.8.6, Predicted environmental concentrations in surface water and groundwater (PECsw and PECgw)	EFSA: It is noted that the 3,6-dichloro analogue is aminopyralid and that the adsorption study for aminopyralid is not evaluated and summarised in this DAR for picloram. As the peer review of the DAR for aminopyralid has not been completed and picloram may progress through the peer review program in advance of aminopyralid an assessment of the available adsorption study needs to be presented.	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.	Open point: RMS to include an assessment of the degradation and adsorption in soil of aminopyralid (=3,6-dichloro analogue) in an addendum. Open point: MSs experts to discuss in a meeting whether the input parameters for the metabolites used in the PECsw calculations are agreed. See also comments 4(25), 4(26) and 4(28).
4(28)	Vol. 3, B.8.6 Predicted environmental concentrations in surface water and groundwater (PECsw and PECgw)	FR: For the chemical specifics input parameters for Step 1 and Step 2 of the metabolites, can you explain why input values of aminopyralid are used?	RMS 04.02.09: Please see our reply to comment 4(25).	See open point for comment 4(27).

PEC in surface water and in ground water (B.8.6)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(29)	Vol. 3, B.8.6, Predicted environmental concentrations in surface water and groundwater (PECsw and PECgw)	EFSA: The application windows used in the FOCUS Step 3 PECsw calculations (15 Feb.-15 March) and the actual appl. dates for winter oilseed rape (February for all scenario) seems to be too early for spring application (and of course too late for autumn appl.). Could RMS please clarify whether the application time is restricted to spring application (in the GAP table only BBCH 14-31 is mentioned)?	RMS 04.02.09: In the Notifier's submission, it was specified that application to winter crops was to be in the spring, not in the autumn, irrespective of what was stated in the GAP table. As the modelling is done on the basis of spring application, it is assumed that some further restriction on timing of application would be recommended (i.e. spring only), and this could be reflected in EFSAs conclusion and the Review Report. With respect to windows of application, this will always be a compromise with FOCUS modelling. From the RMS view, we considered that the window chosen was reasonable given relatively low temperatures (slowing degradation) and likely proximity to wet weather events leading to more worse case drainage and, possibly, run-off events.	Open point: EFSA to include in EFSA conclusion a recommendation for restriction of timing of application to spring.

Fate and behaviour in air and PEC in air (B.8.7-8.8)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(30)	Vol 3, B 8.6, PEC surface water	DAS: RMS comment that field studies for Poland and Germany are not accepted as may not be representative of degradation as showed significant residues in the lowest soil horizon. In addition studies were conducted at times of year when soil temperatures may have been warmer than notified in the GAP. The data presented for lower horizon (0-90cm) for Poland and no leaching >20cm in the German study show that the degradation kinetics presented for the 4 EU field studies are representative of picloram degradation in the field. Furthermore, field standardisation for soil moisture and temperature as recommended by FOCUS allow any temperature differences in the GAP timing to be corrected. Field standardisation gives a DT50 = 8.7 days. Knowles, S.: Recalculation of Field Kinetics for Picloram using FOCUS Kinetics Methodology. Dow AgroSciences unpublished report GHE-P-11573, 02 April 2007 (*see column 3 for report) This will not significantly impact PECsw ***For confidentiality reasons the attachment has been removed by EFSA.**	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 outcome described in the DAR.	Point of clarification for the applicant: Applicant to submit the information on recalculation of field kinetics for Picloram to the RMS. Open point: If RMS accepts this information on recalculation of field kinetics for Picloram from the applicant, RMS to evaluate in an addendum.

Fate and behaviour in air and PEC in air (B.8.7-8.8)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(31)	B 8.6, PEC groundwater	DAS: RMS comment that field studies for Poland and Germany are not accepted as may not be representative of degradation as showed significant residues in the lowest soil horizon. In addition studies were conducted at times of year when soil temperatures may have been warmer than notified in the GAP. The data presented for lower horizon (0-90cm) for Poland and no leaching >20cm in the German study show that the degradation kinetics presented for the 4 EU field studies are representative of picloram degradation in the field. Furthermore, field standardisation for soil moisture and temperature as recommended by FOCUS allow any temperature differences in the GAP timing to be corrected. Field standardisation gives a DT50 = 8.7 days (*see column 3 for report) This will significantly impact PECgw as it would allow annual applications to be applied instead of applications every 3 years as proposed in the DAR. The initial PECgw calculations which were submitted for the Annex II dossier used a DT50 = 30.5 days (non-standardised data, GHE-P-10687, ref MK02) so would represent a conservative assessment for PECgw using field DT50 values. **[*For confidentiality reasons the attachment has been removed by EFSA].**	RMS 04.02.09: Please see reply to comment 4(30).	See point of clarification and open point at comments 4(30).

Other comments				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(32)	List of End Points	EFSA: • Soil Rate box: it should be indicated that the soil classification based on UK/BBA classification or US classification, (w) means that pH was measured in water and where there is no indication what was the media to measure the pH. • Adsorption / desorption data for aminopyralid (3,6-dichloro analogue) are not included but have been used to calculate PECsw • Field dissipation box: pH of the German study is 6.6 while in the DAR is 6.0. The media in which the pH values were measured should be indicated in the LoEP as there were measurements in different medias. • lysimeter box: please indicate clearly that only one application was performed in the first year • PECgw box: please remove data referring to the lysimeter from the box of PECgw • PECsw box: when calculating average from 2 replicates, values <LOQ should be considered as equal with LOQ (here 1.1%) rather than 0.	• EFSA comments cont'd • This would result 5.2% 3,6-dichloro as max in sediment and 1.1% 5,6-dichloro analogue as max in water (instead of 4.6% and 0.6%) or take the actual value from the repetition where it was measured as at least the values of 9.2% and <LOQ are quite far from each other (and do not look like consistent between the two systems). • Quantum yield of direct phototransformation in air: please clarify were the included value come from as no indication for that value in Annex B. RMS 04.02.09: LOEP will be revised at the same time as the addendum is produced.	Open point: RMS to revise LOEP in light of EFSA comments.

Fate and behaviour in air and PEC in air (B.8.7-8.8)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(33)	Vol. 3, B.8.11 References relied on & Vol. 2	EFSA: All references regarded as not relied on should be removed from the lists. References for 'Plant Protection Product' should contain only those studies which particularly refer to the PPP and not the a.i. (e.g. PEC calculations).	RMS 04.02.09: Noted. Data list to be amended	Open point: RMS to amend list of tests and studies relied upon in light of EFSA comments.
4(34)	Vol. 1, Level 2, 2.5.2, Fate and behaviour in soil	DAS: RMS commented that field studies for Poland and Germany are not accepted as may not be representative of degradation as showed significant residues in the lowest soil horizon. In addition studies were conducted at times of year when soil temperatures may have been warmer than notified GAP. See comments 2-5 for DAS clarification of position.	RMS 04.02.09: Please see response to comment 4(30).	See point of clarification and open point at comments 4(30).

5. Ecotoxicology

Birds and mammals (B.9.1 and B.9.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
		FR : Note that DAR is clear and very easy to read!	RMS 04.02.09: Thanks	
5(1)	Vol. 3 B.9.1.1.1. acute oral toxicity to birds, Beavers 1986a study, pag 288	EFSA: RMS could provide an explanation on the conversion factor use to convert the endpoint from picloram potassium salt to picloram acid equivalent	RMS 04.02.09: This information will be provided in an addendum	Open point: 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).
5(2)	Vol. 3, B.9.1.1.1: Active substance ii)	FR: Typographic error: There is a repetition of the sentences “No mortalities occurred…at any dosage tested”.	RMS 04.02.09: Noted	Addressed. RMS to consider in a corrigendunm/revised DAR

<table>
<tr><th colspan="5">Birds and mammals (B.9.1 and B.9.3)</th></tr>
<tr><td>No.</td><td>Column 1
Reference to DAR (vol., point, page)</td><td>Column 2
Comments from Member States or applicant</td><td>Column 3
Evaluation by (RMS) rapporteur and
- if available - (Co-RMS) Co-rapporteur</td><td>Column 4
Data requirement or Open point (if data point not addressed or fulfilled)</td></tr>
<tr><td>5(3)</td><td>Vol. 3 B.9.1.2.1. acute oral toxicity to birds, Beavers 1986b study, pag 290</td><td>EFSA: RMS could provide an explanation on the conversion factor use to convert the endpoint from picloram potassium salt to picloram acid equivalent.
The raw data should be reported for causes of transparency (i.e tables with the body weight and food consumption during the test).</td><td>RMS 04.02.09: see response to point 5(1)
Assume short-term dietary study is meant.. There were no treatment-related effects or mortality at the highest test conc.n of 5620 ppm; the bw and food consumption data used to derive the NOEL of >1904 mg ae/kg bw/day (along with the above corr. factor) are as follows:
<table>
<tr><th rowspan="2">Nominal Picloram K^+ salt content (mg/kg diet)</th><th colspan="3">Mean bodyweight (g)</th><th colspan="2">Mean food consumption (g/bird/day)</th></tr>
<tr><th>day 0</th><th>day 5</th><th>day 8</th><th>days 1 to 5</th><th>days 6 to 8</th></tr>
<tr><td>5620</td><td>20</td><td>31</td><td>41</td><td>10</td><td>14</td></tr>
</table></td><td>Open point.
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. mean body weight and food consumption table included in the reporting table).</td></tr>
</table>

Birds and mammals (B.9.1 and B.9.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(4)	Vol. 3, B.9.3.2, Risk assessment for mammals	DE: The acute and long-term endpoints for mammals used for risk assessment in the German national authorisation (acute oral LD_{50} = 3563 mg as/kg bw, NOEL (rabbit) = 40 mg as/kg bw/d) are lower than the endpoints used in the DAR (acute oral LD_{50} = 4012 mg ae/kg bw, NOEL (rat) = 1000 mg as/kg bw/d; ae = based on acid equivalents). This might result in unacceptable risk and should therefore be clarified.	RMS 04.02.09: The studies conducted with active (picloram acid) are used for classification. If the end points are changed a revised risk assessment will be presnted in an addendum.	Open point 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? Open point: MSs to discuss in a PRAPeR expert meeting the endpoint to be used for risk assessment to mammals, if necessary.

Aquatic organisms (B. 9.2)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(5)	Vol. 3 B.9.2.1.1. acute toxicity to aquatic organisms, Desjardins 2001 study, pag 302	EFSA: The raw data should be reported (i.e. tables with the observations).	RMS 04.02.09: These could be included in future DARs but addition of raw data is not usual. We see little need to repeat what is already clear in study report and summary dossier where it is accurate. Full data on cell count, biomass and growth rate are available in Tables 8.2.6-2 to 8.2.6-4 in Doc. MII, Section 6. The RMS is in agreement with these results and the resulting 72-96 hour EC_{50}s and NOECs for each factor are available in Table B.9.8 in the DAR.	Open point 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 the DAR.

Aquatic organisms (B. 9.2)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(6)	Vol. 3 B.9.2.1.1. acute toxicity to aquatic organisms, Hughes 1990 study, pag 304	EFSA: RMS could provide a explanation on the conversion factor use to convert the endpoint from picloram potassium salt to picloram acid equivalent	RMS 04.02.09: see response to point 5(1)	Open point: 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.
5(7)	Vol. 3, B.9.2.2.2: Hazard Classification/Labelling of plant protection products	FR: We agree with the classification of plant protection product. Could you clarify the effects on the survival of juvenile fish by referring to table B.9.21.	RMS 04.02.09: Table B.9.21 reported that survival was significantly reduced at 2.02 mg/L where mortality at 27% was significantly different to the control (10.8%). $NOEC_{survival}$ would be 1.34 mg picloram acid/L. There was also a concentration:response in growth with both length and weight significantly reduced at 0.88 mg/L and higher. Overall NOEC for chronic effects was 0.55 mg picloram acid/L.	Addressed.
5(8)	Vol. 3, B.9.2.3.1 Fish early life stage toxicity/Fish life cycle test/Chronic toxicity test on juvenile fish b) Metabolites Vol.3, B.9.2.3.5 Effects on aquatic plants b) Metabolites	FR: Typographic error: Note that some concentrations are given in mg a.s/L instead of mg XDE750./L.	RMS 04.02.09: Noted. References in LoEP to XDE-750 are correct.	Addressed. RMS to consider in a corrigendum/revised DAR
5(9)	Vol.3, B.9.2.3.3 Table B.9.26 : Emergence and development data	FR: Typographic error: The lowest concentration is **6.3** instead 63 mg a.e/L.	RMS 04.02.09: Noted. Does not affect endpoint in LoEP.	Addressed. RMS to consider in a corrigendum/revised DAR

Aquatic organisms (B. 9.2)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(10)	Vol.3, B.9.2.4.1 b) Metabolites	FR: It was said that there were 2 degradation products which occurred at >10 % AR in the water/sediment study. However, the 3,6-dichloro analogue (XDE 750) reached a maximum of 8.7% AR in the aqueous phase and 4.6 % AR in the sediment. Please correct this contradiction.	RMS 04.02.09: Agreed, this is a contradiction. However, since the latest guidance on relevant metabolites suggests that those present at >5% might still be considered, if they show significant activity or are otherwise of concern, it is considered prudent to retain an assessment for XDE-750.	Addressed.
5(11)	Vol. 3, B.9.2.4.1 b) Table B.9.31: Summary of acute aquatic toxicity endpoints for the metabolite XDE-750	FR: The 72 h EbC50 for *Navicula pelliculosa* are **19** (nominal) and 18 (mean measured) mg XDE 750/L.	RMS 04.02.09: Agreed. Does not affect assessment and key endpoint in LoEP (18 mg/L) is correct.	Addressed. RMS to consider in a corrigendum/revised DAR

Earthworms and other soil non-target organisms (macro and micro) (B. 9.6, B.9.7 and B.9.8)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(12)	Vol. 3, B.9.6.3.1 Active substance/plant protection product Table B.9.45: TERa values for earthworms based on studies using technical picloram and the formulated product 'GF-224'	FR: When corrected for the test substance purity, the 14-day LC50 value from the acute study using technical picloram is 4475 mg a.s./kg soil. In the table B.9.45, the TERa value is not based on the corrected LC50 value. Please modify the TERa value.	RMS 04.02.09: Agreed, LC50 and PECsoil should both be expressed in same units (mg **ae**/kg dw soil). Dividing >4475 by 0.031 gives a TERa for picloram of >144355. Correction has been made in LoEP, there is no impact on risk assessment. Corrections may be made to DAR at some stage, or *via* a corrigendum.	Addressed. RMS to consider in a corrigendum/revised DAR