PEER REVIEW REPORT ON **DIFLUBENZURON** 08 05 2009

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

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	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. See reporting table 1(1).		22.12.2008 The reason for greying out uses in the GAP has been explained in the revised LoEP. 17.02.2008 A new GAP-table has been prepared in the LoEP.	PRAPeR 61 (13-16 January 2009) Open point still open. Written procedure Open point fulfilled.

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	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 [redacted]	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.
	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. Written procedure

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				Data gap remains The specification is not accepted
	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-1188 has been validated for specificity in this manner. The validation data for the impurity method, GRL-GM-1188,	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 a meeting of experts.	PRAPeR 61 (13-16 January 2009) Point of clarification addressed.

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		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”.		
	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 6,00 3,45	PRAPeR 61 (13-16 January 2009) Open point fulfilled.

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			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.

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	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			PRAPeR 61 (13-16 January 2009) Data gap open. Written procedure Data gap remains New accelerated storage and shelf-life

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	should include the analysis of the relevant impurities.			studies are required.
	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.

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	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. Written procedure The persistent foam issue is addressed in the EFSA conclusion.
	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. Written procedure Data gap remains Provide a new attrition test in accordance with MT 178.2.

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	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. Written procedure Data gap remains New 5 batch data with validated methods of analysis. It is noted that the data are already available and evaluated in the Addendum to Annex C, but in accordance with 1095/2007 it can not be taken in to account in the peer review.
	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.

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	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. Written procedure Data gap remains The applicability of the existing CIPAC method needs to be 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).	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	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.

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		recently published articles (Pihlstrom, T., *et al.*, 2007, Anal. Bioanal. Chem. DOI 10.1007/s00216-007-1425-6; 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. Written procedure Data gap remains It is noted that the data are already available and evaluated in the Addendum to B5, but in accordance with 1095/2007 it can not be taken in to account in the peer review.

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	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 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	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 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	PRAPeR 61 (13-16 January 2009) Open point fulfilled.

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		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.	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.
	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	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	22.12.2008 See comments to open point 1.13.	PRAPeR 61 (13-16 January 2009) Open point fulfilled.

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	questioned as the lowest fortification was 0.1 mg/kg. See reporting table 1(41).	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 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	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. Written procedure Data gap remains Ecotox meeting confirm the NOEC is 0.00004 mg/l and therefore the LOQ for the surface water method is not sufficiently low.

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		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.		
	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. Written procedure Data gap remains It is noted that the data are already available and evaluated in the Addendum to B5, but in accordance with 1095/2007 it can not be taken in to account in the peer review.
	New open point 1.17. RMS to amend the list of end points according to the discussions during the PRAPeR 61 meeting		17.02.2009 The list of endpoints has been revised accordingly.	PRAPeR 61 (13-16 January 2009) Open point open. Written procedure Open point fulfilled The end points have been amended.

2. Mammalian toxicology

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	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. Written procedure: Data gap remains open.
	New open point 2.7 identified at PRAPeR 64 meeting:		17.2.2009 The information has been evaluated	PRAPeR 64 (19-23 January 2009)

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	The last information submitted by the applicant on PCA to be evaluated by the RMS.		(see Addendum 2, February 2009	Open point open. Written procedure: Open point closed.
	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. Methaemoglobinemia 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 AOEL	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) ARfD was not allocated since it is not

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			and ADI and 200 for ARfD, moreover, compensation for 33 % oral absorption are used for AOEL.	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.

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	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.		17.2.2009 Operator, worker and bystander exposure have been recalculated (see Addendum 2, February 2009) and the LoEP has been revised.	PRAPeR 64 (19-23 January 2009) Open point open. Written procedure: Open point closed.
	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. Written procedure: Data gap remains 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).		17.2.2009 For more information about the toxicological relevance of PCA and CPU see Addendum 2, February 2009	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.

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				Written procedure: Data gaps identified during the meeting: Toxicological relevance of CPU and DFBAM Reference values for the toxicologically relevant metabolite PCA Data gap identified after PRAPeR 64: Toxicological relevance of metabolite PCAA

3. Residues

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the Evaluation Meeting
	Section 3 Open points: ***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. Written procedure: Open point remains open. Residue definition in fruits to be re-addressed when study on the effect of processing on the nature of residues is available. Residue definition for mushrooms for risk assessment to be re-addressed when toxicological assessment of the metabolites is finalised.
	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		17.02.2009 Casing treatment;(*Science Horticulturae Vol. 104, issue 3, 2005, pp 351-367*) Casing material or 'soil' (casing) is used in mushroom (*Agaricus bisporus*) culture to cover a nutritional composted substrate colonised with mycelium, and	PRAPeR 65 (19-23 January 2009) 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.

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	the different metabolites of concern (CPU, PCA). The tox section to address tox reference values for PCA metabolite according to the available information received.		has an essential function in stimulating and promoting the development of sporophores (fruit bodies). Casing is the method by which substrate is crumbled into smaller pieces and covered with non-nutritive layer such as peat, vermiculite etc. Diflubenzuron is applied as a course spray immediately after casing. RMS suggests that residue definitions should be set as follows: **DOR for monitoring**: -Diflubenzuron (DFB) for fruit crops (foliar application), -DFBA for mushrooms. **DOR for RA for fruit crops**: Diflubenzuron (DFB) for fruit crops (foliar use) pending further information on the nature of the residues in processed fruit. **DOR for RA in mushrooms:** Sum of DFB+DFBA CPU+PCA	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. Written procedure: See open point 3.1.

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
			expressed as PCA equiv. **DFBA**: Toxicological relevance for DFBA is covered by toxdata for parent (DFB). DFBA is considered to have the same toxicity as parent. **CPU**: According to EPA (*Notice of Filing Pesticide Petition to Establish tolerance for a Certain Pesticide Chemical in or on food). Dec. 14, 2001 (vol. 66 no. 241*) Several studies with CPU have "demonstrated that CPU does not induce methaemoglobin formation and is neither metabolized to PCA nor forms N-hydroxylamine derivative. Since N-hydroxylation is the required first step in the mechanism of action of PCA´s carcinogenicity, it can be concluded that CPU´s mechanism of action and toxicity is different from that of PCA´s" RMS has found very limited data on toxicity of CPU" **PCA**: Is considered of toxicological relevance because of its carcinogenic properties; A TDI of 0.002mg/kg (an extra uncertainty factor of 10) is set by International Programme on Chemical Safety (IPCS) 1994 for PCA.	
	Open point 3.2 MS to discuss the residue definition in animal commodities in an expert	09.11.2008 The residue definition on animals for monitoring and risk assessment should be diflubenzuron only. Since the	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
	meeting. See reporting table 3(12).	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).		Written procedure: Open point remains open. Residue definition for risk assessment for animal matrices to be re-addressed when toxicological evaluation of the metabolites is finalsised.
	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.		17.02.2009 RMS suggests that residue definitions for animal matrices should be set as follows The **DOR for monitoring** should be parent and CPU expressed as parent **DOR for RA**: Sum of DFB+DFBAM+CPU+PCA+PCAA expressed as PCA equiv. Significant levels of DFBA and DFBAM are detected in the urine of rat (*Cameron et al. 1990*). **DFBA:** Is not found in any animal tissue.	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. Written procedure: See open point 3.2.

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
			DFBAM: Is covered by toxicological studies in rat. It is present in goat liver (0.011 mg/kg) and in goat milk (0,005 mg/kg). DFBAM is considered to have the same toxicity as parent **PCAA:** There is now specific information of PCAA´s toxicity. PCA is rapidly metabolized to PCAA (*IPCS, Inte PCAA is closely nati to onal programme on chemical health , Environmental health 184, 1996*) and is detected in animal tissue hen fat (0.005 mg/kg) and egg white (0.007 mg/kg) where no PCA is found. RMS considers PCAA having similar toxicity and endpoints as PCA. **PCA**: Is considered of toxicological relevance because of its carcinogenic properties; A TDI of 0.002mg/kg (an extra uncertainty factor of 10) is set by International Programme on Chemical Safety (IPCS) 1994 for PCA	
	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			PRAPeR 65 (19-23 January 2009)

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	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. Written procedure: Data gap 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
	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 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	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. Written procedure: Data gap remains open.

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			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. See reporting table 3(26).		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 13-14). It is also assessed and approved in DAR Annex B.2.	PRAPeR 65 (19-23 January 2009) 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.		17.02.2009 The hydrolysis study Boelhouwers *et al*. 1988, does exist in the caddy. However it does not include pasteurization (90ºC for 20 minutes at pH 4) which according to guideline 7035/VI/95 rev.5 22/7/1997 is required for fruits and fruit juice. RMS therefore agree to that notifier should provide a new hydrolysis study simulating pasteurization of fruits.	PRAPeR 65 (19-23 January 2009) Data gap open. Written procedure: Data gap 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
	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. Written procedure: Data gap remains open.
	New open point 3.6: RMS to perform a provisional consumer risk assessment and to amend the LoEPs accordingly.		17.02.2009 Highest calculated TMDI values in % of ADI of 0.1 mg/kg bw/d EFSA acute-chronic-model ver-2 DE Child *13.8* NL Child *7.6* FR Toddler *3.3* DK Child *3.2* FR infant *3.1* PT General population *2.8* WHO cluster diet B *2.7* FR all population *2.7* IE adult *2.6* PL General population *2.6* UK toddler *2.1* WHO cluster diet E *2.1* LT adult *2.1* UK infant *2.0* NL general *1.9*	PRAPeR 65 (19-23 January 2009) Open point open. Written procedure: Open point closed. Results of provisional risk assessment have been included in up-dated list of end points.

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			DK adult *1.8* ES child *1.7* SE general population 90th percentile *1.7* ES adult *1.4* IT kids/toddler *1.4* WHO cluster diet F *1.1* UK vegetarian *1.2* WHO regional European diet *1.1* IT adult *1.1* WHO cluster diet D *1.1* UK adult *1.1* FI adult *0.8* The list of endpoints has been revised accordingly.	

4. Environmental fate and behaviour

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the evaluation group
	Section 4 Open points: ***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.

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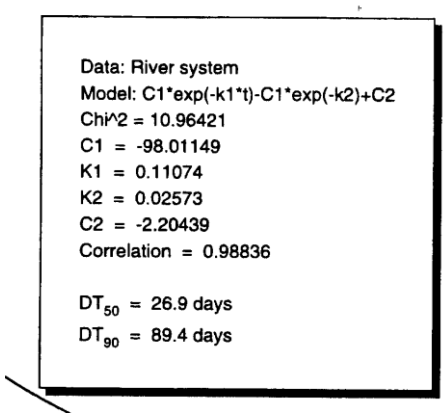
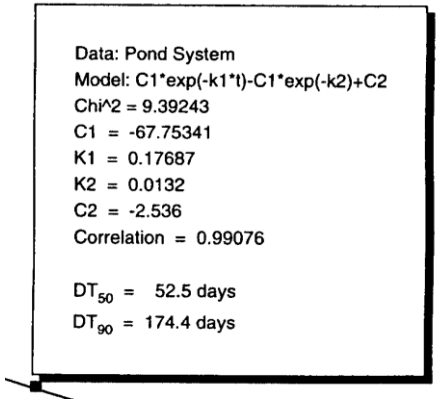
4.1	Point of clarification by the applicant New FOCUS GW using Koc = 0 for metabolite DFBA. Two models should be used following the Opinion of the Scientific Panel on Plant Health, Plant Protection Products and their Residues on a request of EFSA related to FOCUS groundwater models. The EFSA Journal (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	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. Written procedure: Data gap maintained.

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
			estimated DFBA vapour pressure implies that 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.		17.02.2009 The LoEP has been revised accordingly.	PRAPeR 62 (12-16 January 2009) Open point open. Written procedure: Open point closed.
	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.

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the evaluation group
	New open point 4.10 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.		17.02.2009 The LoEP has been revised accordingly.	PRAPeR 62 (12-16 January 2009) Open point open. Written procedure: Open point closed.
	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	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
		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 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	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
		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 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		17.02.2009 The LoEP has been revised accordingly.	PRAPeR 62 (12-16 January 2009) Open point open. Written procedure: Open point closed.

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the evaluation group
	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	PRAPeR 62 (12-16 January 2009) Point of clarification converted to a data gap 4.2. Data gap open. Written procedure: Data gap maintained.

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			application rates differ from 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.

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	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			PRAPeR 62 (12-16 January 2009) Data gap open. Written procedure: Data gap maintained.
	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. 17.02.2009 The LoEP has been revised	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. Written procedure: Open point closed.

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			accordingly.	
	Open point 4.8 RMS to summarize and assess in an addendum FOCUS PEC sw/sed for aerial application. See reporting table 4(27).	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 (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).	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 represent a realistic worst case scenario for the proposed use.	PRAPeR 62 (12-16 January 2009) 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			PRAPeR 62 (12-16 January 2009) Open point open. Written procedure: Open point closed.

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the evaluation group
	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 assessment is triggered.			

5. Ecotoxicology

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the evaluation group
	Section 5 Open points: ***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.

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	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.		17.02.2009 The LoEP has been revised accordingly.	PRAPeR 63 (13-15 January 2009) Open point open. Written procedure: Open point fulfilled.
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.

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	New open point 5.27 is identified at PRAPeR 53 meeting: RMS to update the LoE		17.02.2009 The LoEP has been revised accordingly.	PRAPeR 63 (13-15 January 2009) Open point open. Written procedure: Open point fulfilled.
	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.

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 5.7 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.
	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. Written procedure: Data gap open.
	New open point 5.28 is identified at PRAPeR 63 meeting: RMS to recalculate TERs for zooplankton and to update LoE		17.02.2009 The LoEP has been revised accordingly.	PRAPeR 63 (13-15 January 2009) Open point open. Written procedure: Open point open. (there was a mistake in the endpoint used in the updated LoEP. RMS is kindly asked to update the TERs.
	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.		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	PRAPeR 63 (13-15 January 2009) Open point fulfilled.

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	See reporting table 5(15).		has been included in the addendum (B.9.2.6)	

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	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 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	PRAPeR 63 (13-15 January 2009) Open point fulfilled. New open point 5.29 proposed, see below.

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			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 trigger to 100.		17.02.2009 The LoEP has been revised accordingly.	PRAPeR 63 (13-15 January 2009) Open point open. Written procedure: Open point fulfilled.
	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.

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	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 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).		22.12.2008 TER values for the most sensitive organism with PECsw from FOCUSstep2 has been included in the revised List of Endpoints.	PRAPeR 63 (13-15 January 2009) 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.

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	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.
	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. Written procedure: Open point fulfilled.
	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.

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	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 invertebrates. NOT: The quahogs NOEC = 320 (removal of "1a" mentioned after it). See reporting table 5(32).		22.12.2008 It was the Vol.2 that needed correction not LoEP.	PRAPeR 63 (13-15 January 2009) Open point fulfilled.
	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	PRAPeR 63 (13-15 January 2009) Open point fulfilled. New data gap 5.2 proposed, see below.

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			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 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. Written procedure: 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			PRAPeR 63 (13-15 January 2009) Data gap open.

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	NTA (in-field recovery/recolonisation should be demonstrated)			Written procedure: 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).		17.02.2009 The LoEP has been revised accordingly.	PRAPeR 63 (13-15 January 2009) Open point open. Written procedure: Open point fulfilled.
	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.

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	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).		17.02.2009 The LoEP has been revised accordingly.	PRAPeR 63 (13-15 January 2009) Open point open. Written procedure: Open point fulfilled.
	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 >25% were observed within 28d at application rates below the rate suggested in the GAP. See reporting table 5(53).		22.12.2008 We agree to discuss this at a meeting.	PRAPeR 63 (13-15 January 2009) Open point fulfilled.
	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.

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	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.