PEER REVIEW REPORT ON **CLOFENTEZINE** 10 02 2009

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0. General

General				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
0(1)	Vol. 1, General	EFSA: RMS should consider to use the current harmonised version of the list of end points.	RMS: Due to resource limitations we have not re-formatted the endpoints at this time to the Sept 05 guidance. We undertake to do this in time for the PraPer expert meetings. Open point	Open point RMS to amend the list of endpoints according to the new agreed template
0(2)	Vol. 1, list of end points, list of representative uses, p. 56	EFSA: Taken into account that the proposed decision is that clofentezine cannot be included in Annex I, the uses should be highlighted in grey as described in EPCO Manual E4.	RMS: Endpoints have been updated. Addressed	Addressed
0(3)	Vol. 3, B.2 Physical and chemical properties and B.5 Analytical methods, General	EFSA: RMS to consider in future DARs or a corrigendum to list in the references relied on only studies that were needed for the assessment, i.e. no invalid studies or studies that do not address a data requirement, should be mentioned (as it is done in the "List of information, tests and studies").	RMS: Point noted. The List of information, tests and studies, will be amended. Open point	Addressed RMS to consider in the List of essential studies

Comments received on reporting table, section Physical/Chemical Properties; Details of Uses and Further Information; Methods of Analysis (B.1- B.5)			
Reference to reporting table	MS / Notifier	Comment	EFSA response
0 (1)	DE	Should this not be rather an open point as proposed by the RMS?	Agreed, Reporting table modified

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

Identity (B.1, Annex C)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
1(1)	P7, Vol.1, 1.4.5: Composition of the preparation	NOT: At a minimum purity of 98% the maximal amount of technical clofentezine is 510g/L.	RMS: Agree, should be 510 g/l. Addressed	Addressed
1(2)	Vol. 1, 1.3.9, list of end points, Vol. 4, C.1.2 a) minimum purity	AT: Why is minimum purity always specified in brackets as “dry material”? Is another form available?	RMS: End points have been amended to remove reference to ‘dry material’. Addressed	Addressed
1(3)	Vol. 1, list of end points and Vol. 3, B.2.1.7 to B.2.1.9 appearance of active substance	AT: The purity must be specified and the appearance of the material, which is not reported.	RMS: No information was given on whether the data was from technical or pure, based on where the data was generated it is likely to be pure. No further data were requested as the mean purity of the technical material was 99.3%. Addressed	Addressed
1(4)	Vol. 4, C.1 detailed information on the manufacturing process, p. 3f	EFSA: It seems that some chemical drawings are missing for stage 2 to 4.	RMS: Agree, this information will be included in an addendum to Volume 4. Open point	Addressed RMS to prepare an addendum including the missing information related to manufacturing scheme

Identity (B.1, Annex C)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
1(5)	Vol. 4, C.1.1 detailed information on the manufacturing process, p. 3f	EFSA: Data on the starting material (purity, commercial availability) are missing.	RMS: The information on purity is missing. The RMS proposes that the Notifier is asked to provide this information. Data requirement	Data gap A lack of data on the purity, commercial availability of the starting materials has been identified. It should be noted that the data have been evaluated by the RMS however according to Regulation (EC) No 1095/2007 these data cannot be taken into consideration in the peer review
1(6)	Vol. 4 C.1.1 manufacturing process	AT: The source of starting materials is missing. As well as a description of the manufacturing process possibly used in the second plant (TGAI is produced in 2 plants UK and China).	RMS: The RMS will include this information in a corrigendum /addendum to Volume 4. Open point	Data gap A lack of data on the purity, commercial availability of the starting materials and a description of the manufacturing process possibly used in the second plant have been identified. See also 1(5) It should be noted that the data have been evaluated by the RMS however according to Regulation (EC) No 1095/2007 these data cannot be taken into consideration in the peer review

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1(7)	Vol. 4, C.1 detailed information on the manufacturing process, p. 3ff	EFSA: Could the RMS please confirm that there is only one manufacturing site. It seems that according the quoted report (Shaw, 2000a) only material was analysed which was produced in the first site (mentioned on p. 3, Vol. 4). Where are the batches from the other mentioned source?	RMS: An alternative manufacturing site has been proposed. The RMS will include the information on the alternative manufacturing site in an addendum to Volume 4. Open point	Data gap A lack of data on the manufacturing process used in the second plant has been identified. See also1(6) It should be noted that the data have been evaluated by the RMS however according to Regulation (EC) No 1095/2007 these data cannot be taken into consideration in the peer review Open point RMS to clarify that the new source presented in Add. to vol. 4 is an additional one or the only source, as in C.1 is stated that the Addendum is replacing the previous Volume 4, Annex C, dated August 2005

Identity (B.1, Annex C)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
1(8)	Vol. 4, C.1.3 detailed specification of the active substance	EFSA: RMS should clarify the accepted specification based on dry material. It is unclear whether or not always the dry material is used as no drying step is mentioned in the manufacturing process.	RMS: The RMS proposes that the Notifier is requested to provide this information. Data requirement	Data gap A lack of data on the a.s. content in the formulation has been identified. It should be noted that the data have been evaluated by the RMS however according to Regulation (EC) No 1095/2007 these data cannot be taken into consideration in the peer review
1(9)	Vol. 4, C.1.2 detailed specification of the preparation, p. 9f	EFSA: The minimum purity given in the note 1 needs to be clarified since it is below the specified minimum purity of the technical material.	RMS: Agree, RMS will amend Note 1 in an corrigendum/addendum to specify '98% w/w and 510 g/L'. Open point	Addressed RMS amended the note in the Add. to vol. 4 New data gap A lack of data for the CAS number for the formulant (antifoam) according to the Directive has been identified
1(10)	Vol. 4 (MAK), C.1.1 detailed information on the manufacturing process, p. 8f	EFSA: Data on the starting material (purity, commercial availability) are missing.	RMS: See 1(5).	Addressed See technical data requirement 1(5)

Identity (B.1, Annex C)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
1(11)	Vol. 4, C.1.2 c) batches	AT: A 5-batch analysis, specification of the technical material and an assessment of equivalence for the TGAI produced in the second plant is missing.	RMS: The RMS will include the information on the alternative manufacturing site in an addendum to Volume 4. Open point	Open point RMS to present the assessment of equivalence for the two sources in an Addendum See also open point 1(7)
1(12)	Vol. 4, C.1.3 composition of the PPP	AT: The content of the TGAI should be corrected taking into account that the specified minimum purity is 98%.	RMS: See 1 (9).	Addressed RMS corrected the a.s. content in the Add. to vol. 4
1(13)	Vol.4, C.1.3, detailed specification of the preparation	NL: Note 1 states that the minimum purity of technical substance is 96%, this is not in line with the specification as mentioned in C.1.2 (98%). Accordingly, the maximum amount of technical clofentezine is 510.2 g/l.	RMS: Agree, see 1 (9).	Addressed See 1(9)

Identity (B.1, Annex C)				
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1(14)	Vol. 4, C.1.4.1 analytical method, impurities	AT: The confirmation of analyte identification is not reported. %RSD for accuracy should be reported.	RMS: Agree, confirmatory methods should have been submitted, however as the retention times of the impurities match certified reference samples and the impurities found match the likely impurities to be formed based on the manufacturing process, no further data were requested. %RSD was not reported as only one determination was carried out. Addressed	Addressed Confirmation by retention time matching with (reference) standards was accepted in general by PRAPeR36
1(15)	Vol. 4, C.1.4.1 analytical method, impurities c)	AT: How many samples are determined for the determination of accuracy?	RMS: One, unless stated otherwise. Addressed	See open point 1(14)

Physical and chemical properties of the active substance (B.2.1)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
1(16)	Vol. 1, list of endpoints UV/VIS absorption	AT: ε at 538 nm should be quoted.	RMS: Endpoints have been updated. Addressed	Addressed The list of endpoints has been amended

Physical and chemical properties of the active substance (B.2.1)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
1(17)	Vol. 1, LOEP	NL: ε at 538 nm should be stated in LOEP	RMS: See 1(16).	Addressed The list of endpoints has been amended See also 1(16)
1(18)	Vol. 1, LOEP, solubility in water	NL: Temperature should be stated in LOEP	RMS: Endpoints have been updated. Addressed	Addressed The list of endpoints has been amended
1(19)	Vol. 1, LOEP, partition coefficient	NL: ´Log Pow is independent of pH´ should be stated in LOEP	RMS: Endpoints have been updated. Addressed	Addressed The list of endpoints has been amended
1(20)	Vol. 1, LOEP, flammability	NL : Flammability should be determined according to EC method A10	RMS: The in-house test was considered acceptable to address the data requirement. Addressed	Open point Acceptability of the in-house method to be discussed in an expert meeting
1(21)	Vol. 3, B.2.1.10 Spectra, p. 9	EFSA: The status of the data from Johnson (1989) is unclear. Are they acceptable? Clarification is needed.	RMS: Comment made to indicate additional data were available but were not evaluated as modern up to date GLP studies were available. Addressed	Addressed RMS to remove the reference from the List of references relied on
1(22)	Vol.3, B.2.1.5 Vapour pressure, p. 8	EFSA: For transparency, it should be mentioned which of the listed method in EEC A4 was used.	RMS: Effusion method used. Addressed	Addressed RMS to consider in a revised DAR or corrigendum

Physical and chemical properties of the active substance (B.2.1)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
1(23)	Vol. 3, IIA 2.9, (B.2.1.15) Photochemical degradation	DE: In the study of Kelly (1985), borosilicate glass was used for the determination of the photochemical degradation. The notifier should be asked to confirm that the used glass is able to let UV light from 290 nm upwards through. Otherwise a new method with suitable method design should be submitted.	RMS: Comment noted. The Notifier should be asked to provide sufficient information to address this open point. Data requirement	Data gap A lack of additional information about the method used for determination of the photochemical degradation has been identified
1(24)	Vol. 3, Appearance, p. 8, B2.1.7 – B2.1.9.	EFSA: Being aware that the given data could be regarded as sufficient, but at least a comment why the studies were accepted should be given, taken into account that according to the Directive the data are required for both the technical material as well as for the pure material.	RMS: No information was given on whether the data were from technical or pure, based on were the data was generated it is likely to be pure. No further data were requested as the mean purity of the technical material was 99.3%. Addressed	Addressed
1(25)	Vol.3, B.2.1.20 flammability and auto-flammability	NL: Flammability and auto-flammability should be determined according to EC methods A10 and A16 respectively.	RMS: The in-house test was considered acceptable to address the data requirement. Addressed	See open point 1(20)
1(26)	The whole DAR: Vapour pressure, water solubility, Henrys laws constant, photochemical oxidative degradation in air, PECair	SE: We question the judgement of how clofentezine behave in the air. A similar judgement was made for e.g. fenpropimorph. The Henrys laws constant of fenpropimorph is 0.27 Pa m^3/mol compared to 0.17 Pa m^3/mol for clofentezine and these are very similar. Fenpropimorph is now measured within the Swedish monitoring programme as one of the pesticides having the highest diffuse	RMS: The RMS agrees that this issue could be discussed further in an expert meeting although it appears to be a generic issue not specific to clofentezine (propose to discuss in the Expert Meeting on Fate and Behaviour – see also comment 4(56) below). Open point for discussion	See open point in comment 4(56).

Physical and chemical properties of the active substance (B.2.1)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
		(background sampling station) deposition flux from air (5.2 µg/m^2, during 4 month in S. Sweden year 2004; Törnquist et al., Ekohydrologi 87). It seems as this type of judgement does not describe the field situation very accurate. One reason for this may be that the relatively low vapour pressure cause binding to aerosol particles in the atmosphere, which means a lower proportion in the gas phase and a longer half-life. The Atkinsons-rate estimates apply only to the fraction in the gas phase. Also note that the vapour pressure reported for clofentezine (1,4 µPa) is for the solid state, while it is for the liquid state of fenpropimorph (7,0 mPa). In the environment, it is the liquid state which describes the fate. The Henrys law constant is independent of physical state as long as both vapour pressure and water solubility relate to the same physical state (P_{liquid}/S_{liquid} or P_{solid}/S_{solid}). Thus the Henrys laws constants can be compared, but the vapour pressure and the water solubility can not, unless they are recalculated to the liquid state. Our comment not only apply to the DAR for clofentezine and fenpropimorph, but to many active substances, and we recommend it be discussed on an expert meeting concerning fate		

Physical and chemical properties of the active substance (B.2.1)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
		assessment.		

Physical, chemical and technical properties of the formulation (B.2.2)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
1(27)	Vol.3, B.2.2.7 and 8	NL: It should be avoided to name co-formulants as this is confidential information	RMS: Agree. Comment noted. Addressed	Addressed RMS to consider in a revised DAR or corrigendum
1(28)	Vol.3, B.2.2.11, surface tension	NL: What is the concentration at which the surface tension has been determined?	RMS: 0.05%. Addressed	Addressed RMS to consider in a revised DAR or corrigendum
1(29)	Vol. 3 B.2.2.11 surface tension	AT: The concentration used should be reported.	RMS: 0.05% Addressed.	Addressed See 1(28)
1(30)	Vol.3, B.2.2.15, shelf life	NL: It is not clear if the shelf life test has been carried out in the commercial HDPE-packaging	RMS: Shelf life study was carried out in a HDPE container. Addressed	Addressed RMS to consider in a revised DAR or corrigendum
1(31)	Vol. 3 B.2.2.15 shelf life	AT: The wet sieve test should be included.	RMS: CIPAC MT 59.3 was used. Addressed	Addressed RMS to include the results of the wet sieve test in a revised DAR or corrigendum

Physical, chemical and technical properties of the formulation (B.2.2)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
1(32)	Vol. 3 B.2. tank mixes	AT: Nothing is reported.	RMS: No tank mixes are recommended on the label for 'Apollo 50SC'. Addressed	Addressed

Methods of analysis (B.5)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
1(33)	Vol. 1, LOEP, Methods of analysis, impurities in technical as	NL: HPLC-UV method is also used for the determination of impurities in technical a.s., the detection method (FID) of the GC method should also be stated in LOEP	RMS: Endpoints have been updated. Addressed	Addressed The list of endpoints has been amended
1(34)	Vol. 1, LOEP, Methods of analysis, food/feed of plant origin	NL: It should be stated that the analytical method is only validated for watery matrices (apples, pears, grapes, peaches and strawberries)	RMS: Endpoints have been updated. Addressed	Addressed The list of endpoints has been amended

Methods of analysis (B.5)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
1(35)	Vol. 1, LOEP, Methods of analysis, food/feed of animal origin	NL: It should be stated in the LOEP that there is a Data Requirement for a monitoring method for the determination of the residues of clofentezine in food/feed of animal origin as a monitoring method using diazomethane as methylation reagent is not acceptable. The enforcement method for the determination of the residues of 4-hydroxyclofentazine should be mentioned in the LOEP as 4-hydroxyclofentazine is part of the residue definition	RMS: See also 1 (50). An addendum will be produced and the endpoints will be amended as appropriate. Open point	Addressed The change of the diazomethane to MSTFA has been evaluated in Addendum 1 Data gap A lack of a fully validated method according to Sanco/825/00, including a confirmation method and an ILV for the determination of clofentezine and 4-hydroxy-clofentezine in animal tissues and products. (milk, eggs, muscle, liver, kidney and fat) has been identified
1(36)	Vol. 1, LOEP, Methods of analysis, water	NL: The water types (drinking/surface/ground) for which the AM is validated should be stated in LOEP	RMS: Endpoints have been updated. Addressed	Addressed The list of endpoints has been amended
1(37)	Vol.1, level 3, 3.3 and level 4, 4.1.5	NL: A validated analytical method for the determination of the a.s. in food/feed of animal origin is required (including confirmatory method and ILV) as in the submitted method diazomethane is used as methylation reagent this is not acceptable.	RMS: Agree, data requirement was specified (See Volume 1, Level 3). The data have been submitted and will be evaluated in an addendum. Open point	See data requirement 1(35)

Methods of analysis (B.5)				
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1(38)	Vol. 3 B.5.1 analytical methods, TGAI and formulation	AT: The %RSD of accuracy is not reported.	RMS: %RSD was not reported as only on determination was carried out. Addressed	Data gap A lack of data to address the accuracy of the method for determination of the a.s. in the PPP in accordance with guidance document SANCO 3030/99 rev 4 has been identified
1(39)	Vol. 3, B.5.1 Analytical methods for technical material and formulation analysis, Table B.5.1, p. 46	EFSA: Could the RMS clarify the entry in the column "linearity" for the ppp. It seems that the entry and the heading of the column are not really connected.	RMS: The assumption 80-110% of the content in the ppp is correct, in terms of g/l, the calibration graph was linear up to at least 0.85 g/l. Addressed	Addressed RMS to consider in a revised DAR or corrigendum

Methods of analysis (B.5)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
1(40)	Vol. 3, B.5.2, AM for food/feed of plant origin	NL: It is unclear from the presented data (table B.5.2) if the analytical methods fulfil the validation requirements according to Sanco/825/00: no linearity data are presented, it is not clear what the individual and mean recovery is per concentration level and what the repeatability is per concentration level. Repeatability data of method e (confirmation and ILV method) are missing. A description of method Wende, 2001 is missing. Only fully validated AM (suitable as enforcement methods for the analytes as mentioned in the residue definition) should be presented in a separate table for clarity.	RMS: The methods fulfilled the validation requirements according to Sanco/825/00, linearity and repeatability on individual fortification levels were not included in the table as the table would be too complicated. Linearity and repeatability on individual fortification levels were not included in the table as the table would be too complicated. Agree, however at the time this document was written it was still uncertain whether this approach was going to be adopted for Section 5. Addressed	Addressed RMS to consider the linearity and repeatability on individual fortification levels in a revised DAR or corrigendum Data gap A lack of an acceptable confirmatory method for determination of clofentezine in commodities with high water content has been identified
1(41)	Vol. 3 B.5.2 and B.5.3 analytical methods, residues	AT: No information concerning specificity and linearity for all methods is given. Individual means of recoveries and %RSD for each fortification level is required according to SANCO 825/00.	RMS: The methods fulfilled the validation requirements according to Sanco/825/00, linearity and repeatability on individual fortification levels were not included in the table as the table would be too complicated. Addressed	Addressed RMS to consider in a revised DAR or corrigendum

Methods of analysis (B.5)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
1(42)	Vol. 3, B.5.2 and B.5.3 analytical methods (residues), p. 46ff	EFSA: There is a lack of detail in the presentation of the validation data of the analytical methods, which makes it not easy to confirm the assessment. This was discussed already before. Therefore, the EFSA would like to ask UK to consider previous comments on this issue for further DARs.	RMS: Agree, additional data should have been included in the table and we now do this. Comment noted. Addressed	Addressed RMS to consider in a revised DAR or corrigendum
1(43)	Vol. 3, B.5.3 analytical methods (residues), p. 48ff in relation to B.5.6 references relied on	EFSA: Data generation methods should not be listed in the references relied on (unless they are use as confirmatory method), since this section covers only monitoring methods i.e.: - soil: methods c (Wende, 2001) is not an enforcement method. - water: method c (Wende, 2001c) is not an enforcement In addition, it is unclear whether both "air-methods" were accepted or not. It seems that the first method does not fulfil the requirements of SANCO/825/00.	RMS: Included as at the time of evaluation it was uncertain what was to be included in this section. Method (b) is the monitoring method, due to the method of determination being HPLC-MS/MS, whereas method (a) employs HPLC-UV. Addressed	Addressed RMS to consider in a revised DAR or corrigendum and to remove the data generation methods from the List of references relied on
1(44)	Vol. 3, B.5.3.1 Residues in soil, p. 48	EFSA: Could the RMS clarify why method a (Manley and Snowdon, 1985c) is not mentioned in the list of end points. It seems that the method is valid.	RMS: Only the HPLC-MS/MS method included, due to no precision data being submitted for the HPLC-UV method. Addressed	Addressed RMS to consider in a revised DAR or corrigendum

Methods of analysis (B.5)				
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1(45)	Vol.3, B.5.3.1, residues in soil	NL: Type and source of the soil used for the validation of the AM for the determination of residues in soil should be described. It is unclear from the presented data (table 5.3) if the analytical methods fulfil the validation requirements according to Sanco/825/00: no linearity data are presented, it is not clear what the individual and mean recovery is per concentration level and what the repeatability is per concentration level. Only fully validated AM (suitable as enforcement methods for the analytes as mentioned in the residue definition) should be presented in a separate table for clarity	RMS: Method (a) = Soil type not specified Method (b) = soil type not specified Method (c) = Silt/sand The methods fulfilled the validation requirements according to Sanco/825/00, linearity and repeatability on individual fortification levels were not included in the table as the table would be too complicated. Agree, however at the time this document was written it was still uncertain whether this approach was going to be adopted for Section 5. Addressed	Addressed RMS to consider in a revised DAR or corrigendum

Methods of analysis (B.5)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
1(46)	Vol.3, B.5.3.2, residues in water	NL: Source and characteristics of the surface water used for the validation of the AM for the determination of residues in water should be described. It is unclear from the presented data (table 5.3) if the analytical methods fulfil the validation requirements according to Sanco/825/00: no linearity data are presented, it is not clear what the individual and mean recovery is per concentration level and what the repeatability is per concentration level. Only fully validated AM (suitable as enforcement methods for the analytes as mentioned in the residue definition) should be presented in a separate table for clarity	RMS: Method (b) = Soil type not specified Method (c) = River water from the Nagold (Germany) The methods fulfilled the validation requirements according to Sanco/825/00, linearity and repeatability on individual fortification levels were not included in the table as the table would be too complicated. Agree, method (a) should not have been included. Addressed	Addressed RMS to consider in a revised DAR or corrigendum and to remove the not fully validated method from the List of references relied on

Methods of analysis (B.5)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
1(47)	Vol.3, B.5.3.3, residues in air	NL: It is unclear from the presented data (table 5.3) if the analytical methods fulfil the validation requirements according to Sanco/825/00: no linearity data are presented, it is not clear what the individual and mean recovery is per concentration level and what the repeatability is per concentration level. Only fully validated AM (suitable as enforcement methods for the analytes as mentioned in the residue definition) should be presented in a separate table for clarity	RMS: The methods fulfilled the validation requirements according to Sanco/825/00, linearity and repeatability on individual fortification levels were not included in the table as the table would be too complicated. Agree, method (a) should not have been included. Addressed	Addressed RMS to consider in a revised DAR or corrigendum and to remove the not fully validated method from the List of references relied on
1(48)	Vol. 3, B.5.4.1 Residues in animal tissues and products, p. 50f	EFSA: It seems that none of the methods meets the criteria. Either they are not specific or the LOQs are too high to monitor the proposed MRLs (taken the LOQs for clofentezine and 4-hydroxyclofentezine into account).	RMS: See also 1 (50). An addendum will be produced and the endpoints will be amended as appropriate. Open point	See data gap 1(35)

Methods of analysis (B.5)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
1(49)	Vol. 3, B.5.4.1, residues in animal tissues and products	NL: The methods a,b,c and e are not suitable as enforcement methods as diazomethane is used as methylation reagent. It is unclear from the presented data (table 5.4) if the analytical methods fulfil the validation requirements according to Sanco/825/00: no linearity data are presented, it is not clear what the individual and mean recovery is per concentration level and what the repeatability is per concentration level. Only fully validated AM (suitable as enforcement methods for the analytes as mentioned in the residue definition) should be presented in a separate table for clarity	RMS: See 1(48). The methods fulfilled the validation requirements according to Sanco/825/00, linearity and repeatability on individual fortification levels were not included in the table as the table would be too complicated. Agree, however diazomethane methods included as they were the only validated methods currently available. Addressed	Addressed RMS to remove the studies a, b, c and d from the List of references relied on See also data gap 1(35)

Methods of analysis (B.5)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
1(50)	Vol. 3, B.5.5 Evaluation and assessment	NL: d) residues in animal tissues and products The submitted AM´s (a,b,c,e) for the determination of clofentezine (hydrolysed to 2-chlorobenzoic acid) are not suitable as enforcement method. A description of method g is missing in paragraph B.5.4.1 The submitted AM (d) for the determination of 4-hydroxy-clofentezine is validated for milk and fat. It is not clear if this method is fully validated (see comment above), however it is clear that an ILV is missing. The data requirement should therefore be changed into: A fully validated method according to Sanco/825/00, including a confirmation method and an ILV should be submitted for the determination of clofentezine and 4-hydroxy-clofentezine in animal tissues and products.	RMS: Agree, however diazomethane methods included as they were the only validated methods available. Agree, data requirement for ILV should have been set, plus the method must be validated for the determination of 4-hydroxy-clofentezine in liver, muscle and kidney. However, a method is missing from Section 5 and was deleted in error and this will be presented in an addendum and the Endpoints will be amended accordingly. Open point	See 1(49) See also data gap 1(35)

Methods of analysis (B.5)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
1(51)	Vol. 3, B.5.5 evaluation and assessment	AT: A compilation of determined LOQs contra relevant residue data should be reported.	RMS: Not included as did not want to make the table too complicated and the information is available in the main text. Addressed	Addressed RMS to consider in a revised DAR or corrigendum
1(52)	P18, Vol. 1, 2.2.3: Analytical methods for residue analysis P53, Vol. 1, LOEP: Analytical methods for residue, food/feed of animal origin P82, Vol. 1, 3.1: Background to the proposed decision P87, Vol. 1, 4.1.5: Methods of analysis P54, Vol. 3, B 5.5: evaluation & assessment	NOT: The notifier will provide confirmatory methods for the determination of clofentezine in liver, muscle and kidney. The notifier will provide an ILV for the enforcement animal method. A report (R-17817) is available for submission and evaluation to meet this data requirement.	RMS: The data have been submitted and if appropriate will be evaluated in an addendum. Open point	Data gap A lack of confirmatory methods for the determination of clofentezine in liver, muscle and kidney and the ILV for the enforcement animal method have been identified It should be noted that the data have been evaluated by the RMS however according to Regulation (EC) No 1095/2007 these data cannot be taken into consideration in the peer review

Comments received on reporting table, section Physical/Chemical Properties; Details of Uses and Further Information; Methods of Analysis (B.1- B.5)

Reference to reporting table	MS / Notifier	Comment	EFSA response
1(6)	AT	The specification of the starting materials given in the revised version (June 2007) of volume C is incomplete. As agreed on PRAPeR 1 purity and commercial availability of **all** starting compounds must be specified. The identification of "IRVITA" should be addressed at name and address of the applicant.	Agreed, Reporting table modified
1(7)	UK-RMS	The RMS confirms that the new source presented in Volume 4, Annex C (Revised June 2007) is the only source as the previous source (Volume 4, Annex C, dated August 2005) is no longer manufactured.	Noted
1(9),1(12), 1(13)	AT	It seems that for the calculation the content of pure active substance is used to achieve 100% total, but the content of technical compound must be inserted. In addition it should be discussed in an expert meeting whether it is acceptable not providing the CAS number for a formulant.	Noted, a data requirement was created to provide the CAS number for the formulant according to the Directive
1 (14)	DE	It is unclear why this should be discussed in a meeting of experts. It was agree that retention time matching is not sufficient and EFSA has set in such cases the respective data requirement (e.g. thiobencarb).	Agreed, Reporting table modified.
1(31)	AT	The result of the wet sieve test was meant and not the method used.	Agreed, Reporting table modified
1(35), 1(50)	AT	No calibration data are reported for methods Witte 2004 and Chambers 2006 evaluated by RMS in addendum 1. According to SANCO 825/00 mean recoveries for each fortification must be reported. This is important since some recoveries are <70%.	Noted, data requirement already set
1 (35)	DE	Data requirement is supported by Germany.	Noted
1(38)	AT	The EFSA comment is only considering the PPP The validation of the technical compound (TGAI) and the formulation was criticised.	The accuracy of the method for the a.s. in the TGAI is addressed by interference and precision, evaluated in addendum 1 to vol.3.

Rapporteur: UK

Comments received on reporting table, section Physical/Chemical Properties; Details of Uses and Further Information; Methods of Analysis (B.1- B.5)

Reference to reporting table	MS / Notifier	Comment	EFSA response
1(40)	DE	Germany supports the comment of The Netherlands that some residue analytical methods for the determination of clofentezine in commodities with high water content do not meet the requirements for calibration according to SANCO/825/00. Calibration data are missing for those studies using a Lichrosorb Si-60 column for separation on HPLC prepared in the period 1981-2002. In addition, the same separation principle is used in the study of Pires, 2000. In that study HPLC separation shows serious problems with specifity (interfering peaks are most > 50% in strawberries and peaches). Therefore, the HPLC method using a Lichrosorb Si-60 column for separation seems not qualified for determination of clofentezine. Consequently, an acceptable confirmatory method for determination of clofentezine in commodities with high water content is missing and should be provided.	Agreed, open point and data requirement created

2. Mammalian toxicology

Toxicokinetics (B.6.1)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
2(1)	Vol. 1 Level 2, point 2.3.1	EFSA: since data on bioavailability of clofentezine is not conclusive, and since the issue is important for the definition of the AOEL, the need of a data requirement should be considered.	RMS: The DAR assumes a conservative value based on the available data. A study investigating biliary excretion would provide a more accurate figure and likely increase the AOEL.. Open point for discussion at Expert meeting	Open point Oral absorption value to be agreed on in a meeting of experts
2(2)	Vol. 1, List of Endpoints	NL: At 'toxicologically significant compounds' it is stated 'none'. This should be 'parent compound'.	RMS.: Agree. Endpoints have been amended. Addressed	Addressed
2(3)	Vol. 3, B.6.1.3 Summary of ADME	EFSA: the reasons given to support the non relevance of the metabolite 2-chlorobenzonitrile cannot be considered exhaustive	RMS: The relevance of the metabolite 2-chlorobenzonitrile was dismissed based on the levels in apples i.e. <0.05 mg/kg, which was approximately a tenth of those of the parent residue, with potential consumer intakes of 2-chlorobenzonitrile would be < 0.0007 mg/kg bw/day (>4% of the ADI). Addressed	See 2(14)

Toxicokinetics (B.6.1)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
2(4)	Vol. 3, B.6.1.3, summary of ADME	NL: On page 81 it is concluded that there were no signs for bio-accumulation. However, on page 75, under Table B.6.19 and in Vol. 1 in the List of Endpoints it was concluded that there was a slight suggestion of an accumulation in fat. However, looking at the values in Table B.6.19 and B.6.20, a strange peak is observed at day 20, not only in fat, but also in other organs. This cannot be easily explained. It almost seems that there was a deviation of the study protocol?	RMS: The data show some accumulation in fat but no clear indication of bio-accumulation. The degree of inter-animinal variation at each time point hampers any clear conclusions, other than that the levels rise then appear to plateau in some tissues (liver, kidneys, female heart, skin and ovaries) while in other tissues (adrenals, male heart, muscle, lung and fat) levels also rise but no definite plateau could be discerned. Addressed	Open point The potential for bio-accumulation of clofentezine to be discussed in a meeting of experts
2(5)	Vol. 3, B.6.1.3, summary of ADME	NL: It is not clear how the value of 50% for oral absorption was derived.	RMS: The ADME data is not conclusive as to the systemic bioavailability of clofentezine, a comparison of oral and i.v. dosing indicates that faeces is the major route of excretion in both cases, suggesting that absorption by the oral route is high. However metabolism data show that following oral dosing unchanged clofentezine is a major component in faeces following a single dose of 10 mg/kg bw/day, and the percentage of the administered dose in the faeces increases with dose suggesting saturation. Overall in the absence of data (including biliary sampling) 50% was assumed as a conservative value. Addressed	See 2(1)

Toxicokinetics (B.6.1)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
2(6)	Vol. 3, B.6.1.3, summary of ADME	NL: A figure with the metabolism scheme is not presented (although in this case it is a simple scheme, presentation is still appreciated).	RMS: This will be included in an addendum. Open point	Open point RMS to submit a metabolism scheme in an addendum

Acute toxicity (B.6.2)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
2(7)	P70, Vol.1, LOEP: Acute toxicity	NOT: Whilst very slight irritation may have been detected in the study it was not sufficient to trigger any classification. The entry here should be amended to *"very slight (not classifiable)"*	RMS: Endpoints state 'very slight' and therefore implicit not classified. Addressed	Addressed. It is noted that the list of end point will be revised in a meeting of experts.
2(8)	Vol. 3, B.6.2 Acute toxicity, irritancy and skin sensitisation	EFSA: the RMS considered the studies submitted in this section acceptable, despite of some weaknesses and the pre-GLP status. This might be scientifically acceptable, but for the skin sensitisation study in Guinea pig this is hardly acceptable, since the purity of the test is not specified.	RMS: Agree point but notes that i) the results of the sensitisation study with a 50% formulation (IIIA 7.1.6) was negative and ii) there have been no human incidents of sensitisation in production workers over tha last 10+years. Addressed	Open point The skin sensitisation potential of clofentezine to be discussed in a meeting of experts

Short-term toxicity (B.6.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
2(9)	Vol. 3 B.6.3.2 Oral short term studies in mice	EFSA: the RMS concludes that the relevant NOAEL from the 90-day study in the mouse NOAEL is 1000 ppm, based on effects on liver weight at 5000 ppm. The increase in relative weights starts already at 1000 ppm and it is statistically significant.	RMS: The increased liver weights at 1000 ppm were less than 110% of controls (specifically 106-7% of controls), the RMS considers a statistically significant increase in liver weight of > 110% of control weight as adverse. Addressed	Addressed
2(10)	Vol. 3 B.6.3.3 Oral short term studies in dog	EFSA: to clarify why the effects on RBC and platelets in males are considered of no toxicological relevance and therefore not considered in setting the NOAEL from the 1-year dog study.	RMS: Changes were considered slight and within normal ranges, and therefore of little toxicological significance. Nothing similar was picked up in the 90 day study. Addressed	Addressed

Genotoxicity (B.6.4)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
2(11)	Vol. 1 Level 4, point 4.1.6 Data required before inclusion in Annex I	EFSA: supports the requirement made by the RMS that an Ames test should be repeated due to inadequate positive controls in the submitted reverse mutation assay.	RMS: The data have been submitted and will be evaluated in an addendum. See 2(12) Open point	Data gap Applicant to submit a new Ames test [It should be noted that the study has already been submitted.]
2(12)	P20, Vol.1, 2.3: Impact on human & animal health, genotoxicity studies	NOT: A repeat of the Ames test has been conducted to OECD 471 with adequate positive controls. No significant increases in the frequency	RMS: The data have been submitted and will be evaluated in an addendum. Open point	See 2(11)

Genotoxicity (B.6.4)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
	P70, Vol.1, LOEP: Genotoxicity P82, Vol. 1, 3.1: Background to the proposed decision P85, Vol. 1, 3.3: rationale for postponement of the decision. P87, Vol.1, 4.1.6: Toxicology & metabolism P106, Vol. 3 B6.4.1a: Bacterial reverse mutation	of revertant colonies were recorded for any of the bacterial strains, with any dose of the test material, either with or without metabolic activation. Clofentezine was non mutagenic in this test. The report (R-17812) is available for submission and evaluation to meet this data requirement.		

Reproductive toxicity (B.6.6)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
2(13)	Vol. 1, Appendix 3, List of Endpoints and Vol. 3, point B.6.6.1, Multigeneration study in rats	DE: Please check the NOAELs for parental, reproductive and neonatal toxicity (two generation study in Wistar rats). There are discrepancies in the DAR between Volume 3 and Volume 1 list of endpoints.	RMS: Endpoints have been amended. Addressed	Addressed. It is noted that the list of end point will be revised in a meeting of experts.

Other toxicological studies & Medical data (B.6.8-B.6.9)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
2(14)	Vol. 3, B.6.8 Studies on metabolites	EFSA : The apparent degradation pathway in plants is based on photodegradation to 2-chlorobenzonitrile. This compound is further degraded to 2-chlorobenzoic acid, 2-chlorobenzylalcohol, 2-chlorobenzaldehyde. These compounds are not present in the rat metabolism and their amounts is one order of magnitude lower than that of clofentezine; a major metabolite (2-chlorobenzoic acid (2-chlorobenzylidene) hydrazide) is formed under sterilisation conditions. These metabolites should be regarded as relevant unless it is proven they are not. RMS to provide information (e.g. literature search) to assess their toxicological properties.	RMS: The relevance of the main plant metabolite in apples 2-chlorobenzonitrile is based on levels compared to parent and calculated maximum consumer exposure. RMS does not believe there is any significant human exposure. Addressed	Open point Pending on confirmation from the residue experts' meeting, the toxicological relevance of clofentezine metabolites 2-chlorobenzonitrile (and its degradation products 2-chlorobenzoic acid, 2-chlorobenzylalcohol, 2-chlorobenzaldehyde) and (2-chlorobenzoic acid (2-chlorobenzylidene) hydrazide) has to be discussed in a meeting of experts.

Other toxicological studies & Medical data (B.6.8-B.6.9)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
2(15)	P21, Vol.1, 2.3.1: effects having relevance to human & animal health…. Other toxicological studies P146, Vol. 3, B.6.8.3 b (iv), conclusion P165, Vol.1, B6.10: summary of mammalian toxicology… Other toxicological studies	NOT: The DAR states *"However the doses in the mechanistic studies where hormonal effects were noted were much higher than those in the carcinogenicity study."* Since 400 ppm was a dose tested in both types of study, (carcinogenicity and mechanistic) therefore the sentence should be amended to*"The doses in the mechanistic studies where hormonal effects were noted were at the level or higher than those in the carcinogenicity study."*	RMS: Disagree. The RMS does not propose to change the wording of the DAR. Addressed	Addressed
2(16)	P71, Vol. 1, LOEP: Other toxicological studies	NOT: This statement gives a false impression of the mechanistic work. If the mechanistic work is described here it should also note that at 400 ppm changes in liver weight and UDPGT (a bio effects marker of liver and thyroid toxicity) were seen and the dose level is identical to that used in the rat carcinogenicity study. Therefore the last part of the last sentence ", but only at high dose irrelevant to carcinogenicity" should be deleted.	RMS: Disagree. The RMS believes the statement in the DAR is clear. Addressed	Addressed. It is noted that the list of end point will be revised in a meeting of experts.

Summary of mammalian toxicology and setting of ADI, AOEL and ARfD (B.6.10)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
2(17)	P23, Vol. 1, 2.3.2: Proposal for an ADI P167, Vol. 3, B6.10.1: ADI	NOT: The sentence *"This gives an 860 fold factor over the LOAEL for thyroid tumours in male rats"* should be deleted as it is not relevant since it was concluded in the preceding paragraph that none of the effects were considered to be an indication of carcinogenicity. Also it is agreed that the observed effect is a species (rat) specific effect and therefore not related to human risk assessment.	RMS: This comment is just an indication over the margins and is useful in the context of a risk assessment. Addressed	Addressed

Toxicity of the product(s) (B.6.11)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
2(18)	P16, Vol. 1, 2.1.4.2, Preparation Classification & labelling P74, Vol. 1, App. 3, LOEP P172, Vol. 3, Skin sensitisation P176, Vol. 3, B6.13, toxicological data on non active substance	NOT: The classification Xi, R43, S24 for the preparation is not justified. The adjuvant Proxel XL2 contains ca 9.5% 1,2-benzisothiazolin-3-one (BIT) NOT 20%. Therefore the concentration of BIT in the preparation is <300 ppm (<0.03%w/w) NOT 500ppm and thus is well below the level (>500ppm) at which classification as a skin sensitiser is triggered. Apollo 50SC does not trigger any classification.	RMS: We agree R43 is not appropriate. The endpoints have been amended. Addressed	Addressed

Exposure data (B.6.14)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
2(19)	Vol. 3 B.6.14.1.1.2 Supported use of Apollo 50 SC on protected crops.	EFSA: the reliability of a single study to conclude on operator exposure/risk assessment for activities in greenhouses might be questionable and should be further commented.	RMS: The EUROPOEM has been used because neither the UK POEM nor the German Model have any exposure data on indoor applications. The EUROPOEM study on which the exposure estimate for indoor uses is based has measurements for 19 operators carrying out relevant activities for a full working day. This is considered to be an adequate dataset to derive representative surrogate exposure values. Addressed	Open point Operator exposure to be agreed on in a meeting of experts
2(20)	P177, Vol. 3, B6.14 , exposure data	NOT: See comment 2(18); the notifier considers classification of the product as R43 is not justified. The last paragraph on p177 should be deleted. However it is accepted that PPE (gloves) are required to protect the operators from potential levels of systemic exposure as determined by the modelled estimates presented in the DAR.	RMS: If the formulation is unclassified, there is no longer a requirement for the use of protective clothing (coveralls) when handling the concentrate. In all other respects, the appropriate PPE is that described on page 194 (pdf). Addressed	See 2(19)

Other comments				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
2(21)	P82, Vol. 1, 3.1: Background to the proposed decision P85, Vol. 1, 3.3: rationale for postponement of the decision… P87, Vol. 1, 4.1.6: Toxicology & metabolism	NOT: To expect a breakdown of impurities present in the batches used for tox. studies to the same standard as the analytical results for the batch analyses is not a fair and reasonable question when the analyses have been conducted some 20 years apart. The majority of toxicology studies were conducted in the 1980's with a.i. of very high purity (>97%) and pre-date the requirement in 91/414/EEC to report the impurity levels in the technical material used for each study. A statement on the equivalency of a.i. used in the tox. studies compared to today's manufactured a.i. will be provided.	RMS: The statement on equivalence has been submitted and will be evaluated in an addendum to Volume 4 (Confidential information). The new source of manufactured material will be addressed in this addendum. Open point	Data gap Applicant to submit an equivalence analysis of the batches used in tox studies compared to the currently proposed specification [It should be noted that the information has already been submitted.]
2(22)	Vol. 1 Level 4, point 4.1.6 Data required before inclusion in Annex I	EFSA: supports the requirement made by the RMS that further information of the batches of clofentezine used in mammalian toxicity studies is needed.	RMS: Data have been submitted and wil be evaluated in an addendum. Open point	See 2(21)

Other comments				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
2(23)	P205, Vol. 3, B6.15: references relied on P38-39, Vol. 2: lists of tests and studies	NOT: References IIIA 7.4/01-07 should be deleted from this section of the DAR (including any public version) as they are considered business confidential information and should appear in Vol. C only. The RMS informed EFSA & the notifier on Feb 3 2006 of this error so it should have already been taken care of during the sanitisation of the DAR and is included here for completeness.	RMS: The RMS notified EFSA of this error by email (3 February 2006) and EFSA were requested to remove these references in the sanitisation of the DAR. The references will be added to an addendum to Volume 4 (Confidential information). These references were removed from the List of Information, tests and studies. Open point	Addressed They have been removed during the sanitisation of the DAR and not included in the public version.

3. Residues

Storage Stability (B.7.0)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
3(1)	Vol. 3, B.7.7.1, Storage stability of residues in apples	EFSA : The study reported has been carried out with radioactive material. The given results provide information on the evolution of extractability of residues, but not on the storage stability of clofentezine as such.	RMS: Agree. Addressed	Addressed.
3(2)	Vol. 3, B.7.7.2 and 3, Storage stability of residues in peaches and almonds	EFSA : these studies give erratic results. Their interpretation is difficult and should be reconsidered on the basis of information on procedural recoveries.	RMS: Disagree, the data although slightly erratic indicate that residues of clofentezine in peaches are stable for at least a year if not longer. Addressed	Open point. Storage stability of clofentezine residues to be discussed in expert meeting – Information on procedural recovery in the submitted studies would help discussion.

Metabolism in plants (B.7.1)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
3(3)	Vol. 3, B.7.1.1, Metabolism in apples	EFSA : On foliage a metabolite NC 22505 was identified. The structure of this metabolite should be given in the DAR for transparency. This metabolite was identified only in apple foliage. Was it used as reference compound in the other metabolism studies?	RMS: The structure of the metabolite NC 22505 will be included in the addendum to Volume 4 (Confidential information) see section C1.1. Open point	Open point RMS to check whether NC 22505 was actually as reference compound in lemon peach and grape metabolism studies.

Metabolism in plants (B.7.1)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
3(4)	Vol. 3, B.7.1.5, Summary/assessment of metabolism in plants	EFSA : The proposed metabolic pathway in plants should be given in more details as other degradation products were identified (NC 22505, 2-chlorobenzoic acid, 2-chlorobenzylalcohol, 2-chlorobenzaldehyde)	RMS: Agree, only a limited pathway was provided. RMS suggests Notifier provides a more detailed pathway in plants. Data requirement	Point for clarification. Applicant to propose a metabolic pathway in fruits as complete as possible on the basis of available information.

Metabolism in livestock (B.7.2)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
3(5)	Vol. 3, B.7.2 Metabolism in animals	EFSA : The results of the metabolism studies should be reported in a tabular form, in order to improve the comprehensibility.	RMS: Agree, normally this would have been done, however in this case only one major metabolite was present. Addressed	Open point. RMS to report in tabular form the results of metabolism studies. This should include TRR, % of the TRR which is extractable and not extractable, % age of radioactivity accounted for each identified metabolite, indication of eventual partial conjugation, % age of extracted radioactivity only characterised for chromatographic properties (number of individual fractions…) and any other useful information for assessing validity of studies and appropriateness of the residue definition.
3(6)	Vol. 3, B.7.2.1,	EFSA : Is there an explanation for the	RMS: No explanation has been give. The Notifier will be asked to comment.	Open point.

Metabolism in livestock (B.7.2)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
	Metabolism in cattle	large difference in TTR present in renal fat (0.262 mg/kg) and subcutaneous fat (0.020 mg/kg)?	Data requirement	MS to examine the discrepancy of renal and subcutaneous fat radioactive content in cattle metabolism study.
3(7)	Vol. 3, B.7.2.2, Metabolism in goats	EFSA : It is mentioned at the end of this point that 'conflicting data had been noted between the cow and goat milk studies'… This cannot be clearly understood.	RMS: The cow milk only contained residues of 4-hydroxy metabolite whereas goat milk contained a range of hydroxy metabolites. On re-testing the goat milk, only the 4-hydroxy metabolite was found (as in the milk), the previous sample that was tested had apparently 'gone off'. Addressed	Addressed.
3(8)	Vol. 3, B.7.2 Metabolism in animals	EFSA : In the proposed metabolic pathway presented in figure 7.2.2 some metabolites are present that were not mentioned in the evaluated studies.	RMS: These are predicted/metabolites seen in the rat metabolism study. Addressed	Point for clarification. Applicant to propose a metabolic pathway in livestock based on objective findings in livestock studies. Introduction of expectations from the rat metabolism does not allow a proper comparison between livestock and rodent metabolism.

Residue definition (B.7.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
3(9)	Vol. 3, B.7.3, Residue definition in plants	EFSA : Depending on the toxicological relevance of the metabolites, the residue definition for risk assessment for raw plant commodities and the relevance of the supervised residue trials should be reconsidered.	RMS: Based on the levels in the metabolism studies, it was considered that the metabolites were not of toxicological significance and therefore should not be considered in the residues definition. See 2(14) Addressed	Open point: Residue definition for risk assessment in plant commodities to be discussed in expert meeting. See also comment 3(16)
3(10)	Vol. 3, B.7.3, Residue definition in animals	EFSA : The classification of residues as fat soluble or non fat soluble should be discussed. Information on log Pow of 4-hydroxyclofentezine would be useful. High content of residues in renal fat in goat as well as in poultry fat should be considered.	RMS: Log Pow of 4.1 indicates the potential for clofentezine to accumulate in fat. No data were submitted. This was not surprising considering the Log Pow. Addressed	Open point. Fat solubility of animal residues to be discussed in expert meeting on the basis of the residue definition. Note: The feeding study in lactating cow was conducted with a common moiety method (refer to comment 3.25)

Use pattern, critical GAP, residues trials (B.7.4 to B.7.6)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
3(11)	Vol. 1, pag 9, table 1.5.3 Vol. 3, page 239, B.7.5 Vol 1, LoEP page 51	NL: The table with the intended use is not usable. The amount kg as/hL, the amount of water/ha and the amount of kg as/ha are not in accordance with each other. As it is unknown which of the numbers is correct, it can not be deducted/calculated what the doses should be[1]. The residue section can therefore not be evaluated completely.	RMS: Disagree, highest application rate in terms of kg as/hl or kg as/ha were used. Addressed	Open point. Applicant to clarify the representative uses so that the range of concentrations, the range of water amounts per ha and the range of active substance rates per ha are in accordance. See also comment 3(14)
3(12)	Vol. 1, pag 9, table 1.5.3 Vol. 3, page 239, B.7.5 Vol 1, LoEP page 51	NL: The PHI for grapes should agree with the class distribution as stated in Guideline 7039/VI/95 of 22/7/1997, in this case 28 or 35 days in stead of 30 days.	RMS: We understand why 28 or 35 are considered better, but would disagree with 30 not being allowed. Addressed	Addressed.
3(13)	P88, Vol. 1, 4.2.7, Residues data P258, Vol. 3, B7.6.2, Further residue trials data requirements	NOT: The notifier will develop these data for post Annex I national Member State review of the PPP.	RMS: Point noted. Addressed	See data gap in comment 3(17)
3(14)	Vol. 3, B.7.6	NL: Residue trials cannot be checked at this moment as the table of intended use is incorrect	RMS: Disagree, highest application rate in terms of kg as/hl or kg as/ha were used. Addressed	See open point in comment 3(11)
3(15)	Vol. 3, B.7.6, Supervised residue trials	EFSA : there is a lack of consistency in the underlined values in the summary of supervised trials and those reported in the list of end points: Apples North:	RMS: 0.06 in the list of endpoints should read 0.07, as the residues at 35 days was 0.06, however at 43 days the residue was 0.07. With regards to 0.11, this was missing from the Endpoints and the Endpoints have now	Addressed.

[1] This was also reported to Mr. David Richardson (PSD) by e-mail from Mr. Hans Mulder (CTB) dated 10 April 2006.

Use pattern, critical GAP, residues trials (B.7.4 to B.7.6)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
		the underlined values 0.11 and 0.07 are not present in the list of end points, 0.06 in the list of end points is not found as underlined value in vol. 3.; Plums North: the underlined value 0.03 is not present in the LOE, 3 results at 35 d in Germany should be underlined (0.10, <0.01, 0.07) in vol. 3,0.02 in the list of end points is not found as underlined value in vol. 3; Grapes North: 0.12 in the list of end points is not found as underlined value in vol. 3;	been amended – STMR unaffected by changes. 0.02 in the list of endpoints should read 0.03, as the residue at 35 days was 0.02, however at 43 days the residue was 0.03 - Endpoints updated – STMR unaffected by changes. With regards to the German trials, they should have been underlined. 0.12 should not be in the table, endpoints have been updated. Addressed	
3(16)	Vol. 3, B.7.6, Supervised residue trials	EFSA : Data should be generated concerning the actual level of compounds resulting from photodegradation of clofentezine	RMS: Disagree, total residue in the crop is what is required, not a study on how it may have occurred. Addressed	See open point in comment 3(9)
3(17)	Vol. 3, B.7.6.2, Summary of residues resulting from trials	EFSA : Supports the data requirement for 4 trials on plums in Southern Europe and 8 trials on strawberries under glass.	RMS: Agree. Data requirement for Member States. Addressed	Data gap. Applicant to submit 4 trials on plums in Southern Europe and 8 trials on strawberries under glass. See also comment 3(13)

Use pattern, critical GAP, residues trials (B.7.4 to B.7.6)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
3(18)	Vol. 3, B.7.6.2, Summary of residues resulting from trials	EFSA: The RMS is of opinion that there is no distinct differences in residues on grapes between Northern and Southern regions. However comparing the average results, we have 0.58 mg/kg for the North (4 results considered, 0.12 mg/kg disregarded) and 0.28 mg/kg for the South (9 results considered). Therefore a data requirement for an additional set of 4 trials in Northern region should be fixed.	RMS: The acceptability of the grape trials could be discussed at an Expert meeting. Open point	Data gap. Applicant to submit 4 additional residue trials for the Northern Europe in grapes.

Processing (B.7.7)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
3(19)	Vol. 3, B.7.8.1, Processing, effect on the nature of residues	EFSA : Depending on the toxicological relevance of 2-chlorobenzoic acid (2-chlorobenzylidene) hydrazide, the residue definition for risk assessment for processed commodities and the relevance of the available processing studies should be reconsidered.	RMS: Addressed see 2(14) and 3(9)	Open point. The residue definition for risk assessment in processed commodities needs to be discussed in expert meeting. See also comment 3(20)

Processing (B.7.7)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
3(20)	Vol. 3, B.7.8.1, Processing, effect on the nature of residues	EFSA : Processing data should be produced with analysis of 2-chlorobenzoic acid (2-chlorobenzylidene) hydrazide in order to get more information on its actual level in practice.	RMS: Addressed see 2(14) and 3(9)	See open point in comment 3(19).
3(21)	Vol. 3, B.7.8.2, Processing, effect on the residue level (apples)	EFSA : The study reported under c) should not be used for defining processing factors as apples were washed before analysis, resulting in residues below the LOQ in the raw commodity. We agree with RMS.	RMS: Point noted. Addressed	Addressed.
3(22)	Vol. 3, B.7.8.2, Processing, effect on the residue level (apples)	EFSA : According to the list of end points, 4 trials are available for calculating the transfer factor from apple to apple sauce. However, in Vol. 3, only 2 results seem to be available. This needs to be clarified and depending on this clarification, the list of end points should be amended.	RMS: Endpoints have been updated. Addressed	Addressed.

Processing (B.7.7)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
3(23)	Vol. 3, B.7.8.2, Processing, effect on the residue level (grapes)	EFSA : The processing studies submitted for grape juice are not conclusive (calculated transfer factors are 0, 1.9 and 1.6). An explanation is given related to the presence of particules in one trial. Could it be verified whether juice was pasteurised in each trial? For wine production apparently only one study is available for Reisling, the other studies showing residues in raw grapes at too low level for an appropriate calculation of transfer factors.Based on these comments the number of appropriate studies for juice and wine production should be reconsidered and the list of end points should be amended accordingly.	RMS: No mention is made of pasteurisation. Endpoints have been updated. Addressed	Addressed.
3(24)	Vol. 3, B.7.8.3, Summary/assessment of processing	EFSA : For transparency the individual values from which the average transfer factors mentioned in table B.7.37 should be mentioned in that table or identified as underlined or bold values in the evaluated studies.	RMS: Point noted. Ideally this should have been done in table B.7.37, although it may have made the table too complicated. Addressed	Addressed. RMS to consider in a revised DAR or a corrigendum.

Livestock feeding (B.7.8)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
3(25)	Vol. 3, B.7.9, Livestock feeding studies	EFSA : The amount of residues in tissues are reported as clofentezine equivalents. However as the method of analysis is not described, it is not possible to deduce which compounds are actually included in these results. Do they comply to the proposed residue definition (sum of parent + 4-OH clofentezine)?	RMS: Clofentezine and its metabolites containing the 2-chlorobenzoic moiety were hydrolysed to 2-chlorobenzoic and determined by GC-ECD. The method would pick up both of these components. Addressed	Open point. MS to discuss the appropriateness of the feeding study (method of analysis) with regard to the residue definition in animal products.

Succeeding/Rotational crops (B.7.9)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
3(26)	Vol. 3, B.7.10, Residues in rotational crops	EFSA : The results of the mentioned study by Allen (1997), investigating the scenario of the use of clofentezine for 3 successive years followed by leafy vegetables in the late summer of the third year are not reported.	RMS: Study was not evaluated as positive residues in rotational crops were not expected (See B.7.10.1). Addressed	Addressed.

MRLs related issues and Consumer Risk Assessment (B.7.10 to B.7.15)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
3(27)	Vol. 3, B.7.13, Proposed MRLs	EFSA : The reason for proposing 0.1 mg/kg for kidneys is not understandable as the residues in this tissue was below the LOQ of 0.05 mg/kg in the feeding study.	RMS: Agree, EU MRL for kidney and liver should be 0.05 mg/kg – Endpoints have been updated. Addressed	Addressed.
3(28)	Vol. 3, B.7.16.1, Intakes by domestic animals	EFSA : Normally as fruit pomace is a processed commodity resulting for a mixture of different producers, the STMR should had been used as starting residue level in apples. Nevertheless, this has no influence on the final conclusion	RMS: Agree in principle, but in order to estimate the maximum dietary burden of apples the highest residue was used. Addressed	Addressed.
3(29)	Vol. 3, B.7.16.2.1, chronic exposure assessment	EFSA : According to WHO guidelines, TMDI calculations should be done using the proposed MRLs rather than the HR. Nevertheless, given the low level of ADI exhaustion, this has no influence on the final outcome of risk assessment. In addition it should be specified whether the figures mentioned in table B.7.47 were obtained using the HR or the STMR**.**	RMS: Agree, MRL should have been used. Figures obtained using STMR. Addressed	Addressed.

Other comments				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
3(30)	Vol. 3, B.7	EFSA : As general comment the acceptability of studies is not commented in this section of the DAR	RMS: Studies were considered acceptable, if they were not acceptable a specific comment would have been made. Addresssed	Addressed.

4. Environmental fate and behaviour

Route and rate of degradation in soil (B.8.1)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(1)	Vol 1. List of end points. p.54 Rate of degradation in soil.	EFSA: The kinetic employed should be specified for each single value reported in the list of end points (both for laboratory and field studies).	RMS: All Laboratory DT50/90 values were based on simple first order kinetics and non-linear regression (this is stated in the "Method of calculation" box in the Endpoints). In the field, kinetics used by the Notifier ranged from either simple first order, 1.5th order, √1st order and a 2 compartment model. The Endpoints have been amended to separate field DT50/90 values into the respective kinetic types. The RMS hopes that the amendment is sufficiently clear to fully address this point. Addressed	Addressed
4(2)	Vol. 1, list of endpoints, route of (aerobic) degradation in soil and Vol. 3, B.8.1.1.1. aerobic studies, b)	AT: Metabolites occurring in amounts > 10 % have to be identified and further assessed. The studies were conducted 20 years ago and therefore it might be useful to conduct new studies according to GLP and existing guidelines.	RMS: We agree that a more modern study conducted to agreed guidelines and in accordance with GLP would have been preferred. However our overall evaluation concluded that the route of degradation studies were adequately performed and reported, and were sufficient to meet the data requirements. It should also be considered that the information that we do have from these studies tends to indicate that the first stage in the degradation of the active substance	See open point in 4(7) and 4(11).

Route and rate of degradation in soil (B.8.1)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			was via the cleavage of the tetrazine ring leading ultimately to the formation of the relatively simple metabolite 2-chlorobenzoic acid. It therefore seems unlikely that a new study would provide further information that would significantly alter the current assessment (i.e. the identification of significant new metabolites is unlikely in the opinion of the RMS). See also response to point 4 (11) below. Addressed	
4(3)	Vol. 1, list of endpoints, route of degradation in soil – supplemental studies, soil photolysis	AT: The metabolite 2-chlorobenzonitril reaches its maximum occurrence of 5.5 % at the end of the study and therefore the metabolite should be mentioned in the list of endpoints : "metabolite 2-chlorobenzonitril: 5.5 % after 31 d"	RMS: A comment has been added to the Endpoints that metabolite 2-chlorobenzonitril reached 5.5% after 31 d. However the RMS is of the opinion that this metabolite did not occur at sufficient amounts to warrant further assessment. Photolysis in soil is not considered to be a significant route of degradation of this compound and no additional amendments are proposed by the RMS. Addressed	Point of clarification by the applicant Applicant to further address the photolysis metabolite 2-chlorobenzonitril with respect to potential GW contamination. (EFSA note: According guidance document on assessment of metabolites in GW a metabolite with a max. 5.5 % at the end of a soil degradation study deserves further GW assessment. The photolysis study was performed with natural sunlight in UK (52 °N) between August and September. The study may not be considered to represent worst case EU conditions with respect to photolysis and higher levels could be expected to occur in many EU locations).

Route and rate of degradation in soil (B.8.1)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(4)	Vol .1, list of endpoints, rate of degradation in soil	AT: The DT_{50lab} value for photolysis is missing and should be added. Since the degradation is very low, the following could be added: "DT50 (6.8-28.4°C, photolysis): not determined, limited degradation" or "DT50 (6.8-28.4°C, photolysis) > 31 d"	RMS: A comment has been included in the Endpoints to address this point. Addressed	Addressed
4(5)	Vol. 1, list of endpoints, rate of degradation in soil, field studies	AT: Only residues of the parent were determined and residues of metabolites were not investigated. This should be mentioned in the list of endpoints: "Metabolites were not investigated"	RMS: A comment has been included in the Endpoints to address this point. Addressed	Addressed
4(6)	Vol. 3, B.8.1.1.1, Route of degradation, aerobic studies, Tables B.8.1 and B.8.3.	NL: MWHC >100%, what do these values represent?	RMS: These values represent the maximum water holding capacity at zero suction, determined by the Hilgard cup technique. Some soils are capable of holding more than their weight of water (relative to dry soil weight at 105°C), hence values greater than 100% are possible. See also response to point 4(13). Addressed	See open point in 4(7).
4(7)	B.8.1.1.1. Aerobic studies. a) p. 289	EFSA: The study is considered only supported information but it seems that its results have used both for the route and the rate of clofentezine, even when half lives are extrapolated beyond the duration of the study. Some study drawbacks and deviations of guidelines are: -short duration (only 67 d).	RMS: It was considered the study of Leake and Arnold (1983a) provided supporting information only on the route of degradation, since the relatively short study duration did not allow the full route of degradation to be followed (i.e. ca. 50% of parent compound remained at the end of the study and further significant metabolites could still have been formed if the study had been continued for a longer	Open point MS to discuss the reliability and the use of the aerobic soil degradation studies (Leake and Arnold, 1983a and 1983 b) in the fate and behaviour assessment. See also 4(2), 4(6), 4(8), 4(9), 4(13) and 4(19).

Route and rate of degradation in soil (B.8.1)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
		-artificial formation of AE C522505 -application of non labelled AE C522505 together of the test substance. - very harsh extraction (soxhlet extraction 1- CH_2Cl_2 and 2- $MeOH/H_2O$) -temperature of 15 ºC -Recovery far below 90 % after 67 d If finally found not acceptable the study would need to be removed from the list of studies.	duration). Therefore on its own this study would not have been considered sufficient to address the data requirement for route of degradation in soil. However the information on the route of degradation available from this study, although limited, was still considered valid and it is referenced in the studies relied on. Since the study duration was equivalent to the approximate half life (i.e. amounts of clofentezine remaining at the study termination were 50% in the clay loam soil and 62.6% in the loamy sand) the RMS accepted that reliable DT50 values could be derived from the study. We accept that such values would be subject to a degree of uncertainty since for at least one soil they were extrapolated beyond the duration of the study. The artificial formation of AE C522505 was reported as an analytical artefact due to co-chromatography with unlabelled reference compounds. The RMS accepted the Notifier explanation of this point. The rate of degradation was corrected to standard conditions of 20°C and pF2 prior to using the endpoint from this study in the exposure assessments, therefore the fact that the study was conducted at 15°C is	

Route and rate of degradation in soil (B.8.1)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			considered to be addressed via the correction procedure. If the Soxhlet extraction technique is regarded as being "very harsh", then it is likely that greater levels of clofentezine would have been removed from the soil compared with cold solvent extracts. Therefore the study may result in a more conservative assessment of parent degradation rate. Overall the RMS concludes that these issues could be discussed further in an expert meeting to agree a consistent approach between MS. Open point for discussion	
4(8)	B.8.1.1.1. Aerobic studies. b) p. 292	EFSA: The extraction method employed in this study is very harsh (soxhlet extraction 1- CH_2Cl_2, 2- MeOH/H_2O and CH3CN/ H_2O). In principle it cannot be excluded that some of these extraction steps may have an impact on the nature of the residue (for example second and third extraction steps may eventually contribute to the hydrolysis of the product). No information on the procedural recovery of the extraction and analytical method is provided in the DAR.	RMS: As can be seen from Table B.8.5, minimal residues were removed by the third extraction step (i.e. Soxhlet extraction with acetonitrile:water for 18 hours, which removed less than 1.5% AR). Therefore the RMS concludes that this step is unlikely to have had a major impact on the nature of residues. With regards to the Soxhlet extraction with dichloromethane followed by methanol/water (i.e. Steps 1 and 2), the RMS agrees that it is not possible to conclude from the results presented for this study that these steps did not have an impact on the nature of residues. However the RMS notes that a similar	See open point in 4(7)

Route and rate of degradation in soil (B.8.1)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			extraction scheme was used in the first study (Leak and Arnold, 1983a). In that study good procedural recoveries can be deduced from Table B.8.2, where 91.1 to 97.2% AR was recovered as clofentezine at day 0 using similar extraction techniques. Overall the RMS concludes that the methods of analysis employed would be unlikely to have a significant impact on the nature of residues based on the information available. Addressed	
4(9)	B.8.1.1.1. Aerobic studies. b) p. 293	EFSA: Data at day 0/1 is either not available or shows levels of clofentezine much lower than the ones would be expected from the half lives calculated.	RMS: We agree that the results of recovered clofentezine at the first sampling point are not what would be expected (i.e. recoveries close to 100% AR would be expected). However the degradation rates have been calculated from the measured residues only (and do not take into account any dissipation between the application and the first sampling point). The RMS considered this to be the best way to handle such data in a conservative manner. The degradation rates from this study are considered to represent a reasonable worst case with regards clofentezine degradation. Overall the inclusion of this study leads to a more conservative estimate of DT50 (as can be seen in Table B.8.37). Therefore although the study design was limited it was considered more conservative to retain the endpoints in the assessment. Addressed	See open point in 4(7)

Route and rate of degradation in soil (B.8.1)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(10)	B.8.1.1.1. Aerobic studies. b) Table B.8.4 and B.8.5	EFSA: Values for Unextracted, CO2 and total recovery in Table B.8.4 and B.8.5 do not match. Please clarify.	RMS: The RMS agrees that the DAR is not clear on this point. To clarify, the results in Table B.8.4 are the mean values from replicate samples at each time interval. The values in B.8.5 are the results from a single sample analysed at each time interval. Addressed	Addressed
4(11)	Vol. 3, B.8.1, Route and rate of degradation.	Juan José González: 2-chlorobenzoic acid is a minor soil metabolite because its maximum amount, expressed as %TAR, is below 10%. Because of this compound contains one half of the original radiolabel, its molar fraction should be considered instead of %TAR. After this correction, the maximum amount of 2-chlorobenzoic acid in two studies is above 10% of the applied dose and therefore 2-chlorobenzoic acid should be considered a major soil metabolite.	RMS: The RMS disagrees with this point. The metabolite occurred at a maximum of 6.8% AR and no correction for molar fraction should be performed in our opinion. The 6.8% AR may have been formed completely from the labelled carbon on the right, completely from the labelled carbon on the left, or from a combination of both labelled carbons. We believe the only way to determine molar fractions correctly would be to use different radiolabels (e.g. ^{14}C and ^{13}C) on the two positions of the tetrazine ring. Overall we conclude that this metabolite occurred at a peak of 6.8% and therefore did not trigger the requirements for further assessment. Addressed	Open point MS experts to discuss the need for further assessment of soil metabolite 2-chlorobenzoic acid. (Guidance document in the relevance of metabolites in ground water indicates that the % triggers should be considered on a molar basis. Usually this coincides with the % TAR but not in this case. The theoretical maximum transformation of clofentezine in 2-chlorobenzoic acid is 200 % in molar basis but will result only in 100% in TAR. Therefore the observed %TAR values need to be multiplied by 2 in order to obtain the % in molar basis, this will result in exceedance of 10 % in molar basis) See also 4(2), 4(26), 4(57) and 4(58).
4(12)	Vol. 3, B.8.1, Route and rate of degradation.	Juan José González: On page 326, it is mentioned that the water/sediment study was fitted to a five compartment	RMS: We agree that the DAR should have included additional statistical data to support the goodness of fit.	Open point MS to discuss the adequacy of the input parameters used for FOCUS

Route and rate of degradation in soil (B.8.1)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
		model using inverse parameter estimation. No stadistical data are provided to support the goodness of fit. The assessment of this complex model should include a goodness of fit analysis and a determination of the accuracy of the parameters. A goodness of fit analysis is not enough because the non-linear regression of models with exchange between compartments usually provides estimated parameters with a high level of uncertainty. The fitted exchange of AE C593600 is three orders of magnitude higher than its formation or degradation. In these cases it is not possible to assess in which compartment occurs the formation or degradation of AE C593600. This fact introduces a high level of uncertainty in the calculation of surface water and sediment degradation DT50s for AE C593600.	When evaluating this kinetic fitting, the RMS considered both the statistical data in the original study report, in addition to the graphical outputs of the measured versus observed fits. For completeness statistical results (in the form of B-values) are presented below:- Lode system / Sadlers Farm Reac. Rate (d^{-1}) B-value / Reac. Rate (d^{-1}) B-value A.S. water K12 0.27 0.92 0.16 0.98 K13 0.096 0.14 K15 0.19 0.24 A.S. sed. K21 0.15 0.95 0.023 0.91 K24 <0.001 <0.001 K25 0.013 <0.001 Met. Water K34 77.9 0.78 96.4 0.70 K35 <0.001 0.11 Met. sed K43 50.2 0.97 14.9 0.90 K45 0.067 0.049 Elimination 0.93 0.96 All data 0.91 0.89 Since B-values were close to 1, the RMS considered this as evidence of	SW calculations that were derived from the water sediment study. See also 4(36), 4(42), 4(43), 4(48), 4(49), 4(50) and data requirement 4(45).

Route and rate of degradation in soil (B.8.1)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			an acceptable fit. In addition visual assessment of the graphical fits were considered acceptable by the RMS. However we do agree that such complex fitting will be subject to a high degree of uncertainty, particularly due to a high level of correlation between parameters that determine degradation and partitioning between compartments. Such a complex fitting would not now be recommended using the FOCUS degradation kinetics guidance (which was not available to the RMS at the time of DAR preparation). According to FOCUS kinetics it is our understanding that it is not currently possible to calculate individual water and sediment degradation rates for metabolites. Overall the RMS considered that the values used in the FOCUSsw modelling were acceptable. For the a.s., at Step 2 and 3, the water phase and sediment phase DT50 values were 2.4 and 53.3 d. For the a.s. the hydrolysis DT50 at pH 7 was	

Route and rate of degradation in soil (B.8.1)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			approximately 1 d. The whole system DT50 values in the water sediment system were between 2 and 7d. For metabolite AE C593600, a DT50 of 14.1 d was used for all compartments at Step 1 and 2. Although not originally calculated in the DAR, the RMS has estimated the whole system DT50 for this metabolite form the peak of formation onwards (data used from day 7 to day 42 in the clay loam system). This gave a whole system DT50 of 6.4d assuming SFO kinetics (r^2 = 0.86). Therefore again we consider the actual values used in the exposure assessments to be appropriate for the purposes of the risk assessment (even if the methods used to derive them may be subject to uncertainty). Addressed	
4(13)	B.8.1.1.1. Aerobic studies. a) b)	EFSA: How representative are soils with MWHC (%) above 100 %. FOCUS GW guidance considers a MWHC of 50 % to be representative for a clay soil.	RMS: These values represent the maximum water holding capacity at zero suction, determined by the Hilgard cup technique. Some soils are capable of holding more than their weight of water (relative to dry	See open point in 4(7)

Route and rate of degradation in soil (B.8.1)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			soil weight at 105°C), hence values greater than 100% are possible. In addition the values reported in the FOCUS groundwater guidance were derived using pedotransfer functions from the HYPRES database and are appropriate for undisturbed soil profiles. The measured values from the study reports were based on disturbed soils (i.e. 2mm sieved), which would be expected to have higher water holding capacities. In addition the RMS is aware that the exact method used to determine MWHC can have a significant influence on the result. Because of the differences in the methods used to derive the MWHC, none of the soils studied in the Leake and Arnold references were corrected for moisture content (since the water content in the study was considered higher than the default field capacity level in FOCUS – see Table B.8.37 for further information). Addressed	
4(14)	B.8.1.1.2. Anaerobic study a)	EFSA: The same three soils than for the aerobic conditions were tested under anaerobic conditions, however only the results for an unspecified soil are provided in the DAR (see table B.8.7).	RMS: The recovery of total radioactivity was available in the study report for all three soils tested under anaerobic conditions (i.e. clay, loamy sand and clay loam as shown in Table B.8.6). Characterisation of radioactivity was reported in the study report for the clay soil only (see Table	Addressed

Route and rate of degradation in soil (B.8.1)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			B.8.7). Although we agree it would have been preferable to have reported the full characterisation from all 3 soils, the study was considered by the RMS to meet the data requirements for anaerobic degradation in 1 soil. Addressed	
4(15)	B.8.1.1.2. Anaerobic study a)	EFSA: Values for Unextracted, CO_2 and total recovery in Table 8.6 and B.8.7 do not match. Please clarify.	RMS: The RMS agrees that the DAR is not clear on this point. To clarify, the results in Table B.8.6 are the mean values from replicate samples at each time interval. The values in B.8.7 are the results from a single sample analysed at each time interval. Addressed	Addressed
4(16)	B.8.1.2.1 Rate of degradation. Laboratory studies. a) p 296	EFSA: Extraction procedures employed in this study are considerably milder than the ones employed for the route studies. Results are not necessarily comparable.	RMS: The RMS disagrees that the extraction procedure in the second study (e.g. reflux with dichloromethane/ methanol; Snowdon, 1982b) would be 'considerably milder' than during the route of degradation studies (e.g. Soxhlet extraction with dichloromethane/ methanol; Leake and Arnold, 1983a,b). The additional extraction using acetonitrile/ water in the route studies of Leake and Arnold (1983a,b) did not remove significant amounts of radioactivity so this additional extraction process can be ignored. In reality we would expect very little	Addressed

Route and rate of degradation in soil (B.8.1)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			difference in the severity of the extraction procedures and consider that the studies were conducted using comparable extraction techniques. Addressed	
4(17)	B.8.1.2.1 Rate of degradation. Laboratory studies. a) p 297	EFSA: First order half life has only been calculated by the RMS for the Speyer 2.3 soil, not for the Speyer 2.2. Fitting to first order of the Speyer 2.2 soils seems to be good enough for risk assessment.	RMS: The RMS did not consider the SFO fit for the Speyer 2.2 soil to be acceptable. Although the r^2 value was reasonable (i.e. DT50 = 82.2d, r^2 =0.876), visually the fit was considered unacceptable with poor description of the time 0 concentration, and consistent patterns observed in the residuals between the observed and predicted values. Even if the RMS had accepted the SFO DT50 from this soil, it is not considered that this value would significantly affect the risk assessment. For example, if the corrected DT50 from this soil of 86.6d were included in Table B.8.37, the geometric mean would only have increased from 71.3 to 73.6d. This small increase is not expected to significantly alter the exposure assessments based on this value. Addressed	Open point MS to discuss the goodness of fitting of the Speyer 2.2 soil data to first order kinetics. If adequate also discuss the potential effect of the use of this value in the risk assessment and/or the value more appropriate for the list of end points and further assessments. See also 4(18).
4(18)	Vol.3, Annex B.8, B.8.1.2.1 Laboratory studies, a)	AT: the Rapporteur has calculated a single first order DT50 value for one soil (Speyer 2.3) only, a calculation for the second soil (Speyer 2.2) should also be provided.	RMS: See response to point 4(17) above.	See open point in 4(17)
4(19)	B.8.1.2.1 Rate of degradation.	EFSA: Rates of degradation from study Leake and Arnold 1983 a (considered	RMS: Although this study was regarded as supplementary to meeting the data	See open point in 4(7)

Route and rate of degradation in soil (B.8.1)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
	Laboratory studies. a) Table B.8.12 p 298	as supplementary information by the RMS) should not be used in the risk assessment. Furthermore, there are redundant since degradation in the same soils was investigated in the Leake and Arnold 1983 b following a better methodology.	requirement for route of degradation, it was considered as providing acceptable information on the rate of degradation. See also detailed response to point 4(7) above for further explanation of this point. Although the same 2 soils were investigated in the later study of Leake and Arnold (1983b) the RMS noted that there were some differences in the soil characterisation (e.g. see Tables B.8.1 and B.8.3 – especially particle size distributions and MWHC). The RMS considered that although these soils were likely to have been sampled from the same location, the differences in characteristics were sufficient to regard them as different soils and to include individual values when determining an overall mean DT50 value (rather than meaning values from the 'same' soils prior to determining an overall mean). Addressed	
4(20)	B.8.1.3. Field studies. Field dissipation.	EFSA: From the summary of these studies in the DAR it is not clear if cores at deeper depths than the ones reported (10 cm in most of the cases) were sampled for each trial.	RMS: In general deeper soil cores were sampled (typically 0-30cm in the studies performed by Peatman, or 0-22.5cm in the Snowdon studies). In general quantifiable residues of clofentezine were only detected in the top 0-10cm or 0-7.5cm soil layer of any study. In some trials it was not possible to differentiate the different horizons (i.e. 0-7.5, 7.5 to 15, 15-22.5cm)	Addressed

Route and rate of degradation in soil (B.8.1)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			and therefore in those studies results were reported over the original total core depth. For simplicity in the summary of these studies in the DAR we have reported the results for soil horizons where quantifiable residues were determined only (see Table B.8.13, column 9). Addressed	
4(21)	B.8.1.3. Field studies. Field dissipation. Table B.8.13	EFSA: Does Top fit 1-comp model refers to first order kinetics?	RMS: In this case the use of the Top fit model with a 1 compartment model was equivalent to a single first order fit (i.e. Top fit DT50 = 28d; SFO in MS Excel DT50 = 27.3d). Addressed	Addressed
4(22)	B.8.1.3. Field studies. Field accumulation.	EFSA: It needs to be clarified how plateau concentrations were derived. Was DT_{90} = 640.5 converted in a pseudo first order $DT_{50} \approx$ 200.2 d and then first order kinetic used for the accumulation calculation?	RMS: Plateau concentrations were derived using the best fit kinetics as reported in Table B.8.16. For the Rheinheim field trial site, the best fit to the observed data was obtained with a bi-exponential model (effectively a Double First Order in Parallel model as now described by FOCUS degradation kinetics guidance). Additional parameters for this model are as follows:- Initial conc. In fraction C1= 0.071mg/kg Initial conc. In fraction C2= 0.081mg/kg Deg rate K1 = 0.0618 day^{-1} Deg rate K2 = 0.0026 day^{-1} Dt50 = 48.8d; DT90 = 640.5 d This resulted in a long term residue concentration of 126% of the initial amount	Addressed

Route and rate of degradation in soil (B.8.1)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			following repeated annual applications. Since the calculation of PECsoil is not constrained by any particular type of kinetic, the RMS considered it appropriate to calculate the long term exposure concentrations using the best fit model. Addressed	

Adsorption,desroptionand mobility in soil (B.8.2)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(23)	Vol. 1., List of endpoints, mobility in soil, column leaching, second test	AT: in the leachate 0.49 – 2.05 % AR were detected, there fore it should be written "0.49 – 2.05 % AR" instead of "0.49 -0.99 % AR"	RMS: The RMS disagrees. Due to deflocculation of the Speyer 2.3 soil when water was used, the study was re-run with 0.01M $CaCl_2$. With $CaCl_2$, only 0.98% AR was observed in the leachate (compared with 2.05% in the presence of water as the mobile phase). See Page 315 of DAR for further details. A more modern study to recognised guidelines would have been expected to have used $CaCl_2$ as the mobile phase. The Endpoints have been updated to report the loss of 2.05%. Addressed	Addressed
4(24)	B.8.2.1 Adsorption and desorption.	EFSA: No batch studies on adsorption of clofentezine in soil have been provided based on the low water solubility.	RMS: The Notifier did not provide any further details of what attempts had been made to determine the adsorption potential using	Point of clarification by the applicant Applicant to provide scientifically and consistent valid justification for not

Adsorption,desroptionand mobility in soil (B.8.2)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
		Does the addition of small quantities of co-solvent have been attempted?	standard laboratory methods. The RMS proposes that the Notifier is asked to provide further information to address this point. Data requirement	presenting a soil adsorption desorption study with clofentozine. Data gap for a soil adsorption desorption study with clofentozine may be identified by the experts meeting if no satisfactory clarification is provided. See also point of clarification in 4(29)
4(25)	B.8.2.2.1 Column leaching. a)	EFSA: LOQ of the analytical method employed for clofentezine in the leachate is 20 μg / L. Therefore, this studies are not relevant to assess potential ground water contamination above 0.1 μg / L.	RMS: We agree these studies are not particularly helpful in assessing potential groundwater contamination above 0.1μg/l. Acceptable groundwater exposure assessments were presented in Section B.8.5.1 and indicated that according to the standard FOCUS models, concentrations would not be expected above 0.001μg/l. Addressed	Addressed
4(26)	B.8.2.2.1 Column leaching. b)	EFSA: 2-chlorobenzoic acid (AE C500233) is found in the leachate of the column leaching study. There is no reason or data to support the argument that this should be an impurity of the treatment solution and not a genuine clofentezine metabolite.	RMS: We agree the comment from the Notifier in the DAR is unsupported by sufficient evidence. The RMS considered 2-chlorobenzoic acid (AE C500233) to be a minor metabolite that did not trigger further assessment according to the levels observed in the route of degradation studies in soil. We believe that according to the Relevant Metabolites in Groundwater Guidance the appropriate triggers for requiring further assessment relate to soil degradation studies and lysimeter studies (where an annual average	Addressed See open point in 4(11).

Adsorption,desroptionand mobility in soil (B.8.2)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			concentration in excess of 0.1µg/l would trigger further assessment). We are not aware that concentrations in column leaching studies would trigger further assessment. Addressed	
4(27)	B.8.2.2.2 Aged residue column leaching a)	EFSA: Due to the low overall recovery (72 – 78 % AR) and the lack of information on the LOQ for leachate analytical method no conclusion may be derived with respect to potential ground water contamination form this study.	RMS: We agree these studies are not particularly helpful in assessing potential groundwater contamination above 0.1µg/l. Acceptable groundwater exposure assessments were presented in Section B.8.5.1 and indicated that according to the standard FOCUS models, concentrations would not be expected above 0.001µg/l. Addressed	Addressed

PEC in soil (B.8.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(28)	B.8.3 PEC soil calculation.	EFSA: DT_{50} used for PEC soil calculation is 130d. However, accumulation is calculated based on DT_{90} = 640. 5 d. These two approaches do not match each other.	RMS: DT50 values were selected to give the worst case estimates of "short term" PECsoil values (i.e. over 0-100 d based on the longest simple first order field DT50 of 131.1d) as well as the longer term values (i.e. accumulated residues over multiple years based on the worst case DT90 derived according to DFOP kinetics – see also response to 4(22) above and Table B.8.16 for field DT50/90 values).	Addressed

PEC in soil (B.8.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			If a single DT50 value had been selected for both calculations for consistency, it would have resulted in underestimation of either the short term or long term PECsoil values. Therefore the values used in the DAR are considered appropriate for the purposes of a simple worst case first tier assessment. Addressed	

Fate and behaviour in water and impact on water treatment procedures (B.8.4-B.8.5)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(29)	B.8.4.1 Hydrolysis studies. a)	EFSA: Hydrolysis studies were performed at concentrations of 14 to 26 μg/L, whereas the solubility of clofentezine is below 3 μg/L for any pH between 5 and 9. In fact the low solubility is used to justify the absence of soil adsorption /desorption studies. A clarification is needed on the methodology employed in this study and the potential contribution of precipitation to apparent degradation. Acceptability of the study is doubtful.	RMS: Further details of the preparation of stock solutions during the hydrolysis study are available in the laboratory report. In brief, 0.5 mg of a.s. was dissolved in 1ml acetone and dispersed in 99ml of buffer. Dispersions were shaken for 16 h in a water bath at 22°C, centrifuged at 12,000g for 15 seconds and filtered through a 0.45μ filter (Millipore Type HA). Further dilutions of the stock solutions in acetone were performed such that the final concentration of acetone was 1%. In general it seems reasonable to assume that the solubility's obtained during this study were genuine, and no precipitation of test substance would have been expected and	Point of clarification by the applicant Applicant to provide further information on the possible discrepancy between solubility in the various studies submitted. See also point of clarification in 4(24)

Fate and behaviour in water and impact on water treatment procedures (B.8.4-B.8.5)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			none was reported. The RMS proposes that the Notifier is asked to comment on the possible discrepancy between solubility in the various studies submitted. Results were noted to be wholly consistent with the more modern hydrolysis study that was also available in the DAR (e.g. van der Gaauw, 2001). Data requirement	
4(30)	B.8.4.1 Hydrolysis studies. b)	EFSA: concentration of test substance used in the study is not reported in the DAR.	RMS: This study was performed at a concentration of 2.1µg/l. (note the earlier study of Kelly (1985a) was performed prior to the aqueous solubility of clofentezine being determined). Addressed	Addressed
4(31)	B.8.4.1 Hydrolysis studies.	EFSA: References Kelly, 1985a; Smith and Kelly, 1985b and van der Gaauw, 2001(c) are not in the list of information, test and studies which are considered as relied upon by the RMS.	RMS: These studies are included in Volume 3, B.2.4. The List of information, tests and studies will be amended to include these studies in the Fate section. Open point	Open point RMS to amend the list of information, test and studies which are relied upon to include the missing references (Kelly, 1985a; Smith and Kelly, 1985b and van der Gaauw, 2001(c))
4(32)	B.8.4.2 Aqueous photolysis p.322 a)	EFSA: Acceptability of this photolysis study is highly questionable due to the lack of control on the experimental conditions and the high concentration of test substance employed (250 µg/L;	RMS: While we agree that the study design could be criticised for not being performed under controlled light and temperature conditions, the RMS considers that this study performed under natural conditions (i.e. outdoors in the UK) would be representative of the	Open point MS to discuss in an experts meeting the acceptability of the aqueous photolysis study and the need of further information. See also 4(33).

Fate and behaviour in water and impact on water treatment procedures (B.8.4-B.8.5)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
		solubility < 3 μg/L).	behaviour of clofentezine when exposed to light in the upper most surface water layers of a natural surface water body. Although the concentration tested was high, the significantly slower rate of degradation of clofentezine in the dark control tends to indicate that loss in the light exposed samples was due to photolysis and not simply loss via precipitation on un-dissolved residues. Overall due to the rapid dissipation of residues of the active substance from the water phase of the dark water:sediment study, the RMS concluded that photolysis was unlikely to be a significant route of dissipation in most natural surface waters. (see also response to 5(16) below). Therefore we do not think that additional useful information would be obtained by requesting a repeat photolysis study under controlled conditions. Addressed	
4(33)	B.8.4.2 Aqueous photolysis p.323 Quantum yield a)	EFSA: It is doubtful that the quality of the photolysis study allows determining any reliable quantum yield.	RMS: The RMS agrees that the estimated quantum yield would be subject to a degree of uncertainty since the levels of solar irradiance were not measured during the study (and the estimate hence relies on published data for a similar latitude). Overall due to the rapid dissipation of residues of the active substance from the	See open point in 4(32)

Fate and behaviour in water and impact on water treatment procedures (B.8.4-B.8.5)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			water phase of the dark water:sediment study, the RMS concluded that photolysis was unlikely to be a significant route of dissipation in most natural surface waters. (see also response to 5(16) below). Therefore we do not think that additional useful information would be obtained by requesting a repeat study to determine the quantum yield experimentally. Addressed	
4(34)	B.8.4.2 Aqueous photolysis a) / Quantum yield a)	EFSA: Kelly, 1985 b; Buerkle, 1999a and Maurer, 2000 are not in the list of information, test and studies which are considered as relied upon by the RMS. However, it is not clear from the text that these three studies are considered not reliable by the RMS.	RMS: RMS: These studies are included in Volume 3, B.2.4. The List of information, tests and studies will be amended to include these studies in the Fate section. Open point	Open point RMS to amend the list of information, test and studies which are relied upon to include the missing references (Kelly, 1985 b; Buerkle, 1999a and Maurer, 2000)
4(35)	Vol. 3 Annex B.8, B.8.4.4 Water/Sediment studies	AT: A low material balance of 78.2 – 98.5 % was reached for labelled material, was there any explanation provided?	RMS: No additional explanation was available in the study report and none was provided by the Notifier in their MII summary. The RMS proposes that the Notifier is asked to comment on this issue further. Data requirement	Point of clarification by the applicant Applicant to provide further clarification on the low material balance reached in the water sediment studies. See open point in 4(37)
4(36)	Vol. 3 Annex B.8, B.8.4.4 Water/Sediment	AT: DT50-values for clofentezine in sediment was reported for one sediment only and DT50 values for the metabolite AE C593600 in surface water was reported for one system	RMS: See also response to point 4(12) above for further details of the kinetic fitting. The kinetic fitting did not result in any	See open point in 4(12)

Fate and behaviour in water and impact on water treatment procedures (B.8.4-B.8.5)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
	studies	only. DT50-values should be provided for both systems or an explanation why the calculation was done for one system only should be provided. And this should be corrected in the list of endpoints: "n=1" instead of "n=2".	significant degradation of the a.s. being predicted in the sediment phase of the Sadlers farm system (i.e k24 +k25 = <0.001). Similarly no significant degradation of the metabolite was predicted in the water phase of the Lode system (i.e. k35 = <0.001). The Endpoints have been updated. As stated in point 4(12) above the RMS considers the values used in the FOCUSsw modelling are appropriate. Addressed	
4(37)	B.8.4.4. Water/sediment studies. p. 324. a)	EFSA: A higher ratio of sediment than recommended by SETA guidelines is used in this study. Due to the high adsorption to sediment by this compound this may affect the result with respect to the dissipation from the water phase.	RMS: The RMS commented on this aspect in the DAR. Overall we concluded that due to the low water solubility and strong sorption expected for clofentezine the relatively high sediment to water ratio is not considered by the Rapporteur to affect the results of the study. Addressed	Open point MS to discuss the acceptability of the water sediment study for the risk assessment. For the discussion MS also should take into account responses to data requirements in 4(29), 4(35) 4(40) and 4(41). See also 4(38) and 4(39).
4(38)	B.8.4.4. Water/sediment studies. p. 324. a)	EFSA: In the two systems investigated the water pH is > 8. Due to the fact the hydrolysis is pH dependent a new water / sediment study at neutral or slightly acidic pH would be necessary.	RMS: The RMS commented on this aspect in the DAR. The RMS concluded that "Member States may wish to consider the effect of acidic surface waters on the behaviour of clofentezine, if the pertinent crops and environmental conditions are likely to co-exist (page 328)."	See open point in 4(37)

Fate and behaviour in water and impact on water treatment procedures (B.8.4-B.8.5)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			Under acidic conditions the a.s. can be presumed to be more stable to hydrolysis compared to alkali conditions. However a principle route of dissipation in the water:sediment study appeared to be partitioning to sediment. Even if a study under acidic conditions were performed, it would be expected that clofentezine would partition to sediment (and that lower levels of metabolites in the aqueous phase would form due to reduced hydrolysis). Therefore the RMS considered the study submitted to be acceptable. However MS may wish to consider this aspect further as proposed in the DAR. Addressed	
4(39)	B.8.4.4. Water/sediment studies. p. 324. a)	EFSA: If the microcosm vessels were fully filled of water, the volume of water would be: 0.235 L. Therefore, the minimum concentration applied is of 847 μg/L whereas the solubility at this pH is < 2 μg/L.	RMS: The application rate was selected to represent a field application rate of 1kg a.s./ha assuming 100% overspray. It is possible that testing the a.s. behaviour above the solubility limit may have resulted in loss from the aqueous phase via precipitation of un-dissolved residues. However since the whole system half-lives for clofentezine were very short (i.e. between 2 and 7d) we do not consider that additional useful information would be obtained by repeating the study at lower concentrations. See also comment 4(40) below.	See point of clarification in 4(29) See open point in 4(37)

Fate and behaviour in water and impact on water treatment procedures (B.8.4-B.8.5)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			Addressed	
4(40)	B.8.4.4. Water/sediment studies. p. 324. a)	EFSA: A WP formulation is used in this study instead of the technical active substance. Applicability of this study to assess the representative SC formulation may need to consider the effect of the different co-formulants on the solubility of the compound.	RMS: The RMS proposes that the Notifier be asked to prepare a case for the acceptability of this study. Data requirement	Point of clarification by the applicant. Further information on the appropriateness of the formulation used in the water sediment study (WP) to represent the intended SC formulation. See also open point in 4(37)
4(41)	B.8.4.4. Water/sediment studies. p. 324. a)	EFSA: Three traps for volatiles are used: ethanodiol. ethanolamine and sulphuric acid. However, the separated results for each trap are not presented in the results tables in the DAR. It should be clarified if all volatiles were assumed to be CO_2 and if any test to check the identity of volatiles was performed.	RMS: No separate results were reported in the laboratory report for each trap. Results were presented as $^{14}CO_2$ however it was not clarified how the presence of CO2 was determined. The RMS proposes that the Notifier is asked to clarify how the presence of CO_2 was determined. Data requirement	Point of clarification by the applicant. Applicant to provide further information on how CO_2 was determined in the water sediment study and separated results for the different volatiles traps if they are available in the raw data of the study. See also open point in 4(37)
4(42)	B.8.4.4. Water/sediment studies. p. 326. a) Jene (2001)	EFSA: The number of data points (6 per compound and compartment) is clearly insufficient to fit a multi compartmental model as the one pictured in Fig B.8.2. SETAC and OCDE guidance require a minimum of six data points but FOCUS kinetics recommends a higher number of samples for hydrophobic substances and to derive kinetic	RMS: The DAR was prepared prior to the FOCUS kinetics report being available. The DAR was prepared in accordance with the FOCUSsw guidance with regards to endpoint selection. See also response to point 4(12) above. Overall the RMS considered that the values	See open point in 4(12).

Fate and behaviour in water and impact on water treatment procedures (B.8.4-B.8.5)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
		information on the metabolites.	selected for use in the FOCUSsw modelling were appropriate. Addressed	
4(43)	B.8.4.4. Water/sediment studies. p. 326. a) Jene (2001) B.8.5.2 PEC SW	EFSA: Whole system DT50 needs to be provided to finalise the surface water risk assessment. Following FOCUS Kinetics recommendations, for FOCUS SW a half life of 1000 d should be used for the sediment and the whole system half life for the water phase when it is not possible to obtain reliable degradation parameters for the separated phases.	RMS: The whole system DT50 for clofentezine was 2 to 7 d in the two systems (page 325). These values were taken from the original study report and were determined graphically (consistent with FOCUSsw guidance on parameter estimation). The DAR was prepared prior to the FOCUS kinetics report being available. The DAR was prepared in accordance with the FOCUSsw guidance with regards to endpoint selection. See also response to point 4(12) above.Overall the RMS considered that the values selected for use in the FOCUSsw modelling were appropriate. The RMS proposes that the Notifier should be asked to provide further comment and additional modelling as required. Data requirement	See open point in 4(12) and point of clarification in 4(45).
4(44)	B.8.5.1 PEC GW	EFSA: Only one FOCUS model has been used to assess the potential ground water contamination by clofentezine and its metabolites. At least results of two models are needed to complete the risk assessment.	RMS: Whilst we accept that performing groundwater exposure assessments with both PELMO and PEARL is useful due to potential differences in the model outputs, in this case where both the parent and metabolite are predicted to occur at <0.001µg/l (indicating a low overall concern	Addressed

Fate and behaviour in water and impact on water treatment procedures (B.8.4-B.8.5)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
		(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.)	for groundwater contamination) the RMS does not consider this to be necessary. In the opinion of the RMS it would not be expected that differences in the models would result in concentrations greater than 0.1µg/l if a different model simulation had been performed. Addressed	
4(45)	B.8.5.2 PEC SW	EFSA: It is not clear where the water / sediment whole system DT50 used for FOCUS step 1 calculations (7 d) comes from. Whole system DT_{50} is not calculated in the water/sediment system (EFSA calculated whole system DT50 of 13.4 and 7.9 d).	RMS: The whole system DT50 for clofentezine was reported to be 2 to 7 d in the two systems (page 325). These values were taken from the original study report and were determined graphically (consistent with FOCUSsw guidance on parameter estimation). Overall they seem reasonable for each whole system: Sandy clay loam system, a.s. decreases from 82.7% AR at day 0 to 40% AR after 7 d. Clay loam system a.s. decreases from 93.8% AR at day 0 to 50.3% AR after 2 d. The RMS is unable to replicate the DT50 values proposed by EFSA in column 2 (repeat calculations performed by the RMS assuming SFO kinetics and non-linear regression gave whole system DT50 values of 12.7 and 4.2 d with r^2 greater than 0.75 but poor visual fit, with an overall geomean of 7.3 d).	Point of clarification by the applicant Applicant to provide further justification of the whole system DT50 calculations including goodness of fitting. (NOTE: difference between PSD and EFSA estimates may come from the consideration or not of the residue attached to the glass) See also open point in 4(12) and comments 4(43), 4(48), 4(49) and 4(50)

Fate and behaviour in water and impact on water treatment procedures (B.8.4-B.8.5)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			Since refinement of the FOCUS modelling was required up to Step 4, the values at Step 1 are not considered significant in the overall aquatic risk assessment and small increases in the whole system DT50 at Step 1 would not be expected to significantly alter the decision making based on Step 1 outputs. Addressed	
4(46)	B.8.5.2 PEC SW	EFSA: Since no standard approach is still adopted at EU level, Step 4 run off reductions by vegetative buffer zones need to be specifically justified in the DAR. The papers quoted need to be summarized and RMS should assess if the proposed reduction on runoff mass loadings are justified for the representative uses.	RMS: The papers quoted in the DAR are referenced and relied on by the FOCUS Working Group on Landscape and Mitigation Factors and the RMS used the latest version of this report available at the time of DAR preparation to advise on the appropriateness of the efficiencies of buffer zones to reduce runoff. We are in complete agreement that a standard approach be adopted at EU level to handle the mitigation of runoff within FOCUSsw. We are aware that currently certain Member States may be able to authorise products Nationally on the basis of risk mitigation of runoff through buffer zones. This is not currently possible in the UK. However for the purposes of Annex I listing the UK considers that such mitigation options should be considered if required to	Point of clarification by the applicant. Risk assessment based on Step 3 calculations and Step 4 calculations with spray drift mitigation through spray drift buffer zones only should be provided for the EU risk assessment. (Justification: effect of vegetative buffer zones on runoff mitigation is not as straightforward as originally proposed by FOCUS landscape according to the recent EFSA panel opinion). However, if justified, calculation taking into account run off mitigation may be reported as additional information for MS use.

Fate and behaviour in water and impact on water treatment procedures (B.8.4-B.8.5)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			achieve an acceptable aquatic risk assessment, and that individual MS must consider the appropriateness of such measures during their own National authorisations at Re-registration. As this is not only a specific issue for clofentezine but for many other List 3 compounds, the RMS proposes that this issue be discussed at the next available expert meeting. Open point for discussion but not specific to clofentezine.	

PEC in surface water and in ground water (B.8.6)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(47)	Vol.1 List of end points; PECsw	NL: According to EPCO manual D4 those PEC values should be reported on which the ecotox risk assessment is based. Therefore for early pome/stone fruit also Step 3 calculations must be reported here.	RMS: FOCUS Step 3 estimates were originally excluded since the risk assessment was based on Steps 1, 2 or 4. The Endpoints have been updated to include the Step 3 simulation results. Addressed	Addressed
4(48)	Vol. 1., List of endpoints, route and rate of degradation in	AT: No method of calculation of DT50 for the whole system (water/sediment) was provided. The DT50 values for clofentezine and the metabolite AE C593600 in surface water and	RMS: See response to point 4(45) and 4(12) above.	See point of clarification in 4(45) and open point in 4(12).

PEC in surface water and in ground water (B.8.6)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
	water, degradation in water/sediment and FOCUSsw PEC	sediment were calculated with TopFit 2.0, but no calculation for the whole system was presented (e.g. r^2 value is missing). There is just the remark „first order“ in the list of endpoints.		
4(49)	Vol. 1., List of endpoints, route and rate of degradation in water, degradation in water/sediment and FOCUSsw PEC Parent	AT: It should be clarified if the DT50 water and DT50 sediment values were derived from pseudo first order (degradation in water/sediment) or single first order kinetics (FOCUSsw PEC).	RMS: See response to point 4(45) and 4(12) above.	See point of clarification in 4(45) and open point in 4(12).
4(50)	Vol. 1., List of endpoints, route and rate of degradation in water, degradation in water/sediment and FOCUSsw PEC Metabolite AE C593600	AT: It should be clarified if the DT50 water and DT50 sediment values were derived from pseudo first order (degradation in water/sediment) or single first order kinetics (FOCUSsw PEC).	RMS: See response to point 4(45) and 4(12) above.	See data requirement in 4(45) and open point in 4(12).
4(51)	Vol. 3, Annex B.8, B.8.5.1 PECgw, Table B8.38	AT: A molecular weight of 240.7 is stated. Since the molecular weight of the metabolite is 293.2, it has to be clarified, if the wrong value for the PECgw calculation has been used. If the wrong value has been used for the calculation the PECgw has to be recalculated.	RMS: The modelling submitted by the Notifier did use the incorrect molecular weight for the metabolite. The RMS has repeated the modelling using the correct molecular weight and concentrations remain <0.001µg/l. The Endpoints have been updated to report the molecular weights used. Addressed	Addressed

PEC in surface water and in ground water (B.8.6)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(52)	Vol.3, B.8.5.2 PEC surface water, Table B.8.44, Note to the table	NL: It is stated here that the maximum peak clofentezine PECsw occurred on day 1. This is however on day 0.	RMS: The RMS agrees with the comment, peak PECsw occurred on day 0. Since this is a relatively minor typographical error we do not propose any change to the DAR. Addressed	Addressed RMS to consider in an amended DAR or corrigendum.
4(53)	Vol.3, B.8.5.2 PEC surface water, Tables B.8.46, B.8.47 and B.8.48, Note to the tables	NL: The notes to the tables can be removed.	RMS: The RMS considers the notes to the tables to be useful, since where maximum concentrations occur on day of application it can be deduced that spray drift was the most significant route of entry to surface water (rather than runoff/drainage which would cause peak concentrations to occur on days subsequent to application). Addressed	Addressed
4(54)	Vol.3, B.8.5.2 PEC surface water, Tables B.8.46 and B.8.47	NL: It is stated that the peak concentrations are highlighted, but almost all values for TWA-PEC are highlighted.	RMS: For simplicity the RMS reported full results from 3 scenarios only (D3/ditch; D5/pond; R3/stream) in order to encompass the full range of worst case values. The highest concentrations at each time point are highlighted. The D3/ditch scenario resulted in the highest actual concentration on day 1 and the highest TWA concentrations at all time points, and therefore all these values are highlighted in Table B.8.46. The RMS hoped this form of presentation would make it easier for MS to determine which values should be used in the aquatic risk assessments. Addressed	Addressed

Fate and behaviour in air and PEC in air (B.8.7-8.8)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(55)	B.8.6 Fate and behaviour in air.	EFSA: van der Gaauw, 1990 seems to be listed as van der Gaauw, A, 2001 b in the list of information, test and studies which are considered as relied upon by the RMS; please clarify.	RMS: The reference in the DAR to van der Gaauw, 1990 is incorrect. The correct reference should be to van der Gaauw, A, 2001 b. The correct study is listed in the referenced relied on list (B.8.9). Addressed	Addressed RMS to consider in an amended DAR or corrigendum.
4(56)	The whole DAR: Vapour pressure, water solubility, Henrys laws constant, photochemical oxidative degradation in air, PECair	SE: We question the judgement of how clofentezine behave in the air. A similar judgement was made for e.g. fenpropimorph. The Henrys laws constant of fenpropimorph is 0.27 Pa m^3/mol compared to 0.17 Pa m^3/mol for clofentezine and these are very similar. Fenpropimorph is now measured within the Swedish monitoring programme as one of the pesticides having the highest diffuse (background sampling station) deposition flux from air (5.2 µg/m^2, during 4 month in S. Sweden year 2004; Törnquist et al., Ekohydrologi 87). It seems as this type of judgement does not describe the field situation very accurate. One reason for this may be that the relatively low vapour pressure cause binding to aerosol particles in the atmosphere, which means a lower proportion in the gas phase and a longer half-life. The Atkinsons-rate estimates apply only to the fraction in the gas phase. Also note that the vapour pressure reported for clofentezine (1,4 µPa) is for the solid state,	RMS: See also section B.2.1, no.1(26) above. The RMS agrees that this issue could be discussed further in an expert meeting. Open point for discussion but not specific to clofentezine.	Open point MS experts to discuss the need of further assessment with respect to the air compartment. If considered necessary, the general approach to follow for clofentezine and related substances may need to be discussed as well.

Fate and behaviour in air and PEC in air (B.8.7-8.8)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
		while it is for the liquid state of fenpropimorf (7,0 mPa). In the environment, it is the liquid state which describes the fate. The Henrys law constant is independent of physical state as long as both vapour pressure and water solubility relate to the same physical state (P_{liquid}/S_{liquid} or P_{solid}/S_{solid}). Thus the Henrys laws constants can be compared, but the vapour pressure and the water solubility can not, unless they are recalculated to the liquid state. Our comment not only apply to the DAR for clofentezine and fenpropimorph, but to many active substances, and we recommend it be discussed on an expert meeting concerning fate assessment.		

Definition of the residues (B.8.9)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(57)	Vol. 1, List of endpoints, definition of the Residues	AT: The metabolites should also be mentioned.	RMS: The RMS agrees and the Endpoints have been updated. Addressed	See open point in 4(11)
4(58)	Vol. 3, B.7, Residue definition (this a Fate comment)	Juan José González: Following previous comment 4(11), the 2-chlorobenzoic acid should be considered in soil residue definition	RMS: See response to point 4(11) above. The RMS does not believe that this metabolite would trigger further assessment. Addressed	See open point in 4(11)

Definition of the residues (B.8.9)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(59)	Comment was forwarded from ecotox to the fate section see open point 5(16)	EFSA: No risk assessment was conducted for the metabolite 2-chlorobenzonitrile (AE F023666). The metabolite is formed via photolysis up to 74.6% of AR. The RMS argues that a risk assessment is not necessary because the metabolite was not found in the water/sediment study. However, the water/sediment study was conducted under dark conditions. Solar irradiation could promote the formation of 2-chlorobenzonitrile under natural conditions. Therefore a risk assessment is considered necessary by EFSA.	RMS: The RMS agrees that under natural surface water conditions, clofentezine may be subject to photolytic breakdown in the upper surface water layers. In addition loss from the aqueous phase will occur via a combination of partitioning to sediment and hydrolysis to AEC593600. The RMS considered that the photolysis study design was likely to have maximised the potential for photolytic breakdown (e.g. the study was performed in glass flasks in the presence of solvent to maintain the active substance in solution and in an acidic buffer to minimise hydrolysis). In the dark water:sediment study, clofentezine was rapidly lost from the water phase (water phase DT50 <2d; less than 5% AR remaining as clofentezine in the water phase by day 7). Overall the RMS concluded that under natural surface water conditions, for a substance such as clofentezine with a very low aqueous solubility, the main dissipation routes from the water phase would be likely to be partitioning to sediment. The RMS considered that under such conditions clofentezine would not be available for photolysis in the upper water layers for significant periods, and therefore the major photolysis metabolite 2-chlorobenzonitrile would not form in major amounts requiring further assessment. Addressed	Open point MSs to discuss in an expert meeting whether the major photolytic metabolite is formed under natural conditions and in which amounts. The outcome of the discussion is required for the discussion in ecotox see open point 5(16)

5. Ecotoxicology

Birds and mammals (B.9.1 and B.9.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(1)	Vol. 1, Appendix 3, List of endpoints	AT: Toxicity/exposure ratios for terrestrial vertebrates: Small herbivorous mammals are missing on the table. .	RMS: Endpoints have been amended. Addressed	Addressed
5(2)	Vol. 1, Level 4, Data requirements	EFSA: Data requirements were identified in Vol.3. to support the suggested refinement steps for the long-term risk assessment for insectivorous birds e.g. PD, PT, focal species. These data requirements should be listed in Vol. 1, Level 4	RMS: These requirements are encompassed as are required for further data to address the long term risk to birds, which is in Volume 1, Level 3. Addressed . Please note that the Notifier has undertaken further work – see point 5(5). Addressed	Data gap Applicant to submit -Information to support the PD values for great tit in pome/stone fruit. -justification regarding the focal species in vineyards, PD refinement for cirl bunting and crested lark -justification regarding the focal species in strawberries, PD and PT refinement. -the risk to insectivorous birds in ornamentals needs to be addressed

Birds and mammals (B.9.1 and B.9.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(3)	Vol. 3, B.9.1.4, Risk assessment for birds	EFSA: No risk assessment was conducted for the uptake of contaminated drinking water.	RMS: The following is provided for illustrative purposes only: Assuming maximum application rate of 200 g/ha, an application volume of 200 L/ha, an acute oral LD50 of >3000 mg a.s./kg and a NOEC of 7.62 mg a.s./kg bw/day, a PECsw of 0.047 mg/l (FOCUS Step 1); the resulting exposure estimates are 53.9 mg a.s./kg bw for a 0.01 kg insectivorous bird. The resulting TERa and TERlt are >55.6 and 601 respectively. These indicate a low acute and long-term risk to birds. Addressed	Open point RMS to include in an addendum the risk assessment for birds from uptake of contaminated drinking water.
5(4)	Vol. 3, point B.9.1.4, Risk assessment for birds	DE: Although most of the refinement steps presented by the notifier seem to be appropriate, the data or justification behind some of the refinement steps seems to be relatively scarce. Therefore, a need for further information (see requirements of the RMS summarised in Table B.9.1.24) can generally be supported.	RMS: Further data have been submitted by the Notifier, see 5(5).	See data gap 5(2) and comment 5(5)
5(5)	P32, Vol.1 2.6.1: Effects on terrestrial vertebrates P65, Vol. 1,	NOT: Regarding the long-term risk to birds, an avian ecology study in strawberry fields in Germany will be run in 2006. The protocol has been	RMS: Data have been submitted by the Notifier and will be evaluated in an addendum. Open point	See data gaps 5(2)

Birds and mammals (B.9.1 and B.9.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
	LOEP:Effects on terrestrial vertebrates P84, Vol. 1, 3.1: Background to proposed decision P86, Vol.1, 3.3: Rationale for the postponement… P88, Vol. 1, 4.1.9: Ecotoxicology P377-380, Vol. 3, B9.1.4: Risk assessment, recommendation	discussed with the RMS. The study will include radio-tracking of focal bird species, and analysis of dietary composition. This study will enable identification of appropriate focal species, and quantitative refinements to both PT and PD. Due to the seasonal nature of this type of study the earliest a report can be submitted is by 31 August 2006.		
5(6)	P362-363, Vol.3, B9.1.4: Risk assessment, exposure scenarios and estimate theoretical exposures….	NOT: An independent expert recently undertook a review of modern insect residues studies for ECPA. It is proposed that this review should be taken into account in the risk assessment for birds, particularly in the first tier long-term risk assessment. The report is available for immediate submission.	RMS: The RMS is aware of this work and has been involved in discussions with ECPA regarding this generic dataset. The RMS is currently funding work on this topic with the UK Central Science Laboratory (see http://www.defra.gov.uk/science/project_data/DocumentLibrary/PS2311/PS2311_2674_FRP.doc and http://www2.defra.gov.uk/research/project_data/More.asp?I=PS2323&SCOPE=0&M=PSA&V=NR%3A	Addressed

Birds and mammals (B.9.1 and B.9.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			080) and it is hoped, if possible and appropriate, to combine both the PSD and EFSA datasets. It is also hoped that this combined dataset could, subject to appropriate peer review by EFSA and MS, replace the current default figures. Until this work is finalised, the appropriateness of this dataset should be assessed on a case-by-case basis; however it is the view of the RMS that, whilst this dataset is of interest, it is not yet appropriate to use it for risk assessment purposes. Addressed	
5(7)	Vol. 3, table B.9.1.20, p 372	NL: NMSs should be SMSs	RMS: Point noted. Addressed	Addressed

Birds and mammals (B.9.1 and B.9.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(8)	Vol. 3, B.9.2, Risk assessment for mammals	EFSA: No risk assessment was conducted for the uptake of contaminated drinking water.	RMS: Assuming maximum application rate of 200 g/ha, an application volume of 200 L/ha, an acute oral LD50 of >5200 mg a.s./kg and a NOEC of 40 mg a.s./kg bw/day, a PECsw of 0.047 mg/l (FOCUS Step 1); the resulting exposure estimates are 53.9 mg a.s./kg bw for a 0.01 kg insectivorous mammal. The resulting TERa and TERlt are >165.7 and 5425 respectively. These indicate a low acute and long-term risk to mammals. Addressed	Open point RMS to include in an addendum the risk assessment for mammals from uptake of contaminated drinking water.
5(9)	Vol. 3, point B.9.3, Effects on other terrestrial vertebrates	DE: A long-term NOAEL for mammals of 40 mg as/kg bw/d (rat, multi-generation study) is used for risk assessment. However, this endpoint is not present in the list of endpoints (Volume 1, Appendix 3).	RMS: Mammalian toxicology endpoint sheet has been updated. Addressed	Addressed

Aquatic organisms (B. 9.2)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(10)	Vol. 1, Level 2, List of Endpoints	EFSA: TERs for aquatic organisms. It would be beneficial to include all uses where the trigger is not met for the worst case use. From the provided list it is not possible to see if the long-term TER is above 10 for fish for the use in pome fruit and vine and which buffer zones are needed.	RMS: The RMS notes this point and highlights that the risk assessment and associated endpoint table will be updated if appropriate in an addendum (see 5(19) below) Open point	Open point RMS to include the aquatic TERs for all uses in the LoEP.
5(11)	Vol. 3, B. 9.2.1, Acute toxicity to aquatic organisms	EFSA: More information on the studies with aquatic organisms should be given: e.g: batch no., tested concentrations, analytical methods, number of replicates, water parameters (hardness, pH, oxygen saturation, temperature) photoperiod, loading rate, feeding, observation of sublethal effects, statistical methods.	RMS: It should be noted that all studies were carried out to standard protocols and hence issues such as temperature, pH etc were all met. It should however further be noted that few of these studies were considered appropriate for risk assessment purposes – see Table B.9.2.16 (a), (b) and (c). Addressed	Open point RMS to include in an addendum all details on the studies with aquatic organisms which are required for a transparent and comprehensible evaluation of the endpoints derived from the studies. If the RMS does not wish to report water parameters, photoperiod, fish size/load it is agreed that it would be enough to state that this was assessed by the RMS as being in accordance with the respective guideline. However key information such as tested concentrations, observed mortality/effects at each concentration, observation of sublethal effects, statistical methods, confidence intervals, analytical methods, batch no., should always be reported in the study summaries for reasons of transparency and to facilitate the peer-review of the suggested endpoints. See also comment 5(17)

Aquatic organisms (B. 9.2)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(12)	Vol.3, B.9.2.1, plant protection products, acute toxicity to fish, b; p:384	NL: Measured concentrations were 64% of nominal. Therefore results should be in measured concentrations.	RMS: Agree – Endpoints have been amended accordingly. This point does not affect the risk assessment. Addressed	Addressed The endpoint was changed in the LoEP and should also be included in a corrigendum to the DAR.
5(13)	Vol.3, B.9.2.1, plant protection products, acute toxicity to algae, p:385-386	NL: Since the initial measured concentrations ranged between 46 and 87.5% of the nominal; the NOEC of 34 mg a.s./L is preferred.	RMS: Agree – Endpoints have been amended accordingly. This point does not affect the risk assessment. Addressed	Addressed The endpoint was changed in the LoEP and should also be included in a corrigendum to the DAR.
5(14)	Vol.3, B.9.2.2, chronic toxicity, fish, a, p:388, concluding sentence	NL: NOEC is 0.007 mg a.s./L in stead of 0.07 mg a.s./L	RMS: Point noted – typographical error does not affect the risk assessment. Addressed	Addressed

Aquatic organisms (B. 9.2)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(15)	Vol. 3, B. 9.2.3, Aquatic risk assessment	EFSA: The relevance of the NOEC of 0.025 mg a.s./L for the risk assessment for daphnids is questionable (only one concentration tested) since a higher NOEC of 0.25 mg a.s./L from a test with the formulation is available. However, the observed higher endpoint could also be due to the presence of sediment. It may be helpful for the decision on the appropriate endpoint to report the tested concentrations from the second 21d chronic study with the formulation.	RMS: The key chronic *Daphnia* study is considered to be the one conducted by Barber and Lattimore (1992) – this study was conducted under flow-through conditions and concentrations of clofentezine were maintained. The fact that only one concentration is not considered to be a draw back – it highlights that at ten times the water solubility there are no long-term/chronic effects on *Daphnia*. Further supporting evidence is supplied by the study conducted in the presence of sediment (Mattock 1999). As regards the Barber and Barrett (1990) study – this is not considered to be as reliable as the other two studies as concentrations were not maintained. When the data from the first two studies are considered, it is clear that (i) the chronic risk to fish is potentially driving the risk assessment as inverts are less sensitive and (ii) clofentezine is of low chronic toxicity to *Daphnia*. Addressed	Open point RMS to report in an addendum the observations/endpoint from the 21 d chronic daphnia study with the formulation (Barber and Barrett, 1990) and to clarify why the study was considered not acceptable. MSs to discuss in an expert meeting the setting of the NOEC for daphnids. (This may be necessary if the chronic endpoint for fish which is currently triggering the risk assessment is changed to a higher value - see open point 5(19)
5(16)	Vol. 3, B. 9.2.3, Aquatic risk assessment	EFSA: No risk assessment was conducted for the metabolite 2-chlorobenzonitrile (AE F023666). The metabolite is formed via photolysis up to 74.6% of AR. The RMS argues that a risk assessment is not necessary because the metabolite was not found in the water/sediment study. However, the water/sediment study was	RMS: The RMS agrees that under natural surface water conditions, clofentezine may be subject to photolytic breakdown in the upper surface water layers. In addition loss from the aqueous phase will occur via a combination of partitioning to sediment and hydrolysis to AEC593600. The RMS considered that the photolysis study design was likely to have maximised the potential for photolytic	Open point MSs to discuss in an expert meeting the necessity of an aquatic risk assessment taking into consideration the outcome of the fate meeting. Comment was also forwarded to the fate section see point 4(59).

Aquatic organisms (B. 9.2)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
		conducted under dark conditions. Solar irradiation could promote the formation of 2-chlorobenzonitrile under natural conditions. Therefore a risk assessment is considered necessary by EFSA.	breakdown (e.g. the study was performed in glass flasks in the presence of solvent to maintain the active substance in solution and in an acidic buffer to minimise hydrolysis). In the dark water:sediment study, clofentezine was rapidly lost from the water phase (water phase DT50 <2d; less than 5% AR remaining as clofentezine in the water phase by day 7). Overall the RMS concluded that under natural surface water conditions, for a substance such as clofentezine with a very low aqueous solubility, the main dissipation routes from the water phase would be likely to be partitioning to sediment. The RMS considered that under such conditions clofentezine would not be available for photolysis in the upper water layers for significant periods, and therefore the major photolysis metabolite 2-chlorobenzonitrile would not form in major amounts requiring further assessment. Addressed	

Aquatic organisms (B. 9.2)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(17)	Vol. 3, point B.9.2.3, Risk assessment for aquatic organisms	DE: The risk assessment is acceptable, especially taking into account that the use of PEC_{twa} values would result in clearly lower TER values. Since the RMS provided no summaries on the non-GLP acute studies with the as, it can, however, not be decided whether the exclusion of the results of these studies from the risk assessment due to solubility problems is appropriate.	RMS: The use of twa for risk assessment is contentious and only appropriate if a time to effect assessment has been carried out. As such an assessment has not been carried out, the RMS did not use a twa approach. Several active substance studies were submitted, many of these were conducted at concentrations significantly above the water solubility level (see Table B.9.2.1 and associated footnote). Due to issues of solubility, it was decided that studies on the formulation were more appropriate for risk assessment purposes Addressed	See open point 5(11)
5(18)	Vol. 3, point B.9.2.3, Risk assessment for aquatic organisms	DE: There is an inconsistency in the information given on the applied test substance between the list of endpoints and Vol. 3. For the endpoints, Rainbow trout 21-d and *Daphnia magna* 21-d (modified study) as test substance "active substance" is listed in the list of endpoints whereat in Vol. 3 it is described that this studies were executed with preparations.	RMS: Point noted – Endpoints have been amended. Addressed	Addressed
5(19)	P32 Vol. 1, 2.6.2: Effects on aquatic species P67, Vol. 1, LOEP: TER's for the most sensitive aquatic organisms	NOT: The chronic risk assessment for fish determines the overall outcome of the aquatic assessment. The proposed buffer zones are triggered by the limit of solubility, not by effects on fish. A new fish ELS study with the *formulation,* which enabled testing at	RMS: The data have been submitted and will be evaluated if appropriate and presented in an addendum. Open point	Open point RMS to evaluate in an addendum the new fish ELS study with the formulation.

Aquatic organisms (B. 9.2)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
	P399-400, Vol. 3, B9.2.3: Risk assessment, chronic risk to fish	greater than the limit of solubility, has been conducted. The study report is now available for submission. Based on the results new TER's >10 can be calculated, hence no risk mitigation measures are needed.		

Bees and non-target arthropods (B. 9.4 and B.9.5)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(20)	Vol. 1, Level 2, List of Endpoints	EFSA: HQ values for non-target arthropods should be included in the LOEP. It is stated that data from field or semi-field tests indicate that overall effect is less than 50%. However no study summaries were provided in Vol. 3, B9.	RMS: Point noted, Endpoints have been amended. Addressed	Open point It seems that it was not possible for the RMS to assess the field studies with *T. pyri* since the study reports were either not complete and/or in German language only. Therefore it is suggested to delete the resultds of the field data from the LoEP. See also data requirement 5(23) and comment 5(29)
5(21)	Vol. 1, Appendix 3, List of endpoints	AT: Effects on other arthropod species - Field tests: Please indicate the application rates of the field data.	RMS: Point noted, Endpoints have been amended. Addressed	See open point 5(29)
5(22)	P32, Vol.1 2.6.3: Effects on bees & other arthropod species	NOT: Studies on *C. septempunctata* (including exposure of the egg) and on *A. bilineata* (eggs laid into treated soil)	RMS: Point noted, studies will be evaluated in an addendum.	Open point RMS to evaluate in an addendum the new studies with *C. septempunctata* and *A.*

Bees and non-target arthropods (B. 9.4 and B.9.5)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
	P68, Vol. 1, LOEP: Effects on other arthropod species P84, Vol. 1, 3.1: Background to proposed decision P86, Vol.1, 3.3: Rationale for the postponement… P87, Vol. 1, 4.1.9: Ecotoxicology P422, Vol. 3, B9.5.2c: Conclusion	have been conducted. Both studies show NO effects at 200 g a.s./ha (highest rate tested). Hence, it should now be possible to complete the risk assessment and conclude that there is no risk to non-target arthropods. Both studies have been submitted to RMS (8th April 2005) but have not been evaluated thus far.	Open point	*bilineata*.
5(23)	Vol. 3, B.9.5.1, Risk assessment for other non-target arthropods	EFSA: The field studies with *Typhlodromus pyri* are not summarized in Vol. 3. But in the LOEP it is stated that the data from the field studies indicate that the overall effect is < 50%. To verify this assessment the studies should be reported in the DAR. The field studies may provide information to conclude on the risk to non adult life stages.	RMS: The studies with T pyri were all conducted to a standardised BBA protocol; consequently only summaries were submitted these were presented in the dossier and hence summaries are presented in DAR Volume 3, Appendix 5. Addressed	Point for clarification Applicant to submit an English translation of the semi-field and field studies with *T. pyri*. See open point 5(20)

Earthworms and other soil non-target organisms (macro and micro) (B. 9.6, B.9.7 and B.9.8)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(24)	Vol.3, B.9.6.1, earthworm field study	NL: It is unclear whether the field study could be used for risk assessment.	RMS: The field study was not considered of sufficient quality to be used in the risk assessment. Addressed	Addressed
5(25)	Vol. 3, B.9.6.2, Risk assessment for earthworms	EFSA: It is not clear if the long-term risk to earthworms is fully addressed. The NOEC from the study of Stäbler (2002) would result in a TER of 3.7. If the NOEC from the study of Rodgers (2001) is used the TER would be 11. However only one application rate was tested in this study. At least some argumentation should be provided why this higher NOEC is more appropriate. A more detailed reporting of the earthworm field study may help to conclude whether the long-term risk to earthworms is sufficiently addressed.	RMS: In order to address the long-term risk to worms two long-term studies were presented. The first study by Stäbler produced a NOEC of 1.5 kg a.s/ha, equivalent to 1.0 mg a.s./kg soil once adjusted for organic matter content. This endpoint gave a TERlt of 3.7 – it should be noted that this NOEC was the top rate tested. A further study was conducted by Rodger and this produced a NOEC of 5.5 a.s. kg/ha, equivalent to 2.75 kg a.s./ha once adjusted for organic matter content. If this endpoint in terms of application rate is compared to the exposure endpoint in terms of rate, a TER of 11 is produced, which is greater than the Annex VI value of 5. It should be noted that the field study was not used in the risk assessment, and the final assessment was based on the Rodger study which was considered to be acceptable for risk assessment purposes. Addressed	Open point RMS to provide in an addendum a long-term risk assessment for earthworms based on concentrations of the a.s. in soil and not on application rates. The endpoint from the study of Rodger should be expressed as mg a.s./kg soil. Comparing the application rates used in the test and in the GAPs does not cover the maximum plateau PECsoil which is reached after 4-5 years. MSs to discuss the endpoint to be used in the long-term risk assessment for earthworms. In the study of Stäbler (2002)b effects on reproduction were observed at concentrations of 4-8 mg a.s./kg soil and the NOEC was set to 2 mg/kg soil while the NOEC of 5.5 kg a.s./ha from the study of Rodgers (2001) was considered relevant by the RMS for the risk assessment.

Earthworms and other soil non-target organisms (macro and micro) (B. 9.6, B.9.7 and B.9.8)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(26)	Vol. 3, B.9.6., Effects on earthworms	AT: Acute toxicity study for relevant metabolite (AE C593600) is missing (13% AR at 30 d).	RMS: No acute earthworm toxicity data were supplied for the metabolite AEC593600. The Notifier has submitted a case to address the soil metabolite (AE C593600) and risk to non-target soil organisms and processes. This will be evaluated in an addendum. See 5(29). Open point	Open point RMS to evaluate in an addendum the case to address the risk from metabolite AE C593600 to soil non-target organisms. See also comment 5(29)
5(27)	Vol. 3, B.9.7., Effects on non-target soil macro-organisms	AT: Litter bag study has to be submitted (DT90 of the active ingredient > 365 d).	RMS: The Notifier has submitted a litter bag study and this will be evaluated in an addendum, see 5(28). Open point	See open point 5(28)
5(28)	P32, Vol.1 2.6.4: Effects on earthworms & other soil macro-organisms P84, Vol. 1, 3.1: Background to proposed decision P86, Vol.1, 3.3: Rationale for the postponement… P88, Vol. 1, 4.1.9: Ecotoxicology P428, Vol. 3, B9.7.2: Risk assessment	NOT: As stated in the DAR the notifier will submit a litter- bag study. The study was initiated late April 2005. As the last sampling is one year after treatment (June 2005), the earliest time a final report can be submitted is 30 July 2006. No differences were noted between control and Apollo 50 SC groups 6 months after treatment. Ref: Carter, J.N. (2006). Clofentezine (Apollo 50 SC); Breakdown of organic matter in litter bags. Irvita Study no.: R-17802.	RMS: The study will be evaluated in an addendum. Open point	Open point RMS to evaluate in an addendum the litter bag study.

Earthworms and other soil non-target organisms (macro and micro) (B. 9.6, B.9.7 and B.9.8)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(29)	Vol. 3, B.9.8., Effects on non-target soil micro-organisms	AT: Acute toxicity study for relevant metabolite (AE C593600) is missing (13% AR at 30 d).	RMS: No acute earthworm toxicity data were supplied for the metabolite AEC593600. The Notifier has submitted a case to address the soil metabolite (AE C593600) and risk to non-target soil organisms and processes. This will be evaluated in an addendum. See 5(26) Open point	See open point 5(26)