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

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13-15.01.2009	PRAPeR expert meeting 61	Physical and Chemical Properties
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REPORT OF PRAPeR EXPERT MEETING 61

CLOFENTEZINE

Rapporteur Member State: UK

Specific comments on the active substance in the section

1. Physical and Chemical Properties

are already listed in the relevant reporting table. Comments submitted for this meeting are listed below.

1. Comments submitted for this meeting:

Date	Supplier	File Name
none		

2. Documents submitted for meeting:

Date	Supplier	File Name
December 2008	UK	Clofentezine addendum 2 Vol3 B5-B6-B7-B8-B9 (December 2008).doc
June 2007	UK	Clofentezine addendum1 Vol3 B5-B6-B7-B9 (June 2007).doc
2008-12-22	UK	Clofentezine evaluation table rev.1-0 (2008-12-22).doc
December 2008	UK	Clofentezine list of endpoints (December 2008).doc
2008-01-03	UK	Clofentezine reporting table rev1-2 (2008-01-03).doc
June 2007	UK	Clofentezine rev Vol4 (June 2007).doc

3. Documents tabled at the meeting:

Date	Supplier	File Name
none		

The conclusions of the meeting were as follows:

4. **Data on preparations:** Apollo 50SC

5. **Classification and labelling:** Not discussed.

6. **Recommended restrictions/conditions for use:** None.

7. **Reference list:** Not discussed

Areas of concern: No specification and no enforcement method for food/feed of animal origin.

Appendix 1: Discussion table: CLOFENTEZINE

Appendix 2: Evaluation table

Appendix 1: Discussion Table, Clofentezine (Ac)

1. Physical and Chemical Properties

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	Open point 1.1 RMS to amend the list of endpoints according to the new agreed template. See reporting table 0(1)	The list of endpoints has been updated accordingly.	Open point fulfilled.
	Data gap 1.1 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. See reporting table 1(5)	The meeting agreed that this issue should have been set as a point of clarification. The meeting discussed whether the information provided was sufficient. It was agreed to amend the EFSA Working Document concerning the need to have the purity of non-reactants of the manufacturing process.	Data gap changed into a point of clarification. Point of clarification addressed.

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	Data gap 1.2 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 See reporting table 1(6)	The meeting agreed that this issue should have been set as a point of clarification. See data gap 1.1 above.	Data gap changed into a point of clarification. Point of clarification addressed.
	Data gap 1.3 A lack of data on the manufacturing process used in the second plant has been identified.	The meeting agreed that this issue should have been set as a point of clarification. The information is provided in the Addendum to Volume 4 of the DAR (dated June 2007).	Data gap changed into a point of clarification. Point of clarification addressed.

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	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 See reporting table 1(7)		
	Open point 1.2 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 See reporting table 1(7)	It was clarified that the original source was no longer applicable as the original manufacturing site was no longer in use. The only source is now the Chinese source.	Open point fulfilled.
	Data gap 1.4 A lack of data on the a.s. content in the	The meeting agreed that this issue should have been set as a point of clarification. It was confirmed that the material is always dried down to form a TC and not a TK.	Data gap changed into a point of clarification. Point of clarification addressed.

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	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 See reporting table 1(8)		
	Open point 1.3 RMS to present the assessment of equivalence for the two sources in an Addendum. See also open point 1(7) See reporting table 1(11)	The RMS indicated that the information is presented in the Addendum to Volume 4 (dated June 2007). It was highlighted that the values in Table C.6 are correct, but they are not linked to the batches originally indicated in Volume 4. The meeting then agreed that the data on the Chinese source could not be considered, because the data was provided after the deadline in the Regulation (EC) No 1095/2007.	Open point fulfilled. New data gap proposed for formal reason, see below.
	New data gap 1.10 identified at PRAPeR 61 meeting: New data gap to provide specification		Data gap open.

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	and supporting batch data.		
	Open point 1.4 Acceptability of the in-house method to be discussed in an expert meeting. See reporting table 1(20)	The meeting considered that the method was not in line with the EC method A10, but was sufficient to address this Annex II point. The new study was not used to come to this conclusion. It was also agreed that data on auto-flammability (IIA 2.16) was not needed, taking into account flammability, melting point and temperature of decomposition.	Open point fulfilled.
	Data gap 1.5 A lack of additional information about the method used for determination of the photochemical degradation has been identified. See reporting table 1(23)	The meeting agreed that this issue should have been set as a point of clarification. The meeting agreed that the use of borosilicate was acceptable.	Data gap changed into a point of clarification. Point of clarification addressed.
	Data gap 1.6 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,	The RMS highlighted that they did not accept the applicant's case. Therefore, the meeting discussed whether the method was acceptable. The meeting agreed with the RMS' view as presented in Column C of the Evaluation Table. It also appears that the environmental method (HPLC-MS-MS) could be validated.	Data gap still open.

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	muscle, liver, kidney and fat) has been identified. See reporting table 1(35)		
	Data gap 1.7 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. See reporting table 1(38)	The meeting agreed that this issue should have been set as a point of clarification. The meeting accepted the clarification of the applicant provided in Column B of the Evaluation Table.	Data gap changed into a point of clarification. Point of clarification addressed.
	Data gap 1.8 A lack of an acceptable confirmatory method for determination of clofentezine in commodities with high water content has been identified. See reporting table 1(40)	It was agreed that the data presented in the Addendum could not be considered because the data was provided after the deadline in the Regulation (EC) No 1095/2007.	Data gap still open.
	Data gap 1.9 A lack of confirmatory	It was agreed that the data presented in the Addendum could not be considered because the data was provided after the deadline in the Regulation (EC) No 1095/2007.	Data gap still open.

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	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. See reporting table 1(52)		
	New open point 1.5 RMS to amend the list of endpoints according to the discussions during the PRAPeR 61 meeting.	The LOEP amendments are as follows: Min purity to be amended to 'open'. Flammability should be amended to 'not highly flammable' and the purity stated. Melting point to be deleted in the flammability box. The molar absorption at 290nm should also be stated. UV absorption maxima should also be stated. The ISO common name should be inserted in the summary of intended uses table. The reason for the greying out of the uses should be given. In the box for food of animal origin should be 'open'. In the box for plant origin should be indicated that the confirmatory method is missing. The header needs to be completed (RMS, date and active substance).	Open point open.

Appendix 2: Evaluation table

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

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the Evaluation Meeting
	Section 1 Open points: ***1*** Points for clarification: ***0*** Data gaps: ***4***			
	Open point 1.1 RMS to amend the list of endpoints according to the new agreed template See reporting table 0(1)	-	RMS: 19.12.2008 Endpoints have been amended. Point closed.	PRAPeR 61 (13-15 January 2009) Open point fulfilled.
	Data gap 1.1 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	As indicated in Column A, purity and commercial availability of **all starting materials** are mentioned in the addendum to DAR Volume 4 prepared by the RMS.	RMS: 19:12:2008 The RMS suggests that this information be handled as a point of clarification, rather than a data gap. This information is presented in the addendum to Volume 4 of the DAR (dated June 2007).	PRAPeR 61 (13-15 January 2009) Data gap changed into a point of clarification. Point of clarification addressed.

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the Evaluation Meeting
	the peer review. See reporting table 1(5)			
	Data gap 1.2 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. See reporting table 1(6)	As indicated in Column A, source of all starting materials and description of the manufacturing process in the China plant (similar to that used in the UK plant) are mentioned in the addendum to DAR Volume 4 prepared by the RMS. **Clarification** in response to AT comment 1(6) reporting table rev.1-2 (03.01.2008), page 25/110: Ethanol, acetic acid and toluene are not starting materials but solvents or reagents which are recycled at the end of the manufacturing process. Hence, the information for **all starting materials** is available in DAR addendum.	RMS: 19:12:2008 The RMS suggests that this information be handled as a point of clarification, rather than a data gap. This information is presented in the addendum to Volume 4 of the DAR (dated June 2007).	PRAPeR 61 (13-15 January 2009) Data gap changed into a point of clarification. Point of clarification addressed.

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the Evaluation Meeting
	Data gap 1.3 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 See reporting table 1(7)	As indicated in Column A, the manufacturing process in the China plant (similar to that used in the UK plant) is described in the addendum to DAR Volume 4 prepared by the RMS.	RMS: 19:12:2008 This information is presented in the addendum to Volume 4 of the DAR (dated June 2007).	PRAPeR 61 (13-15 January 2009) Data gap changed into a point of clarification. Point of clarification addressed.
	Open point 1.2 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 See reporting table 1(7)	-	RMS: 19.12.2008 The source presented is an Addendum to the DAR and details an additional source of clofentezine and this is the current commercially manufactured source of clofentezine.	PRAPeR 61 (13-15 January 2009) Open point fulfilled.

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the Evaluation Meeting
	Data gap 1.4 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 See reporting table 1(8)	**Clarification of existing study:** As indicated in the manufacturing process, the product is, in the final step, washed with acetic acid and then with water. Hence, drying is needed. Given that drying is a technical procedure without relevance to the chemical process and product quality, it was not specified as a step in the manufacturing process. Content of a.s. is always analysed after this drying procedure.	RMS: 19.12.2008 This information is presented in the addendum to Volume 4 of the DAR (dated June 2007).	PRAPeR 61 (13-15 January 2009) Data gap changed into a point of clarification. Point of clarification addressed.
	Open point 1.3 RMS to present the assessment of equivalence for the two sources in an Addendum. See also open point 1(7) See reporting table 1(11)	-	RMS: 19.12.2008 The Addendum to Volume 4 (dated June 2007) contains an equivalence check (see Table C.6) Open point addressed.	PRAPeR 61 (13-15 January 2009) Open point fulfilled. New data gap proposed for formal reason, see below.
	New data gap 1.10 identified at PRAPeR 61 meeting: New data gap to provide specification and supporting batch data.			Data gap open.

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the Evaluation Meeting
	Open point 1.4 Acceptability of the in-house method to be discussed in an expert meeting. See reporting table 1(20)	It should be noted that the results obtained by this in-house method were confirmed by those obtained with the EC method A10 (report R-21216, sent to the RMS): Clofentezine technical (99.7% pure) was shown not to be flammable under the conditions of the test. However according to Regulation (EC) No 1095/2007, these data are not supposed to be taken into consideration in the peer review.	RMS:19:12:2008 EEC A10 confirms clofentezine technical is non-flammable Open point addressed	PRAPeR 61 (13-15 January 2009) Open point fulfilled.
	Data gap 1.5 A lack of additional information about the method used for determination of the photochemical degradation has been identified. See reporting table 1(23)	**Clarification of existing study:** Concerning reporting table comment 1(23), borosilicate glass is often used as the standard material for test vessels used in aqueous photolysis experiments. In the study by Kelly (1985) no measurements of irradiance from the sunlight incident on the test solutions after passing through the borosilicate glass test vessels is reported. However, in many similar tests conducted at a CRO (Huntingdon Life Sciences) over the years where irradiance measurements from an artificial xenon light source (Suntest apparatus) have been made, borosilicate glass vessels have been shown to transmit light at wavelengths >290 nm. The radiation spectrum measured has been shown to be	RMS:19.12.2008 See applicants case in the left hand column. Data point fulfilled.	PRAPeR 61 (13-15 January 2009) Data gap changed into a point of clarification. Point of clarification addressed.

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the Evaluation Meeting
		comparable to that of natural sunlight. Thus it is very unlikely that the test vessels used by Kelly were inappropriate and this would seem not to be a valid reason for rejecting the study. **Additionally**, it should be also noted that an aqueous photolysis study (R-18905) was recently conducted to meet a request from Japanese Regulatory Authorities. It includes further work on clofentezine photolysis in both natural water (relevant to JMAFF guidelines) and in buffer (relevant to EU guidelines) and experimental determination of the quantum yield. This study and a report on the real half-lives (R-18905a) have been sent to the RMS.		
	Data gap 1.6 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. See reporting table 1(35)	**Clarification of existing studies :** Clarification of the methods described in the DAR addendum (R-17532 and ILV R-20408) is provided in the **Attachment IRV1-01** to this table. This document shows that: - The method is designed to determine clofentezine residues in animal products **as defined in Reg (EC) No. 396/2005** (**=sum of all compounds containing the 2-chlorobenzoyl moiety expressed as clofentezine**).	RMS: 19.12.2008 The data submitted by the applicant to address the outstanding data required, was correct with regards to the approach taken. However, there are a number of major issues associated with the acceptance of the method for the purpose of enforcement and with the associated validation data. a) The method is a common moiety method, which involves the hydrolysis of clofentezine to 2-	PRAPeR 61 (13-15 January 2009) Data gap still open.

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the Evaluation Meeting
		- Based on this residue definition, any new method would still require an acid hydrolysis step to ensure conjugated metabolites were accounted for. - It has been proved that the method converts clofentezine and metabolites into the analyte (2-CBA) with a molar conversion ratio of 1:1. - Since the method is highly specific (GC/MS using 3 fragment ions with an m/z > 100), confirmatory method is not necessary.	chlorobenzoic acid. The issue here is that a number of other pesticides (i.e. clomazone, cumylone, flufenzine) contain this moiety and thus if present in the sample, would give a false positive/inflated result. b) The use of a derivatising agent in an enforcement method is strongly discouraged. The applicant has tried to address this concern by changing the derivatising reagent from diazomethane to MSTFA, however it is difficult to understand why the HPLC-MS/MS methods used in the environment methods were not modified and employed here (applicant had already shown that HPLC-UV could be used to analyse for 4-hydroxyclofentezine in animal products). c) The enforcement method was only validated for clofentezine, whereas the residues definition is clofentezine and its metabolite 4-hydroxyclofentezine and no validation data were submitted on kidney. However, the ILV data covered both clofentezine and 4-hydroxclofentezine and kidney, although there is an issue that the ILV data, which did not address the amount of 2-chlorobenzoic acid produce by the two components. In	

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the Evaluation Meeting
			the case of clofentezine, the molecule contains two 2-chlorophenyl groups whereas 4-hydroxyclofentezine contains only one, with the other 2-chlorophenyl ring having an OH group in the 4 position (no indication was give as to whether this would be removed on hydrolysis, which appears unlikely). Therefore, if the OH group is not removed, the retention time may be different and the ions produced during determination by MS may also be different and as SIM is being used, would not be picked up. The result of this would be if 4-hydroxyclofentezine is present in significant amounts and the calibration is based on clofentezine, the residue in the sample would be significantly lower than the true value. Therefore the RMS recommends that a HPLC-MS/MS is developed (along the lines of the environment methods) and validated for clofentezine and its metabolite 4-hydroxyclofentezine (including ILV data) for animal products (milk, eggs, muscle, liver, kidney and fat). Data gap still open.	

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the Evaluation Meeting
	Data gap 1.7 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. See reporting table 1(38)	**Clarification of existing studies:** As given in Table B 5.1 of the DAR (Vol. 3, p 46), 5 determinations of accuracy were reported. The mean (n = 5) was 99.7% for TGAI and 99.8% for the product. The %RSD of these measurements was 0.28% for both TGAI and product and was reported as the precision in the Table B.5.1.	RMS: 19.12.2008 See applicants case in the left hand column. Data gap fulfilled.	PRAPeR 61 (13-15 January 2009) Data gap changed into a point of clarification. Point of clarification addressed.
	Data gap 1.8 A lack of an acceptable confirmatory method for determination of clofentezine in commodities with high water content has been identified. See reporting table 1(40)	It should be noted that a fully validated confirmatory method (GC-MS/MS) was submitted in Germany in May 2008 (report R-22236, sent to the RMS). However according to Regulation (EC) No 1095/2007, these data are not supposed to be taken into consideration in the peer review.	RMS: 19:10.2008 Validated confirmatory method (LC-MS/MS) for the determination of clofentezine in commodities with high water content – See addendum 2 Data gap fulfilled.	PRAPeR 61 (13-15 January 2009) Data gap still open.

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the Evaluation Meeting
	Data gap 1.9 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. See reporting table 1(52)	See above data gap linked to reporting table 1(35).	RMS: 19:10.2008 'Data gap' (See Addendum 1 – B.5.4.1)	PRAPeR 61 (13-15 January 2009) Data gap still open.
	New open point 1.5 RMS to amend the list of endpoints according to the discussions during the PRAPeR 61 meeting. (Refer to Discussion table)			PRAPeR 61 (13-15 January 2009) Open point open.

REPORT OF PRAPeR EXPERT MEETING 62

CLOFENTEZINE

Rapporteur Member State: UK

Specific comments on the active substance in the section

4. Fate and behaviour in the environment

are already listed in the relevant reporting table. Comments submitted for this meeting are listed below.

1. Comments submitted for this meeting:

Date	Supplier	File Name
none		

2. Documents submitted for meeting:

Date	Supplier	File Name
December 2008	UK	Clofentezine addendum 2 Vol3 B5-B6-B7-B8-B9 (December 2008).doc
2008-12-22	UK	Clofentezine evaluation table rev.1-0 (2008-12-22).doc
December 2008	UK	Clofentezine list of endpoints (December 2008).doc
2008-01-03	UK	Clofentezine reporting table rev1-2 (2008-01-03).doc
June 2007	UK	Clofentezine rev Vol4 (June 2007) cover page.doc

3. Documents tabled at the meeting:

Date	Supplier	File Name
None		

The conclusions of the meeting were as follows:

4. Data on preparations: APOLLO 50SC

5. Classification and labelling: Candidate for R53

6. Recommended restrictions/conditions for use: None identified.

7. Reference list: Open points still open to update the list of studies relied on.

Areas of concern: groundwater exposure assessment not finalised for 2 chlorobenzoic acid and 2 chlorobennitrile. Potential for long range atmospheric transport (clofentezine).

Appendix 1: Discussion table: CLOFENTEZINE

Appendix 2: Evaluation table

Appendix 1: Discussion Table, Clofentezine (Ac)

4. Fate and behaviour

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
4.1	Point of clarification for the applicant Applicant to further address the photolysis metabolite 2-chlorobenzonitril with respect to potential GW contamination. (EFSA note: According to 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	In the reporting table a MS required that photolysis metabolite 2-chlorobenzonitril had to be included in the list of end points since it reached 5.5 % AR after 31 d. The RMS agreed to include it in the LoEP, but expressed the opinion that no further assessment would be necessary. A point of clarification was proposed requesting the applicant to address potential GW contamination by this metabolite. The applicant provided FOCUS GW (PELMO 3.3.2) calculations for this metabolite based on a worst case assumed DT50 = 1000 d and a Koc of 162 mL/g (derived with EPWIN software). Formation fraction assumed was identical to the maximum observed at the end of the photolysis in soil study (5.5 %). The limit of 0.1 μg / L was exceeded for 5 out of 9 FOCUS GW scenarios in apple, 0 out of 7 scenarios in early vines and 2 out of 4 scenarios in early strawberries. Using a formation fraction of 10 % (to take into account potential higher formation in other EU locations and the fact that ff are expected to be higher than the maximum observed, and Q10 – 2.2 or 2.58 as updated by PPR panel), the applicant estimated the soil half-life that would need to be to obtain an 80th percentile leachate concentration below 0.1 μg / L for all four early strawberries scenarios (Kremsmuenster early strawberries resulted in the worst case in the first simulation). Under these assumptions, if DT50 was 390 d (Q10 = 2.2) or 360 d (Q10 = 2.58) all four early strawberries scenarios would be safe. In the opinion of the applicant it was considered highly unlikely that a molecule such as 2-chlorobenzonitrile would persist in the environment for such a long period of time due to the potential degradation to the amide and subsequent formation of the carboxylic acid. The RMS summarised and assessed the applicant's calculations in Addendum 2. Overall the RMS considered that although the applicant had made a reasonable attempt to address this point of clarification within confines of Regulation No. 1095/2007, there was	Point of clarification addressed. New data gap proposed, see below. Message sent to tox.

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	expected to occur in many EU locations). See reporting table 4(3)	still a large degree of uncertainty in the submitted groundwater assessment. However, the RMS expected that in more natural conditions where shading, leaching out of the upper soil layer, and competing degradation processes will occur it may be expected to reduce the possibility of direct photolysis occurring relative to what occurred in the laboratory photolysis study. In the opinion of the RMS, the point of clarification can be considered addressed for EU risk assessment. However, individual MS may still wish to consider the potential for formation of 2-chlorobenzonitrile under specific national conditions and the conclusion of the EU peer review could include reference to this metabolite for consideration at MS level. EFSA notes that the metabolite 2-clorobenzonitrile is not covered by the rat toxicological studies and it is also found as part of the residue in plants. Its toxicological relevance needs to be addressed in order to clarify the residue definition in food. The experts in the meeting discussed the information available and concluded that they agreed with the calculations provided by the applicant assessed in the addendum. The experts agreed they could support the position of the RMS, if it is concluded that 2-clorobenzonitrile is not relevant following the conclusion of the mammalian toxicology consideration. It would need to be further addressed at EU level in case it is relevant or if its relevance cannot be concluded. Message to tox regarding relevance of 2-clorobenzonitrile as well as residues a potential groundwater issue.	
	New data gap 4.2 identified at PRAPeR 62 meeting: Data gap to further address the photolysis metabolite 2-chlorobenzonitril with respect to potential GW contamination, in	Potential data gap if toxicological non relevance of 2-clorobenzonitrile cannot be confirmed.	Data gap open.

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	case it is relevant or if its toxicological relevance cannot be concluded. (data gap pending confirmation from tox section).		
	Open point 4.1 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). See reporting table 4(7)	The applicant presented its position supporting the validity of the half lives provided by this study in the evaluation table. The RMS reiterated the position already expressed in the reporting table 4(7) that the study was considered only supporting information with respect to the route of degradation but reliable with respect to the determination of the half lives in soil (with some degree of uncertainty for one soil where the half-life needs to be extrapolated beyond the duration of the study (duration 67 d)). The EFSA concern with respect to the harsh extraction is related to the potential contribution of hydrolysis by the second and third steps (see RT 4(8)). In these acidic soils normalised half lives have been calculated to be 48 and 70.8 d. For the “other” two acidic soils the calculated normalised half lives are 168 and 191.5 d. In fact, the second set of two experiments were performed in the same soils (same name classification pH and OM, slight differences in the soil characterisation specially particle size distributions and MWHC). In case the two first half lives were not considered acceptable or the soils were considered identical, a data gap for an additional half life would be needed, since only data on three soils would remain (in case the meeting confirms that the rate of degradation of the Speyer 2.2 soil is not reliable, see OP 4.4). The experts in the meeting discussed the information available and concluded that the experiment at 15°C could be used for the rate of degradation for the active substance only, though it was agreed that it provided valuable information on the level of metabolite 2 chlorobenzoic acid (AE C500233). They confirmed that the 25°C experiment can be used for assessing both the route and rate of degradation. This was in line with the RMS position in the DAR. The experts considered that the properties of the two soils retained by the RMS assessment in the DAR (Cottenham and Bottisham) were too similar to be handled in the assessment as 4 different soils. The experts considered that the rate values in both temperature experiments were reliable and a geomean for Cottenham and geomean for Bottisham (after normalisation) should be used as the agreed endpoints from the Cottenham and Bottisham soils (109 days 96 days respectively).	Open point fulfilled.

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		After discussion of OP 4.4 no further degradation in soil experiments were found necessary, since the experiment in the soil Speyer 2.2 was considered to provide a reliable half-life (see OP 4.4).	
	Open point 4.2 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	The applicant presented a case that has been summarised and assessed in Addendum 2. The applicant's case is based on the loss of symmetry upon chemical hydrolysis yielding to two different fragments from the chlorophenyl rings: one of the fragments yields 2-chlorobenzoic acid and the other yields a hydrazide derivative that subsequently hydrolyses to 2-chlorobenzaldehide. The argumentation of the applicant says that since only one of the rings directly yields 2-chlorobenzoic acid, the amount of this metabolite observed as AR in the aerobic degradation study in soil corresponds to its formation also in molar basis and does not need to be corrected. The RMS in principle accepted the argument but noted that it is based on a laboratory hydrolysis experiment using concentrated hydrobromic acid. EFSA noted a weak point in the argumentation presented: - In this case, the symmetry is loss in a "non oxidising" hydrolysis experiment. The final product of the other side of the molecule is 2-chlorobenzaldehide that may be expected to be readily oxidised in soil to 2-chlorobenzoic acid under aerobic conditions. The experts in the meeting discussed the information available and also noted they have to pay attention to the trigger of 5% in route studies at 2 time points for a soil leaching assessment. In the available route studies with widely spaced sampling intervals residues of 2-chlorobenzoic acid were found at one time point at 6.2 and 6.8%AR (different experiments) which could equate to 12.4 and13.6% on a molar basis. Therefore the experts considered that at least a leaching assessment was triggered for 2-chlorobenzoic acid. At greater than 10% in soil (expected molar level) the experts agreed that a soil exposure and soil dwelling risk assessment should be performed. An assessment of drainage and runoff input to surface water should also be performed. The experts agreed to inform the ecotoxicology experts' meeting that soil concentrations of 2-chlorobenzoic acid of up to 0.019 mg/kg needs to be assessed (0.268mg/kg x 0.136 x 156/303) (0.268mg/kg is a maximum accumulated soil PEC for clofentezine). A data gap was identified for groundwater and surface water exposure assessments for 2-	Open point fulfilled. Message sent to ecotox. New data gap proposed, see below.

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	10 % in molar basis) See also 4(2), 4(11), 4(26), 4(57) and 4(58). See reporting table 4(11)	chlorobenzoic acid.	
	New data gap 4.3 identified at PRAPeR 62 meting: Data gap identified for groundwater and surface water exposure assessments for 2-chlorobenzoic acid.		Data gap open.
	Open point 4.3 MS to discuss the adequacy of the input parameters used for FOCUS 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). See reporting table 4.(12)	The issue was raised by a public comment from an individual EU citizen. The comment questioned the reliability of the five compartments model using inverse parameter estimation to derive the kinetic parameters from the water / sediment study and points out the lack of statistic information in the DAR. Other comments in the RT also challenge the reliability of this fitting exercise taking into account the number of compounds and processes that are considered with only 6 sampling data points. Additionally, some comments refer to the whole system half-life (used by the applicant in FOCUS Step 1) see point of clarification 4.7. The RMS has reproduced in addendum 2 page 25 the information (some consideration on the visual assessment of the fittings and the statistic available to assess the goodness fitting) and the assessment already expressed in the RT. Whereas the RMS agrees that the complex fitting used may not give fully reliable kinetic parameters and it is not recommended by FOCUS kinetics, the dossier was produced before the FOCUS kinetics document became available. Hydrolysis of clofentezine occurs in between 4 h and 10 d (depending on the pH) which are comparable to the whole system half lives of 4.2 to 12.7 d, and the water phase half lives of 1.8 and 2.4 d. With respect to the metabolite AE	Open point fulfilled. New open points proposed, see below.

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
		C593600, the half-life of 14.1 d (worst case of sediment phase) is used for both compartments in Step 1 and Step 2 calculations. This may be regarded as a worst case with respect to the whole system half lives of 6.4 d estimated by the RMS (estimation not available in the DAR, only in RT and addendum 2). Overall, the RMS is of the opinion that the input parameters used in the PEC SW calculations are appropriate for the purpose of the risk assessment and that no further information is required to address this point. EFSA indicated that two separated issues need to be discussed: end points considered reliable enough to be reported in the LoEP for future use by MSs, and the acceptability of the current PEC SW where maybe different end points have been used. The experts considered that in the original DAR (on page 327) the kinetic model used is presented. The model is complex and the number of parameters fitted is large compared to the number of experimental data points available. Therefore the experts had reservations about the validity of the separate DT50 values derived for water and sediment and were sceptical if they would represent degradation as required by FOCUS models for calculating PEC. The experts considered that just the whole system values of 13.1 and 7.1 days (see point of clarification 4.7) should be present in the LoEP for the water sediment studies. The RMS proposed to calculate water dissipation DT50 from the 2 experiments in an addendum after the meeting of experts as useful information for use at national level. The experts agreed that even though they did not agree with the kinetic fitting of the sediment water study in the DAR (separate water and sediment rate values), they would not require new FOCUS surface water calculations for the EU intended uses of 1 application per year, if the ecotoxicology experts retain a single input RAC higher than a multiple input RAC, new FOCUSsw simulations will not be required, as adsorption and not degradation rates will drive the maximum PEC. The reasoning for this can be found at point of clarification 4.8.	

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	New open point 4.11 RMS to remove separate water and sediment DT50 from the LoEP water sediment study box and just include whole system values of 13.1 and 7.1 days.		Open point open.
	New open point 4.12 RMS to calculate a water dissipation DT50 from the 2 experiments in an addendum (values should not be put in the LoEP).		Open point open.
	Open point 4.4 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).	The RMS has presented a new fitting and goodness of fitting analysis of the data from the degradation in this soil following FOCUS kinetics. The RMS is of the opinion that although $\chi^2 < 15$ ($\chi^2 = 9.3$), the residuals and the poor description of the parent concentration at time 0 still justifies not to include this study in the LoEP and not to use it in the exposure assessment. Furthermore, the RMS notes that the effect of the addition of this study to the data set on the geometric mean is minor (from 71.3 d to 73.6 d). EFSA indicates that two separated issues need to be discussed: whether the half-life is considered reliable enough to be reported in the LoEP for future use by MSs, and the acceptability of the current assessment where this half-life has not been considered. In that case potential effect of the new data on the observed pH dependence may also need to be considered. The experts in the meeting discussed the information available and concluded that based on the fitting in the addendum on page 27, the fit is not optimal but the value should not be excluded from the overall dataset, as the overall quality of the fit is comparable to that seen with other substances in list 3 and the approach followed regarding the study discussed under open point 4.1. With this DT50 of 86.5 days (normalised) added to the dataset, the overall geomean from the 4 soils is 62.4 days. It was noted that for the FOCUS simulations available a longer value of 71.3 days had been used. Whilst pH	Open point fulfilled. New open point proposed, see below.

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	See reporting table 4 (17)	dependence cannot be completely excluded (the one alkali experiment has the shortest DT50), the experts agreed that a geomean value should be used for exposure assessment in this case, as the data are insufficient to be confident that the relationship is real.	
	New open point 4.13 RMS to update the LoEP rate of degradation in soil (laboratory) in line with the discussion table conclusions for open points 4.1 and 4.4.		Open point open.
4.2	Point of clarification for the applicant Applicant to provide scientifically and consistent valid justification for not presenting a soil adsorption desorption study with clofentezine. See reporting table 4(24)	The applicant presented the required justification that has been reproduced and assessed by the RMS in addendum 2. The RMS considers that at least preliminary experiments to show the technical difficulties to perform the experiment should have been reported. However, on basis of the other experimental studies available (column leaching studies and soil TLC showing low mobility of clofentezine) the RMS considers that the calculated Koc is appropriate for the risk assessment. The experts noted that the case provided does not address why the use of a co-solvent has not been attempted. In fact, it seems that previous dissolution in a small volume of acetone allowed the preparation of solutions up to 26 μg /L used in one of the hydrolysis experiments, EFSA agrees with the RMS that the case would be stronger if at least preliminary experiments had been attempted and reported. The experts in the meeting discussed the information available. They concluded that whilst the effort made to try and determine an experimental adsorption value was limited, they were content in this case that the assessment could be completed with the available information. This available information used a QSAR approach supported by the column leaching and soil TLC data. The high adsorption value that was estimated gave reassurance in this case and was accepted, as an anionic form of the compound was not expected.	Point of clarification addressed.
	Data gap 4.1 Data gap for a soil adsorption desorption study with clofentezine may be identified by	See point of clarification 4.2 above for the discussion. The experts agreed that the data gap is redundant (not confirmed).	Data gap closed.

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	the experts' meeting if no satisfactory clarification is provided. See also point of clarification in 4(29) See reporting table 4(24)		
4.3	Point of clarification for the applicant Applicant to provide further information on the possible discrepancy between solubility in the various studies submitted. See also data requirement in 4(24) See reporting table 4(29)	A clarification is provided by the applicant in the Evaluation Table. The applicant explains that the hydrolysis study was designed on basis of a preliminary solubility study, where clofentezine had been first solved in 1 mL of acetone and diluted in the buffer solution (solubility 29 μg /L). When a guideline solubility study was performed, they realised that the real solubility in pure buffered water was only of 2.54 μg /L for pH 5 and < 2 μg /L for pH 7 and 9. Thus, the applicant concludes that in the hydrolysis study by Kelly the clofentezine could not have been fully dissolved. However, the authors of the study were able to derive half lives from these experiments. The applicant points out that another hydrolysis study exists (van der Gaauw, 2001) performed at pH ≈ 5, 7, 9 and temperatures of 10, 22 and 38 ºC in compliance with OECD 111 and GLP. This study was performed at 2 μg /L (below solubility) and comparable results were obtained at pH 7. The applicant proposes that the DAR is amended to report the tested concentrations in the van der Gaauw study. The RMS is requested to confirm the concentrations used in the van der Gaauw study and to include the results of this study in the LoEP (with a footnote indicating the concentration tested). EFSA noted that the discrepancy also occurs with respect to other studies such as the aqueous photolysis study where a concentration of 250 μg /L is reported to have been tested (to be discussed in OP 4.6). The same applies to the water sediment study (to be discussed on OP 4.8 and PC 4.4 and PC 4.5). The experts in the meeting discussed the information available and concluded that the information provided by the applicant in the evaluation table was reasonable.	Point of clarification addressed. New open point proposed, see below.

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	New open point 4.14 RMS is requested to confirm the concentrations used in the van der Gaauw study and to include the results of this study in the LoEP (with a footnote indicating the concentration tested).		Open point open.
	Open point 4.5 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)) See reporting table 4(31)	The RMS has included the study van der Gaauw, 2001c in the "List of Annex II studies that were considered as relied upon for the evaluation with a view to Annex I inclusion, and for which the main notifier has claimed data protection" The studies Kelly, 1985a and Smith and Kelly, 1985 b have not been included in the final list, as the Notifier did not claim data protection for these studies. The RMS considers this open point addressed. EFSA noted that the commission guidance indicates that all relied on studies should be listed irrespective of whether data protection has been claimed.	Open point open. 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.
	Open point 4.6 MS to discuss in an experts meeting the acceptability of the aqueous photolysis study and the need of further information. See also 4(33).	The quality of the study presented in the dossier was questioned during the commenting period due the lack of control in the experimental conditions and the tested concentration above the solubility limit (250 μg /L vs ≈2 μg /L). Also the reliability of a quantum yield derived from this study was challenged. The RMS recognised the limitations of this study (in the evaluation table) but considered that under natural environmental conditions aqueous photolysis would not play an important role on the degradation of clofentezine due to rapid adsorption to sediment and that therefore more accurate information on the aqueous photolysis is not needed to finalise the risk assessment. With respect to the photolysis metabolite (ET OP 4.10) the RMS additionally considers that it is to be considered less toxic than the parent by two orders of magnitude based on data for fish, daphnia and algae, and that it does not need	Open point fulfilled. New data gap proposed, see below.

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	See reporting table 4(32)	further consideration. The applicant has submitted to the RMS a new aqueous photolysis study. The applicant claims that in this new study current guidelines have been followed and that the experiments have been performed below the solubility limit. However, according to Regulation (EC) No 1095/2007, these new data cannot be considered further during this peer review process. EFSA indicated that two separate issues need to be discussed: -the scientific acceptability of the study available in the dossier -the need or not of further information on aqueous photolysis to finalise the EU risk assessment. The experts considered that the available study in the original dossier was not reliable regarding any estimation of the rate of aqueous photolysis of the active substance. A data gap for formal reasons and not essential was proposed in order that the new study available can be requested and evaluated at a later stage by MSs. Since the OP 4.10 is also related to the aqueous photolysis, should be taken into account for this discussion. The OP 4.10 was transferred from the ecotox section were it was commented the need to address the major aqueous photolysis metabolite AE F023666 (2-chlorobenzonitrile, up to 79 % AR). The experts in the meeting discussed the information available (by consulting the original study report) and concluded that the study was not in accordance with current standards following current guidelines. However, they agreed that the metabolite AE F023666 (2-chlorobenzonitrile, formed at up to 79 % AR which was not transient being present at significant levels i.e (66% by day 10 and 75% at the end of the study 31 days)) has the potential to be formed in significant amounts in water under natural sunlight. The experts also noted that no samples were taken between time zero and 10 days. Therefore, in natural water systems it cannot be excluded that 2-chlorobenzonitrile will be present in significant amounts shortly after water is exposed to the active substance, even though the active substance will also rapidly partition (to sediment or other organic materials), biodegrade and hydrolyse.	
	New data gap 4.4 identified at PRAPeR 62 meeting: A new aqueous photolysis study is		Data gap open.

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	required. The experts agreed it was not essential to complete the EU level exposure assessment.		
	Open point 4.7 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) See reporting table 4(34)	The studies Buerkle, 1999a and Maurer, 2000 have been included in the "List of Annex II studies that were considered as relied upon for the evaluation with a view to Annex I inclusion and for which the main notifier has claimed data protection". The study Kelly (1985b) has not been included in this final list as the Notifier did not claim data protection for this study. The RMS considers that this open point is addressed. EFSA noted that the commission guidance indicates that all relied on studies should be listed irrespective of whether data protection has been claimed.	Open point open. RMS to amend the list of information, test and studies which are relied upon to include the missing references Kelly, 1985 b.
4.4	Point of clarification for the applicant Applicant to provide further clarification on the low material balance reached in the water sediment studies. See reporting table 4 (35)	Additional information on the existing studies has been submitted by the applicant, and summarised and evaluated by the RMS in Addendum 2 page 31. The applicant has examined the raw data of the study to examine the possible reasons for the low radioactivity recovery observed at some sampling times (0, 21, 42 DAT in Lode system and 14 and 21 DAT in the Saddlers Farm system). The applicant concluded that the low recovery of radioactivity at some sampling points cannot be explained by a single reason. It is likely that for the Lode 0 DAT sample there was an experimental error in the quantification of the water phase (due to sample handling and manipulation, some clorentezine could have been remained attached to the glass ware). In later samples of both test systems, low quantification of $^{14}CO_2$ and/or bound residues is considered a more probable source of the low recovery. Estimates of clofentezine and its degradation products are considered by the applicant to be accurate, apart from the determination of clofentezine at the Lode 0 DAT. In any case, the lower level of clofentezine quantified at Lode 0 DAT is expected to result in more conservative end points (longer half lives). Overall, the RMS accepted the possible reasons for the low recovery and concluded that the end points could be relied upon for the purpose of the exposure assessment. The experts in the meeting discussed the information available and concluded that they	Point of clarification addressed.

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		agreed with the assessment made by the RMS.	
	Open point 4.8 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). See reporting table 4(37)	The RMS noted in the DAR that a higher ratio of sediment than recommended by SETAC was present. During the peer review it was commented that this may have an impact on the results of the study due to the high adsorption of clofentezine to sediment. For the same reason the RMS was of the opinion that the amount of sediment is not expected to have an impact on the results. The applicant provided additional information related to this issue that has been summarised and assessed by the RMS in Addendum 2 on page 34. The applicant indicated that the water / sediment ratio based on the heights of each phase is not the approach required in current guidelines (mass ratios should be used). The applicant recognises that for this study the exact water / sediment ratio on a mass basis cannot be established; however, they were of the opinion that it may be estimated from the raw data of the study to be shown within the guidelines. The oven dry weight of the sediment is not available, nor the total water to sediment on a weight to weight basis. The applicant estimated water sediment ratio on basis of the final dry weight of sediment after extraction and the total volume of the test system (assuming water density of 1 ml / cm^3 for water and 1.5 ml / cm^3 for sediment). The water: sediment ratios calculated by the applicant in this way were 1:7 and 1:4 and therefore within the guidelines limits. The RMS declared in the addendum that it was unable to fully validate all the statements provided by the applicant because information from the raw study data that detailed dry weights of sediments post extraction were not provided. The RMS agrees that the estimation on basis of the heights of the compartments is not the correct approach to determine the ratio of water to sediment specified in current guidelines. From the original study report a layer of sediment of 9 cm with an overlaying water layer of 12 cm. The RMS considers that if the pore volume was taken into consideration it is likely that a ratio closer to acceptable levels. Overall, the RMS considered that the experimental set up was likely to be acceptable and considered that no further information was required. EFSA noted that additionally to this issue, issues discussed in point of clarification 4.4 – 4.7 should be taken into account to conclude on the acceptability of the water sediment study. The meeting should also consider the fact that in both systems investigated the pH of the water compartment was > 8.	Open point fulfilled. New open point proposed, see below.

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		The experts in the meeting discussed the information available and concluded that the study can be relied on for use in the exposure assessment. It was noted that a majority of natural surface water systems are alkaline, but that as for this substance hydrolysis may be a less important process under acidic conditions. Therefore, in member states where water bodies associated with agriculture are acidic, degradation might be expected to be slower than estimated in these studies. The experts asked that EFSA note in the conclusion that member states that have acidic surface water bodies may wish to request additional information to address this situation.	
	New open point 4.15 EFSA to indicate in the conclusion that member states that have acidic surface water bodies associated with agriculture may wish to request additional information to address this situation. (degradation might be expected to be slower than estimated in the studies – refer to open point 4.8 above)		Open point open.
4.5	Point of clarification for the applicant Further information on the appropriateness of the formulation used in the water sediment study (WP) to represent the intended SC formulation.	Additional information on the existing studies has been submitted by the applicant and summarised and evaluated by the RMS in Addendum 2. The applicant explains that a simulated formulation was prepared in order to being able to perform the study at concentrations that mimic realistic application rates and to ensure homogeneous application of the active substance to the water sediment systems overcoming the low solubility limit of the substance. The formulation was not intended to mimic any commercial product but to allow investigating the fate and behaviour of the active substance clofentezine in the water sediment systems. Therefore, the results should be considered for the active substance irrespective to the commercial formulation. Details on the actual co-formulants used are provided in addendum 2. All the formulants are inert	Point of clarification addressed.

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	See also open point in 4(37) See reporting table 4(40)	and intended not to increase solubility but to guarantee homogeneous dispersion. In the opinion of the RMS the formulation is unlikely to have had a major adverse impact on the fate and behaviour of the active substance over the duration of the water sediment study and the results are applicable to other formulations. The experts in the meeting discussed the information available and confirmed that they agreed with the opinion of the RMS.	
4.6	Point of clarification for 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) See reporting table 4(41)	Additional information on the existing studies has been submitted by the applicant and summarised and evaluated by the RMS in Addendum 2 on page 36. The applicant clarified that volatiles were captured in a trapping line made of three traps: ethanediol (for neutral organic volatiles eventually including parent clorofentezine), ethanolamine (for acidic volatiles) and sulphuric acid (for alkaline volatiles, erroneously the applicant says acidic degradates here). According to the applicant, the raw data of the study were used to elaborate the table presented in addendum 2. The study authors assumed that all radioactivity trapped in the ethanolamine trap was CO_2. However, no specific assay to prove that no other acidic volatiles were trapped was performed. The standard precipitation with barium is not applicable when the CO_2 is trapped with ethanolamine. According to the applicant, this approach is common in environmental studies. The applicant believed that the conclusion that the ca 30 % AR measured in the ethanolamine trap was CO_2 resulting from the complete mineralisation of clofentezine is a sound scientific one, even if not absolutely proven. From the examination of the tables it may be seen that the radioactivity trapped in the other two traps is negligible (< 0.2 % AR). The RMS declared in the addendum that they were unable to fully validate all the statements provided by the applicant, because information from the raw study data that detailed the sampling of the volatile traps were not provided. However, the RMS accepted the additional information as providing useful supporting information to address this point of clarification, and considered that no further information was required. EFSA noted that the information provided in the tables in the addendum is in line of what would be expected for these kind of studies. The fact that no specific method is used to demonstrate the identity of CO_2 is unfortunately common in many environmental studies. However, specific methods for CO_2 exist (such as the Grignard reaction) that can be employed. The experts in the meeting agreed that the clarification provided was appropriate.	Point of clarification addressed.

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4.7	Point of clarification for 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 or not from the consideration 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) See reporting table 4(45)	In the DAR the whole system half-life is only used in FOCUS SW Step 1 calculations. However, the origin of the half-life used (7 d) was not reported. A clarification was required from the applicant. It seems that no further information has been provided by the Applicant. However, the RMS has re-evaluated the whole system DT50 following FOCUS kinetics recommendations in the addendum 2. Fitting has been performed including and excluding clofentezine adsorbed to experimental glass ware (up to 8.2 % AR in the clay loam system). Whole system half lives were 12.7 d (χ^2 = 15.5) and 4.2 d (χ^2 = 28.6) when the substance attached to the glassware is not considered. Otherwise, the half lives are 13.1 d (χ^2 = 10.1) and 7.1 d (χ^2 = 25.4). EFSA noted that whole system half-life may become more relevant for future calculations, if the derived separated water and sediment half lives are finally considered not reliable (issue discussed under OP 4.3). The experts in the meeting discussed the information available and concluded that the endpoints of 13.1 d and 7.1 d (including residue associated with the glassware) were selected in this case just to get an agreed endpoint. There was a discussion on what would be the most appropriate reason for selecting one or other pair of values, but they could not identify a good scientific justification for that taken (the pairs of values are quite similar) with the level of detail on the experiment available. (i.e. whether the glass associated residue would have been available for degradation or not in the systems).	Point of clarification addressed.
4.8	Point of clarification for 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.	No further information has been provided by the applicant. However, the RMS addressed this point of clarification in addendum 2. The RMS rightly noted in addendum 2 that the wording of this point of clarification was done before the final version of the FOCUS Landscape and mitigation that was noted by the Standing Committee in 2008. Original mitigation at Step 4 for spray drift on pome / stone fruit (early) applications with implementation of a 35 m no spray buffer mitigation would seem to result in a spray drift mitigation greater than the 95 % maximum proposed by FOCUS. Spray drift mitigation for late pome /stone fruits applications, vines and strawberry was within the maximum capped mitigation levels proposed by FOCUS.	Point of clarification addressed. New open point proposed, see below.

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	(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. See reporting table 4(46)	For the run off the applicant assumed a 90 % reduction of pesticide mass due to the presence of vegetative filter strips. However, the runoff volumes were considered unaffected by the vegetated filer strip. This would not be consistent with FOCUS Landscape and mitigation guidance. As a result of the updated assessment of ecotoxicology end points, the RMS proposed in that chapter two different acceptable concentrations: 25 μg /L when exposure is the result of a single spray drift event. 5 μg / L when exposure results from multiple run off, drainage or spray drift events. In the DAR only Step 3 results for the scenarios that gave the maximum Step 3 PEC SW calculations for the pome use fruit were reported. The RMS provided in the addendum additional results for all Step 3 uses, and pertinent scenarios are provided in addendum 2 (p 45-46) based on the original calculations on Heinmann 2003b). In the opinion of the RMS acceptable concentrations (< 5 μg / L) are found for the grapevine, strawberry and ornamental use already at Step 3 level, irrespective of the main route of entry to SW. For apple, pear and plum use some scenarios exceed the concentration of 5 μg / L, but none the concentration of 25 μg /L. It is the opinion of the RMS that since the main route of entry to SW in these scenarios is spray drift, the concentrations should be regarded as acceptable. Overall, the RMS considered that since acceptable concentration is found for all uses and scenarios at Step 3 level, the Step 4 calculations become irrelevant. EFSA noted that the Step 3 calculations are the same that in the DAR, therefore any consideration made on the input parameters used may be relevant here. EFSA also noted that the need for further refinement (Step 4) will ultimately depend on the result of the ecotoxicology meeting PRAPeR 63 accepting or not the levels proposed. Finally, EFSA noted that the level of 5 μg / L refers to multiple exposure events and therefore cannot be evaluated only on basis of the peak concentrations and the major route of entry (minor routes of entry may eventually contribute to repeated exposures below the peak but above the level of 5 μg / L) The experts in the meeting discussed the information available. The RMS pointed out that in a table on page 341 of the DAR that includes FOCUS step 3	

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
		results and step 4 mitigation with just drift mitigated and with step 4 with drift and runoff mitigated, it is apparent that drift is the dominant route of entry to surface water when application equipment is air assisted broadcast sprayers, and these are the situations where PEC are above 5µg/L (the RAC (effect concentration including uncertainty factor) for a multiple aquatic organism exposure situation). Because multiple entry events simulated (occur due to runoff and drainage) are always <5µg/L and the intended use at the EU level only considers a single application per year (multiple drift events excluded), the experts considered that new PEC calculations were not required as the TOXSWA model would be insensitive to water and sediment DT50 when drift events are the dominant input route, provided that only the max PEC for an individual scenario water body combination (and not TWA) is used for risk assessment. The experts agreed that if the ecotoxicology experts retain a single input RAC higher than a multiple input RAC, new FOCUSsw simulations will not be required as adsorption and not degradation rates will drive the maximum PEC. **Post meeting note:** **The meeting of experts in ecotoxicology PRAPeR 63 did not agree with the RAC of 25 µg /L. The end point driving the risk assessment at this stage is 0.7 µg /L. Mitigation would most likely be needed to be able to demonstrate acceptable uses with this low level and therefore up to FOCUS Step 4 calculations seem to be necessary. However, this low level end point is pending on the confirmation of the acceptability of an ecotoxicological study that cannot be taken into consideration at this stage on basis of the Regulation 1095/2007. In case the new studies were considered acceptable (which may occur when the new studies became assessed and peer reviewed), it is most likely that the RAC of 5 µg /L become the driving end point both for single and multiple applications. If the later end point is confirmed, it is likely that concentrations calculated with FOCUS SW at the level of Step 3 may show some acceptable scenarios. New proper FOCUS Step 3 calculations will then be needed to identify and characterize such situations.**	
	New open point 4.16 New FOCUSsw simulations (at step 3 and if necessary step 4) are necessary if		Open point open.

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	conclusions on RAC changes significantly. (See also point of clarification 4.8 above and open point 5.7 – ecotoxicological section)		
	Open point 4.9 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. See reporting table 4(56)	During the commenting period, a MS questioned the assessment performed for the air compartment, since substances with similar Henry Law constant (fepropimorph) are measured in air monitoring programs. Henry Law constant for clofentezine is 0.168 Pa m^3 / mol. Half-life in the atmosphere calculated according to Atkinson is 5.1 d. However, maximum loss by volatilisation over a period of 24 h was only 1.1-1.8 % from plants and 0.8 – 1.7 % from soil (calculated by difference using the assumption that applied radioactivity not recovered in plants or soil was assumed to be volatilised). The RMS provided its position in addendum 2. The RMS noted the soil and plant volatilisation studies available and proposed to have a more general discussion in the experts meeting. The experts noted that EFSA will include the pertinent information in the conclusion and it will be noted that due to the atmospheric half-life of 5 days, EFSA will indicate that clofentezine has the potential for long range atmospheric transport, as aerosols may be formed at the time of spraying. It was noted that contrary to fenpropimorph (which has a higher vapour pressure than clofentezine), volatilisation from soil or plants will be lower, as whilst the Henry's law constants are similar, this is because water solubility of clofentezine is very low, but in the presence of a lipophilic matrix (eg. soil or plants), loss to the atmosphere would be expected to be lower than for fenpropimorph.	Open point fulfilled. New open point proposed, see below.
	New open point 4.17 EFSA to include the pertinent information in the conclusion and due to the atmospheric half-life of 5 days, EFSA shall indicate that clofentezine has the potential for long		Open point open.

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	range atmospheric transport.		
	Open point 4.10 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) See reporting table 4(59)	See discussion under OP 4.6. The experts agreed that the photolysis metabolite (2-chloro benzonitrile) will be formed under natural conditions. A PEC in water for this metabolite has been used to complete a risk assessment (in the list of endpoints ecotoxicology section). However, the experts (including the RMS fate expert) did not know how this value had been derived. The RMS is asked to provide the calculation for this PEC including all assumptions used for its derivation in an addendum and update the LoEP (fate section).	Open point fulfilled. New open point proposed, see below.
	New open point 4.18 RMS to provide the calculation for 2-chloro benzonitrile PEC in surface water including all assumptions used for its derivation in an addendum, and update the LoEP (fate section).		Open point open.
	New open point 4.19 Definition of the residue for assessment by other sections or for which a groundwater exposure assessment is triggered:	The experts agreed the definition of the residues in the LoEP fate section, but noted that 2 chlorobenzoic acid (AE C500233) needs to be added for soil and groundwater and surface water (via drainage and runoff), and 2-chlorobenzonitrile (formed in soil and water by photolysis) needs to be added to the definition for groundwater and surface water.	Open point open.

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	RMS to update the LoEP and add 2 chlorobenzoic acid (AE C500233) for soil and groundwater and surface water (via drainage and runoff), and to add 2-chlorobenzonitrile (formed in soil and water by photolysis) to the definition for groundwater and surface water.		
	Message to PRAPeR 64 meeting of experts (mammalian toxicology) regarding: relevance of metabolites 2-clorobenzonitrile and 2-chlorobenzoic acid as well as for residues in food a potential groundwater issue may arise.		Message sent to tox section.
	Message to PRAPeR 63 meeting of experts (ecotoxicology): The experts agreed to inform the ecotoxicology experts' meeting that soil concentrations of 2-		Message sent to ecotox section.

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	chlorobenzoic acid of up to 0.019 mg/kg needs to be assessed (0.268mg/kg x 0.136 x 156/303) (0.268mg/kg is a maximum accumulated soil PEC for clofentezine).		

Appendix 2: Evaluation table

4. Environmental fate and behaviour

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the evaluation group
	Section 4 Open points: ***11*** Points for clarification: ***0*** Data gaps: ***3***			
4.1	Point of clarification for the applicant Applicant to further address the photolysis metabolite 2-chlorobenzonitril with respect to potential GW contamination. (EFSA note: According to 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	**Additional information on existing studies:** Information is provided in the **Attachment IRV4-01**. This additional information is based on existing studies already described in the DAR and consequently it can be taken into consideration in the peer review according to EFSA document dated 15 November 2007 on the common understanding to clarify the difference between information that may be requested and a study that may not in the context of Regulation (EC) No 1095/2007.	RMS: 19:12:2008 The additional information supplied by the Notifier has been evaluated in Addendum 2. Although the RMS considered that there were a number of uncertainties associated with the approach taken by the Notifier, overall the RMS concluded that the point of clarification had been sufficiently addressed and no further information was considered necessary. The RMS considers that point is addressed.	PRAPeR 62 (13-15 January 2009) Point of clarification addressed. New data gap proposed, see below. Message sent to tox.

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the evaluation group
	conditions with respect to photolysis and higher levels could be expected to occur in many EU locations). See reporting table 4(3)			
	New data gap 4.2 identified at PRAPeR 62 meeting: Data gap to further address the photolysis metabolite 2-chlorobenzonitril with respect to potential GW contamination, in case it is relevant or if its toxicological relevance cannot be concluded. (data gap pending confirmation from tox section).			PRAPeR 62 (13-15 January 2009) Data gap open.
	Open point 4.1 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). See reporting table 4(7)	**Clarification of existing studies:** The notifier agrees with the answers to EFSA provided by the RMS in reporting table 4(7) and wants to add the following points: • The EFSA are incorrect to say that there was "*application of non labelled AE C522505 together with the test substance*". This was not the case. The EFSA have misinterpreted the explanation in the DAR for the formation of AE C52205 where AE C52205 was co-chromatographed with extracts of soil causing conversion	RMS: 19:12:2008 In addition to the information provided by the Notifier in Column B the RMS also wishes to reiterate the points made in the original Reporting Table comment – see 4(7). The RMS considers that this open point is addressed.	PRAPeR 62 (13-15 January 2009) Open point fulfilled.

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the evaluation group
		on the TLC plate of clofentezine to AE C522505. • As noted, the DT_{50} values were extrapolated a short time beyond the duration of the study. However it should be noted that there was a good linear fit of the data with r^2 values >0.94, thus, reducing the uncertainty in the values obtained. Comparing the pattern of extraction and mineralisation in this study with that of Leake & Arnold, 1983b, strongly suggests that the low recovery of radioactivity recorded for both soils at 67 DAT was due to inefficient trapping of $^{14}CO_2$ and not any loss of unchanged clofentezine. The question as to whether soxhlet extraction should be considered a "very harsh extraction" is debatable. Whilst using a hot solvent to percolate through the soil, it does not cause disruption to the soil matrix. However, the objective of any extraction is to maximise the extraction of the unchanged compound and its degradation products. The study clearly demonstrates that extraction method developed and applied by Leake & Arnold in this study maximises the extraction of intact clofentezine (0 DAT recovery of clofentezine was 97.2% AR in the loamy sand). The notifier agrees with the RMS that cold solvent extraction would have		

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the evaluation group
		underestimated the DT_{50} values for clofentezine in soil. The notifier supports the view that this study is adequate for determination of the rate of degradation but provides only supporting information on the route of degradation which is more robustly characterised in Leake & Arnold, 1983b. The DT_{50} values should be retained for use with the other results in the groundwater risk assessment (DAR, Table B8.37 P 330).		
	Open point 4.2 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	**Clarification of existing studies:** The open point 4.2 questions on the molar conversion ratio between clofentezine and 2-chlorobenzoic acid (2-CBA). This molar ratio conversion between clofentezine and 2-CBA is 1:1 as experimentally shown in the article[1] provided as appendix to the above mentioned **Attachment IRV1-01** submitted with this evaluation table: The authors clearly explain that "Given the symmetrical nature of this particular molecule, conversion of one mole of clofentezine to two moles of 2-CBA was theoretically possible, as suggested in Fig. 1. Laboratory testing, however, showed this not to be the case; **only one mole of 2-CBA was essentially being formed per mole of**	RMS: 19:12:2008 The additional information supplied by the Notifier has been evaluated in Addendum 2. On the basis of the information provided, the RMS accepts that the theoretical maximum transformation of clofentezine into 2-chlorobenzoic acid of 200% on a molar basis outlined in Open point 4.2 would not occur in practice. The RMS considers that this open point is addressed.	PRAPeR 62 (13-15 January 2009) Open point fulfilled. Message sent to ecotox. New data gap proposed, see below.

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the evaluation group
	%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). See reporting table 4(11)	**clofentezine,** as determined by gas chromatography with mass selective detection (CGC/MSD) following methylation of 2-CBA with diazomethane. A postulated mechanism is shown in Fig. 2." [1] P. J. Snowdon, R. J. Whiteoak and J. D. Manley, 1991, "The hydrolysis of clofentezine and related tetrazines as the basis of determination of residues in bovine tissues", Fresenius J Anal Chem (1991) **339**:444-447.		
	New data gap 4.3 identified at PRAPeR 62 meting: Data gap identified for groundwater and surface water exposure assessments for 2-chlorobenzoic acid.			PRAPeR 62 (13-15 January 2009) Data gap open.
	Open point 4.3 MS to discuss the adequacy of the input parameters used for FOCUS 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). See reporting table 4.(12)	Please note that reporting table 4(45) does not lead to a data requirement as indicated in Column A but to a point of clarification (see below point of clarification 4.7 and related **Attachment IRV4-04** to this evaluation table).	RMS: 19:12:2008 The RMS has included the response from the original Reporting Table in Addendum 2. The RMS considers the open point is addressed.	PRAPeR 62 (13-15 January 2009) Open point fulfilled. New open points proposed, see below.

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the evaluation group
	New open point 4.11 RMS to remove separate water and sediment DT50 from the LoEP water sediment study box, and just include whole system values of 13.1 and 7.1 days.			PRAPeR 62 (13-15 January 2009) Open point open.
	New open point 4.12 RMS to calculate a water dissipation DT50 from the 2 experiments in an addendum (values should not be put in the LoEP).			PRAPeR 62 (13-15 January 2009) Open point open.
	Open point 4.4 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). See reporting table 4 (17)	-	RMS: 19:12:2008 Additional information on the kinetic fitting for the Speyer 2.2 soil is provided in Addendum 2. The RMS considers the open point is addressed.	PRAPeR 62 (13-15 January 2009) Open point fulfilled. New open point proposed, see below.

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the evaluation group
	New open point 4.13 RMS to update the LoEP rate of degradation in soil (laboratory) in line with the discussion table conclusions for open points 4.1 and 4.4.			PRAPeR 62 (13-15 January 2009) Open point open.
4.2	Point of clarification for the applicant Applicant to provide scientifically and consistent valid justification for not presenting a soil adsorption desorption study with clofentezine. See reporting table 4(24)	**Clarification of existing studies:** A justification for non-submission of a soil adsorption/desorption study is provided as an Attachment to this Evaluation Table (See **Attachment IRV4-02**). This document is based on existing studies and consequently it can be taken into consideration in the peer review according to EFSA document dated 15 November 2007 on the common understanding to clarify the difference between information that may be requested and a study that may not in the context of Regulation (EC) No 1095/2007.	RMS: 19:12:2008 The additional information supplied by the Notifier has been evaluated in Addendum 2. Overall the UK RMS accepted that the estimated Koc value for clofentezine was sufficiently validated for use in the exposure assessments, particularly taking into account the low mobility demonstrated in at least 4 other laboratory experimental studies. The RMS considers that this point of clarification is addressed.	PRAPeR 62 (13-15 January 2009) Point of clarification addressed.
	Data gap 4.1 Data gap for a soil adsorption desorption study with clofentezine may be identified by the experts' meeting if no satisfactory clarification is provided. See also point of clarification in 4(29) See reporting table 4(24)	See above.	See above.	PRAPeR 62 (13-15 January 2009) Data gap closed.

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the evaluation group
4.3	Point of clarification for the applicant Applicant to provide further information on the possible discrepancy between solubility in the various studies submitted. See also data requirement in 4(24) See reporting table 4(29)	**Clarification on existing studies:** In a preliminary experiment to the hydrolysis study (reported in Kelly, 1985a, Annex IIA 2.9.1/01 DAR pages 12 and 321), the water solubility of clofentezine was determined by adding clofentezine dissolved in acetone to buffer and shaking in a water bath for 16 hours at 22ºC. The solution was then centrifuged and filtered. The total radioactivity in the filtrate was measured and taken to be the actual solubility of clofentezine (0.029 mg/L). The hydrolysis study proceeded using concentrations of 48% and 88% of this value, 0.014 and 0.026 mg/L respectively. Later the water solubility was determined in a much more rigorous way, with shorter equilibration time, lower initial concentration and the filtrate being analysed chromatographically (Smith & Kelly, 1985. Annex II A 2.6/01, DAR page 9). From this, the water solubility at pH 5 was determined to be 2.52 µg/L and <2 µg/L at pH 7 and 9. Thus, it has to be concluded that, in the hydrolysis study by Kelly, the clofentezine could not have been fully dissolved. Irrespective of this conclusion, it appears that the authors were able to determine rates of hydrolysis at different pH values and	RMS: 19:12:2008 The RMS has no further information to add to the detailed response provided by the Notifier in Column B. The RMS considers that this point of clarification is addressed.	PRAPeR 62 (13-15 January 2009) Point of clarification addressed. New open point proposed, see below.

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the evaluation group
		temperatures. As the study was conducted at a clofentezine concentration above its water solubility, the notifier can understand the concern of the EFSA regarding the validity of the rates of hydrolysis reported by Kelly. However, a second study conducted at below the water solubility, 2 µg/L (van der Gaauw, 2001, Annex II A 2.9.1/03, DAR Pages 13 and 322) in compliance with OECD 111 and GLP, has also been conducted and evaluated by RMS. The results from this study were completely in line with those from the Kelly study, with rates at pH 7 in the range of 0.2 days at 38°C to 1.4 days at 22°C. Thus, on this occasion, the solubilisation of clofentezine does not appear to have influenced the kinetics of the rate of degradation. Thus, as concluded in the DAR, both studies can be used to provide data on the rates of clofentezine hydrolysis with varying pH and temperature. For clarification, the DAR should be amended to further include concentration of the van der Gaauw study.		

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the evaluation group
	New open point 4.14 RMS is requested to confirm the concentrations used in the van der Gaauw study and to include the results of this study in the LoEP (with a footnote indicating the concentration tested).			PRAPeR 62 (13-15 January 2009) Open point open.
	Open point 4.5 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)) See reporting table 4(31)	-	RMS: 19:12:2008 The study van der Gaauw, 2001c has been included in the 'List of Annex II studies which were considered as relied upon for the evaluation with a view to Annex I inclusion and for which the main submitter has claimed data protection, Version 2 – final (June 2008). The studies Kelly, 1985a, and Smith and Kelly, 1985b, have not been included in this final list as the Notifier, did not claim data protection for these studies. The RMS considers this open point is addressed.	PRAPeR 62 (13-15 January 2009) Open point open. 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.
	Open point 4.6 MS to discuss in an experts meeting the acceptability of the aqueous photolysis study and the need of further information. See also 4(33).	It should be noted that the notifier has independently decided to repeat this study following regulatory authorities' request and that the results of this study **do not alter the overall conclusions** made by the RMS in column 3, that photolysis was unlikely to be a significant route of dissipation in most natural surface waters.	RMS: 19:12:2008 According to Regulation (EC) No. 1095/2007, the RMS has not evaluated the repeat aqueous photolysis study mentioned in Column B. The RMS has therefore reiterated their comments from the original Reporting Table (see 4(32)).	PRAPeR 62 (13-15 January 2009) Open point fulfilled. New data gap proposed, see below.

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the evaluation group
	See reporting table 4(32)	This new study (R-18905) includes work on clofentezine photolysis in both natural water (relevant to JMAFF guidelines) and in buffer (relevant to EU guidelines). This study was conducted to current guidelines and with clofentezine applied below its water solubility. It provides a better estimate of the rate of aqueous photolysis and the quantum yield for clofentezine. It also provides an experimentally derived quantum yield to current guidelines and a report (R-18905a) uses this data to estimate the real half lives of the molecule. Both reports (and a summary) have been sent to the RMS. However according to Regulation (EC) No 1095/2007, these data are not supposed to be taken into consideration in the peer review.	*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 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.* The RMS considers this open point is addressed. However, if further assessment is required it is proposed that a full evaluation of new aqueous	

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the evaluation group
			photolysis study be performed to ensure that the assessment is based on the most appropriate information.	
	New data gap 4.4 identified at PRAPeR 62 meeting: A new aqueous photolysis study is required. The experts agreed it was not essential to complete the EU level exposure assessment.			PRAPeR 62 (13-15 January 2009) Data gap open.
	Open point 4.7 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) See reporting table 4(34)	--	RMS: 19:12:2008 The studies Buerkle, 1999a and Maurer, 2000, have been included in the 'List of Annex II studies which were considered as relied upon for the evaluation with a view to Annex I inclusion and for which the main submitter has claimed data protection, Version 2 – final (June 2008). The study Kelly (1985b) has not been included in this final list as the Notifier, did not claim data protection for this study. The RMS considers this open point is addressed.	PRAPeR 62 (13-15 January 2009) Open point open. RMS to amend the list of information, test and studies which are relied upon to include the missing references Kelly, 1985 b.
4.4	Point of clarification for the applicant Applicant to provide further clarification on the low material balance reached in the water sediment studies.	**Clarification of existing studies:** Clarification on the low material balance reached in the water/sediment study is provided as part of the **Attachment IRV4-03** submitted with this evaluation table. The clarification refers to the raw data	RMS: 19:12:2008 The additional information supplied by the Notifier has been evaluated in Addendum 2. Overall, the UK RMS accepted the	PRAPeR 62 (13-15 January 2009) Point of clarification addressed.

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the evaluation group
	See reporting table 4 (35)	of the existing study and it can be taken into consideration in the peer review according to the document prepared by EFSA in November 2007 on the common understanding to clarify the difference between information that may be requested and a study that may not in the context of Regulation (EC) No 1095/2007 dated 15 Nov. 2007.	possible reasons for low recovery and concluded that the endpoints from the study could be relied upon for the purposes of the exposure assessment. The RMS considers that this point of clarification is addressed.	
	Open point 4.8 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). See reporting table 4(37)	See Points of clarification 4.4, 4.5 and 4.6.	RMS: 19:12:2008 The additional information supplied by the Notifier has been evaluated in Addendum 2. Overall the UK RMS considered that the experimental set-up in the water sediment study was likely to be acceptable and considered that no further information was required. The RMS considers that this open point is addressed.	PRAPeR 62 (13-15 January 2009) Open point fulfilled. New open point proposed, see below.
	New open point 4.15 EFSA to indicate in the conclusion that member states that have acidic surface water bodies associated with agriculture may wish to request additional information to address this situation. (degradation might be			PRAPeR 62 (13-15 January 2009) Open point open.

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the evaluation group
	expected to be slower than estimated in the studies – refer to open point 4.8 of discussion table)			
4.5	Point of clarification for 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) See reporting table 4(40)	**Clarification of existing studies:** As requested, further information is provided in the **Attachment IRV4-03** to this evaluation table, to answer this point of clarification. The document is based on the existing study and can be taken into consideration in the peer review according to the document prepared by EFSA in November 2007 on the common understanding to clarify the difference between information that may be requested and a study that may not in the context of Regulation (EC) No 1095/2007 dated 15 Nov. 2007.	RMS: 19:12:2008 The additional information supplied by the Notifier has been evaluated in Addendum 2. In the opinion of the UK RMS the formulation is unlikely to have had a major adverse impact on the fate and behaviour of the active substance over the duration of the entire water sediment study, and therefore results from this study can be read across to other formulations as appropriate. No further information is considered necessary. The RMS considers that this point of clarification is addressed.	PRAPeR 62 (13-15 January 2009) Point of clarification addressed.
4.6	Point of clarification for 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.	**Clarification of existing studies:** As requested, further information is provided in the **Attachment IRV4-03** to this evaluation table, to answer this point of clarification. The document is based on the existing study and can be taken into consideration in the peer review according to the document prepared by EFSA in November 2007 on the common understanding to clarify the	RMS: 19:12:2008 The additional information supplied by the Notifier has been evaluated in Addendum 2. The RMS considers that this point of clarification is addressed.	PRAPeR 62 (13-15 January 2009) Point of clarification addressed.

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the evaluation group
	See also open point in 4(37) See reporting table 4(41)	difference between information that may be requested and a study that may not in the context of Regulation (EC) No 1095/2007 dated 15 Nov. 2007.		
4.7	Point of clarification for 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 or not from the consideration 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) See reporting table 4(45)	**Clarification of existing studies:** As requested, further information is provided in the **Attachment IRV4-04** to this evaluation table, to answer this point of clarification. The document is based on the existing study and can be taken into consideration in the peer review according to the document prepared by EFSA in November 2007 on the common understanding to clarify the difference between information that may be requested and a study that may not in the context of Regulation (EC) No 1095/2007 dated 15 Nov. 2007.	RMS: 19:12:2008 Additional information on the kinetic fitting of the whole water sediment systems has been provided in Addendum 2. The RMS considers that this point of clarification is addressed.	PRAPeR 62 (13-15 January 2009) Point of clarification addressed.
4.8	Point of clarification for 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	**Clarification of existing studies:** A revised acute and chronic aquatic risk assessment to fish and invertebrates is presented by the RMS in the DAR addendum (See B 9.2.3, p 69). This concluded that ”the acute and chronic risk to fish, aquatic invertebrates and algae arising from all proposed uses of clofentezine in 'Apollo 50SC' applications is low and risk mitigation is not required”. TERs	RMS: 19:12:2008 Additional information on the surface water exposure assessment has been provided in Addendum 2. Additional summary results of the Step 3 FOCUSsw assessments have been provided in the light of a re-assessment of the effects evaluation.	PRAPeR 62 (13-15 January 2009) Point of clarification addressed. New open point proposed, see below.

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	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. See reporting table 4(46)	were >10 with worst case Step 3 PECsw. The use of vegetative filter strips is not required for mitigation. Thus, the question if the mitigation and refined PECs used in the *original* risk assessment were performed correctly or not is not relevant anymore to the evaluation. Extract from DAR addendum: *"The fathead minnow chronic study is considered to be the more appropriate ELS study for use in the risk assessment since a suitably maintained dose range was employed. This study was preferred to the rainbow trout ELS study which used technical material at one low dose (NOEC = 0.007 mg a.s./L) to overcome solubility problems. Similarly, the D. magna chronic study using 'Apollo 50SC' in a more natural sediment:water system was selected for risk assessment".* The conclusions were: - *"All TERs are >10 for FOCUS step 1 PECsw indicate that there is a low chronic risk to fish from all the proposed uses of clofentezine.* *Using FOCUS step 2 total load PECsws (see DAR B.8.5.2), TERs >10 were derived for aquatic invertebrates*	Overall the UK RMS concludes that this point of clarification has been adequately addressed.	

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		for all crop uses apart from early pome/stone fruit and ornamentals. However, with worse case FOCUS Step 3 PECsw scenarios, TERs >10 were obtained indicating low risk to aquatic invertebrates also for these uses."		
	New open point 4.16 New FOCUSsw simulations (at step 3 and if necessary step 4) are necessary if conclusions on RAC changes significantly. (refer to point of clarification 4.8 of the discussion table and open point 5.7 – ecotoxicological section)			PRAPeR 62 (13-15 January 2009) Open point open.
	Open point 4.9 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. See reporting table 4(56)	-	RMS: 19:12:2008 A response from the RMS has been included in Addendum 2. The RMS considers that this open point should be further discussed in an expert meeting to ensure that a consistent approach be taken.	PRAPeR 62 (13-15 January 2009) Open point fulfilled. New open point proposed, see below.

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the evaluation group
	New open point 4.17 EFSA to include the pertinent information in the conclusion and due to the atmospheric half-life of 5 days, EFSA shall indicate that clofentezine has the potential for long range atmospheric transport.			PRAPeR 62 (13-15 January 2009) Open point open.
	Open point 4.10 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(6) See reporting table 4(59)	-	RMS: 19:12:2008 In the original DAR, the RMS considered that the results of the water/sediment studies would be expected to be more representative of the behaviour expected in natural water bodies compared with the aqueous photolysis studies for this substance. Therefore the photolysis metabolites were considered unlikely to be formed in major amounts in natural water bodies due to the rapid dissipation out of the uppermost surface water layers where photolysis may occur and the subsequent partitioning to sediment. Therefore no further consideration of the metabolite 2-chlorobenzonitrile was considered necessary. It should also be noted that on the basis of acute ecotox effects data for the 2-chlorobenzonitrile metabolite, the metabolite would be considered to be less toxic than the parent by at least	PRAPeR 62 (13-15 January 2009) Open point fulfilled. New open point proposed, see below.

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the evaluation group
			two orders of magnitude based on data for fish, daphnia and algae (see Table B.9.2.2, page 383 of the Ecotox section of the DAR). On this basis no further consideration of the metabolite 2-chlorobenzonitrile was considered necessary. The RMS considers this open point is addressed.	
	New open point 4.18 RMS to provide the calculation for 2-chloro benzonitrile PEC in surface water including all assumptions used for its derivation in an addendum, and update the LoEP (fate section).			PRAPeR 62 (13-15 January 2009) Open point open.
	New open point 4.19 Definition of the residue for assessment by other sections or for which a groundwater exposure assessment is triggered: RMS to update the LoEP and add 2 chlorobenzoic acid (AE C500233) for soil and groundwater and surface water (via drainage and runoff), and to add 2-chlorobenzonitrile (formed in soil and water by photolysis)			PRAPeR 62 (13-15 January 2009) Open point open.

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	to the definition for groundwater and surface water.			

REPORT OF PRAPeR EXPERT MEETING 63

CLOFENTEZINE

Rapporteur Member State: UK

Specific comments on the active substance in the section

5. Ecotoxicology

are already listed in the relevant reporting table. Comments submitted for this meeting are listed below.

1. Comments submitted for this meeting:

Date	Supplier	File Name
none		

2. Documents submitted for meeting:

Date	Supplier	File Name
December 2008	UK	Clofentezine addendum 2 Vol3 B5-B6-B7-B8-B9 (December 2008).doc
June 2007	UK	Clofentezine addendum1 Vol3 B5-B6-B7-B9 (June 2007).doc
2008-12-22	UK	Clofentezine evaluation table rev.1-0 (2008-12-22).doc
December 2008	UK	Clofentezine list of endpoints (December 2008).doc
2008-01-03	UK	Clofentezine reporting table rev1-2 (2008-01-03).doc
June 2007	UK	Clofentezine rev Vol4 (June 2007) cover page.doc

3. Documents tabled at the meeting:

Date	Supplier	File Name
none		

The conclusions of the meeting were as follows:

4. **Data on preparations:** Apollo 50 SC

5. **Classification and labelling:** R50/R53

6. **Recommended restrictions/conditions for use:** None

7. **Reference list:** Not discussed.

Areas of concern: birds, aquatic organisms, NTA, soil function (litter bag study)

Appendix 1: Discussion table: CLOFENTEZINE

Appendix 2: Evaluation table

Appendix 1: Discussion Table, Clofentezine (Ac)

5. Ecotoxicology

	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	Data gap 5.1 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 See reporting table 5(2)	Data to support the risk assessment have been provided to the RMS. The RMS evaluated the studies in addendum1 and addendum2, however they cannot be considered in the peer review according to the Commission Regulation (EC) No 1095/2007. No PD and PT refinements can be taken into account.	Data gap still open. New open point proposed, see below.

	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	New open point: 5.13 RMS to delete from the LoEP the higher tier risk assessment to birds based on PD and PT refinements.		Open point open.
	Open point 5.1 RMS to include in an addendum the risk assessment for birds from uptake of contaminated drinking water. See reporting table 5(3)	The risk assessment has been reported in addendum 2. The PEC FOCUS step1 were used for the long-term risk.	Open point open. RMS to update the LoEP with the acute risk assessment from uptake of drinking water.
	Open point 5.2 RMS to include in an addendum the risk assessment for mammals from uptake of contaminated drinking water. See reporting table 5(8)	The risk assessment has been reported in addendum 2. The PEC FOCUS step1 were used for the long-term risk.	Open point open. RMS to update the LoEP with the acute risk assessment from uptake of drinking water.
	Open point 5.3 RMS to include the aquatic TERs for all uses in the LoEP. See reporting table 5(10)	The list of endpoints has been updated accordingly.	Open point fulfilled.

	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	Open point 5.4 RMS to include in an addendum all details on the studies with aquatic organisms which are required for a transparent and comprehensive 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	Regarding the studies with aquatic organisms the key information such as tested concentrations, observed effects at each concentration, statistics,confidence intervals should be reported in an addendum for transparency reasons.	Open point open. RMS to provide the key information on the aquatics studies in an addendum.

	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	for reasons of transparency and to facilitate the peer-review of the suggested endpoints. See also comment 5(17) See reporting table 5(11)		
	Open point 5.5 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)	An assessment of the long-term studies on *Daphnia magna* was reported in the addendum 2. The RMS proposed to use the endpoint of 0.25 mg a.s./L based on the formulation (study conducted in the presence of sediment), in case the major route of exposure is spary drift. If the route of exposure is driven by drainflow and runoff, the endpoint based on active substance of 0.05 mg a.s./L should be used. The meeting agreed to use the endpoint 0.25 mg a.s./L only with the step1 and step2 FOCUS calculations, considering the total load into surface water. The endpoint 0.05 mg a.s./L should be used with FOCUS step3 PEC surface water. Message to fate expert meeting: to verify if the endpoint of 0.25 mg a.s./L can be used with the step1 and step2 FOCUS calculations, considering the total load into surface water.	Open point open. RMS to update the LoEP. Message sent to fate section.

	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	See reporting table 5(15)		
	Open point 5.6 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) See reporting table 5(16)	According to the fate meeting the photolytic metabolite is formed under natural condition (see open point 4.10). The meeting agreed that the risk for this metabolite can be considered addressed, since it is less toxic than the parent. A worst case risk assessment could be based on the assumption that the a.s. is immediately converted into metabolite (RMS to update the LoEP using the highest PEC surface water for the parent from the FOCUS step 1).	Open point open. RMS to update the LoEP using the highest PEC surface water for the parent from the FOCUS step 1.
	Open point 5.7 RMS to evaluate in an addendum the new fish ELS study with the formulation. See reporting table 5(19)	The RMS has evaluated the new fish ELS study in the addendum 1. For the ELS study on fish originally reported in the DAR only one concentration was tested (0.007 mg a.s./L). The new ELS study submitted has more than one concentration tested and gives an endpoint of 1.0 mg a.s./L. However, according to Commission Regulation (EC) No 1095/2007 it cannot be taken into account in the peer review. Therefore, the experts agreed to base the risk assessment on the endpoint of 0.007 mg a.s./L.	Open point open. RMS to remove from the LoEP the endpoint derived from the new fish ELS study with the formulation, and to update the risk assessment in the LoEP with the endpoint 0.007 mg a.s./L. Note: the endpoint of 0.007 mg a.s./L becomes the endpoint driving the aquatic risk assessment (RAC=0.7µg a.s./L).

	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
			New data gap proposed for formal reason, see below.
	New data gap 5.2 identified at PRAPeR 63 meeting: Applicant to provide a new fish ELS study with the formulation.		Data gap open.
	Open point 5.8 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 results of the field data from the LoEP. See also data requirement 5(23) and comment 5(29) See reporting table 5(20)	Only brief summaries were provided in English language. The RMS could not assess the full studies. The RMS has removed the results of field data on T.pyri from the LoEP.	Open point fulfilled.
	Open point 5.9 RMS to evaluate in an addendum the new studies with *C. septempunctata* and	The new studies were evaluated by the RMS in the addendum 1, however, according to Commission Regulation (EC) No 1095/2007 they cannot be taken into account in the peer review. The endpoints should be removed from the LoEP.	Open point open. RMS to remove the endpoints derived from the new studies on *C.septempunctata* and *A.*

	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	A. bilineata See reporting table 5(22)		*bilineata* from the LoEP. New data gap proposed, see below.
	New data gap 5.3 identified at PRAPeR 61 meeting: Notifier to complete the dossier for NTA based on the most sensitive life stages.		Data gap open.
5.1	Point of clarification Applicant to submit an English translation of the semi-field and field studies with *T. pyri*. See open point 5(20) See reporting table 5(23)	Refer to open point 5.8 Only brief summaries were provided in English language. However, as it was agreed to remove the results of field data on *T.pyri* from the LoEP and as the results would not change the overall risk assessment, the meeting considered this information no longer necessary.	Point of clarification closed.
	Open point 5.10 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	The RMS reassessed the chronic risk to earthworms in addendum 1. The endpoints were converted from g a.s/ha to mg a.s./kg soil. The correct value to be used is NOEC of 2.56 mg a.s/kg soil.	Open point open. RMS to correct the LoEP with the NOEC of 2.56 mg a.s/kg soil.

	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	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. See reporting table 5(25)		
	Open point 5.11 RMS to evaluate in an addendum the case to address the risk from metabolite AE	The applicant proposed to address the risk to soil organisms for the metabolite AE C593600 by the risk assessment of the parent (due to the similar structure, low toxicity expected, likely presence of metabolite in the studies with the parent). The RMS agreed with the applicant. The meeting agreed.	Open point fulfilled.

	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	C593600 to soil non-target organisms. See also comment 5(29) See reporting table 5(26)		
	Open point 5.12 RMS to evaluate in an addendum the litter bag study. See reporting table 5(28)	The RMS evaluated the study in addendum 1, however in accordance with Commission Regulation (EC) No 1095/2007, it cannot be taken into account in the peer review. Since the DT90f is >365 days, the meeting considered the study necessary.	Open point fulfilled. New data gap proposed, see below.
	New data gap 5.4 identified at PRAPeR 63 meeting: Applicant to provide a litter bag study.		Data gap open.
	Message from PRAPeR 62 meeting of experts (fate section): The experts agreed to inform the ecotoxicology experts' meeting that soil concentrations of 2-chlorobenzoic acid of up to 0.019 mg/kg needs to be assessed (0.268mg/kg x 0.136 x	The experts agreed to calculate the TER for the soil metabolite 2-chlorobenzoic acid assuming a 10 times higher toxicity than the parent for this metabolite.	Answer: New open point proposed, see below.

	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	156/303). (0.268mg/kg is a maximum accumulated soil PEC for clofentezine)		
	New open point: 5.14 RMS to provide in the LoEP TER for the soil metabolite 2-chlorobenzoic acid, assuming a 10 times higher toxicity than the parent for this metabolite.		Open point open.

Appendix 2: Evaluation table

5. Ecotoxicology

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the evaluation group
	Section 5 Open points: ***10*** Points of clarification: ***0*** Data gaps: ***4***			
	Data gap 5.1 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 See reporting table 5(2)	**Clarification of existing studies:** Data to support risk assessment (survey study, radio tracking study…) were provided to the RMS and evaluated in the DAR addendum for orchard and strawberry uses. A new risk assessment based on these data is available in the DAR addendum which concludes that the long term risk to birds is acceptable. Ornamental and grape use can be addressed at MS level.	RMS: 19:12:2008 Refined risk assessment is presented in Addendum 1 and summarised in Addendum 2. For the use on strawberries data were provided on focal species and two species were deemed appropriate for the use – skylark and yellow wagtail. As regards PT 90th values of 0.95 and 0.99 were used for the yellow wagtail and skylark respectively; 50th percentile values of 0.6 and 0.86 were used for yellow wagtail and skylark. Data on FIR and PD were also factored in to the revised risk assessment and the corresponding TERlt for the yellow wagtail were 7.7 and 4.9 depending whether a 50th or 90th percentile was used for PT. As for the skylark, the TERlt were 10.1 and 8.74 depending whether a 50th or 90th percentile was used for PT.	PRAPeR 63 (13-15 January 2009) Data gap still open. New open point proposed, see below.

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the evaluation group
			As regards use on pome fruit data were submitted on focal species and PD and as a result the TERlt was 6.0. No data were submitted to refine the risk to birds present in grapes.	
	New open point: 5.13 RMS to delete from the LoEP the higher tier risk assessment to birds based on PD and PT refinements.			PRAPeR 63 (13-15 January 2009) Open point open.
	Open point 5.1 RMS to include in an addendum the risk assessment for birds from uptake of contaminated drinking water. See reporting table 5(3)	-	RMS: 19:12:2008 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.	PRAPeR 63 (13-15 January 2009) Open point open. RMS to update the LoEP with the acute risk assessment from uptake of drinking water.
	Open point 5.2 RMS to include in an addendum the risk assessment for mammals from uptake of contaminated	-	RMS: 19:12:2008 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	PRAPeR 63 (13-15 January 2009) Open point open. RMS to update the LoEP with the acute

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the evaluation group
	drinking water. See reporting table 5(8)		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.	risk assessment from uptake of drinking water.
	Open point 5.3 RMS to include the aquatic TERs for all uses in the LoEP See reporting table 5(10)	-	RMS: 19:12:2008 Endpoint sheet has been updated.	PRAPeR 63 (13-15 January 2009) Open point fulfilled.
	Open point 5.4 RMS to include in an addendum all details on the studies with aquatic organisms which are required for a transparent and comprehensive 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	-	RMS: 19:12:2008 It should be noted that all studies were carried out to standard protocols and hence issues such as temperature, pH, fish loading 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) in the original DAR.	PRAPeR 63 (13-15 January 2009) Open point open. RMS to provide the key information on the aquatics studies in an addendum.

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the evaluation group
	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) See reporting table 5(11)			
	Open point 5.5 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	-	RMS: 19:12:2008 An assessment of the long-term/chronic *Daphnia magna* studies is provided in Addendum 2. As the water solubility of clofentezine is 0.00252 mg/L or 2.52 µg/L, difficulties were experienced in carrying out studies. As regards the chronic or long-term risk to *Daphnia magna*, it is proposed that one of two endpoints should be used depending upon the main route of exposure – for those where spray drift is the major route, it is proposed to use the endpoint based on the formulation (i.e. 0.25 mg/L), whereas when the route of exposure is	PRAPeR 63 (13-15 January 2009) Open point open. RMS to update the LoEP. Message sent to fate section.

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the evaluation group
	which is currently triggering the risk assessment is changed to a higher value - see open point 5(19) See reporting table 5(15)		due to either drainflow or runoff, an endpoint based on the active substance will be used (i.e. 0.05 mg a.s./L).	
	Open point 5.6 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) See reporting table 5(16)	-	RMS: 19:12:2008 See Open point 4(10) above	PRAPeR 63 (13-15 January 2009) Open point open. RMS to update the LoEP using the highest PEC surface water for the parent from the FOCUS step 1.
	Open point 5.7 RMS to evaluate in an addendum the new fish ELS study with the formulation. See reporting table 5(19)	-	RMS: 19:12:2008 Study has been submitted and evaluated and is presented in Addendum 1. The study was carried to OECD 210 and to GLP and used the formulation. The formulation was used to try to address concerns regarding solubility. The study was considered to be acceptable and the 28-day NOEC was determined to be 1000 µg/L equivalent to 1 mg/L. This was the highest concentration tested.	PRAPeR 63 (13-15 January 2009) Open point open. RMS to remove from the LoEP the endpoint derived from the new fish ELS study with the formulation, and to update the risk assessment in the LoEP with the endpoint 0.007 mg a.s./L. Note: the endpoint of 0.007 mg a.s./L becomes the endpoint driving the aquatic risk assessment (RAC=0.7µg a.s./L).

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the evaluation group
				New data gap proposed for formal reason, see below.
	New data gap 5.2 identified at PRAPeR 63 meeting: Applicant to provide a new fish ELS study with the formulation.			PRAPeR 63 (13-15 January 2009) Data gap open.
	Open point 5.8 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 results of the field data from the LoEP. See also data requirement 5(23) and comment 5(29) See reporting table 5(20)	See below point of clarification 5.1.	RMS: 19:12:2008 See 5.1 point below.	PRAPeR 63 (13-15 January 2009) Open point fulfilled.
	Open point 5.9 RMS to evaluate in an addendum the new studies with *C. septempunctata* and *A. bilineata* See reporting table 5(22)	-	RMS: 19:12:2008 Two studies have been submitted on the toxicity of clofentezine as 'Apollo 50SC'. These studies were designed to determine whether there was any ovicidal or reproductive effect on *C. septempunctata* and *A. bilineata*. These studies indicate that the overall impact of clofentezine on these	PRAPeR 63 (13-15 January 2009) Open point open. RMS to remove the endpoints derived from the new studies on *C.septempunctata* and *A. bilineata* from the LoEP.

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the evaluation group
			species was low. Full details are presented in Addendum 1.	New data gap proposed, see below.
	New data gap 5.3 identified at PRAPeR 61 meeting: Notifier to complete the dossier for NTA based on the most sensitive life stages.			PRAPeR 63 (13-15 January 2009) Data gap open.
5.1	Point of clarification Applicant to submit an English translation of the semi-field and field studies with *T. pyri*. See open point 5(20) See reporting table 5(23)	**Clarification of existing studies:** English translation of the semi-field and field studies with *T. pyri* is provided in the **Attachment IRV5-01** submitted with this evaluation table. The document is based on the existing studies and consequently, it can be taken into consideration in the peer review according to the EFSA document dated 15 November 2007 on the common understanding to clarify the difference between information that may be requested and a study that may not in the context of Regulation (EC) No 1095/2007 dated 15 Nov. 2007.	RMS: 19:12:2008 The Applicant has submitted English translations of these studies and these are presented in Addendum 2.	PRAPeR 63 (13-15 January 2009) Point of clarification closed.
	Open point 5.10 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.	-	RMS: 19:12:2008 In the original DAR a low acute and chronic risk to earthworm from the proposed uses of clofentezine was determined. However, there was some concern regarding the long term risk assessment not being sufficiently addressed, primarily with respect to the selection of the chronic NOEC used in the risk assessment. In the DAR	PRAPeR 63 (13-15 January 2009) Open point open. RMS to correct the LoEP with the NOEC of 2.56 mg a.s/kg soil.

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the evaluation group
	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. See reporting table 5(25)		results from two chronic earthworm studies were considered acceptable: Staebler, 2002b and Rodgers, 2001. A NOEC of 1.5 kg a.s./ha (based on effects at 3.0 kg a.s./ha) using 'Apollo 50SC' was derived in the former study, whilst a NOEC of 5.5 kg a.s./ha, the only rate tested, using another SC formulation was derived from the latter. The Notifier has submitted a case where the effects endpoints have been converted from g a.s./ha in to mg/kg. On the basis of this it is concluded that the long-term risk to earthworms is acceptable. The full assessment is presented in Addendum 1.	
	Open point 5.11 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)	-	RMS: 19:12:2008 The Notifier has proposed that the risk to soil organisms is addressed by the risk assessment for the active substance, due to the following reasons: Similar structure of metabolite AEC593600 to clofentezine Low toxicity of clofentezine to soil	PRAPeR 63 (13-15 January 2009) Open point fulfilled.

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the evaluation group
	See reporting table 5(26)		organisms, Likely presence of the metabolite in studies that assess the toxicity of the active substance (DT50 of clofentezine = 71.3 days). The RMS is in agreement with this and the full case/reasoning is presented in Addendum 1.	
	Open point 5.12 RMS to evaluate in an addendum the litter bag study. See reporting table 5(28)	-	RMS: 19:12:2008 The Notifier has submitted a litter bag study. This study has been conducted according to the latest guidance from EPFES and is considered to be acceptable. There were no significant effects on soil litter degradation over 12 months in soil treated with predicted maximum soil plateau clofentezine level followed by an annual maximum clofentezine application (worse case as no interception assumed). Therefore, the RMS is of the view that this study indicates a low risk to soil processes. An evaluation of this study is presented in Addendum 1.	PRAPeR 63 (13-15 January 2009) Open point fulfilled. New data gap proposed, see below.
	New data gap 5.4 identified at PRAPeR 63 meeting: Applicant to provide a litter bag study.			PRAPeR 63 (13-15 January 2009) Data gap open.
	Message from PRAPeR 62 meeting of experts (fate section): The experts agreed to inform the ecotoxicology experts'			PRAPeR 63 (13-15 January 2009) Answer: The experts agreed to calculate the TER for the soil metabolite 2-chlorobenzoic acid assuming a 10 times higher toxicity

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the evaluation group
	meeting that soil concentrations of 2-chlorobenzoic acid of up to 0.019 mg/kg needs to be assessed (0.268mg/kg x 0.136 x 156/303). (0.268mg/kg is a maximum accumulated soil PEC for clofentezine)			than the parent for this metabolite. New open point proposed, see below.
	New open point: 5.14 RMS to provide in the LoEP TER for the soil metabolite 2-chlorobenzoic acid, assuming a 10 times higher toxicity than the parent for this metabolite.			PRAPeR 63 (13-15 January 2009) Open point open.

Report of PRAPeR Expert MEETING 64

CLOFENTEZINE

Rapporteur Member State: UK

Specific comments on the active substance in the section

2. Mammalian Toxicology

are already listed in the relevant reporting table. Comments submitted for this meeting are listed below.

1. Comments submitted for this meeting:

Date	Supplier	File Name
none		

2. Documents submitted for meeting:

Date	Supplier	File Name
December 2008	UK	Clofentezine addendum 2 Vol3 B5-B6-B7-B8-B9 (December 2008).doc
June 2007	UK	Clofentezine addendum1 Vol3 B5-B6-B7-B9 (June 2007).doc
2008-12-22	UK	Clofentezine evaluation table rev.1-0 (2008-12-22).doc
December 2008	UK	Clofentezine list of endpoints (December 2008).doc
2008-01-03	UK	Clofentezine reporting table rev1-2 (2008-01-03).doc
June 2007	UK	Clofentezine rev Vol4 (June 2007) cover page.doc

3. Documents tabled at the meeting:

Date	Supplier	File Name
none		

The conclusions of the meeting were as follows:

4. **Data on preparations:** Apollo 50 SC

5. **Classification and labelling:** None

6. **Recommended restrictions/conditions for use:** None

7. **Reference List:** Not discussed

Areas of concern: none

Appendix 1: Discussion table: CLOFENTEZINE

Appendix 2: Evaluation table

Appendix 1: Discussion Table, Clofentezine (Ac)

2. Mammalian toxicology

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	Open point 2.1 Oral absorption value to be agreed on in a meeting of experts. See reporting table 2(1)	Studies in 5 species are available, but no data on bile excretion. Therefore the RMS made a very conservative approach and recommended 50% oral absorption. The amount excreted via urine and faeces does not seem to differ after oral or intravenous application. Even if 50% seems to be very conservative, the picture seems to be very unclear and no exact figure of oral absorption can be concluded. The experts decided that the oral absorption seems to be at least 50%, although it is regarded as a very conservative approach.	Open point fulfilled.
	Open point 2.2 The potential for bio-accumulation of clofentezine to be discussed in a meeting of experts. See reporting table 2(4)	No consistent findings in plasma, but some strange peaks were found. Elimination was quite complete after 96h. The overall picture from the study analysed (see tables 6.19 and 6.20 in the DAR) is not consistent; however, it was clear that clofentezine is not bioaccumulating.	Open point fulfilled.
	Open point 2.3 RMS to submit a metabolism scheme in an addendum. See reporting table 2(6)	The metabolic pathway was presented in the addendum 1 to the DAR. The experts agreed upon the Figure B.6.1 on the proposed metabolism of clofentezine in animals.	Open point fulfilled.

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	Open point 2.4 The skin sensitisation potential of clofentezine to be discussed in a meeting of experts. See reporting table 2(8)	The experts agreed that clofentezine is not a skin sensitizer, although the negative M&K test shows some limitations.	Open point fulfilled.
	Data gap 2.1 Applicant to submit a new Ames test. [It should be noted that the study has already been submitted.] See reporting table 2(11)	The new Ames Test was presented in the addendum 2 to the DAR, but it was submitted after the Commission deadline in accordance with Commission Regulation 1095/2007. At the MS level the study can (and should) be considered. The experts re-discussed the available mutagenicity data package of clofentezine and agreed that clofentezine does not have a genotoxic potential. It was also considered that the new Ames test is not expected to change the overall genotox picture of clofentezine.	Data gap open, however it is a requirement at MS level only.
	Open point 2.5 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. See reporting table 2(14)	Limited toxicological information on some metabolites (2-chlorobenzoic acid, 2-chlorobenzonitrile, 2- chlorobenzamide) was reported in the addendum 2 to the DAR. However, this was considered not sufficient to conclude on the toxicological relevance of the metabolites, as well as on specific trigger values. Furthermore, in the residue section their amount has to be clarified after degradation when an eating step is included in the process.	Open point fulfilled.

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	Open point 2.6 Operator exposure to be agreed on in a meeting of experts. See reporting table 2(19)	The operator exposure for greenhouses is based on one EUROPOEM field study (of good quality; 19 operators), but the question has been raised whether this approach would be enough. One expert stated that the safe use is warranted also by Dutch model. The proposal was made to start with a Dutch model and refine/confirm it by field studies (tier-approach). However, due to the ongoing activity of the PPR Panel to prepare an updated Guidance Document on operator exposure assessment, the experts agreed that the safe use proven in the one EURPOEM study is warranted.	Open point fulfilled.
	Data gap 2.2 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.] See reporting table 2(21)	The new China source cannot be accepted (due to Commission Regulation (EC) No 1095/2007), the old one is not valid, because not produced any more. All toxicity studies were performed with the old source. Comparison of tox batches and new source are available, but no comparison of tox batches used and the old source are available. It is not clear if the method of manufacture changed or not. The technical material has 98% purity. The toxicological batches have 98.4% or greater than 99% purity. About the 2% left, information is provided in the Addendum 2 to Volume 4, that can not be taken into account according to Commission Regulation (EC) No 1095/2007.	Data gap open for formal reason. Equivalence of the batches tested in the mammalian toxicology to the representative specification is missing.
	Question from the residue session (PRAPeR 65 meeting) regarding the proportion of 4-hydroxyclofentazine in renal and subcutaneous fat.	It is not unexpected to find this metabolite present in renal fat. It is also expected that renal fat would contain slightly higher amount of the metabolite than in the epidermal fat because of the proximity to the kidneys.	
	Message from fate section (PRAPeR 62 meeting) regarding: relevance of metabolites 2-clorobenzonitrile and 2-chlorobenzoic acid as well as for residues in food a potential groundwater issue may arise.	Limited toxicological information on metabolites 2-chlorobenzoic acid and 2-chlorobenzonitrile was reported in the addendum 2 to the DAR. However, this was considered not sufficient to conclude on the toxicological relevance of the metabolites, as well as on specific trigger values.	

Appendix 2: Evaluation table

2. Mammalian toxicology

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the Evaluation Meeting
	Section 2 Open points: ***0*** Points for clarification: ***0*** Data gaps: ***2***			
	Open point 2.1 Oral absorption value to be agreed on in a meeting of experts. See reporting table 2(1)	**Clarification of existing studies:** The notifier agrees that the 50% figure used is a conservative estimate and absorption is likely to be higher. The notifier draws attention to the fact that, due to rounding of the AOEL (0.01 mg/kg bw/day), the correction for absorption is, in reality even lower at 37%.	RMS : 19.12.2008 The RMS agrees with the Notifier.	PRAPeR 64 (21-23 January 2009) Open point fulfilled.
	Open point 2.2 The potential for bio-accumulation of clofentezine to be discussed in a meeting of experts. See reporting table 2(4)	-		PRAPeR 64 (21-23 January 2009) Open point fulfilled.
	Open point 2.3 RMS to submit a metabolism scheme in an addendum. See reporting table 2(6)	**Clarification of existing studies:** This is shown in the DAR, section B.7.2, Figure 7.2.2, page 236. It has been copied in the DAR addendum under section B.6.1 to	RMS:19.12.2008 See Addendum 1 – proposed metabolism of clofentezine in animals.	PRAPeR 64 (21-23 January 2009) Open point fulfilled.

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the Evaluation Meeting
		meet the NL request. See also point of clarification 3.2		
	Open point 2.4 The skin sensitisation potential of clofentezine to be discussed in a meeting of experts. See reporting table 2(8)	**Additional information on the existing study:** According to reporting table 2(8), clarification of batch used is needed since purity of clofentezine technical (batch CR20099/8) was not recorded in the report. This information has been found in the raw data of the study (See **Attachment IRV2-01**): **The purity** for batch CR20099/8 in January 1982 was **99.7%.** Thus this study is also valid and acceptable. Since this additional information is from raw data of the existing study, it can be taken into consideration in the peer review according to the document prepared by EFSA in November 2007 on the common understanding to clarify the difference between information that may be requested and a study that may not in the context of Regulation (EC) No 1095/2007 dated 15 Nov. 2007. This information was also provided to the RMS in September 2006 as part of the answer to data requirement 4.1.6 (DAR, vol.1, page 87).	RMS 19.12.2008 The RMS notes comments from Notifier, which resolves this issue.	PRAPeR 64 (21-23 January 2009) Open point fulfilled.
	Data gap 2.1 Applicant to submit a new Ames test.	As indicated in Column A, the study (report R-17812) has been already submitted in September 2006. It has been evaluated by the RMS and	RMS: 19.12.2008 The RMS confirms the 'data gap'. The Notifier submitted these data and it has been evaluated by the RMS in	PRAPeR 64 (21-23 January 2009) Data gap open, however it is a requirement at MS level only.

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the Evaluation Meeting
	[It should be noted that the study has already been submitted.] See reporting table 2(11)	described in the DAR addendum. It shows that clofentezine was not mutagenic at up to 5000 µg/plate.	Addendum 1 (Section B.6.4).	
	Open point 2.5 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. See reporting table 2(14)	**Clarification of existing studies:** A document from the notifier on the toxicological relevance of the plant metabolites is provided (See **Attachment IRV2-02**, submitted with this Evaluation Table). The given clarifications further support the conclusion in the DAR that the residue definition for food and feed of plant origin should be clofentezine only. This document is based on the existing studies already described in the DAR. Hence it can be taken into consideration in the peer review according to EFSA document dated 15 November 2007 on the common understanding to clarify the difference between information that may be requested and a study that may not in the context of Regulation (EC) No 1095/2007.	RMS: 19:12:2008 The main residues in fruit crops are the parent clofentezine, and metabolite 2-chlorobenzonitrile. The levels of 2-chlorobenzonitrile found were <0.05 mg/kg, which was approximately a tenth of those of the parent residue. Based on a residue of 0.05 mg/kg and intakes figures for apples (which are the highest values of the proposed crops), potential consumer intakes of 2-chlorobenzonitrile would be < 0.0007 mg/kg bw/day (>4% of the ADI). The issue of the degradation products of 2-chlorobenzonitrile appears to have arisen from their mention in a static study on photo degradation in the Physical Properties Section. In the grape metabolism study they were measured as a total 'polar fraction' (i.e. total sum of all degradation products of 2-chlorobenzonitrile). At the field rate application the sum of all degradation products of 2-chlorobenzonitrile amounted to 0 005 mg/kg or 1.4% of the TRR.	PRAPeR 64 (21-23 January 2009) Open point fulfilled.

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the Evaluation Meeting
			Overall it is considered by the RMS that 2-chlorobenzonitrile or the degradation products of 2-chlorobenzonitrile are of no toxicological significance at these levels, and should not be included in the residue definition. RMS has provided a brief summary of the Notifers case in Addendum 2.	
	Open point 2.6 Operator exposure to be agreed on in a meeting of experts. See reporting table 2(19)	-		PRAPeR 64 (21-23 January 2009) Open point fulfilled.
	Data gap 2.2 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.] See reporting table 2(21)	**Additional information on existing studies:** The equivalence analysis of the batches used in toxicity studies compared to the currently proposed specification was submitted to the RMS in Sep. 2006 to meet data requirement 4.1.6 (DAR, vol.1, page 87) and described in the addendum to the DAR Volume 4. The provided information included the following documents: • Two tables summarising the information known on the test compound used for each toxicity test. • A copy of the detailed certificate of analysis of batch number CR20099/12	RMS: 19:10.2008 'Data gap' (see also open point 1.3 above). See Addendum to Volume 4.	PRAPeR 64 (21-23 January 2009) Data gap open for formal reason. Equivalence of the batches tested in the mammalian toxicology to the representative specification is missing.

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the Evaluation Meeting
		used in many toxicity studies, • A statement (R-20188b – should be treated as confidential business information) giving the historical background to product specification and batch analyses. The tables summarising the information known on the test compounds used in the toxicity studies show that the technical material used was of very high purity (98%, often >99%) all along the years. Only one certificate of analysis including the impurity profile has been found in the archives. It concerns the batch CR 20099/12 used in 8 studies covering all animal species and all type of studies including the most important ones (2-year rat; 18-month mouse; teratology rabbit; 2-generation rat; mutagenicity). The analysis shows that this batch, even from a pilot plant, complies with specifications of the product at that time and it should be considered chemically equivalent to the material being produced today. The document R-20188b demonstrates that: - the active substance has been produced to a very high purity all over the years, - the impurity profile has remained identical all over the years,		

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the Evaluation Meeting
		- the impurities concentrations have remained very similar all over the years. **The material being manufactured today is clearly representative of the material used to assess the toxicity of clofentezine in the 1980's and consequently all end-points should be considered valid for use in risk assessment as appropriate.** This additional information is based on batch analysis information found in the raw data of the existing toxicity studies already described in the DAR and on clofentezine declared specification all over the years. Hence, this information can be taken into consideration in the peer review according to the document dated 15 November 2007 prepared by EFSA on the common understanding to clarify the difference between information that may be requested and a study that may not in the context of Regulation (EC) No 1095/2007.		

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the Evaluation Meeting
	Question from the residue section (PRAPeR 65 meeting) regarding the proportion of 4-hydrohyclofentazine in renal and subcutaneous fat.			PRAPeR 64 (21-23 January 2009) Answer: It is not unexpected to find this metabolite present in renal fat. It is also expected that renal fat would contain slightly higher amount of the metabolite than in the epidermal fat because of the proximity to the kidneys.
	Message from fate section (PRAPeR 62 meeting) regarding: relevance of metabolites 2-clorobenzonitrile and 2-chlorobenzoic acid as well as for residues in food a potential groundwater issue may arise.			PRAPeR 64 (21-23 January 2009) Answer: Limited toxicological information on metabolites 2-chlorobenzoic acid and 2-chlorobenzonitrile was reported in the addendum 2 to the DAR. However, this was considered not sufficient to conclude on the toxicological relevance of the metabolites, as well as on specific trigger values.

REPORT OF PRAPeR EXPERT MEETING 65

CLOFENTEZINE

Rapporteur Member State: UK

Specific comments on the active substance in the section

3. Residues

are already listed in the relevant reporting table. Comments submitted for this meeting are listed below.

1. Comments submitted for this meeting:

Date	Supplier	File Name
none		

2. Documents submitted for meeting:

Date	Supplier	File Name
December 2008	UK	Clofentezine addendum 2 Vol3 B5-B6-B7-B8-B9 (December 2008).doc
June 2007	UK	Clofentezine addendum1 Vol3 B5-B6-B7-B9 (June 2007).doc
2008-12-22	UK	Clofentezine evaluation table rev.1-0 (2008-12-22).doc
December 2008	UK	Clofentezine list of endpoints (December 2008).doc
2008-01-03	UK	Clofentezine reporting table rev1-2 (2008-01-03).doc
June 2007	UK	Clofentezine rev Vol4 (June 2007) cover page.doc

3. Documents tabled at the meeting:

Date	Supplier	File Name
none		

The conclusions of the meeting were as follows:

4. **Data on preparations:** APOLLO 50 SC

5. **Classification and labelling:** None.

6. **Recommended restrictions/conditions for use:** Only the fruit crop category is covered by acceptable metabolism studies.

7. **Reference List:** No discussed.

Areas of concern: The consumer risk assessment cannot be finalised because the residue definition for processed commodities is provisional expecting clarification on the toxicological relevance of identified metabolites both in primary crops and in processed commodities (2-chlorobenzonitrile may be more toxic than the parent). Insufficient number of residue trials (except of strawberries-outdoor) on apples, plums and grapes in compliance with the supported uses. In addition, no conclusion can be drawn on the residue definition for products of animal origin.

Appendix 1: Discussion table: CLOFENTEZINE

Appendix 2: Evaluation table

Appendix 1: Discussion Table, Clofentezine (Ac)

3. Residues

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	Open point. 3.1 Storage stability of clofentezine residues to be discussed in expert meeting – Information on procedural recovery in the submitted studies would help discussion. See reporting table 3(2)	The RMS confirmed that procedural recovery data are available showing recoveries of 73%-100% for peaches and 62%-83% for almonds (these data were not reported in the DAR but only in the reporting table and the evaluation table). <u>Peaches:</u> In the DAR (Table B.7.22), recoveries were very low (61%) for both the 2 fortification levels at one time point (after a frozen storage period of 246 days), although the procedural recoveries amounted 91%. Recoveries were however above 70% for the other time intervals, up to 2 years. The meeting noted that there was no clear increase in the recoveries after 246 days, which means that there may have been some underestimation in the recovered residue levels from the residue trials. However, the RMS mentioned that the maximum storage interval for all the residue trials samples was of 98 days. This storage interval is covered by acceptable recoveries. The meeting concluded that the peach frozen storage stability study was acceptable. <u>Almonds:</u> The recoveries were very low after 3 months (49-61%) at the 2 fortification levels in almond nutmeat. There is no data between the 0 and 3 months time points. This is not a real concern, since oil containing commodities are not supported uses. In the raw data the RSD values were reported for almonds nutmeat (19 %) for the 2 fortification levels that is quite high, but still acceptable (trigger: 20%). The meeting was of the opinion that this study was not useful considering the supported use pattern. But one has to keep in mind that further clarifications should be brought about the low recoveries observed in the DAR (table B.7.23) for almond nutmeat, once further uses on oily matrices will be supported in the future.	Open point fulfilled.

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	Open point 3.2 RMS to check whether NC 22505 was actually as reference compound in lemon peach and grape metabolism studies. See reporting table 3(3)	The metabolite NC 22505 was found in the apple metabolism study. The applicant provided an argumentation that this metabolite was in fact an artefact on the TLC analysis. To address this point, the notifier provided an attachment IRV3-02. This was proven to be the case in a later study reported by Leake and Arnold, 1983a (DAR, p 289-290). Therefore, the meeting agreed that it can be concluded that the metabolite NC 22505 is not a plant metabolite.	Open point fulfilled.
3.1	Point of clarification for the applicant Applicant to propose a metabolic pathway in fruits as complete as possible on the basis of available information. See reporting table 3(4)	A complete fruit metabolic pathway has been provided in the Addendum 2 of December 2008, this pathway is in line with the metabolism data provided in the DAR on apples, lemons, peaches and grapes.	Point of clarification addressed.
	Open point.3.3 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	The cattle metabolism study has been summarised in tabular form in the tables B.7.1 and B.7.2, page 13 of the Addendum 2 of December 2008. According to these data, the parent compound was never detected. Only the metabolite 4-OH-clofentezine was recovered at significant levels ranging from 68% TRR (fat) to 83% TRR (kidney). However, a significant part of the TRR was not characterised (22%, 18% and 12% of the TRR in fat, milk and liver respectively). The meeting pointed out that the metabolic pathway presented in the addendum 2 (Figure 7.2) shows metabolites that were not observed in the goat study described in the residue section of the DAR, where only the 3-OH-clofentezine and 4-OH-clofentezine were detected. The RMS explained that this metabolic pathway was based on the goat metabolism studies reported both in the mammalian toxicology section and the residue section of the DAR; the study available in the toxicology section (1985) giving further information on the metabolites identified in liver.	Open point fulfilled. New open point proposed, see below.

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	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. See reporting table 3(5)	The meeting was of the opinion that all the available metabolism studies on ruminants must be evaluated together in the residue section in order to give a robust and complete picture of the metabolic pathway of clofentezine and asked the RMS to provide a complete assessment based on all the available studies. No residue definition for products of animal origin was proposed by the meeting. This point should be discussed again, pending the complete assessment of the available goat metabolism studies and the outcome of the residue definition for processed commodities (see open point 3.9).	
	New open point 3.10 RMS to provide a complete assessment of the available metabolism studies in ruminants (from the mammalian toxicology and residue sections) in order to depict a complete metabolic pathway of clofentezine in ruminants and to propose a residue definition for products of animal origin.		Open point open.
	Open point. 3.4 MS to examine the discrepancy of renal and subcutaneous fat radioactive content in cattle metabolism	In the cattle metabolism study, the residue levels in renal fat and in subcutaneous fat matrices were respectively 0.262 mg/kg and 0.020 mg/kg (Table B.7.16 in the DAR). According to the clarification provided by the applicant, the higher residue level observed in renal fat reflects the proximity of this matrix from the excretion organs. The meeting considered this assumption as a new approach that should be further discussed with veterinary or toxicological experts. Therefore, the mammalian toxicology	Open point fulfilled. (see answer to Message 2 from the mammalian toxicology section).

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	study. See reporting table 3(6)	expert meeting was asked to give its opinion on this concern. The following answer was returned to the residues meeting: "*It is not unexpected to find this metabolite present in renal fat. It is also expected that renal fat would contain slightly higher amount of the metabolite than in the epidermal fat because of the proximity to the kidneys"*. Taking into account this answer, the meeting considered the explanation provided by the applicant as satisfactory.	
3.2	Point of clarification for the applicant 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. See reporting table 3(8)	The notifier provided a metabolic pathway for ruminants in the addendum 2 (Figure B.7.2). The RMS explained that the pathway provided is based on the metabolism studies performed on rat and on the goat metabolism studies provided both in the mammalian toxicology and residue sections of the DAR. Thus, this point of clarification was considered as addressed by the meeting. However, the metabolic pathway has to be discussed again with regard to the new open point 3.10 (see also open point 3.3).	Point of clarification addressed. (refer to the new open point 3.10).
	Open point: 3.5 Residue definition for risk assessment in plant commodities to be discussed in expert meeting. See also comment 3(16)	The **residue definition for monitoring** in plant commodities is **clofentezine**, alone (fruit crops only). According to the RMS tox experts, the metabolite 2-chlorobenzonitrile should not be included in the residue definition for risk assessment. This metabolite was recovered in the surface washings in proportions of 8.9% in the lemon study and 8.4% in the peach study (at 54 and 62 days PHI respectively), and accounted 11.3% of the TRR in the dichlomethane grape fractions at 24-25 days PHI. The meeting expressed its concern regarding 2-chlorobenzonitrile, since this metabolite is: - classified,	Open point fulfilled. New data gap proposed, see below.

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	See reporting table 3(9)	- more acute toxic than the parent, - recovered at non negligible amounts in the processed commodities, - not recovered in the rat metabolism and therefore not covered by the mammalian toxicology studies. Since this metabolite is expected to be present in proportion of *c.a.* 10% of the TRR and taking into account the highest residue levels of 0.24 mg/kg observed in the apple residue trials, 2-chlorobenzonitrile residue levels are supposed to be 0.024 mg/kg. In addition, the experts were informed that the meeting on mammalian toxicology concluded that the available studies were not sufficient to give an opinion on the toxicological relevance of this metabolite. The meeting has a concern whether this metabolite is covered by the ADI of the parent compound and the fact that an ARfD was considered as unnecessary. Considering the points above, the meeting decided, as a precautionary measure, to **include the 2-chlorobenzonitrile in the residue definition for the risk assessment,** and concluded that a conversion factor has to be derived from the metabolism studies on fruits. Finally, the residue meeting was of the opinion that the applicant should provide clarification on the necessity to set toxicological reference values for the 2-chlorobenzonitrile.	
	New data gap 3.3 identified at PRAPeR 65 meeting: The notifier to address the toxicological relevance of the 2-chlorobenzonitrile.		Data gap open.
	Open point.3.6 Fat solubility of animal residues to be discussed in an expert meeting on the basis of	For clofentezine, the Log Pow is 4.09 at 25°C and 3.1 at 20°C (see List of endpoints). Based on these values, the Log Pow for 4-OH-clofentezine is estimated to be 3.61 (by calculation) and this compound should also be considered as fat soluble. In conclusion and according to the provisional residue definition (parent + 4-OH-clofentezine), the residues has to be considered as fat soluble and the open point fulfilled.	Open point fulfilled. (see new open point 3.10 related to open point 3.3)

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	the residue definition. Note: The feeding study in lactating cow was conducted with a common moiety method (refer to comment 3.25) See reporting table 3(10)	If necessary and pending the new open point 3.10 under open point 3.3, this point should be reopened.	
	Open point.3.7 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) See reporting table 3(11)	Clarifications concerning the dose rates were provided by the applicant (see Evaluation table). The spray volume concentrations in the DAR (as kg a.s./ha) were calculated for a water volume of 1000 L/ha. The list of endpoints has to be updated.	Open point fulfilled. New open point proposed, see below.
	New open point 3.11 RMS to update the GAP in the list of endpoints taking into account the clarification concerning the dose rate.		Open point open.

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	Data gap 3.1 Applicant to submit 4 trials on plums in Southern Europe and 8 trials on strawberries under glass. See also comment 3(13) See reporting table 3(17)	Except for strawberries, the meeting noted that most of the residue trials were performed with an application rate of 300 g as/ha instead of 200 g as/ha as specified in the critical GAPs, and with two applications instead of one. The meeting had a general discussion on whether this complete overdosed residue data package can be acceptable. Finally, the experts concluded that such a data base is not fully acceptable to set MRLs and additional information has to be requested. **- On plums,** all the available trials were performed at 2 applications at 300 g as/ha and therefore the complete residue data base cannot be accepted because of the overestimation of the actual residue levels on this crop (critical GAP: 1 application at 200 g as/ha). **- On grapes**, all the trials were conducted with and application rate of 300 g as/ha (instead of 200 g as/ha) and some of them with a total of two applications. **- On apples**, the expression of the dose rates is unclear, the dose rates being often expressed as g as/hl but without information on the amount of water applied, and finally without information on the dose rates per ha. Moreover, contrary to the conclusion expressed in the DAR, the residue database for apples should be considered as not complete, since many replicate values from a single residue trial (same location, same variety, same application date…) were considered as individual residue trial. Considering the above reasons, the meeting confirmed that additional residue trials performed in compliance with the critical GAP have to be requested on plums, grapes and apples. Taking into account the discussion under the open point 3.5, the applicant should also consider the 2-chlorobenzonitrile in the new residue data package. The data gap has to remain open. Nevertheless, the experts highlighted that the MRLs proposed in the DAR and derived from these overdosed trials lead to an overestimation in the risk assessment calculation. On strawberry, the database was considered complete for outdoor uses only. No information was provided to support the indoor use and the data gap has to remain open. It seems that the notifier has indoor trials on strawberries, but he did not provide them.	Data gap still open: The data requested on plums in Southern EU and strawberries (indoor) remain open. New data gap proposed, see below.
	New data gap 3.4 identified at PRAPeR 65 meeting:		Data gap open.

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	The notifier is asked to provide a complete date base for plum, grape and apple in compliance with the intended GAP. In addition, the notifier should consider the analysis of the 2-chlorobenzonitrile in the new residue data package.		
	Data gap 3.2 Applicant to submit 4 additional residue trials for the Northern Europe in grapes. See reporting table 3(18)	The request is covered by the data gap mentioned above.	Data gap closed. (see data gaps 3.1 and 3.4 above)
	Open point.3.8 The residue definition for risk assessment in processed commodities needs to be discussed in expert meeting. See also comment 3(20) See reporting table 3(19)	According to the study on the nature of the residues (Table B.7.25 in the DAR), the following metabolites might be recovered in the processed commodities: 2-chlorobenzoic acid [(2-chlorobenzylidene) hydrazide], 2-chlorobenzonitrile and, 2-chlorobenzamide. The increase of the temperature in the process increases the parent degradation. At 120°C and pH 6 the parent clofentezine is totally degraded into these 3 metabolites (77%, 4.9 % and 17 % of the TRR, respectively). Moreover, these metabolites were not recovered in the rat metabolism study, and 2-chlorobenzonitrile is considered as toxicologically relevant (see open point 3.5). Except one study (table B.7.30 in the DAR), these metabolites were not analysed in the processing studies, and no information was provided concerning their possible residue levels in the processed commodities. Moreover, there are clear evidences of a possible	Open point fulfilled. New open point proposed, see below. New data gaps proposed, see below.

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
		degradation of the parent compound during the process, since clofentezine residue levels were shown to be higher in wet pomace than in dry pomace (see table B.7.31 in the DAR). Different questions were raised about whether or not all the metabolites have a higher toxicity than the parent compound or whether these metabolites show a similar toxicological profile or not. In conclusion, the meeting was of the opinion that the **residue definition for monitoring** for processed commodities should at least include the **parent clofentezine and 2-chlorobenzonitrile metabolite**. However, considering the study on the nature of the residue where the 2-chlorobenzoic acid and 2-chlorobenzamide were observed in significant proportions, and taking into account the information collected after a rapid check on the website stating that 2-chlorobenzamide is suspected to be carcinogen, the meeting concluded that these two additional metabolites should not be ignored. The meeting concluded that further clarification on the toxicological relevance of the 2-chlorobenzoic acid and 2-chlorobenzamide are needed in order to finalise the residue definition for risk assessment. Pending the outcome of this clarification, the residue definition for risk assessment in processed commodities should be: - either limited to the parent and the 2-chlorobenzonitrile only, - or extended to the parent and the 3 mentioned metabolites. In addition, further studies on the magnitude of residues in processed commodities taken into account the final residue definition for risk assessment have to be provided for all the supported crops. It was also mentioned that the processing experiments should include a heating step of at least 90 °C (pasteurization/sterilization in canned fruit, brewing for cereals, …). Considering the current residue definition as stated in EC Regulation 396/2005, “sum of all compounds containing the 2-chlorobenzoyl moiety expressed as clofentezine”, the meeting noted that a possible residue definition for risk assessment might be the “sum of	

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
		all compounds containing the 2-chlorobenzoyl moiety expressed as the most toxic compound".	
	New data gap 3.5 identified at PRAPeR 65 meeting: Notifier to provide further clarification on the toxicological relevance of the 2-chlorobenzoic acid and 2-chlorobenzamide (Toxicological relevance of 2-chlorobenzonitrile requested under new data gap 3.3)		Data gap open.
	New data gap 3.6 identified at PRAPeR 65 meeting: Notifier to provide new processing studies according to the new definition of residue for risk assessment established in processed commodities.		Data gap open.
	New open point 3.13 The proposal for a residue definition for risk assessment in the processed commodities has to be reconsidered with regard to the		Open point open.

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	toxicological relevance of the metabolites (see new data gap 3.5) and the results of the processing studies requested under the new data gap 3.6		
	Open point.3.9 MS to discuss the appropriateness of the feeding study (method of analysis) with regard to the residue definition in animal products. See reporting table 3(25)	A common moiety analytical method was used to perform the analyses in the feeding studies. This method was designed to determine clofentezine as sum of all compounds containing the 2-chlorobenzoyl moiety (expressed as clofentezine), this common moiety method being sufficiently validated. For clofentezine, the meeting calculated the dietary intake by livestock to be 0.0147 mg/kg bw/day (dairy cattle) and 0.0519 mg/kg bw/day (beef cattle) using the STMR-p for apple pomace (STMR apple 0.16 mg/kg x Processing Factor 5.8). Hence, the overdosing factor can be considered as 11 fold the lower dose rate used in the feeding study, and the residue levels in all the animal matrices are expected to be below 0.02 mg/kg. However, the meeting raised the concern that this calculation is based on the intake of the parent compound only. The actual residue level (parent + possible metabolites) in the processed feed (apple pomace) is unknown in order to estimate the actual dietary intake by animals. There is a lack of information on the metabolites recovered in pomace. Moreover, clarification on the toxicological relevance of the different metabolites is needed and the residue definition in animal matrices is not finalised (see open point 3.8). In conclusion, the meeting was unable to conclude on the appropriateness of the available feeding studies and the open point was left open.	Open point fulfilled. New open point proposed, see below.
	New open point 3.14 The appropriateness of the feeding study has to be reconsidered when the residue definition for products of animal origin and the residue definition		Open point open.

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	for the processed commodities are finalised (see new open point 3.10 and open point 3.8)		
	New open point 3.12 RMS to amend the List of endpoints according to the discussions at the PRAPeR 65 meeting.		Open point open.
	Message 1 to mammalian toxicology meeting (PRAPeR 64) regarding the toxicological relevance of clofentezine metabolites (2-chlorobenzoic acid, 2-chlorobenzonitrile, 2-chlorobenzamide).	Message 1 Clofentezine is totally degraded under conditions simulating pasteurization to 2-chlorobenzoic acid (78% TRR), 2-chlorobenzonitrile (5% TRR) and 2-chlorobenzamide (17% TRR). No information was provided on the possible residue levels of these degradation compounds in processed commodities where only the parent clofentezine was analyzed for. Having regard to the residue levels observed in the raw agricultural commodities when clofentezine is used in compliance with the proposed GAP (MRLs; apples 0.5 mg/kg, grapes 1 mg/kg, strawberries 2 mg/kg…), significant levels of these degradation products could be expected in the processed commodities when an eating step is included in the industrial process. 1 - Are any of these degradation compounds of significant toxicological concern to be taken into account in the processed commodities? 2 - Are toxicological end-points available for these degradation compounds?	Answer from PRAPeR 64 meeting (mammalian toxicology): Limited toxicological information on some metabolites (2-chlorobenzoic acid, 2-chlorobenzonitrile, 2-chlorobenzamide) was reported in the addendum 2 to the DAR. However, this was considered not sufficient to conclude on the toxicological relevance of the metabolites, as well as on specific trigger values. Further, it has to be clarified in the residue section their amount after degradation when an eating step is included in the process
	Message 2 to mammalian toxicology meeting (PRAPeR 64) regarding the proportion of 4-hydroxyclofentezine in renal and	Message 2 In the cattle metabolism study a discrepancy was observed in the TRR levels detected in the renal fat (0.26 mg/kg) and the subcutaneous fat (0.02 mg/kg). Considering that the residue mainly consists of 4-OH-clofentezine (70% TRR), (the parent compound being not observed), the explanation provided by the applicant is the following: “This difference reflects the proximity of the renal fat samples to the main organs of	Answer from PRAPeR 64 meeting (mammalian toxicology): It is not unexpected to find this metabolite present in renal fat. It is also expected that renal fat would contain slightly higher amount of the

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	subcutaneous fat.	excretion. The only major residue in the renal fat was 4-hydroxyclofentezine which is also the major product excreted in urine". Is it usual to observe such a difference and is this explanation acceptable?	metabolite than in the epidermal fat because of the proximity to the kidneys."

Appendix 2: Evaluation table

3. Residues

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the Evaluation Meeting
	Section 3 Open points: ***4*** Points for clarification: ***0*** Data gaps: ***5***			
	Open point. 3.1 Storage stability of clofentezine residues to be discussed in expert meeting – Information on procedural recovery in the submitted studies would help discussion. See reporting table 3(2)	**Clarification of existing study:** Information on procedural recovery has been summarised in the **Attachment IRV3-01** submitted with this evaluation table. The figures provided in this document come from the study reports already listed in the DAR. Hence, they can be taken into consideration in the peer review according to EFSA document dated 15 November 2007 on the common understanding to clarify the difference between information that may be requested and a study that may not in the context of Regulation (EC) No 1095/2007.	RMS: 19:12:2008 Procedural recovery data were available for peaches and almonds and showed recoveries of 73 – 100% for peaches and 62-83% for almonds. In the case of peaches the procedural recoveries associated with the 246 day sample were recoveries were low (61%), the procedural recovery was 91%. For the almond nut meal 3 and 24 month samples which gave recoveries of 49-61% and nd-34%, procedural recoveries were 72-114% and 62-69%. The RMS still considers that the studies indicate stability after 21 months for peaches and 12 months for nut meal Open point addressed.	PRAPeR 65 (22-23 January 2009): Open point fulfilled.

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the Evaluation Meeting
	Open point 3.2 RMS to check whether NC 22505 was actually as reference compound in lemon peach and grape metabolism studies. See reporting table 3(3)	**Clarification of existing studies:** A clarification from the notifier to address this point is provided (See **Attachment IRV3-02**, submitted with this Evaluation Table). This document demonstrates that the compound NC 22505 reported as a plant metabolite by Warner (DAR, p 207-209) was an artifact of the TLC analysis used in the study. This was proven to be the case in a later study reported by Leake and Arnold, 1983a (DAR, p 289-290). Therefore, it can be concluded that NC 22505 is not a plant metabolite. As not expected to be a genuine metabolite, the reference substance NC 22505 was not used in later plant metabolism studies, and is not included in the plant metabolism scheme. Since the Attachment IRV3-02 is based on existing studies already described in the DAR, it can be taken into consideration in the peer review according to EFSA document dated 15 November 2007 on the common understanding to clarify the difference between information that may be requested and a study that may not in the context of Regulation (EC) No	RMS: 19:12:2008 See applicants case in the left hand column, which RMS considers addresses the open point. Open point addressed.	PRAPeR 65 (22-23 January 2009): Open point fulfilled.

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the Evaluation Meeting
		1095/2007. **Important footnote:** *NC 22505 is reported as a plant metabolite in the present discussion. Hence, the comment about the Vol 4, confidential information, in Column 3 of the reporting table point 3(3) is inadequate and the notifier requests that **this comment should be deleted (sanitised)** from any documentation prior to publication of the final peer review report.*		
3.1	Point of clarification for the applicant Applicant to propose a metabolic pathway in fruits as complete as possible on the basis of available information. See reporting table 3(4)	**Clarification of existing studies:** A metabolism pathway in fruits is proposed on the basis of existing studies already described in the DAR. The scheme is provided in **Figure 1** of the above mentioned **Attachment IRV3-02** submitted with this Evaluation Table. This scheme can replace that given in Figure 7.1 of the DAR (page 228). This better reflects the results of the plant metabolism studies summarised in both the dossier and DAR. Attachment IRV3-02 clarifies the route of degradation in plants but does not in any way alter the primary conclusion that the definition of the residues for both risk assessment and monitoring in	RMS: 19:12:2008 Updated pathway in Addendum 2 Point addressed.	PRAPeR 65 (22-23 January 2009): Point of clarification addressed.

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the Evaluation Meeting
		plants should be clofentezine only (see DAR, page 237).		
	Open point.3.3 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. See reporting table 3(5)	-	RMS: 19:12:2008 Table in Addendum 2 for the cattle study (hen study already contains the required table) Open point addressed.	PRAPeR 65 (22-23 January 2009): Open point fulfilled. New open point proposed, see below.
	New open point 3.10 RMS to provide a complete assessment of the available metabolism studies in ruminants (from the mammalian toxicology and			PRAPeR 65 (22-23 January 2009): Open point open.

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the Evaluation Meeting
	residue sections) in order to depict a complete metabolism pathway of clofentezine in ruminants.			
	Open point. 3.4 MS to examine the discrepancy of renal and subcutaneous fat radioactive content in cattle metabolism study. See reporting table 3(6)	**Clarification of existing studies:** A clarification from the notifier on discrepancy of renal and subcutaneous fat radioactive content in cattle metabolism study is provided to answer comment 3(6) of the reporting table (See **Attachment IRV3-03**), submitted with this Evaluation Table). The 10-fold difference in TRR observed in renal fat and subcutaneous fat 16 hours after the last of 3 oral doses of [^{14}C]clofentezine to a cow reflects the proximity of the renal fat samples to the main organs of excretion. The only major residue in the renal fat was 4-hydroxyclofentezine which is also the major product excreted in urine. Other studies in rats provide evidence that the residue is likely to be rapidly eliminated and does not bioaccumulate in this tissue. This document is based on the existing studies already described in the DAR. Hence it can be taken into consideration in the peer review according to EFSA document dated 15	RMS: 19:12:2008 See applicants case in the left hand column, which RMS considers addresses the open point. Open point addressed.	PRAPeR 65 (22-23 January 2009): Open point fulfilled. (see answer to Message 2 from the mammalian toxicology section).

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the Evaluation Meeting
		November 2007 on the common understanding to clarify the difference between information that may be requested and a study that may not in the context of Regulation (EC) No 1095/2007.		
3.2	Point of clarification for the applicant 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. See reporting table 3(8)	**Clarification of existing studies:** A scheme of metabolism pathway in livestock is provided as **Attachment IRV3-04** to this evaluation table. It is based on livestock metabolism studies reported in the DAR under section B.7 and on comparative metabolism studies reported in the DAR under section B.6. This attachment first includes a table detailing the metabolites of clofentezine and the matrices in which they are reported for ease of reference. To clarify, 3- & 4-hydroxy clofentezine were detected in the baboon, goat, cow, calf & hen. The 5-hydroxy clofentezine and the methyl thio metabolite were detected in the calf and goat. All the above were detected in the rat. Thus the scheme included in the Attachment IRV3-04 (reported as Fig 7.2.2, DAR p 236) correctly represents the metabolism in animals (rodent and livestock).	RMS: 19:12:2008 See applicants case in the left hand column, which RMS considers addresses the point. Point of clarification addressed.	PRAPeR 65 (22-23 January 2009): Point of clarification addressed. (see also new open point 3.10).

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the Evaluation Meeting
	Open point:3.5 Residue definition for risk assessment in plant commodities to be discussed in expert meeting. See also comment 3(16) See reporting table 3(9)	**Clarification of existing studies:** As indicated above (see open point 2.5), clarifications from the notifier on the toxicological relevance of the plant metabolites are provided (see above mentioned **Attachment IRV2-02**, submitted with this Evaluation Table). The given clarifications further support the conclusion in the DAR that the residue definition for food and feed of plant origin should be clofentezine only. Since this clarification document is based on the existing studies already described in the DAR, it can be taken into consideration in the peer review according to EFSA document dated 15 November 2007 on the common understanding to clarify the difference between information that may be requested and a study that may not in the context of Regulation (EC) No 1095/2007.	RMS: 19:12:2008 The main residues in fruit crops are the parent clofentezine, and metabolite 2-chlorobenzonitrile. The levels of 2-chlorobenzonitrile found were <0.05 mg/kg, which was approximately a tenth of those of the parent residue. Based on a residue of 0.05 mg/kg and intakes figures for apples (which are the highest values of the proposed crops), potential consumer intakes of 2-chlorobenzonitrile would be < 0.0007 mg/kg bw/day (>4% of the ADI). Overall it is considered that 2-chlorobenzonitrile is of no toxicological significance at these levels, and should not be included in the residue definition. Open point addressed.	PRAPeR 65 (22-23 January 2009): Open point fulfilled. New data gap proposed, see below.
	New data gap 3.3 identified at PRAPeR 65 meeting: Notifier to address the toxicological relevance of 2-chlorobenzonitrile.			PRAPeR 65 (22-23 January 2009): Data gap open.
	Open point.3.6 Fat solubility of animal residues to be discussed in	See related open point 3.4 above. **Clarification of existing studies:**	RMS: 19:12:2008 See applicants case in the left hand column, which RMS considers	PRAPeR 65 (22-23 January 2009):

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the Evaluation Meeting
	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) See reporting table 3(10)	Using the physical chemical properties prediction software, EPIWIN V 3.12 the Log Kow (KOWWIN v 1.67 estimate) for clofentezine is 2.70 and for 4-hydroxy clofentezine 2.22. Experimentally derived Log Kow for clofentezine is 4.09 (DAR page 11). EPIWIN can also make an estimate of the adjustment in value of the parent by the addition of an OH fragment. This value is -0.48 giving a Log Kow for 4-OH clofentezine of 3.61. On this basis 4-OH would be expected to be fat-soluble. This is evidenced by the fact that it was the major residue in cow renal fat samples. However, there is no evidence to suggest that either clofentezine or the metabolite will bioaccumulate in fat tissue. This is discussed in the **Attachment IRV3-03** attached to this table. The residue definition for foodstuffs of **animal** origin should be confirmed as stated in **Reg (EC) No 396/2005** as the **sum of all compounds containing the 2-chlorobenzoyl moiety expressed as clofentezine**	addresses the open point .Open point addressed.	Open point fulfilled. (see new open point 3.10 related to open point 3.3)
	Open point.3.7 Applicant to clarify the representative uses so that	**Clarification on intended uses:** In the list of intended uses in Europe presented in tabular form in the DAR,	RMS: See applicants case in the left hand column, which RMS considers addresses the open point	PRAPeR 65 (22-23 January 2009): Open point fulfilled.

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	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) See reporting table 3(11)	spray volume concentrations (kg a.s./hL) were only calculated for a water volume of 1000 L/ha: - In orchards, strawberries and ornamentals, the minimum and maximum rates are 0.1 and 0.2 kg a.s./ha, which correspond to 0.01 and 0.02 kg a.s./hL, respectively, with a water volume of 1000 L/ha. - In grapes, the rates range 0.1-0.15 kg a.s./ha corresponding to 0.01-0.015 kg a.s./hL when a water volume of 1000 L/ha is used. The notifier agrees that this option can have been made the reading of the GAP table confusing. However, the notifier totally supports the view of the RMS concerning residue trials evaluation. To clarify, at the maximum application rate of **0.2 kg a.s./ha** (orchards, strawberries, ornamentals), the concentration ranges are as follows: Orchards --> 0.013-0.05 kg a.s./hL (400–1500 L water/ha) Strawberries --> 0.013-0.04 kg a.s./hL (500–1500 L water/ha) Ornamentals --> 0.008-0.04 kg a.s/hL	Open point addressed.	New open point proposed, see below.

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		(500-2500 L water/ha) At the maximum application rate of **0.15 kg a.s./ha** (grapes), the concentration range is as follows: Grapes --> 0.015-0.05 kg a.s/hL (300-1000 L water/ha)		
	New open point 3.11 RMS to update the GAP in the list of endpoints taking into account the clarification concerning the dose rate.			PRAPeR 65 (22-23 January 2009): Open point open.
	Data gap 3.1 Applicant to submit 4 trials on plums in Southern Europe and 8 trials on strawberries under glass. See also comment 3(13) See reporting table 3(17)	Strawberry data are available upon request. Plum use is not supported anymore.		PRAPeR 65 (22-23 January 2009): Data gap still open: The data requested on plums in Southern EU and strawberries (indoor) remain open. New data gap proposed, see below.
	New data gap 3.4 identified at PRAPeR 65 meeting: The notifier is asked to provide a complete data base for plum, grape and apple in compliance with the intended GAP. In addition, the notifier should			PRAPeR 65 (22-23 January 2009): Data gap open.

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	consider the analysis of the 2-chlorobenzonitrile in the new residue data package.			
	Data gap 3.2 Applicant to submit 4 additional residue trials for the Northern Europe in grapes. See reporting table 3(18)	**Clarification on existing studies:** As stated in the DAR (p258*): "Observed residues in these trials fluctuate quite significantly"*. Deciding if the trials should be treated separately based on a comparison of the mean values is not valid when the data are scattered. The ranges of residues detected 0.12[1]-0.89 for NEU and 0.09-0.67 for SEU show considerable overlap, as do the statistical ranges when the standard deviation of the mean values is considered. When this is taken into account the NEU mean ± SD value is 0.48 ± 0.34 ppm (5 results[1]) and the SEU mean ± SD value is 0.28 ± 0.19 ppm (9 results). Thus statistically residues lie in the range (mean to one sigma limit) 0.14-0.82 ppm for NEU and 0.09-0.47 ppm for SEU and overlap. This method is recommended in SANCO 7525/VI/95-rev 2 section 2.2. Furthermore, the Rmax values are falling in neighbouring MRL categories (1 and 2 mg/kg), thus, meeting the second criteria of the guidance document.	RMS: 19:12:2008 Agrees with the data requirement for 4 further trials from Northern member states, as the mean residue and maximum residue are higher in the Northern member state trial samples. Data requirement.	PRAPeR 65 (22-23 January 2009): Data gap closed. (see data gaps 3.1 and 3.4 above)

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		The overall MRL calculation takes this variation into account and as stated in the DAR the MRL of 1 ppm "*is in line with the current EU MRL and whilst this supports a GAP at 2 X application rate all residues were below the current MRL*". In conclusion, the notifier agrees with the RMS handling of these trials as described in the DAR. [1] This value should not be disregarded: Trial Chaintré, France, 1991, NEU (DAR p 253) has residue 0.12 underlined in the DAR. Thus the LOEP is correct as the SMTR and the endpoints should not have been updated as indicated in the reporting table, comment 3(15).		
	Open point.3.8 The residue definition for risk assessment in processed commodities needs to be discussed in expert meeting. See also comment 3(20) See reporting table 3(19)	-	RMS: 19:12:2008 Overall it is considered by the RMS that 2-chlorobenzonitrile or the degradation products of 2-chlorobenzonitrile are of no toxicological significance at these levels, and should not be included in the residue definition and further data are not required.	PRAPeR 65 (22-23 January 2009): Open point fulfilled. New open point proposed, see below. New data gaps proposed, see below.
	New data gap 3.5 identified at PRAPeR 65 meeting: Notifier to provide further			PRAPeR 65 (22-23 January 2009): Data gap open.

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	clarification on the toxicological relevance of the 2-chlorobenzoic acid and 2-chlorobenzamide (Toxicological relevance of 2-chlorobenzonitrile requested under new data gap 3.3)			
	New data gap 3.6 identified at PRAPeR 65 meeting: Notifier to provide new processing studies according to the new definition of residue for risk assessment established in processed commodities.			PRAPeR 65 (22-23 January 2009): Data gap open.
	New open point 3.13 The proposal for a residue definition for risk assessment in the processed commodities has to be reconsidered with regard to the toxicological relevance of the metabolites (see new data gap 3.5) and the results of the processing studies requested under the new data gap 3.6			PRAPeR 65 (22-23 January 2009): Open point open.
	Open point.3.9 MS to discuss the appropriateness of the	**Clarification of existing studies:** The provided method of analysis is designed to determine clofentezine	RMS: 19:12:2008 Residues in animal products based on the animal transfer study are expected	PRAPeR 65 (22-23 January 2009): Open point fulfilled.

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	feeding study (method of analysis) with regard to the residue definition in animal products. See reporting table 3(25)	residues in animal products **as defined in Reg (EC) No. 396/2005** (= sum of all compounds containing the 2-chlorobenzoyl moiety expressed as clofentezine). Furthermore, as explained in the above mentioned **Attachment IRV1-01** provided with this evaluation table: • It has been proved that the method converts clofentezine and metabolites into the analyte (2-CBA) with a molar conversion ratio of 1:1. • Any new method would still require an acid hydrolysis step to ensure conjugated metabolites were accounted for.	to be below the limit of determination (LOD MRLs set), using a method which determines all compounds containing the 2-chlorobenzoyl moiety, which includes both parent clofentezine and 4-hydroxyclofentezine (residues definition). The problem with the method is that it is not specific to clofentezine, however for monitoring there is a validated HPLC method (See section B.5.4.1d) which determines parent clofentezine and 4-hydroxyclofentezine as the individual components, therefore this method should be used for monitoring. Open point addressed.	New open point proposed, see below.
	New open point 3.14 The appropriateness of the feeding study has to be reconsidered when the residue definition for products of animal origin and the residue definition for the processed commodities are finalised (see new open point 3.10 and open point 3.8)			PRAPeR 65 (22-23 January 2009): Open point open.
	New open point 3.12 RMS to amend the list of			PRAPeR 65 (22-23 January 2009):

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	endpoints according to the discussions at PRAPeR 65 meeting (see discussion table).			Open point open.
	Message 1 to mammalian toxicology meeting (PRAPeR 64) regarding the toxicological relevance of clofentezine metabolites (2-chlorobenzoic acid, 2-chlorobenzonitrile, 2-chlorobenzamide): 1 - Are any of these degradation compounds of significant toxicological concern to be taken into account in the processed commodities? 2 - Are toxicological end-points available for these degradation compounds?			Answer from PRAPeR 64 meeting (mammalian toxicology): Limited toxicological information on some metabolites (2-chlorobenzoic acid, 2-chlorobenzonitrile, 2- chlorobenzamide) was reported in the addendum 2 to the DAR. However, this was considered not sufficient to conclude on the toxicological relevance of the metabolites, as well as on specific trigger values. Further, it has to be clarified in the residue section their amount after degradation when an eating step is included in the process
	Message 2 to mammalian toxicology meeting (PRAPeR 64) regarding the proportion of 4-hydroxyclofentezine in renal and subcutaneous fat: In the cattle metabolism study a discrepancy was observed in the TRR levels			Answer from PRAPeR 64 meeting (mammalian toxicology): It is not unexpected to find this metabolite present in renal fat. It is also expected that renal fat would contain slightly higher amount of the metabolite than in the epidermal fat because of the proximity to the kidneys.”

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	detected in the renal fat (0.26 mg/kg) and the subcutaneous fat (0.02 mg/kg). Considering that the residue mainly consists of 4-OH-clofentezine (70% TRR), (the parent compound being not observed), the explanation provided by the applicant is the following: "This difference reflects the proximity of the renal fat samples to the main organs of excretion. The only major residue in the renal fat was 4-hydroxyclofentezine which is also the major product excreted in urine". Is it usual to observe such a difference and is this explanation acceptable?			