PEER REVIEW REPORT ON **FLUOPICOLIDE** 05 02 2008

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Comments on the Draft Assessment Report on fluopicolide (NAS)

RMS UK

End of commenting period: 12 April 2006 (MS, NOT)

Date	Supplier	File
14.03.2006	France	01 fluopicolide comments FR 2006-03-14.doc
20.03.2006	The Netherlands	02 fluopicolide comments NL 2006-03-20.doc
03.04.2006	Bayer	03 fluopicolide comments BCS 2006-04-03.doc
10.04.2006	Austria	04 fluopicolide comments AT 2006-04-10.doc
11.04.2006	Germany	05 fluopicolide comments DE 2006-04-11.doc
08.05.2006	Germany	05 fluopicolide comments DE 2006-05-08 additional phys-chem.doc
03.07.2006	EFSA	06 fluopicolide comments EFSA 2006-07-03.doc

section 5 - Ecotoxicology (B.9)

1. Ecotoxicology (B.9)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	DAR	FR: the DAR is very clear and consistent with guidance documents. We only suggest the following minor comments.	
(2)	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?	
(3)	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?	
(4)	Vol. 3, point B.9.6.3 eathworm 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?	
(5)	Vol. 1, list of endpoints-birds and mammals	FR: would it be possible to add TER from secondary poisoning for completeness?	

* When mentioning page numbers of the DAR in your comments, **the page numbers should refer to the pdf-version** (not the WORD-version) of the DAR to ensure consistency among the Member States.

2. Physical/Chemical Properties; Details of Uses and Further Information; Methods of Analysis (B.1-B.5)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca. 10 lines)	Column 3 Further explanations
(1)	Vol. 1, 1.3.3, chemical name	NL: IUPAC name is: 2,6-dichloro-N-[3-chloro-5-(trifluoromethyl)-2-pyridylmethyl]benzamide	
(2)	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	
(3)	Vol. 1, LOEP, chemical name (IUPAC)	NL: IUPAC name is: 2,6-dichloro-N-[3-chloro-5-(trifluoromethyl)-2-pyridylmethyl]benzamide	
(4)	Vol. 1, LOEP, minimum purity of the active substance as manufactured	NL: Please add: *based on pilot plant production*	
(5)	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.	
(6)	Vol. 1, LOEP, melting point	NL: Purity is missing	
(7)	Vol. 1, LOEP, boiling point	NL: Change not measured in not measurable	
(8)	Vol. 1, LOEP, appearance	NL: The appearance of both, the technical a.s. and the pure a.s. should be given in the LOEP.	
(9)	Vol. 1, LOEP, relative density	NL: Relative density doesn't have an unit	
(10)	Vol.1, LOEP, surface tension	NL: The concentration should be given for clarity	

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section 1 - Physical/Chemical Properties; Details of Uses and Further Information; Methods of Analysis (B.1-B.5)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca. 10 lines)	Column 3 Further explanations
(11)	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	
(12)	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)	
(13)	Vol.1, LOEP, AM for residues, plant origin	NL: For clarity at least the type of matrices should be named (e.g. dry, watery etc.) for which the AM has been validated Please also indicate that an ILV is available	
(14)	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.	
(15)	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	
(16)	Vol.1, 3.1, Background to proposed decision	NL: IUPAC name is: 2,6-dichloro-N-[3-chloro-5-(trifluoromethyl)-2-pyridylmethyl]benzamide	
(17)	Vol. 3, B.1.1.3, chemical name	NL: IUPAC name is: 2,6-dichloro-N-[3-chloro-5-(trifluoromethyl)-2-pyridylmethyl]benzamide	
(18)	Vol. 3, B.2.2.10, pH, SC formulation	NL: Is this the pH from the pure or the 1% solution?	

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section 1 - Physical/Chemical Properties; Details of Uses and Further Information; Methods of Analysis (B.1-B.5)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca. 10 lines)	Column 3 Further explanations
(19)	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.	
(20)	Vol. 3, B.2.2.10, pH, WG formulation	NL: Is this the pH from the 1% solution?	
(21)	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.	
(22)	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 before and after the storage test. Those technical charateristics are however required for WG formulations.	

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section 1 - Physical/Chemical Properties; Details of Uses and Further Information; Methods of Analysis (B.1-B.5)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca. 10 lines)	Column 3 Further explanations
(23)	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	
(24)	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.	
(25)	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.	
(26)	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)	

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section 1 - Physical/Chemical Properties; Details of Uses and Further Information; Methods of Analysis (B.1-B.5)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca. 10 lines)	Column 3 Further explanations
(27)	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	
(28)	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?	
(29)	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)	

3. Mammalian toxicology (B.6)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca. 10 lines)	Column 3 Further explanations
(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).	
(2)	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 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.	
(3)	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.	
(4)	Vol. 3, B.6.10.2, Acute Reference Dose	NL: Is it necessary to derive an ARfD for fluopicolide?	

section 2 - Mammalian toxicology (B.6)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca. 10 lines)	Column 3 Further explanations
(5)	Vol. 3, B.6.12.2, Dermal absorption *in vivo*	NL: Tape stripping was performed, but all the material in the stratum corneum is 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.	

section 3 - Residues (B.7)

4. Residues (B.7)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	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?	
(2)	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.	

section 3 - Residues (B.7)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(3)	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.	

section 3 - Residues (B.7)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(4)	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.	
(5)	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.	

section 4 - Environmental fate and behaviour (B.8)

5. Environmental fate and behaviour (B.8)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	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.	
(2)	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.	
(3)	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.	
(4)	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.	
(5)	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.	

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section 4 - Environmental fate and behaviour (B.8)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(6)	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?	
(7)	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)	
(8)	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.	
(9)	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.	
(10)	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	

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section 4 - Environmental fate and behaviour (B.8)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(11)	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).	
(12)	Vol.3, B.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.	
(13)	Vol.3, B.8.1.7, filed 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.	
(14)	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.	
(15)	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.	

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section 4 - Environmental fate and behaviour (B.8)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(16)	Vol.1, 2.5.1, definition of the residue	NL: It would be very nice if the definition of the residu 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.	
(17)	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.	
(18)	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.	
(19)	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.	
(20)	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)	
(21)	Vol.1, list of endpoints	NL: The box of classification and proposed labeling is empty. To our opinion this should reed none proposed for flupicolide.	

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6. Ecotoxicology (B.9)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	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.	
(2)	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.	
(3)	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.	
(4)	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.	
(5)	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.	

7. Physical/Chemical Properties; Details of Uses and Further Information; Methods of Analysis (B.1-B.5)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
1	Vol. 3, B.2.1.13	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.	
2	Vol. 3, B.5.1, method validation	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"	
3	Vol. 3, B.5.2 B.5.5, analytical methods for residue analysis	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. 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.	

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8. Mammalian toxicology (B.6)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
1	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	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 at 1000 mg/kg/d in the 90-day dog study.	
2	Vol. 3, B.6.3.6, summary short-term tox	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.	
3	Vol. 1, Level 2, 2.3.1, long-term toxicology	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).	

section 2 - Mammalian toxicology (B.6)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
4	Vol. 3, B.6.10, summary mammalian toxicology	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 .	Page 468, 1. paragraph: Different values are given for the % of bioavailability: “The extent of oral absorption after a 10 mg/kg bw dose was determined to be for phenyl-labelled fluopicolide 82 % in males and 90 % in females and for the pyridyl radiolabel 74 % in males and 79 % in females when the extent of radiolabel is used to interpret the 168 h recovery studies. The extent of oral absorption after a 10 mg/kg bw dose based on the biliary excretion study only was approximately 62% for the pyridyl radiolabel and 80% for the phenyl radiolabel.” 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 .
5	Vol. 3, B.6.10, summary mammalian toxicology, reproductive toxicology	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.	

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No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
6	Vol. 1, Level 2, 2.3.3; Vol. 1, Level 2, Appendix 3 and Volume 3, B.6.10.2, ARfD	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.	Following the "Guidance on setting of acute reference dose (ARfD) for pesticides" (Solecki et al, 2005), the evaluation of the total data base of fluopicolide showed no appropriate endpoints for setting an ARfD. Flupicolide is devoid of any acute oral toxicity with an oral LD50 higher than 5000 mg/kg. During repeated exposures with fluopicolide, the liver and the kidneys were identified as target organs. Nevertheless, the liver effects were clearly considered to be adaptative and not adverse and thus of no relevance for ARfD setting (Solecki et al, 2005). In addition, kidney effects observed within sub-chronic and/or chronic exposures were also considered to be either specific to the male rat (accumulation of hyaline droplets associated with cortical basophilia) and thus of no relevance to humans, either only observed after prolonged exposures (mineralization and/or interstitial inflammation only observed within the two-generation reproduction and carcinogenicity studies performed in rats) and thus of no relevance for ARfD setting. According to the guidance document, an appropriate toxicological endpoint for ARfD setting should be observed during a single day exposure. All these findings were therefore of no relevance for ARfD setting. 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.
7	Vol. 3, B.6.10.3, AOEL	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.	

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No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
8	Vol. 3, B.6.11.2b, acute dermal study	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).	
9	Vol. 3B.6.11.4 b, acute dermal study	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**	
10	Vol. 3, B.6, Table B.6.203, operator exposure calculation	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)"	

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
11	Vol. 3, B.6, Table B.6.206, EUROPOEM data	Page 509: "The **relevant EUROPOEM data** are those derived from an operator monitoring study…… A summary of the study application parameters is 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.	

9. Residues (B.7)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
1	Vol. 3, B.7.1.1, metabolism in lettuce	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.	
2	Vol. 3, B.7.1.4, confined rotational crops	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".	Page 553 BCS propose similar rewording Paragraph 3, Line 5 "In the 133 day study…, again the three components". [NB Correct 80% for pyridinyl study instead of 53% and only fluopicolide was found]. Paragraph 4, Line 1 "For radish tops the three components..." Paragraph 4, Line 7 "In the 133 day study…, again the three components". [NB 72% in the pyridinyl study was fluopicolide only.] Paragraph 5, Line 1 "For radish root the three components..." Paragraph 5, Line 5 "In the 133 day study…, again the three components" Paragraph 6, Line 1"For wheat grain the three components..." Paragraph 6, Line 7 "In the 133 day study…, again the three components" Paragraph 7, Line 1"For wheat straw the three components..."
3	Vol. 3, B.7.1.4, confined rotational crops	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.	BCS concluded that the reason residue levels in the 133 day study were lower than the 365 day study was largely due to greater amounts of metabolites M-01, M-02 and M-05 present in soil aged for 365 days and available for uptake and metabolism by the plants. M-01 is metabolised to hydroxyl M-01 (or M-04) in plants while M-02 is metabolised to M-05 (also formed in soil), M-08 and M-09. The use of spring wheat for the 365 day study and winter wheat for the 133 day study is also likely to have contributed to the difference in radioactive residue levels.

section 3 - Residues (B.7)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
4	Vol. 3, B.7.1.4 confined rotational crops	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.	BCS suggest both points are addressed using footnotes to the figure.
5	Vol. 3, B.7.1.5, confined rotational crops	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”.	BCS propose similar rewording Paragraph 5, Line 4 “In the 133 day study…, again the three components”. [NB Correct 80% for pyridinyl study instead of 53% and only fluopicolide was found]. Paragraph 6, Line 1 “For radish tops the three components...” Paragraph 6, Line 6 “In the 133 day study…, again the three components”. [NB 72% in the pyridinyl study was fluopicolide only.] Paragraph 7, Line 1 “For radish root the three components...” Paragraph 7, Line 4 “In the 133 day study…, again the three components” Paragraph 8, Line 1 “For wheat grain the three components...” Page 559, Paragraph 1, Line 7 “For wheat straw the three components...” Page 559, Paragraph 1, Line 11 “In the 133 day study…, again the three components”

section 3 - Residues (B.7)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
6	Vol. 3, B.7.1.5, confined rotational crops	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.	
7	Vol. 3, B.7.2.1, cattle metabolism	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.	
8	Vol. 3, B.7.2.1, cattle metabolism	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.	
9	Vol. 3, B.7.2.1, cattle metabolism	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%.	
10	Vol. 3, B.7.2.1, cattle metabolism	Page 562, table B.7.15: Fat, Fluopicolide: the value should be correct to 78% instead of 76%.	

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section 3 - Residues (B.7)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
11	Vol. 3, B.7.2.2, poultry metabolism	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	
12	Vol. 3, B.7.2.2, poultry metabolism	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.	
13	Vol. 3, B.7.2.4, summary of livestock metabolism	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……..	
14	Vol. 3, B.7.2.4, summary of livestock metabolism	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.	
15	Vol. 3, B.7.2.4, summary of livestock metabolism	Page 569, 13th line: ….accounted for less than 44%... this was for phenyl study only.	

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section 3 - Residues (B.7)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
16	Vol. 3, B.7.5, summary critical GAP	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.	
17	Vol. 1, Level 2, Appendix 3, residue data summary	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	
18	Vol. 3, B.7.6, residue summary	Page 575-576, Table B.7.21: The last 5 trials with 4 treatments are not representing the critical GAP (see also next comment).	
19	Vol. 3, B.7.6.1.1, summary of residues, grapes	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	
20	Vol. 3, B.7.6.1.2, summary of residues, potatoes	Page 584: paragraph Southern Europe (potatoes): “Twenty trials……”, correct to “Thirteen trials…..”	
21	Vol. 1, Level 2, Appendix 3, processing factors	p. 116: Table with processing factors, last column: The values should be 27% for wine, 45% for must and 100% for raisins.	
22	Vol. 3, B.7.8.2.1, effect of processing, grapes	Page 587: last para, 3rd line: Please correct: ….residues in the grapes were 0.32-0.**62** mg/kg.	

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section 3 - Residues (B.7)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
23	Vol. 3, B.7.9.1, cow feeding study	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.	
24	Vol. 3, B.7.9.3, cow feeding study	Page 590: 1st sentence: It should be…..dairy cattle dosed **equivalent to** 0.5, 1.5 and 5 mg/kg in feed.	
25	Vol. 3, B.7.16.2.1, STMR value grapes	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”).	
26	Vol. 3, B.7.16.2.1, NEDI values	Page 599: After recalculation of the Table B.7.36 the values of the 1st table on this page have to be changed accordingly.	

10. Environmental fate and behaviour (B.8)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
1	Vol. 1, Level 2, 2.5.2, fate in soil and Vol. 1, Level 2, Appendix 3, DT50 soil, lab	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.	
2	Vol. 3, B.8.1.1, soil metabolism	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	
3	Vol. 3, B.8.1.1; Vol. 3, B.8.1.4 and Vol. 3, B.8.1.8	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.	
4	Vol. 3, B.8.1.4, soil degradation	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.	
5	Vol. 3, B.8.1.4, soil degradation	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?	

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section 4 - Environmental fate and behaviour (B.8)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
6	Vol. 3, B.8.1.4, DT50 values soil	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.	For clarity BCS suggest removing the column for FOCUS corrected DT50 values from Table B.8.88 because these values are derived from studies 1, 2 and 3 listed in the previous column in addition to values from Hardy 2003. These values have to be included in a final summary table at the end of Section 8.1.4 (see comment for Page 657, Table B.8.87) as they are not listed elsewhere.
7	Vol. 3, B.8.1.5, dissipation rate in soil	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).	

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
8	Vol. 3, B.8.1.5, dissipation rate of fluopicolide	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.	Page 666, Table B.8.94: The fitting criteria given in the original report (mentioned as r^2) was calculated to 0.987, according the following equation (better known as B value): $B = 1 - \frac{\sum (m-c)^2}{\sum m^2}$ Further fitting criteria were supplied to PSD on 11. May 2005. These included r^2 values are based on the following equation. This r^2 value for Rödelsee was 0.94. $r^2 = 1 - \frac{\sum (m-c)^2}{\sum (m-\overline{m})^2}$ where m= measured value, c= calculated value and $\overline{m}$ = mean of the measured values. 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.
9	Vol. 3, B.8.1.5, residues in soil	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.	

section 4 - Environmental fate and behaviour (B.8)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
10	Vol. 3, B.8.1.5, field accumulation	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.	
11	Vol. 3, B.8.1.5, dissipation rate of fluopicolide	Page 679, Table B.8.116: RMS DT50 value for fluopicolide is not given.	
12	Vol. 1, Level 2, 2.5.2, soil accumulation	Page 39: Soil accumulation testing: Table: Need to add the countries and north / south to the locations	
13	Vol. 3, B.8.1.7, plateau concentrations	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.	
14	Vol. 3, B.8.1.7, plateau concentrations	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.	

section 4 - Environmental fate and behaviour (B.8)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
15	Vol. 3, B.8.1.7 and B.8.1.8, accumulation studies / summary of soil accumulation studies	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.	Page 703, Paragraph 1: BCS concluded in the final report Pollmann, 2005b that after 5 years at Appilly although the upper limit of the saw teeth curve still appears to be increasing, the plateau concentration for the lower limit of the saw teeth curve has been reached. The apparent increase of the upper limit can be explained with variations in the sampling and homogenisation procedure caused by the main amount of the substance being present in a very thin layer on top of the soil core immediately after application. The experimental data from the study has been further evaluated in a position paper (M-267721-01-1) to assess whether the plateau concentrations of fluopicolide and M-01 measured in the field had been reached after four years or if further increases would be expected in successive years. The comparison of the predicted and measured plateau concentrations at Appilly confirmed that fluopicolide residues had reached a plateau during the study, with particular reliance given to the Clow, max values. The fit to the measured M-01 concentrations provided a good agreement with the final measured plateau concentrations. No additional increase in soil concentrations of fluopicolide or M1 was predicted by modelling additional applications in successive years. The position paper can be made available upon request.
16	Vol. 3, B.8.1.8, summary of laboratory studies	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.	

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No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
17	Vol. 3, B.8.1.8, summary of laboratory studies	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.	Page 710, Paragraph 2: Suggested rewording of paragraph 2: "Aerobic degradation under non-sterile laboratory conditions led to fluopicolide degrading to a minimum of 53% AR after 120 days. Transformation led to the formation of the metabolite M-03 (max 11% AR) which was degraded to form the separate pyridinyl and benzoyl rings. There is some evidence that M-03 reaches its highest levels in acid soils, probably as a result of slower degradation of M-03 in such soils. Cleavage between the benzoyl and the pyridinyl rings led to the formation of the metabolite M-02 (max 7% AR) plus additional unknown metabolites A, B, C and D (max 4% AR up to 120 days); and the metabolite M-01 (max 25% AR at end of study up to 200 days). No other metabolites were observed in route and rate degradation studies conducted with parent although additional minor metabolites were observed in laboratory studies conducted with metabolites. CO_2 and other ……." This will be consisted with the description Volume 1, Level 3 page 119.
18	Vol. 1, Level 2, Appendix 3, DT50 soil, lab	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.	

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section 4 - Environmental fate and behaviour (B.8)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
19	Vol. 3, B.8.1.8, calculation of DT 50 values	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).	

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
20	Vol. 1, Level 2, 2.5.2, field dissipation and Vol. 3, B.8.1.8, metabolites in field dissipation studies	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.	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 correct. The levels of M-01 measured in 2000 will be as a result of fluopicolide applied in both years and therefore in order to select the appropriate value of fluopicolide applied (mg/kg) for the calculation both applications need to be considered. However it is not appropriate to simply add the maximum measured amount of fluopicolide from both years as the amount measured directly after application in 2000 includes residual residues from 1999. This will result in a % formation for M-01 which is too low. Nor is it appropriate to consider either the fluopicolide value in 1999 or 2000 alone as the amount of M-01 formed are a result of both applications, and the % formation will be too high. Also molar mass values for M-01 (29.5%) and M-02 (21.3%) included for Senas 2000 have been calculated differently. The M-01 value is based on 1999 and 2000 applications while M-02 was based on 2000 only. M-02 is rapidly degraded and thus no residual residues of M-02 are detected at application in 2000. However the levels of M-02 detected following the second application are a result of both applications of fluopicolide (as some residual residues of fluopicolide remained in the soil at the second application) and thus the % formation of 21.3% is too high. The only valid approach is to use to calculate a theoretical concentration based on the nominal application rates. Because of these difficulties BCS suggest removing the values for Senas 2000 in Table B.8.145.

section 4 - Environmental fate and behaviour (B.8)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
21	Vol. 3, B.8.1.8, groundwater assessment	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.	Page 727 Paragraph 1, Line 4: BCS suggest the phase "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. Degradation rates for fluopicolide could not be assessed reliably under laboratory conditions as the degradation of fluopicolide in soil under laboratory conditions is slow. It was necessary to assess fluopicolide under field conditions to determine actual degradation rates. Degradation rates assessed under laboratory conditions are therefore not relevant to groundwater assessments.
22	Vol. 3, B.8.1.8, summary of soil accumulation testing	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.	

<table>
<tr><th>No.</th><th>Column 1
Reference to draft assessment report *</th><th>Column 2
Comment * (restricted to 500 characters, ca.10 lines)</th><th>Column 3
Further explanations</th></tr>
<tr><td>23</td><td>Vol. 3, B.8.1.8, summary of soil accumulation testing</td><td>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.</td><td>Page 728, Paragraph 1 continued: The maximum of the low values of the saw-teeth curve for the total depth of soil mg/kg expressed as a concentration in the 0-10 cm depth increases in one of the three experimental plots, decreases in a second plot and remains the same level in a third plot. Thus in two of the three plots a maximum residual plateau concentration for the total amount of fluopicolide is observed in June 2002, one year before study termination. Considering all three plots, the total residual concentration of 0.09 mg/kg (calculated from the total depth of soil and expressed as if observed in 0-10 cm), equivalent to 135 g/ha (assuming a soil bulk density of 1.5 g/cm^3), was observed in 2002 (372 days after application 3) and 2003 (355 days after application 4). Furthermore, actual residual plateau concentrations have been measured in the 0-10 cm depth of soil and decrease from 0.08 mg/kg in 2002 to 0.06 mg/kg in 2003.
<table>
<tr><td colspan="6">Maximum low plateau (considering total soil depth, expressed as mg/kg in 0-10 cm depth)</td></tr>
<tr><td colspan="2">Eyre, 2003a</td><td>Plot 1</td><td>Plot 2</td><td>Plot 4</td><td rowspan="2">Average</td></tr>
<tr><td colspan="2">Pollmann, 2004b</td><td>Plot T2n</td><td>Plot T1</td><td>Plot T3</td></tr>
<tr><td>18-Jun-00</td><td>360 DAA</td><td>0.043</td><td>0.05</td><td>0.045</td><td>0.046</td></tr>
<tr><td>18-Jun-01</td><td>363 DAA2</td><td>0.065</td><td>0.097</td><td>0.070</td><td>0.077</td></tr>
<tr><td>26-Jun-02</td><td>372 DAA3</td><td>0.071</td><td>0.102</td><td>0.089</td><td>0.087</td></tr>
<tr><td>17-Jun-03</td><td>355 DAA4</td><td>0.103</td><td>0.102</td><td>0.071</td><td>0.092</td></tr>
</table>
<table>
<tr><td colspan="3">Maximum low plateau values (measured in mg/kg in 0-10 cm depth)</td></tr>
<tr><td>18-Jun-00</td><td>360 DAA</td><td>0.046</td></tr>
<tr><td>18-Jun-01</td><td>363 DAA2</td><td>0.074</td></tr>
<tr><td>26-Jun-02</td><td>372 DAA3</td><td>0.082</td></tr>
<tr><td>17-Jun-03</td><td>355 DAA4</td><td>0.061</td></tr>
</table></td></tr>
</table>

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section 4 - Environmental fate and behaviour (B.8)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
24	Vol. 3, B.8.1.8, summary of soil accumulation testing	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.	
25	Vol. 1, Level 2, Appendix 3, leaching studies	Page 73, Lysimeter/ field leaching studies: Include statement “All metabolites shown to be non-relevant”.	
26	Vol. 1, Level 2, Appendix 3, PEC soil and Vol. 3, B.8.3, maximum predicted soil concentration	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 %.	
27	Vol. 3, B.8.1.7, crop interception , Vol. 3, B.8.3, PECsoil and Vol. 3, B.8.6.2, PECgw	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.	

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section 4 - Environmental fate and behaviour (B.8)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
28	Vol. 3, B.8.3, PECsoil	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.	Page 772, Paragraph 4: NB. In the modelling report Hammel 2004a it is stated the growth stages BBCH 35 to 89 were considered for potatoes. BCS concluded the risk assessment was also appropriate for the EU GAP of 4 x 100 g/ha at minimum interval of 7 days between growth stages BBCH 20 to 91. PEC soil accumulation values were calculated for 4 x 100 g/ha at 5 day intervals with crop interception rates of 50%, 50%, 80% and 80% assuming application once every two years. FOCUS recommend crop interception rates of 50% between BBCH 20-39, 80% between BBCH 40 - 89, and then 50% again between BBCH 90-99 as the crop senescence. Thus a risk assessment of the earliest use would be conducted assuming crop intercepts of 2 x 50% followed by 2 x 80% identical to that reported in Hammel, 2003a. Later use covering up to BBCH 91 (and assuming a minimum spray interval of 7 days) would be simulated assuming crop intercepts of 1 x 50%, 2 x 80%, 1 x 50%, which would have minimal differences from PEC soil values reported in Hammel, 2003a as the crop interception rates are equivalent. In general, for a moderately degradable compound (DT50 of 139 d) slight differences in application dates would have very little impact on degradation and therefore on the predicted soil concentrations.

<table>
<tr><th>No.</th><th>Column 1
Reference to draft assessment report *</th><th>Column 2
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Further explanations</th></tr>
<tr><td>29</td><td>Vol. 3, B.8.3, plateau concentrations in soil</td><td>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.</td><td>Page 774, last paragraph: It is stated in the DAR “… have not included … the timepoints at which the soil concentrations … are reached”.

In the following table the time-points at which the maximum concentrations were estimated have been added. The number of years after the first application at which the maximum concentration occurred are given in brackets. It should be noted for potatoes the substance was applied only every second year. These time-points are sensitive to weather conditions. Therefore it can not be concluded that the plateau concentration is reached only after these years. Similar, but only slightly lower concentrations were reached much earlier, and can be considered as the plateau concentration as well. The overall highest values out of 20 application seasons have been reported.

<table>
<tr><th rowspan="3">Report</th><th rowspan="3">Location</th><th rowspan="3">Plateau</th><th colspan="2">Fluopicolide (mg/kg)</th><th colspan="2">M-01 (mg/kg)</th></tr>
<tr><th>Vine</th><th>Potatoes</th><th>Vine</th><th>Potatoes</th></tr>
<tr><th>0-10 cm</th><th>0-20 cm</th><th>0-10 cm</th><th>0-20 cm</th></tr>
<tr><td rowspan="4">C036744</td><td rowspan="2">Hamburg</td><td>High</td><td>0.104 (7)</td><td>0.067 (8)</td><td>0.011 (7)</td><td>0.009 (8)</td></tr>
<tr><td>Low</td><td>0.044 (8)</td><td>0.022 (30)</td><td>0.004 (21)</td><td>0.004 (40)</td></tr>
<tr><td rowspan="2">Thiva</td><td>High</td><td>0.086 (4)</td><td>0.053 (24)</td><td>0.005 (21)</td><td>0.007 (40)</td></tr>
<tr><td>Low</td><td>0.010 (4)</td><td>0.007 (24)</td><td>0.001 (4)</td><td>0.002 (24)</td></tr>
</table>
</td></tr>
</table>

<table>
<tr><th>No.</th><th>Column 1
Reference to draft assessment report *</th><th>Column 2
Comment * (restricted to 500 characters, ca.10 lines)</th><th>Column 3
Further explanations</th></tr>
<tr><td>30</td><td>Vol. 3, B.8.3, maximum soil accumulation concentration</td><td>Page 774, Paragraph 1: The RMS concludes that the soil accumulation concentrations $C_{high,max}$ and $C_{low,max}$ calculated by 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%.</td><td>Page 774, Paragraph 1: The RMS concludes that the maximum soil accumulation concentration $C_{high,max}$ and the maximum soil accumulation concentration on the day before the first application in a season $C_{low,max}$ calculated by modelling are lower than those detected in the field accumulation studies, even allowing for 50% crop interception.
BCS do not agree with this conclusion. BCS conclude that the soil concentration predicted by modelling (Table B.8.195) and measured in the field (Table B.8.147) after correction for appropriate crop interception rates are in good agreement, particularly for the parent compound. For vine overall crop interception values of 75 % (2 x 70 %, 1 x 85%) and for potatoes of 65 % (2 x 50%, 2 x80%) were selected. The values of $C_{high,max}$ and $C_{low,max}$ measured in the field, corrected for crop interception (and an application rate of 500 g/ha at Senas) are tabulated below. For vine the values in 0-10cm depth are 25 % of that measured in the field (75 % crop interception) and for potatoes the values in 0-20 cm depth are 35 % of that measured in the field (65 % crop interception).
<table>
<tr><th rowspan="3">Report</th><th rowspan="3">Location</th><th rowspan="3">Plateau</th><th colspan="2">Fluopicolide (mg/kg)</th><th colspan="2">M-01 (mg/kg)</th></tr>
<tr><th>Vine</th><th>Potatoes</th><th>Vine</th><th>Potatoes</th></tr>
<tr><th>0-10 cm</th><th>0-20 cm</th><th>0-10 cm</th><th>0-20 cm</th></tr>
<tr><td rowspan="2">C037581</td><td rowspan="2">Senas</td><td>High</td><td>0.071</td><td>0.054</td><td>0.009</td><td>0.008</td></tr>
<tr><td>Low</td><td>0.016</td><td>0.013</td><td>0.003</td><td>0.004</td></tr>
<tr><td rowspan="2">C048340</td><td rowspan="2">Appilly</td><td>High</td><td>0.097</td><td>0.069</td><td>0.009</td><td>0.009</td></tr>
<tr><td>Low</td><td>0.036</td><td>0.028</td><td>0.009</td><td>0.009</td></tr>
<tr><td rowspan="2">C047266</td><td rowspan="2">Philippsburg</td><td>High</td><td>0.085</td><td>0.067</td><td>0.018</td><td>0.015</td></tr>
<tr><td>Low</td><td>0.024</td><td>0.022</td><td>0.006</td><td>0.007</td></tr>
<tr><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td rowspan="4">C036744</td><td rowspan="2">Hamburg</td><td>High</td><td>0.104</td><td>0.067</td><td>0.011</td><td>0.009</td></tr>
<tr><td>Low</td><td>0.044</td><td>0.022</td><td>0.004</td><td>0.004</td></tr>
<tr><td rowspan="2">Thiva</td><td>High</td><td>0.086</td><td>0.053</td><td>0.005</td><td>0.007</td></tr>
<tr><td>Low</td><td>0.01</td><td>0.007</td><td>0.001</td><td>0.002</td></tr>
</table>
</td></tr>
</table>

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section 4 - Environmental fate and behaviour (B.8)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
31	Vol. 1, Level 2, Appendix 3, PEC soil	Page 75, PEC (soil) (Annex IIIA, point 9.1.3) – Parent : No PEC values over 0 to 100 days included.	
32	Vol. 1, Level 2, Appendix 3 and Vol. 3, B.8.3, soil depth for PECsoil calculation	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.	Page 75 and Page 776 Paragraph 4: The RMS considers that 10 cm depth is too deep a depth to calculate long term PECsoil in a no- or minimum tillage situation such as vineyards. BCS do not agree with this conclusion. - In detailed discussions during the evaluation process for the EPFES document (final 2002) it was agreed to use 20 cm for long term soil simulations for annual crops. An already more conservative estimation using a depth of 10 cm was agreed for crops with no or minimum tillage such as vineyards. BCS followed this proposal. - In order to justify the use of such a soil depth, the dispersion of fluopicolide through soil was considered in more detail (M-268742-01-1). In addition to the consideration of experimental field results, the transport behaviour of fluopicolide was studied using the PEARL model for selected trial sites. This position paper can be made available upon request.
33	Vol. 3, B.8.3, calculation of accumulation potential	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.	
34	Vol. 3, B.8.3, calculation of soil accumulation	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.	

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<table>
<tr><th>No.</th><th>Column 1
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Further explanations</th></tr>
<tr><td>35</td><td>Vol. 1, Level 2, Appendix 3 and Vol. 3, B.8.3, PECsoil values</td><td>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.</td><td>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.

- In general, BCS has used the model approach, which gives a more detailed and scientific description of processes such as temperature and moisture effects, formation and degradation of metabolites and multiple applications. Comparing results with the field accumulation data will result in very similar concentrations, see comment to page 774, Paragraph 1.

- If, nevertheless, a more simplistic approach is preferred, BCS would propose to do estimations for potatoes for a depth of 20 cm and for vine for a depth of 10 cm, as described above.
On this basis, and with the final application into 5cm depth, simplistic PECsoil values following use in vines are given below:

<table>
<tr><th rowspan="2">Crop</th><th colspan="2">Fluopicolide</th><th colspan="2">M-01</th></tr>
<tr><th>Peak (mg/kg)</th><th>Steady state (mg/kg)</th><th>Peak (mg/kg)</th><th>Steady state (mg/kg)</th></tr>
<tr><td>Vines - 10 cm, last application in 5 cm (% increase)</td><td>0.209 (215%)</td><td>0.059 (164%)</td><td>0.032 (178%)</td><td>0.01 (111%)</td></tr>
<tr><td>Vines -10 cm (% increase)</td><td>0.134 (138%)</td><td>0.059 (164%)</td><td>0.021 (117%)</td><td>0.01 (111%)</td></tr>
</table>
The concentrations are very conservative compared to the values measured in the field accumulation studies, once field concentrations have been corrected for appropriate crop interception rates. The % increase compared to corrected field values are given in the table above. See also the comments to page 665, last paragraph (M-01) and page 668, Table B.8.97 for fluopicolide</td></tr>
</table>

section 4 - Environmental fate and behaviour (B.8)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
36	Vol. 3, B.8.3, maximum predicted soil concentration	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 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**.	Page 779, Paragraph 2 + 3: The RMS states: "If the reduced dose from crop interception were to be factored into the result from the field dissipation study, the maximum concentration might be expected to be reduced to 0.116 mg/kg. Thus, in comparison to the actual field study, the calculation appears to be predicting higher accumulated concentrations of fluopicolide;…." Using the approach favoured by BCS, the maximum long term predicted concentrations in soil were observed using the Hamburg scenario with crop intercepts of 70%, 70% and 85%. This gave an overall crop interception rate of 75% and a maximum predicted concentration in 0-10 cm of 0.104 mg/kg of fluopicolide. Applying the same crop intercept to the maximum concentration of fluopicolide in the 0-10 cm soil layer in the bare soil field accumulation study at the Appilly site (0.387 mg/kg) **gave a value of 0.097 mg/kg**. Thus the modelling and field data appear to be in agreement for fluopicolide. See calculations for comments to page 774, Paragraph 1. Similar calculations are also carried out for M01, see calculations for comments to page 774, Paragraph 1.
37	Vol. 1, Level 2, 2.5.2, aqueous hydrolysis	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.	

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section 4 - Environmental fate and behaviour (B.8)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
38	Vol. 1, Level 2, 2.5.2, water / sediment	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.	
39	Vol. 3, B.8.6.1, drift rate in vines	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.	
40	Vol. 1, Level 2, Appendix 3, PECsw and PECsed and Vol. 3, B.8.6.2, PECsw and PECsed in vines	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).	Page 87 and footnote to Table B.8.240 on page 819 give incorrect FOCUS Step 1 calculations for M-03 on vines. At Step 1 multiple applications are typically added at one time point unless the time between applications is more than three times the DT50 value for the total water sediment system as is the case for AE 0608000 (DT50 1.9 days) with application of fluopicolide at 10 day intervals to vines. Correct values are PECsw Step 1 = 4.2633 ug/L and PECsed Step 1 = 4.6381 ug/kg.
41	Vol. 1, Level 2, Appendix 3	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”	

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section 4 - Environmental fate and behaviour (B.8)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
42	Vol. 1, Level 3, metabolites in groundwater	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	
43	Vol. 3, B.8.10, assessment of the relevance of groundwater metabolites	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.	

11. Ecotoxicology (B.9)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
1	Vol. 3, B.9.1.4.2, Tier 1 risk assessment for birds	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.	
2	Vol. 3, B.9.2.4, endpoints for aquatic risk assessment	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 growth rate (ErC50) and possibly to the yield but the EbC50 is not considered as a relevant endpoint anymore.	Considering that the revised OECD 201 guideline (October 2004) now clearly promote the expression of the effects according to the growth rate (ErC50) and because of strong scientific arguments in favour of the ErC50 (i.e. the figures are directly comparable for species sensitivity distributions with other aquatic plants and algae, they are directly influencing production rated of the biomass pool in water bodies, they better evaluate recovery), BCS would suggest to consider the ErC50 as the basic endpoint for the risk assessment and to possibly indicate the EbC50 for information only.

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
3	Vol 1, Level 2, Appendix 3 and Vol. 3, B.9.3.1, endpoint for mammalian risk assessment	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. 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.	BCS does not consider the rabbit developmental toxicity NOAEL of 20 mg/kg bw/day as relevant to assess the long term and reproductive risk to mammals. Endpoints taken from the rat reproduction study are considered much more robust and appropriate for the following reasons: • The guidance document on Risk assessment for Birds and Mammals under Coucil directive 91/414/EEC (Sanco/4145/2000, 25 September 2002) stresses that endpoints should be selected according to their ecological relevance • In the rabbit developmental toxicity, the exposure is rather short (22 days) compared to the rat multi-generation. • In the rabbit developmental toxicity, animals are fed by gavage which does not mimic natural conditions, especially for a long term assessment. • In the rabbit developmental toxicity, only pregnant females are treated and therefore possible effects to normal population are overlooked. • On the other hand, endpoints taken from the rat multigeneration study have not these shortcomings as they better reflect possible ecologically relevant effects such as pairing, fertility and reproductive performance, multigeneration endpoints, survival of the offsprings, histopathological examination of reproductive tissues etc. • In the rat multigeneration, several types of population are exposed, females and males, adults and young which better mimics the natural state of a population. The exposure period of 38 weeks fully covers the period where contaminated food could be available to small mammals. 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.

* When mentioning page numbers of the DAR in your comments, **the page numbers should refer to the pdf-version** (not the WORD-version) of the DAR to ensure consistency among the Member States.

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
4	Vol. 3, B.9.5.1.2, Typhlodromus study	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).	
5	Vol. 1, Level 2, Appendix 3, TER values	P.102: TER values for Folsomia for potato use are missing.	

section 1 - Physical/Chemical Properties; Details of Uses and Further Information; Methods of Analysis (B.1-B.5)

12. Physical/Chemical Properties; Details of Uses and Further Information; Methods of Analysis (B.1-B.5)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 1, Vol. 3, and LOE identity	AT: The CIPAC number is 787.	
(2)	Vol. 1, 2.1.2 phys.-chem. properties	AT: A conclusion concerning the formulation is not reported.	
(3)	Vol. 1, LOE relevant impurities	AT: M-01 is considered to be relevant, therefore it is not confidential information.	
(4)	Vol. 1, LOE melting point	AT: The purity is not reported.	
(5)	Vol. 1, LOE and Vol. 3 B.2.1.24 surface tension	AT: The concentration used is not reported.	
(6)	Vol. 3, B.2 in general	AT: Information whether GLP is applied or not should be reported.	
(7)	Vol. 3, B.2.1.1 melting point	AT: The method used should be mentioned.	
(8)	Vol. 3 B.2.2.11 surface tension	AT: The concentration used is not reported.	SC formulation
(9)	Vol. 3 B.2.2.15 shelf life	AT: The content of M-01 before and after storage must be determined.	SC formulation
(10)	Vol. 3, B.2. Physical and chemical compatibility of tank mixes	AT: Nothing is reported.	SC formulation
(11)	Vol. 3 B.2.2.15 shelf life	AT: The content of M-01 before and after storage must be determined.	WG formulation

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section 1 - Physical/Chemical Properties; Details of Uses and Further Information; Methods of Analysis (B.1-B.5)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(12)	Vol. 3, B.2. Physical and chemical compatibility of tank mixes	AT: Nothing is reported.	WG formulation
(13)	Vol. 3, B.5 analytical methods in general	AT: No information about linearity is provided.	
(14)	Vol. 3, B.5.1.3 method for fluopicolide in PPP	AT: The analytical method is not confidential.	
(15)	Vol. 3, B.5.1.3 method for relevant impurities in the formulation	AT: A method for M-01 is required.	
(16)	Vol. 3, B.5.5 evaluation and assessment	AT: A compilation of determined LOQs contra relevant residue data should be reported.	
(17)	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.	
(18)	Vol. 4, C.3a composition of the SC formulation	AT: The closure of TGAIs and formulants should be 1000 g/kg.	
(19)	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.	

* When mentioning page numbers of the DAR in your comments, **the page numbers should refer to the pdf-version** (not the WORD-version) of the DAR to ensure consistency among the Member States.

section 2 - Mammalian toxicology (B.6)

13. Mammalian toxicology (B.6)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/notifier>>: <<comment>>	

* When mentioning page numbers of the DAR in your comments, **the page numbers should refer to the pdf-version** (not the WORD-version) of the DAR to ensure consistency among the Member States.

section 3 - Residues (B.7)

14. Residues (B.7)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/notifier>>: <<comment>>	

* When mentioning page numbers of the DAR in your comments, **the page numbers should refer to the pdf-version** (not the WORD-version) of the DAR to ensure consistency among the Member States.

section 4 - Environmental fate and behaviour (B.8)

15. Environmental fate and behaviour (B.8)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/notifier>>: <<comment>>	

section 5 - Ecotoxicology (B.9)

16. Ecotoxicology (B.9)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	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.	

17. Physical/Chemical Properties; Details of Uses and Further Information; Methods of Analysis (B.1-B.5)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 1, Level 2 (2.1.1)	DE: Statement is missing.	
(2)	Vol. 1, Level 2 (2.1.3)	DE: Statement is missing.	
(3)	Vol. 1, List of Endpoints (general)	DE: If it is possible, the LOEP should be brought in the new format.	
(4)	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.	
(5)	Vol. 1, List of Endpoints (relevant impurities)	DE: The identity of relevant impurities is not a confidential information, only information about the identity of significant impurities are confidential. Please delete the accordant sentence in the second column.	
(6)	Vol. 1, List of Endpoints (Solubility in organic solvents)	DE: It should be *n*-hexan**e** and dimeth**y**lsulfoxide	
(7)	Vol. 1, List of Endpoints (methods of analysis, PPP)	DE: Please change “were” with “was”.	
(8)	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 5 a different M-code number is used for the two metabolites than in this chapter.	

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(9)	Vol. 3, B.2.1 (2.2)	DE: The relative density was measured at 30 °C and not at 4 °C.	
(10)	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.	
(11)	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.	
(12)	Vol. 3, B.2.1 (2.5, UV/VIS)	DE: More detailed information about the measurement should be given, e.g. solvent, maximum absorbance.	
(13)	Vol. 3, B.2.1 (2.9, hydrolysis rate)	DE: Information about DT_{50}-values are missing.	
(14)	Vol. 3, B.2.1 (2.9, quantum yield)	DE: Unit and basis of the used calculation method are missing.	
(15)	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.	
(16)	Vol. 3, B.2.1 (2.13)	DE: The test was only applied for thermal sensibility, information about mechanical sensibility are missing.	
(17)	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.	
(18)	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.	
(19)	Vol. 3, B.3.4.1	DE: The information should be given here, a reference to the safety data sheet is not sufficient.	

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(20)	Vol. 3, B.3.4.2 (controlled incineration)	DE: The first sentence makes no sense, it is just a description of the data requirement.	
(21)	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?	
(22)	Vol. 3, B.3.4.3	DE: The information should be given here, a reference to the safety data sheet is not sufficient.	
(23)	Vol. 3, B 4 (references relied on)	DE: References for the active substance are missing.	
(24)	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.	
(25)	Vol. 4, C.2.1 (1.10)	DE: Toluene is classified as Xn (harmful to health). Should it be considered as a relevant impurity?	
(26)	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.

section 1 - Physical/Chemical Properties; Details of Uses and Further Information; Methods of Analysis (B.1-B.5)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(27)	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.
(28)	Vol. 4, C.4.2 (4.1, analytical methods)	DE: In table C.4 information about the concentration levels regarding precision/repeatability are missing.	
(29)	Vol. 4, C.4.2 (4.1, analytical methods)	DE: In table C.4 information about the fortification levels regarding accuracy are missing.	
(30)	Vol. 4, C.4.2 (4.1)	DE: Information about the identification procedures for the impurities are missing.	
(31)	Vol. 4, C.5.1	DE: It is very unusual to include material safety data sheets into Volume 4. What is the reason?	

18. Mammalian toxicology (B.6)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca. 10 lines)	Column 3 Further explanations
(1)	Vol. 3, B.6.10.1, ADI	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.
(2)	Vol. 3, B.6.10.2, ARfD	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 animals showed decreased defecation, reduced hay consumption, hypoactivity, bristling coat, pultaceous feces and discolored urine. One animal of this dose group showed increased salivation.
(3)	Vol. 3, B.6.10.3, AOEL	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.	
(4)	Vol. 3, B.6.12, Dermal Absorption	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.	

19. Environmental fate and behaviour (B.8)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	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.	

20. Ecotoxicology (B.9)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca. 10 lines)	Column 3 Further explanations
(1)	Vol. 1, 3.1, Background to proposed decision	DE: The Level 3 evaluation of ecotoxicity is missing completely. Please amend.	
(2)	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 gree, 1 diatom) was stated to be not acceptable by the same RMS.	

21. Physical/Chemical Properties; Details of Uses and Further Information; Methods of Analysis (B.1-B.5)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(32)	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)	The acetone/water ratio in extraction module E1was modified to 8:1 (as normal 2:1) In the extraction module E7 the required aliquot was not taken (and a complete extraction was also not performed!). The selectivity of the method was not demonstrated for apple at LOQ. The chromatogram of a standards in solvent cannot be assigned to a concentration of one of calibration standards. The chromatogram of the matrix standard show peak intensities 300 times higher than the LOQ. It cannot be assigned to a concentration of one of calibration standards. Based on the calibration graphs, the matrix effect of potato should result in a reduction of peak intensity by a factor of 10. This is a very strange observation. A confirmation at LOQ with m/z 173 is obviously impossible for residues in potato and oil seed rape.
(33)	Vol. 3, B.5.3.1 Analytical Methods for Soil	DE: It is unclear, in which way positive findings in soil can be confirmed.	
(34)	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, 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.	

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(35)	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.	
(36)	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.	
(37)	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.	
(38)	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.)	Taylor, 2004: quadratic calibration function used. Cavaille & Rasati, 2003: The response of standards and samples does not correspond to the calibration graphs in appendix 2. Even at equal concentration very different peak areas were observed. Dorn, 2003: quadratic calibration function used.

22. Physical/Chemical Properties; Details of Uses and Further Information; Methods of Analysis (B.1-B.5)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(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.	
(2)	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.	
(3)	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.	
(4)	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.	
(5)	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.	

section 1 - Physical/Chemical Properties; Details of Uses and Further Information; Methods of Analysis (B.1-B.5)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(6)	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 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)	
(7)	Vol. 3, B.2.1.19 Stability in air, p. 14	EFSA: The programme used for the calculation should be mentioned.	
(8)	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".	
(9)	Vol. 3, Table B.5.1, p. 57ff	EFSA: RMS should clarify the fortification 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?)	

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section 2 - Mammalian toxicology (B.6)

23. Mammalian toxicology (B.6)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	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.	
(2)	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.	

section 3 - Residues (B.7)

24. Residues (B.7)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	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)	
(2)	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.	

section 3 - Residues (B.7)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(3)	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)?	
(4)	Vol. 3, B.7.1.2, Metabolism in grapes	EFSA: Same comments as for metabolism in lettuce (comment 1 and 2).	
(5)	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-09 is provided.	

section 3 - Residues (B.7)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(6)	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?	
(7)	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)?	
(8)	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).	
(9)	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?	

section 4 - Environmental fate and behaviour (B.8)

25. Environmental fate and behaviour (B.8)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(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.	
(2)	Vol 1. List of End points. Classification and labelling. p 96	EFSA: R53 must be proposed since fluopicolide is not readily biodegradable.	
(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.	
(4)	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.	
(5)	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.	

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section 4 - Environmental fate and behaviour (B.8)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(6)	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).	
(7)	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 is this soil is actually not known (study not long enough) and it do not seems correct to assume that it was 0. It would be more appropriate use the worst case of the two values available (38.4 %)	
(8)	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.	

section 4 - Environmental fate and behaviour (B.8)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(9)	Vol. 3. B.8.1.5.1 Kinetic evaluation of field dissipation studies.	EFSA: It is noted that the conceptual model presented does not considers a direct 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).	
(10)	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.	
(11)	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.	

section 4 - Environmental fate and behaviour (B.8)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(12)	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).	
(13)	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.	

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section 4 - Environmental fate and behaviour (B.8)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(14)	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.	
(15)	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. .	

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section 4 - Environmental fate and behaviour (B.8)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(16)	Vol 3. B.8.3. Predicted environmental concentration in soil (PEC soil).Applicant approach. p 772.	EFSA: For vines interception should be 60 % (at least for the firsts applications) to 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.	
(17)	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.	
(18)	Vol 3. B.8.3. Predicted environmental concentration in soil (PEC soil). Applicant approach. p 772.	EFSA: Field DT_{50}s are used in the modelling exercise by the applicant to calculate PEC 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.	
(19)	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.	

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section 4 - Environmental fate and behaviour (B.8)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(20)	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.	
(21)	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.	
(22)	Vol 3. B.8.3. Predicted environmental concentration in soil (PEC soil). RMS approach. p. 777.	EFSA: Table B.8.198 is confusing since it is not clear which values were actually used for the risk assessment.	
(23)	Vol 3. B.8.3. Predicted environmental concentration in soil (PEC soil). RMS approach. p. 777.	EFSA: it is not clear if the RMS has used soil depth of 5 ofr 20 cm for last application in potatoes to calculate the peak concentration. Please clarify.	
(24)	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.	

section 4 - Environmental fate and behaviour (B.8)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(25)	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.	
(26)	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 groundwater models. The EFSA Journal (2004) 93, 1-20.)**	
(27)	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.	
(28)	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.	

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section 4 - Environmental fate and behaviour (B.8)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(29)	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.	

section 5 - Ecotoxicology (B.9)

26. Ecotoxicology (B.9)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	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.	
(2)	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.	
(3)	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.	
(4)	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*.	
(5)	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.	

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section 5 - Ecotoxicology (B.9)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(6)	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.	
(7)	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.	
(8)	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.	
(9)	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?	
(10)	Vol. 3, B.9.1., Risk to birds	EFSA: Why are no studies with the lead formulations considered necessary?	
(11)	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.	
(12)	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.	

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section 5 - Ecotoxicology (B.9)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(13)	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 birds and mammals as they could not be found in the section on Fate and behaviour.	
(14)	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.	
(15)	Vol. 3, B.9.3, Effects on mammals	EFSA: It is noted that also two acute toxicity studies with the lead formulations are available.	
(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?	
(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%).	

section 5 - Ecotoxicology (B.9)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(18)	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?	
(19)	Vol. 3, B.9.2, Effects on aquatic organisms	EFSA: What is the logPow of the major aquatic metabolites?	
(20)	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.	
(21)	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.	
(22)	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 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	

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section 5 - Ecotoxicology (B.9)

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(23)	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 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.	
(24)	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.	
(25)	Vol. 3, B.9.2.4, Risk to aquatic organisms	EFSA: Please discuss also briefly the BCF in fish in the aquatic risk assessment.	
(26)	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.	
(27)	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.	

section 5 - Ecotoxicology (B.9)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(28)	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.	
(29)	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.	
(30)	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?	
(31)	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.	
(32)	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?	

section 5 - Ecotoxicology (B.9)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(33)	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.	
(34)	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.	