PEER REVIEW REPORT ON **FLUOPICOLIDE** 06 02 2008

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0. General

General				
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0(1)	DAR	FR: the DAR is very clear and consistent with guidance documents. We only suggest the following minor comments.	RMS: Thank you, comment noted. Addressed.	Addressed: No further action required.

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)	General, Identity	EFSA: Due to the fact that fluopicolide is produced in a pilot plant, a general data requirement for the large scale batch analysis should be set to keep track of it.	RMS: Agreed. The following data requirement should be specified: Once full scale manufacturing is in progress, the specification of the technical fluopicolide produced at the manufacturing plant must be compared with that from the pilot plant. If the specifications are comparable then no further work is required. If differences emerge then at least 5 different production batches from the manufacturing plant will have to be analysed with a view to revising the specification.	Data requirement: Once full scale manufacturing is in progress, the specification of the technical fluopicolide produced at the manufacturing plant must be compared with that from the pilot plant. If the specifications are comparable then no further work is required. If differences emerge then at least 5 different production batches from the manufacturing plant will have to be analysed with a view to revising the specification.
1(2)	Vol. 1, Vol. 3, and LOE identity	AT: The CIPAC number is 787.	RMS: Agreed. The end points have been amended. Addressed.	Addressed: The end points have been amended. Also see 1(3).
1(3)	Vol. 1, list of end points, CIPAC no, p. 61	EFSA: It should be noted that recently the CIPAC number was allocated for fluopicolide. The number is 787.	RMS: Agreed. The end points have been amended. Addressed.	See comment 1(2).
1(4)	Vol. 1, 1.3.3, chemical name	NL: IUPAC name is: 2,6-dichloro-N-[3-chloro-5-(trifluoromethyl)-2-pyridylmethyl]benzamide	RMS: Agreed. The end points have been amended. Addressed.	Addressed: The end points have been amended.
1(5)	Vol. 4, C.2.1 (1.10)	DE: Toluene is classified as Xn (harmful to health). Should it be considered as a relevant impurity?	RMS: Disagree: Toluene is classified with Xn; Repr. Cat 3 R63; Xn; R48/20, R65 and Xi; R38, R67. An upper generic limit of 1% may be set for toluene in the active substance based	Open point: In the PRAPeR toxicology expert meeting 09 it was concluded for the active substance flonicamid that toluene is

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			on the most critical criterion R63 compared with maximum 0.5% specification for pilot plant batches (Volume 4). However, it should be noted that this is considered unduly stringent for an active substance as the lower limit for consideration as relevant impurity in a formulation is 5% for R63 classification 10% for Xn R48 classification and 15% for R67. Provided the minimum purity of the active substance is also set at more than 95% then toluene should not be considered as a relevant impurity. Addressed.	relevant it is therefore unclear why in this case it would not be relevant.
1(6)	Vol. 3, B.2.1.13	BCS: Page 12/13: General comment: All metabolites should be named as in the other chapters, that means as M-01, M-02, etc. and not as metabolite 1 or metabolite 2 and so on. For metabolite 1 all Log Pow's are measured at 23°C instead of 20°C.	RMS: Point noted. However, the identity of the metabolites is clearly stated in the 'comment box'. RMS: Agreed. The DAR should read 23°C. Points addressed.	Addressed: Rapporteur to consider in a revised DAR or corrigendum.

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1(7)	Vol. 4, C.2.2 (1.11)	DE: It has to be clarified if it was possible to separate the impurities AE C636523 and toluene satisfactory in the study Bowen, 2004 (document no C040168). In the study Bowen, 2003 (report no AF03/007) it is shown that there is no big difference between the retention times of both impurities. But from the chromatograms given in both studies it can not be concluded if a satisfactory separation is possible	RMS: Based on the data submitted, toluene and AE C636523 could be separated by the method. The applicant submitted further information in report AF05/100, which confirms no interference between toluene and AE C636523. An addendum can be produced in time for the Expert meetings. Open Point: to be discussed at an Expert Meeting.	Open Point: Rapporteur to clarify the chromatographic separation of impurities AE C636523 from toluene. From column 3 of the reporting table it is noted that some additional data have been supplied by the applicant. If this data are useful then it should be evaluated in an addendum.
1(8)	Vol. 4, C.2.2 (1.11)	DE: In the study Bowen, 2004 (document no C040168) no information about the used calibration range is given. The used analytical methods are not described in detail, only references on the methods AM000203FP1 and AM000303FP1 are given. But the calibration range given in method AM000203FP1 is for some impurities not adequate to the measured concentrations.	RMS: Based on the data submitted, it was considered that sufficient calibration data were available. The applicant submitted further information in report AF05/100, which confirms that sufficient data are available. An addendum can be produced in time for the Expert meetings. Open Point: to be discussed at an Expert Meeting.	Open point: For the impurity method Bowen, 2004 there are no calibration ranges given and this should be clarified. It is noted that in column 3 of the reporting table it is mentioned that additional data have been submitted. If the new data are relevant then they should be evaluated and presented in an addendum.
1(9)	Vol. 4, C.2.2 a) analytical profile of batches	AT: A lower minimum purity is used in the tox. batch OP 2050046 than specified for the active substance. A clarification is required.	RMS: The use of a test batch with a lower minimum impurity is not considered a concern for the hazard and risk evaluation of the active substance for the following reasons: i) The difference in purities of the active substance tested is small and will not affect the toxicity of the material tested such that there is no need to adjust for purity for the material	Addressed: It is not clear why a lower purity material would be an issue in this case.

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			tested. ii) There are no significant differences in the impurity profiles of the test batches used in toxicity studies and batch OP 2050046 is comparable with other test batches. The tests with the tox. batch OP 2050046 are in fact considered less of a concern than a test with a high purity test batch, which may not be achieved during production and it may address any potential toxicity arising from increases in impurity, which might arise in production batches. Addressed.	
1(10)	Vol. 4, C.3a composition of the SC formulation	AT: The closure of TGAIs and formulants should be 1000 g/kg.	RMS: Agreed. However, the '@ 14.9' in the contents column should read 'up to 14.9' or 'maximum 14.9' and would be adjusted to give a closure of 1000 g/kg. Addressed.	Open point: The corrected formulation details should be given.
1(11)	Vol. 4, Table C.4	NL: Not all validation data are presented in the table: -linearity data are missing -LOQ? -accuracy-recovery: concentration level? Based on how many measurements? -precision-repeatability: concentration level? According to Horowitz?	RMS: Linearity data are presented in the 2nd column of the table LOQ < 0.004 g/kg Accuracy and recovery determinations were carried out at approximately ten times the specified maximum content in the technical specification. There were 5 measurements Addressed.	Open point: It should be discussed by a meeting of experts if recovery and accuracy determinations at 10 times the specification levels for impurities can be accepted. Also see points 1(12), 1(13)

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1(12)	Vol. 4, C.4.2 (4.1, analytical methods)	DE: In table C.4 information about the concentration levels regarding precision/repeatability are missing.	RMS: Carried out at approximately ten times higher than the specified maximum content. Addressed.	See open point in comment 1(11).
1(13)	Vol. 4, C.4.2 (4.1, analytical methods)	DE: In table C.4 information about the fortification levels regarding accuracy are missing.	RMS: Accuracy determinations were carried out at ten times the specified maximum content Addressed.	See open point in comment 1(11).
1(14)	Vol. 4, C.4.2 (4.1)	DE: Information about the identification procedures for the impurities are missing.	RMS: As stated in C.4.2a, identification was based on MS and NMR data. Addressed.	Addressed: Identification was by MS and NMR.
1(15)	Vol. 4, C.4.2, impurities	NL: AM and validation data for impurity 10 (AE 1423809) are missing. Impurity 10 is a significant impurity in 2 of the tox batches and has also been analysed in the 5-batch analyis (although not found: <0.1 g/kg and therfore not part of the specification)	RMS: As the impurity is present at less than 0.1%w/w in the batches used to set the technical specification, no further data were requested. Addressed.	Addressed: As long as it is not in the specification no further data are required.
1(16)	Vol. 4, C.4.3 method for the determination of the impurities -validation	AT: A justification with respect to chemical structure and chromatographic behaviour concerning the use of a different reference material for the validation of one impurity is required. A LOQ for the relevant impurity M-01 is required.	RMS: Justification is presented as a footnote under Table C.4. LOQ = 0.02% w/w Addressed.	Open point: A justification with respect to chemical structure and chromatographic behaviour concerning the use of a different reference material for the validation of one impurity is required. In addition to this it was requested in the comments on column 4 of the reporting table that the retention times for all impurities and the active substance should be reported. These issues should be discussed in a meeting of experts.

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1(17)	Vol. 4, C.5.1	DE: It is very unusual to include material safety data sheets into Volume 4. What is the reason?	RMS: Comment noted. Addressed.	Addressed: The MSDS are not confidential.

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(18)	Vol. 1, LOEP, chemical name (IUPAC)	NL: IUPAC name is: 2,6-dichloro-N-[3-chloro-5-(trifluoromethyl)-2-pyridylmethyl]benzamide	RMS: Agreed. The end points have been amended. Addressed.	Addressed: The endpoints have been amended.
1(19)	Vol. 1, LOEP, minimum purity of the active substance as manufactured	NL: Please add: *based on pilot plant production*	RMS: Agreed. The end points have been amended. Addressed.	Addressed: The end points have been amended.
1(20)	Vol. 1, LOEP, identity of relevant impurities	NL: Relevant impurities are not confidential. Relevant impurities should be named here or when not present this should clearly be indicated.	RMS: Agreed. M-01 is stated as the only relevant impurity because it is toxicologically comparable with the parent with the exception of its acute oral toxicity. Secondly it is the most significant residue other than parent fluopicolide. The end points have been amended. Addressed.	Addressed: The endpoints have been amended.
1(21)	Vol. 1, LOEP, melting point	NL: Purity is missing	RMS: Agreed. The end points have been amended. Addressed.	Addressed: The endpoints have been amended.

Physical and chemical properties of the active substance (B.2.1)				
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1(22)	Vol. 1, LOEP, boiling point	NL: Change not measured in not measurable	RMS: Agreed. The end points have been amended. Addressed.	Addressed: The endpoints have been amended.
1(23)	Vol. 1, LOEP, appearance	NL: The appearance of both, the technical a.s. and the pure a.s. should be given in the LOEP.	RMS: Agreed. The end points have been amended. Addressed.	Addressed: The endpoints have been amended.
1(24)	Vol. 1, LOEP, relative density	NL: Relative density doesn't have an unit	RMS: Agreed. The end points have been amended. Addressed.	Open point: LOEP relative density the purity should be given..
1(25)	Vol.1, LOEP, surface tension	NL: The concentration should be given for clarity	RMS: Agreed. The concentration is 2.52 mg/l. The end points have been amended. Addressed.	Addressed: The endpoints have been amended.
1(26)	Vol.1, LOEP, solubility in water	NL: The solubility in water as given in the LOEP (0.0029 g/l) is slightly different from the water solubility as given in § 2.1.2 (0.0028 g/l). Give also the solubilities at pH 4 and 9 or state that the water solubility is independent of the pH. See also volume 3, B.2.3.1	RMS: The 0.0029 g/l results from the round up of 0.00286 g/l Water solubility is independent of pH. The end points have been amended. Addressed.	Addressed: The endpoints have been amended.
1(27)	Vol.1, LOEP, partition co-efficient	NL: Give also the log Pow at pH 4 and 9 or state that the log Pow is independent of the pH. (See also Vol.1, §2.1.2 and Vol.3, B.2.3.1)	RMS: Agreed. Log Pow is independent of pH. The end points have been amended. Addressed.	Open point: It should state for the Log Pow that it is independent of pH.
1(28)	Vol.1, LOEP, AM for	NL: For clarity at least the type of matrices	RMS: Agreed. The matrices were grape, wheat grain and potato.	Addressed:

Physical and chemical properties of the active substance (B.2.1)				
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	residues, plant origin	should be named (e.g. dry, watery etc.) for which the AM has been validated Please also indicate that an ILV is available	ILV data are available. The end points have been amended as appropriate. Addressed.	The endpoints have been amended.
1(29)	Vol.1, LOEP, AM for residues, animal origin	NL: Please indicate that no ILV is available. Also indicate that a method for food/feed of animal origin is not necessary as no residues are expected.	RMS: ILV data were not submitted as positive residues would not be expected in animal products from the proposed uses of fluopicolide Disagree, method was required in order to analyse the samples from the animal transfer studies. Addressed.	Open point: It should be noted in the endpoints that the method is not required as no MRLs will be set. This does not impact on the reliance on this method for the pre-registration data. See also 1(56), 1(95).
1(30)	Vol.1, LOEP, AM for residues, water	NL: For clarity the types of water should be named (tap- and surface water) for which the AM has been validated	RMS: Agreed. The type of water were tap water and surface water (Saone river water). End points have been amended. Addressed.	Addressed: The endpoints have been amended.
1(31)	Vol. 1, LOE relevant impurities	AT: M-01 is considered to be relevant, therefore it is not confidential information.	RMS: Agreed. The end points have been amended. Addressed.	Addressed: The endpoints have been amended.
1(32)	Vol. 1, LOE melting point	AT: The purity is not reported.	RMS: Agreed. The end points have been amended. Addressed.	Addressed: The endpoints have been amended.

Physical and chemical properties of the active substance (B.2.1)				
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1(33)	Vol. 1, List of Endpoints (general)	DE: If it is possible, the LOEP should be brought in the new format.	RMS: Due to resource limitations we have not re-formatted the endpoints at this time to the Sept 05 guidance. We will undertake this in time for the PraPer expert meetings. Open Point: endpoints to be revised.	Open point: The endpoints should use the current agreed template.
1(34)	Vol. , List of Endpoints (general)	DE: It is not necessary to repeat the text of the first column in the second one. Please delete the accordant entries.	RMS: The end points have been amended. Addressed.	Addressed: The endpoints have been amended.
1(35)	Vol. 1, List of Endpoints (relevant impurities)	DE: The identity of relevant impurities is not confidential information, only information about the identity of significant impurities are confidential. Please delete the accordant sentence in the second column.	RMS: Agreed. See 1(20). Addressed.	Addressed: The endpoints have been amended.
1(36)	Vol. 1, List of Endpoints (Solubility in organic solvents)	DE: It should be *n*-hexan**e** and dimeth**y**lsulfoxide	RMS: Agreed. The end points have been amended. Addressed.	Addressed: The endpoints have been amended.
1(37)	Vol. 3, B.2 in general	AT: Information whether GLP is applied or not should be reported.	RMS: All the studies were carried out to GLP. Addressed.	Addressed: The studies were to GLP.
1(38)	Vol. 3, B.2.1 and B.2.3.1, general	DE: Why is information given about the impurity 2,6-dichlorobenzamid and the metabolites AEC657188 and AE0608000? Are these substances considered as relevant? is the information relevant for the evaluation of the active substance? In the "List of metabolites" in Appendix	RMS: Data was submitted as the applicant thought that these metabolites may be of concern. It is agreed that it would have been more consistent to include the M-code numbers and these have been added below. The impurity 2,6-dichlorobenzamid (M-01) isa relevant impurty. It is also one of the most significant metabolites and residue of	Addressed: The impurity is considered relevant as are the metabolites.

Physical and chemical properties of the active substance (B.2.1)				
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		5 a different M-code number is used for the two metabolites than in this chapter.	fluopicolide. AE0608000 (M-03) was found only as a soil metabolite and it's toxicological significance is a valid consideration as it is not found in rats. AEC657188 (M-02) is a metabolite in rats. The data provided helps to address questions such as raised at No. 3(9). Addressed.	
1(39)	Vol. 1, Level 2 (2.1.1)	DE: Statement is missing.	RMS: Agreed. A summary of the identity section (2.1.1) should have been included under the heading. However, see B1.3. Addressed.	Addressed: Rapporteur to consider in a revised DAR or corrigendum.
1(40)	Vol. 3, B.2.1.1 melting point	AT: The method used should be mentioned.	RMS: Method is stated to be EEC method A1. Addressed.	Open point: For melting point which sub method of A1 was used.
1(41)	Vol. 3, B.2.1 (2.2)	DE: The relative density was measured at 30 °C and not at 4 °C.	RMS: Agreed. End points have been amended. Addressed.	Addressed: The end points have been amended.
1(42)	Vol. 3, B.2.1 (2.3, vapour pressure)	DE: The study Bright, 2000a does not contain the raw data like chromatograms from the applied analytical method.	RMS: Point noted. However, based on the RMS experience it is considered that there is sufficient data within the studies for them to be acceptable and to make a decision. Addressed.	Addressed: The study was considered acceptable by the rapporteur.

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(43)	Vol. 3, B.2.1 (2.3, volatility)	DE: The values for water solubility and vapour pressure, which were used for the calculation, should be stated.	RMS: Point noted. We did not include them as have not previously been requested to do so. However, the vapour pressure is 3.03×10^{-7} Pa (at 20°C) and solubility 2.8 mg/l (at pH 7 and 20°C)	Addressed: Rapporteur to consider in a revised DAR or corrigendum.
1(44)	Vol. 3, B.2.1 (2.5, UV/VIS)	DE: More detailed information about the measurement should be given, e.g. solvent, maximum absorbance.	RMS: Point noted. We did not include them as we have not previously been requested to do so. However, if necessary the information can be presented in an addendum. Open point: The RMS can provide an addendum if necessary	Open point: For the UV/VIS More detailed information about the measurement should be given, e.g. solvent, maximum absorbance.
1(45)	Vol. 3, B.2.1 (2.9, hydrolysis rate)	DE: Information about DT_{50}-values are missing.	RMS: DT_{50}-values could not be calculated based on the information available. However, further information on DT50s can be found in section B.8.4.1.	Addressed: The active can be considered as stable no DT50s are required.
1(46)	Vol. 3, B.2.1 (2.9, quantum yield)	DE: Unit and basis of the used calculation method are missing.	RMS: RMS: Point noted. Quantum yield does not have units as it is a ratio. It was calculated using PNAP-PYR chemical actinometer. However, we did not include them as have not previously been requested to do so.	Addressed: The information provided is acceptable.
1(47)	Vol. 3, B.2.1 (2.10)	DE: Information about the method of calculation and used values for concentration of OH-radicals and rate constant are missing.	RMS: Point noted. The method used for calculation was AOPWIN. The OH concentration was 0.5×10^{6} radicals/cm^3 (long-term) and 1.5 (short-term). The rate constant was 4.7570×10^{-12} cm^3 $molucule^{-1}$ sec^{-1}. We did not include them as have not previously been requested to do so.	Addressed: Rapporteur to consider in a revised DAR or corrigendum.

Physical and chemical properties of the active substance (B.2.1)				
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1(48)	Vol. 3, B.2.1 (2.13)	DE: The test was only applied for thermal sensibility, information about mechanical sensibility are missing.	RMS: RMS considers that this information is not really required. However, a new study has been submitted to address this point which indicates the technical material is non-explosive with regards to mechanical. This information can be presented in an addendum for the Expert Meetings. Open Point: RMS to prepare an addendum.	Data requirement: Explosive properties mechanical sensitivity data should be provided. [This should be considered as a technical data requirement as the study has already been submitted]
1(49)	Vol. 3, B.2.1 (2.15)	DE: It should be stated that the result was not obtained because of a study but because of theoretical considerations.	RMS: Agree. Point noted. Addressed.	Addressed: Rapporteur to consider in a revised DAR or corrigendum.
1(50)	Vol. 1, 2.1.2 phys.-chem. properties	AT: A conclusion concerning the formulation is not reported.	RMS: Point noted. Apologies, however a conclusion is provided in Vol 3 Section B.2.3.2. Addressed.	Addressed: Rapporteur to consider in a revised DAR or corrigendum.
1(51)	Vol. 1, Level 2 (2.1.3)	DE: Statement is missing.	RMS: Agreed. A summary of the identity section (2.1.1) should have been included under the heading. However, see B.3.6. Addressed.	Addressed: Rapporteur to consider in a revised DAR or corrigendum.
1(52)	Vol. 3, B.2.1.4 relative density, p.9	EFSA: In addition to the fact that the relative density has no unit, it should be confirmed that the measurement was conducted as 4 °C. Usually the measured value for the substance is compared with the value of water at 4 °C. The entry in the list of end points should be amended if appropriate.	RMS: Agreed. Temperature should read 30 ºC not 4 ºC. The end points have been amended. Addressed.	Addressed: Rapporteur to consider in a revised DAR or corrigendum.
1(53)	Vol. 3, B.2.1.5 Vapour pressure, p. 10	EFSA: It is unclear why the data for the impurity are given. It seems that the technical material does	RMS: M-01 is a relevant impurity. We presented the information for completeness, as it had	Addressed: The impurity is relevant.

Physical and chemical properties of the active substance (B.2.1)				
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		not contain any relevant impurity (list of end points, volume 4). Therefore, information on this impurity should be regarded as confidential. In the case that the impurity has to be regarded as relevant, than at least the list of end points needs to be amended accordingly. This comment is also applicable for the spectra (B.2.1.10), the solubility in water (B.2.1.11), the partition coefficient (B.2.1.13) and the dissociation constant (B.2.1.18)	been provided by the applicant. Data of this nature has previously been included in this section. Addressed.	
1(54)	Vol. 3, B.2.1.19 Stability in air, p. 14	EFSA: The programme used for the calculation should be mentioned.	RMS: Agreed. The Atmospheric Oxidation Programme (AOPWIN) was used. Addressed.	Addressed: Rapporteur to consider in a revised DAR or corrigendum.
1(55)	Vol. 1, LOE and Vol. 3 B.2.1.24 surface tension	AT: The concentration used is not reported.	RMS: The concentration is 2.52 mg/l at 25 ºC. The end points have been amended. Addressed.	Addressed: The end points have been amended.
1(56)	Vol. 1, 2.2.3, Analytical methods for residue analysis	NL: A residu analytical method for food/feed in animal matrices is not necessary as no residues are expected. The submitted method is vaid however not ILV has been submitted	RMS: Agree, method included in case in the future an additional use results in positive residues in animal products. Addressed.	See open point in comment 1(29).
1(57)	Vol. 3, B.2.2.10, pH, WG formulation	NL: Is this the pH from the 1% solution?	RMS: 1% solution. Addressed.	Addressed: Rapporteur to consider in a revised DAR or corrigendum.

Physical and chemical properties of the active substance (B.2.1)				
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1(58)	Vol. 3, B.2.2.10, pH, SC formulation	NL: Is this the pH from the pure or the 1% solution?	RMS: 1% solution. Addressed.	Addressed: Rapporteur to consider in a revised DAR or corrigendum.
1(59)	Vol. 3, B.2.2.14 and B.2.2.15, SC formulation	NL: It is not clear if the storage stability test and shelf life test are carried out in the commercial packaging According to B.3.5.1, the resistance of packaging material to its contents has been tested in accordance with GIFAP 17 for 14 days at 54 °C and for 7 days at 0 °C. Nothing has been stated for the 2 year stability test.	RMS: 2 year data are now available which indicate the packaging is fit for purpose. The evaluation can be presented in an addendum. Open Point: RMS to prepare an addendum.	Data requirement: A 2 year storage stability study in the commercial packaging. [This should be regarded as a technical data requirement as it is noted that a study has already been provided (SC).]
1(60)	Vol. 3, B.2.2.14 and B.2.2.15, WG formulation	NL: It is not clear if the storage stability test and shelf life test are carried out in the commercial packaging According to B.3.5.1, the resistance of packaging material to its contents has been tested in accordance with GIFAP 17 for 14 days at 54 °C. Nothing has been stated for the 2 year stability test.	RMS: 2 year data are now available which indicate the packaging is fit for purpose. The evaluation can be presented in an addendum. Open Point: RMS to prepare an addendum.	Data requirement: A 2 year storage stability study in the commercial packaging. [This should be regarded as a technical data requirement as it is noted that a study has already been provided (WG).]
1(61)	Vol. 3, B.2.2.15, WG formulation	NL: According to the results, the pourability of this WG formulation has been determined. This is no requirement for a WG formulation. According to the results, the wet sieve, the particle size, the dustiness, the attrition and the flowability are not determined	RMS: Agreed. The text should have been as follows: Chemically and physically stable for two years at ambient. Physical properties tested before and after storage– appearance, particle size, pH,	Addressed: Rapporteur to consider in a revised DAR or 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)
		before and after the storage test. Those technical charateristics are however required for WG formulations.	dispersibility, suspensibility, wet sieve, wettability, attrition, acidity, dustiness and persistent foam. Addressed.	
1(62)	Vol. 3, B.2.2.15 Shelf-life, p. 22	EFSA: RMS should confirm the given results. It seems that the entry of the SC formulation was copied and pasted. In the submitted study for the WG preparation (Güldner, 2005, Lab. ID. 02-99) different parameters were analysed. Furthermore, it seems that the reference for this shelf-life study is not mentioned in the "references relied on".	RMS: Agreed. The text should have been as follows: Chemically and physically stable for two years at ambient. Physical properties tested before and after storage– appearance, particle size, pH, dispersibility, suspensibility, wet sieve, wettability, attrition, acidity, dustiness and persistent foam. Due to the study coming in late, the reference list was mistakenly not updated. However, it will be included in the list of references relied on. Open Point: The list of references relied on to be updated.	Open point: The reference Güldner, 2005, Lab. ID. 02-99 should be added to the list of references relied on. The storage stability correction should be considered in a revised DAR or corrigendum (WG).

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(63)	Vol. 3, B.2.3.1, active substance	NL: The name of the impurity is confidential, unless this impurity is relevant According to C.2.1 however, **no** impurities of particular toxicological and environmental concern in fluopicolide technical material are present The named impurity is also metabolite M-01 So change the sentence in *Limited data were also submitted on metabolite M-01(.....)* Make also clear that AEC657188 = M-02 and AE0608000 = M-03	RMS: Agreed. Comments noted. Addressed.	Addressed: Rapporteur to consider in revised DAR or corrigendum.
1(64)	Vol. 3, B.2.4	DE: The studies Zietz, 2004b and Billian and Schöning, 2004 should be deleted from the list because they belong to Annex II, 6.0.	RMS: Agreed. Comments noted. Open Point: The list of references relied on to be updated.	Open point: The studies Zietz, 2004b and Billian and Schöning, 2004 should be deleted from the list of references relied on because they belong to Annex II, 6.0.

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(65)	Vol. 3 B.2.2.11 surface tension	AT: The concentration used is not reported. SC formulation	RMS: The concentration used was 10g/l. Addressed.	Addressed: Rapproteur to consider in a revised DAR or corrigendum.
1(66)	Vol. 3 B.2.2.15 shelf life	AT: The content of M-01 before and after storage must be determined. SC formulation	RMS: Not required as the active substance content only fell by 0.8% after 2 years storage. Addressed.	Data requirement: The relevant impurity must be analysed for before and after two years storage and a validated method of analysis is required SC and WG formulation. It should be noted that the applicant has stated in there comments that they disagree with this compound being considered as relevant. See also 1(68), 1(85)
1(67)	Vol. 3, B.2. Physical and chemical compatibility of tank mixes	AT: Nothing is reported. SC formulation	RMS: EXP11120A is the SC formulation and as stated in the evlauation no compatabilities were requested. Addressed.	Addressed: No compatabilities were requested.
1(68)	Vol. 3 B.2.2.15 shelf life	AT: The content of M-01 before and after storage must be determined. WG formulation	RMS: Not required as the active substance content only fell by 2.8% after 2 years storage. Addressed.	See data requirement in comment 1(66).
1(69)	Vol. 3, B.2. Physical and chemical compatibility of tank mixes	AT: Nothing is reported. WG formulation	RMS: EXP11074B is the WG formulation and as stated in the evaluation no compatabilities were requested. Addressed.	Addressed: No compatabilities were requested.

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(70)	Vol.1, 3.1, Background to proposed decision	NL: IUPAC name is: 2,6-dichloro-N-[3-chloro-5-(trifluoromethyl)-2-pyridylmethyl]benzamide	RMS: Agreed. End points have been amended. Addressed.	Addressed: Rapporteur to consider in a revised DAR or corrigendum.
1(71)	Vol. 1, list of end points, Summary of representative uses, p. 63	EFSA: The column "g as/hL" should be filled in for the use in potatoes.	RMS: Agreed. The applicant has now provided the information and the end points have been amended. Addressed.	Addressed: The end points have been amended.
1(72)	Vol. 1, list of end points, analytical methods for residues, p. 65	EFSA: RMS should consider to clarify the LOQs for each analyte instead of given a range.	RMS: Point noted. However, the information is provided in Table B5.1 in Volume 3. We do not intend to amend the LOEP. Addressed.	Open point: The LOQs should be given for each analyte in the list of end points.
1(73)	Vol. 3, B.3.4.1	DE: The information should be given here, a reference to the safety data sheet is not sufficient.	RMS: The applicant addressed this point by cross-referencing the MSDS. The information would be the same. Addressed.	Addressed: The information is available in the DAR.
1(74)	Vol. 3, B.3.4.2 (detailed instruction for safe disposal)	DE: The method described should be stated under "controlled incineration". There is a disagreement to the previous information. It should be stated clear, if a temperature of 800 °C is sufficient or if a temperature of 1100 °C is necessary. If the second case applies: is there a possibility that polyhalogenated dibenzo-p-dioxines and dibenzo-furans are formed during incineration at lower temperatures?	RMS: Agreed. The applicant has now clarified that this was an error in the dossier and section on controlled incineration should read as follows: 'As a safe means of disposal BCS recommends to burn the product in an incinerator following the EU Regulation (European Directive EC/94/67, Article 6) with the conditions : - temperature above 1100 °C, - residence time greater than 2 seconds and - presence of more than 6 % of oxygen in order to prevent the formation of polyhalogenated dibenzo-p-dioxins and dibenzo-furans.	Addressed: Rapporteur to consider in a revised DAR or corrigendum.

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)
			From the chemical structure of fluopicolide the w/w percentage content of halogen can be calculated as approximately 42.59% w/w halogens. Therefore, since the halogen content of AE C638206 (42.59% w/w halogens) is below the 60 % threshold (Directive 94/37/EEC), a study of the pyrolytic behaviour of the active substance under controlled conditions at 1100 °C and the content of polyhalogenated dibenzo-p-dioxins and dibenzo-furans in the product of pyrolysis is not required. In addition, a chemical consideration of fluopicolide also indicates that no orthochlorophenol moiety is present in the molecule. Therefore, the probability of formation of dibenzo-p-dioxins and dibenzo-furans is very low and the presence of such compounds is unexpected. See also the Bayer statement (D. Renaud, 2004): "Incineration as a safe means disposal and pyrolytic behaviour under controlled reactions - Code : AE C638206" (Doc N° : C039169 or M-226555-01-1). Addressed.	
1(75)	Vol. 3, B.3.4.2 (controlled incineration)	DE: The first sentence makes no sense, it is just a description of the data requirement.	RMS: This was an editorial error and the first sentence should be a heading to the text below. Addressed.	Addressed: The first sentence simply states that it is the applicants wording and not the

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)
				rapporteurs.
1(76)	Vol. 3, B.3.4.3	DE: The information should be given here, a reference to the safety data sheet is not sufficient.	RMS: The applicant addressed this point by cross-referencing the MSDS. The information would be the same. Addressed.	Addressed: The information is available in the DAR.

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(77)	Vol. 1, List of Endpoints (methods of analysis, PPP)	DE: Please change “were” with “was”.	RMS: End points updated. Addressed.	Addressed: The end points have been amended.
1(78)	Vol. 3, B.5 analytical methods in general	AT: No information about linearity is provided.	RMS: The RMS confirms that in all cases acceptable linearity data were submitted. Addressed.	Open point: At least the linearity range should be given for all the residue methods. See also 1(81).

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(79)	Vol. 3, B.5.1, method validation	BCS: Page 57: General comment: Limit of determination is the same as limit of quantification. Not to mix it up with limit of detection it would be better to say "limit of quantification"	RMS: Agree. Point noted. Addressed.	Addressed: Rapporteur to consider in a revised DAR or corrigendum.
1(80)	Vol. 3, B.5.1.1, technical active substance	NL: The AM for the determination of the a.s. in the t.a.s is not confidential and should be presented in this paragraph.	RMS: Comment noted. RMS will consider presenting this information in an addendum. Open Point: RMS to prepare an addendum.	Addressed: Actually it is confidential.
1(81)	Vol. 3, Table B.5.1	NL: Not all validation data are presented in the table: -linearity data are missing -interference? -It is not clear what the mean recovery is at each individual concentration level -It is not clear what the precision-repeatability is at each individual concentration level (and on how many measuremnts the precision is based)	RMS: RMS can confirm that in all cases acceptable linearity and interference data were submitted. RMS can confirm that all recoveries and precision data were acceptable, overall mean only recorded in order not to make the table over cumbersome Addressed.	Open point: For the residue methods the mean recovery at each fortification level should be given. The % RSD should be calculated and given for each level and the number of samples should also be given. The linearity issue is already addressed by the comment in 1(78). See also 1(83).
1(82)	Vol. 3, B.5.1	DE: The methods for the analysis of the active substance and relevant impurities in the technical material and the plant protection products are not considered as confidential. Appropriate information should be given here.	RMS: Comment noted. RMS will consider presenting this information in an addendum. Open Point: RMS to prepare an addendum.	Addressed: Rapporteur to consider in a revised DAR or corrigendum.
1(83)	Vol. 3, Table B.5.1, p.	EFSA: RMS should clarify the fortification	RMS: There were at least 5 replicates at the two	See open point in comment 1(81)

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)
	57ff	levels and the number of recovery experiments available to avoid misunderstandings. According to the given details it is unclear how many repetitions were conducted on each level (e.g. does " 0.02 - 0.2 n = 10" mean that at "0.02 and 0.2" each had 5 repetitions validated? Or were more than two fortification levels validated?)	fortification levels. Addressed.	
1(84)	Vol. 3, B.5.1.3 method for fluopicolide in PPP	AT: The analytical method is not confidential.	RMS: Comment noted. RMS will consider presenting this information in an addendum. Open Point: RMS to prepare an addendum.	Addressed: Rapporteur to consider in a revised DAR or corrigendum.
1(85)	Vol. 3, B.5.1.3 method for relevant impurities in the formulation	AT: A method for M-01 is required.	RMS: Not required as the active substance content only fell by less than 3% after 2 years storage. Addressed.	See data requirement in comment 1(66)
1(86)	Vol. 3, B.5.1.3, plant protection products	NL: The AM for the determination of the a.s. in the ppp is not confidential and should be presented in this paragraph.	RMS: Comment noted. RMS will consider presenting this information in an addendum. Open Point: RMS to prepare an addendum.	Addressed: Rapporteur to consider in a revised DAR or corrigendum.
1(87)	Vol. 3, B.5.2 B.5.5, analytical methods for residue analysis	BCS: Pages 55 and 60: All samples were analysed with the means of the following submitted analytical methods: **C024784** (Zietz E, 2002) **C031433** (Schöning, R, Billian, P, 2003) **C038955** (Schöning, R, Billian, P.,2003) **C038960** (Schöning, R, Billian, P.2004). but not with the multiresidue method S19 as mentioned in the DAR. These methods are missing in the reference list.	RMS: Only enforcement methods appear in section 5, these methods are summarised in section 7. Addressed.	Addressed: Only enforcement methods appear in B.5.

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)
		Remark: The methods cited in the DAR under 5.2. Peatman & Harrand 2003a and Taylor 2004, are the validation and ILV study for the multi-residue method for enforcement purposes.		
1(88)	Vol. 3, B.5.2 Analytical Methods for treated plants ...	DE: The study of Taylor, 2004 is for several reasons not acceptable (valid). Other studies of the dossier have to be included in the DAR (methods based on LC-MS/MS from Zietz, 2002 and Schoening/Billian, 2003)	RMS: The RMS considers that the Taylor (2204) is acceptable. Only enforcement methods appear in section 5, the other residue methods are summarised in section 7. Addressed.	Addressed: The LC-MS/MS are data generation methods not enforcement methods and it is not clear what the issue is with the GC-MS method.
1(89)	Vol. 3, B.5.2 – B.5.4	DE: Due to the ongoing discussion about the need of linear calibrations we would like to highlight that several accepted studies are not based on linear calibrations or does not allow to evaluate linearity. (DE has no problems with the acceptance of the studies, but with the need of linearity.)	RMS: Point noted. Addressed.	Addressed: This is more a general issue.
1(90)	Vol. 3, B.5.3.1 Analytical Methods for Soil	DE: It is unclear, in which way positive findings in soil can be confirmed.	RMS: As the method used was LC/MS/MS a confirmatory method was not considered necessary	Addressed: A confirmatory method is not required.
1(91)	Vol. 3, B.5.3.2 Analytical Methods for Drinking Water	DE: In chapter 2.5.1 and in the LOEP the residue definition for ground water includes parent and metabolites M-01, M-02, M-03, M-05, M-10, M-11, M-12,	RMS: Point noted. However, the metabolites mentioned in the LOEP are those that the fate evaluation identified as needing to be considered in the risk assessment. The	Addressed: The methods can analyse for the current residue definition.

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)
		M-13 and M-14. The method of Queyrel and Rosati, 2003 allows the determination of parent, M-01 and M-02 only. Data requirement: An analytical method for residues of M-03, M-05, M-10, M-11, M-12, M-13 and M-14 is needed.	mammalian toxicology evaluation only identified M01 as of concern; the only finding of toxicological significance for M01 compared with parent from bridging studies was an increase in the acute oral toxicity. The remaining metabolites were of equivalent or lower toxicity than the parent. M-01 is an important residue of fluopicolide, the remaining metabolites do not occur in significant amounts as residues. The ecotox assessment also discounted the metabolites as not relevant. See also 5(26) and 5(27). The listed metabolites are not considered relevant. Therefore, further analytical data are not considered necessary. Addressed.	
1(92)	Vol. 3, B.5.3.2 Analytical Methods for Surface Water	DE: In chapter 2.5.1 and in the LOEP the residue definition for ground water includes parent and metabolites M-01, M-02, and M-03. The method of Queyrel and Rosati, 2003 allows the determination of parent, M-01 and M-02 only. Data requirement: An analytical method for residues of M-03 is needed.	RMS: See 1(91), 5(26) and 5(27). M-03 is not considered relevant, therefore, further analytical data are not considered necessary. Addressed.	Addressed: The methods can analyse for the current residue definition
1(93)	Vol. 3, B.5.3.1 Analytical Methods for S Drinking Water	DE: It is unclear, in which way positive findings in drinking water can be confirmed.	RMS: As the method used was LC/MS/MS a confirmatory method is not considered necessary because of the accuracy involved with an LC/MS/MS method. Addressed.	Addressed: A confirmatory method is not required

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(94)	Vol. 3, B.5.3.1 Analytical Methods for Surface Water	DE: It is unclear, in which way positive findings in surface can be confirmed.	RMS: See 1(93). A confirmatory method is not needed due to the accuracy of a LC/MS/MS method. Addressed.	Addressed: A confirmatory method is not required
1(95)	Vol. 3, B.5.5, Summary of Methods of Analysis	NL: A residue analytical method for food/feed in animal matrices is not necessary as no residues are expected. The submitted method is valid however not ILV has been submitted	RMS: Agree, method included in case in the future an additional use results in positive residues in animal products. The method was also required in order to analyse the samples from the animal transfer studies ILV data were not submitted as positive residues would not be expected in animal products from the proposed uses of fluopicolide Addressed.	See open point in comment 1(29).
1(96)	Vol. 3, B.5.5 evaluation and assessment	AT: A compilation of determined LOQs contra relevant residue data should be reported.	RMS: The LOQs information can be found in section B.5, Table B.5.1.	Addressed: The information is available in the DAR

Comments received on reporting table, section Physical/Chemical Properties; Details of Uses and Further Information; Methods of Analysis (B.1- B.5)			
Reference to reporting table	MS / Notifier	Comment	EFSA response
1(5)	NOT	BCS agrees with the RMS that toluene should not be classified as a relevant impurity. A detailed position paper (Payraudeau, V; Report M-284199-01-1, Fluopicolide: Toxicological relevance of the solvent toluene present as an impurity in the technical grade active substance) is available and can be submitted upon request.	Noted toluene has been considered relevant for other active substances.

Comments received on reporting table, section Physical/Chemical Properties; Details of Uses and Further Information; Methods of Analysis (B.1- B.5)			
Reference to reporting table	MS / Notifier	Comment	EFSA response
1(5)	AT	We support DE and EFSA that toluene is considered relevant. (The amount is only important for the classification.) Thus it must be demonstrated that the contents of toluene do not increase during storage in both formulations by the means of valid analytical methods which are required as well. According to SANCO 3030/99 the methods must be capable determining each in the presence of the other and in the presence of the active substance if the preparations contain more than one relevant impurity (toluene and M-01).	Noted
1(7)	NOT	BCS agrees with the rapporteur. The expert statement submitted to PSD (Bowen, T; report AF05/100; M-261425-01-1) can be made available upon request.	Noted
1(8)	NOT	BCS agrees with the rapporteur. The expert statement submitted to PSD (Bowen, T; report AF05/100; M-261425-01-1) can be made available upon request (see also comment under 1(11); 1(12) and 1(13).	Noted
1(11); 1(12); 1(13)	NOT	Regarding the acceptability of recovery and accuracy determinations at 10 times the specification levels of impurities, BCS has prepared an additional position paper in the context of the national evaluation of fluopicolide in Germany. This paper (Bowen, T; report AF07/023, M-284628-01-1) can be made available upon request.	Noted
1(16)	AT	The reply of the RMS concerning the justification should be discussed in an expert meeting. As discussed and agreed at EPCO 20 the use of another compound can be accepted if a justification by the notifier is provided and the chemical structure and the chromatographic behaviour is similar. In this case the molecular structure of the mentioned impurity differs significantly to the one of the active substance. The retention times of all impurities and the active substance should be reported as well.	The point has been changed from addressed to an open point

Comments received on reporting table, section Physical/Chemical Properties; Details of Uses and Further Information; Methods of Analysis (B.1- B.5)			
Reference to reporting table	MS / Notifier	Comment	EFSA response
1(20)	NOT	AE C653711 (M-01) is toxicologically comparable with the parent with the exception of its acute oral toxicity [LD50 = 2000 (male rats) and 500 mg/kg bw (female rats), respectively, for M-01 versus LD50 > 5000 mg/kg bw for Fluopicolide]. Provided the minimum purity of the active substance is set at more than 97.0 % and taking into account that the specification limit for M-01 is set at max. 0.4 %, AE C653711 should not be considered as a relevant impurity. The fact that M-01 is the most significant residue other than the parent is no basis for deriving relevant impurities.	Noted
1(24)	NL	Minor issue: density is now correctly displayed, however, purity should be stated as well.	The point has been made an open point.
1(29)	NOT	Although formally not required, an ILV supporting the analytical method for animal commodities is available now. The report (Bacher, R; report M-262176-01-1) can be made available upon request (see also 1(95).	Noted but for the moment it is not required
1(38), 1(53), 1(66), 1(68), 1(85)	NOT	BCS disagrees with the classification of M-01 as a relevant impurity. See also comment under 1(20) above	Noted a note has been added to the reporting table under 1(66)
1(40)	AT	A detailed description of EEC/A.1 (this was reported in the DAR anyway) was requested as capillary method, hot stage methods, freezing temperature determinations, methods of thermal analysis and determination of the pour point (as developed for petroleum oils).	OK open point.
1(88)	NOT	Although the RMS considered the study of Taylor (2004) as acceptable, BCS has carried out an additional ILV in order to address concerns of MS about deviations in the extraction module E1. The new ILV (Rzepka, S; Report no. M-280096-01-1) can be submitted upon request.	Noted
1(95)	NOT	Although formally not required, an ILV supporting the analytical method for animal commodities is available now. The report (Bacher, R; report M-262176-01-1) can be made available upon request (see also 1(29).	Noted

2. Mammalian toxicology

Toxicokinetics (B.6.1)				
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)
2(1)	Vol. 3, B.6 General comment	NL: The DAR contains many tables and in the text many times reference is made to the particular table which is clarified by the text. However, in most cases, the table number referred to is not correct (starting at page 207).	RMS: Point noted. Apologies this is an editorial error. The RMS could produce an addendum if considered necessary. Open Point: RMS to produce an addendum if necessary.	Addressed RMS to consider in a revised DAR or corrigendum
2(2)	Vol. 3, B 4 (references relied on)	DE: References for the active substance are missing.	RMS: The references for the active substance are listed (as indicated by the Annex II point numbers). Only the heading is missing. Addressed.	Addressed

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(3)	Vol. 1, Level 2, 2.3.1, Vol. 3, B.6.3.3 and Vol. 3, B.6.3.6 NOAEL in 90 days dog	BCS: Page 25, paragraph 3 and page 230, text under table 6.57 and page 236 paragraph 5: BCS considers that the effects observed in the liver at 1000 mg/kg/d are of no toxicological relevance due to the low magnitude of liver weight increase without any histopathological associated changes. The overall toxicity data package on fluopicolide showed that the effects observed in the liver following repeated exposure to fluopicolide in rats, mice and dogs are considered as adaptive and not adverse. Therefore, the NOAEL should be set	RMS: Disagree: the liver is a target organ in 3 animal species with evidence of effects on liver function (clinical chemistry and histopathology). The NOAEL in the 90-day dietary study in dogs was 70 mg/kg bw/day based on increased absolute and relative liver weight at 1000 mg/kg bw/day for both sexes. The findings at 1000 mg/kg bw/day are consistent with those found at the same dose levels in the 28-day and 52-week dog studies.	Open point The relevance of the liver weight increase in the 90 day study in dog to be agreed on in an experts' meeting

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)
		at 1000 mg/kg/d in the 90-day dog study.	Addressed.	
2(4)	Vol. 3, B.6.3.6, summary short-term tox	BCS: Page 237, table B.6.60, 28-day rat study (Higgs 2000): BCS suggests to not mention the " statistically non-significant increase in the absolute and relative liver weights in males" as findings observed at the LOAEL since they are considered as non adverse.	RMS: Disagree. Whilst the increases in liver weight in males are not statistically significant, they are consistent with findings in other rat studies and with other indicators of liver function in this study. Reviewers would consider specific information on this endpoint helpful when interpreting the relevance of the increased levels of cholesterol and the increased incidence and/or severity of centrilobular hepatocyte hypertrophy in both sexes in his study. Addressed.	Addressed
2(5)	Vol. 1, Level 2, 2.3.1, long-term toxicology	BCS: Pg. 27, paragraph 3: This paragraph should be moved down into the reproductive toxicity section (following the first paragraph of reproductive section on page 27).	RMS: Comment noted. Addressed.	Addressed RMS to consider in a revised DAR or corrigendum

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.6.5.2, chronic tox and carcinogenicity mouse	NL: Page 299: fluopicolide caused an increase in hepatocellular adenomas. In the DAR it is stated that the mechanism (P450 induction comparable with phenobarbital; however, phenobarbital was not concurrently tested in the same study!) is	RMS: Disagree. It would be preferable to have Phenobarbital tested concurrently in the same mechanistic study. However, there is much published literature on Phenobarbital-type liver enzyme induction (e.g. see Para 52, IPCS Harmonization Project: IPCS Framework For Analysing The Relevance Of A Cancer Mode	Open point The carcinogenic potential of fluopicolide to be discussed in an experts' meeting, in particular with regard to the possible mode of action involved and the need for classification

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)
		not relevant to humans. Can this be stated this explicitely? Another conclusion could be: for this mechansim a threshold can be derived, but classification with R40 should be considered.	Of Action For Humans) and it is considered possible to assess human risk adequately from the information available. The 28-day study with phenobarbital and substantial evidence in published literature identifies the relevance and adequacy of the biomarkers used in the mechanistic study for fluopicolide. This suggests a phenobarbital-type mechanism for rodent liver tumours which is recognised to be not relevant to humans. In the 2-year dietary study in mice with fluopicolide, there was a clear NOAEL for liver tumours and associated pre-neoplastic findings, suggesting that these tumours occurred above the Maximum tolerated dose. For this reason, it is considered inappropriate to classify with R40 as a hazard to humans. Addressed.	

Other toxicological studies & Medical data (B.6.8-B.6.9)				
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.6.8.1.1, L), re-examination of histopathology from 2-year rat with M-01	NL: The hepatocellular adenomas observed in female rats are of concern. Not statistically significant does not always mean not biologically relevant. Classification with R40 (if that is possible for a metabolite) should be considered.	RMS: Disagree. Please see also point 2(6). M-01 has been identified as the primary metabolite of fluopicolide and the evidence from the catrcinogenicity and mechanistic studies on fluopicolide would apply to M-01 See 2(6). Evidence for carcinogenicity in the 2-year rat study was limited and the Classification of M-01 with R40 is considered unwarranted as it is for fluopicolide, the parent. Addressed.	See 2(6)

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(8)	Vol. 3, B.6.10, summary mammalian toxicology	BCS: Page 468, 1. paragraph: Different values are given for the % of bioavailability: The value proposed by the notifier was 74% as the percentage present in the urine is higher in the single dose at 10 mg/kg when compared to the biliary excretion study at 10 mg/kg. This suggests that the urine excretion is expected to be higher. As a consequence, the value of 74% is still supported by the notifier and should be proposed in the DAR.	Disagree: The main route of elimination of radiolabel is in faeces. The critical point is the difference in biliary excretion levels between pyridyl and phenyl radiolabel and the biological reasons for such a difference. For the biliary studies, recovery of radiolabel was excellent, approximately 100% so justification for attempting to use another study in which biliary study is unknown is necessary. "A correction factor of 0.62 was allowed to account for the extent of oral absorption which is based on that determined for the pyridyl radiolabel in the biliary excretion study. The basis for lower oral absorption estimate using	Open point The amount of bioavailable fluopicolide after oral administration to be agreed on in an experts' meeting

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)
			the pyridyl radiolabel (62%), rather than the phenyl radiolabel (80%) is unclear and hence the more conservative estimate has been relied upon for the derivation of the AOEL." There is also no basis to find an average of pyridyl and phenyl radiolabel unless there is biological justification. Addressed.	
2(9)	Vol. 3, B.6.10, summary mammalian toxicology, reproductive toxicology	BCS: Page 473, 1. paragraph: The NOAEL for rats should read 60 mg/kg bw/d instead of 20 mg/kg bw/d. as correctly stated on page 27 in Volume 1.	Agree: This is an error. The correct NOAEL for rats was 60 mg/kg bw/day and not 20 mg/kg bw/day. Addressed.	Addressed RMS to consider in a revised DAR or corrigendum
2(10)	Vol. 3, B.6.10.1, ADI	DE: The ADI of 0.08 mg/kg bw derived from the NOAEL of 7.9 mg/kg bw/day in the 78-week dietary study in mice and a 100-fold safety margin is agreed. The ADI value is supported by the 104-week dietary study in rats.	RMS: Noted. Addressed.	Addressed
2(11)	Vol. 3, B.6.10.2, Acute Reference Dose	NL: Is it necessary to derive an ARfD for fluopicolide?	RMS: Please see MS comments at 2(13) and justification in the DAR. Addressed.	See 2(12)

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(12)	Vol. 1, Level 2, 2.3.3; Vol. 1, Level 2, Appendix 3 and Volume 3, B.6.10.2, ARfD	BCS: Pages 33, 109 and 680, ARfD setting: ARfD at 0.18 mg/kg based on the 28-day rat oral study (NOAEL = 17.7 mg/kg/d). BCS disagrees and supports that in view of the overall toxicological data package available for fluopicolide, the setting of an ARfD is not appropriate. A more detailed position paper was prepared by BCS ("Waiver for an acute reference dose setting", Payraudeau, V; March 31, 2006) which can be made available upon request.	RMS: Please see MS comments at 2(13) and justification in the DAR. Addressed.	Open point The need for setting an ARfD, and the most relevant study to be considered, to be discussed in an experts' meeting
2(13)	Vol. 3, B.6.10.2, ARfD	DE: An ARfD of 0.18 mg/kg bw derived from the NOAEL of the 28 day dietary study in rats of 17.7 mg/kg bw/day supported by the developmental toxicity study in rabbits is agreed. The NOAEL for foetotoxicity and maternal toxicity in rabbits was 20 mg/kg bw/day based on mortality, high incidence of premature delivery and reduction in body weight gain and food consumption in dams and reduction in foetal body weights and foetal crown-rump lengths in foetuses at dose levels of 60 mg/kg bw/day. Three animals of this high dose group were found dead and 15 animals of this group were killed after premature delivery from day 22-29 of gestation. These	RMS: Agree. Addressed.	See 2(12)

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)
		animals showed decreased defecation, reduced hay consumption, hypoactivity, bristling coat, pultaceous feces and discolored urine. One animal of this dose group showed increased salivation.		
2(14)	Vol. 3, B.6.10.3, AOEL	DE: The AOEL of 0.05 mg/kg bw/day derived from the modified NOAEL of 8.4 mg/kg bw/day from the 90-day dietary study in rats, a 100-fold safety margin and a correction factor of 0.62 is agreed.	RMS: Noted. Addressed.	Addressed (see also 2(8))
2(15)	Vol. 3, B.6.10.3, AOEL	BCS: In the DAR (page 482) " A correction factor of 0.62 was allowed to account for the extent of oral absorption which is based on that determined for the pyridyl radiolabel in the biliary excretion study. The basis for lower oral absorption estimate using the pyridyl radiolabel (62%), rather than the phenyl radiolabel (80%) is unclear and hence the more conservative estimate has been relied upon for the derivation of the AOEL." Should be corrected to integrate the 74% correction factor.	RMS: Disagree: Please see detailed explanation at 2(8). Addressed.	See 2(8)

Toxicity of the product(s) (B.6.11)				
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(16)	Vol. 3, B.6.11.2b, acute dermal study	BCS: Page 487, last paragraph: Acute dermal toxicity of 'EXP11074B' For EXP 11074 the dose applied to animals was 2000 mg/kg/bw / day and not 4000. Acute dermal LD 50 is > 2000mg/kg/bw / day (also on page 487, fourth paragraph).	RMS: Agree: The the dose applied to animals was 2000 mg/kg/bw / day. However, there is an apparent error at Section 6.5.2 of the actual study (Reference T0072218, Krotlinger, 2003). The 4000 mg/kg bw applied dose indicated appears to have been incorrectly calculated. Therefore the Notifier should provide revised GLP compliant revision of the study report. Data Requirement: The Notifier should provide a revised GLP compliant revision of the acute dermal study report (Reference T0072218, Krotlinger, 2003).	Data requirement Applicant to provide a GLP revision of the acute dermal study (Krotlinger 2003) The applicant announced in the written procedure that the report M-220872-02-1 (Krotlinger 2003) is available and can be submitted immediately.
2(17)	Vol. 3B.6.11.4 b, acute dermal study	BCS: Page 490: The measured concentrations are not included in this summary while they are presented in all other studies. "Batch no. OP220266, containing fluopicolide 62.5 g/l and propamocarb 625 g/l" is in fact Batch no., OP220266, **containing 43.5 g/kg fluopicolide and 687 g/kg fosetyl aluminium**	RMS: Agree. The summary table is incorrect and the table should be the same as the text and read 43.5 g/kg fluopicolide and 687 g/kg fosetyl aluminium. Addressed.	Addressed RMS to consider in a revised DAR or corrigendum

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(18)	Vol. 3, B.6.12.2, Dermal absorption *in vivo*	NL: Tape stripping was performed, but all the material in the stratum corneum is	RMS: Disagree: The estimates of dermal absorption are highly conservative but	Open point RMS to provide further details on the

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)
		regarded as absorped, why? The presentation in the Table is too limited: separate values should be given for urine, treated skin and stratum corneum. Only then it will be clear what happens with the material in the stratum corneum. Furthermore, the results are remarkable: the total absorbed dose decreases in time, where a cumulative increase is expected (the sacrifice time was not presented in the table). Therefore, the values after 144 hours are in this case not the most conservative estimates.	justifiable given the very limited extent of dermal absorption. The only and critical factor accounting for any unexpected trend in values at any time point is inadequate recovery of the unabsorbed dose (gauze wash, skin swabs + surface dose) which is then lower than expected. This is very clear from the data and has been taken into consideration. The amount of radiolabel in blood continued to increase up to 144 hours suggesting that bioavailable radiolabel in the skin should not be discounted and also that the 144h values are the most relevant and conservative estimate. Addressed.	results of the *in vivo* dermal absorption study (see comment by NL) in an addendum
2(19)	Vol. 3, B.6.12, Dermal Absorption	DE: A dermal absorption of 0.24 % for the concentrate and of 2.75 % for the spray dilutions based on rat in vivo and comparative in vitro (human/rat skin) is agreed.	RMS: Noted. Addressed.	Open point Dermal absorption to be discussed in a meeting of experts (see also 2(18))

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(20)	Vol. 3, B.6.12 Dermal absorption	EFSA: dermal absorption to fluopicolide was tested with the SC formulation (fluopicolide and propamocarb) in *in vivo* and *in vitro* studies. The values derived were used for exposure estimates for both SC and WG (fluopicolide and fosety-Al) formulations. RMS to provide a justification on the applicability of the SC dermal values to WG formulation.	RMS: Based on the experience of the RMS, systemic exposure from a wettable granule formulation can be expected to be significantly less than that of a suspension concentrate formulated at comparable concentrations. Therefore, it is considered unnecessary to conduct new studies to confirm this. However. MSs may wish to discuss this at an Expert Meeting. Open Point: To be discussed at an Expert meeting, if considered necessary.	See 2(19)

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(21)	Vol. 3, B.6, Table B.6.203, operator exposure calculation	BCS: Page 508: Replace "representative medium volume (100 l/ha) or high volume (500 l/ha) uses (using appropriate versions of the UK POEM)" by "representative medium volume (100 l/ha) or high volume (1500 l/ha) uses (using appropriate versions of the UK POEM)"	RMS: The existing text is correct. Although the maximum proposed application volume for the use of EXP 11074B (the lowest spray concentration) is 1500 l/ha, the worst case for operator exposure when using the UK POEM for high-volume broadcast air-assisted sprayers is 500 l/ha (i.e. the highest spray concentration representing high-volume use). Addressed.	Open point The experts to consider whether the default given by the UK POEM model for high-volume broadcast air-assisted sprayers (500 l/ha) is representative for the real scenarios.
2(22)	Vol. 3, B.6, Table B.6.206, EUROPOEM data	BCS: Page 509: "The **relevant EUROPOEM data** are those derived from an operator monitoring study…… A summary of the study application parameters is	RMS: The EUROPOEM report was published in 1996 and these data are publicly available (www.europoem.csl.gov.uk). EUROPOEM data have been used in support of several EU	Open point The experts to agree on the operator exposure assessment for fluopicolide.

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)
		given in Table B.6.206." BCS comment: The EUROPOEM data are not yet publicly available. BCS questions why those unofficial data are used in an operator risk assessment for EU. The values obtained in the presented study are showing lower exposure and therefore a more favourable picture. BCS would be pleased to use them as being more representative of vineyard application. However, to be consistent with its position in other DARs, BCS suggests that those data should be removed from the DAR.	evaluations for EAS and NAS when relevant data in the UK POEM or the German Model are absent or limited. Addressed.	It is noted that the EUROPOEM is not yet validated for use in the regulatory risk assessment; the EUROPOEM group highlighted in the final report some drawbacks still to be clarified.
2(23)	Vol. 3, B.6.14 Exposure data	EFSA: the operator, worker and bystander risk assessment has been performed on the basis of fluopicolide only. The submitted risk assessment cannot be regarded as conclusive.	RMS: This evaluation is to consider the Annex I inclusion of fluopicolide. Products including mixed active substance are subject to assessment in line with the Uniform Principles at re-registration following a decision on inclusion. Addressed.	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(24)				New data requirement Applicant to provide information on the composition of the batch mixture tested in acute toxicity, genotoxicity and reproductive toxicity, and its comparability to the proposed specification New open point Based on information provided in Annex C to the DAR, it seems that some of the impurities present in the tested tox batches will be increased in the proposed specification (pending also on data requirement above). Experts to discuss in a meeting.
2(25)	Point transferred from the environmental fate section: Vol. 3, B.8.10, Assessment of the relevance of groundwater metabolites	DE: This point makes reference to sections B.6.1.4.1 and B.10.7.5 for an assessment of the relevance of groundwater metabolites. The latter section does not exist in the provided issue of the DAR. Possibly B.10.7.5 is identical to B.6.1.4.1. If not, the RMS is requested to provide section B.10.7.5 for further evaluation.	RMS – Section B.10 is the Efficacy assessment. Section B.6.1.4.1 is an overview of the information and B.10.7.5 will be presented in an addendum for completeness. Open point: RMS to prepare an addendum.	Open point RMS to present the complete assessment for the relevance of ground water metabolites in an addendum. Special attention should be paid to the fact that at this stage for metabolites M01, M05 and M10 the trigger of 0.75 µg/L is also exceeded either in the lysimeter or the FOCUS modelling.

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(26)	Question transferred from the residue section Vol. 3, B.1.5, Summary of metabolism in plants (see 3(10))			Open point Some metabolites are found in rotational crops. Their toxicity should be discussed compared to the toxicological properties of the parent. See 3(10). See notifier's comments provided during the written procedure

Comments received on reporting table, section Mammalian Toxicology (B.6)			
Reference to reporting table	MS / Notifier	Comment	EFSA response
General	NL	Agree with the open points to be discussed in an expert meeting	Noted
2(3)	NOT	BCS disagrees and considers the higher RLW observed in short term dog studies as non adverse as they were not associated with liver function impairment (only slight cholesterol increases in the 28-day dog study in 1/2 male, with no histopathological findings following 28-day, 90-day or 52-week exposure periods). Fluopicolide was shown to have a Phenobarbital-like mechanism in mice which is a MOA considered as non relevant to humans by current international guidance (US EPA and UK PSD).	Noted. The point will be discussed in an experts' meeting
2(6)	NOT	BCS agrees with the RMS that fluopicolide has a Phenobarbital-like mechanism for liver tumour formation in mice. The Phenobarbital study started with only one week delay to the fluopicolide one to avoid any logistical problems within the facility. For BCS an R40 classification is unwarranted according to international guidances on the relevance to humans of liver tumours	Noted. The point will be discussed in an experts' meeting

Comments received on reporting table, section Mammalian Toxicology (B.6)			
Reference to reporting table	MS / Notifier	Comment	EFSA response
		found in mice. A detailed position paper is available (Payraudeau, V. Report M-275342-01-1) and can be submitted upon request.	
2(7)	NOT	BCS agrees with the RMS that a classification of M-01 with R40 is unwarranted. Two detailed experts statements are available to address the statistical relevance and the carcinogenic potential (Payraudeau, V. Report M-274220-02-1; Pallen, C. Report M-273467-01-1) and can be submitted upon request.	Noted. The point will be discussed in an experts' meeting
2(7)	NL	The metabolite M-01 (BAM) is also formed in the metabolism of the active substance dichlobenil. NL is RMS for dichlobenil and the DAR is almost finished. It should be realised that the discussion in the expert meeting also concerns dichlobenil.	Noted
2(8)	NOT	BCS still supports the value of 74% as given in the dossier. A detailed position paper will be prepared until end of March and can be made available upon request, see also 2(15)	Noted. The point will be discussed in an experts' meeting
2(12)	NOT	BCS considers that the setting of an ARfD is not appropriate for fluopicolide. A position paper addressing this is available (Payraudeau, V. Report M-269338-01-1) and can be submitted upon request.	Noted. The point will be discussed in an experts' meeting
2(15)	NOT	see comment under 2(8)	Noted. The point will be discussed in an experts' meeting
2(16)	NOT	A GLP compliant revised report is available (Kroetlinger, F. Report M-220872-02-1) and can be submitted immediately.	Noted
2(18)	NOT	BCS considers that the proposed in vivo absorption values are indeed highly conservative (as stated by the RMS) and that it may be possible to exclude the radioactivity found in the outer layers of the stratum corneum at 144 hours post dose as there are indications that the levels in blood and excreta do not change significantly between the 72 hour and 144 hour sampling points	Noted. The point will be discussed in an experts' meeting
2(20)	NOT	BCS agrees with the statement made by the RMS that the use of data from an SC formulation for a WG formulation is a conservative approach as it would be expected that the proportional absorption would be higher from an SC formulation.	Noted. The point will be discussed in an experts' meeting

Comments received on reporting table, section Mammalian Toxicology (B.6)			
Reference to reporting table	MS / Notifier	Comment	EFSA response
2(24)	NOT	Information on the composition of the batch mixture tested in the tox studies was submitted with the dossier. The corresponding report (Cousin, J. Report M-232334-01-1) can be submitted again on request. BCS is fully convinced that the tox profiles of the impurities were covered during tox testing of the parent compound.	Noted. A summary table on the batches used in the key tox studies is missing in the DAR. Data requirement and open point confirmed
2(26)	NOT	see comment under 3(10)	Noted. The point will be discussed in an experts' meeting

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)	Metabolism studies: General comment	EFSA: It would facilitate the reading and understanding of the metabolism studies if in the table providing the results of partitioning of extractable radioactivity the concentration of the radioactivity (in mg/kg) and the %TRR is provided for each fraction.	RMS: Point noted. However, RMS believes it would make the tables too complex and difficult to understand. Addressed.	Addressed. RMS to consider in a corrigendum or a revised DAR.
3(2)	Vol. 3, B.7.1.1, Metabolism in lettuce	EFSA: 1. In table B-7.2 and B.7.4 the extractable radioactivity is characterised. Is it correct that the "extractable radioactivity" contains both fractions, the surface wash and the extractable radioactivity (as mentioned in Table B.7.1)? 2. What solvent is used for the surface wash ? Is it also acetonitril? 3. Table B.7.2: Was there an additional sampling day on day 29 or is this a typing error (it should read day 21)?	RMS: 1. Yes 2. Yes 3. Apologies should read 21. Addressed.	Addressed. RMS to consider in a corrigendum or a revised DAR.
3(3)	Vol. 3, B.7.1.1, metabolism in lettuce	BCS: Page 547, Table B.7.2: Correct Day 29 % of M-06 from 0.9 - 1.0% to 0.9%. Correct Day 29 concentration of M-06 from 0.11 - 0.01 mg/kg to 0.01 mg/kg.	RMS: Agree. Addressed.	Addressed. RMS to consider in a corrigendum or a revised DAR.

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(4)	Vol. 3, B.7.1.2, Metabolism in grapes	EFSA: Same comments as for metabolism in lettuce (comment 1 and 2).	RMS: Same response as given for 3(2). Addressed.	Addressed. RMS to consider in a corrigendum or a revised DAR.
3(5)	Vol. 3, B.7.1.4, confined rotational crops	BCS: Page 553, Paragraph 3, Line 1: BCS suggests the following sentence is reworded for clarity. "For lettuce the three components accounted for 92% (phenyl study) and 50% (pyridinyl study) of the total radioactivity in the crop at harvest". BCS propose the following rewording "For lettuce fluopicolide and M-01 accounted for 92% (phenyl study) and fluopicolide with M-02 accounted for 53% (pyridinyl study) of the total radioactivity in the crop at harvest".	RMS: Disagree. RMS considers the text as proposed in the DAR more clearly represents our conclusions. See B.7.1.4. Addressed.	Addressed. RMS to consider in a corrigendum or a revised DAR.
3(6)	Vol. 3, B.7.1.4, confined rotational crops	BCS: Page 555, Line 1: The RMS states in a footnote to Table B.7.11: "*Total [14C] residues in the 133 day study were lower than the [14C] residues in the 365 day study due possibly to the plot being flooded before the crops were planted (initial intention was for a 90 day study)." BCS suggest this is removed.	RMS: Disagree. RMS feels the wording clarifies why these results occurred. Addressed.	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(7)	Vol. 3, B.7.1.4 confined rotational crops	BCS: Page 557, Figure B.7.2: The metabolites M-05 (AE 1344122) and M-04 (AE C657378) are listed as major components of rotational crop residues. This is not correct for radish or lettuce where M-04 is not detected at all and M-05 is only detected at low levels. They only form major components of the residue in wheat. In Figure B.7.2 the metabolites are referred to by BCS codes and not M-01, M-02 etc as used throughout the rest of the DAR..	RMS: Disagree. Although it is correct that in radish and lettuce M04 & M05 were not detected, as a whole when looking at all rotational crops they were major metabolites. This is clearly stated in the DAR. Addressed.	Addressed
3(8)	Vol. 3, B.7.1.5, confined rotational crops	BCS: Page 558, Paragraph 5, Line 1: BCS suggests the following sentence is reworded for clarity. "For lettuce the three components accounted for 92% (phenyl study) and 50% (pyridinyl study) of the total radioactivity in the crop at harvest". BCS propose the following rewording "For lettuce fluopicolide and M-01 accounted for 92% (phenyl study) and fluopicolide with M-02 accounted for 53% (pyridinyl study) of the total radioactivity in the crop at harvest".	RMS: Disagree. See 3(5). Addressed.	Addressed. RMS to consider in a corrigendum or a revised DAR.

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(9)	Vol. 3, B.7.1.5, confined rotational crops	BCS: Page 559, Paragraph 2, Line 2: RMS states "However, the metabolites M-04, M-05, M-08 and AEB102859 were not found in the rat, but were not considered to be of toxicological concern at the levels present in the studies (see Section B.6.8.1)" BCS agree that the metabolites M-04, M-05, M-08 and AEB102859 should not be considered of toxicological concern. However the statement could imply that no toxicological information is available. Although M-04 was not detected in parent studies, it was present in an ADME study conducted with M-01.	RMS: Noted. There is extensive bridging data for the metabolites M-04 and M-05 whilst the amounts of residues of the remaining metabolites is noted to be very limited and unlikely to present a toxicological concern. Additionally for M-08 and M-09 (AEB 102859), significant structural similarity can be identified with M-02 for which extensive bridging toxicological data is provided. It can be predicted that M-08 and M-09 share the same intermediary metabolic pathway as M-02 and can be predicted not to differ significantly in toxicity profile. See Section B.6.8.1. for further details Addressed	Addressed. RMS to consider in a corrigendum or a revised DAR.
3(10)	Vol. 3, B.1.5, Summary of metabolism in plants	EFSA: The proposed residue definition from the RMS contains only parent fluopicolide. However, as in lettuce, in potatoes and in succeeding crops significant amounts of the metabolite M-01 was observed, this metabolite should be considered to be included in the residue definition. In the last paragraph of this section it is mentioned that some of the metabolites in plants were not found in rat metabolism studies, but they were not considered to be of toxicological concern. However, no information on the toxicological significance of metabolites M-08 and M-	RMS: In section B.7.3 (definition of Residue), M-01 has been included in the residues definition for risk assessment, due to it having similar mammalian toxicity to parent fluopicolide. However, the residue definition for monitoring is *parent fluopicolide only* because M-01 is not unique to fluopicolide. The toxicity of these metabolites is addressed in Section B.6.8.1. For comments on M-08 and M-09 - see comments at 3(9)above.	Open point. Residue definition for risk assessment in rotational crops to be discussed in an expert meeting See also comments 3(21), 3(24) Question referred to Section 2: Can it be concluded from the data provided on metabolites which ones should be considered as toxic as the parent or do not participate to the toxicological effects of the parent.

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)
		09 is provided.		

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(11)	Vol. 3, B.7.2.1, cattle metabolism	BCS: Page 559, 1st para: It should be clarified that the animals were dosed via capsule and that these dosages were equivalent to 1 mg/kg and 10 mg/kg in feed.	RMS: Point noted. RMS agrees that animals were dosed via capsule, however this is the standard way of dosing. The dosages are correctly stated in the DAR). Addressed	Addressed
3(12)	Vol. 3, B.7.2.1, cattle metabolism	BCS: Page 559, 3rd para should be corrected: A plateau in the 10 mg/kg studies was reached **after 5 days** for the phenyl and **after 32 hours** for the pyridinyl study. In the 1 mg/kg studies residues in the milk did not exceed **0.002 mg/kg** instead of 0.01 mg/kg.	RMS: Disagree. It is the opinion of RMS that a plateau is reached after 4 days. 0.01 mg/kg was the LOQ used as the method of analysis in the animal transfer studies. Therefore, the results reported in the animal metabolism studies are in line with the LOQ. Addressed	Addressed

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(13)	Vol. 3, B.7.2.1, cattle metabolism	BCS: Page 560: 1st para, 1st line: Only the percentage of the 10 mg/kg studies are summarised in Table B.7.14 1st para, 3rd line: Delete reference to table B.7.18 and B.7.19 7th line: Remaining unextractable radioactivity accounted for less than **18%** instead of 15%. 8th line: Delete…..in the egg yolk and white, replace by milk. 2nd para, 5th line: Residue in kidney was for the phenyl and the pyridinyl study 0.03 mg/kg. 3rd para, 3rd line: It should be 73-**78%** instead of 73-76%. 3rd para, 14th line: It should be 64-**74**% instead of 64-75%.	RMS: Point noted. Table B.7.15and B.7.16 are correctly quoted not B.7.18 and B.7.19 Agree. Point noted. Agree. Point noted. Agree. Point noted. Agree. Point noted. Agree. Point noted. Points addressed	Addressed. RMS to consider in a corrigendum or a revised DAR.
3(14)	Vol. 3, B.7.2.1, cattle metabolism	BCS: Page 562, table B.7.15: Fat, Fluopicolide: the value should be correct to 78% instead of 76%.	RMS: Agree. Point noted. Addressed	Addressed. RMS to consider in a corrigendum or a revised DAR.
3(15)	Vol. 3, B.7.2.2, poultry metabolism	BCS: Page 563: It should be clarified that the animals were dosed via capsule and that these dosages were equivalent to 1 mg/kg and 10 mg/kg in feed	RMS: Point noted. RMS agrees that animals were dosed via capsule, however this is the standard way of dosing. The dosages are correctly stated in the DAR. Addressed	Addressed. RMS to consider in a corrigendum or a revised DAR.

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(16)	Vol. 3, B.7.2.2, poultry metabolism	BCS: Page 564: discrepancy in % values, suggest that the first sentence should read: "Overall recovery was 83-96%, the bulk of the radioactivity was excreted (82-95%), with less than 0.2% in the eggs and less than 0.3% in the tissues." 5th para, 11th line: It should be clarified that the 44% value is for the phenyl study only.	RMS: Point noted. However, this is a rounding issue and makes no difference to the overall conclusion. Addressed	Addressed
3(17)	Vol. 3, B.7.2.4, summary of livestock metabolism	BCS: Page 567, 2nd sentence should be corrected as followed: Four lactating cows dosed via capsule 14 times over 7 days at a rate equivalent to 1 and 10 mg/kg in feed per day……..	RMS: Point noted. Addressed	Addressed. RMS to consider in a corrigendum or a revised DAR.
3(18)	Vol. 3, B.7.2.4, summary of livestock metabolism	BCS: Page 568: Last paragraph, first sentence: "Overall recovery was 83-96%, the bulk of the radioactivity was excreted (82-95%), with less than 0.2% in the eggs and less than 0.3% in the tissues." Page 568, 8th line: It should be less than **18%** instead of 15%. 10th line: It should be : …representing 73-**78%** of the total… 20th line: It should be ….accounted for 64-**74%**..... instead of 64-75%. 31th line: Replace liver by kidney. 2nd para: 1st sentence should be corrected as followed: For chickens dosed via capsule 14 days at a rate equivalent to 1 and 10 mg/kg in feed per day.	RMS: Agree. Point noted. Agree. Point noted. Agree. Point noted. Agree. Point noted. Disagree. We believe the text is correct. Agree. Point noted. Points addressed	Addressed. RMS to consider in a corrigendum or a revised DAR.
3(19)	Vol. 3, B.7.2.4, summary of livestock metabolism	BCS: Page 569, 13th line: ….accounted for less than 44%... this was for phenyl study only.	RMS: Agree. Point noted. Addressed	Addressed

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(20)	Vol. 3, B.7.2.4, Summary of metabolism in livestock	EFSA: Just for clarification: According to table B.7.15, parent fluopicolide accounted for 37% of TRR in milk. In the summary assessment, 29 % are reported. Which figure is correct?	RMS: 37% is the correct figure Addressed	Addressed. RMS to consider in a corrigendum or a revised DAR.
3(21)	Vol. 3, B.7.3, Residue definition	EFSA: RMS please provide information from which other pesticides metabolite M-01 may result. What conversion factor is proposed for the residue definition monitoring to residue definition risk assessment (for both, plant and animal products)?	RMS: M01 is a common moiety in a number of other pesticides for example dichlobenil Based on the residues in crops a conversion factor is not required as the residue of parent fluopicolide is present at far greater quantities than the residues of M01 in the crop. Addressed	See open point in comment 3(10)
3(22)	Vol. 3, B.7.6, Residues arising from supervised trials	EFSA: Note: no reside trials are available for SEU PHI of 35 days (representative use according to List of End Points).	RMS: Agreed. There are no trials to support the PHI of 35 days that is indicated in the representative use table. However, the residues evaluation at B.7.6 was actually based on the PHI that was included in the residues section of the dossier. In the dossier the proposed PHI for Southern Europe was reported to be 21. On querying this discrepancy, the applicant has now indicated that they actually wish the PHI to be 28 days. Therefore, on re-examining the residue trials data to see if this change is acceptable, it is noted that only 5 trials support this amended GAP. However, authorisation could be granted for 28 days based on the 21	Addressed. Note : If the intended PHI is 28 days in Southern Europe, results at 21 days can be considered appropriate for consideration in MRL setting, as they fall in the 25 % deviation acceptable range. Moreover, the active substance is very persistent on grapes and its residues do not decrease significantly along time

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)
			day data being more critical, the 21 day residues trails data for Northern and Southern Europe being very similar (highest residue in the Northern trials was 0.96 mg/kg and in the Southern 1.2 mg/kg) and resulting in the same proposed EU MRL (2 mg/kg). This information can be presented in an addendum if necessary The endpoints have been amended to give a PHI of 28 days. Open point: The RMS to produce an addendum if necessary.	
3(23)	Vol. 3, B.7.10, Residues in succeeding or rotational crops	EFSA: Please report on which soil types the rotational crops trials were performed? Soils sould be chosen which experience has shown to break down the active substance most slowly and under the most unfavourable conditions. Is this the case in the submitted trials? In succeeding crops residues of parent compound and metabolites might be expected in crops with a shorter vegetation period than the crops tested (e.g. treatment of early potatoes according to representative use, planting of a second crop on the treated area in the same season like lettuce). Are there any restrictions proposed for succeeding crops?	RMS: The crops were grown in a range of soil types around Europe from sandy loam to silty loam soils in which these crops are normally grown and hence are considered representative. No restrictions are proposed for succeeding crops due to the available data indicating that positive residues of parent would not be found in rotational crops. Addressed	Open point MS to consider whether rotational crop studies are sufficient for drawing final conclusions and whether restrictions are needed in an expert meeting. See also comment 3(34) See notifier's comments provided during the written procedure

Residue definition (B.7.3)				
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)
3(24)	B.7.3. (residue definition)	NL: No conversion factor for residue definition from monitoring to residue definition for risk assessment is proposed. Primary crops (treatment) Potato tuber (foliar): 1,5 Lettuce (drench): 1,3 Grape (foliar): 1 A conversion factor of 1.5 is proposed for leafy and tuber vegetables Rotational crops (planted DAT) Lettuce (29): CF = 9, relevant residue 0.93 mg/kg Radish roots (29): 2, relevant residue 0.09 mg/kg Wheat straw (133): 1.5, relevant residue 0.35 mg/kg In rotational crops with pyridinyl label, also M02 (lettuce and radish planted 29DAT), M09 (straw from wheat planted 133 DAT) and M05 (straw from wheat planted 365 DAT) were found as major metabolites which should be taken into consideration for calculation of livestock dietary burden and consumption of follow up crops.	RMS: Based on the residues in crops a conversion factor is not required as the residue of parent fluopicolide far out weighs the residues of M01 in the crop Significant residues of relevant components (parent and M01) did not result in crop samples from the 'cold study' (see Section B.7.10) to justify conversion factors being set M-02 was seen in the plant metabolism study but was also identified in the rat metabolism studies and considered to be of concern. The metabolites M-04, M-05, M-08 and M-09 were not found in the rat, but were not considered to be of toxicological concern at the levels present in the studies (see Section B.6.8.1). Therefore, it is not considered necessary to include them in the calculations. Addressed	See open point 3(10)

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(25)	Vol. 1, List of end points, Summary of representative uses evaluated Vol. 3, B.7.5 Identification of critical GAP	EFSA: Please clarify the details of envisaged uses for vine. The information provided in the List of End Points does not correspond with the data provided as critical GAP in Section B.7.5. The stated use rate and PHIs for vine differ: List of end points 1-3 * 100 to 133 g as/ha, PHI 35 d FR, IT, P, ES and 21 d for CZ B.7.5: 3 * 1.3 kg as/ha, PHI 21 d (N&SEU)	RMS: Agreed. The PHIs have been clarified and the LOEP amended. See 3(22) for further details. The critical use should be * 1.3 kg as/ha, PHI 21 d (NEU). Addressed	Addressed
3(26)	Vol. 3, B.7.5, summary critical GAP	BCS: Page 570, Table B. 7.20: Rate of application (grapes): The correct number is 0.13 kg as/ha instead of 1.3 kg/ha.	RMS: Agree correct figure is 0.13. Addressed	Addressed. RMS to consider in a corrigendum or a revised DAR.
3(27)	B.7.6. (residue trials grape)	NL: It is clear why higher residue values at higher PHI are used for calculation of the STMR, sine it represents the worst case STMR. However, it is unclear why these values are not used for calculation of MRLs.	RMS: They are used. See summary of critical residues data in the LOEPs. Addressed	Addressed
3(28)	Vol. 3, B.7.6, residue summary	BCS: Page 575-576, Table B.7.21: The last 5 trials with 4 treatments are not representing the critical GAP (see also next comment).	RMS: Disagree, critical application is the last one, from a residues point of view. Addressed	Open point. MRL proposal on grapes to be discussed in an expert meeting (validity of the trials with 4 applications, considering the

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)
				persistency of the compound) RMS to provide the meeting with statistical analysis of the results. See also comments 3(29), 3(30), 3(36), 3(37), 3(38)
3(29)	Vol. 3, B.7.6.1.1, summary of residues, grapes	BCS: Page 584, Northern Europe: 2nd sentence: It should be: **14** trials (for the 2001 trials…. and it should be ….up to 0.66 mg/kg, the STMR should be corrected to 0.35 mg/kg. Southern Europe: STMR should be corrected to 0.32 mg/kg	RMS: Disagree, text is correct. Addressed	See open point in comment 3(28)
3(30)	Vol. 3, B.7.6.1.2, summary of residues, potatoes	BCS: Page 584: paragraph Southern Europe (potatoes): "Twenty trials……", correct to "Thirteen trials….."	RMS: Disagree, text is correct. Addressed	See open point in comment 3(28)

Succeeding/Rotational crops (B.7.9)				
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(31)	Vol. 3, B.7.9.1, cow feeding study	BCS: Page 589: 2nd sentence should be corrected as followed: Nine lactating cows (three per dose group) each received orally by capsule twenty eight daily doses of fluopicolide, at rates equivalent to 0.5 (7N), 1.5 **(21N instead of 20N)** and 5 (70N) mg/kg in feed.	RMS: Disagree, text is correct. Addressed	Addressed
3(32)	Vol. 3, B.7.9.3, cow feeding	BCS: Page 590: 1st sentence: It should be…..dairy	RMS: Disagree, text is correct.	Addressed

Succeeding/Rotational crops (B.7.9)				
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)
	study	cattle dosed **equivalent to** 0.5, 1.5 and 5 mg/kg in feed.	Addressed	

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(33)	B.7.10 (rotational crops)	NL: It is concluded that parent fluopicolide is always < 0.05 mg/kg However, low levels of fluopicolide and it metabolites M01 and M02 are found in some trials. It is proposed to make a calculation of human dietary intake on these relevant residues which might occur in follow up crops, to assess the relative contribution of intake of residues from rotational crops compared to primary crops.	RMS: This has already been done (see Section B.7.16). Addressed	Open point. MS to discuss the approach for risk assessment depending on final decision on residue definition for risk assessment in rotational crops

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(34)	Vol. 3, Table B.7.11 B.7.1.4 (rotational crops)	NL : Lettuce planted 29 DAT, contained 0.11 mg/kg fluopicolide and 0.82 mg/kg M01. Since M01 is a relevant metabolite total relevant residue in lettuce planted 29 DAT is 0.93 mg/kg Therefore, a question arises: can residues be expected in leafy follow up crops as brassicas planted in the same season after for instance the culture of early potatoes?	RMS: Based on the results from the 'cold' rotation crop studies (Section B.7.10), residues in leafy crops would not exceed 0.05 mg/kg. Addressed	See open point in comment 3(23)
3(35)	B.7.1.3. (metabolism plants) Figure B.7.1. & B.7.1.4 (rotational crops) Figure B.7.2	NL: Codes (M01, M02, etc,) are different in figures and text, which is confusing.	RMS: Agreed. However, a key to the codes is provided in Appendix 5 of the DAR. Addressed	Addressed
3(36)	Vol. 3, B.7.16.2.1, STMR value grapes	BCS: Page 598: Table B.7.36: STMR value for grape-table is 0.33 mg/kg instead of 0.38 mg/kg. For wine the value is 0.13 mg/kg instead of 0.14 mg/kg. Therefore NEDI values need to be recalculated.. Statement under table is incorrect ("STMR is 0.38").	RMS: Disagree, text is correct as the RMS considers there to be 18 trials results that are relevant to the critical GAP and therefore this results in an STMR of0.38 mg/kg. Addressed	See open point in comment 3(28)
3(37)	Vol. 3, B.7.16.2.1, NEDI values	BCS: Page 599: After recalculation of the Table B.7.36 the values of the 1st table on this page have to be changed accordingly.	RMS: Disagree, text is correct. See 3(36) above. Addressed	See open point in comment 3(28)

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)
3(38)	Vol. 1, Level 2, Appendix 3, residue data summary	BCS: Page 115: Grape (table and wine) N: The following values should be deleted because they are not falling under the critical GAP (application rate too high): 0.32; 0.56; 0.83; 0.96. Therefore the STMR should be corrected to 0.35. Grape (table and wine) S: Value 0.36 should be deleted, does not exist as trial result, therefore the STMR should be corrected to 0.32	RMS: Disagree, text is correct. See 3(36) above. Addressed	See open point in comment 3(28)
3(39)	Vol. 1, Level 2, Appendix 3, processing factors	BCS: p. 116: Table with processing factors, last column: The values should be 27% for wine, 45% for must and 100% for raisins.	RMS: Disagree, text is correct. Addressed	Open point. RMS to check if balance data allow %ages of transference to be calculated
3(40)	Vol. 3, B.8.10, Assessment of the relevance of groundwater metabolites	DE: This point makes reference to sections B.6.1.4.1 and B.10.7.5 for an assessment of the relevance of groundwater metabolites. The latter section does not exist in the provided issue of the DAR. Possibly B.10.7.5 is identical to B.6.1.4.1. If not, the RMS is requested to provide section B.10.7.5 for further evaluation.	RMS – Section B.10 is the Efficacy assessment. Section B.6.1.4.1 is an overview of the information and B.10.7.5 will be presented in an addendum for completeness. Open point: RMS to prepare an addendum.	Open point RMS to present the complete assessment for the relevance of ground water metabolites in and addendum. Special attention should be paid to the fact that at this stage for metabolites M01, M05 and M10 the trigger of 0.75 µg/L is also exceeded either in the lysimeter or the FOCUS modelling. This open point is relevant for the sections of toxicology, ecotoxicology and residues. Therefore it has been copied in the corresponding table sections from the fate section.

Comments received on reporting table, section Residues (B.7)			
Reference to reporting table	MS / Notifier	Comment	EFSA response
3(10), 3(33)	NOT	The metabolite M-01 is a common rat metabolite and is included in the evaluation of the toxicological properties for fluopicolide. Moreover, a comprehensive tox package was submitted for M-01. Based on the findings of radiolabelled plant metabolism and confined rotational crop studies, data gathering analysis of field residue trials included M-01. Residues of M-01 in crops from residue trials were low and the proposed residue definition is parent fluopicolide. Fluopicolide was found to be the major component of grape residues, with M-01 detected at a maximum of 0.01 mg/kg in Northern European residue trials and 0.05 mg/kg in Southern European residue trials. In potato tubers all component residues, including M-01, were low and detected only at or below the LOQ of 0.01 mg/kg. The residue profile in field samples of rotational crops showed maximum residues levels of M-01 at 0.04 mg/kg in mature cabbage heads, supporting the proposal not to include M-01 in the DoR for MRL setting and monitoring. Information on the toxicological significance of rotational crop metabolites: For M-08 and M-09, toxicological data are provided for the structurally related compound M-02 (see RMS comment under 3(9)). M-02 has been separately evaluated for toxicological properties and is considered of no toxicological concern. M-08 and M-09 were not detected in metabolism studies in lettuce, potatoes or vines. In the confined rotational crop study M-08 was detected in some 365 day RACs and in 133 day straw, but not exceeding 9.4% TRR or 0.028 mg/kg in crops for animal fodder. It did not exceed 9.5% TRR or 0.003 mg/kg in RACs considered as representative for human consumption. M-09 was detected at a maximum concentration of 0.052 mg/kg (4.8% TRR) and 0.003 mg/kg (19.1% TRR) in RACs representative for animal fodder and human consumption. Both metabolites were either found below 10% TRR or in the case of percentages higher than 10 % TRR were always <0.05 mg/kg in RACS for animal fodder or <0.01 mg/kg in RACS for direct human consumption. Thus, M-08 and M-09 should not be included in the DoR for MRL setting and monitoring.	A reference to these comments is included under 2(26) of the reporting table
3(22)	NOT	See also comment under 3(28) regarding statistical evaluation of residue data	Noted
3(23)	NOT	Rotational crop trials were conducted at five trial sites in 2000. A second year of trials was	A reference to these comments

Comments received on reporting table, section Residues (B.7)			
Reference to reporting table	MS / Notifier	Comment	EFSA response
		conducted at two of these sites and a further two sites in 2001. Thus, trials were conducted at seven locations in total, with rotational crops grown in a range of different soil types at sites throughout Europe. Furthermore, in soil laboratory and field dissipation studies there was no correlation of dissipation/degradation rates of fluopicolide with soil organic carbon content or soil pH. In accordance with EU guideline 7524/VI/95 rev.2, a representative crop (cabbage) of the leafy vegetable group had been planted at the shortest plant back interval scenario possible in both field rotational crop studies. Cabbage plants were planted between 32 and 49 days after the last treatment and mature cabbage was harvested between 249 and 319 days after the last application. Residues of fluopicolide, M-01 and M-02 were always < 0.01 mg/kg except for M-01 were residues of 0.02 and 0.04 mg/kg were detected in two trials. Growing periods of other leafy vegetables (i.e. lettuce) are only marginally shorter than the ones seen for cabbage in the presented trials, hence no residues of parent compound are to be expected in rotational crops and no restrictions should be proposed. Additionally, BCS would like to state that it will apply in Q3 2007 for registration of fluopicolide on bulb-, flowering-, brassica- and leafy vegetables in all major MS. First residue results indicate residue levels of parent fluopicolide at levels around 5 mg/kg e.g. in lettuce. Thus, MRLs on leafy vegetables as primary crops will be established in the future.	is included under 3(23) of the reporting table
3(25)	NOT	BCS likes to point out that the correct application rate is 0.13 instead of 1.3 kg a.s./ha	Noted
3(28)	NOT	A statistical evaluation of the residue data is available (Kaethner, M; Report no. M-234980-01-1) and can be submitted upon request	Noted
3(38)	NOT	BCS likes to point out that no % transference values are given in the table. The values should be 27% for wine, 45% for must and 100% for raisins.	Noted
3(40)	NOT	BCS has prepared a comprehensive assessment of the relevance of groundwater metabolites which was also included in the dossier. The document (Leake, C. et al. Report no. M-227293-01-1) can be submitted upon request.	Noted

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 1. List of End points. General.	EFSA: In some of the boxes a extensive explanation is given, for clarity it would be desirable to have a more concise presentation of the information.	RMS – given the complexity of the data submitted and the evaluation, it was considered that the information presented in the LOEP was concise. The RMS would welcome any proposal for more concise wording.	Addressed
4(2)	Vol 1. List of End points. Classification and labelling. p 96	EFSA: R53 must be proposed since fluopicolide is not readily biodegradable.	RMS – accepted. The LOEPs have been amended. Addressed.	Addressed
4(3)	Vol. 3. B.8. Environmental fate and behaviour.	EFSA: Application rates assumed in the fate section are 4 x 100 g a.s / ha in potatoes and 3 x 133 g a.s /ha in vines. Please clarify the table of representative uses in the List of End points in order to indicate that the second number (after the +) refers to the second formulation component Fosetyl Aluminium or Propamocarb.	RMS – The endpoints have been clarified. Addressed.	Addressed
4(4)	Vol. 1, Level 2, Appendix 3, leaching studies	BCS: Page 73, Lysimeter/ field leaching studies: Include statement "All metabolites shown to be non-relevant".	RMS – do not agree as wording later in this section states that modelling indicates exceedance of 0.1 µg/l for metabolites, and subsequent assessment indicates that these are not relevant. Addressed.	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(5)	Vol. 1, Level 2, Appendix 3, PEC soil and Vol. 3, B.8.3, maximum predicted soil concentration	BCS: Page 76, PEC (soil) (Annex IIIA, point 9.1.3) – Other Metabolites and Page 779, Paragraphs 4 and 5: The metabolites M-02 and M-03 are rapidly degraded in soil. They do not accumulate in soil as demonstrated in a range of field dissipation and accumulation studies. BCS do not think it is appropriate to calculate peak plateau concentrations for these metabolites. Additionally, the maximum observed percentages are not consistent with Table B.8.145. For M-02 the value should be 16.3 % and for M-03 6.1 %.	RMS – disagree. Whilst we do not dispute the impersistence of these metabolites, there is the potential for these metabolites to form from accumulated residues of fluopicolide. This calculation is required for a worst case assessment of risk from these metabolites. Agree that p.76 of Vol 1 is inconsistent with Table B.8.145 – this can be amended to reflect the % observed formation on a molar basis. However it should be noted that formation % for this calculation used is the subject of discussion in comment 4(49). Addressed.	See open point in 4(44) See also 4(49)
4(6)	Vol. 1, Level 2, Appendix 3, DT50 soil, lab	BCS: Page 70, Rate of degradation in soil – Laboratory studies – Metabolite DT50lab (normalised to 20 ºC and pF2, aerobic): Include the values derived from the M-02 study for M-05, M-10 and M-14. in the list of DT50lab (normalised to 20 ºC and pF2, aerobic). These are included in the mean values. Correct "FOCUS degradation DT50 parameters (days) **including values** derived from modelling of metabolites in M-02 study.	RMS – agree. The LOEP have been amended. Addressed.	Open point Half lives for metabolites derived in the studies where they are dosed as starting material are seen by the RMS as more reliable, specially with respect to M14 (see DAR p 661). Therefore, only these DT50 should be reported in the list of end points. RMS to amend the list of end points accordingly. MS experts to discuss if the half lives derived from the study dosed with M02 may however still be used for modelling. See also 4(18) and 4(23)

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. 1, Level 2, 2.5.2, soil accumulation	BCS: Page 39: Soil accumulation testing: Table: Need to add the countries and north / south to the locations	RMS – Point noted. However, this information is provided in section volume 3, B.8. Addressed	Addressed
4(8)	Vol. 1, Level 2, 2.5.2, fate in soil and Vol. 1, Level 2, Appendix 3, DT50 soil, lab	BCS: Page 38, Paragraph 4, Line 2 and Page 70, Rate of degradation in soil – Laboratory studies – Metabolite DT50lab (normalised to 20 ºC and pF2, aerobic): BCS cannot reproduce the DT50 values for the metabolite M-01 under laboratory conditions, normalised to 20˚C and pF2.	RMS – This is a difference of opinion with respect to calculation of DT50 values; this difference may be due to differences in software packages or approach. Addressed	See open point in 4(10)
4(9)	Vol. 3, B.8.1.1, soil metabolism	BCS: Pages 621-623: Tables B.8.20, B.8.21, B.8.22 and B.8.23: In the headline please add [14C]-benzoyl before fluopicolide	RMS – Point noted. Addressed	Addressed RMS to consider in an amended DAR or corrigendum.

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.8.1.1; Vol. 3, B.8.1.4 and Vol. 3, B.8.1.8	BCS: Page 620, Paragraph 1; Page 648, Table B.8.69 and Page 715, Table B.8.142: BCS cannot reproduce RMS DT50 values normalised for moisture and temperature for report Allan, 2003c, Report B004074 although can reproduce RMS non-normalised DT50 values.	RMS – This is a difference of opinion with respect to calculation of DT50 values; this difference may be due to differences in software packages or approach. Addressed	Open point RMS to clarify normalized laboratory DT50's values for fluopicolide and metabolites. I.e for fluopicolide in LoEP the range is 194 – 333 d when for example in Allan 2003 c study degradation in one soil results in a normalized DT_{50} = 373 d (or for another example 664 d for Lamberton soil in Allan 2003e). Please do it in an addendum or in an updated list of end points following the updated template where the origin of the different end points and normalization procedures may be easily tracked. See also 4(8), 4(19) , 4(22), 4(23) 4(24), 4(47), 4(86) and 4(88).
4(11)	Vol.3, B.8.1.1, route of degradation	NL: The dose rate used in the studies a to c is much lower than the maximum in the proposed GAP (4x 400 g/ha). The sentence 'to simulate the maximum anticipated seasonal use rate' is therefore not correct.	RMS – the sentence reflects the Notifier's opinion. Addressed	MS are invited to comment on the need to discuss in an experts meeting the potential effect of the application rate on the derived kinetic parameters. If there is a need this will become an open point for discussion otherwise it is addressed. Written procedure Applicant clarifies that the proposed GAP is 4 x 100 g/ha.

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)
				Addressed
4(12)	Vol.3, B.8.1.2, route of metabolite degradation	NL: In study a) the application rate was 1.2 mg/kg equivalent to 1.6 kg/ha. Should this perhaps read active substance? For metabolite M01 this dose rate is very high.	RMS – the wording in the DAR is correct. Dose may seem high, but this is not considered by the RMS to be problematic. Addressed	MS are invited to comment on the need to discuss in an experts meeting the potential effect of the application rate on the derived kinetic parameters. If there is a need this will become an open point for discussion otherwise it is addressed. Written procedure Open point MSs to discuss the effect of the applied high concentration on the soil degradation study with metabolite M01 and the adequate DT50 for PECsoil and PECsw and PEC GW calculations.

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.8.1.2, route of metabolite degradation	NL: In study b) the application rate was equivalent to 400 g/ha. Should this perhaps read active substance? For metabolite M03 this dose rate is very high.	RMS - the wording in the DAR is correct. Dose may seem high, but this is not considered by the RMS to be problematic. Addressed	MS are invited to comment on the need to discuss in an experts meeting the potential effect of the application rate on the derived kinetic parameters. If there is a need this will become an open point for discussion otherwise it is addressed. Written procedure Concerned MS find no need to discuss this issue since it is not expected to change the result of the risk assessment already based on worst case assumptions (see comment in the "Comments received in the reporting table" Addressed
4(14)	Vol 3. B.8.1.3.3 Soil photolysis. Pg 640/	EFSA: Soil photolysis was performed simulating irradiation in Scotland (latitude 55 ºN). This may be considered acceptable to simulate conditions in Northern EU. However, since also uses in Southern EU are intended, contribution of photolysis to soil degradation at latitudes around 40 ºN should be calculated.	RMS – we are not convinced of the need for such a calculation to be performed. It is clear that the influence of photolysis is relatively minor from the test. It is suggested that as it is unclear how photolytic processes can be incorporated into Annex I assessments, that this should be left to MSs for their own registrations. Addressed	Data requirement Notifier to provide an estimation of soil photolysis half lives at other latitudes (i.e 40 ºN and 45 ºN). Applicant indicated to submit a position paper (Report MEF-06/495) by April 2007. See also open point in 4(42)

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(15)	Vol.3, B.8.1.4, rate of degradation	NL: Study a), the DT_{50} values were recalculated by RMS using the Solver function with EXCEL. RMS reports r^2 values that are 1) negative and 2) nearly zero. Are these really 'standard' r^2 values or are these other fitting parameters?	RMS – the r^2 values quoted are r^2 values, not another fitting parameter. Addressed	Addressed
4(16)	Vol 3. B.8.1.4 Soil rate of degradation studies-laboratory. (a) Allan 2003e p 648	EFSA: It is not easy to understand how the applicant may obtain a higher r^2 than the RMS by constraining the initial concentration to 100 %. In principle should be the opposite. Further, text (first paragraph in p648) and footnote in table B8.69 are contradictory.	RMS – the further text and footnote appear to have the same values, and do not appear to be contradictory. The RMS would be grateful if EFSA could provide clarification on this point. Addressed	Addressed
4(17)	Vol 3. B.8.1.4 Soil rate of degradation studies-laboratory. (h) kinetic evaluation (Hardt, 2004a). p 662	EFSA: Mean formation fraction for the metabolite M-14 (25.2 %) was calculated considering that this fraction was 0 % in the Munster soil. However the reason this metabolite is not observed in this soil is that the degradation is very slow. Therefore, the formation fraction in this soil is actually not known (study not long enough) and it does not seem correct to assume that it was 0. It would be more appropriate use the worst case of the two values available (38.4 %)	RMS – the questioning of formation fraction and DT50 in points 4(17) and 4(18) should discussed at an Expert meeting. If more appropriate input parameters can be agreed these could be given to the Notifier and used for revised modelling. Open Point: To be discussed at an Expert Meeting	Open point MS experts to discuss the formation fractions derived from laboratory studies for modelling purposes. This discussion should also include the effect of temperature and moisture normalization procedures. See also open point in 4(34) See also 4(18)

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(18)	Vol 3. B.8.1.4 Soil rate of degradation studies-laboratory. (h) kinetic evaluation (Hardt, 2004a).	EFSA: It is stated that values in table B.8.88 are used for FOCUS modelling. These half lives are obtained with the study performed with M-02. However, for some of these metabolites studies are available were the metabolite was directly applied. It is expected that these other studies are more appropriate for the corresponding metabolites (M-05, M-10 and M-14).	RMS – see response under point 4(17). Open Point: To be discussed at an Expert Meeting	See open point in 4(6) and in 4(17)/
4(19)	Vol.3, B.8.1.4, rate of degradation	NL: Study b), the DT_{50} values as calculated are summarised in table 8.69. Values recalculated by RMS are corrected for temperature and moisture content. It seems to us that these latter values are used for R.A. However, the DT_{50} derived by RMS for the Lamberton soil should, to our opinion, be excluded. The fit is not appropriate, fitting parameter 0.58 reported in the table, fitting parameter 0.006 reported before and below the table. Why are the data from the study by Keirs (2003b) not included in the normalised dataset? (Also table 8.142 on page 715)	RMS – we agree with the comment regarding the Lamberton soil that the r^2 value is too low and should be excluded from consideration for use in risk assessment. It should be pointed out that these values have not been used in risk assessment – PEC calculations for the a.s. are based on field derived DT50 values and field studies were clearly triggered irrespective of whether this value was considered. Therefore this value has minimal influence on the assessment. With respect to the Keirs (2003b) data, the study description indicates that the incubation conditions were at 20˚C and pF2, thus no correction was necessary. We realise that the way the table has been presented could lead to confusion. Addressed	See open point in 4(10)
4(20)	Vol.3, B.8.1.4, rate of degradation	NL: Study g table 8.87: not number 2 beneath the table has no reference in the table.	RMS – this should refer to the fitting criteria for the RMS calculations for M-03 at Abington and Sarotti. Addressed	Addressed RMS to consider in an amended DAR or 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(21)	Vol. 3, B.8.1.4, soil degradation	BCS: Page 657, Table B.8.87: For clarity BCS suggest Table B.8.87 is moved to the end of Section B.8.1.4 and the DT50 values determined for the metabolites M-05, M-10, M-11/12, M13 and M14 from the study with M-02 are included in Table B.8.87.	RMS – Point noted. Addressed	Addressed
4(22)	Vol. 3, B.8.1.4, soil degradation	BCS: Page 657, Table B.8.87: BCS are able to reproduce RMS DT50 values. But BCS cannot reproduce most of the DT50 values corrected for moisture and temperature (except DT50 values of M-03). Why are not all DT50 values normalised?	RMS – This is a difference of opinion with respect to calculation of DT50 values; this difference may be due to differences in software packages or approach. With respect to the question relating to normalisation of the RMS DT50, the RMS values here are not used for risk assessment purposes. It is suggested that whilst this is an omission, as the values are not critical, no action is required. Addressed	See open point in 4(10)
4(23)	Vol. 3, B.8.1.4, DT50 values soil	BCS: Page 661, Table B.8.88: Optimised DT50 values (Abington, Münster, Sarotti, Geometric Mean) are from the study conducted for M-02 (Simmonds, 2003b, Hardy 2003). The DT50 values listed under FOCUS corrected values for M-05, M-10 and M-14 also include DT50 values from the studies 1) Arthur, Shepherd and Dominic, 2003a, 2) Arthur, Shepherd and Dominic, 2003b and 3) Nicolaus and Brumhard, 2003a.	RMS – agree with this comment. In response to point 4(6), the LOEPs have been amended to include the range of DT50 values both from laboratory studies using the metabolites as the starting material, and the DT50 values for these metabolites calculated from the M-02 route study. We suggest that this action should be sufficient to address this point. Addressed	See open points in 4 (6) and 4 (10)

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(24)	Vol. 3, B.8.1.5, dissipation rate in soil	BCS: Page 665, last paragraph: BCS were not able to reproduce the RMS SFO DT50 of 133 d for fluopicolide or the DT50 of 315.2 d for M-01. The values BCS derived for a SFO dissipation with free fitting of C0 were 239.6 d for fluopicolide and 299 d for M-01 (starting at 120 d).	RMS - this difference may be due to differences in software packages or approach. Addressed	See open point in 4(10)
4(25)	Vol. 3, B.8.1.5, dissipation rate of fluopicolide	BCS: Page 666, Table B.8.94: BCS suggest an additional column is added to the table to include both the reported B value and determination coefficient r^2. The same comment applies to Tables B.8.101, B.8.113, and B.8.116.	RMS - Whilst this may be useful, it is not considered to add significantly to the information in the DAR. Addressed	Addressed
4(26)	B.8.1.5 Soil rate of degradation-Field studies.	EFSA: In general, method of extraction of soil residues was milder in the field studies than the laboratory ones.	RMS – agree. Addressed	Open point MS experts to discuss potential influence of the different extraction method employed on the respective results of the laboratory and field studies. Applicant provided an explanatory note in the “Comments to the reporting table”. To be considered by MSs experts in their discussion.

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(27)	Vol. 3, B.8.1.5, rate of degradation-field studies	NL: Study b) page 667, textual; procedural recoveries are reported in table 8.96 instead of 8.90. This seems to be a copy paste error. Please be aware of several of this types of discrepancies further on in the document.	RMS – agree. Point noted. Addressed	Addressed RMS to consider in an amended DAR or corrigendum.
4(28)	Vol. 3, B.8.1.5, rate of degradation-field studies	NL: Study c); the star in table 8.105 does not refer to any explanatory description. Same remark for study d) table 8.111	RMS – the explanation for the * is situated below Table B.8.106. Our apologies that this has been omitted for Table B.8.111. Addressed	Addressed RMS to consider in an amended DAR or corrigendum.
4(29)	Vol. 3, B.8.1.5, rate of degradation-field studies	NL: Study e); RMS calculated a DT_{50} for M01. This value however should not be included in R.A. as it has been demonstrated in the study that M01 leaches. The same comment goes for study g).	RMS – values are acceptable provided that they are treated as dissipation DT50 from the sampled soil horizons. The RMS calculated values have not been used in modelling as degradation rates as this would be incorrect. Addressed	Open point RMS to clarify if half life values from field studies have been used for M01 in FOCUS exposure modelling as it is suggested in the list of end points. In case RMS confirms that these values should not be used in modelling then the LoEP needs to be amended. See also open point in 4(62) and open point in 4(34).

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(30)	Vol. 3, B.8.1.5, residues in soil	BCS: Page 668, Table B.8.97: The value of 0.162 mg/kg in 0 - 10 cm at day 120 is the mean value of three replicate values of 0.120, 0.100 and 0.267 mg/kg. Prior to deriving DT50 values we discarded the value of 0.267 mg/kg as an outlier, and a mean value of 0.110 mg/kg was used for the two remaining replicates. This will also affect the DT50 for fluopicolide. A SFO DT50 including free fitting of C0 of 276.2 d was derived instead of 290 d. See Page 669, Paragraph 2, Line 2.	RMS – this is a useful explanation of the data manipulation conducted by the Applicant. The impact of the change in this individual SFO DT50 value is unlikely to be significant on the overall regulatory database on fluopicolide degradation/dissipation, and so the comment is simply noted. Addressed.	Addressed
4(31)	Vol. 3, B.8.1.5, field accumulation	BCS: Page 677, last paragraph: BCS were not able to reproduce the RMS SFO DT50 of 133 d for fluopicolide. Using a SFO dissipation with free fitting C0 BCS derived a value of 121.4 d for fluopicolide.	RMS – this difference may be due to differences in software packages or treatment of values >LOQ etc. This is considered to be a relatively small difference. Addressed.	Addressed
4(32)	Vol. 3, B.8.1.5, dissipation rate of fluopicolide	BCS: Page 679, Table B.8.116: RMS DT50 value for fluopicolide is not given.	RMS – the reason that this particular DT50 was not included was that the r^2 value was less than 0.85, and thus not suitable for use in assessment. For information, the DT50 calculated was 248 days. Addressed.	See open point 4(36)
4(33)	Vol.3, B.8.1.5.1, kinetic evaluation of field dissipation studies	NL: Page 684 under table 8.120, textual; a reference is made to table 8.116 this is not the correct table.	RMS – apologies, this should read Table B.8.119. Addressed.	Addressed RMS to consider in an amended DAR or corrigendum.
4(34)	Vol. 3. B.8.1.5.1 Kinetic evaluation of field	EFSA: It is noted that the conceptual model presented does not considers a direct	RMS – it is agreed that this may be the case, however, it must be borne in mind that the major objective for this modelling is derivation	Open point MS experts to discuss the conceptual

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)
	dissipation studies.	pathway from the parent to the sink compartment (this excludes dissipation mechanisms such as direct bounding or strong adsorption to the soil matrix). As a consequence, degradation rates of metabolites calculated with this scheme should be considered overestimations (resulting in lower DT 50s).	of input parameters for groundwater modelling. The important issue here is that the degradation schemes chosen for kinetic evaluation and groundwater modelling are comparable, which they are for the scheme to the initial metabolites. It must also be borne in mind that implicit in the modelling is the concept of formation fraction; formation fraction and degradation rate are strongly correlated. Whilst subsequent degradation rates of metabolites may be faster with the absence of a route to a 'sink' compartment, more of the active substance is assumed to be converted to the metabolites because of the lack of a direct pathway to 'sink'. Thus the RMS considers that the overall effect of excluding a direct pathway to 'sink' is negligible. Addressed.	model used to derive the kinetic paramenters used for modelling. In particular paying attention to: – the absence of a flow from the parent to the sink compartment and – the effect of normalization of degradation constants without the corresponding normalization of the formation constants. Applicant provided an explanatory note in the "Comments to the reporting table". To be considered by MSs experts in their discussion. See also open points in 4(17) and in 4(29).
4(35)	Vol. 3. B.8.1.5.1 Kinetic evaluation of field dissipation studies.	EFSA: Scheme in Figure B.8.7 states that Tier 1 evaluation is based on 0-10 cm soil layer results, whereas text in p 682 states 0-50 cm data are used. Please, clarify.	RMS – our apologies, the Tier 1 information in Figure B.8.7 is incorrect, it should read '0 – 50cm'. Addressed.	Addressed RMS to consider in an amended DAR or corrigendum.

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(36)	Vol. 3. B.8.1.5.1 Kinetic evaluation of field dissipation studies. P 689. Table B.8.120	EFSA: for some of the sites "measured initial concentration" is relatively far of the "nominal application rate" and the "calibrated application rate". Reasons for these differences are not clear. Also the selection of the fixed "initial concentration" may need to be examined case by case in order to confirm the reliability of the results obtained in this fitting exercise.	RMS – we agree with EFSAs observation. The issues of measured initial concentration and fixing of initial concentration were extremely difficult with respect to determination of whether the Applicant's approach was appropriate or not. It is recognised that many aspects of the kinetic approaches used by the Applicant in the fluopicolide submission are complex and difficult to understand. If EFSA and the MS consider it necessary, it may be worthwhile discussing the approaches at an expert meeting to determine the overall EU opinion. Open Point: To be discussed at an Expert Meeting.	Open point MS experts to discuss in an experts meeting the kinetic evaluation of field dissipation studies. See also 4(32) and 4(43) and 4(48).
4(37)	Vol. 3, B.8.1.7, crop interception , Vol. 3, B.8.3, PECsoil and Vol. 3, B.8.6.2, PECgw	BCS: Page 697, Paragraph 1, Line 3, Page 772, Paragraph 3, Line 4 and Page 827, Paragraph 1, Line 4: The RMS states that the crop cover recommended by the FOCUS groundwater report for vine BBCH 53 to 81 ranges from 60 to 85%. According to FOCUS recommendations the crop intercepts during leaf development of vines is 60% and during flowering is 70%. BBCH 53 corresponds to "inflorescences clearly visible" and thus BCS concludes a minimum crop intercept of 70% is appropriate.	RMS – we consider that the 'inflorescence clearly visible stage' is likely to occur at a relatively earlier growth stage than the 'flowering' stage given in the FOCUSgw report. GS53 is clearly significantly prior to the flowers actually opening, and thus we consider that an interception value of 50% is justifiable. This also leads to a relatively more precautionary risk assessment to allow for differences in interpretation which may occur from reading the label instruction for use of the plant protection product. Addressed.	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(38)	Vol.3, B.8.1.7, field accumulation	NL: Study a) last paragraph on page 696 says concentrations have been calculated by RMS table 8.128. However table 8.128 only contains applicant calculations.	RMS – apologies, it was decided to remove the RMS calculations from the DAR as these were not considered to be sufficiently different from the Applicant calculations to justify inclusion. Unfortunately the text in the preceding paragraph was not amended. Addressed.	Addressed RMS to consider in an amended DAR or corrigendum.
4(39)	Vol. 3, B.8.1.7, plateau concentrations	BCS: Page 696, Paragraph 2, Line 3 states "these concentrations have been recalculated by the RMS to include all detected residues (Table B.8.128)." Table B.8.1.128 contains values submitted by BCS only.	RMS – see comment for point 4(38). Addressed.	Addressed RMS to consider in an amended DAR or corrigendum.
4(40)	Vol. 3, B.8.1.7, plateau concentrations	BCS: Page 703, Table B.8.134: Correct high plateau concentration for fluopicolide in 0-20 cm from 0.196 mg/kg to 0.199 mg/kg.	RMS – we are unsure why this request has been made, as we understand that we have reported the applicant's calculation correctly.	Addressed
4(41)	Vol. 3, B.8.1.7 and B.8.1.8, accumulation studies / summary of soil accumulation studies	BCS: Page 703, paragraph 2 and page 728, paragraph 5: The RMS concludes that fluopicolide and M-01 residues in the accumulation study at Appilly had not reached a plateau at study termination. BCS do not agree with this conclusion. The study has been further evaluated in a position paper (M-267721-01-1) to assess whether the soil plateau concentrations measured in the field had been reached after four years. No additional increase in soil concentrations was predicted by modelling additional applications in successive years. The position paper can be made available upon request.	RMS – the RMS conclusion was based on the results of this study alone and particularly the graphical representation of the soil residues during the course of these studies. The applicant's position paper will be evaluated at a later date prior to an expert group meeting. Open Point: to be discussed at an Expert Meeting.	Data requirement Applicant to present the position paper with their evaluation of the accumulation studies. Applicant indicated to submit a position paper assessing the field accumulation studies (Kley, C; Mackenzie, E.; Report no. M-267721-01-1) by April 2007. See also 4(51) and 4(73).

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(42)	Vol 3. B.8.1.8 Summary and Assessment – Soil route and rate of degradation studies. Field dissipation testing. p 716.	EFSA: RMS considers that soil photolysis would have a minimal influence on the results of field studies. Taking into consideration the photolysis in the laboratory soil studies and the fact that all the field studies were performed with fluopicolide sprayed on surface of bare soil (maintained free of vegetation during the duration of the studies) is at least clear that potential contribution of photolysis is enhanced under field study conditions with respect to the normal conditions of uses proposed for representative uses. In order to use field dissipation data for the risk assessment of the representative uses, applicant should provide further data that confirm the results of the available field studies under more realistic conditions. (In fact photolysis may explain the biphasic behaviour observed in the field studies where degradation is faster in the initial period when the product is more exposed to sun irradiation).	RMS – in our response to comment 4(14), we argue that the influence of soil photolytic processes is relatively minor. We agree with the Applicants assessment that the influence of soil surface processes such as photolysis would have been relatively minor and unlikely to have influenced the results of the field dissipation studies significantly. The RMS considers that in the field situation, the magnitude of the photolytic DT50 combined with the mobility characteristics of the a.s. would result in the substance not being present at the soil surface for sufficient time for photolysis to have had a significant influence on the decline rate. Thus we suggest that further studies are not required. Addressed.	Open point MS experts to discuss the potential influence of photolysis on the results of the field studies and the use of field dissipation half lives for modelling environmental fate and behaviour (FOCUS SW and FOCUS GW). See also 4(50) and open point in 4(14)
4(43)	Vol 3. B.8.1.8 Summary and Assessment – Soil route and rate of degradation studies. Field dissipation testing. p 718-723.	EFSA: Observation of the graphs show that first order fitting or second phase of Hockey-stick models descried better the overall and long term degradation of fluopicolide.	RMS – tend to agree that, with respect to consideration of dissipation of fluopicolide in relation to regulatory trigger values in Annex II and VI requirements, the bi-phasic pattern should be taken into account. However, with respect to modelling (particularly use of	See open point in 4(36).

Route and rate of degradation in soil (B.8.1)				
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			FOCUS models), first-order kinetics is necessary. Whilst the regulatory assessment must be precautionary, a balance has to be achieved. The RMS is concerned that use of the first order rate constant from the second (slower) phase to calculate PEC values may be too precautionary. If the resulting risk assessment failed, this would inevitably stimulate higher tier exposure assessment, with the likely result that the assessment would return to that originally submitted by the Applicant. Thus, whilst a reassessment as implied by EFSA might provide some additional information, we have a concern that in practice there would be little overall impact on the assessment in exchange for the time required for the re-assessment.	
4(44)	Vol. 3, B.8.1.8, summary and assessment	NL: Page 727 just below table 8.146a; RMS stated that the normalised field DT_{50} values are relevant for PEC values for terrestrial assessments. However, as the kinetics used for derivation of DT_{50} values seems in accordance with the latest concept of the FOCUS guidance on this subject, it is more appropriate to use the non-normalised DT_{50} for terrestrial assessment in line with the guidance.	RMS – the wording used states that the normalised values are appropriate for 'environmental exposure assessment' – we did not specifically state that the normalised values are suitable for terrestrial assessment. As can be seen later in the assessment for PECsoil, the RMS has concerns relating to the use of FOCUS groundwater scenarios for the terrestrial assessment, particularly the potential for leaching in a vulnerable leaching scenario to reduce soil residues in the soil horizons of concern. The RMS favours a simpler approach for terrestrial assessment using worst case non-normalised first-order field dissipation rates.	See open point in 4(61)

Route and rate of degradation in soil (B.8.1)				
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4(45)	Vol. 3, B.8.1.8, summary of laboratory studies	BCS: Page 710, Paragraph 2: Delete "(53% AR after 120 days was recorded, however, AR recovery was only 77% at this timepoint)". The recovery at this time-point was quantitative (Sarotti, Day 120, overall recovery = 92.4%) and not only 77% as stated.	RMS – Agreed. BCS comment is correct and noted. Addressed.	Addressed RMS to consider in an amended DAR or corrigendum.
4(46)	Vol. 3, B.8.1.8, summary of laboratory studies	BCS: Page 710, Paragraph 2: Correct "the benzoyl ring degraded to metabolites … M-03". M-03 is formed by hydroxylation of the parent which is cleaved and results in the formation of M-01. Correct "other minor unidentified metabolites (max 0.2%)". No metabolites other than M-01or M-03 were observed in laboratory route and rate studies with parent labelled in benzoyl ring.	RMS – Point noted. Addressed.	Addressed
4(47)	Vol. 3, B.8.1.8, calculation of DT 50 values	BCS: Page 716, Table B.8.143: see comments to page 657 Table 8.87. - BCS cannot reproduce most of the DT50 values corrected for moisture and temperature (except DT50 values of M-03). Why are not all DT50 values normalised? - BCS suggest including additional DT50 values for M-02, M-05, M-10, M11/12, M-13 and M-14 from M-02 study (Simmonds, 2003b, Hardy 2003) to summarise all the DT50 values corrected as recommended by FOCUS and used in risk assessments (as given in the last column of Table 8.88).	RMS – first comment, please see our response to comment 4(22). Second comment, in response to earlier comments, the LOEP has been amended to give results from both laboratory studies using various metabolites as starting material, and DT50 values where these have been derived from kinetic modelling of the M-02 study. We consider this to be sufficient. Addressed.	See open point in 4(10)

Route and rate of degradation in soil (B.8.1)				
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4(48)	Vol 3. B.8.1.8 Summary and Assessment – Soil route and rate of degradation studies. Field dissipation testing. P. 726 Table B.8.146.	EFSA: It is stated that the values in this table are used for the risk assessment. This is true for the metabolites or for the parent as well?. With respect to the parent, it may be expected that the result of the fitting of the parent alone will be more accurate that the result of the multicompartmental fitting of the parent and metabolites. If these values are the ones used for the risk assessment of the parent it would be helpful to reproduce the fitted curves in the DAR (to compare with the previous fittings with the parent alone). In this case the initial concentration for the parent was fixed by the applicant; however it is recognized that when initial concentration was not fixed for the parent a better fit for this compound was obtained.	RMS – values for both parent and metabolites have been used in exposure assessments by the Applicant. Note RMS does not agree with use of 90th percentile values and has concerns about the PECsoil approach used by the Applicant. Therefore, an alternative approach is proposed by the RMS in the DAR. This should be discussed further at an Expert meeting. Fitted dissipation curves from the kinetic evaluation of the field studies are on Pages 685 – 687 of the DAR (Figures B.8.8-B.8.10 for the Philippsburg, Rodelsee and Huntlosen sites. Open Point: To be discussed at an Expert Meeting.	See open points in 4(36), 4(60), 4(61) and 4(62).

Route and rate of degradation in soil (B.8.1)				
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4(49)	Vol. 1, Level 2, 2.5.2, field dissipation and Vol. 3, B.8.1.8, metabolites in field dissipation studies	BCS: Page 38, Paragraph 7, Line 1 and Page 725, Table B.8.145: BCS do not think the method used to calculate % maximum metabolite formation at Senas in 2000 (following application in 1999 and in 2000) is valid. BCS propose 24.1% and 16.4% are the maximum formation levels for the metabolites M-01 and M-02 BCS suggest removing the values for Senas 2000 in Page 725, Table B.8.145.	RMS – the approach that the RMS has taken with respect to calculation of observed formation of the metabolites at this site is open to debate as it is the result of two years application and is therefore not conventional. This could be discussed at an expert meeting. This is potentially an important point as the highest formations are calculated for this particular site. Open Point: to be discussed at an Expert Meeting.	See open point in 4(84) and comment in 4(5)
4(50)	Vol. 3, B.8.1.8, groundwater assessment	BCS: Page 727 Paragraph 1, Line 4: BCS suggest the phrase "It is anticipated by the RMS that use of laboratory soil degradation rates for fluopicolide in groundwater assessment are likely to result in adverse results with respect to the 0.1 µg/l limit, particularly in situations where annual application may be made (see Section B.8.6.1 for groundwater assessment for vines)." is removed.	RMS – the statement in the DAR is the opinion of the RMS. It is clear from FOCUSgw guidance that use of either laboratory or field derived DT50 values are justifiable; the RMS comment was meant to reflect the fact that if acceptable laboratory studies have been submitted, use of lab DT50 is an option for groundwater modelling. Clearly, different behaviour appears to be exhibited in the field situation compared to the laboratory, but the reasons for this cannot be completely explained. If laboratory degradation rates for the parent are considered by the Applicant to be unreliable then the same could be said of the metabolite information. However, in the RMS experience, differences	See open point in 4(42)

Route and rate of degradation in soil (B.8.1)				
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			in behaviour are often seen in laboratory and field studies. These differences do not necessarily lead to the laboratory results being considered unreliable. Therefore, the RMS believes that the comment should stay as it indicates that acceptable laboratory studies have been submitted and lab DT50 can be used for groundwater modelling. Addressed.	
4(51)	Vol. 3, B.8.1.8, summary of soil accumulation testing	BCS: Page 728, Paragraph 1: RMS concluded results of the accumulation study at Senas were inconclusive and a plateau concentration may not have been reached. BCS do not agree with this conclusion. The study has been further evaluated in a position paper (M-267721-01-1) to assess whether the plateau concentrations of fluopicolide measured in the field had been reached after four years. No further increase in soil concentration was predicted by modelling additional applications in successive years. The position paper can be made available upon request.	RMS - The applicant's position paper will be evaluated prior to the expert group meeting. An addendum will be produced if necessary. Open Point: RMS to produce an addendum if necessary.	See data requirement in 4(41)

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(52)	Vol. 3, B.8.1.8, summary of soil accumulation testing	BCS: Page 728, Paragraph 1 continued: The DAR states that the maximum of the low values of the saw teeth curve increased at the end of the accumulation period at the Senas site. BCS do not agree. A residual concentration of 0.09 mg/kg (calculated from the total depth of soil and expressed as if observed in 0-10 cm) was observed in 2002 (372 days after application 3) and 2003 (355 days after application 4). Furthermore, actual residual plateau concentrations measured in the 0-10 cm depth of soil decrease from 0.08 mg/kg in 2002 to 0.06 mg/kg in 2003.	RMS – depths below 10cm were also considered in this study, and the RMS original conclusion is still considered valid. Addressed.	Addressed
4(53)	Vol. 3, B.8.1.8, summary of soil accumulation testing	BCS: Page 728, Paragraph 1 continued: The RMS also stated that at the end of 1999 the level of fluopicolide was 0.046 mg/kg; which is lower than the levels found at the end of 2000, 2001 and 2002 indicating that the plateau may not have been reached. BCS do not follow the reasoning that led to this conclusion. The residual concentration increased initially before reaching a plateau concentration.	RMS – The RMS still considers that the results of this study do not conclusively demonstrate that a plateau has been achieved. Addressed.	Addressed

Adsorption, desorption and 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(54)	Vol 3. B.8.2.3.3. Lysimeter leaching studies. (a) p. 756	EFSA: It is stated that in the laboratory soil degradation studies conducted with the metabolites the slowest degradation rate was observed with the Munster soil from this lysimeter. However, this should not be considered an indication that this study represents a worst case with respect to the metabolites (as suggested by the applicant) since we do not know the relative rate of parent degradation in this soil. If parent degradation was also slower concentration peaks of metabolites could be lower than in other soils where faster degradation may occur. .	RMS – Point noted and the RMS suggests that this is discussed further at an Expert meeting. Open Point: To be discussed at an Expert meeting.	Open point MS experts to discuss whether the lysimeter study represents a worst case with respect to the formation of metabolites.

PEC in soil (B.8.3)				
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)
4(55)	Vol. 1, Level 2, 2.5.2, aqueous hydrolysis	BCS: Page 41, Paragraph 1: Correct paragraph 1 by moving the sentence "This was confirmed in a standard OECD study where DT50 at 20˚C and pH 5 was 45.5 hours but 0.14 hours at pH 8.2" to the end of paragraph 1. The study was conducted with M-03 but has been placed in a description of the properties of M-01.	RMS – we agree with this comment, apologies, the penultimate and final sentences in the subsection describing aqueous hydrolysis appear to have been reversed. Addressed.	Addressed RMS to consider in an amended DAR or corrigendum.

PEC in soil (B.8.3)				
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)
4(56)	Vol. 1, Level 2, 2.5.2, water / sediment	BCS: Page 41, Paragraph 6, Line 4: BCS propose the longest DT50 for dissipation from the water phase is 182 days. The value of 263 days proposed by the RMS is based on an evaluation in which C0 and the rate were optimised but underestimates C0 by 15 to 16%. BCS conclude the value of 182 days with C0 fixed and the rate optimised provides a better evaluation of the dissipation rate.	RMS – the issue of fixing initial concentration in DT50 calculation was consistent throughout the fluopicolide evaluation. Whilst we recognise that fits for water phase dissipation are not very good, at the time of assessment we were not entirely convinced that fixing initial concentration to obtain a good r^2 value was justifiable. However, these values are not used in FOCUSsw exposure assessment. Addressed.	Addressed
4(57)	Vol. 1, Level 2, Appendix 3, PEC soil	BCS: Page 75, PEC (soil) (Annex IIIA, point 9.1.3) – Parent : No PEC values over 0 to 100 days included.	RMS – as PECsoil values between 0 and 100 days after the highest concentration are not required in risk assessment, these were not calculated. Addressed.	Addressed
4(58)	Vol. 1, Level 2, Appendix 3 and Vol. 3, B.8.3, soil depth for PECsoil calculation	BCS: Page 75 and page 776 Paragraph 4: The RMS considers that 10 cm depth is too deep to calculate long term PECsoil in a no- or minimum tillage situation such as vineyards. BCS do not agree with this conclusion and have followed the EPFES proposal for crops with no or minimum tillage such as vineyards. Additionally BCS have prepared a position paper (M-268742-01-1) to assess the diffusion and dispersion of fluopicolide in soil with time, which justifies the use of this soil depth in long term PECsoil calculations. This position paper can be made available upon request.	RMS - The applicant's position paper will be evaluated prior to the expert group meeting. An addendum will be produced if necessary. Open Point: RMS to produce an addendum if necessary.	See open point in 4(69)
4(59)	Vol 3. B.8.3. Predicted environmental	EFSA: For vines interception should be 60 % (at least for the firsts applications) to	RMS – please note that text on page 772 was reporting the Applicant approach. As can be seen later, the RMS does not necessarily agree	See open point in 4(69)

PEC in soil (B.8.3)				
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)
	concentration in soil (PEC soil).Applicant approach. p 772.	represent the worst case). For potatoes minimum application interval is 7d and not 5 d. There is no indication in the table of representative uses that application will occur once every two years (as calculated) and not every year.	with the Applicant approach in general. Addressed.	Written procedure Applicant indicated in the "Comments to the reporting table" that the correct minimum interval for potatoes is 5 d and that GAP table needs to be updated. Open point RMS to update GAP table with 5d minimum application interval for potatoes.
4(60)	Vol 3. B.8.3. Predicted environmental concentration in soil (PEC soil). Applicant approach. p 772.	EFSA: As already highlighted by the RMS (in p. 776), the approach of using the 90 percentile DT50 instead of the worst case is not an agreed procedure at EU level.	RMS – Point noted and the RMS suggests that this is discussed further at an Expert meeting. See also 4(48). Open Point: To be discussed at an Expert meeting.	Open point MS experts to discuss if the use of the 90th percentile is appropriate for PEC soil calculations. See also 4(48), 5(45) and 5(47)
4(61)	Vol 3. B.8.3. Predicted environmental concentration in soil (PEC soil). Applicant approach. p 772	EFSA: As already indicated by the RMS (in p. 776), use of FOCUS GW scenarios for PEC soil calculation does not seems appropriate since FOCUS GW scenarios were selected to represented worst case situations for leaching and therefore will constitute a "best case" with respect to the persistence of the substance in the soil surface.	RMS – Point noted and the RMS suggests that this is discussed further at an Expert meeting. Open Point: To be discussed at an Expert meeting.	Open point MS experts to discuss if FOCUS GW scenarios with normalized DT_{50} 's are appropriate for PEC soil calculation. See also 4(44), 4(48), 5(45) and 5(47)
4(62)	Vol 3. B.8.3. Predicted environmental	EFSA: Field DT_{50}s are used in the modelling exercise by the applicant to calculate PEC	RMS – RMS does not agree with EFSA comment. The field DT50 values used were calculated in the normalisation procedure conducted on the	Open point MS to discuss wheather the M01 half lives

PEC in soil (B.8.3)				
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)
	concentration in soil (PEC soil). Applicant approach. p 772.	soil. Since M-01 has a high leaching potential it seems more appropriate to use degradation rates derived from the laboratory studies for modelling. Otherwise the dissipation through leaching is "counted" twice in the modelling and in the parameter.	field dissipation studies. The RMS is content that the procedure used was sufficiently robust to be able to use the calculated M-01 DT50 as a degradation DT50 as leaching in the studies was accounted for during the normalisation procedure. Addressed.	may be considered appropriate degradation half lives for modelling PEC soil. See also open point in 4(29) and 4(48). See also 5(45) and 5(47).
4(63)	Vol. 3, B.8.3, calculation of accumulation potential	BCS: Page 777, Paragraph 2, Line 8: The maximum formation of M-01 at this site (Rödelsee) was 15.2% not 14.6%. See Page 725, Table B.8.145. The worst case SFO DT50 values of fluopicolide and M-01 should be checked, as already mentioned in comments to pages 665 and 668-669.	RMS – the highest formation of M-01on a mass basis, i.e. weight/weight basis was 14.6% at Senas (2000) site. This equates to 29.5% on a molar basis. We appreciate that this is on the basis of a calculation that BCS do not agree with.	See open point in 4(65)
4(64)	Vol 3. B.8.3. Predicted environmental concentration in soil (PEC soil). RMS approach. p. 777.	EFSA: It is not clear were the worst case used by the RMS (DT50 = 290 d) comes from. In table B.8.143a worst case field DT50 for fluopicolide is 276.2 d.	RMS – this value comes from the Huntlosen field dissipation study, see page 669, final paragraph; this is a value calculated by the RMS. Whilst this value has an r^2 value less than 0.85 and should not be used for the purposes of comparison against regulatory 'trigger' values, EFSA have previously stated in EPCO/EFSA meetings that even simple PEC calculations would be considered as modelling, and thus first order DT50 between 0.7 and 0.85 can be used for such a purpose. Addressed.	Addressed

PEC in soil (B.8.3)				
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)
4(65)	Vol 3. B.8.3. Predicted environmental concentration in soil (PEC soil). RMS approach. p. 777.	EFSA: In our understanding the maximum amount of M-01 formed in molar basis is 40.2 % that would corresponds to 19.9 % in mass basis. It is not clear where the 14.6 % comes from.	RMS – we are uncertain where the value of 40.2% has been found. Please could EFSA clarify? The maximum % observed formation in the field studies is 29.5% molar basis, 14.6% mass (wt/wt) basis (see Table B.8.145). Open Point: EFSA to clarify where the value of 40.2% has been found.	Open point MS experts to discuss which maximum amount formed of M01 should be considered for PEC soil calculations. 40.2 % comes form laboratory studies. It is doubtful that field studies are capable to identify the maximum formation of a metabolite. See also 4(63), 5(45) and 5(47)
4(66)	Vol 3. B.8.3. Predicted environmental concentration in soil (PEC soil). RMS approach. p. 778.	EFSA: Table B.8.198 is confusing since it is not clear which values were actually used for the risk assessment.	RMS – Point noted. However, the reason why the different values were presented was to allow the ecotoxicologist conducting the risk assessment to use an appropriate value to compare with the concentrations used in the litter bag study which may express the concentrations over different soil depths. The values actually used are stated in Section B.9. Addressed.	Addressed See 5(45)
4(67)	Vol 3. B.8.3. Predicted environmental concentration in soil (PEC soil). RMS approach. p. 778.	EFSA: it is not clear if the RMS has used soil depth of 5 of 20 cm for last application in potatoes to calculate the peak concentration. Please clarify.	RMS – please see explanation to comment 4(66) above. Hopefully this provides sufficient clarification. Addressed.	Addressed See 5(45)

PEC in soil (B.8.3)				
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4(68)	Vol. 3, B.8.3, calculation of soil accumulation	BCS: Page 777, Table B.196: The peak plateau concentration for M-01 in 5 cm assuming 14.6% formation would be 0.041, not 0.043 mg/kg. However BCS concludes that the long term PECsoil for fluopicolide and M-01 should be calculated in 0-10 cm depth of soil following application to vines. See comment on Page 776, paragraph 4.	RMS - The applicant's position paper will be evaluated prior to the expert group meeting. An addendum will be produced if necessary. Open Point: RMS to prepare an addendum if necessary.	See 4(69)
4(69)	Vol. 1, Level 2, Appendix 3 and Vol. 3, B.8.3, PECsoil values	BCS: Page 75 and page 778, Table B.8.198: BCS has concerns that the RMS has selected the worst case PECsoil values from two very different approaches to determine long term PECsoil concentrations. BCS considers it inappropriate to chose one approach for vines and another for potatoes. BCS considers that the same approach should be used for vines and potatoes to calculate PECsoil values.	RMS – whilst the RMS admits that the approach was probably far from ideal, a choice had to be made in that the RMS disagreed with the Applicants approach, but the Applicant's approach gave a worst case for one of the supported GAPs. Overall, a realistic worst case risk assessment should be achieved. It may be profitable for this to be discussed at an expert meeting. Open Point: To be discussed at an Expert meeting.	Open point MS experts to discuss the different approaches taken for the PEC soil calculation. See also 4(58), 4 (59), 4(68), 5(45) and 5(47). See also comment 4(81) with respect to the rotation every two years assumed for the calculation in potatoes.
4(70)	Vol. 3, B.8.3, maximum predicted soil concentration	BCS: Page 779, Paragraph 2 + 3: The DAR states modelling predicts higher accumulated concentrations of fluopicolide than measured in the field. BCS do not agree and conclude the modelling provided by BCS is in good agreement with field data once corrected for crop interception. The maximum predicted concentration in 0-10 cm was 0.104 mg/kg (Hamburg scenario) assuming crop intercepts of 70, 70, 85%, an overall rate of 75%. Applying the same crop intercept to the maximum	RMS – as this comment relates to a difference in opinion, it is proposed that this comment is not considered further as the RMS assessment is presented in full in the DAR. The RMS terrestrial risk is acceptable with the calculated PECsoil values. Addressed.	Addressed

PEC in soil (B.8.3)				
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)
		concentration measured in 0-10 cm in the bare soil accumulation studies (0.387 mg/kg, Appilly) **gave a value of 0.097 mg/kg**.		
4(71)	Vol.3, B.8.3., PECsoil	NL: RMS commented on the calculations done by the notifier. One major point in the calculations is however the proposed GAP. According to the summary on representative uses the maximum application rate in potatoes is 400 g a.i. **per application** instead of this being the total annual rate.	RMS – we are unsure where NL has found this information. Please refer to Volume 1, section 1.5.3.1b (p 15) for the GAP on potatoes. It is clear that up to four applications of 100 g a.s./ha can be made, a maximum total dose of 400 g a.s./ha per crop. Addressed.	Addressed
4(72)	Vol. 3, B.8.3, PECsoil	BCS: Page 772, Paragraph 4: The intended use for potatoes is between growth stage BBCH 20 to 91. Please correct the growth stage given in paragraph 3 from BBCH 35 to 89 to BBCH 20 to 91.	RMS – the information presented at this point in the DAR is what the Applicant had originally submitted. This does not make a difference to the crop interception values used in the Applicant assessment. Addressed.	Addressed
4(73)	Vol. 3, B.8.3, plateau concentrations in soil	BCS: Page 774, last paragraph: It is stated in the DAR "… have not included … the timepoints at which the soil concentrations … are reached". The time-points at which the maximum concentrations were estimated are provided.	RMS – the Applicant has provided the number of years after treatment that these values were seen. These will be provided in an addendum in time for the Expert meetings. However, as previously stated, the RMS is in disagreement with the Applicants assessment method. Open Point: RMS to provide an addendum.	See data requirement in 4(41).
4(74)	Vol. 3, B.8.3, maximum soil accumulation concentration	BCS: Page 774, Paragraph 1: The RMS concludes that the soil accumulation concentrations $C_{high,max}$ and $C_{low,max}$ calculated by	RMS - as this comment relates to a difference in opinion, it is proposed that this comment is not considered further, as the RMS assessment is	Addressed

PEC in soil (B.8.3)				
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)
		modelling are lower than those detected in the field accumulation studies, even allowing for 50% crop interception. BCS maintain that the concentrations predicted by modelling and measured in the field, after correction for appropriate crop interception rates, are in good agreement. Crop interception rates used for vines were 2x70, 1x85%, equivalent to an overall rate of 75% and for potatoes 2x50, 2x80%, equivalent to an overall rate of 65%.	presented in full in the DAR. The RMS terrestrial risk is acceptable with the calculated PECsoil values. Addressed.	
4(75)	Vol 3. B.8.3. Predicted environmental concentration in soil (PEC soil).	EFSA: In the ecotoxicology section it seems that the PEC soil for potatoes calculated by the applicant has been used for the risk assessment. The reason for this is not clear.	RMS – please see comment 5(45) in Ecotox section in relation to PECsoil values used in terrestrial risk assessment. Addressed.	Addressed See 5(45)

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(76)	Vol 3. B.8.4.3 Ready biodegradation.	EFSA: Degradation of fluopicolide is much faster in the ready biodegradation tests that in the available water sediment studies. The reasons for this high difference are not well understood from the information available. However, the readily biodegradability should not be based on the degradation of the parent compound but on the complete mineralization.	RMS – The values presented in section B.8.4.3a) are based on the theoretical maximum amount of carbon dioxide produced, rather than being a true degradation value for fluopicolide. Differences between the ready biodegradability test and water/sediment study are unsurprising given that the ready biodegradability test uses activated sewage sludge, most probably with a much high microbial population than a natural water/sediment system. Addressed.	Addressed

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(77)	Vol. 3, B.8.6.1, drift rate in vines	BCS: Page 815, paragraph 2: The DAR states "It should be noted that this is a worst case in terms of spray drift, but it is not known what influence this has on crop interception." BCS suggest this sentence should be rephrased to "It should be noted that this is a worst case in terms of spray drift." The more conservative drift rates of 'late vines' were chosen for the early and the late application period in FOCUS step 3 calcu- lations. This option 'late vine' only influences the drift rate, the crop interception rate is calculated by the model based on a growth model and therefore dependent on the application day.	RMS – the reason that this was stated is that at Step 3, the amount of crop interception is calculated by MACRO and PRZM depending on date of application and the crop set. Thus it is not readily apparent what the effect on crop interception was by setting the crop option to 'late vines' had on the early vines simulation. This may impact on the drainage and/or run-off inputs. Addressed.	Addressed
4(78)	Vol. 1, Level 2, Appendix 3, PECsw and PECsed and Vol. 3, B.8.6.2, PECsw and PECsed in vines	BCS: Page 87 and Page 819, Table B.8.240: PECsw and PECsed values for M-03 are incorrect. Correct values are PECsw Step 1 = 4.2633 ug/L and PECsed Step 1 = 4.6381 ug/kg (not 12.789 ug/l and 13.9143 ug/L). NB. on page 87 PECsed units wrong (ug/kg not ug/L).	RMS – please note the footnote at the base of the table. The Step 1 values are from a single application, not multiple applications. Comment regarding units noted and LOEP have been amended. Addressed.	Addressed
4(79)	B.8.6.2 PEC GW	EFSA: Only one FOCUS model has been used to assess the potential ground water contamination by fluopicolide and its metabolites. At least results of two models are needed to complete the risk assessment. (**Opinion of the Scientific Panel on Plant Health, Plant Protection Products and their Residues on a request of EFSA related to FOCUS**	RMS – At the time of submission, this opinion was not in place; it was considered by the RMS as unreasonable to insist on the Applicant submitting more modelling to meet a opinion published after submission. The majority of a.s. concentrations predicted are much more than an order of magnitude lower than the 0.1 µg/l statutory limit, thus for the a.s. the regulatory decision is clear, i.e. there are acceptable uses for fluopicolide. The	Data requirement Applicant to provide results with a second FOCUS model following the recommendations given in the PPR Opinion: **Opinion of the Scientific Panel on Plant Health, Plant Protection Products and their Residues on a request of EFSA related to FOCUS groundwater models. The EFSA Journal**

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)
		groundwater models. The EFSA Journal (2004) 93, 1-20.)	metabolites have been subject to relevance assessment, and it would not be anticipated that PEARL modelling would make a significant difference to the outcome of that assessment. Addressed.	**(2004) 93, 1-20.** For some of the metabolites it may not be confirmed that the triggers of 0.75 µg/L and 10 µg/L are not exceeded in some scenarios. A second model is necessary to reduce the uncertainty and confirm the non relevance of the metabolites. Applicant indicated to submit new PEC GW calculations with a second model and lower interception rate for vines by May 2007. See also open point in 4(42) and data requirement in 4(80)
4(80)	B.8.6.2 PEC GW	EFSA: To assess the representative uses proposed by the applicant, a minimum interception of 60 % should be assumed at least for the first application in vines.	RMS – agree with the comment by EFSA. However, that would probably result in earlier application timing probably associated with more favourable time of year for degradation. Thus, overall, it may be that modelling an earlier application timing with lower interception would little influence on overall results. Open Point: To be discussed at an Expert Meeting.	Data requirement Applicant to repeat the FOCUS GW calculations following the GAP as reported in the Representative uses table. Applicant indicated to submit repeated PEC GW calculations with a lower interception rate for vines by May 2007. See comment 4(81), open point in 4(42) and data requirement in 4(80).

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(81)	B.8.6.2 PEC GW	EFSA: The GAP for potatoes presented in the table of representative uses does not propose any restriction to use the product one every two (as assumed in PEC soil calculations) or three years (as proposed for PEC GW calculation). Therefore, concentrations resulting from application every year should be modelled.	RMS – we considered the selected rotations to be agronomically justified, and that it would be extremely unlikely in practice for closer rotations to occur. In fact, we consider that the one in two rotation is too close, but the Applicant chose this as a very worst case. Thus we think that the one in three rotation is representative of good agricultural practice and that it would not be justified to model applications every year. Addressed.	See data requirement in 4(80) Whereas crop rotation is a recommended agricultural practice in potatoes it is not mandatory that this rotation occurs every three years. Furthermore, the "representative" use concept implies that the assessment does not necessarily circumscribe to the specific crop listed but to other crops represented by it. Therefore, if application every year is not possible due to a high risk of ground water contamination it should be clearly indicated in the table of representative uses that application one of every three years is proposed as a risk mitigation measure. In order to decide if this mitigation measure has to be proposed, calculations need to be repeated following the GAP proposed in the representative uses for potato (without rotation).

Definition of the residues (B.8.9)				
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(82)	Vol.1, 2.5.1, definition of the residue	NL: It would be very nice if the definition of the residue is separated in residues relevant for risk assessment and residues relevant for monitoring. In such a way it becomes clear for which compound an analytical method for environmental compartments is required.	RMS – we have proposed this in section B.8.9. In the past there has been much discussion on the presentation of the residue definition for the environment, and we thought that we had done it correctly with this compound. Addressed.	Addressed Residue definitions are routinely discussed and confirmed during PRAPeR experts meetings.
4(83)	Vol. 1, Level 2, Appendix 3	BCS: Page 95: Definition of the residue: This should only include parent compound. See vol. 3, Annex B.8.9 p834 "Based on the Rapporteur's assessment, the following is proposed as the relevant residue for monitoring in the environment: fluopicolide in soil, in surface water, in groundwater, (see section B.8.10) in sediment and in air"	RMS – disagree as EFSA have requested that residue definition in LOEP contains the residue for risk assessment purposes. Addressed.	Addressed
4(84)	B.8.9 Definition of the residue / Vol 1. List of end points p 95.	EFSA: M-02 is listed as a major component of soils residue. However, it does not reach the level of 10 % at any data point in the studies. Also it does not reach the 5 % at two sampling consecutive points or at the end of the studies. For the same reasons this metabolite does not seems to need further assessment in surface or ground water.	RMS – higher levels were seen in the field. In addition, M-02 is important in the Applicants proposed degradation pathway. Certainly, M-02 has been included in all the proposed exposure assessments, and on this it should be acknowledged that they have taken a precautionary approach. Addressed.	Open point MS experts to discuss the approach taken by the RMS to calculate the amount of M02 form in field Open point RMS to indicate in the LoEP box "relevant metabolites" in soil the max. amount of M02 (with respect to applied fluopicolide) found in field studies (at this stage this value is 21.3 %). See comments 4(5) and 4(49)

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(85)	Vol. 3, General	NL: In the layout of the summaries there is no reference header included. Including such a heading for general study information will improve the readability of Vol. 3. Please consider for next DARs.	RMS – Comment noted. Addressed.	Addressed
4(86)	Vol. 3, General	NL: There is no information included by RMS on the acceptability of the studies. Values are mostly recalculated by RMS it is however not mentioned which values are (to be) used for risk assessment. Shortcomings are reported for several studies however if and how this effects the acceptability as well as which values are actually used for risk assessment, requires time consuming searching through the DAR.	RMS – in general, all submitted studies were found to be of a acceptable scientific standard and thus acceptable. As the NL comment points out, there are shortcomings in some places. The Fate evaluation of this substance was exceptionally complex, with some endpoints identified by the Applicant being deemed acceptable, and some not; this is reflected in the presentation of the DAR which we acknowledge is not perfect. Addressed.	See open point in 4(10)
4(87)	Vol.1 , General	NL: In volume 1 no information about PECs is included. It is just a brief summary of the studies from volume 3.	RMS – agreed. The PECs are presented in the endpoints which are part of Volume 1. Addressed.	Addressed

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(88)	Vol.1, list of endpoints	NL: Please add to the DT_{50} field values which values are included as in vol.3 several approaches were followed and there it is also not included which are the values that are (to be) used for which assessment.	RMS – Agreed. LOEP have been amended. Addressed.	See open point in 4(10) Written procedure Open point RMS to clarify in the LoEP which DT_{50} field values are actually used in modelling (e.g values not all values for M01 are to be used).
4(89)	Vol.1 list of endpoints	NL: Ready biodegradable. It is more convenient to include 'failing the 10 day window' behind the no and than include >70% degradation after 28 days. As for classification and labeling there is no restriction on the time period.	RMS – Agreed. LOEP have been amended. Addressed.	Addressed
4(90)	Vol.1, list of endpoint	NL: Why are not all 9 FOCUS scenarios calculated for the parent with application to potatoes. (Comment refers to Vol.3 B.8.6.2 as well)	RMS – all 9 GW scenarios were used for the parent. Six scenarios predicted concentrations <0.001 µg/l. Addressed.	Addressed
4(91)	Vol.1, list of endpoints	NL: The box of classification and proposed labeling is empty. To our opinion this should reed none proposed for Fluopicolide.	RMS – Agreed. LOEP have been amended. Addressed.	Addressed R53 is proposed in the LoEP

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(92)	Vol. 3, B.8.10, Assessment of the relevance of groundwater metabolites	DE: This point makes reference to sections B.6.1.4.1 and B.10.7.5 for an assessment of the relevance of groundwater metabolites. The latter section does not exist in the provided issue of the DAR. Possibly B.10.7.5 is identical to B.6.1.4.1. If not, the RMS is requested to provide section B.10.7.5 for further evaluation.	RMS – Section B.10 is the Efficacy assessment. Section B.6.1.4.1 is an overview of the information and B.10.7.5 will be presented in an addendum for completeness. Open point: RMS to prepare an addendum.	Open point RMS to present the complete assessment for the relevance of ground water metabolites in and addendum. Special attention should be paid to the fact that at this stage for metabolites M01, M05 and M10 the trigger of 0.75 µg/L is also exceeded either in the lysimeter or the FOCUS modelling. This open point is relevant for the sections of toxicology, ecotoxicology and residues. Therefore it has been copied in the corresponding table sections from the fate section.
4(93)	Vol. 1, Level 3, metabolites in groundwater	BCS: Page 119: 4th para: Correct >0.1µ/l to >0.1µg/L 5th para : Correct >0.1µ/l to >0.1µg/L 6th para: Correct >0.1µ/l to >0.1µg/L	RMS – Error noted. However, minor point and no action to be taken. Addressed.	Addressed
4(94)	Vol. 3, B.8.10, assessment of the relevance of groundwater metabolites	BCS: Page 834, Paragraph 7: Metabolite M-02, which was not detected in leachate or predicted to leach, was also shown to be non-relevant and is missing from list of non-relevant metabolites under B.8.10.	RMS – the reason it was not included in the list is that it was not predicted in groundwater at >0.1 µg/l and thus was not assessed for relevance. Addressed.	Addressed

Comments received on reporting table, section Environmental fate and behaviour (B.8)			
Reference to reporting table	MS / Notifier	Comment	EFSA response
4(6)	NOT	As a general principle, BCS considers valid half lives can be derived for metabolites from studies dosed with parent or precursor metabolites.	Noted
4(6)	NL	It is not possible to exclude the indirect values form the LoEP but still use them for modelling. Either the values are acceptable or they are not. (see also 4(23)	Noted
4(10)	NL	Agree with open point.	Noted
4(10), 4(22), 4(24), 4(31), 4(47), 4(64), 4(86)	NOT	It would be very useful for BCS to understand the calculations used to derive DT50 values by the RMS, particularly values proposed for use in risk assessments.	Noted
4(11)	NOT	The proposed GAP is 4 x 100 g/ha and not 4 x 400 g/ha.	Noted, an explanatory not has been added to the RT.
4(11), 4(12), 4(13)	DE	We wonder that such basic scientific issue has been proposed to be addressed via a written procedure. The basic question how absolute concentrations in a soil degradation study might affect the results is clearly worth a discussion on expert level. This does not necessarily mean that such discussion should be linked to the specific substance fluopicolide, but it is, in our view, no point where the written procedure is appropriate.	Noted, an explanatory not has been added to the RT.
4(11), 4(12), 4(13)	FR	FR: as we understand the intended uses reported in the LOEP, the maximum application rate is 3x133 g/ha (active substance) for vine and 4x100 g/ha (active substance) for potato. The route of degradation of degradation study was done with an application rate of 400 g/ha (active substance). So it is our opinion that it simulated the maximum anticipated seasonal use rate and that there is no need to make an open point on this topic specifically for fluopicolide. However, we think that such discussion should take place in an experts meeting but not directly linked to fluopicolide.	Noted, an explanatory not has been added to the RT.
4(11)	FI	According to NL, the GAP of Flupicolide is 4 × 400 g/ha, which is much higher than that used in experiments of degradation route. The maximum seasonal dose rate is not 4 × 400 g/ha. Instead, dose rates of 3 × 133 g/ha for vine and 4 × 100 g/ha for potato are given in GAP and these	Noted, an explanatory not has been added to the RT.

Comments received on reporting table, section Environmental fate and behaviour (B.8)			
Reference to reporting table	MS / Notifier	Comment	EFSA response
		corresponds to the dose rate used in experiments of degradation route.	
4(11)	NL	For the a.s., we misunderstood the GAP (see 4(71)). The rates applied in the study reflect well the intended use pattern. Point solved for the a.s. For the metabolites M01 and M03 the issue of the high dosing remains intact (see 4(12) and 4(13))	Noted, an explanatory not has been added to the RT.
4(12)	FI	The dose rate of the metabolite M-01 is indeed high, perhaps due to analytical requirements. However, based on the ecotoxicological profile of M-01 we are of opinion that the dose rates used are unlikely to affect the derived kinetic parameters.	Noted, a open point for discussion in the expert's meeting has been added to the RT.
4(12)	NL	M01: Whilst the dose of the test will not affect the route of degradation, it may affect the rate in an unknown way (faster or slower). If the SFO fit is very well, then it may be concluded that the degradation is not dose-dependent. However, in this case the SFO fit gave r^2 values of 0.73-0.87, which is not very good. So, a dose dependency cannot be excluded. Since there are field studies available for M01, these data can be used for PEC calculations, however, this only applies to PECsoil since RMS has stated that DT50field values are not to be used for modelling (dissipation, not degradation). NB See remark at 4(29) ! A possible way forward to solving the modelling input problems is to use only the field studies where no leaching problems (or other problems) were observed, this would result in a geomean DT50 of 125 days (excluding study c, e and g). *[NB this was done by the Netherlands for this same metabolite BAM in the dichlobenil DAR]* This might be discussed in an expert meeting.	Noted, a open point for discussion in the expert's meeting has been added to the RT.
4(13)	FI	Based on the available data of ecotoxicological properties of M-03 we are of opinion that the dose rates used are unlikely to affect the derived kinetic parameters.	Noted, an explanatory not has been added to the RT.
4(13)	NL	M03: Whilst the dose of the test will not affect the route of degradation, it may affect the rate in an unknown way. If the SFO fit is very well, then it may be concluded that the degradation is not dose-dependent. In this case the r^2 values for the SFO fit are somewhat higher than for M01 (0.87-0.98). In view of the very short half-lives NL thinks that a supposedly existing dose	Noted, an explanatory not has been added to the RT.

Comments received on reporting table, section Environmental fate and behaviour (B.8)			
Reference to reporting table	MS / Notifier	Comment	EFSA response
		dependency will eventually not lead to a change in the risk assessment. The PECsoil calculation is based on accumulated parent concentrations corrected for formation fraction and thus is worst-case since fluopicolide is much more persistent than M03. NB. For PECsw a combination of lab DT50 and field DT50 values is taken, which is not according to guidance. Since for surface water and sediment only a STEP 1-2 calculation is performed, this has no influence on the results. For PECgw a division is made for the acid soils (DT50 field of 55 days) and neutral-basic soils (DT50 of 0.09 days, where does this value come from? DT50lab is <1.0 - 4.7 days). This is not critical since the acidic scenarios Hamburg and Porto represent a worst-case, which with a worst-case DT50 lab of 4.7 probably would not be overruled by the neutral-basic scenarios.	
4(14)	NOT	BCS have prepared a position paper that includes an estimation of soil photolysis half lives at other latitudes (Report MEF-06/495). This will be available in April 2007 and can be submitted upon request.	Noted, information collected in the RT.
4(14)	DE	We wonder why such a data requirement has been set, despite it will not be of relevance for the decision-making on EU level. This would have been a better point than the aforementioned for the written procedure, because also formal aspects are touched to a significant extent. The statement of the RMS is available and MS could decide on that basis whether they considered a data requirement or open point meaningful in the procedure for fluopicolide or not. DE would be able to support the RMS position that soil photolysis issues could be addressed on MS level, since there is no agreed way to include them in EU decision-making.	Noted
4(14)	NL	Agree on data requirement.	Noted
4(15)	NL	Addressed. It remains strange that negative r^2 values are calculated by RMS, while the notifier found extremely good fits. This might have to do with the SOLVER tool, please check.	Noted
4(17)	NL	Agree with the open point.	Noted
4(18)	NL	The matter of using indirect studies for the metabolites should be solved consistingly. We agree	Noted

Comments received on reporting table, section Environmental fate and behaviour (B.8)			
Reference to reporting table	MS / Notifier	Comment	EFSA response
		with the open point (see 4(6) and 4(23)).	
4(18)	NOT	As a general principle, BCS considers valid half lives can be derived for metabolites from studies dosed with parent or precursor metabolites.	Noted
4(19)	NL	Addressed, see open point 4(10). We agree on excluding the Lamberton study and including the Keirs study.	Noted
4(20)	NL	Addressed.	Noted
4(26)	NOT	The extraction efficiency of the analytical method for field dissipation studies was confirmed as part of the study. Details are given in the report C017634 (M-204661-01-1), page 24, Point 6.6. For fluopicolide, M-01 and M-03, the substances for which field studies were used in risk assessments, an additional extraction step removed at most a further 2%. BCS concludes further extraction steps were not warranted and would have had no significant impact on the results of the field studies.	Noted, a call to this table is added to the RT.
4(26)	FI	Milder extraction of soil residues in field studies might be a problem, if sorption to soil increases with time in such an extent that the extraction efficiency in field samples gets worse compared to that in laboratory samples (thus overestimating the dissipation rate in field). At the initiation of the experiments the extraction efficiencies in methods used in field and laboratory seemed more or less comparable to each other. Perhaps some data or evidence is available for sufficient extraction efficiency of long incubation time field samples.	Noted
4(26)	NL	If the extraction method used in the field is validated (in B.5) then the results are acceptable. Check validation criteria for the field studies for the used method (recovery, d.l. etc.)	Noted
4(27)	NL	Addressed.	Noted
4(28)	NL	Addressed.	Noted
4(29)	NL	If RMS has treated the values as dissipation values only, then we can agree. We agree with the open point, please clarify which values for M01 have been used for modelling. From the list of endpoints it still seems that the geomean of the normalised field data of 137.7 days was used!	Noted

Comments received on reporting table, section Environmental fate and behaviour (B.8)			
Reference to reporting table	MS / Notifier	Comment	EFSA response
		This is including the studies with demonstrated leaching. See also remark at 4(12).	
4(29)	NL	See our comment at 4(12)	Noted
4(33)	NL	Addressed.	Noted
4(34)	NOT	Temperature and moisture normalisation is taken into account for evaluation of degradation rates, if these are intended for detailed modelling. A normalisation is generally considered for all rates and pathways in a soil system, for overall rates as well as for partial rates of parallel pathways. As formation fractions are defined as a ratio of parallel degradation rates, the normalisation is in principal implicitly included in the standard evaluation. Generally, these evaluations are done according FOCUS gw and FOCUS kinetics requirements.	Noted, a call to this table is added to the RT.
4(34)	NL	Agree with the open points. Some initial thoughts: - it seems to us that by using day-step normalization the fitted formation fractions are also already normalized - the approach without a sink is worst-case with regard to the metabolites. Since the parent also shows some tendency to leach it may not be worst-case for the parent.	Noted
4(36)	NOT	BCS will prepare a position paper summarising and describing the kinetic evaluation of field dissipation studies, including documentation supplied to the rapporteur on the approach used by BCS to initial concentrations in modelling field data. This will be available in May 2007 and can be submitted upon request.	Noted
4(36)	FI	It could be worthwhile to discuss the kinetic evaluation of field dissipation studies in an expert meeting, even though RMS has already done significant effort to clarify this complex matter in DAR.	Noted
4(36)	NL	Agree with open point	Noted
4(38)	NL	Addressed.	Noted
4(41)	NOT	A position paper assessing the field accumulation studies of fluopicolide (Kley, C; Mackenzie, E.;	Noted

Comments received on reporting table, section Environmental fate and behaviour (B.8)			
Reference to reporting table	MS / Notifier	Comment	EFSA response
		Report no. M-267721-01-1) is available and can be submitted upon request.	
4(41)	NL	We agree on the data requirement concerning a position paper about the accumulation plateau. (see also 4(51))	Noted
4(42)	NOT	The position paper (Kley, C; Mackenzie, E.; Report no. MEF-06/495) will be available in Apriland can be submitted upon request.	Noted
4(42)	NL	Agree with discussion in expert meeting on the role of photolytic processes in the field study, however seems to have been of minor influence (according to RMS, we tend to agree). In practice photolysis is likely to be of minor importance.	Noted
4(43)	NL	We agree with RMS.	Noted
4(44)	NL	It seems that NL and RMS agree that the non-normalised field degradation data should be used for PECsoil calculations.	Noted
4(44 & 61)	FI	FI agrees with opinions of EFSA on point 4(61) and of RMS on point 4(44).	Noted
4(48)	NOT	BCS will prepare a position paper describing the kinetic evaluation of field dissipation studies. See comment 4(36).	Noted
4(51), 4(52), 4(53)	NOT	The position paper (Kley, C; Mackenzie, E.; Report no. M-267721-01-1) is available and can be submitted upon request. See comment 4(41) above.	Noted
4(54)	FI	FI agree with opinion of EFSA. A slow degradation of metabolites in the Münster soil does not necessarily mean that it would be a worst-case candidate soil for the leaching of metabolites.	Noted
4(54)	NL	Agreed with open point	Noted
4(58)	NOT	The position paper (Kley, C; Mackenzie, E.; Report no. M-268742-01-1) is available and can be submitted upon request.	Noted
4(59)	NOT	BCS apologises for a mistake in the submitted GAP table. The correct minimum application interval in potatoes is 5 days. An updated GAP table can be provided upon request.	Noted, a explanatory not is added to the RT.

Comments received on reporting table, section Environmental fate and behaviour (B.8)			
Reference to reporting table	MS / Notifier	Comment	EFSA response
4(60)	NL	Use of 90-th percentile for PECsoil. Refer to discussion paper on use of DT50 (DE + NL). Agree on open point as a general issue.	Noted
4(61)	NL	OK with open point (we agree with RMS that the use of pelmo for PECsoil does not provide worst-case PECs values)	Noted
4(62)	NL	For PECsoil a worst-case field dissipation halflife can be used, provided that this value comes from a representative study for the intended use.	Noted
4(65)	NL	It is stated in the Loep that 40.2 % was formed long after 120 days. Therefore it seems more realistic to us to use the highest formation % of M01 in the lab at any time point < 120 days.	Noted
4(68)	NOT	The position paper (Kley, C; Mackenzie, E.; Report no. M-268742-01-1) is available and can be submitted upon request. See comment 4(58) above.	Noted
4(69)	NL	Agree with open point and favour the approach of RMS (no PELMO, just spreadsheet PECs calculation) for PIECsoil. For PECaccumulation, crop rotation should be implemented in the calculations. This probably should be done by means of a model.	Noted
4(71)	NL	Addressed, we misunderstood the GAP.	Noted
4(79)	NOT	The notifier supports the position of the RMS that at the time of the submission there was no requirement to submit modelling conducted with a second model since the FOCUS groundwater report concluded that modelling with any one of the FOCUS recommended models was sufficient to determine a safe use at EU level. However since EFSA has made this a data requirement BCS will provide a second FOCUS modelling report which will be available in May 2007.	Noted, information has been collected in the RT.
4(79)	DE	DE does not agree to the additional requirement for principal reasons. The possible implications of terming assessments based on “only one” groundwater leaching model as “unreliable” go beyond scientific assessment issues. The PPR panel opinion was based on the observation that that the currently used leaching models	Noted, the need of unambiguous results by risk managers justifies the requirement for a second model in order to have comparable information for all

Comments received on reporting table, section Environmental fate and behaviour (B.8)			
Reference to reporting table	MS / Notifier	Comment	EFSA response
		may give different results, especially for concentrations below 1 µg/L. It was thus recommended that the risk assessment should be based on two models, PEARL and either PELMO or PRZM (i.e., one representative for each concept), rather than on a single model. When the results from both models are on the same side of the trigger values, the risk assessment could be finalised at that step. When the results from the two models give values either side of the trigger value, higher-tier assessments would be necessary. However, no agreement currently exists on the regulatory level what kind of approach could be accepted as a higher-tier assessment and according to which criteria it should be assessed. However, as the concentration in groundwater is a decisive criterion for Annex I inclusion and national authorisations, any such decision must be based on unambiguous criteria.	substances.
4(79)	NL	We agree with the data requirement that a second model is needed, preferably PEARL.	Noted
4(80)	NOT	BCS agree to repeat FOCUS groundwater modelling using a lower crop interception rate for vines. The report will be available in May 2007.	Noted, information has been collected in the RT.
4(80)	NL	We agree with the data requirement and discussing the new modelling outcomes based on the realistic GAP in relation to interception values.	Noted
4(81)	NOT	The notifier supports the position of the RMS that a one in three year rotation for potatoes to be grown in the same ground is representative of good agricultural practice. BCS is aware that this practice has a strong basis to prevent potato cyst nematode and is strongly followed in countries were it is not mandatory or legally enforced as it is in some EU countries. Because there are some specific uses known to BCS (e.g. starch potatoes in the Netherlands) where potatoes are grown in a two year rotation this very worst case was used for the modelling. BCS would also like to mention that the use in vines covers a year on year use. BCS does not understand EFSA's comment that potatoes are in this case "representative" for other crops since modelling is required for every crop separately (e.g. potato, vines , lettuce, tomato) taking into account the type of crop, the growth stages at the time of application of each crop to determine the crop interception factors and hence the amount reaching the soil. Hence	Noted

Comments received on reporting table, section Environmental fate and behaviour (B.8)			
Reference to reporting table	MS / Notifier	Comment	EFSA response
		potatoes are only representative of potatoes. However since this is given as a data requirement BCS will provide the requested modelling in May 2007.	
4(81)	NL	Agreed, notifier should clarify crop rotation on label if this is a prerequisite for inclusion. Based on phytosanitary circumstances a crop rotation of 1 per 3 years is defendable.	Noted
4(82)	NOT	BCS agrees with the comment from NL. BCS has already experienced confusion during the national evaluation with one MS. A clear definition of the residue definition for the environment is needed.	Noted
4(82)	NL	Addressed. We agree that in B8.9 the residue definition is described fine. We propose that a geberal discussion about where the residue definitions should be presented separated (i.e., Volume 1 or Volume 3) should be held at a PRAPeR meeting.	Noted
4(84)	NL	Agree with open points.	Noted
4(85)	NL	Addressed.	Noted
4(86)	NL	Addressed, we accept the explanation by RMS and hope that for future DARs the acceptability of studies and endpoints to be used for RA will be expressed more clearly.	Noted
4(87)	NL	Addressed. We however are of the opinion that a brief summary of PEC values (e.g. only highest tier results) is preferably also presented in the text of Vol. 1 to increase readability.	Noted
4(88)	NL	In the list of endpoints a remark is now made that normalised field values are to be used in modelling *as appropriate*, it is however not stated when a value is appropriate; e.g., the values from all M01 studies are used in the calculation of the geomean, while it is agreed that in some studies leaching of M01 cannot be excluded. Please elaborate more.	New open point added to the RT.
4(89)	NL	Addressed.	Noted
4(90)	NL	Addressed, 9 scenarios employed for potatoes and 7 for vines.	Noted

Comments received on reporting table, section Environmental fate and behaviour (B.8)			
Reference to reporting table	MS / Notifier	Comment	EFSA response
4(91)	NL	Addressed. However, NL is of the opinion that the R53 is not necessary in view of the biodegradability of > 70 % at 28 days and the fact that there is no restriction on the time period (see also remark in 4(89))	Noted
4(92)	NOT	A detailed position paper on the non-relevance of fluopicolide metabolites (Report M-227293-01-1) is available and can be submitted upon request.	Noted
4(92)	NL	Agree with open point that relevance assessment should be presented in the DAR, however, it is not a fate issue. For fate this open point can be closed.	Noted, since new modelling is awaited fate may need to confirm the levels of metabolites to be considered by toxicology and residue experts in their relevance assessment.
General	NL	We agree to all related open points to be discussed.	Noted

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)
5(1)	Vol. 1, 3.1, Background to proposed decision	DE: The Level 3 evaluation of ecotoxicity is missing completely. Please amend.	RMS: Point noted. Vol 1, level 2 contains an overview of the ecotoxicology. It was considered that no major issues were identified. Addressed.	Addressed
5(2)	Vol. 1, List of endpoints, General	EFSA: Sometimes studies were performed with a solo formulation AE C638206 SC480 containing 480 g fluopicolide/L. The results of these studies are sometimes reported in the list of endpoints as if performed with the technical material fluopicolide. For reasons of transparency it should be clearly indicated in those cases that the study was performed with this formulation.	RMS Agree: - the 'SC 480' solo fluopicolide formulation was used in *S. subspicatus,A. rhopalosiphi, T. pyri*, soil litter bag and non-target plant studies. The latter two studies were cited in the endpoint list in terms of fluopicolide content - the derivation from SC 480 has been indicated in revised LOEPs. NB see also point 5(51). Addressed.	Addressed. A footnote has been added to the list of endpoints clarifying what test substance was used in the litter bag study and in the post emergence phytotoxicity test with plants.
5(3)	Vol. 1, list of endpoints-birds and mammals	FR: would it be possible to add TER from secondary poisoning for completeness?	RMS: Strictly speaking these assessments were not triggered (fluopicolide logPow<3), however TERs have been included with bird and mammal LOEPs for completeness (see also point 5(10) below. Addressed.	Addressed. TER values have been included in the list of endpoints.

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.9.1., Risk to birds	EFSA: Why are no studies with the lead formulations considered necessary?	RMS Components of EXP 11120A and EXP11074B formulations will rapidly decline by decay and dilution after foliar spray application and hence formulation compositional integrity is not expected to be significantly sustained. Fluopicolide has low acute/short term avian toxicity. The second active substances in these formulations, namely propamocarbHCl and fosetyl-Al, also have very low acute/short term avian toxicity. Hence, since, a) birds are likely to be exposed to insignificant dietary levels of formulation, and b) avian toxicity of all component active substances is low, an overall low avian risk can be reasonably predicted for the formulations without further vertebrate testing. Addressed.	Addressed.
5(5)	Vol. 3, B.9.1.2, Dietary toxicity to birds	EFSA: It is noted that the recalculation to daily dose of the dietary endpoints was performed by the RMS with the mean body mass at day 5. This should be performed with the average of day 0 and day 5.	RMS Agree: - recalculated fluopicolide LC50 values for mallard and bobwhite quail are >2946 and >2064 mg/kg bw/d. Less worse case than those proposed in the DAR and hence without impact on avian risk assessment conclusion. LOEPs have been revised. Addressed.	Addressed. RMS to consider in a corrigendum. List of endpoints has been amended.
5(6)	Vol. 3, B.9.1.3, Long term/reproductive toxicity to birds	EFSA: For reasons of transparency it is preferred that the mean body weight and feed consumption data, used to recalculate the NOEC to a daily dose value, are given.	RMS: Agree - the repro NOECs for bobwhite quail and mallard were based on mean bodyweights of 199.75 and 1072.25g and mean food consumptions of 17.76 and 151 g food/d, respectively. Addressed.	Addressed. RMS to consider in a corrigendum.

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(7)	Vol. 3, B.9.1.3, Long term/reproductive toxicity to birds	EFSA: Although not statistically significant, a dose related effect can be observed on e.g. 14-day old survivors per female in the reproduction study with mallard duck. Why was this not considered while setting the NOEC?	RMS: The RMS considered that overall it was not possible to confidently discern a clear and consistent dose-related response with enough certainty to confidently establish reliable effect endpoints. For example, differences between 0 and 160ppm groups and between 400 and 1000ppm groups could not always be clearly distinguished for many of the parameters. Thus the mallard NOEC was based on the highest dose which, when converted to daily dose was less worse case than the NOEC derived for bobwhite quail. Addressed.	Addressed.
5(8)	Vol. 3, B.9.1.4, Risk to birds and B.9.3.2, Risk to mammals	EFSA: A more extensive argumentation why it is not considered necessary to assess the short and long term risk for birds and the long term risk to mammals from exposure to contaminated drinking water is considered necessary.	RMS: SANCO/4145/2000 is unspecific with respect to appropriate bird and mammal drinking water risk assessment requirements. It was considered that evidence suggests that sufficient moisture for bird and mammals would normally be provided in herbivorous and insectivorous diets without the need for supplementary DW. Nevertheless, an assessment of the risk to the dietary indicator bird and mammal indicator species from water consumption of diluted spray application was undertaken (assumes this is the sole source of bird & mammal water needs). Low acute (& short term) risk was indicated. Due to continual residue decay and dilution and foliage deterioration/ removal long term and repeated exposure to such concentrations was considered to be unrealistic in these crops.	Addressed. Note: It was agreed in the PRAPeR 08 expert meeting that "that until new guidance is available (especially on options for refinements) a risk assessment for birds and mammals should be done only for the acute time scale and be based on intake of drinking water from puddles of spray liquid or reservoirs in leaf axils. A dilution factor of 5 should be applied and the daily water intake should be calculated allometrically as outlined in the Guidance Document on Risk Assessment for Birds and Mammals (Sanco 4145)".

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)
			Furthermore the risk from consumption of contaminated surface water was also considered negligible due to minimal exposure based on highly diluted PECsw estimates. Addressed.	
5(9)	Vol. 3, B.9.1.4, Risk to birds	EFSA: It is not understood how the MAF was calculated for the assessment of the risk to birds in potatoes.	RMS: The GAP for use of EXP 11120A on potato is max 4 applications with a min 7d interval between applications. SANCO/4145/2000 gives the MAFa and MAFst/lt values of 1.8 and 2.2, respectively, for such an application regime. From SANCO/4145/2000 Table 3 it is apparent that MAFa is the same for short grass and leafy crops, this despite being based on distribution of residue which is unlikely to be similar, and PSD MAF calculator computes different values for leafy crops. A MAFa value of 1.96 was derived for the potato (leafy crop) regime i.e more worse case than short grass. The MAFst/lt value of 2.23 was calculated from the formula as described in Table 5 of SANCO /4145/2000. However, using MAF values from SANCO/4145/200 (Tables 1 and 3), TERs for herbivorous still indicate low risk although, as was stated in the DAR, potato leaf is unattractive food for birds. Please note this also addresses point 5(12) below. Addressed.	Open point: RMS to clarify in an addendum how the MAF for different vegetation was calculated and used in the assessment of risk to birds. Note: This open point was set after a comment on the reporting table during the written procedure. See also 5(12).
5(10)	Vol. 3, B.9.1.4, Risk to birds and B.9.3.2, Risk to mammals	EFSA: Please verify the twa PECsw values used in the risk assessment for fish-eating	RMS Agree: -These assessments were not triggered (see also 5(3)) but were conducted as a precautionary measure. However, they do	Addressed. For transparency reasons the information in column 3 could be inserted in a

Birds and mammals (B.9.1 and B.9.3)				
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		birds and mammals as they could not be found in the section on Fate and behaviour.	need correction as the PECsw values were subsequently refined without corresponding adjustment to the fish-eating bird and mammal assessments. Worse case FOCUS step3 PECsw 21d twa values of 0.166 (Table B.8.245) and 2.309 (Table B.8.250) µg a.s./L were considered most realistic for vine and potato use, respectively. A revised risk assessment using these PECs for fish-eating bird and mammals following vine treatment gave revised TERs which still indicate low risk. LOEPs has been amended. Addressed.	corrigendum.
5(11)	Vol. 3, B.9.1.4, Risk to birds and B.9.3.2, Risk to mammals	EFSA: It is noted that the default f_{twa}-factor of 0.53 was used. This factor is valid for an interval between applications of at least 3 weeks while the minimum interval in potatoes is only 7 days.	RMS disagree: SANCO/4145/2000 (page 17) states that for a Tier 1 herbivorous bird & mammal long term risk assessment a default ftwa of 0.53 is appropriate (based on residue decline DT50 = 10d over a 21d time window default, following last application), though SANCO/4145 recognises this may underestimate exposure when multiple applications have spray intervals < 21d window, as is the case here (but it should be taken in consideration if refinement by residue decline is required - not the case here). Addressed.	Addressed

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(12)	Vol. 3, B.9.1.4.2, Tier 1 risk assessment for birds	BCS: P. 863, Table B.9.1.15 – A MAF of 1.96 has been used to calculate the acute ETE for herbivorous birds. According to the SANCO/4145/2000, a MAF = 1.8 is indicated for 4 applications with 7 days interval. BCS would suggest to rather use this standard value, for knowing that this will have no impact on the risk assessment. The corresponding ETE will be 11.9 instead of 12.99 mg/kg bw/day.	RMS: Addressed at point 5 (9).	See 5(9)
5(13)	Vol. 3, B.9.3, Effects on mammals	EFSA: It is noted that also two acute toxicity studies with the lead formulations are available.	RMS: EXP 11074B and EXP 11120A mammalian acute toxicity to rat were evaluated at B.6.11.1& 2. LD50s >2000 mg/kgbw (highest dose) were determined for both and hence do not indicate toxicity concerns. Since mammals are unlikely to be exposed to formulation in diet it was considered appropriate to use a.s. data in risk assessment (see also avian discussion at 5(4)). Addressed.	Addressed
5(14)	Vol 1, Level 2, Appendix 3 and Vol. 3, B.9.3.1, endpoint for mammalian risk assessment	BCS: Page 97 and p. 943, PSD has considered the rabbit developmental toxicity NOAEL of 20 mg/kg bw/day as a precautionary endpoint for the long term assessment of mammals. Even if this worst case approach did not indicate a need for refinement, BCS considers that the rat multigeneration study is a more appropriate endpoint to assess the long term and reproductive risk to mammals.	RMS: There was no specific evidence of reproductive toxicity in both the rat multigeneration and rabbit developmental toxicity studies and the NOAEL for reproduction in the rat was 103.4 mg/kg bw/d. However, in the rabbit the NOAEL for maternal and developmental toxicity was 20 mg/kg bw/day based on mortality, high incidence of premature delivery and reduction in body weight gain and food consumption in dams and reduction in foetal body weights and	Addressed

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)
		For these reasons, BCS consider the NOAEL of 25.5 mg/kg bw/day from the multigeneration rat study as the relevant endpoint to assess the long term effects to mammals. Additionally, BCS has prepared a more detailed position paper (M-268483-01-1) which can be made available upon request.	foetal crown-rump lengths in foetuses at dose levels of 60 mg/kg bw/day. The more precautionary end point was preferred for the ecotoxicological mammalian risk assessment. See also 2(9). Addressed.	
5(15)	Vol. 3, B.9.3.2 Risk assessment for mammals	AT: In Table B.9.3.3 in the column "Flupicolide conc. in food/water" the value 0.053, which takes deposition into account, is not justified since in the RUD values of 85 and 46 an interception factor of 0.4 (deposition of 0.6) is already included (see SANCO 4145/2002). Respective ETE and TER values should be recalculated and changes amended in the list of end points.	RMS Agree: - the Tier 1canopy interception (40%) should not have been modified in Table.B.9.3.3. Hence the ETEa and ETElt should be 23.45 and 7.77 mg a.s./kg bw/d, respectively, and the TERa and TERlt should be >213 and 2.57, respectively. This indicates a refined risk assessment is necessary. Fluopicolide is applied to vine between growth stages BBCH 53-81 (from end of foliage development through flowering up to grape ripening). This corresponds most closely to an interception of 70% (30% deposition) on subcanopy vegetation. Thus a Tier II refined risk assessment will amend the RUDa and RUDlt to 43 and 23, respectively. Revised ETEa and ETElt values of 11.72 and 3.89 mg a.s./kg bw/d were derived which gave TERa and TERlt values of >426 and 5.15, respectively, indicating low mammalian risk. LOEPs have been amended. (also addresses 5(16). Addressed.	Open point: RMS to include the corrected calculations and the refined RA in an addendum. List of endpoints has been amended. No discussion in expert meeting required unless required by MS. See also 5(17)

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(16)	Vol. 3, B.9.3.2, Risk to mammals	EFSA: It is noted that the risk to mammals from exposure to contaminated drinking water was assessed for a mammal with a similar body weight as the standard indicator species for vines. Can it be excluded that smaller mammals will be exposed to contaminated drinking water in vines?	RMS: SANCO 4145/2000 guidance is unspecific with respect to appropriate indicator species for bird and mammal DW risk assessment. Indicator mammals for dietary food assessment were selected for DW assessment as most at risk (see also comment on avian DW assessment at 5(8) above which also apply). Addressed.	Addressed
5(17)	Vol. 3, B.9.3.2, Risk to mammals	EFSA: To calculate the risk to herbivorous mammals the dose rate was multiplied by a factor of 0.4 as 60% interception was assumed. Although we agree that interception will occur for a fungicide, we do not agree by multiplying the application rate with 0.4 as the interception is already taken into account in the RUD factor which is 142 for herbicides (no interception) and 85 for fungicides (interception of 40%).	RMS: Addressed at 5 (15) Addressed.	See 5(15)

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(18)	Vol. 1, List of endpoints, Toxicity data for aquatic species	EFSA: Preferably the endpoints for the lead formulations are also given in mg a.s./L to enhance the comparability with the endpoints from the active substance alone.	RMS Agree: - LOEPs amended to include EXP 11074B (mg fluopicolide/L) *O. mykiss* 96h LC50 = 0.385 *D. magna* 48hEC50 = >1.128 *N. pelliculosa* 72hEbC50 = 0.026 EXP 11120A (mg fluopicolide/L) *O. mykiss* 96h LC50 = 0.380 *D. magna* 48h EC50 = >6.47 *N. pelliculosa* 72h EbC50 = 0.023 Addressed.	Addressed. List of endpoints has been updated.
5(19)	Vol. 3, B.9.2, Effects on aquatic organisms, acute toxicity a.s.	NL : In the header of the study with the a.s. on the marine diatom *Skeletonema costatum* (Table B.9.2.24) a NOEC of 0.0046 mg/L is mentioned, while at the end of the summary of the study a NOEC of 0.046 mg/L is mentioned. It looks like the latter NOEC-value is the right one.	RMS Agree: - the NOEC = 0.046 mg/L is correct . Addressed.	Addressed. RMS to consider in a corrigendum.
5(20)	Vol. 3, B.9.2, Effects on aquatic organisms	EFSA: The only study with the metabolites M-01, M-02 and M-05 on the most sensitive algal species *N. pelliculosa* is a non-GLP study which was not reported in full. Why this study was considered valid?	RMS disagree: Fully GLP-compliant studies were provided for M-01 and M-05 for the most sensitive aquatic organism, *N. pelliculosa.* The endpoints (both 72h EcB50 >10 mg fluopicolide/L) were used in the aquatic risk assessment to establish low aquatic risk in surface water (M-01) and groundwater (M-05) scenarios from both uses. For M02 a non-GLP range-finding study for *N. pelliculosa* study was only available, however, data from GLP studies on *O. mykiss* for M-01, M-02 and M-05 (all LC50>100 mg a.s./L) indicated that all	Addressed.

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)
			3 metabolites were >200x less toxic than fluopicolide to fish . This, and the fact that M-02 is an intermediate in the derivation of, and is structurally related to, M-05 were considered to be strongly indicative of a low aquatic SW risk from M-02. The non-GLP *N..pelliculosa* study was regarded as confirmatory information in that aquatic toxicity was >3 mg/L for M-01, M-02 and M-05 for the most sensitive aquatic organism, i.e. all much less sensitive than fluopicolide. Addressed.	
5(21)	Vol. 3, B.9.2, Effects on aquatic organisms	EFSA: What is the logPow of the major aquatic metabolites?	RMS: Log Pow values: Fluopicolide 2.9 (pH7.0/20°C) M03(AEC060800) 2.34 (pH7.0/20°C) M01(AEC653711) 0.51 (pH/°C; unspecified) M02(AEC657188) -2.0 (pH7.0/23°C) All other aquatic metabolites discussed are substituted derivatives of M02 which will likely have similarly low logPows. Addressed.	Open point: RMS to include the information on Log Pow values for the metabolites in an addendum (only data for M02 and M03 are available in Vol.B.2.1 of the DAR. No discussion in an experts meeting is required.

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(22)	Vol. 3, point B.9.2.1 acute toxicity study with *Brachydanio rerio*	FR: active substance recovery in the test media is 85-103%, i.e. recovery would be similar as for the study with *Cyprinus carpio*. Is that correct?	RMS Agree: - copying error. Value correct for *Cyprinus carpio* but for *Brachydanio rerio* the following should apply: LOQ 0.0624 mg a.s./L Measured values were 94-109% nominal with mean measured test concentrations of: 0.12, 0.25, 0.51, 1.0 & 2.1 mg a.s./L . Addressed.	Addressed. RMS to include in a corrigendum.
5(23)	Vol. 3, point B.9.2.1 acute toxicity study with *Cypronidon variegatus*	FR: active substance recovery in the test media is 93-100%, i.e. recovery would be similar as for the study with *Oryzias latipes*. Is that correct?	RMS Agree: - copying errors. Correct values should be as follows *Oryzias latipes:* LOQ 0.104 mg a.s./L Measured values were 91-103% nominal with mean measured test concentrations of: 0.28, 0.44, 0.65, 0.99 & 1.5 mg a.s./L *Cyprinodon variegatus:* LOQ 0.014 mg a.s./L Measured values were 76-83% nominal with mean measured test concentrations of: 0.2, 0.35, 0.58, 1.0 & 1.6 mg a.s./L. Addressed.	Addressed. RMS to include in a corrigendum.

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(24)	Vol. 3, B.9.2.4, Risk to aquatic organisms	EFSA: If the applicant would like to lower the Annex VI trigger value for algae as 5 species were tested than an argumentation in line with the opinion of the PPR Panel on this subject is considered necessary.	RMS: The RMS did not evaluate the Notifier aquatic risk refinement proposals as low (safe) aquatic GW and SW risk scenarios were identified indicating safe uses for both vine and potato application. The RMS merely pointed out that the Notifier had proposed various options for refinement of aquatic risk assessment in potential SW risk scenarios for consideration at MS level if appropriate. One of the options proposed by the Notifier was that since five algal species were tested a lower Annex VI trigger may be used to accommodate reduced interspecies uncertainty. The RMS did not specifically endorse this (or any other refinement option proposed by the Notifier), but see also point for (5.(26)) for further related comment. (also addresses point 5(28)).	Addressed.
5(25)	Vol. 3, B.9.2.4, Risk to aquatic organisms	EFSA: It is noted that the risk to *D. magna* for the formulation EXP 11074B is calculated for an endpoint >100 mg/L instead of >25 mg/L.	RMS Agree: - >25mg/L is correct respective TERs at 3, 5 and 10m should be >312, >691 and >2032. LOEPs amended. Addressed.	Open point: RMS to include the correction in a corrigendum and to update the list of endpoint. Since trigger values are different for algae and fish/invertebrates we would prefer to have TER values also for fish and invertebrates in the list of endpoints even if algae was the most sensitive organism group.
5(26)	Vol. 3, B.9.2.4, Risk to aquatic organisms	EFSA: It is agreed that during the hydrolysis study the DT_{50} for the surface water metabolite M-03 was only 45 minutes at	RMS: Fluopicolide is a pyridinyl-benzamide fungicide. M03 is a transient hydroxylated fluopicolide intermediate formed immediately	Addressed

Aquatic organisms (B. 9.2)				
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		the environmental relevant pH of 7. So it can be concluded that M-03 is not stable. However it is considered necessary that the need for an algae study on M-03 should also be considered given the repeated or pulsed exposure as it will enter the surface water via drainage and run-off from soil in which it is a major metabolite. In a first step the endpoint of the parent could indeed be used to do this risk assessment but, according to SANCO/3268/2001, the endpoint from the parent should then be divided by 10. This was not done in the DAR	prior to its degradative cleavage to M01 and M02, benzyl and pyridinyl metabolites. M03 is only stable under very acidic conditions and only hydrolytically stable at pH ≤ 3 hence toxicological testing of aquatic organisms, particularly, Algal studies (most sensitive *N. pelliculosa*) normally conducted at pH7.4-9.0 were considered neither feasible nor meaningful. Parent endpoint was considered to be an appropriate surrogate since M03 structure is virtually identical, differing by a single hydroxyl- group, the 0.1x factor was considered more appropriate for metabolites of dissimilar structure and likely dissimilar toxicology. It should also be noted that more realistic FOCUS Step 3 PECsw endpoints were not derived for M03 which would likely generate TER >10 with parent endpoint x0.1. However, it should also be noted that *N. pelliculosa* is a particularly sensitive algal species and it may be appropriate to determine a more representative endpoint for algae (The EFSA J. (2005), 301) by determining the geometric mean of the algal species endpoints. Addressed.	
5(27)	Vol. 3, B.9.2.4, Risk to aquatic organisms	EFSA: On p. 936-937 it is stated that the metabolites M-01, M-02, M-05, M-10, M-11, M-12 and M-13 retain no parent biological activity. On which data are these statements based? An assessment of	RMS: Theoretical groundwater estimates predict that following vine and potato applications fluopicolide metabolites M01, M03 (vine treatment only), M05, M10, M11, M12 and M13 at >0.1µg/L.	Open point: RMS to include the information and argumentation regarding the ecotoxicological relevance of GW metabolites presented in column 3 in an

Aquatic organisms (B. 9.2)				
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		the biological activity in line with the guidance document on the assessment of the relevance of metabolites in groundwater (SANCO/221/2000) is considered necessary.	Fluopicolide is a pyridinyl-benzamide fungicide. Numerous biological screening data confirm that fluopicolide does not have significant herbicidal or insecticidal activity [Nguyen & Gosch, 2003abcd, Latorse & Flahout,2004, Rosinger, 2001, Sabbert, 2004, Jans, 2001]. In fluopicolide and M01 screens on 5 soil fungal species of different classes only one species, Phytophora (oomycetes), was sensitive to fluopicolide and none were sensitive to M01[Lechelt-Kunze, 2003e-m]. In tests on fluopicolide-sensitive fungi, grape downy mildew (*Plasmopara viticola*) and potato late blight (*Phytophthora infestans*), fluopicolide metabolites M-01, M-02, M-05, M-10, M-14 and M-15 were all shown to be <<50% active compared with parent [Latorse & Flahout,2004]. The fact that M-01and M-02, benzyl and pyridinyl derivatives formed from fluopicolide cleavage at the amide bridge (and their substituted derivatives M-05, M10 and M14) all retain no fungicidal activity is strongly indicative that fluopicolide biological activity is only expressed via an intact pyridnyl-benzamide molecule. Untested GW metabolites M11 and M12 (isomers), tentatively identified as hydroxylated derivatives of M10, and M13, an hydroxylated derivative of M02, are structurally similar and	addendum for the sake of completeness. We agree that since the TER for M05 is >18519 (vine) and >58824 (potato) for algae and this metabolite is the one of highest concentration in the $FOCUS_{gw}$ modelling, apart from M01, the risk from M10, M11, M12 and M13 to aquatic organisms can be considered to be low. The information presented is however of value for the assessment of "pesticidal activity". No discussion in an experts meeting is required.

Aquatic organisms (B. 9.2)				
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			considered extremely unlikely to retain biological activity. M03 is a structurally-related transient hydroxylated-derivative of fluopicolide and is an unstable intermediate during cleavage of fluopioclide to M01 and M02. It is very unstable in water and at environmental pH will rapidly degrade to M01 and M02 and the RMS considers it inconceivable that significant exposure to M03 will occur via GW. Thus the RMS concludes that all metabolites theoretically occurring in GW >0.1**µg/L** will not retain or express biological activity of the parent, fluopicolide. All GW metabolites were considered to be irrelevant in terms of mammalian risk (see B.6.1.4 and B.6.80). M01 was formed in the hen metabolism study indicating that fluopicolide avian toxicity test encompass M01 effects, and on a molar basis M01 was not more acutely toxic to birds. Low avian risk from M01 was also indicated. In aquatic tests M01, M02 and M05 were at least 10x < toxic than fluopicolide which included the most sensitive species, *N. Pelliculosa*,and low risk to aquatic organisms was indicated. M10, M11, M12 and M13 are GW metabolites not tested on aquatic species, but are structurally similar to M02 and M05, which were significantly less toxic than fluopicolide when tested on most sensitive fish and algae species. M01, M02 and M03 were not more toxic to	

Aquatic organisms (B. 9.2)				
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			worms than fluopicolide and constituted less overall risk. Folsomia, soil microbes, soil fungi and litter decomposition, non-target plants were not more sensitive to M01 than fluopicolide and low risk was indicated. Therefore the RMS considers that the weight of evidence suggests that GW metabolites can be regarded as not ecotoxicologically relevant. (also addressed point 5(30)). Addressed.	
5(28)	Vol. 3, B.9.2.4, Summary and risk assessment	DE: The risk assessment of the RMS can be supported although the argument for possible consideration of a TER trigger reduction with respect to risks for algae is not comprehensible and would be contradictory to the line of argumentation in the DAR on diflufenican where a reduction of the safety factor for algae based on 5 species (2 blue, 2 green, 1 diatom) was stated to be not acceptable by the same RMS.	RMS: Addressed at 5(24).	Addressed. See 5(24)
5(29)	Vol. 3, B.9.2.4, endpoints for aquatic risk assessment	BCS: Page 930: General comment for the risk assessment: PSD has considered the EbC50 (biomass) as endpoint to primarily assess the risk to algae and the ErC50 (growth rate) as a possible refinement at member state level. The revised OECD 201 guideline (October 2004) now clearly promote the expression of the effects according to the	RMS: The RMS is aware that expression of algal effects by consideration of the algal ErC50 (growth rate) in aquatic risk assessment has been promoted as a more concise parameter and more relevant to field scenarios. Nevertheless, until the ecological significance is validated and the approach more widely accepted, although both values were presented, use of the EbC50 (biomass) parameter, which	Addressed. Consistent with the evaluation of other active substances.

Aquatic organisms (B. 9.2)				
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		growth rate (ErC50) and possibly to the yield but the EbC50 is not considered as a relevant endpoint anymore.	here represents a more precautionary worse case for risk assessment, is preferred by the RMS in line with current guidance. Addressed.	
5(30)	Vol. 3, B.9.2.4, Risk to aquatic organisms	EFSA: We would like to discuss the need for studies on aquatic organisms with the groundwater metabolites M-10, M-11, M-12 and M-13 at an expert meeting. Although these metabolites show some structural similarity to M-05, it has been noted that there are differences in functional groups.	RMS We believe that this point has been addressed. See point 5(27). Addressed.	Addressed. See 5(27)
5(31)	Vol. 3, B.9.2.4, Risk to aquatic organisms	EFSA: Please discuss also briefly the BCF in fish in the aquatic risk assessment.	RMS: - Although fluopicolide has a log Pow of 2.9 a bioaccumulation test was undertaken on blue gill sunfish (B.9.2.3.4) which indicated that fluopicolide had a low bioconcentration factor (maximum BCF= 121) in whole fish. Depuration was rapid ($t_{½}$ = 0.51d) and biphasic with a time to 90% steady state (t_{90}) of 1.7d. These data indicate that fluopicolide will have negligible propensity to bio-concentrate in fish. Addressed.	Addressed. RMS to consider in a corrigendum for the sake of completeness.

Aquatic organisms (B. 9.2)				
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5(32)	Vol. 3, B.9.2.4, Risk to aquatic organisms	EFSA: Why was not the max. PECsw of 12.94 µg/L for metabolite M-02 in potatoes, used to assess the risk from this metabolite.	RMS Agree: - the SW aquatic risk assessment was not adjusted to accommodate late revision to FOCUSsw Step 2 end points for M-02 following potato use. Table B.9.2.82 amendments Step1 Step2 PECsw PECsed PECsw PECsed M-02 12.94 0.77 0.652 0.039 Table B.9.2.86 amendments Step1 PECsw TER M-02 12.94 >232 No impact on risk assessment conclusion LOEPs amended. Addressed.	Addressed. RMS to consider in a corrigendum. List of endpoints has been amended with the new TER of >232..
5(33)	Vol. 3, B.9.2.4, Risk to aquatic organisms	EFSA: The risk from the lead formulations could also have been calculated with the PEC values from the FOCUS calculations if the endpoints are expressed in g a.s./L.	RMS disagree: Aquatic formulation toxicological endpoints will reflect combined toxicity of cofomulants, the 2nd a.s. and fluopicolide. Exposure (PECsw) values are based on fluopicolide data only, hence risk assessment based on formulation tox end pts. is less scientifically meaningful. It is also inconceivable that significant formulation compositional integrity will be maintained in SW exposure scenarios derived from contaminated soil. Spray drift was considered more pertinent to address formulation risk using PECs derived	Addressed

Aquatic organisms (B. 9.2)				
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			solely from spray drift where retention of formulation compositional integrity is more likely. However, it should be noted that formulation toxicological endpoints expressed as a.s. fall within the 95% confidence limits of that derived for the a.s., probably indicative that fluopicolide is probably the principal toxic agent. The narrower 95% confidence limits of the fluopicolide a.s. end point also suggest that the a.s. endpoint is more reliable.	

Bees and non-target arthropods (B. 9.4 and B.9.5)				
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)
5(34)	Vol. 1, Level 2, Appendix 3, TER values	BCS: P.102: TER values for Folsomia for potato use are missing.	RMS agree: - TERs for potato use for fluopicolide and M-01effects on Folsomia are 155 and 1437, respectively. LOEPs amended (also addresses point 5(37). Addressed.	Addressed. List of endpoints has been updated.
5(35)	Vol. 1, List of endpoints, Effects on honeybees	EFSA: It should be clearly indicated if the results for bees are expressed in µg a.s. or product per bee. Preferably the endpoints for the lead formulations are also given in µg a.s./bee to enhance the comparability with the endpoints from the active substance alone.	RMS agree: - bee acute formulation tox endpoints expressed as fluopicolide content have been included in LOEPs as follows: EXP 11074B: Oral >8.0, Contact >3.3 (µg a.s./bee) EXP 11120A: Oral >11.7, Contact >8.2 (µg a.s./bee)	Addressed. List of endpoints has been updated.

Bees and non-target arthropods (B. 9.4 and B.9.5)				
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)
			Addressed.	
5(36)	Vol. 3, B.9.5.1.2, Typhlodromus study	BCS: P.962, table B.9.5.8 – at the treatment of 6.9 kg/ha, the mean number of eggs/female is 4.75 (and not 4.97 as indicated).	RMS Agree: Correction noted. Addressed.	Addressed. RMS to consider in a corrigendum.

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(37)	Vol. 1, List of endpoints, Effects on *F. candida*	EFSA: It is noted that the TER values for *F. candida* for the potato use are not included in the list of endpoints.	RMS Agree: - addressed at point 5(37) Addressed.	Addressed. See 5(37)
5(38)	Vol. 1, List of endpoints, Effects on NTA	EFSA: Preferably also the effects on fecundity are listed for the extended laboratory studies with 'EXP 11120A' on *A. rhopalosiphi* and *T. pyri*.	RMS Agree:- fecundity will be included *T. pyri* <50% effect @ 4.17 L/ha *A.rhopalosiphi* <50% effects @ 2.0L/ha LOEPs amended. Addressed.	Open point: RMS to correct the list of endpoint with exact %-age effect on fecundity instead of <50%. Note that highest conc. with effects <50% for *A. rhopalosiphi* was 2 L/ha
5(39)	Vol. 1, List of endpoints, Effects on earthworms	EFSA: It should be clearly indicated if the results for earthworms are expressed in mg a.s. or product per kg DS. Preferably the endpoints for the lead formulations are also given in mg a.s./kg DS to enhance the comparability with the endpoints from the active substance alone.	RMS Agree: - earthworm endpoints/TERs need clarification & correction. LOEPs have been amended as appropriate: VINE / Tox endpt. / PECsoil[5] / TER Acute 14d LC50 / mg/kg DS Fluopicolide >500[1] 0.268 >1866 M01 750 0.043 17442	Open point: RMS to update the list of endpoints for earthworms. It is still not clear if the values for the formulation are based on a.s. or formulation concentrations. Furthermore, values should be given as mg/kg DS. Corrected calculations should be included

Earthworms and other soil non-target organisms (macro and micro) (B. 9.6, B.9.7 and B.9.8)				
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			M02 >1000 0.026 >38462 M03 >500[1] 0.017 >29412 EXP11074B(a.s)>500[1](>21.8[1]) - n.r. Chronic (NOEC) mg/kg DS Fluopicolide 62.5[2]/250[3] 0.268 233.2[4] M01 500[2]/250[3] 0.043 5814[4] EXP11074B(a.s) 54.0[2,3] (2.4[2,3]) - n.r. POTATO Tox endpt. PECsoil TER Acute 14d LC50 mg/kg DS Fluopicolide >500[1] 0.202 >2475 M01 750 0.017 44118 M02 >1000 0.019 >52632 M03 >500[1] 0.013 >38462 EXP11120A(a.s)>500[1](>28.6[1]) - n.r. Chronic (NOEC) mg/kg DS Fluopicolide 62.5[2]/250[3] 0.202 309.4[4] M01 500[2]/250[3] 0.017 14705[4] EXP11120A(a.s) 45.2[2,3](2.6[2,3]) - n.r. [1]corrected (x0.5) for logPow>2/10% peat [2] 28d growth; [3]56d repro [4] based on worse case tox end.pt [5] worse case PECsoil (see B.8.3) n.r. not relevant M-01 and M-02 have logPow <2.0 hence no end point correction required. Acute- fluopicolide, M-03, fluopicolide in 'EXP 11074B' & 'EXP 11120A' have logPow	in a corrigendum. See also the comment from the applicant on the reporting table to be discussed in an experts meeting.

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)
			>2.0 hence endpoint (x0.5) correction required in artificial soil (10% peat). Chronic- fluopicolide, 'EXP 11074B' and 'EXP 11120A' tests were conducted in artificial soil (5% peat) and no endpoint adjustment is necessary. Formulation end pt. adjustment is questionable anyhow as it assumes that all toxicity is manifested via fluopicolide alone. The RMS also considers that risk assessment using formulation tox. fluopicolide end pts. is not meaningful as exposure (PECsoil) is based only on a.s. data (see also 5(33)). NB the above also addresses points 5(40), 5(41), 5(42), 5(43) Addressed.	
5(40)	Vol. 3, point B.9.6.3 earthworm risk assessment	FR: would it be possible to check if chronic endpoints (NOEC for parent and M-01 of 62.5 and 250 mg/kg respectively) also have to be corrected for organic carbon content in the tests?	RMS: Addressed at 5(39) Addressed.	Addressed. See 5(39).
5(41)	Vol. 3, B.9.6.3.1, risk to earthworms	EFSA: It is noted that the long term risk to earthworms from the metabolite M-01 in vines was calculated with a PEC of 0.046 mg/kg instead of 0.043 mg/kg. A PEC of 0.043 mg/kg would lead to a TER-value of 5814 instead of 5435.	RMS Agree: - addressed at 5(39) Addressed.	Addressed. See 5(39).

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(42)	Vol. 3, B.9.6.3.1 Earthworm risk assessment for EXP 11074 B	NL: Table B.9.6.21: The chronic NOEC for fluopicolide of 62.5 mg/kg should be reduced by a factor of 2, because the test has been done in artificial soil.	RMS Disagree: - addressed at 5(39) Addressed.	Addressed. See 5(39).
5(43)	Vol. 3, B.9.6.3.1 Earthworm risk assessment for EXP 11120 A	NL: Table B.9.6.22: The chronic NOEC for fluopicolide of 62.5 mg/kg should be reduced by a factor of 2, because the test has been done in artificial soil.	RMS Disagree: - addressed at 5(39) Addressed.	Addressed. See 5(39).
5(44)	Vol. 3, B.9.7.1, Effects on collembola	EFSA: Why was the observed effect on reproduction at 62.5 mg /kg of the first assay with the a.s. disregarded?	RMS: In the 2nd fluopicolide Folsomia assay (0 - 62.5 mg/kg DS) no statistical significant effect on Folsomia reproduction was observed at the highest dose, and a NOEC 62.5 mg/kg DS could be established (Table B.9.7.2). This assay was conducted because in the 1st assay statistically significant effects were observed at the lowest dose 62.5 mg/kg giving a NOEC<62.5 mg/kg DS. However, comparison of control and lowest treatment doses in both assays suggested that the control value in Assay 1 was probably unreliable and hence the statistical significance of treatment values (compared to control) in Assay 1 may also be questionable. Assuming a reproduction control value of approx 700 mean nos. of juveniles (see also M01 Folsomia assay control) it might be concluded that the true repro NOEC was possibly between 125-250 mg/kg DS, thus setting the NOEC at 62.5 mg/kg DS was also considered to be precautionary. In Assay 2 a statistically significant mortality	Addressed Based on the comments received from MS during the written procedure the NOEC of 62.5 mg/kg dry soil for *Folsomia candida* as proposed by the RMS is retained.

Earthworms and other soil non-target organisms (macro and micro) (B. 9.6, B.9.7 and B.9.8)				
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			was also observed at 31.3 mg/kg DS, however, this was considered to be anomalous as significant mortality was not observed at higher doses in both Assays, hence data from this treatment dose are ignored. It should also be noted that setting an extremely cautious NOEC based on absence of any effect, i.e. 15.6 mg/kg DS would still derive acceptable TERs in the risk assessments. Addressed.	
5(45)	Vol. 3, B.9.7.3 Risk assessment for soil macro-organisms	NL: Why a predicted maximum peak accumulated fluopicolide and M-01 over 10 cm has been taken. Normally a depth of 5 cm is used.	RMS: The PECsoil values presented in Table B.8.198 were used for the ecotoxicological terrestrial risk assessment for soil organisms. Justification for the derivation of PEC soil values is provided in Section B.8.3. However a brief explanation is also given below: For earthworm and Folsomia risk assessment 'worst case' (5cm) max. peak accumulated soil values for fluopicolide, M01, M02 and M03 were used for vines. For potato treatment 5cm values were used apart from M01 where the 10cm value was considered more realistic 'worse case' for M01 soil distribution from potato cultivation (a low risk, however, would still be indicated with 5cm M01soil values) According to EPFES 2002, litter bag studies should be conducted in 10cm soil at a plateau substance concentration estimated for 20cm depth (to allow for tillage) for M01and for fluopicolide (+ one spray application assuming 50% interception for fluopicolide). Therefore,	Open point: Pending on the discussion on the PECsoil in the section on Fate and behaviour, a revision of the risk assessment for soil organisms might be necessary. See open points in 4(60), 4(61), 4(62), 4(65) and 4(69).

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)
			worse case (represented by vine use) in 10cm is represented by 0.029 + 0.134 mg fluopicolide/kg DS and 0.011 mg M01/kg DS. Mean measured values were 0.186 mg fluopicolide and 0.010 mg M01/kg DS, which approximately encompass predicted values for both vine and potato use. Composition of AE C638206 SC 480, a solo fluopicolide formulation, will be requested. NB also addresses point 5(46) Addressed.	
5(46)	Vol. 3, B.9.7.3, Risk assessment litter bag studies	EFSA: Why is it considered more appropriate to compare the measured concentrations in the litterbag studies to PECsoil values over a depth of 10 cm while the risk to earthworms and *F. candida* is based on the standard PECsoil values over a depth of 5 cm. Furthermore the composition of the tested formulation AE C638206 SC480 should be made available.	RMS: Addressed at point 5(45) Addressed.	Addressed. See 5(45)

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(47)	Vol. 3, B.9.7-B.9.8, Risk to soil organisms	EFSA: Pending on the discussion on the PECsoil in the section on Fate and behaviour, a revision of the risk assessment for soil organisms might be necessary.	RMS: Noted - but ENV Fate do not propose changes to PECsoil values.	Open point: Pending on the discussion on the PECsoil in the section on Fate and behaviour, a revision of the risk assessment for soil organisms might be necessary. See open points in 4(60), 4(61), 4(62), 4(65) and 4(69).
5(48)	Vol. 3, B.9.8, Effects on soil micro-organisms	EFSA: Why are no studies on soil micro-organisms with the major soil metabolite M-03 considered necessary?	RMS: OECD 216/217 guidance for soil microbial activity recommends tests to be undertaken at soil pH 5.5 - 7.5. At these pHs M03 has a DT50 <1.0d and in acidic soils pH5.0 - 5.5 M03 has a DT50 of <5d (B.8.1.8). Therefore rapid decay would be expected in these soils and any resulting toxicity mostly expressed via M01 and M02 derivatives of M03. Furthermore, it is likely that soil microorganism could be exposed transiently to M03 in fluopicolide and product soil microorganism studies which were all conducted at soil pH5.4 - 5.9 over 28d where no effects were reported. Moreover, no effects of M03 on earthworm at 1000 mg/kg DS (pH 5.7-6.0) over 14d were reported and TERs for acute (14d) and long term (56d) fluopicolide effects > Annex VI (soil pH 6 -7) over 56d, where some transient M03 formation may be expected. Fluopicolide also did not affect straw litter bag decomposition in soil (pH 6.72) over 184d again where some transient	Open point: RMS to include the argumentation for why no studies with soil micro-organisms are required with M 03 in an addendum for the sake of completeness. No discussion in an expert meeting is required.

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)
			exposure to M03 might be assumed. Where tested M01 and M02, both M03 soil degradation products, also had no significant impact on soil organisms and processes. Therefore overall the RMS considered that there was sufficient weight of evidence to suggest that M03 would not have a significant effect on soil organisms and processes in the absence of a soil microbial M03 study. Addressed.	

Other non-target organisms (flora and fauna), sewage treatment (B.9.9 and B.9.10)				
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)
5(49)	Vol. 3, B.9.9, Risk to non-target plants	EFSA: It is stated that the risk from metabolite M-01 to non-target plants is low at typical exposure levels. For reasons of transparency these 'typical exposure levels' should be given.	RMS agree: - For non-target plants off-field risk is only considered and contamination will result primarily from spray drift. M01 is a soil metabolite and not present in spray applications. Hence, only pre-emergent effects on non-target plants following M01 formation in off-field soil contaminated with fluopicolide by spray drift are relevant. The pre-emergent M01 study revealed no effects >50% on seedling germination and growth at rates ≤ 0.0121 mg/kg soil and an ER50 of >0.0121 mg M01/kg DS (5 cm) was established. From theoretical in-field PECsoils (Table B.8.198) for fluopicolide and M01and spray drift values	Open point: RMS to include the argumentation regarding risk to non-target plants from exposure to M 01 in an addendum for the sake of completeness. No discussion in an expert meeting is required.

Other non-target organisms (flora and fauna), sewage treatment (B.9.9 and B.9.10)				
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)
			(6.9% for vine; 1.9% for potato), max. M01 off-field PECsoils of 0.00196 and 0.00039 mg/kg (5cm) can be derived for vine and potato use, respectively. Thus TERs of >6 and >31 can be established for M01 off-field pre-emergent effects on non-target plants indicating low risk. This is considered to be a worse case scenario as it assumes no off-field interception of spray drift deposition. The LOEPs have been amended. Addressed.	

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)
5(50)	Vol. 1, General	NL: Volume 1, level 2 consists of very short summaries of the assessment of the different ecotox-aspects. No TER-values are mentioned. In the opinion of the NL this part is too short. Mentioning tables with relevant endpoints and TER-values should be helpful.	RMS: Point noted. However, the TERs are presented in the LOEPs. Addressed.	Addressed. RMS to consider for future DARs.

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)
5(51)	Vol. 3, B.9.11, References relied upon, p. 1037	EFSA: The 2 studies by Roehlig U. on *T. pyri* and *A. rhopalosiphi* performed with a solo formulation are not really relied upon in the risk assessment for NTA. Therefore it is proposed to delete these studies from B.9.11, References relied upon.	RMS Disagree: - The 'SC480' formulation NTA can be regarded as representative of a.s. data and some indication of effect without the presence of the 2nd a.s. in 'EXP 11074B' and 'EXP 11120A'. Therefore the data provide info and support for the NTA endpoints and can be considered as being relied on (but have not been included in LOEPs).	Addressed.
5(52)	Other ecotox errors noted by the RMS.		i) Tables B.9.2.60 and B.9.2.63 need amendment (2nd a.s. is propamocarbHCl not fosetyl-Al as reported) ii)Tables B.9.5.1-4; B.9.9.3-4; text pp.958/0,1014/5. 'SC 40' should be 'SC480' iii) B.9.2.2.1 S phrases (and Vol 1) should be amended to 'S60 This material and its container must be disposed of as hazardous waste' and 'S61 Avoid release to the environment. Refer to special instructions/safety data sheets' Justification 'Recommended for substances that may cause effects in the environment'. iv) B.9.7.3.2,9.8.3.2 '10cm' should be '5 and 10cm' v) B.9.7.3.1/9.8.3.1 '10cm' should be '5cm' vi) Table B.9.9.15 M01 '0.046' should be '0.043'.	RMS to include in a corrigendum.

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)
5(53)	Vol. 3, B.8.10, Assessment of the relevance of groundwater metabolites	DE: This point makes reference to sections B.6.1.4.1 and B.10.7.5 for an assessment of the relevance of groundwater metabolites. The latter section does not exist in the provided issue of the DAR. Possibly B.10.7.5 is identical to B.6.1.4.1. If not, the RMS is requested to provide section B.10.7.5 for further evaluation.	RMS – Section B.10 is the Efficacy assessment. Section B.6.1.4.1 is an overview of the information and B.10.7.5 will be presented in an addendum for completeness. Open point: RMS to prepare an addendum.	Open point RMS to present the complete assessment for the relevance of ground water metabolites in and addendum. Special attention should be paid to the fact that at this stage for metabolites M01, M05 and M10 the trigger of 0.75 µg/L is also exceeded either in the lysimeter or the FOCUS modelling. This open point is relevant for the sections of toxicology, ecotoxicology and residues. Therefore it has been copied in the corresponding table sections from the fate section.

Comments received on reporting table, section Ecotoxicology (B.9)			
Reference to reporting table	MS / Notifier	Comment	EFSA response
5(9), 5(12)	DE	Knowing that this is a point with no impact on the final outcome of the risk assessment, we would like to state that it is still not very clear from the comment what was actually done. The MAF itself is a quite simple and schematic construct, based on number of applications, interval, and DT50 only, transforming a series of single applications into a fictitious single application or in the meaning of a summed up residue. If the reasoning in column 3 is to be inserted in a corrigendum/addendum, this issue should be explained in more detail. For the acute scenario, the overall 90th percentile of residues has to be addressed, i.e. lower percentiles for each individual	Based on this comment an open point was set in the reporting table.

Comments received on reporting table, section Ecotoxicology (B.9)			
Reference to reporting table	MS / Notifier	Comment	EFSA response
		application event must be considered (like in the assessment of spray drift).However, it is not clear how the RMS derives different values for leafy crops and short grass.	
5(14)	NOT	BCS considers that the rat multigeneration study gives a more appropriate endpoint to assess the long term and reproductive risk to mammals. A more detailed position paper (Payraudeau, V; Radix, P; report M-268483-01-1) is available and can be submitted upon request.	Noted
5(18), 5(35)	NOT	In case of formulations comprising of two active substances (or more), BCS does not consider it to be appropriate to express the endpoint in mg fluopicolide/L. Doing so, one would assume that the toxicity of the formulation is driven only by fluopicolide, which may be not correct.	Noted
5(39)	NOT	In case of formulations comprising of two active substances (or more), BCS does not consider it to be appropriate to express the endpoint in mg fluopicolide/L. Doing so, one would assume that the toxicity of the formulation is driven only by fluopicolide, which may be not correct. In the case of earthworms and if a TER calculation is deemed necessary with the endpoint based on the formulation, BCS would suggest to calculate the TER according to application rates (L/ha) rather than mg a.s./kg soil. For instance, the chronic 56d-NOEC with EXP11120A expressed in terms of dose per hectare corresponded to 30 L prod./ha. This NOEC value can be directly compared to a PEC value calculated as the maximum application rate (1.6 L/ha) corrected by a MAF value of 3.4 (as defined for 4 applications and for soil dwelling organisms) and assuming a minimum of 50% foliage interception. The corresponding TER value would be TER = 30 / (1.6 x 3.4 x 0.5) = 11.	Noted. To be discussed in the experts meeting.
5(44)	DE	The explanation provided by the RMS appears satisfactory. If there are, however, doubts regarding the control in the first assay, wouldn’t that affect the validity of that study?	Noted. Based on the comments received the NOEC of 62.5 mg/kg dry soil for *Folsomia canduida* is proposed to be retained.
5(44)	FI	FI agree with RMS, as the justification of RMS for using a reproductive NOEC of 62,5 mg/kg in Folsomia assay seems reasonable.	Noted. See above.
5(44)	FR	Looking back at the DAR, point B.9.7.1.1. study of fluopicolide effects on the reproduction of the	Noted. See above.

Comments received on reporting table, section Ecotoxicology (B.9)			
Reference to reporting table	MS / Notifier	Comment	EFSA response
		collembolan *Folsomia candida* in artificial soil, effects of fluopicolide are quite limited in the species. The hypothesis of an abnormal reproduction in the control of assay 1 may be liable but there is no indisputable argument in order to validate it. The proposal of the RMS to consider a NOEC of 62.5 mg/kg soil is reasonable.	
5(44)	NL	NL can agree with line of reasoning of RMS on the setting of the NOEC for reproduction effects on *F. candida* at 62.5 mg a.s./kg soil.	Noted. See above.
5(45), 5(46)	NOT	BCS considers that when dealing with compounds potentially persistent in soil, the plateau concentration is more appropriate to assess the long term risk to soil organisms. This plateau concentration for long term risk assessment should be calculated for a 10 cm layer in the case of no tillage crops (like vine) or a 20 cm layer in the case of crops grown on tilled soil (like potato). Regarding the acute risk assessment, the PECmax corresponding to a 5cm layer is considered appropriate.	Noted. The soil PEC calculation and the corresponding risk assessment for soil organisms will be discussed in expert meetings.