PEER REVIEW REPORT ON **DIFLUBENZURON** 13 02 2009

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List of all reports from PRAPeR Expert Meetings

Date		Section
13-16.01.2009	PRAPeR expert meeting 61	Physical and Chemical Properties
12-16.01.2009	PRAPeR expert meeting 62	Environmental Fate and Behaviour
12-16.01.2009	PRAPeR expert meeting 63	Ecotoxicology
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REPORT OF PRAPeR EXPERT MEETING 61

DIFLUBENZURON

Rapporteur Member State: SE

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
Dec 2008	SE	Diflubenzuron addendum vol 4 Dec 2008 (2) cover page.doc
Dec 2008	SE	Diflubenzuron Addendum Vol3_B5 (Dec 2008).doc
Dec 2008	SE	Diflubenzuron Corrigendum Vol3_B2 (Dec 2008).doc
22.12.2008	SE	Diflubenzuron evaluation table rev1-0 (22.12.2008).doc
December 2008	SE	Diflubenzuron list of endpoints (December 2008).doc
2007-12-20	SE	Diflubenzuron reporting table rev1-2 (2007-12-20).doc
Dec 2008	SE	Diflubenzuron Revised DAR Vol3_ B4 (Dec 2008).doc
Dec 2008	SE	Diflubenzuron Revised DAR Vol3_B3 (Dec 2008).doc
Dec 2008	SE	List of essential studies relied upon_Diflubenzuron_Dec2008.doc

3. Documents tabled at the meeting:

Date	Supplier	File Name
none		

The conclusions of the meeting were as follows:

4. **Data on preparations:** Dimilin WG-80

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

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

7. **Reference list:** Not discussed

Areas of concern: No specification.

Appendix 1: Discussion table: DIFLUBENZURON

Appendix 2: Evaluation table

Appendix 1: Discussion Table, Diflubenzuron (In)

1. Physical and Chemical Properties

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	Open point 1.1 It should be discussed in a meeting of experts if the FAO specification for the TK should be ignored as we are only dealing with a TC or should we at least consider the particle size clause. To this end could the rapporteur ask the company to explain what the difference is between the TC and the TK. See reporting table 0(2).	The RMS explained that the FAO specification is not applicable and the meeting agreed.	Open point fulfilled.
	Open point 1.2 In the LOEP the reason for greying out the GAPs should be given. For example The risk assessment has revealed a data gap(s) in section 1.	The RMS confirmed that this has been done in the LOEPs. However, the meeting agreed that more details are required.	Open point still open.

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	See reporting table 1(1).		
	Open point 1.3 The rapporteur should provide in an addendum the additional QC data and the specification should then be considered by a meeting of experts. The QC data should be summarised taking into account the proposed requirements given in the EFSA working document for PRAPeR meetings of experts. The comparison of the tox and ecotox batches with specification should be provided in an addendum for discussion at the tox and ecotox meetings of experts. See reporting table 1(2).	The RMS explained that a further detail on QC data and statistical information has been presented in the Addendum. The meeting agreed that the QC information could be considered as it was not considered as new data. However, the new 8-batch data could not be considered because the data was provided after the deadline in the Regulation (EC) No 1095/2007. The meeting concluded that the minimum purity of the active substance and the maximum level of impurities (D05, D07 and D17) are not supported by the original batches and QC data. The sulphated ash should not form part of the spec. Loss on drying, if components are relevant or are above 0.1% they should be individually specified. The meeting also discussed the impurity and wished to highlight this to the Fate meeting. Section 1 would like to draw the attention to the fact that impurity D07 is a fluorinated version of BAM and is specified at a maximum of 2%. Post meeting note: Fate confirmed that there is no known issue with this compound.	Open point fulfilled. New data gap 1.5 proposed, see below.
	New data gap 1.5 identified at the		Data gap open.

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	PRAPeR 61 meeting: The notifier to provide a new specification.		
	Open point 1.4 The analytical closure of the batches should be given. See reporting table 1(3).	The RMS indicated that analytical closures are reported in the addendum, but these are based on the new 8-batch data and as mentioned above they can not be considered. However this open point is now redundant. See issue on new batch data below (data gap on page 8).	Open point fulfilled.
	Open point 1.5 The correct values should be presented for the specification in table C.1.2.3.1. See reporting table 1(4).	See above discussions.	Open point fulfilled.
1.1	Point of clarification for the applicant: Specificity: Methods for the (initial) identification of the impurities must be reported. Please note unless it can be demonstrated that the UV spectra are unique then DAD is not considered to be sufficiently specific.	The RMS explained that the notifier had submitted information on UV-spectra. This information was regarded as a statement and not new data, so could be considered. Therefore the point of clarification was agreed to be addressed. This information was considered by some experts not sufficient to identify the impurities. It was not possible to come to a conclusion whether new data was necessary. The experts highlighted the need for further guidance on what information is required for the identification of impurities. Also see discussion in General Discussion document.	Point of clarification addressed.

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	See reporting table 1(5).		
	Open point 1.6 The case considered in the DAR for partition coefficient should be considered by a meeting of experts See reporting table 1(9).	The meeting accepted the information provided in the DAR.	Open point fulfilled.
	Open point 1.7 The Physical compatibility of the recommended tank mixes should be discussed by a meeting of experts. See reporting table 1(14).	The meeting accepted the information provided regarding the in-house method.	Open point fulfilled.
	Open point 1.8 The oxidising properties of the formulation should be discussed in a meeting of experts. See reporting table 1(16).	The meeting accepted the RMS reasoning for not asking for a new study.	Open point fulfilled.

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	Open point 1.9 The acceptability of the formulation shelf life study should be discussed by a meeting of experts. See reporting table 1(18).	The meeting discussed the shelf life study and it was considered to be not acceptability. The new data gap also takes in to account the data gap below.	Open point fulfilled. New data gap 1.6 proposed, see below.
	New data gap 1.6 Identified at PRAPeR 61 meeting: The notifier should provide new studies for shelf- life and accelerated storage stability for the WG-formulation. This should include the analysis of the relevant impurities.		Data gap open.
	Data gap 1.1: The content of 4-chloroaniline should be measured before and after storage and therefore a new shelf-life study is required. See reporting table 1(19).	See above new data gap 1.6.	Data gap redundant, see new data gap 1.6

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	Open point 1.10 The result of the persistent foam study should be discussed by a meeting of experts. See reporting table 1(20).	The meeting discussed the persistent foam study and noted that there was more than 25 ml foaming in the study. EFSA to make this clear in the EFSA Conclusion.	Open point fulfilled. New open point 1.18 proposed, see below.
	New open point 1.18 indentified at PRAPeR 61 meeting: EFSA to note the persistent foam issue in the Conclusion.		Open point open.
	Open point 1.11 The in house attrition test should be considered by a meeting of experts. See reporting table 1(22).	The meeting discussed the in house attrition test and considered that the method was not comparable to method MT 178.2.	Open point fulfilled. New data gap 1.7 proposed, see below.
	New data gap 1.7 Identified at PRAPeR 61 meeting: The notifer to provide a new attrition test in		Data gap open.

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	accordance with MT 178.2.		
	Data gap 1.2: New 5 batch data with fully validated methods of analysis is required. The applicant has stated that this will have been provided by September 2007. See reporting table 1(28).	See also open point 1.4	Data gap remains open.
	Open point 1.12 It should be discussed by a meeting of experts if the CIPAC method for the WP can be extrapolated to a WG. See reporting table 1(29).	It was clarified that the formulation is a granule (GR) and not a WG and the GR method can not be accepted for a WG. The meeting also considered that this extrapolation could not be done without chromatograms to demonstrate the lack of interference.	Open point fulfilled. New data gap 1.8 proposed, see below.
	New data gap 1.8 indentified at PRAPeR 61 meeting: The applicability of the existing CIPAC method needs to be		Data gap open.

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	demonstrated with chromatograms.		
1.2	Point of clarification for the applicant: The applicability of a multi-residue method such as DFG S19 must be addressed. See reporting table 1(30).	The RMS indicated that a new study was available. However, it was agreed that the data could not be considered because the data was provided after the deadline in the Regulation (EC) No 1095/2007.	Point of clarification addressed. New data gap 1.9 proposed, see below.
	New data gap 1.9 indentified at PRAPeR 61 meeting: The applicability of the multi-residue method needs to be addressed.		Data gap open.
	Open point 1.13 The acceptability of the validation data for the plant residue methods should be discussed by a meeting of experts. See reporting table 1(31).	The RMS explained that additional clarification has been provided in the Addendum B.5. It was accepted that sufficient data was available for apples and mushrooms with an LOQ of 0.1 mg/kg. It was not possible to conclude on the need for further validation data on a fortification level 10x LOQ. The meeting discussed the confirmatory apple method and concluded that there is sufficient information with respect to the confirmatory method.	Open point fulfilled.

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	Open point 1.14 Details of the type of soil used in the soil method should be given. See reporting table 1(36).	The RMS confirmed that the soil used in the available validation study is reported as a sandy loam type and is presented in the Addendum.	Open point fulfilled.
	Open point 1.15 Source and characteristics of the surface water should be reported. See reporting table 1(37).	The information has been presented in the Addendum and the meeting agreed that this was acceptable.	Open point fulfilled.
	Open point 1.16 Method for apples. From the statement in column 3 of the reporting table it now appears that there is no confirmatory method and the ILV is not infact ILV but a different method with a different detector. This needs further explanation. Also the LOQ is questioned as the lowest fortification was 0.1 mg/kg.	See Open point 1.13	Open point fulfilled.

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	See reporting table 1(41).		
	Data gap 1.3: As the LOQ for surface water is not low enough given the current NOEC a new method for surface water is required. See reporting table 1(46).	Ecotox meeting confirm the NOEC is 0.00004 mg/l and therefore the LOQ for surface water method is not sufficiently low.	Data gap remains.
	Data gap 1.4: Analytical method for air. [It is noted that this has already been submitted however for technical reasons this remains as a data requirement] See reporting table 1(56).	The data could not be considered because the data was provided after the deadline in the Regulation (EC) No 1095/2007	Data gap remains.
	New open point 1.17 RMS to amend the list of end points according to the discussions during the	The information in the 'FAO Specification' box should be deleted and replaced by 'none for TC'. The min. purity box should be 'open'.	Open point open. .

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	PRAPeR 61 meeting.	The unit for vapour pressure and UV absorption coefficient should be added. The statement validity under discussion should be deleted. The summary of representative uses the active substance should be given in the title. The table on the GAP should be clarified or deleted. The diflubenzuron LOQ for mushrooms should be amended to 0.1 mg/kg In the analytical boxes the phrase for apples LOQ under discussion can be deleted. For mushrooms the phrase validity of method/validation data under discussion can be deleted. The box for air should be 'open'. In the box for water it should be indicated that surface water was used and the method for surface water to remain open. The method is sufficiently sensitive for drinking water.	

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: ***16*** Points for clarification: ***2*** Data gaps: ***4***			Section ***1*** Open points: ***3*** Points for clarification: ***0*** Data gaps: ***8***
	Open point 1.1 It should be discussed in a meeting of experts if the FAO specification for the TK should be ignored as we are only dealing with a TC or should we at least consider the particle size clause. To this end could the rapporteur ask the company to explain what the difference is between the TC and the TK. See reporting table 0(2).	09.11.2008 The Technical Concentrate (TC) is a pre-concentrate also known as PC-90 which contains technical material at a nominal concentration of 900 g/kg with silicon dioxide, a grinding aid (50 g/kg and aluminium silicates; kaolin/china clay, a carrier (50 g/kg).	22.12.2008 It appears that the FAO-specification does not apply, but a discussion is required.	PRAPeR 61 (13-16 January 2009) Open point fulfilled
	Open point 1.2 In the LOEP the reason for greying out the GAPs should be given. For example The risk assessment has revealed a data gap(s) in section 1.		22.12.2008 The reason for greying out uses in the GAP has been explained in the revised LoEP.	PRAPeR 61 (13-16 January 2009) Open point 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
	See reporting table 1(1).			
	Open point 1.3 The rapporteur should provide in an addendum the additional QC data and the specification should then be considered by a meeting of experts. The QC data should be summarised taking into account the proposed requirements given in the EFSA working document for PRAPeR meetings of experts. The comparison of the tox and ecotox batches with specification should be provided in an addendum for discussion at the tox and ecotox meetings of experts. See reporting table 1(2).	09.11.2008 The statistical analysis (report GRL-12498, Explanation of the Certified Limits of Diflubenzuron Technical, Tutty, D. G., 27 February 2007) of the QA/QC data from the manufacturing plant for the following components does provide support for the certified limits of those components; diflubenzuron; 4-chloroaniline; N,N'-bis(4-chlorophenyl)urea; 2,6-difluorobenzamide; methyl 4-chlorophenylcarbamate; 2-chloro-N-{[(4-chlorophenyl)amino]carbonyl}-6-fluorobenzamide. The heat loss and ash components, from the specification, were not statistically analyzed in the March 2007 report. Specific data for the analysis of these two components has shown that the specification limit is not fully supported when analyzing these parameters. However, Chemtura wishes to maintain the specification of these two parameters as all parameters are tied together and allow for statistical variation in the manufacturing process.	22.12.2008 The QC-data has been summarised in the agreed way in the Addendum to Annex C together with the applicant's statistical evaluation of the data and the justification for the current specification. The data is not clearly supportive of the current specification with regards to minimum purity and the maximum levels for some of the impurities and this issue needs to be discussed at the meeting of experts.	PRAPeR 61 (13-16 January 2009) Open point fulfilled New data gap 1.5 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 Meeting
	New data gap 1.5 identified at PRAPeR 61 meeting: The notifier to provide a new specification.			PRAPeR 61 (13-16 January 2009) Data gap open.
	Open point 1.4 The analytical closure of the batches should be given. See reporting table 1(3).	09.11.2008 The new preliminary analysis study, study number GRL-12508, Preliminary Analysis of Diflubenzuron Technical, Riggs, A. S., 18 September 2007, provides an assessment of analytical closure.	22.12.2008 The analytical closures are reported for the new 8-batch analysis in the Addendum to Annex C, and it is thus not considered necessary to revise the original Annex C.	PRAPeR 61 (13-16 January 2009) Open point fulfilled.
	Open point 1.5 The correct values should be presented for the specification in table C.1.2.3.1. See reporting table 1(4).	09.11.2008 The certified limits are the same, but expressed in different units. The limits mentioned on pages 14 and 15 are expressed in % w/w or ppm (4-chloroaniline), whereas on page 10 and 11 they are expressed in g/kg.	22.12.2008 Correct values for the specification are given in the Addendum to Annex C and it is therefore not considered necessary to revise the original Annex C.	PRAPeR 61 (13-16 January 2009) Open point fulfilled.
1.1	Point of clarification for the applicant: Specificity: Methods for the (initial) identification of the impurities must be reported. Please note unless it can be demonstrated that the UV spectra are unique then DAD is not considered to be sufficiently specific. See reporting table 1(5).	09.11.2008 The specificity of the method is defined in terms of the species analysed and the technique used for the analysis. For the chromatographic impurity method this is accomplished by examining and comparing of the analyte(s) in the sample with a purified authenticated analytical standard using diode-array uv/vis spectroscopy and the retention time of the analyte(s) and standard. Analytical Method GRL-GM-	22.12.2008 The data on the assessment of the specificity of the method for the impurities is included in the Addendum to Annex C. The provided spectra of the DAD-peaks of the impurities appear to be sufficiently different and the RMS therefore agrees that it seems unlikely that a different substance can have the same UV-spectra and the same retention time. However this needs to be discussed at	PRAPeR 61 (13-16 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
		1188 has been validated for specificity in this manner. The validation data for the impurity method, GRL-GM-1188, exceeds the requirements described in European Commission document SANCO/3030/99 rev. 4, 11/07/00 entitled “Technical Materials and Preparations: Guidance for generating and reporting methods of analysis in support of pre- and post-registration data requirements for Annex II (part A, Section 4) and Annex III (part A, Section 5) of Directive 91/414”.	a meeting of experts.	
	Open point 1.6 The case considered in the DAR for partition coefficient should be considered by a meeting of experts See reporting table 1(9).		22.12.2008 Agreed. It should be noted that the ACD/Log*P* DB (available through www.acdlabs.com) gives a predicted Log P_{ow} of 3.68 ± 0.45 which is in good agreement with the experimentally derived value of 3.89 at pH 3. However, pKa and log D (pH dependant octanol : water distribution constant) predictions using MarvinSketch 4.1.11 (i.e. available through ChemIDplus Advance on the web) indicates a pKa of ~6.4 and the following log D’s pH log D 4,00 3,62 4,50 3,62 5,00 3,61 5,50 3,56	PRAPeR 61 (13-16 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
			6,00 3,45 6,50 3,22 7,00 2,87 7,50 2,45 8,00 2,05 8,50 1,76 9,00 1,59 This indicates a significant pH dependence of the log P_{ow} within the environmentally relevant pH range. In this respect it should however be noted that the water solubility test in the DAR gave solubilities of 10×10^{-5} and 8×10^{-5} g/l at pH 4 and 7 respectively and 32×10^{-5} g/l at pH 10 which does not indicate a significant ionization within that range. In any case, a log P_{ow} of 3.89 should be a worst case value.	
	Open point 1.7 The Physical compatibility of the recommended tank mixes should be discussed by a meeting of experts. See reporting table 1(14).		22.12.2008 Agreed. The procedure used in the available study is described in detail in the reporting table 1(14)	PRAPeR 61 (13-16 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 1.8 The oxidising properties of the formulation should be discussed in a meeting of experts. See reporting table 1(16).		22.12.2008 Agreed. The RMS still considers it unnecessary to require a new test on the formulation according to EEC A.17 given that the available additional tests were negative and as the formulation contains 80% of diflubenzuron which was shown not to be oxidizing in the sense of EEC A.17 and as none of the remaining components are classified as oxidizers.	PRAPeR 61 (13-16 January 2009) Open point fulfilled.
	Open point 1.9 The acceptability of the formulation shelf life study should be discussed by a meeting of experts. See reporting table 1(18).	09.11.2008 A new shelf-life and/or an accelerated storage study can be initiated with measurements before and after storage, of the active ingredient and the relevant impurities, including 4-chloroaniline, and the appropriate physico-chemical parameters. The shelf-life study can be submitted in February 2011. In the interim, an accelerated storage study could be conducted and completed by March 2009.	22.12.2008 Agreed. The need for testing of all phys.chem. parameters relevant to a WG-formulation also needs to be discussed.	PRAPeR 61 (13-16 January 2009) Open point fulfilled. New data gap 1.6 proposed, see below.
	New data gap 1.6 Identified at PRAPeR 61 meeting: The notifier should provide new studies for shelf- life and accelerated storage stability for the WG-formulation. This should include the analysis of			PRAPeR 61 (13-16 January 2009) 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
	the relevant impurities.			
	Data gap 1.1: The content of 4-chloroaniline should be measured before and after storage and therefore a new shelf-life study is required. See reporting table 1(19).	09.11.2008 A new shelf-life and/or an accelerated storage study can be initiated with measurements before and after storage, of the active ingredient and the relevant impurities, including 4-chloroaniline, and the appropriate physico-chemical parameters. The shelf-life study can be submitted in February 2011. In the interim, an accelerated storage study could be conducted and completed by March 2009.	22.12.2008 Agreed.	PRAPeR 61 (13-16 January 2009) Data gap redundant, see above.
	Open point 1.10 The result of the persistent foam study should be discussed by a meeting of experts. See reporting table 1(20).		22.12.2008 Agreed. It should be noted that the volume of foam formed at a concentration of 1%, initially and after 15 min was 29.4 ml and 28.1 ml respectively and the criteria is max. 25 ml. Regarding the statement by the applicant, that an adjuvant is always required when used in forestry (see reporting table 1(20)), this statement is not given in the proposed label (document C of the original dossier).	PRAPeR 61 (13-16 January 2009) Open point fulfilled. New open point 1.18 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 Meeting
	New open point 1.18 indentified at PRAPeR 61 meeting: EFSA to note the persistent foam issue in the Conclusion.			PRAPeR 61 (13-16 January 2009) Open point open.
	Open point 1.11 The in house attrition test should be considered by a meeting of experts. See reporting table 1(22).		22.12.2008 Agreed. The used procedure in the available study and the deviations in comparison to CIPAC 178.2 are described in the reporting table 1(22).	PRAPeR 61 (13-16 January 2009) Open point fulfilled.
	New data gap 1.7 Identified at PRAPeR 61 meeting: The notifer to provide a new attrition test in accordance with MT 178.2.			PRAPeR 61 (13-16 January 2009) 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
	Data gap 1.2: New 5 batch data with fully validated methods of analysis is required. The applicant has stated that this will have been provided by September 2007. See reporting table 1(28).	09.11.2008 A new preliminary analysis study was conducted under study number GRL-12508, Preliminary Analysis of Diflubenzuron Technical, Riggs, A. S., 18 September 2007 using fully validated analytical methods.	22.12.2008 The new 8-batch data was provided in 26.09.2007 (Riggs, 2007) and it is included and evaluated in the Addendum to Annex C. The data was derived using fully validated methods (the method used for the active is included in the Addendum to Annex B.5 and the method used for the impurities is included in the Addendum to Annex C) and it is deemed acceptable.	PRAPeR 61 (13-16 January 2009) Data gap remains open.
	Open point 1.12 It should be discussed by a meeting of experts if the CIPAC method for the WP can be extrapolated to a WG. See reporting table 1(29).	09.11.2008 The CIPAC method, 339, may be applied to the WG formulation. Analytical Method, GRL-GM-1066 version 3.1, is adapted from the CIPAC method and provides method validation data to support the analysis of the WG formulation. The validation data exceeds the requirements described in European Commission document SANCO/3030/99 rev. 4, 11/07/00 entitled “Technical Materials and Preparations: Guidance for generating and reporting methods of analysis in support of pre- and post-registration data requirements for Annex II (part A, Section 4) and Annex III (part A, Section 5) of Directive 91/414”.	22.12.2008 The applicant has informed that the scope of CIPAC method 339 has been extended to include the analysis of granules, suspension concentrates and tablets (confirmed by CIPAC/4546 /P). However it seems that the actual revision of the method has not been published as yet. The RMS has therefore not been able to judge if the extension to granules also applies to WG-formulations, so this might need to be discussed.	PRAPeR 61 (13-16 January 2009) Open point fulfilled. New data gap 1.8 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 Meeting
	New data gap 1.8 indentified at PRAPeR 61 meeting: The applicability of the existing CIPAC method needs to be demonstrated with chromatograms.			PRAPeR 61 (13-16 January 2009) Data gap open
1.2	Point of clarification for the applicant: The applicability of a multi-residue method such as DFG S19 must be addressed. See reporting table 1(30).	09.11.2008 The feasibility to use a multi-residue method for residue analysis has been investigated and is reported by 'Allan, E. and Pouwelse, A. V. Determination of diflubenzuron residues according to multiresidue methods described in FDA's pesticide analytical manuals. C.303.50.019, 11 August 1993' (Document DI-8654). The study demonstrated that diflubenzuron cannot be analysed by the FDA multi-residue method due to the thermal instability of the molecule, and therefore a HPLC method was developed. As such, DFG S19 multi-residue method, which is GC-based, is not applicable to diflubenzuron. The applicability of multi-residue analysis of diflubenzuron in crops using liquid chromatography/tandem mass spectrometry was described in two recently published articles (Pihlstrom, T., *et al.*, 2007, Anal. Bioanal. Chem. DOI 10.1007/s00216-	22.12.2008 In January 2007 the applicant provided a study (Allan & Pouwelse, 1993) aimed to analyse diflubenzuron according to the FDA's multiresidue methods. Diflubenzuron was shown to decompose due to thermal instability under the mild GC-conditions used. This finding is considered sufficient to support the statement that diflubenzuron is not applicable to the DFG S19 multiresidue method, as it is also based on GC. The study of Allan & Pouwelse, 1993 is reported in the Addendum to Annex B.5.	PRAPeR 61 (13-16 January 2009) Point of clarification for the applicant addressed. New data gap 1.9 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 Meeting
		007-1425-6; Klein and Alder, 2003, Journal of AOAC International, Vol. 86, No. 5.) They show clearly that diflubenzuron is amenable to LC/MS/MS analysis in the negative ESI mode, producing two transitions, giving good sensitivity, precision and accuracy.		
	New data gap 1.9 indentified at PRAPeR 61 meeting: The applicability of the multi-residue method needs to be addressed.			PRAPeR 61 (13-16 January 2009) Data gap open.
	Open point 1.13 The acceptability of the validation data for the plant residue methods should be discussed by a meeting of experts. See reporting table 1(31).	09.11.2008 The analytical method (Thus and Allan, 1995 and 1996 Addendum, Study No. C.303.60.030) was validated on four different types of apples (Idared, Elstar, Jonagold and James Grieve) in replicates and at two concentration levels (0.1 and 1.0 mg/kg). Overall recoveries (82%/99%), standard deviation (12%/3.1%) and relative standard deviation (14%/3.2%) were all within acceptable criteria and scientifically sound. Method validation was also conducted on apple pomace and apple juice at two concentration levels (0.1 and 1.0 mg/kg), each with four replicates. Overall recoveries, standard deviation and relative standard deviation were all within acceptable criteria. The method also demonstrated linearity from 0.1 to 1.1	22.12.2008 The situation for the method for residues in apples, pomace and juice has been clarified in the Addendum to Annex B.5. In conclusion it should be noted that the primary method was fully validated for 0.1 mg/kg (LOQ) and 1.0 mg/kg whereas the ILV-study was performed using the exact same method for 0.01 mg/kg and 0.1 mg/kg. An acceptable confirmatory procedure (LC-MS) was also presented within the ILV-study. The validity of performing the primary validation and the ILV at different fortification levels therefore needs to be discussed. It should also be noted that the LOQ of 0.01 mg/kg referred to by the applicant in their response is stated to be based on 3 x the	PRAPeR 61 (13-16 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
		µg/mL, with r^2 of 0.999. Since the validations on apple, apple pomace, and apple juice were conducted prior to the data requirement of SANCO/825/00 rev. 6 (2000) or 7 (2004), the five replicates approach should not be applied. The method validations were conducted with sound scientific principles. Although the method was validated at the low end of 0.1 mg/kg, this level was not considered the LOQ. In the report, it stated that "the limit of quantitation is at least a factor of 10 below the lowest spiking level of 0.1 mg/kg". The LOQ was further elaborated and clarified in the 1996 report addendum to be 0.01 mg/kg.	background noise (given in the 1996 Addendum), which is not sufficient in the sense of SANCO/825/00 rev.7 Furthermore, the situation for the method for residues in mushrooms has also been clarified in the Addendum to Annex B.5. In conclusion it should be noted that a too small sample set was used in the primary validation (i.e. two samples per level with additional samples at one more level) and that diflubenzuron levels >30% were found in the blanks in the ILV-study. The acceptance of the method needs to be discussed on the basis of these findings. An acceptable confirmatory method is presented in the ILV-study.	
	Open point 1.14 Details of the type of soil used in the soil method should be given. See reporting table 1(36).	09.11.2008 The type of soil used in the study (Faltynski, 2003; Study No. 2002-059) was a sandy loam soil.	22.12.2008 The soil used in the available validation study is reported as a sandy loam type. The information is included in the Addendum to Annex B.5.	PRAPeR 61 (13-16 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 1.15 Source and characteristics of the surface water should be reported. See reporting table 1(37).	09.11.2008 The report stated that the water was obtained from a local pond (Winston-Salem, NC, U.S.A.). The water characterisation report by Agvise (DI-11737 Agvise water characterization report.pdf) has been send to the RMS.	22.12.2008 In January 2007, the applicant submitted a water characterisation report (dated 21.03.2003) which is included in the Addendum to Annex B.5 together with a statement on the source of the water (i.e. local pond water).	PRAPeR 61 (13-16 January 2009) Open point fulfilled.
	Open point 1.16 Method for apples. From the statement in column 3 of the reporting table it now appears that there is no confirmatory method and the ILV is not infact ILV but a different method with a different detector. This needs further explanation. Also the LOQ is questioned as the lowest fortification was 0.1 mg/kg. See reporting table 1(41).	09.11.2008 The analytical method for apple, apple pomace, and apple juice was independently validated (ILV) by a second laboratory (Rose, 2001; RP-00009) at 0.01 and 0.1 mg/kg levels and with 5 replicates at each level, and was conducted according to SANCO/825/00 rev. 6 guideline. The ILV was conducted under similar conditions (HPLC/UV) as specified in the original method (Duphar 56835/49/94, issued March 1995). The ILV also provided LC/MS confirmation of diflubenzuron in apple matrix and is therefore considered a confirmatory method. Under the LC/MS conditions, a parent ion with m/z 309 and a 2nd ion with m/z at 355 were observed. LC/MS techniques are considered highly specific, and therefore met SANCO/825/00 requirements. The LOQ in the original method (Thus and Allan, 1995 and 1996 addendum, study no. C.303.60.030) was	22.12.2008 See comments to open point 1.13.	PRAPeR 61 (13-16 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
		designated at 0.01 mg/kg, although the low fortification level was at conducted at 0.1 mg/kg for apple residue analysis.		
	Data gap 1.3: As the LOQ for surface water is not low enough given the current NOEC a new method for surface water is required. See reporting table 1(46).	09.11.2008 The analytical method (Faltynski, 2003; Study No. 2003-038) for surface water was validated at the low level of 0.1 µg/L (designated as LOQ level). The limit of detection for diflubenzuron was determined to be 0.02 µg/L in the study. The LOQ level in the study was attained with a 10 mL final extract, and a 10 µL injection into LC/MS. Lower LOQ could be obtained by further concentration of the extract to a smaller volume (e.g., 3 - 5 mL), or with a larger injection volume, such as 20 µL, or a combination of modifying both parameters. Therefore, the requirement for a NOEC of 0.04 ug/L detection limit could be readily attained using the framework outlined in this method with minor adjustments, given the high sensitivity and selectivity of LC/MS/MS techniques.	22.12.2008 The LOQ is sufficient with respect to the proposed EAC of 0.7 µg/L. We have to await the discussions on ecotox to see whether this EAC will be accepted or not.	PRAPeR 61 (13-16 January 2009) Data gap remains.

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: Analytical method for air. [It is noted that this has already been submitted however for technical reasons this remains as a data requirement] See reporting table 1(56).	09.11.2008 A new report about the analysis in air has been send to the RMS in May 2006 (Bacher, R. (2006) Validation of an analytical confirmatory method for the determination of diflubenzuron in air. PTRL Europe, Germany, Report No. B 1000 G (Chemtura 2006-001; DI–11817).	22.12.2008 The new study was submitted in May 2006 and it is evaluated and reported in the Addendum to Annex B.5. The method is deemed acceptable.	PRAPeR 61 (13-16 January 2009) Data gap remains.
	New open point 1.17. RMS to amend the list of end points according to the discussions during the PRAPeR 61 meeting			PRAPeR 61 (13-16 January 2009) Open point open

REPORT OF PRAPeR EXPERT MEETING 62

DIFLUBENZURON

Rapporteur Member State: SE

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
Dec 2008	SE	Diflubenzuron addendum vol 4 Dec 2008 (2) cover page.doc
Dec 2008	SE	Diflubenzuron Addendum Vol3_ B8-9 (Dec 2008).doc
22.12.2008	SE	Diflubenzuron evaluation table rev1-0 (22.12.2008).doc
December 2008	SE	Diflubenzuron list of endpoints (December 2008).doc
2007-12-20	SE	Diflubenzuron reporting table rev1-2 (2007-12-20).doc
Dec 2008	SE	Diflubenzuron Revised DAR vol3_B8 (Dec 2008).doc
Dec 2008	SE	List of essential studies relied upon_Diflubenzuron_Dec2008.doc

3. Documents tabled at the meeting:

Date	Supplier	File Name
None		

The conclusions of the meeting were as follows:

4. Data on preparations: Dimilin WG-80

5. Classification and labelling: Candidate for R53

6. Recommended restrictions/conditions for use: None identified

7. Reference list: Not discussed

Areas of concern: Surface water exposure assessment following tractor mounted spraying application in forestry and hand held spraying application in orchards has not been finalised. Environmental exposure assessment from the use on protected mushrooms not available.

Appendix 1: Discussion table: DIFLUBENZURON

Appendix 2: Evaluation table

Appendix 1: Discussion Table, Diflubenzuron (In)

4. Fate and behaviour

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	Open point 4.1 MS to discuss the need for further identification of volatiles in the alkaline trap taking into consideration that one of the major soil metabolites is a volatile organic acid. See reporting table 4(1).	In the DAR it was not clear if the identity of the volatiles trapped in the alkaline traps of the two aerobic degradation studies were further investigated. In the study Van der Gaauw 2003 the carbon dioxide in the volatile traps was identified using barium hydroxide precipitation and non carbon dioxide radioactivity only accounted for 1.2% AR. This information was clarified in the evaluation table and is included in the original study report. The experts agreed that the potential concern had been addressed by this clarification.	Open point fulfilled.
4.1	Point of clarification by the applicant New FOCUS GW using Koc = 0 for metabolite DFBA. Two models should be used following the Opinion of the Scientific Panel on Plant Health, Plant Protection Products and their Residues on a request of EFSA related to FOCUS groundwater models. The EFSA Journal	The requested modelling was evaluated by the RMS in the addendum December 2008 (page 5). The validity of the vapour pressure and water solubility values used in the new GW modelling for the major metabolite DFBA were discussed. These values were EPI Suite 3.1 estimates. Whilst there is uncertainty in these estimates as the water solubility used was high (3063 mg/L) the experts considered that this would result in volatilisation contributing little to the material balance in the modelling. Hence the leaching estimates would not have been invalidated by the use of EPI Suite estimates for deriving the air water partition utilised by the model. The experts discussed the application rate used for simulations (calculated equivalent dose rate at the soil surface pertinent to DFBA). The experts could not reproduce the value provided but accepted it as it was higher than the value they calculated should have been used (16.1 g/ha compared to 6.1 g/ha).	Point of clarification changed into a data gap 4.1, as only the RMS had received the new modelling report (Uwe Wanner 2007). Data gap open New open point 4.9, see below.

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	(2004) 93, 1-20.) Applicant informed that new FOCUS GW modeling has been provided on 27 February 2007. See reporting table 4(5).	The experts accepted that the modelling indicated the groundwater limit was respected for the assessed uses outdoors. The RMS should update the LoEP in with the new modelling simulations.	
	New open point 4.9 is indentified at PRAPeR 62 meeting: RMS to update the list of end points with the new groundwater model simulations for DFBA.		Open point open.
	Open point 4.2 To summarize the report with the calculation of Koc for metabolite DFBA in an addendum and in the list of studies relied on if it is finally used in the risk assessment. Pending result of data requirement 4.1. See reporting table 4(6).	A description on the calculation of Koc value for metabolite DFBA was provided in the addendum of December 2008 on pages 3 to 4. The calculation is a PCKOCWIN QSAR estimate. As DFBA will dissociate at environmentally relevant pH and it is likely that the QSAR estimate is for the non dissociated form, the experts agreed that this Koc estimate should not be included in the LoEP and should not be used for exposure assessment. This report of this calculation has not been included in the list of studies relied on, which is consequent with the decision of the experts.	Open point fulfilled. New open point 4.10 proposed, see below.

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	New open point 4.10 is indentified at PRAPeR 62 meeting: RMS to delete the Koc for DFBA from the LoEP and insert, data not available, not required when a default of 0 mL/g can be used in exposure assessment.		Open point open.
	Open point 4.3 RMS to provide the re-evaluation of the ready biodegradability study in an addendum and to amend the list of end points accordingly. To discuss applicant's comment (in table of comments to the RT) during the expert's meeting. See reporting table 4(12).	The evaluation of the study was included in a revised DAR dated December 2008 on page 36 and some comments from the RMS were included in the addendum of December 2008. The experts agreed that the study resulted in diflubenzuron being classified as not readily biodegradable under the conditions defined for the test. The LoEP has been amended accordingly.	Open point fulfilled.
	Open point 4.4 RMS to provide further details an assessment of the models used to derive the kinetic	Some information requested was included in the revised DAR dated December 2008 on page 39. The RMS clarified in the meeting that a multi compartment model had been used to calculate the DT50 of the metabolite CPU, as follow: diflubenzuron to metabolite CPU to	Open point fulfilled. New open point 4.11 proposed, see below.

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	parameters in the water/sediment study. If a multi-compartmental model has been used to fit the different degradation parameters a scheme would help to the discussion in the MSs experts meeting. See reporting table 4(13).	sink. The water sediment system was considered to be a single compartment (i.e. as a whole system). The RMS indicated that the DT50 used in FOCUS modelling (geomean DT50wholesyst = 37.6 days) and reported in the LoEP came from the evaluation from Volkl 1999 using the Moore-Fit model and ModelMaker had not been used. The experts considered the Moore-Fit approach acceptable and therefore the RMS was requested to delete the incorrect reference to ModelMaker from the LoEP.	
	New open point 4.11 is indentified at PRAPeR 62 meeting: RMS to remove the incorrect reference to ModelMaker from the LoEP in the water sediment DT50 box		Open point open.
	Open point 4.5 RMS to provide further details on the nature of light used in the irradiated water sediment study in an addendum. Assessment of the light source with respect to natural light at different	The requested information was included in the revised DAR dated December 2008 on page 36. Column B of the reporting table also contained some information regarding the vessel material in the study. The experts were content that the endpoints from this study (irradiated sediment water study) were not used in the exposure assessment or included in the LoEP. An assessment of the light energy in this irradiated sediment water study compared to natural sunlight was not available, but is not required when the study is not relied on to indicate photolysis processes. No further actions necessary.	Open point fulfilled.

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	latitudes is necessary. See reporting table 4(15).		
4.2	Point of clarification by the applicant PECsw/sed following tractor mounted spray in forests and hand held application in orchards should be provided. Comments from AT, DK and UK to be considered by the NOT in their calculation and the experts' meeting. See reporting table 4(22).	The requested calculations were not provided by the applicant. As a data gap was identified for further effects data on aquatic insects by the ecotoxicologist experts in PRAPeR 63, a data gap will be identified in the EFSA conclusion for PEC calculations using FOCUSsw tools for the uses of hand held sprayers in orchards and for tractor mounted application in forestry. For these calculations, spray drift with buffer zones resulting in a maximum spray drift mitigation of 95% should be implemented using the SWASH spray drift calculator. Runoff should not be mitigated by more than 90%. The best advice of the experts was that the pome / stone fruit FOCUSsw scenarios should be used to represent forestry in the calculations.	Point of clarification converted to a data gap 4.2. Data gap open.
	Open point 4.6 NL to provide further details on the Dutch surface water exposure assessment model for mushrooms. MSs to discuss the relevance of this model for the EU risk assessment and if exposure to surface water may be	The experts from the Netherlands gave a brief presentation of the Dutch exposure assessment model that indicated that exposure from mushroom growing facilities cannot automatically be considered to be negligible. It was noted that many of the assumptions and monitoring information that are the basis for the model may be specific to particular member states, so the Dutch approach is probably not universally applicable. It was also noted that it is common practice in some member states to spread used mushroom compost on agricultural land at the end of the mushroom growing cycle. It was concluded that EFSA should include in the conclusion that surface water, groundwater and soil exposure assessments for the requested uses in mushrooms are not available as the experts did not accept that exposure would be negligible. Consequently the conclusion will identify a data gap for these exposure and consequent risk	Open point fulfilled. New data gap 4.3 proposed, see below.

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	considered negligible for the representative use in mushrooms. MS's consider forwarding the issue of mushroom production assessment to PPR Panel. See reporting table 4(24).	assessments. The PRAPeR experts agreed to inform the EFSA PPR panel secretariat that there was a need for guidance on completing environmental exposure assessments as a consequence of uses being requested in protected mushroom productions.	
	New data gap 4.3 is indentified at PRAPeR 62 meeting: Identified for surface water, groundwater and soil exposure assessments for the requested uses in protected mushroom production		Data gap open.
	Open point 4.7 Arithmetic mean Koc should be used for calculation of FOCUS PEC GW. List of end points to be amended accordingly. See reporting table 4(25).	The experts confirmed that the correct value that should have been used in leaching modelling for diflubenzuron would be an arithmetic mean of 4620 mL/g (1/n 1.1) for diflubenzuron. However it was agreed that new leaching simulations were not required even though the available simulations had used a value of 9148 mL/g. The experts requested that a footnote should be added to the LoEP for groundwater modelling box that the correct value that should have been used was 4620 mL/g. Of course, the actual value used for the simulations should be retained. It was noted a similar footnote would also be applicable for the surface water modelling box in the LoEP.	Open point open. RMS to add a footnote to the LoEP groundwater and surface water modelling box that the correct Koc value for diflubenzuron that should have been used in simulations was 4620 mL/g.

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	Open point 4.8 RMS to summarize and assess in an addendum FOCUS PEC sw/sed for aerial application. See reporting table 4(27).	The information requested was included in the addendum dated December 2008 on page 8. The experts agreed with the assessment of the RMS that the calculations provided by the applicant were not acceptable. The experts agreed the PECsw from aerial application in forestry in the DAR that was calculated by the RMS. It was noted that for aerial application in forestry and hand held application in forestry and ornamentals PECsediment were not available in the DAR. Currently using the available litoral enclosure study dosed twice the risk assessment to some aquatic species can be completed without a PEC sediment. However as a data gap was agreed to address the risk to aquatic insects (in the meeting of ecotoxicology experts) the conclusion will indicate that when addressing this risk exposure via sediment will need to be covered.	Open point fulfilled. New open point 4.12 proposed, see below.
	New open point 4.12 is indentified at PRAPeR 62 meeting: EFSA to indicate in the conclusion that when addressing this risk to aquatic insects, exposure via sediment will need to be covered		Open point open.
	Message from ecotox PRAPeR 63 meeting: to confirm that DT90 field would be less than 100 days for the metabolite CPU, considering that the DT90 lab is in the range of 55.7-111.8 d.		Answer from section 4: This is not possible as there are no field studies in the dossier. Any reply provided would be conjecture.
	Definition of residues requiring assessment in other disciplines or for which a groundwater exposure	soil: diflubenzuron, CPU, DFBA groundwater: diflubenzuron, CPU, DFBA surface water: diflubenzuron, CPU, DFBA sediment: diflubenzuron, CPU	

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	assessment is triggered.	air: diflubenzuron	

Appendix 2: Evaluation table

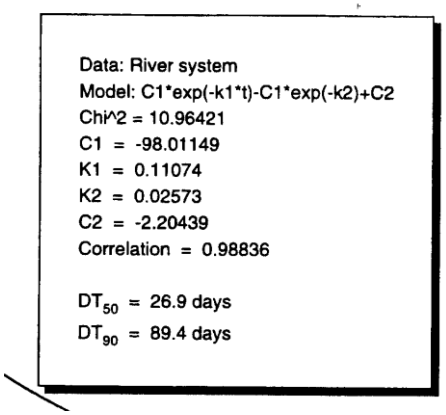
2. Environmental fate and behaviour

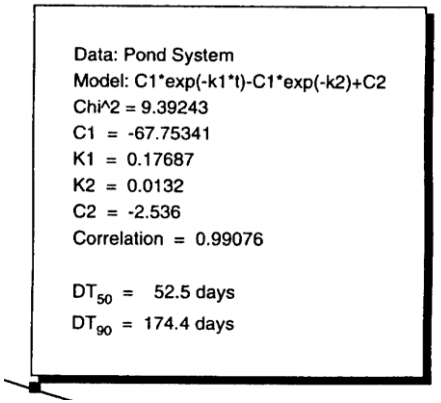
No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the evaluation group
	Section 4 Open points: ***8*** Points for clarification: ***2*** Data gaps: ***0***			Section 4 Open points: ***5*** Points for clarification: ***0*** Data gaps: ***3***
	Open point 4.1 MS to discuss the need for further identification of volatiles in the alkaline trap taking into consideration that one of the major soil metabolites is a volatile organic acid. See reporting table 4(1).	09.11.2008 Indeed, Walstra *et al*. (1990) did not conduct any $^{14}CO_3^{2-}$ precipitation of the caustic traps. Still, it is unlikely that any 'volatile, organic acid' was trapped as the amounts of major metabolites clearly show a formation/degradation pattern over the entire incubation period. If one volatile 'acidic' metabolite were to be formed, it would have immediately been trapped in the KOH-traps, which automatically would exclude any visible, slower degradation pattern. Van der Gaauw clearly confirmed this point as the amount of trapped $^{14}CO_2$ was confirmed by $Ba(OH)_2$ precipitation. Further, the author states that other volatiles, trapped in ethylene glycol, did not exceed 1.2% of the applied radioactivity. As a result, the identity of the vast majority of volatile degradation products (i.e. $^{14}CO_2$) was confirmed.	22.12.2008 We agree to discuss this point at an experts meeting	PRAPeR 62 (12-16 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
4.1	Point of clarification by the applicant New FOCUS GW using Koc = 0 for metabolite DFBA. Two models should be used following the Opinion of the Scientific Panel on Plant Health, Plant Protection Products and their Residues on a request of EFSA related to FOCUS groundwater models. The EFSA Journal (2004) 93, 1-20.) Applicant informed that new FOCUS GW modeling has been provided on 27 February 2007. See reporting table 4(5).	09.11.2008 A new ground water risk assessment (Wanner 2008, Study # 2007-010) was conducted to assess the potential risk of DFBA leaching if zero adsorption to the soil matrix were assumed. However, both FOCUS PELMO 3.3.2 as well as FOCUS PEARL 3.3.3 revealed that PECs for DFBA for all relevant locations were calculated to be significantly less than 0.1 µg/L. Therefore, there can be confidence that DFBA will not exceed 0.1 µg/L in ground water following the use of Dimilin 80WG® in pome/stone fruits even if a worst-case adsorption scenario is assumed.	22.12.2008 The RMS has summarised the provided information in an addendum. The predicted environmental concentrations (PECs) DFBA after the application of the Dimilin in orchards were calculated using FOCUS PELMO 3.3.2 and FOCUS PEARL 3.3.3. These calculations were based on the assumption that DFBA does not show any adsorption to soil (K_{OC}= 0 mL/g). The PEC_{GW} of all relevant locations were calculated to be less than 0.1 µg/L. The following difference from the original modelling in the DAR was noted; A crop interception value of 50 i.e. FOCUS interception value for early applications (i.e., no leaf canopy present)) was used when calculating the metabolite application rate, this is considered as acceptable by the RMS. Further, the vapour pressure was estimated (based on chemical structure using EPI Suite version 3.10) to 0.235 Pa and used to model dissipation through volatilisation; in the DAR this dissipation route was excluded in the absence of data. The vapour pressure for diflubenzuron is ≤ 1.2×10^{-7} Pa and hence the estimated vapour pressure for DFBA is considerably higher. The estimated DFBA vapour pressure implies that	PRAPeR 62 (12-16 January 2009) Point of clarification open changed into a data gap 4.1,as only the RMS had received the new modelling report (Uwe Wanner 2007). Data gap open. New open point 4.9, 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
			DFBA is moderately volatile, and hence volatilisation may have had an impact on the final PECgw estimated in the modelling. The RMS is uncertain if the estimated vapour pressure should be accepted and this may need to be discussed.	
	New open point 4.9 is indentified at PRAPeR 62 meeting: RMS to update the LoEP with the new groundwater model simulations for DFBA.			PRAPeR 62 (12-16 January 2009) Open point open.
	Open point 4.2 To summarize the report with the calculation of Koc for metabolite DFBA in an addendum and in the list of studies relied on if it is finally used in the risk assessment. Pending result of data requirement 4.1. See reporting table 4(6).	09.11.2008 The DFBA ground water risk assessment based on a K_{OC} of zero, i.e. no adsorption to soil matrix, still showed no risk for any groundwater contamination. Therefore, there is no need to provide a list of studies on the calculation of the KOC for metabolite DFBA.	22.12.2008 The RMS agree with the notifier that the report should not be included in the list of studies relied on. Further, the RMS has clarified in LoEP that Koc= 0 should be used for FOCUS GW simulations.	PRAPeR 62 (12-16 January 2009) Open point fulfilled. New open point 4.10 proposed, see below.
	New open point 4.10 is indentified at PRAPeR 62 meeting: RMS to delete the Koc for			PRAPeR 62 (12-16 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
	DFBA from the LoEP and insert, data not available, not required when a default of 0 mL/g can be used in exposure assessment.			
	Open point 4.3 RMS to provide the re-evaluation of the ready biodegradability study in an addendum and to amend the list of end points accordingly. To discuss applicant's comment (in table of comments to the RT) during the expert's meeting. See reporting table 4(12).	09.11.2008 Indeed, diflubenzuron does not fulfil the strict definition of ready biodegradability as set in the OECD 301 series: 60% of theoretical CO_2 formation (Thus, 1993 indicated a production of 25% of theoretical CO_2). However, as stated in the Annex VI of the consolidated version of directive 67/548/EEC "This criterion applies to substances unless there exists additional evidence concerning degradation and/or toxicity sufficient to provide an adequate assurance that neither the substance nor its degradation products will constitute a potential long-term and/or delayed danger to the aquatic environment." Higher-tiered, hence more realistic, water/sediment studies (Völkel, 1999) proved that DFB and its degradation products CPU and DFBA degraded rapidly in natural aquatic environments: DT_{50} values (whole system, geometric means) diflubenzuron → 4.5 days; DFBA → 2.7 days; CPU → 37.6 days. These higher-tiered evaluations clearly provide an adequate assurance that neither diflubenzuron nor its	22.12.2008 We have re-evaluated the study in the amended DAR. This issue has been discussed at the Technical Committee for classification and labelling in January 2007 which concluded that diflubenzuron should be classified N; R50-53 and S 60-61.	PRAPeR 62 (12-16 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
		degradation products will constitute a potential long-term and/or delayed danger to the aquatic environment.		
	Open point 4.4 RMS to provide further details an assessment of the models used to derive the kinetic parameters in the water/sediment study. If a multi-compartmental model has been used to fit the different degradation parameters a scheme would help to the discussion in the MSs experts meeting. See reporting table 4(13).	09.11.2008 In the initial surface water report (Wanner, 2004; Study # 2004-011) attempts were made to calculate the degradation kinetics of diflubenzuron, DFBA and CPU in the individual phases as well as in the total aquatic system using multi-compartment models developed with ModelMaker 4.0 (see Figure 2, page 53 of 2002 of the initial report). The multi-compartment models did not provide adequate DT_{50} values for each individual phase. However, the model used for calculation of DT_{50} for the whole system provided results similar to those reported by Völkel (1999). Völkel used single first-order kinetics for diflubenzuron and DFBA and a Moore-Fit approach which applied the formula for a series of first-order reaction kinetics based on Moore, J.W. & Pearson, R.G. (1981) "Kinetics and Mechanism", 3rd edition, John Wiley & Sons, NY. The formulas are given in the figures 9, 11, and 13 of Völkel (1999). The amended surface water report (Wanner, 2005; Study # 2004-011 supplemental report) was based on the geometric means of the whole-system DT_{50} values as reported by	22.12.2008 This has been clarified in an in an amended DAR. For the discussion the formulas used by Völkel for CPU are given below  Data: River system Model: C1*exp(-k1*t)-C1*exp(-k2)+C2 Chi^2 = 10.96421 C1 = -98.01149 K1 = 0.11074 K2 = 0.02573 C2 = -2.20439 Correlation = 0.98836 DT_{50} = 26.9 days DT_{90} = 89.4 days	PRAPeR 62 (12-16 January 2009) Open point fulfilled. New open point 4.11 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
		Völkel (1999) – see Table 4, page 17 of 321 of Wanner (2005).	 For a comparison with ModelMaker 4.0 results the average total system DT50's were 2.2 and 40.6 (compared with 2.7 and 37.6 calculated in the Völkel report) days for DFBA and CPU, respectively. Hence, we consider that the data used for the FOCUS-SW modelling is acceptable. .	
	New open point 4.11 is indentified at PRAPeR 62 meeting: RMS to remove the incorrect reference to ModelMaker from the LoEP in the water sediment DT50 box			PRAPeR 62 (12-16 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
	Open point 4.5 RMS to provide further details on the nature of light used in the irradiated water sediment study in an addendum. Assessment of the light source with respect to natural light at different latitudes is necessary. See reporting table 4(15).	09.11.2008 The report does not provide more information on the light source than "…six 20 Watt fluorescent lamps which burned for 12 hours every day were installed over the tubes." Based on the fact that the lamps were not Hg-pressure lamps (or similar) but fluorescent lights, combined with the fact that the set-up was made most likely with normal silica-boron glass (not quartz glass) as indicated in the schematic set-up in Figure 2 of the report, it is legitimate to assume that the water/sediment systems were not exposed to any UV light.	22.12.2008 In the report it is stated that "six 20 watt fluorescent lamps which burned for 12 h every day were installed over the tubes". This will be clarified in the amended DAR.	PRAPeR 62 (12-16 January 2009) Open point fulfilled.
4.2	Point of clarification by the applicant PECsw/sed following tractor mounted spray in forests and hand held application in orchards should be provided. Comments from AT, DK and UK to be considered by the NOT in their calculation and the experts' meeting. See reporting table 4(22).	09.11.2008 No further PEC surface water reports following tractor-mounted spray applications or hand-held orchard applications were finalised. However, a detailed amended surface water report (including PECs based on Step 1 through Step 4, i.e. inclusive detailed buffer zone mitigations) was provided (Wanner, 2005; Study # 2004-011 supplemental report). This report provided several safe uses for the highest load applications, i.e. orchard uses based on the NOEC (or EAC) of 0.7 µg/L.	22.12.2008 The EAC will be discussed by the ecotoxicology expert meeting. RMS considers that the EAC should be 0.07 µg/L and using this EAC no safe use is demonstrated for the orchard scenario and the notifiers reasoning fail. If the ectox meeting agrees with the notifier that the EAC should be 0.7 µg/L then safe use has been demonstrated for some FOCUS scenarios if a bufferzone of 20 m is implemented for the orchard use. Nevertheless it is still unclear which buffer zones that will be needed for the tractor mounted application in forest since the application rates differ from	PRAPeR 62 (12-16 January 2009) Point of clarification converted to a data gap 4.2. 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 group
			the orchard use (48 g/ha compared to 180 g/ha). Our conclusion is that since the notifier has not provided further data it will not be possible to conclude on the risk for surface water resulting from hand held use in orchards or from tractor mounted application in forest.	
	Open point 4.6 NL to provide further details on the Dutch surface water exposure assessment model for mushrooms. MSs to discuss the relevance of this model for the EU risk assessment and if exposure to surface water may be considered negligible for the representative use in mushrooms. MS's consider forwarding the issue of mushroom production assessment to PPR Panel. See reporting table 4(24).		22.12.2008 Agree to discuss this issue at the meeting	PRAPeR 62 (12-16 January 2009) Open point fulfilled. New data gap 4.3 proposed, see below..
	New data gap 4.3 is indentified at PRAPeR 62 meeting:			PRAPeR 62 (12-16 January 2009) 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 group
	Identified for surface water, groundwater and soil exposure assessments for the requested uses in protected mushroom production			
	Open point 4.7 Arithmetic mean Koc should be used for calculation of FOCUS PEC GW. List of end points to be amended accordingly. See reporting table 4(25).	09.11.2008 The original ground water PEC report (Goodyear 2003) states: "…For the purposes of this modelling exercise, in all scenarios the Koc of diflubenzuron in soil was taken to be 9148 mL/g, which represents a mean of the available data and is an approach consistent with the FOCUS guidance…Adsorption data for the degradate CPU was measured in four soils and a mean Freundlich Koc of 245 mL/g was obtained…" As not specifically stated that geometric means were used, it is more than reasonable to assume that the reported means are de facto arithmetic averages. For DFBA, see the ground water assessment with zero adsorption.	22.12.2008 The average Koc=9148ml/g, which was used for the FOCUS GW modelling, includes values from studies not considered by the RMS to be valid. Based on additional studies submitted by the notifier in 2004 (D. Adam. 2004. Adsorption of 14C-diflubenzuron on two soils.), the appropriate arithmetic mean is 4620 mg/L (geometric mean 4609mg/L). Even though this value is lower than what is used in the simulations this is considered acceptable since the appropriate Koc still is high and the RMS does not believe that a simulation using the new average would result in a leaching above acceptable trigger.	PRAPeR 62 (12-16 January 2009) Open point open. RMS to add a footnote to the LoEP groundwater and surface water modelling box that the correct Koc value for diflubenzuron that should have been used in simulations was 4620 mL/g.
	Open point 4.8 RMS to summarize and assess in an addendum FOCUS PEC sw/sed for aerial application.	09.11.2008 A detailed amended surface water report (including PECs based on Step 1 through Step 4, i.e. inclusive detailed buffer zone mitigations) was provided	22.12.2008 The report has been summarised in the amended DAR. In conclusion the RMS considers that the result from this simulation cannot be considered to	PRAPeR 62 (12-16 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 4(27).	(Wanner, 2005; Study # 2004-011 supplemental report). This report provided several safe uses for the highest load applications, i.e. orchard uses based on the NOEC (or EAC) of 0.7 µg/L. In addition, the risk for surface water after aerial application over forests was assessed based on a state-of-the-art forestry drift model combined with the standardized FOCUS surface water models (see Wanner, 2005; Study # 2005-036).	represent a realistic worst case scenario for the proposed use.	New open point 4.12 proposed, see below.
	New open point 4.12 is indentified at PRAPeR 62 meeting: EFSA to indicate in the conclusion that when addressing this risk to aquatic insects, exposure via sediment will need to be covered			PRAPeR 62 (12-16 January 2009) Open point open.
	Message from ecotox PRAPeR 63 meeting: to confirm that DT90 field would be less than 100 days for the metabolite CPU, considering that the DT90 lab is in the range of 55.7-111.8 d.			Answer from section 4: This is not possible as there are no field studies in the dossier. Any reply provided would be conjecture.
	Definition of residues requiring assessment in other disciplines or for which a			

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
	groundwater exposure assessment is triggered.			

REPORT OF PRAPeR EXPERT MEETING 63

DIFLUBENZURON

Rapporteur Member State: SE

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
Dec 2008	SE	Diflubenzuron addendum vol 4 Dec 2008 (2) cover page.doc
Dec 2008	SE	Diflubenzuron addendum Vol3_ B8-9 (Dec 2008).doc
22.12.2008	SE	Diflubenzuron evaluation table rev1-0 (22.12.2008).doc
December 2008	SE	Diflubenzuron list of endpoints (December 2008).doc
2007-12-20	SE	Diflubenzuron reporting table rev1-2 (2007-12-20).doc
Dec 2008	SE	Diflubenzuron Revised DAR Vol3_ B9 (Dec 2008).doc
Dec 2008	SE	List of essential studies relied upon_Diflubenzuron_Dec2008.doc

3. Documents tabled at the meeting:

Date	Supplier	File Name
none		

The conclusions of the meeting were as follows:

4. **Data on preparations:** Dimilin WG-80

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

6. **Recommended restrictions/conditions for use:** not to be applied to during the flowering period.

7. **Reference list:** not discussed

Areas of concern: aquatic organisms, bees, non target arthropods

Appendix 1: Discussion table: DIFLUBENZURON

Appendix 2: Evaluation table

Appendix 1: Discussion Table, Diflubenzuron (In)

5. Ecotoxicology

	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	Open point 5.1 RMS to include the food consumption and body weight data for short-term dietary and reproduction studies with birds in a revised DAR. See reporting table 5(1).	This has been done and the meeting agreed.	Open point fulfilled.
	Open point 5.2 RMS to include tables with the full results of the short-term dietary and reproduction studies with birds in an addendum or a revised DAR. See reporting table 5(2).	This has been done and the meeting agreed.	Open point fulfilled.
	Open point 5.3 MSs to discuss whether the application of an interception factors of 60% (40% deposition)	Applicant proposed the interception factor 60% for orchard and 50% for forestry. No data were provided to support this. However the meeting considered those values enough conservative according to the gap and to FOCUS interception factor for orchards.	Open point fulfilled.

	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	for the use in orchards and 50% (50% deposition) for the use in forestry are appropriate for the risk assessment for herbivorous mammals. See reporting table 5(5).		
5.1	Point of clarification for the applicant: Applicant to submit a risk assessment for birds from uptake of contaminated drinking water according to SANCO 4145/2000. See reporting table 5(6).	The experts accepted the risk assessment presented in the addendum and the RMS is now asked to amend the list of end points accordingly	Point of clarification addressed. New open point 5.26 proposed, see below.
	New open point 5.26 is indentified at PRAPeR 63 meeting: RMS to update the list of end points concerning the risk assessment to birds.		Open point open.
5.2	Point of clarification for the applicant: Applicant to submit a risk assessment for earthworm- and fish-eating mammals and	The experts accepted the risk assessment presented in the addendum and the RMS is now asked to amend the list of end points accordingly	Point of clarification addressed. New open point 5.27 proposed, see below.

	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	from uptake of contaminated drinking water according to SANCO 4145/2000. See reporting table 5(7).		
	New open point 5.27 is indentified at PRAPeR 63 meeting: RMS to update the LoE.		Open point open
	Open point 5.4 RMS to correct the TER values for fish-eating birds in a revised DAR. See reporting table 5(10).	This has been done and the meeting agreed.	Open point fulfilled.
	Open point 5.5 RMS to correct the daily intake values for long-term exposure of mammals in a revised DAR. See reporting table 5(11).	This has been done and the meeting agreed.	Open point fulfilled.
	Open point 5.6 RMS to correct the endpoint for fish to 106 mg/L in Table	This has been done and the meeting agreed.	Open point fulfilled.

	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	9.2.9a (Vol. 3) in a revised DAR. See reporting table 5(12).		
	Open point 5.7 MSs to discuss the aquatic risk assessment in an expert meeting. See reporting table 5(13).	RMS has presented an overall evaluation of the effects based on lab data, littoral study and literature review. At 0.7 µg/L effects were observed to zooplankton (recovery was not observed but would be expected to occur after 8 weeks). Effects on amphipods were observed at 0.7 µg/L without recovery. The information did not address the risk to insects and amphipods but there was some indication that insect had similar sensitivity as Daphnia. The RMS proposed a NOAEAC of 0.7 µg/L with an assessment factor (AF) of 10 to account for uncertainty with regard to recovery (univoltine insect species). The experts considered enough an AF of 5, if the endpoint is used to address the risk to zooplankton. The experts were of the opinion that the risk to insects (and amphipods) needs to be addressed by further data, to demonstrate that they are less sensitive or recovery can take place in an acceptable time after the exposure events. Therefore a data gap was identified.	Open point fulfilled. New data gap 5.1 proposed, see below. New open point 5.28, proposed, see below.
	New data gap 5.1 is indentified at PRAPeR 63 meeting: Further address the risk to insects (and amphipods).		Data gap open.
	New open point 5.28 is indentified at PRAPeR 63 meeting: RMS to recalculate TERs for zooplankton and to update the LoE.		Open point open.
	Open point 5.8 RMS to evaluate and include the log Pow values for CPU and DFBA in an addendum to the DAR to address	LogPow values of CPU (1.14) and of DFBA (-0.02) were included in the corrigendum to B.2. The risk of bioaccumulation was considered low.	Open point fulfilled.

	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	the risk of bioconcentration. See reporting table 5(15).		
	Open point 5.9 RMS to update the risk assessment in an addendum/revised DAR taking into account that diflubenzuron is not readily biodegradable and the BCF trigger of 100. See reporting table 5(16).	The meting agreed to the RMS that the risk for bioconcentration is low.	Open point fulfilled. New open point 5.29 proposed, see below.
	New open point 5.29 is defined at PRAPeR 63 meeting: RMS to include the reasoning provided in the evaluation table also in the LoE and to correct bioconcentration trigger to 100.		Open point open.
	Open point 5.10 RMS to correct the endpoint for the acute toxicity to daphnids (EC50 = 2.6 µg/L) in the proposal for classification and	This has been done and the meeting agreed.	Open point fulfilled.

	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	labeling in a revised DAR or addendum to the DAR. See reporting table 5(17).		
	Open point 5.11 RMS to include the toxicity data for the formulation for fish, daphnids and algae in the List of Endpoints. See reporting table 5(22).	This has been done and the meeting agreed.	Open point fulfilled.
	Open point 5.12 RMS to delete the footnotes (1 – 3) in the headline of the TER table for aquatic organisms for the application in pome fruit in the List of Endpoints. See reporting table 5(23).	This has been done and the meeting agreed.	Open point fulfilled.
	Open point 5.13 RMS to include the TERvalues for the most sensitive organism with PECsw from FOCUSstep2 in a revised List of	This has been done and the meeting agreed.	Open point fulfilled.

	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	Endpoints. See reporting table 5(24).		
	Open point 5.14 RMS to provide a re-evaluation of the study of Berends & Thus (1992) in an addendum. If considered as not acceptable it should also be deleted from the references relied on and the list of information, tests and studies relied upon. See reporting table 5(27).	This has been done and the meeting agreed.	Open point fulfilled.
	Open point 5.15 RMS to include an evaluation of the reports of Wyness & Pijst (2005, DI-11802 in an addendum to the DAR. See reporting table 5(29).	This has been done and the meeting agreed. Refer to 5.8	Open point fulfilled.
	Open point 5.16 The aquatic risk assessment needs to		Open point still open. RMS to update the risk

	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	be updated according to the outcome of the discussion in the fate section. See reporting table 5(30).		assessment if necessary.
	Open point 5.17 RMS to verify if the LOEP needs to be corrected (It seems that the comment of the NOT does not relate to the List of Endpoints the applicant refers to Vol. 1, Level 2: page 27, (NOT: last sentence: EC50 mentioned here is incorrect. It should be: EC50 = 2.6 µg/L (see also page 56)) See reporting table 5(31).	This has been done and the meeting agreed.	Open point fulfilled.
	Open point 5.18 RMS to verify if the LOEP needs to be corrected (It seems that the comment of the NOT does not relate to the List of Endpoints) Vol. 1, Level 2: page 56	This has been done and the meeting agreed.	Open point fulfilled.

	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	Table 2.6.2.b Aquatic invertebrates. NOT: The quahogs NOEC = 320 (removal of "1a" mentioned after it). See reporting table 5(32).		
	Open point 5.19 RMS to correct the application rates for the use in forestry (it should read 0.048 kg a.s./ha) and the endpoint for algae (it should be EC50 > 80 mg/ L). See reporting table 5(34).	This has been done and the meeting agreed.	Open point fulfilled.
	Open point 5.20 MSs to discuss the risk assessment for bees in an expert meeting taking into account the additional report from a field study (S.Beuschel (2005). See reporting table 5(35).	The study was evaluated by the RMS in the addendum. However it could not take into account according to the regulation 1095/2007. The risk to bee larvae was not address in the DAR and therefore the experts agreed to restrict the use to avoid the exposure of the pollinators. A data gap was identified to further address the risk to bees.	Open point fulfilled. New data gap 5.2 proposed, see below.
	New data gap 5.2 is identified at PRAPeR		Data gap open.

	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	63 meeting: Address the risk to bees		
	Open point 5.21 MSs to discuss the risk assessment for other non-target arthropods including risk mitigation measures in an expert meeting. See reporting table 5(36).	Standard lab tests and extended lab tests are available. No aged residues, semi-field and field studies were provide and as additional information to address the mode of action (IGR) only literature data was available. However literature data did not address the risk to the most sensitive species (i.e. C. Carnea). The setting of the correction factor was discussed and the experts agreed that the information is not sufficient to reduce the factor to 1. Since for 3 different species the most sensitive stages were tested it was considered appropriate to applied a correction factor of 5 as recommended in the ESCORT 2 guidance for higher tier risk assessment. The experts agreed to a data gap to further address the risk to NTA (in-field recovery/recolonisation should be demonstrated).	Open point fulfilled New data gap 5.3 proposed, see below. New open point 5.30 proposed, see below.
	New data gap 5.3 is indentified at PRAPeR 63 meeting: Further address the risk to NTA (in-field recovery/recolonisatio n should be demonstrated).		Data gap open.
	New open point 5.30 is indentified at PRAPeR 63 meeting: The RMS to update the LoE (to chance the sentence that the in-field risk is acceptable).		Open point open.
	Open point 5.22 RMS to correct the application rate in the LoEP for forestry (it should read 0.048 kg	This has been done and the meeting agreed.	Open point fulfilled.

	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	a.s./ha) and the heading in the table with non-target arthropods (g a.s./ha instead of kg a.s./ha). See reporting table 5(48).		
	Open point 5.23 MSs to discuss in an expert meeting whether testing with the soil metabolite CPU and soil non-target macro-organisms is required. See reporting table 5(52).	RMS suggested that no testing with the soil metabolite are necessary. The meeting agreed with the RMS since the DT90lab ranges between 55.7 and 111.8 d, therefore it is considered unlikely that the DT90 field would be greater than 100 d. Message to fate meeting: to confirm this assumption. The fate meeting could not confirm the assumption, since no field studies are available. Differences on the acute toxicity tests with daphnia suggested that the IGR mode of action is not present in CPU metabolite. The meeting agreed to request the RMS to put an argumentation on the LoE on this issue.	Open point open, pending on the answer of the fate meeting. New open point 5.31 propose, see below.
	New open point 5.31 is identified at PRAPeR 63 meeting: RMS to put a foot note on the list of end points on this issue (IGR mode of action not present in CPU metabolite.		Open point open.
	Open point 5.24 MSs to discuss in an expert meeting the risk assessment for soil non-target micro-organisms taking into account that effects of	Effects >25% were observed in a study at dose ranges 75-750 g a.s/ha after 28 days. However based on a second study the effects on nitrate formation were less than 25% after 2 month at 750 g a.s./ha. The meeting agreed that the risk could be considered addressed.	Open point fulfilled.

	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	>25% were observed within 28d at application rates below the rate suggested in the GAP. See reporting table 5(53).		
	Open point 5.25 RMS to delete the reference Dykstra, A.C., Lewis, G., Mackay, N. (2003) from the references relied on and from the list of information, test and studies. See reporting table 5(56).	This has been done and the meeting agreed.	Open point fulfilled.
	Message to PRAPeR 63 fate meeting: to confirm that DT90 field would be less than 100 days for the metabolite CPU, considering that the DT90 lab is in the range of 55.7-111.8 d.		Answer from PRAPeR 63 fate meeting: This is not possible as there are no field studies in the dossier. Any reply provided would be conjecture.

Appendix 2: Evaluation table

3. 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: ***25*** Points for clarification: ***2*** Data gaps: ***0***			Section 5 Open points: ***7*** Points for clarification: ***0*** Data gaps: ***3***
	Open point 5.1 RMS to include the food consumption and body weight data for short-term dietary and reproduction studies with birds in a revised DAR. See reporting table 5(1).		22.12.2008 The food consumption and body weight data for the highest dose is included in the amended DAR.	PRAPeR 63 (13-15 January 2009) Open point fulfilled.
	Open point 5.2 RMS to include tables with the full results of the short-term dietary and reproduction studies with birds in an addendum or a revised DAR. See reporting table 5(2).		22.12.2008 Further information on the results has been included in the addendum.	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
	Open point 5.3 MSs to discuss whether the application of an interception factors of 60% (40% deposition) for the use in orchards and 50% (50% deposition) for the use in forestry are appropriate for the risk assessment for herbivorous mammals. See reporting table 5(5).		22.12.2008 We agree to discuss this.	PRAPeR 63 (13-15 January 2009) Open point fulfilled.
5.1	Point of clarification for the applicant: Applicant to submit a risk assessment for birds from uptake of contaminated drinking water according to SANCO 4145/2000. See reporting table 5(6).		22.12.2008 A risk assessment for birds for uptake via contaminated drinking water has been included in the addendum. All TER was above annex VI triggers. For use in orchards birds was assumed to be exposed only through drinking surface waters since diflubenzuron is neither applied in summer nor in crops liable to hold water in the axils of leaves. For the use in forests risk assessment was in addition to exposure via surface water also consider exposure via drinking from puddles since diflubenzuron may be applied during summer months in forests (for hand- and tractor-mounted application only, since it is not assumed that aerial application will result in puddles of spray liquid).	PRAPeR 63 (13-15 January 2009) Point of clarification addressed. New open point 5.26 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 5.26 is identified at PRAPeR 63 meeting: RMS to update the list of end points concerning the risk assessment to birds.			PRAPeR 63 (13-15 January 2009) Open point open.
5.2	Point of clarification for the applicant: Applicant to submit a risk assessment for earthworm- and fish-eating mammals and from uptake of contaminated drinking water according to SANCO 4145/2000. See reporting table 5(7).		22.12.2008 A risk assessment for mammals for uptake via contaminated drinking water has been included in the addendum. For use in orchards mammals were assumed to be exposed only via surface waters since diflubenzuron is neither applied in summer nor in crops liable to hold water in the axils of leaves. For the use in forests risk assessment was in addition to exposure via surface water also consider exposure via drinking from puddles since diflubenzuron may be applied during summer months in forests (for hand- and tractor-mounted application only, since it is not assumed that aerial application will result in puddles of spray liquid). A risk assessment for mammals for the uptake of contaminated earthworms and fish will be included in the addendum.	PRAPeR 63 (13-15 January 2009) Point of clarification addressed. New open point 5.27 proposed, see below.
	New open point 5.27 is identified at PRAPeR 53 meeting: RMS to update the LoE			PRAPeR 63 (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
	Open point 5.4 RMS to correct the TER values for fish-eating birds in a revised DAR. See reporting table 5(10).		22.12.2008 This has been corrected in the revised DAR	PRAPeR 63 (13-15 January 2009) Open point fulfilled.
	Open point 5.5 RMS to correct the daily intake values for long-term exposure of mammals in a revised DAR. See reporting table 5(11).		22.12.2008 This has been corrected in the revised DAR	PRAPeR 63 (13-15 January 2009) Open point fulfilled.
	Open point 5.6 RMS to correct the endpoint for fish to 106 mg/L in Table 9.2.9a (Vol. 3) in a revised DAR. See reporting table 5(12).		22.12.2008 This has been corrected in the revised DAR	PRAPeR 63 (13-15 January 2009) Open point fulfilled.
	Open point 5.7 MSs to discuss the aquatic risk assessment in an expert meeting. See reporting table 5(13).		22.12.2008 We agree to discuss this at the meeting.	PRAPeR 63 (13-15 January 2009) Open point fulfilled. New data gap 5.1 proposed, see below. New open point 5.28 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 data gap 5.1 is identified at PRAPeR 63 meeting: Further address the risk to insects (and amphipods).			PRAPeR 63 (13-15 January 2009) Data gap open.
	New open point 5.28 is identified at PRAPeR 63 meeting: RMS to recalculate TERs for zooplankton and to update LoE			PRAPeR 63 (13-15 January 2009) Open point open.
	Open point 5.8 RMS to evaluate and include the log Pow values for CPU and DFBA in an addendum to the DAR to address the risk of bioconcentration. See reporting table 5(15).		22.12.2008 The log Pow of CPU is 1.14 and of DFBA -0.02 (this information has been included in a corrigendum to B.2.), hence the risk of bioconcentration of these metabolites is low. This rational has been included in the addendum (B.9.2.6)	PRAPeR 63 (13-15 January 2009) Open point fulfilled.
	Open point 5.9 RMS to update the risk assessment in an addendum/revised DAR taking into account that diflubenzuron is not readily biodegradable and the BCF trigger of 100. See reporting table 5(16).		22.12.2008 RMS has updated DAR taking into account that diflubenzuron is not biodegradable (see addendum section B. 4). The study investigating the BCF had some shortcomings, e.g. only one concentration was tested, and the measured concentration was not maintained within 20% of nominal concentration (for further details see the DAR). The BCF from this study was 320 and since this was	PRAPeR 63 (13-15 January 2009) Open point fulfilled. New open point 5.29 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
			considerably lower that the trigger of 1000 for readily biodegradable substances the study was considered as acceptable. However, since diflubenzuron is considered as non biodegradable the BCF trigger of 100 is breached and a higher tier risk assessment is required, considering (according to Aquatic Guidance doc.) - Direct long-term effects in fish due to bioconcentration: However since the diflubenzuron EC50 > 0.1mg/L no further data for long term effects in fish is needed - Secondary poisoning of birds and mammals: for bird this is provided in the DAR (see section B 9.1.5) and for mammals in section B.9.3 in the addendum. - Biomagnification in aquatic food-chains: is not needed since the BCF< 1000 and DT90< 100 days.	
	New open point 5.29 is indentified at PRAPeR 63 meeting: RMS to include the reasoning provided in the evaluation table also in the LoE and to correct bioconcentration			PRAPeR 63 (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
	trigger to 100.			
	Open point 5.10 RMS to correct the endpoint for the acute toxicity to daphnids (EC50 = 2.6 µg/L) in the proposal for classification and labeling in a revised DAR or addendum to the DAR. See reporting table 5(17).		22.12.2008 This has bee corrected in the revised DAR.	PRAPeR 63 (13-15 January 2009) Open point fulfilled.
	Open point 5.11 RMS to include the toxicity data for the formulation for fish, daphnids and algae in the List of Endpoints. See reporting table 5(22).		22.12.2008 This has been included in the revised LoEP.	PRAPeR 63 (13-15 January 2009) Open point fulfilled.
	Open point 5.12 RMS to delete the footnotes (1 – 3) in the headline of the TER table for aquatic organisms for the application in pome fruit in the List of Endpoints. See reporting table 5(23).		22.12.2008 This has been included in the revised LoEP.	PRAPeR 63 (13-15 January 2009) Open point fulfilled.
	Open point 5.13		22.12.2008	PRAPeR 63 (13-15 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 group
	RMS to include the TERvalues for the most sensitive organism with PECsw from FOCUSstep2 in a revised List of Endpoints. See reporting table 5(24).		TER values for the most sensitive organism with PECsw from FOCUSstep2 has been included in the revised List of Endpoints.	Open point fulfilled.
	Open point 5.14 RMS to provide a re-evaluation of the study of Berends & Thus (1992) in an addendum. If considered as not acceptable it should also be deleted from the references relied on and the list of information, tests and studies relied upon. See reporting table 5(27).		22.12.2008 The study has been re-evaluated and is not considered as acceptable. This is corrected in an amended DAR. This does however not affect the conclusion of the risk assessment since results from tests using *S. capricornutum* was used for the risk assessment. The study is deleted from the references relied on and the list of information, tests and studies relied upon.	PRAPeR 63 (13-15 January 2009) Open point fulfilled.
	Open point 5.15 RMS to include an evaluation of the reports of Wyness & Pijst (2005, DI-11802 in an addendum to the DAR. See reporting table 5(29).		22.12.2008 An evaluation of the report has been included in the addendum.	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
	Open point 5.16 The aquatic risk assessment needs to be updated according to the outcome of the discussion in the fate section. See reporting table 5(30).		22.12.2008 We agree.	PRAPeR 63 (13-15 January 2009) Open point still open. RMS to update the risk assessment if necessary.
	Open point 5.17 RMS to verify if the LOEP needs to be corrected (It seems that the comment of the NOT does not relate to the List of Endpoints the applicant refers to Vol. 1, Level 2: page 27, (NOT: last sentence: EC50 mentioned here is incorrect. It should be: EC50 = 2.6 µg/L (see also page 56)) See reporting table 5(31).		22.12.2008 It was the Vol.1 and B.4. that needed correction not LoEP.	PRAPeR 63 (13-15 January 2009) Open point fulfilled.
	Open point 5.18 RMS to verify if the LOEP needs to be corrected (It seems that the comment of the NOT does not relate to the List of Endpoints) Vol. 1, Level 2: page 56 Table 2.6.2.b Aquatic		22.12.2008 It was the Vol.2 that needed correction not LoEP.	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
	invertebrates. NOT: The quahogs NOEC = 320 (removal of "1a" mentioned after it). See reporting table 5(32).			
	Open point 5.19 RMS to correct the application rates for the use in forestry (it should read 0.048 kg a.s./ha) and the endpoint for algae (it should be EC50 > 80 mg/ L). See reporting table 5(34).		22.12.2008 This has been corrected in the revised LoEP	PRAPeR 63 (13-15 January 2009) Open point fulfilled.
	Open point 5.20 MSs to discuss the risk assessment for bees in an expert meeting taking into account the additional report from a field study (S.Beuschel (2005). See reporting table 5(35).		22.12.2008 The study has been summarised and evaluated in the addendum. The study was well performed and is considered as valid for risk assessment. In this study no adverse effects on honey bees were observed following treatment with diflubenzuron. However, the RMS notes that diflubenzuron is mentioned as a reference substance in the OECD Draft guidance document on honey bee (*Apis mellifera* L.) brood test under semi-field conditions (February 2006) and consider that this fact need to be	PRAPeR 63 (13-15 January 2009) Open point fulfilled. New data gap 5.2 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
			discussed at an expert meeting before the restriction that diflubenzuron should not be applied to flowering crop is removed.	
	New data gap 5.2 is indentified at PRAPeR 63 meeting: Address the risk to bees			PRAPeR 63 (13-15 January 2009) Data gap open.
	Open point 5.21 MSs to discuss the risk assessment for other non-target arthropods including risk mitigation measures in an expert meeting. See reporting table 5(36).		22.12.2008 We agree to discuss the assessment at the meeting.	PRAPeR 63 (13-15 January 2009) Open point fulfilled. New data gap 5.3 proposed, see below. New open point 5.30 proposed, see below.
	New data gap 5.3 is indentified at PRAPeR 63 meeting: Further address the risk to NTA (in-field recovery/recolonisation should be demonstrated)			PRAPeR 63 (13-15 January 2009) Data gap open.
	New open point 5.30 is indentified at PRAPeR 63 meeting: The RMS to update the LoE (to change the sentence that the in-field risk is acceptable).			PRAPeR 63 (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
	Open point 5.22 RMS to correct the application rate in the LoEP for forestry (it should read 0.048 kg a.s./ha) and the heading in the table with non-target arthropods (g a.s./ha instead of kg a.s./ha). See reporting table 5(48).		22.12.2008 This has been corrected in the revised LoEP	PRAPeR 63 (13-15 January 2009) Open point fulfilled.
	Open point 5.23 MSs to discuss in an expert meeting whether testing with the soil metabolite CPU and soil non-target macro-organisms is required. See reporting table 5(52).		22.12.2008 In the terrestrial guidance document it is stated that studies on soil non target macro-organisms should be undertaken if the DT90f>100 d. Since the DT90lab for CPU ranges between 55.7-111.8 d (mean 77.3 d) it unlikely that the field dissipation rate would exceed 100 days and therefore the RMS considers this test as unnecessary.	PRAPeR 63 (13-15 January 2009) Open point may be fulfilled pending on the answer of the fate meeting. New open point 5.31 proposed, see below.
	New open point 5.31 is identifies at PRAPeR 63 meeting: RMS to put a foot note on the LoE on this issue (IGR mode of action not present in CPU metabolite).			PRAPeR 63 (13-15 January 2009) Open point open.
	Open point 5.24 MSs to discuss in an expert meeting the risk assessment		22.12.2008 We agree to discuss this at a meeting.	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
	for soil non-target micro-organisms taking into account that effects of >25% were observed within 28d at application rates below the rate suggested in the GAP. See reporting table 5(53).			
	Open point 5.25 RMS to delete the reference Dykstra, A.C., Lewis, G., Mackay, N. (2003) from the references relied on and from the list of information, test and studies. See reporting table 5(56).		22.12.2008 This has been deleted.	PRAPeR 63 (13-15 January 2009) Open point fulfilled.
	Message to fate PRAPeR 63 meeting: to confirm that DT90 field would be less than 100 days for the metabolite CPU, considering that the DT90 lab is in the range of 55.7-111.8 d.			PRAPeR 63 (13-15 January 2009) Answer from fate PRAPeR 63meeting: This is not possible as there are no field studies in the dossier. Any reply provided would be conjecture.

Report of PRAPeR Expert MEETING 64

DIFLUBENZURON

Rapporteur Member State: SE

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
Dec 2008	SE	Diflubenzuron addendum vol 4 Dec 2008 (2) cover page.doc
Dec 2008	SE	Diflubenzuron Addendum Vol3_B6 (Dec 2008).doc
22.12.2008	SE	Diflubenzuron evaluation table rev1-0 (22.12.2008).doc
December 2008	SE	Diflubenzuron list of endpoints (December 2008).doc
2007-12-20	SE	Diflubenzuron reporting table rev1-2 (2007-12-20).doc
Dec 2008	SE	Diflubenzuron Revised DAR Vol3_B6 (Dec 2008).doc
Dec 20008	SE	List of essential studies relied upon_Diflubenzuron_Dec2008.doc

3. Documents tabled at the meeting:

Date	Supplier	File Name
none		

The conclusions of the meeting were as follows:

4. **Data on preparations:** “Dimilin WG 80”

5. **Classification and labelling:** none

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

7. **Reference List:** not discussed

Areas of concern: aerial application in forestry inconclusive

Appendix 1: Discussion table: DIFLUBENZURON

Appendix 2: Evaluation table

Appendix 1: Discussion Table, Diflubenzuron (In)

2. Mammalian toxicology

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	Open point 2.1 The acute toxicity to be agreed on in an experts' meeting considering the different batches tested. See reporting table 2(2).	In some acute toxicity studies the purity of the batches used was not reported. It was clarified by the RMS in the addendum that most of the batches have a purity of > 99.6%. In the sensitizing study it was 95.6%. In the 5 batch analysis the range of diflubenzuron purity is between 97.9% and 99.1%. The experts agreed that the level of impurities in the acute tox studies is acceptable. With regard to the batches tested in other tox tests, it was raised the point of their equivalence to the currently proposed specification (taking into account that no final specification was agreed by the phys-chem meeting).	Open point fulfilled. New open point 2.6 proposed, see below.
	New open point 2.6 identified at PRAPeR 64 meeting: The comparison of the current specification and the batches tested in the mammalian toxicity data package	1) No analysis of tox batches is available, no specification was agreed. The applicant has to evaluate the equivalence of the tox batches and technical specification. 2) The latest information on 4-chloroaniline (PCA) (presented during the meeting, although submitted in 2006) should be evaluated by RMS.	Open point open. New data gap 2.1 proposed, see below. New open point 2.7 proposed, see below.
	New data gap 2.1 identified at PRAPeR 64 meeting: Equivalence of the batches tested in the mammalian toxicology to the representative specification missing		Data gap open.

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	New open point 2.7 identified at PRAPeR 64 meeting: The last information submitted by the applicant on PCA to be evaluated by the RMS.		Open point open.
	Open point 2.2 The toxicological relevance of increased methaemoglobin to be discussed in a meeting of experts. See reporting table 2(5).	Methaemoglobinemia is a consistent finding in all studies as well as other changes in blood parameters. Effects on liver and spleen weight together with histopatological findings like haemosiderosis were also observed. In the original DAR an overall picture of findings was considered, not the single effect "methaemoglobinemia", whereas in the Addendum and revised DAR the RMS proposed to lower many of originally proposed NOAELs. The experts agreed that the NOAEL of the 1-year dog study (crucial for setting the AOEL) could be set at 10 mg/kg bw/d (as stated in the original DAR), based on effects indicating blood toxicity (pigmentation, organ weight changes and methaemoglobinemia) at 50 mg/kg bw/d. In the 13-weeks rat study (Burdock at al.) the NOAEL was set at 11 mg/kg bw/d in the original DAR (based on decreased erythrocyte counts, increased methaemoglobin and reticulocytes percentage and increased spleen and liver weight together with histopatological findings at 27.5 mg/kg bw/d), whereas it was changed to LOAEL in the Addendum and in the revised DAR. After the discussion the experts agreed to disregard the revised NOAELs in the Addendum and revised DAR, which are based solely on methaemoglobin increase and therefore regarded as not sufficient (with regard to the 1-year dog study and the 13-weeks rat study the NOAELs of 10 and 11 mg/kg bw/day, respectively, were agreed on). In addition, the RMS proposed a new labeling as R48/22 based on effects on haemotological parameters. The majority of the experts proposed no classification as Xn, R48/22. Nevertheless, the proposal Xn, R48/22 should be flagged to EChA for decision.	Open point fulfilled. Methaemoglobinemia is a relevant finding when considered in the overall picture of haematological effects.

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	Open point 2.3 Reference values to be agreed on at an experts' meeting See reporting table 2(9).	Original DAR: the Acceptable Daily Intake (ADI) was proposed at 0.02 mg/kg bw/d (1-year dog, SF 100, but based on NOEL of 2 mg/kg bw/d) Addendum and revised DAR: ADI was proposed at 0.012 mg/kg bw/d (91-week mouse, SF 100, based on NOAEL of 1.2 mg/kg bw/d) The experts agreed that the ADI should be based on the 1-year dog study (NOAEL of 10 mg/kg bw/d, supported by 91-week mouse study) = 0.1 mg/kg bw/d In the DAR 2 long term toxicity studies in rats were available. The first study showed an NOAEL of 31.2 mg/kg bw/day based on haematological changes. The second long-term rat study (1976) was used by JMPR (2001) for setting the ADI of 0.02 mg/kg bw/d; however, the RMS considered the study not acceptable (very high mortality observed, several other limitations). The only effect was an increase of methaemoglobin but well within the biological variation. Original DAR: AOEL was proposed at 0.033 mg/kg bw/d (an overall NOAEL of 1-year dog, 90 day rat, 90 day mouse, SF 100) Addendum and revised DAR: AOEL was proposed at 0.0066 mg/kg bw/d (1 year dog, SF 100, based on NOAEL of 2 mg/kg bw/d, 33% oral absorption) The experts in the meeting agreed that the AOEL should be based on the 1-year dog study (NOAEL of 10 mg/kg bw/d, supported by 13-week rat study, 33% oral absorption and SF 100) = 0.033 mg/kg bw/d. Original DAR: ArfD was not allocated since it was not considered necessary. The experts agreed.	Open point fulfilled. The ADI of 0.1 mg/kg bw/d was based on the 1-year dog study (NOAEL of 10 mg/kg bw/d, supported by 91-week mouse study, SF 100) The AOEL of 0.033 mg/kg bw/d was based on the 1-year dog study (NOAEL of 10 mg/kg bw/d, supported by 13-week rat study, 33% oral absorption and SF 100) ARfD was not allocated since it is not necessary due to the toxicological profile of diflubenzuron.
	Open point 2.4 Dermal absorption to be confirmed in an experts' meeting. See reporting table 2(14).	The test substance in the summarized in vivo study was diflubenzuron, not the representative formulation (which contains 80% diflubenzuron) The experts assumed that the co-formulants in WG formulation would probably not increase the value. In the original DAR: 0.5% (without amount in the skin), for concentrate and dilution was proposed, whereas in the revised DAR and Addendum: 6% (including the	Open point fulfilled. The experts agreed on 6% dermal absorption for both the concentrate and the dilution.

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
		amount stored in the skin), for concentrate and dilution was proposed. The experts agreed on 6% dermal absorption for both the concentrate and the dilution.	
2.1	Point of clarification: (for formal reason, already submitted by the applicant) Applicant to provide further exposure details based on the intended uses See reporting table 2(16).	NOT submitted the information and this was evaluated in the revised DAR and the Addendum.	Point of clarification addressed.
	Open point 2.5 Operator, worker and bystander exposure to be confirmed at a meeting of experts. See reporting table 2(16).	Due to the revised AOEL and dermal absorption value the exposure for operator, worker and bystander will be recalculated. It was re-iterated that the exposure models should be primarily used in their original form, before being refined (tier approach). If modifications apply, a justification/description should be provided. The following are the agreed input parameters to be used for the revised risk assessment by the RMS. <u>OPERATOR</u> Orchards: Tractor-mounted: RMS made a refinement for the UK POEM – the treated area to be reduced from 15ha to 8ha, 60 kg body weight. The experts decided to use the original value of 15ha, because no reason to reduce. Body weight 60 kg German model: 8ha and 70 kg bw Hand-held: UK POEM: 1ha, 60 kg bw, 2.5L tank German model : 1ha, 70 kg bw Mushrooms Only German Model used Application area 0.15 ha (it was noted this is not a standard value; however it was	Open point fulfilled. New open point 2.8 proposed, see below New data gap 2.2 proposed, see below.

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
		agreed as being representative) Body weight should be increased to 70kg Forestry If tractor or hand-held application - same parameters as in orchards For aerial application no reliable exposure calculations were provided. <u>WORKER</u> Orchards: EUROPOEM; DFR should be changed to from 1 to 3 µg/cm^2 Mushrooms No model existing, NOT submitted a field study (4 workers filling pots with soil) The experts agreed that it might be the worst case. Taking into account that the treatment is performed at the early stage, direct contamination of mushrooms should not occur (only soil is contaminated). The study can be regarded as supportive of a worst case if re-entry exposure would occur (unlikely) Forestry The re-entry should be calculated by RMS (e.g. 2h scouting activities) <u>BYSTANDER</u> Orchards Calculations already presented. Input parameters agreed on. Mushrooms No bystander exposure expected. Forestry Same calculations should be performed as for orchards (ground application).	

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	New open point 2.8 identified at PRAPeR 64 meeting (for RMS): Operator, worker and bystander exposure to be recalculated according to agreed input parameters and considering the new AOEL and dermal absorption value.		Open point open.
	New data gap 2.2 identified at PRAPeR 64 meeting: Reliable aerial application calculations in forestry missing.		Data gap open.
	Question from the residue session PRAPeR 65 meeting: toxicological relevance of metabolites 4-chloroaniline (PCA), 2,6-Difluorobenzoic acid (DFBA), 2,6-difluorobenzamid (DFBAM) and 4-chlorphenylurea (CPU).	DFBA: LD50 = 4600 mg/kg bw (literature data not present in the DAR) and it occurs in the rat metabolism in high amount; if necessary, the trigger values of the parent can be used (same tox profile) CPU: LD50 = 1100 mg/kg bw, (literature data not present in the DAR) and unclear amount in the rat metabolism (the information was received during the meeting and could not be evaluated, so no conclusion on the tox relevance at the moment) PCA: Carc. Cat. 2 (of toxicological relevance because of tox properties; the RMS provided the day before the meeting a position paper prepared by the applicant; however, due to the late submission it was not possible to assess it properly; therefore, it was not possible setting specific reference values). DFBAM: LD50 = 2065 mg/kg bw (literature data literature data not present in the DAR). Due to lack of enough data no conclusion of the tox relevance at the moment.	Answer to the question from the residue session PRAPeR 65 meeting: DFBA is expected to have the same tox profile as diflubenzuron, and the same reference values could be used. With regard to CPU and DFBAM it was not possible to conclude on their toxicological relevance. PCA was considered of toxicological relevance because of its carcinogenic properties; however, it was not possible setting specific reference values.

Appendix 2: Evaluation table

4. 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: ***5*** Points for clarification: ***1*** Data gaps: ***0***			Section 2 Open points: 3 Points for clarification: ***0*** Data gaps: ***2***
	Open point 2.1 The acute toxicity to be agreed on in an experts' meeting considering the different batches tested. See reporting table 2(2).		22.12.2008 RMS has received a document with the acute toxicity purity levels and it has been added to the addendum and the correct concentrations have also been added in the revised DAR.	PRAPeR 64 (19-23 January 2009) Open point fulfilled. New open point 2.6 proposed, see below.
	New open point 2.6 identified at PRAPeR 64 meeting: The comparison of the current specification and the batches tested in the mammalian toxicity data package.			PRAPeR 64 (19-23 January 2009) Open point open. New data gap 2.1 proposed, see below. New open point 2.7 proposed, see below.
	New data gap 2.1 identified at PRAPeR 64 meeting: Equivalence of the batches tested in the mammalian toxicology to the representative specification missing.			PRAPeR 64 (19-23 January 2009) 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
	New open point 2.7 identified at PRAPeR 64 meeting: The last information submitted by the applicant on PCA to be evaluated by the RMS.			PRAPeR 64 (19-23 January 2009) Open point open.
	Open point 2.2 The toxicological relevance of increased methaemoglobin to be discussed in a meeting of experts. See reporting table 2(5).		22.12.2008 According to RMS, detected increase of methaemoglobin should be considered as an adverse effect (see addendum).	PRAPeR 64 (19-23 January 2009) Open point fulfilled. Mthaemoglbinemia is a relevant finding when considered in the overall picture of haematological effects.
	Open point 2.3 Reference values to be agreed on at an experts' meeting See reporting table 2(9).		22.12.2008 RMS has the following opinion: AOEL = 0.0066 mg/kg bw/day using NOAEL 2 mg/kg bw/day from 1 y dog study based on increased methaemoglobin and sulfhaemoglobin formation. ADI = 0.012 mg/kg bw/day using NOAEL 1.2 mg/kg bw/day from 91 w mouse study based on increased methaemoglobin and sulfhaemoglobin in both sexes. ARfD = 0.4 mg/kg bw/day based on LOAEL 80 mg/kg bw/day from 28-day rat study. A safety factor of 100 is used for	PRAPeR 64 (19-23 January 2009) Open point fulfilled. The ADI of 0.1 mg/kg bw/d was based on the 1-year dog study (NOAEL of 10 mg/kg bw/d, supported by 91-week mouse study, SF 100) The AOEL of 0.033 mg/kg bw/d was based on the 1-year dog study (NOAEL of 10 mg/kg bw/d, supported by 13-week rat study, 33% oral absorption and SF 100)

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
			AOEL and ADI and 200 for ARfD, moreover, compensation for 33 % oral absorption are used for AOEL.	ARfD was not allocated since it is not necessary due to the toxicological profile of diflubenzuron
	Open point 2.4 Dermal absorption to be confirmed in an experts' meeting. See reporting table 2(14).		22.12.2008 RMS agrees with the comment from NL and DK that the dermal absorption should be considered to be 6 % as the amount remaining in the skin after 10 hours can be absorbed. It has been changed in the DAR and used in the addendum for the exposure calculations.	PRAPeR 64 (19-23 January 2009) Open point fullfilled. The experts agreed on 6% dermal absorption for both the concentrate and the dilution.
2.1	Point of clarification: (for formal reason, already submitted by the applicant) Applicant to provide further exposure details based on the intended uses See reporting table 2(16).		22.12.2008 Calculations for operator exposure in forestry using either tractor-mounted or hand-held spray are added to the addendum. Calculations for bystanders and workers in the orchard have also been included.	PRAPeR 64 (19-23 January 2009) Point of clarification addressed.
	Open point 2.5 Operator, worker and bystander exposure to be confirmed at a meeting of experts. See reporting table 2(16).		22.12.2008 Calculations for operator exposure in forestry using either tractor-mounted or hand-held spray are added to the addendum. Calculations for bystanders and workers in the orchard have also been included.	PRAPeR 64 (19-23 January 2009) Open point fulfilled New open point 2.8 proposed, see below. New data gap 2.2 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 Meeting
	New open point 2.8 identified at PRAPeR 64 meeting (for RMS): Operator, worker and bystander exposure to be recalculated according to agreed input parameters and considering the new AOEL and dermal absorption value.			PRAPeR 64 (19-23 January 2009) Open point open.
	New data gap 2.2 identified at PRAPeR 64 meeting: Reliable aerial application calculations in forestry missing.			PRAPeR 64 (19-23 January 2009) Data gap open.
	Question from the residue session PRAPeR 65 meeting: toxicological relevance of metabolites 4-chloroaniline (PCA), 2,6-Difluorobenzoic acid (DFBA), 2,6-difluorobenzamid (DFBAM) and 4-chlorphenylurea (CPU).			PRAPeR 64 (19-23 January 2009) Answer to the question from the residue session PRAPeR 65 meeting: DFBA is expected to have the same tox profile as diflubenzuron, and the same reference values could be used. With regard to CPU and DFBAM it was not possible to conclude on their toxicological relevance. PCA was considered of toxicological relevance because of its carcinogenic properties; however, it was not possible setting specific reference values.

REPORT OF PRAPeR EXPERT MEETING 65

DIFLUBENZURON

Rapporteur Member State: SE

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	SE	Diflubenzuron Addendum Vol3_B7 (Dec 2008).doc
December 2008	SE	Diflubenzuron Corrigendum Vol3_ B7 (Dec 2008).doc
22.12.2008	SE	Diflubenzuron evaluation table rev1-0 (22.12.2008).doc
December 2008	SE	Diflubenzuron list of endpoints (December 2008).doc
2007-12-20	SE	Diflubenzuron reporting table rev1-2 (2007-12-20).doc
Dec 2008	SE	Diflubenzuron vol 4 Dec 2008 (2) cover page.doc
Dec 2008	SE	List of essential studies relied upon_Diflubenzuron_Dec2008.doc

3. Documents tabled at the meeting:

Date	Supplier	File Name
none		

The conclusions of the meeting were as follows:

4. **Data on preparations:** DIMILIN WG 80

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

6. **Recommended restrictions/conditions for use:** Fruit crops and forest (foliar application only). Mushrooms (soil application)

7. **Reference List:** Not discussed.

Areas of concern: Provisional risk assessment with regard to the provisional DOR in plants and animals, residue levels in processed products and animal matrices.

Appendix 1: Discussion table: DIFLUBENZURON

Appendix 2: Evaluation table

Appendix 1: Discussion Table, Diflubenzuron (In)

3. Residues

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	Open point 3.1 MS to discuss the residue definition for plant commodities in an expert meeting. See reporting table 3(11).	Metabolism studies in apples, oranges and mushrooms were provided in the DAR. Very little degradation of the parent compound was observed in the metabolism studies on apples and oranges (foliar application). Diflubenzuron was found at up to 97% TRR in apples and oranges. The metabolites PCA, CPU and DFBA were below the LOQ of 0.001 mg/kg (Table B.7.1.5-1 in the DAR). In the mushrooms metabolism study (casing treatment) performed at 5 fold the critical dose rate of application (1 g as/m2), the following metabolites were found: DFBA, CPU and PCA. The parent was found at a very low level (0.5% TRR) whereas DFBA was found at a level of 91% TRR (approximately 100 fold the parent level); CPU at 0.8% TRR), PCA at 0.6% TRR. Casing treatment: the a.s. is mixed with the soil and the mushrooms are added. No further clarification on the use pattern could be provided by RMS. It is unlikely that considerable amounts of the parent compound are taken up from the soil since the DT90 of the parent is short. The meeting stated that metabolism studies are only available for foliar application on fruit crops and soil application on mushrooms. <u>The tox meeting provided the following information:</u> **Diflubenzuron:** **ADI** = 0.1 mg/kg bw/d **ArfD** was not allocated **DFBA:** LD50 = 4600 mg/kg bw, it occurs in the rat metabolism in high amount; if necessary, the trigger values of the parent can be used (same tox profile) **CPU**: LD50 = 1100 mg/kg bw, unclear amount in the rat metabolism (the information was received during the meeting and could not be evaluated, so no conclusion on the tox relevance at the moment)	Open point remains open.

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
		PCA: Carc. Cat. 2 (of toxicological relevance; the information was received during the meeting and could not be evaluated, so no further conclusion risk assessment for the consumer possible at the moment) **DFBAM**: LD50 = 2065 mg/kg bw (due to lack of data no conclusion of the tox relevance at the moment) Residue definitions should be set as follows: **DOR for monitoring**: -Diflubenzuron for fruit crops (foliar application), -DFBA for mushrooms. **Provisional DOR for RA for fruit crops**: Diflubenzuron for fruit crops (foliar use) pending further information on the nature of the residues in processed fruit. The meeting discussed which metabolites have to be included in the DOR for RA for mushrooms focusing on the tox relevance of PCA (carcinogenicity-categ.2). The meeting was not able to conclude on the residue definition for risk assessment in absence of a final toxicological assessment of the different metabolites of concern. In the available US trials (Addendum from December 2008) quantifiable residues of DFB, PCA and CPU were found. No residue trials were provided in compliance with the proposed DOR for monitoring. **Provisional DOR for RA in mushrooms:** **a)DFBA** **b)Sum of DFB+CPU+PCA expressed as PCA equiv.** When the tox relevance of the metabolites is clarified, this DOR should be discussed taking into account all components with an adjustment factor for PCA for the DOR. In the future, if further crops are supported with soil/foliar application, further metabolism studies will be needed. The meeting mentioned that the OECD deleted the mushrooms out from fruit category and put them in another category. The meeting noted that the metabolite DFBA was a common structure for different active	

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
		substances.	
	Message 3.1 to the tox section PRAPeR 65 meeting: The meeting was not able to conclude on the residue definition for risk assessment in absence of the final toxicological assessment of the different metabolites of concern (CPU, PCA). The tox section to address tox reference values for PCA metabolite according to the available information received.		Answer from tox section PRAPeR 64 meeting: DFBA is expected to have the same tox profile as diflubenzuron, and the same reference values could be used. With regard to CPU and DFBAM it was not possible to conclude on their toxicological relevance. PCA was considered of toxicological relevance because of its carcinogenic properties; however, it was not possible setting specific reference values.
	Open point 3.2 MS to discuss the residue definition in animal commodities in an expert meeting. See reporting table 3(12).	In animal products, the metabolite CPU is formed in all the laying hen matrices except in egg white. The parent was the dominant metabolite in the fat. In goat, only milk and liver were investigated for metabolite identification. The parent was not detected in milk and recovered at a very low level in liver (3.8-5.4 % TRR). No data were provided for the other matrices (muscle, kidney and fat) of the ruminants although according to the notifier attempts were made but were unsuccessful. It was noted that at the high dose, the total residues found in ruminant muscle were: 0.02-0.05 ppm, fat: 0.12-0.03 ppm and kidney: 0.36-1.02 ppm. The meeting discussed this point. It was agreed that the TRR in muscle was so low that any attempt to identify metabolites should fail. For fat, it is very likely that the residue pattern will be similar as the one observed in hens as the parent molecule is fatsuloble. For kidney, no information was given. The **DOR for monitoring** should be <u>parent and CPU expressed as parent</u>. The meeting considered that both the parent and CPU were valid indicators of the total residues in all	Open point remains open.

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
		poultry matrices and in milk and ruminant liver (in high dose group: parent: almost 100% TRR in poultry fat/skin, 76% of TRR in poultry muscle, 91% TRR in egg yolk, 49% TRR in poultry liver, 22% TRR in poultry kidney; 5% in goat liver – CPU: up to 3% TRR in poultry fat/skin, 15% of TRR in poultry muscle, 11% TRR in egg yolk, 22% TRR in poultry liver, 28% TRR in poultry kidney;15% in goat liver and 42% in milk). The meeting was of the opinion to request the tox to address the tox relevance of the metabolite PCAA recovered in poultry liver, fat and egg white resp. at levels of 2.6, 0.5 and 37% TRR (low dose). **DOR for RA for animal matrices**: Sum of DFB+CPU+PCA+PCAA expressed as PCA equiv.	
	Message 3.2 to the tox section PRAPeR 65 meeting: The meeting was not able to conclude on the residue definition for risk assessment in absence of the final toxicological assessment of the different metabolites of concern (CPU, PCA, DFBAM, PCAA). The tox section to address tox reference values for PCA metabolite according to the available information received.		Answer from tox section PRAPeR 64 meeting: DFBA is expected to have the same tox profile as diflubenzuron, and the same reference values could be used. With regard to CPU and DFBAM it was not possible to conclude on their toxicological relevance. PCA was considered of toxicological relevance because of its carcinogenic properties; however, it was not possible setting specific reference values.
	Open point 3.3 RMS to report the US trials on mushrooms in an addendum for consideration in expert	Additional indoor residue trials were reported in the addendum. Trials were performed with 2 different formulations at 2 different sites in the US, but only one trial for each of those combinations. RMS noted that the recovered residue levels were higher. The proposed DOR discussed during the meeting did not cover the trials since the major metabolite in mushrooms DFBA was not analysed in these trials.	Open point fulfilled. New data gap 3.2 proposed, see below.

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	meeting. See reporting table 3(15).	A complete residue database on mushrooms (indoor-minor) has to be provided in compliance with the DOR for RA.	
	New data gap 3.2 identified at the PRAPeR 65 meeting: The notifier to provide a complete residue database on mushrooms (indoor-minor) in compliance with the DOR for RA. Notifier to assure that the analytical method for PCA demonstrates acceptable recoveries and RSD. Notifier to give sufficient information on the stability of PCA during frozen storage.		Data gap open.
	Data gap 3.1 Notifier to submit further residue data in mushrooms taking into account the storage stability of compounds to be determined. See reporting table 3(17).	The notifier referred to the available residue trials presented in the DAR without addressing the storage stability of the different compounds. In the presented EU residue trials, RMS noted that the residue level of metabolite PCA was analysed after 18-24 months storage at -18°C. The notifier mentioned that additional storage stability studies would not change the findings and that PCA is not stable due to the fact that PCA is bound to plant compounds. The notifier has to consider the instability of metabolite PCA in the new required residue data base on mushrooms. The meeting had some doubts about the argumentation provided by the notifier on the instability of PCA. In Table B.7.1.1.3 (presenting the results from the validation of the analytical method), the recoveries of PCA were very low along with high values of RSD (>20 %), making the values very uncertain. In the storage stability study (B.7.6.2) the procedural recoveries were acceptable (within 70-110%) but the recoveries of the stored	Data gap remains open. The notifier to consider the loss of metabolite PCA in the new required residue database on mushrooms.

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
		samples for PCA were very low. The meeting had some doubt on the argumentation of the notifier that the low recoveries of PCA should be explained by the binding of this metabolite to lignin. The notifier should take the measures to avoid any loss during the extraction steps. Notifier to assure that the analytical method for PCA demonstrates acceptable recoveries and RSD. PCA is relevant for mushrooms and animal matrices.	
	Open point 3.4 MS to consider whether hydrolysis studies reflecting the effect of processing on the nature of residues is needed in an expert meeting. See reporting table 3(26).	RMS considered that the available data in the DAR were sufficient to address this point under chapter B.7.7.1: The representative hydrolytic conditions following industrial processing of fruits are heating to 90 °C for 20 min. at pH 4 (pasteurization). According to the data, Diflubenzuron was demonstrated to be hydrolytically stable under acidic and neutral conditions. The meeting was unable to check the raw data to agree on that conclusion. Point of clarification: Does the hydrolysis study simulating pasteurization exist? Data gap: A new hydrolysis study simulating pasteurization of fruits if the study to which the RMS referred does not exist. Pending the outcome of this hydrolysis study, further data on the magnitude of the residues in processed apples should be required. The meeting was of the opinion that it was not necessary to require a new study on the nature of the residues for sterilization (relevant for mushrooms) since the parent is not recovered in mushrooms (only DFBA: 91 % TRR). There won't be any further degradation.	Open point fulfilled. New data gap 3.3 proposed, see below.
	New data gap 3.3 identified at PRAPeR 65 meeting: Notifier to provide a new hydrolysis study simulating pasteurization if the study to which the RMS referred does not exist.		Data gap open.
	Open point 3.5 MS to discuss the	The meeting had a general discussion on how to carry out the dietary burden calculation (see Report PRAPeR 65 – general).	Open point fulfilled.

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	need for a feeding study in lactating cows in an expert meeting. See reporting table 3(29).	The outcome of the livestock dietary burden calculation for diflubenzuron will depend on the conclusion from the study on the nature of the residues (hydrolysis study simulating pasteurization on apples) and also on the DOR for RA in animal products. A provisional intake calculation considering the amount of parent can be performed. Inputs: STMR apple: 0.41 (NE), mean PF: 3.2: Intake: 0.6 mg/kg DM (dairy) and 1.7 mg/kg DM (beef cattle). Some experts pointed out that the intake per body weight for goats and cattle might be different. The current EU guidelines stated the extrapolation of metabolism data from goat to cattle. No distinction is made between these 2 ruminants. Notifier to provide either a feeding study in ruminants or a justification on the basis of the metabolism study showing that a feeding study is not required.	New data gap 3.4 proposed, see below.
	New data gap 3.4 identified at PRAPeR 65 meeting: Notifier to provide either a feeding study in ruminants or a justification on the basis of the metabolism study showing that a feeding study is not required.		Data gap open.
	New open point 3.6: RMS to perform a provisional consumer risk assessment and to amend the LoEPs accordingly.	RMS to perform a provisional consumer risk assessment and to amend the LoEPs accordingly.	Open point open.

Appendix 2: Evaluation table

5. 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: ***5*** Points for clarification: ***0*** Data gaps: ***1***			Section 3 Open points:***3*** Points for clarification: ***0*** Data gaps: ***4***
	Open point 3.1 MS to discuss the residue definition for plant commodities in an expert meeting. See reporting table 3(11).	09.11.2008 The residue definition in plants for monitoring and risk assessment should be diflubenzuron only. Although DFBA was found in the metabolism of mushrooms, it is not a residue of particular toxicological concern, and world-wide intake of mushrooms is quite low. In residue trials, CPU residues are usually quite low, typically near or below the LOQ, and residues of PCA is below the LOQ (0.01 mg/kg). Moreover, the analytical methods for diflubenzuron, DFBA, CPU, and PCA are very laborious, making it unpractical and not cost-effective for monitoring purposes.	22.12.2008 Agreed to be discussed in an expert meeting.	PRAPeR 65 (19-23 January 2009) Open point remains open.
	Message 3.1 to the tox section PRAPeR 65 meeting: The meeting was not able to conclude on the residue			PRAPeR 65 (19-23 January 2009) Answer from tox section PRAPeR 64 meeting:

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
	definition for risk assessment in absence of the final toxicological assessment of the different metabolites of concern (CPU, PCA). The tox section to address tox reference values for PCA metabolite according to the available information received.			DFBA is expected to have the same tox profile as diflubenzuron, and the same reference values could be used. With regard to CPU and DFBAM it was not possible to conclude on their toxicological relevance. PCA was considered of toxicological relevance because of its carcinogenic properties; however, it was not possible setting specific reference values.
	Open point 3.2 MS to discuss the residue definition in animal commodities in an expert meeting. See reporting table 3(12).	09.11.2008 The residue definition on animals for monitoring and risk assessment should be diflubenzuron only. Since the proposed uses of diflubenzuron within EU are primarily on apples, pears, and mushrooms, the amounts of residues in animal products is very minor. In the most recent US EPA Health and Effects Division (HED) review for residue of concern for cancer risk assessment, CPU should not be included in the cancer risk assessment Since high doses of CPU did not cause methemoglobinemia and CPU was not metabolized to PCA in rats (Gay, *et al*, Study No. 98203, 2001).	22.12.2008 Agreed to be discussed in an expert meeting.	PRAPeR 65 (19-23 January 2009) Open point remains 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
	Message 3.2 to the tox section PRAPeR 65 meeting: The meeting was not able to conclude on the residue definition for risk assessment in absence of the final toxicological assessment of the different metabolites of concern (CPU, PCA, DFBAM, PCAA). The tox section to address tox reference values for PCA metabolite according to the available information received.			PRAPeR 65 (19-23 January 2009) Answer from section PRAPeR 64 meeting: DFBA is expected to have the same tox profile as diflubenzuron, and the same reference values could be used. With regard to CPU and DFBAM it was not possible to conclude on their toxicological relevance. PCA was considered of toxicological relevance because of its carcinogenic properties; however, it was not possible setting specific reference values.
	Open point 3.3 RMS to report the US trials on mushrooms in an addendum for consideration in expert meeting. See reporting table 3(15).		22.12.2008 US trials have been reported in an Addendum	PRAPeR 65 (19-23 January 2009) Open point fulfilled. New data gap 3.2 proposed, see below
	New data gap 3.2 identified at the PRAPeR 65 meeting: The notifier to provide a complete residue database on mushrooms (indoor-minor)			PRAPeR 65 (19-23 January 2009) 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
	in compliance with the DOR for RA. Notifier to assure that the analytical method for PCA demonstrates acceptable recoveries and RSD. Notifier to give sufficient information on the stability of PCA during frozen storage.			
	Data gap 3.1 Notifier to submit further residue data in mushrooms taking into account the storage stability of compounds to be determined. See reporting table 3(17).	09.12.2008 Five trials were conducted on mushrooms during 2002, three in the UK and two in the Netherlands. As mushroom is a minor crop and the intended use is indoor, four trials are considered adequate for proposing MRL within the EU. From the five trials conducted under similar GAPs (single application, 0.96 to 1.03 g ai/sq. meter, PHI of 18 to 19 days), residues of diflubenzuron in mushroom were in the range of <0.01 to 0.02 mg/kg only. Chemtura believes that adequate data on residues in mushrooms are available to set an EU MRL.	22.12.2008 RMS agrees to that mushroom is a minor crop and when the intended use is indoor, four trials are considered adequate for proposing MRL within the EU. However in the presented EU trials RMS is criticizing that the residue level of metabolite PCA was analysed after 18-24 months storage at -18ºC. Mushrooms analysed for PCA should best be analysed directly after harvest as only 14% of PCA is recovered after 1 month in frozen storage (DAR, table 7.6.2-3). In the US trials reported in the Addendum the time from harvest to storage is acceptable for DFB, and CPU, as data show that these substances are stable for 18-19 months (see DAR, Tables 6.2.2 and 6.2.3) and in trials from Pennsylvania	PRAPeR 65 (19-23 January 2009) Data gap remains open. The notifier to consider the loss of metabolite PCA in the new required residue database on mushrooms.

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
			DFB was analysed after 37-39 days, and CPU after 29-39 days (see Addendum B.7.6). PCA, however was analysed after 43-78 days storage at -18ºC. No additional residue data for mushrooms considering the storage stability of PCA has been submitted. On the other hand RMS can support the Notfiers comment in reporting table 3(16). Additional storage studies may not alter the findings that PCA is not stable due to that compounds like PCA bind to plant compounds. “Therefore, this is not a stability issue and the observed results reflect the concentration of available PCA residues in mushrooms”. It should however also be mentioned that PCA in egg yolk seems to be stable at 10 months freezing storage (DAR table B.7.2.1-7). RMS suggests that stability of PCA should be discussed in an expert meeting.	
	Open point 3.4 MS to consider whether hydrolysis studies reflecting the effect of processing on the nature of residues is needed in an expert meeting.		22.12.2008 RMS considers that hydrolysis studies reflecting the effect of processing of fruits (heating to 90ºC for 20 minutes at pH 4) is well described in the dossier (i.e. MIIA section 1 point 2 page 13-	PRAPeR 65 (19-23 January 2009) Open point fulfilled. New data gap 3.3 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 Meeting
	See reporting table 3(26).		14). It is also assessed and approved in DAR Annex B.2.	
	New data gap 3.3 identified at PRAPeR 65 meeting: Notifier to provide a new hydrolysis study simulating pasteurization if the study to which the RMS referred does not exist.			PRAPeR 65 (19-23 January 2009) Data gap open.
	Open point 3.5 MS to discuss the need for a feeding study in lactating cows in an expert meeting. See reporting table 3(29).		22.12.2008 Agreed to be discussed in an expert meeting.	PRAPeR 65 (19-23 January 2009) Open point fulfilled. New data gap 3.4 proposed, see below.
	New data gap 3.4 identified at PRAPeR 65 meeting: Notifier to provide either a feeding study in ruminants or a justification on the basis of the metabolism study showing that a feeding study is not required.			PRAPeR 65 (19-23 January 2009) Data gap open.
	New open point 3.6: RMS to perform a provisional consumer risk assessment			PRAPeR 65 (19-23 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
	and to amend the LoEPs accordingly.			