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0. General

General				
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0(1)	Vol. 1, Level 2: page 26 – 75	NOT: Headings not correct: Page 26-66 = Level 2 Page 67-75 = Appendix 1	The RMS agrees. The correct headings will be presented in an amended DAR.	Addressed: Rapporteur to consider in a revised DAR or corrigendum
0(2)	Vol. 1, Appendix 3 list of end points, FAO specification	EFSA: Details of the new 2005 FAO specification must be included and this must include the particle size clause.	RMS: The applicant has pointed out that the FAO-specification is for a TK and not for the technical material (TC). The RMS hereby wishes to discuss (e.g. on an expert meeting) the use of including the FAO specification in the LoEP. Nevertheless the LoEP has been revised to include the FAO specification. Since the particle size distribution of the TK has not been addressed under the evaluation, the RMS thus wonder if it should be set as a new data requirement?	Open point: 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 also 0(3)
0(3)	Vol. 1, appendix 3, Listing of endpoints, FAO specification	NL: FAO specification is available, LOEP should be adapted	See the comments to (0)2 above.	See open point in comment 0(2)

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

Identity (B.1, Annex C)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data gap or Open point (if data point not addressed or fulfilled)
1(1)	Vol. 1, Appendix 3 list of end points, Table of representative uses	EFSA: The reason for greying out the GAPs should be given in the remarks column.	RMS: The reason for greying out the GAPs has been given in the revised LoEP.	Open point: 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.
1(2)	Vol. 4, C.1.2.3.1 Batch analysis	EFSA: The minimum purity of the active substance is not justified as well as the maximum level of the impurities in the specification. Either a justification is required or the specification should be revised. In addition to this comparison will need to be made to the material used in the tox and ecotox studies.	RMS: In March 2007 the applicant submitted a report (Tutty, D.G. 2007) containing a thorough statistical judgment of the analysis of a total of 258 batches manufactured in 2006-January 2007 using statistical programs which supports the current specification. However it should be noted that a minimum purity of 96% would be derived using the normal approach of mean – 5 x SD on these data. In the report it is stated that the manufacturer analyses all produced batched and 10 out of the 258 batches were rejected due to one or more results outside of the current technical specification. The RMS proposes to include this information in an amended Annex C. However, the report does not deal with the specification for solvents (i.e. loss on drying). Since the loss on drying was shown	Open point: 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.

Identity (B.1, Annex C)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data gap or Open point (if data point not addressed or fulfilled)
			to be less than 1 g/kg in the 5-batch analysis, the RMS proposes that this certified limit is removed from the specification. Alternatively the exact identity of the solvents needs to be stated in the specification and a validated analytical method for these species is thus required. Furthermore a new analytical method validated for all organic impurities included in the technical specification was submitted during the evaluation period (see 1(55, 59, 60) below). If that method is considered sufficiently validated the RMS proposes that an analysis of five batches using that method is set as a new data requirement. This to replace 5-batch data derived from a tlc-method (one impurity) and data generated from a method not considered to be fully validated (one impurity). Moreover the applicant has submitted a table containing batch No. and purity of all batches used in ecotox and tox tests (see also 2(2)). The RMS proposes to include this information in the tox and ecotox sections of an amended DAR.	

Identity (B.1, Annex C)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data gap or Open point (if data point not addressed or fulfilled)
1(3)	Vol. 4, C.1.2.3.1 5-batches	AT: The closures of the a.i. and the impurities are missing.	RMS: If considered required the closure could be included in an amended DAR.	Open point: The analytical closure of the batches should be given.
1(4)	Vol.4, C.1.2.3.1, Analysis of five representiative production batches of diflubenzuron technical	NL: The certified limit in table C.1.2.3.1 of impurity D, G and H do not match with the impurities stated in C.1.2.2.2.	RMS: The applicant could not explain the discrepancy in the certified limits. The correct specification is given in table C.1.2.2.2 and the RMS hereby proposes to correct table C.1.2.3.1 accordingly in an amended Annex C.	Open point: The correct values should be presented for the specification in table C.1.2.3.1.
1(5)	Vol. 4, C.1.2.4 determination of the impurities	AT: Specificity: Methods for the (initial) identification of the impurities must be reported.	RMS comments: No information on the initial confirmation of the identity of the impurities is included in the original analytical methods. However, the applicant has submitted a new validation study (see 1(2, 55, 59, 60)) which includes data for all impurities included in the specification. In that study the identity of the impurities are confirmed by comparing the DAD-spectra of standards and the technical material. The RMS proposes to evaluate the new validation study in an Addendum to Annex C and if considered acceptable it should override the need for providing information on the initial confirmation of the identity of the impurities.	Point of clarification for the applicant: Specificity: Methods for the (initial) identification of the impurities should be provided. Please note unless it can be demonstrated that the UV spectra are unique then DAD is not considered to be sufficiently specific.

Physical and chemical properties of the active substance (B.2.1)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data gap or Open point (if data point not addressed or fulfilled)
1(6)	Vol. 3, B.2.1.4.1, Colour and Physical state	EFSA: The material tested is not representative of technical material as it has a purity of 99.1 % and the minimum purity of technical material is 95 %.	The RMS agrees that colour and physical state were determined on technical material with higher purity than the specified minimum purity. However, the purity of the used material is representative of the technical material as produced according to the QC-data referred to in the comments to 1(2), where the mean was determined to be 98.5%. The RMS proposes that this issue is discussed on an expert meeting.	Addressed: The material tested was technical material and this is considered sufficient.
1(7)	Vol. 3, B.2.1.5.1.3, UV/VIS spectrometry	NL: It is unclear if there is any absorption above 290 nm	RMS: As given in the result the scan range was 800-200 nm and absorption maxima was only observed at the stated 257 nm. However at 290 nm the following was observed (data from van der Voorden, 1993, used to address the quantum yield): A ε 290 nm 0.182 1.05×10^4 For clarification this information could be included in the RMS comments under 2.1.5.1 in an amended DAR. The LoEP has been revised accordingly.	Addressed: The end points have been amended.

Physical and chemical properties of the active substance (B.2.1)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data gap or Open point (if data point not addressed or fulfilled)
1(8)	Vol. 3, B.2.1.7, Solubility in organic solvents	EFSA: Neither of the materials tested are representative of technical material with a minimum purity of 95 %.	RMS: In the first study (Kempen, Feenstra-Bielders, 1995) were the solubility in most of the solvents was assessed, analytical grade diflubenzuron was used (>99.5%). However in the second study (Yu, 1999) the same batch of technical material (i.e. FUN95F14A) as in the test on colour and physical state was used (purity 99.1%). Hereby, see the comments to 1(6). The RMS does not believe that the use of the purer material in the test significantly should have altered the solubility in organic solvents (i.e. this might need to be discussed).	Addressed: The data are sufficient technical material has been used.
1(9)	Vol. 3, B.2.1.8, Partition coefficient	EFSA: The case presented by the rapporteur should be considered at a meeting of experts.	RMS: Agrees	Open point: The case considered in the DAR for partition coefficient should be considered by a meeting of experts
1(10)	Vol. 1, Appendix 3 list of end points, dissociation constant Vol. 3, B.2.1.9.4	EFSA: Solubility in water is not a criteria for requiring the test to be done.	RMS comments: According to recommended guideline OECD 112 only the spectrophotometric method is suitable for substances with low solubility in water. From a UV-VIS spectra recorded on a solution with the recommended concentration (i.e. half the saturation concentration), the notifier concluded that it would not be feasible or practical to determine the dissociation constant even with the most sensitive method.	Addressed: The case is accepted and the end points have been amended.

Physical and chemical properties of the active substance (B.2.1)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data gap or Open point (if data point not addressed or fulfilled)
			Therefore, not to cause any confusion the endpoint has been revised into "No data available-justification accepted". Moreover if considered required a more detailed comment could be included under point B.2.9.4 in an amended DAR.	
1(11)	Vol. 3, B.2.1.11.1/2, flammability and auto flammability.	EFSA: The material tested is not representative of technical material.	RMS: Technical material with a purity of 99.1% was used (batch FUN95F14A). According to the conclusion of PRAPeR16 it should be accepted for this parameter since technical material with a purity above the minimum purity has been used.	Addressed: Technical material has been tested.
1(12)	Vol 3, B.2.1.13, explosive properties.	EFSA: The material tested is not representative of technical material.	RMS: The same argument as in 1(11) applies here as the same batch was used.	Addressed: Technical material has been tested.
1(13)	Vol. 3, B.2.1.15, oxidising properties	EFSA: The material tested is not representative of technical material.	RMS: The same argument as in 1(11) applies here as the same batch was used.	Addressed: Technical material has been tested.

Physical, chemical and technical properties of the formulation (B.2.2)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data gap or Open point (if data point not addressed or fulfilled)
1(14)	Vol. 3, B2.2.9.1, Physical compatibility of tank mixes	EFSA: As details of the test method used are not given and detailed results are not given it is not possible to conclude on this point.	RMS comments: An in-house method (LOI 345-02-001) was used. It includes the mixing of Dimilin WG-80 with the stated products at the end concentration of 0.07% (i.e. maximum concentration for use on mushrooms). The products are considered	Open point: The Physical compatibility of the recommended tank mixes should be discussed by a meeting of experts.

Physical, chemical and technical properties of the formulation (B.2.2)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data gap or Open point (if data point not addressed or fulfilled)
			compatible when there is no coalescence, creaming or sedimentation caused by the combination. The products are also shaken individually to see if sedimentation or creaming is caused by the products themselves. All the mixtures were considered stable and there was no mixture resulting in an extreme foam formation or a very persistent foam. If considered required the test method could be described in more details in an amended DAR. The RMS does not intend to give detailed information on the amount of foam formed in the mixtures and the persistence of the formed foam, since this would result in a very extensive table (i.e. this could of course be discussed)	
1(15)	Vol. 3, B.2.2.2.1, Explosive properties	NL: A test according to EC A14 should be performed or a statement taking all formulants into account. PPP might be explosive, change Volume 1, level 2, 2.1.2.2 Add data requirement, Volume 1, level 4 PPP might be explosive, change Volume 3, B 2.2.11, change also table B.2.2.11	The RMS opinion is that the result from the test on explosivity of dust together with the fact that the product consists of 80% diflubenzuron, which was proven not to be explosive, makes it unjustified requiring a test according to EEC A14. This issue might be discussed on an expert meeting.	Addressed: It is a dust explosion even things like flour will explode as a powder in air. It is clear that the formulation will not be explosive in the sense of A14.
1(16)	Vol. 3, B.2.2.2.2, Oxidizing properties	NL: Only test 1 should be taken into account. The other tests (test 2 and 3) are not	The RMS opinion is that a substance with oxidizing properties always will react	Open point: The oxidising properties of the formulation

Physical, chemical and technical properties of the formulation (B.2.2)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data gap or Open point (if data point not addressed or fulfilled)
		determining the oxidizing properties in the sense of EEC A17 (Oxidizing compounds (oxidisers) in the sense of EC method A17 are products that can easily transfer oxygen to other compounds. Depending on the rate of oxygen transfer, they can cause inflammation of combustible materials and/or promote ongoing fires.). As in test 1 only the preliminary test has been carried out, a data requirement should be set to perform a complete test according to EC method A17. PPP might be oxidizing, change Volume 1, level 2, 2.1.2.2 Add data requirement, Volume 1, level 4 PPP might be oxidizing, change Volume 3, B 2.2.11, change also table B.2.2.11	exothermically with a reducing agent (e.g. zinc granules). The fact that Dimilin did not react violently with zinc granules together with the fact that it was shown not to be corrosive towards various packing materials and that diflubenzuron itself was proven not to be an oxidizer indicates a very low probability of Dimilin being an oxidizer in the sense of EEC A.17. The RMS therefore finds it unjustified to require a new test according to EEC A.17. This issue might be discussed on an expert meeting.	should be discussed in a meeting of experts. See also 1(17).
1(17)	Vol. 3, B.2.2.2.2 oxidising properties	AT: A complete test according to EEC/A17 is required.	RMS: See comments to 1(15) above	See 1(16)
1(18)	Vol.3, B.2.2.7.3, shelf life	NL: Persistent foam test (CIPAC MT 47) , the wet sieve test (CIPAC MT 167), the content of dust (CIPAC MT 171) and the Attrition/Friability test (CIPAC MT 178.2) should also be performed after the storage period. It is furthermore not clear if the storage test is carried out in the commercial packaging. Add data requirements, Volume 1, level 4	RMS: The storage study was performed with the product in the recommended packing. If considered required this can be made clearer in an amended DAR. Further, the RMS agrees that not all physico-chemical parameters relevant for WG-formulations were analysed during the shelf-life study. However we would like to ask for the other member states and EFSA's opinions on the need for requiring a new	Open point: The acceptability of the formulation shelf life study should be discussed by a meeting of experts. See also 1(19)

Physical, chemical and technical properties of the formulation (B.2.2)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data gap or Open point (if data point not addressed or fulfilled)
			shelf-life study where the missing parameters are assessed when there was no significant change in the studied parameters.	
1(19)	Vol. 3, B.2.2.7.3 shelf life	AT: Since 4-chloroaniline is regarded as relevant impurity, the content before and after storage must determined. The pH value of a 1% solution, persistent foam, degree of dispersion and dustiness are also missing.	RMS opinion is that substances of ecotoxicological, toxicological or environmental concern which might be formed by degradation of the active substance or the formulants should be quantified during the shelf-life study. 4-chloroaniline however is an impurity formed in the synthesis of the technical material and is not believed to increase during storage. This is also supported by the fact that there was no decrease in the active ingredient content during storage. Therefore the RMS does not believe that the content of 4-chloroaniline needs to be determined before and after storage. This issue might be discussed at an expert meeting. Regarding the other missing parameters see comments to 1(18) above.	Data gap: The content of 4-chloroaniline should be measured before and after storage and therefore a new shelf-life study has been identified as a data gap. For the second issue see open point in comment 1(18).
1(20)	Vol. 3, B.2.2.8.2 persistent foam	AT: Using CIPAC MT 47 the foam value should be max. 25 mL for the highest application rate. In forestry the application concentration is >1% and a further increase of foam volume is to be expected. Therefore the composition of the formulation should be reconsidered to avoid complications when using the	The RMS is not familiar with the given max of 25 mL foam when using CIPAC MT 47 (e.g no max is given either in the CIPAC method or in the Manual on Development and use of FAO and WHO specifications for Pesticides). Does it refer to the PSD Data Requirements Handbook stated max of 60 mL when using CIPAC MT 47.2, which	Open point: The result of the persistent foam study should be discussed by a meeting of experts.

Physical, chemical and technical properties of the formulation (B.2.2)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data gap or Open point (if data point not addressed or fulfilled)
		product.	would correspond to 24 mL when using CIPAC 47? It should be noted that a volume of 26.2 ml persists after 30 min for the 1% suspension. The applicant has also given the following statement for this point: "With regard to the use of higher levels of product (>1 %) in forestry. It is always necessary in this application to mix an oil-based adjuvant with the product. The oils contained in such adjuvants are often also the basis for non-silicone antifoams. We therefore expect less foam to be produced in forestry applications despite the higher formulation concentrations involved. We can state that Dimilin WG-80 has been produced and used since the mid 90's and as far as we are aware, there have not been any significant issues with persistent foaming." If considered required this information can be included in an amended Annex B.2.	
1(21)	Vol.3, B.2.2.8.5.1, Dry sieve test	NL: The test has bee carried out (and is applicable also to WG formulations), see B.2.2.7.3, shelf life	The RMS agrees. It could be changed in an amended DAR into "The parameter needs not to be assessed since Dimilin WG-80 is not a dustable powder. However a dry sieve test was performed in the shelf-life	Addressed: Rapporteur to consider in a revised DAR or corrigendum.

Physical, chemical and technical properties of the formulation (B.2.2)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data gap or Open point (if data point not addressed or fulfilled)
			study……", where after the result is presented also under B.2.2.8.5.1.	
1(22)	Vol.3, B.2.2.8.6.3, Friability and attrition characteristics of granules	NL: It is not clear if the method is carried out according to CIPAC MT 178.2	RMS: At the time of the test (1995) there was no standardized test method available (i.e. CIPAC 178.2 was published as a provisional method 2002). The test was therefore performed according to an in-house version of an attrition test (BBA Guideline, Part I, 1-2, June 1987, Page 17, Section 18), which differs from CIPAC 178.2 in the following way: No sieving was performed prior to the test, a porcelain jar was used instead of a glass bottle and after simulated handling and transport the dust content was determined according to CIPAC 171 instead of measuring the mass remaining on a 125 µm sieve and subsequent calculating the attrition resistance. If considered required a more detailed description of the test method and also a description of the differences of the test method compared to CIPAC 178.2 (e.g. as described above) could be included in an amended DAR.	Open point: The in house attrition test should be considered by a meeting of experts.

Further information (B.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data gap or Open point (if data point not addressed or fulfilled)
1(23)	Vol.3, B.3.5.1.3, Resistance of the packaging	NL: Doesn't describe the resistance of the packaging to its content. It is not clear from the shelf life test if the storage test is carried out in the commercial packaging.	RMS: The storage stability study was performed with the product in the recommended packing (see 1(18)). A reference to the storage stability study could be given here in an amended DAR.	Addressed: Rapporteur to consider in a revised DAR or corrigendum.
1(24)	Volume 3, point B.3.1, Data on application relevant to the active substance, point B.3.2, Data on application relevant to the plant protection product and point B.3.3, Summary of data on application	DE: In the pest list of pome fruits the name of a mite (*Aculus schlechtendali*) is given. In Germany we have no hints for an efficacy of diflubenzuron against mites. If diflubenzuron shows an efficacy against mites then in the function part the word "acaricide" has to be added and also in the other corresponding parts the word "mites" or "acaricide" has to be added.	The notifier suggests to remove the mite species Aculus schlechtendali from this list, because it only concerns a side-effect. The main activity of diflubenzuron is and remains insecticidal.Further, there are some insects species that need to be removed from the list in the pome fruit use, namely the winter moth, clouded drabmoth and vapourer moth, these are all early insects. The RMS suggest to remove these in an amended DAR.	Addressed: Rapporteur to consider in a revised DAR or corrigendum.
1(25)	Vol. 3, Annex B3: page 9 Data on application and further information B.3.2.4 Table B.3.2.6 Method of application	NOT: The spray volume in forestry for ULV should be 3-5 "water + oil" in stead of "oil" (the oil is added to the water to prevent evaporation). The maximum* application rate for mushrooms should be "1 g a.s./m2" (= 10.000 g a.s./ha)" (* is in fact not relevant considering the typical growing conditions).	RMS: This will be amended in the revised DAR.	Addressed: Rapporteur to consider in a revised DAR or corrigendum.

Further information (B.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data gap or Open point (if data point not addressed or fulfilled)
1(26)	Vol. 1, Level 1: page 10 Table 1.5.3b Vol. 1, Level 2: page 81 Appendix 3. Listing of endpoints Table: Forestry and woody ornamentals – aerial application (ULV) *[2] Mushrooms	NOT: The spray volume in forestry for ULV should be 3-5 "water + oil" in stead of "oil" (the oil is added to the water to prevent evaporation).	RMS: This will be amended in the revised LoEP.	Addressed: The end points have been amended.
1(27)	Vol. 1, Level 1: page 10 Table 1.5.3b Vol. 1, Level 2: page 81 Appendix 3. Listing of endpoints Table: Mushrooms	NOT: The maximum* application rate for mushrooms should be "1 g a.s./$m^{2"}$ (= 10.000 g a.s./ha)" (* is in fact not relevant considering the typical growing conditions).	RMS: This will be amended in the revised DAR.	Addressed: The use rate is 1g as/m^2

Classification and labelling (B.4)

For comments on classification and labelling see the relevant sections.

Methods of analysis (B.5)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data gap or Open point (if data point not addressed or fulfilled)
1(28)	Vol 3, B.5.1.2, analytical methods for determination of	UK: TLC method BAI 42004 used for impurities B & E in technical material: were method details and validation data	RMS: No validation data for the tlc-method BAI 42004 was included in the dossier.	Data gap: New 5 batch data with fully validated methods of analysis have been identified as

Methods of analysis (B.5)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data gap or Open point (if data point not addressed or fulfilled)
	impurities	supplied? No data appears to be mentioned in the DAR and both impurities are listed in the tech spec.	However, it should be noted that a fully validated HPLC-method for B was included in the dossier and presented in Annex C, but this method was not employed in the 5-batch analysis. Moreover, the concentration of E in the 5-batch analysis was determined using both the tlc-method BAI 42004 and the HPLC-method BAI 42002, for which validation data was presented in Annex C. The concentration of E was found to be below 1 g/kg using both methods. Nevertheless, since 5-batch data was generated from non validated methods the RMS proposes that a new 5-batch analysis using fully validated methods is set as a new data requirement (see 1(2, 55, 59, 60))	data gaps. The applicant has stated that this will have been provided by September 2007. See also 1(35), 1(39), 1(55), 1(57), 1(59), 1(60)
1(29)	Vol. 3, B.5.1 Method for the formulation	EFSA: It is stated that there is a CIPAC method available for the formulation. However this is for a WP not the WG which is considered in the DAR.	RMS: From an analytical perspective WP and WG are practically the same. Therefore, the RMS opinion is that the CIPAC method for WP-formulation should be applicable to the WG-formulation. This statement will be included in an amended DAR.	Open point: It should be discussed by a meeting of experts if the CIPAC method for the WP can be extrapolated to a WG.
1(30)	Vol. 3, B.5.2 Method in plants	EFSA: The applicability of a multi-residue method such as DFG S19 must be addressed.	RMS: Diflubenzuron is not possible to analyse using a standard multimethod. RMS proposes that a statement/proof of this is included in an addendum to the DAR.	Point of clarification for the applicant: The applicability of a multi-residue method such as DFG S19 must be addressed.

Methods of analysis (B.5)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data gap or Open point (if data point not addressed or fulfilled)
1(31)	Vol.3, B.5.2.1, Analytical methods for analysis of residues in food of plant origin.	NL: The analytical method (Thus and Allan) is not acceptable: precision is not calculated, the linearity is not given and moreover an LOQ of 0.01 cannot be claimed based on the presented data. Method 1 and 2 in table B.5.5.2	RMS: This is stated in the DAR, together with a holistic argument why the method/validation is considered acceptable. ILV validation, a very strong practice, was satisfactory and the deviations in the validation of the developing laboratory was more of a formal nature. RMS proposes that the corrected validation report with stated RSD:s and r or r^2 is evaluated in an amendment of the DAR.	Open point: The acceptability of the validation data for the plant residue methods should be discussed by a meeting of experts. See also 1(32), 1(33), 1(34), 1(43), 1(44)
1(32)	Vol.3, B.5.2.1, Analytical methods for analysis of residues in food of plant origin.	NL: The analytical method (Gaydosh) is not acceptable: individual recoveries and precision are not reported. The complete (individual) validation data of the LOQ level should at least be known Method 4 in table B.5.5.2	RMS: This is stated in the DAR. The notifier has accepted to make the necessary corrections of the report. RMS proposes that these corrections are evaluated in an amended DAR.	See open point in comment 1(31).
1(33)	Vol.1, level 1, Appendix 3 listing of endpoints	NL: Add to the LOEP ((AM for food/feed of plant origin) that more validation data are necessary	RMS: see 1(31, 32) above	See open point in comment 1(31).
1(34)	Vol.1, level 4, 4.5 Method of analysis	NL: the two analytical methods for analysis of residues in food of plant origin are not acceptable: lack of validation data. (The ILV studies are acceptable) Method 1,2 and 4 in table B.5.5.2	RMS: This is stated in the DAR, together with holistic argument why the method/validation is considered acceptable. See 1(31, 32)	See open point in comment 1(31).
1(35)	Vol.1, level 4, 4.5 Method of analysis	NL: The complete validation data of each impurity should be given in a table. Validation data should confirm the claimed LOQ's for each impurity.	RMS: A new validation study is available (see 1(2, 55, 59, 60). The RMS proposes that it is evaluated in an Addendum to Annex C, whereby this comment would be addressed.	See data gap in comment 1(28).

Methods of analysis (B.5)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data gap or Open point (if data point not addressed or fulfilled)
1(36)	Vol.3, B.5.3.1, Analytical method for the determination of residues in soil	NL: type of soil should be reported	RMS: The information on type of soil was included in the study and RMS proposes to present it in an amended DAR.	Open point: Details of the type of soil used in the soil method should be given.
1(37)	Vol.3, B.5.3.2, Analytical method for the determination of residues in surface water	NL: Source and characteristics of the surface water should be reported.	RMS: RMS proposes that information about source and characteristics of the surface water that have been used is included in an amendment of the DAR	Open point: Source and characteristics of the surface water should be reported.
1(38)	Vol.3, B.5.5.1, Analytical methods for formulation analysis	NL: The Detection limit for the active substance in the technical active substance and the formulation are not confidential	RMS agrees. This will be corrected in an amended DAR.	Addressed: Rapporteur to consider in a revised DAR or corrigendum.
1(39)	Vol.4, C.1.2.4, Methods of analysis for the determination of impurities	NL: The validation data of each impurity should be given in a table. The validation data for all impurities should be complete. The missing recovery of impurity PCA (= impurity?) should be determined and the precision for all impurities should be compared with the Horowitz values (Also in the case of impurity??). It is not acceptable to calculate the LOQ for impurities. Validation data should confirm the claimed LOQ's for each impurity. See also Volume B.5.1.2	RMS: The notifier has reported a new validation study in this area (see 1(2, 55, 59, 60). The new study contains validation data for all impurities included in the specification. RMS proposes that this study is evaluated in an addendum to the DAR, whereby this comment would be addressed.	See data gap in comment 1(29).
1(40)	Vol. 3, B.5.1.1, B.5.1.2, B.5.1.3	AT: The % RSDs of accuracy (recovery) are missing. A method for the determination of the relevant impurity PCA in the formulation is	RMS: Regarding accuracy see 1(39). The RMS proposes that the requirement of a method for determining PCA in the	See data requirement in 1(19) and 1(28).

Methods of analysis (B.5)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data gap or Open point (if data point not addressed or fulfilled)
		missing.	formulation is discussed at an expert meeting (see also 1(19)).	
1(41)	Vol. 3, B.5.2.1 residue in apples, apple pomace and juice	AT: A confirmatory technique is missing. The LOQ should be set to the lowest fortification level (= 0.1 mg/kg) according to SANCO 825/00.	RMS: No additional confirmatory method is reported by the developing laboratory but the primary method is specifiic, which is proved by confirmatory LC-MS data (ILV). This fact in combination with the fact that a very narrow range of analytes and matrices is used supports that the method/validation is considered acceptable. About LOQ see next issue, 1(42).	Open point: 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 also 1(42)
1(42)	Vol. 3, B.5.2.1 and LOE residue in apples, apple pomace and juice (ILV)	AT: Although the LOQ is set to 0.01 mg/kg in this study, the LOQ of the original method (see above) is sufficiently validated at 0.1 mg/kg. This value should also be considered in the list of endpoints.	RMS: This is stated in the DAR, together with holistic argument why the method/validation is considered acceptable. The use of an Independent Laboratory Validation is very strong and beyond normal practice (mostly in-house validation) in most pesticide analytical control laboratories around Europe. This should permit that techniques are updated without mandatory re-validation in the developing laboratory.	See open point in comment 1(41)
1(43)	Vol. 3, B.5.2.1 mushrooms	AT: Due to the fact that no recoveries and no number of samples are reported the method is not valid according to SANCO 825/00. A confirmatory technique is missing.	RMS: It is stated in the DAR that individual recoveries are not reported, although acceptable mean recoveries are reported. It is also stated that the method/validation is considered acceptable under the condition that the notifier makes the necessary formal	See open point in comment 1(31)

Methods of analysis (B.5)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data gap or Open point (if data point not addressed or fulfilled)
			corrections. RMS proposes that additional data/information are evaluated in an amended DAR. Although the developing laboratory did not report a confirmatory method in the first place, the detection technique was upgraded to LC-MS/MS later on (ILV), why the validation is consiered acceptable (LC-MS/MS does not require further confirmation), see also above, 1(42).	
1(44)	Vol. 3, B.5.2.1 mushrooms (ILV)	AT: I am of the opinion that an ILV has to be based on a sufficiently validated method (see above). This method can be regarded as original method. Then an additional ILV is required.	RMS: See above, 1(42) and 1(43).	See open point in comment 1(31)
1(45)	Vol. 3, B.5.3.4 air	AT: The unit of the concentrations used for the calibration curve (µg/m3) seems unreliable.	RMS agrees. This is an error in the DAR; the correct unit is mg/ml, which is used in the notifiers report. This will be corrected in an amended DAR.	Addressed: Rapporteur to consider in a revised DAR or corrigendum.
1(46)	Volume 1, Level 2, point 2.2.3, Analytical methods for residue analysis	DE: It should be added that the validated LOQ of the LC-MS/MS method proposed for surface water exceeds a concentration which has an impact on aquatic non-target organisms. A more sensitive method is required. The most sensitive aquatic organism is *Daphnia magna* with an NOEC of 0.04 µg/L. In contrast the validated LOQ of the proposed method for surface water is 0.1 µg/L.	RMS: It is stated in the DAR that this method might need to be revised when a new safety margin is available; this issue will be discussed at a forthcoming ecotox expert meeting, but a plausible NOEC value that will be suggested at the meeting is 0.7 µg/L which is far higher than the LOQ = 0.1 µg/L.	Data gap: As the LOQ for surface water is not low enough given the current NOEC a method for surface water has been identified as a data gap. See also 1(48), 1(49), 1(54)
1(47)	Volume 1, Level 2, point	DE: It should be added that validated	RMS: It is stated in the DAR that the validation of	Addressed:

Methods of analysis (B.5)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data gap or Open point (if data point not addressed or fulfilled)
	2.2.3, Analytical methods for residue analysis	confirmatory methods for diflubenzuron and relevant metabolites in soil, water and air are missing. The specificity of LC-MS/MS methods has to be confirmed by using two transitions for validation.	the analytical method intended for air analysis is incomplete. About the number of transitions it is correct that two transitions are better than one, but there is not a requirement of two transitions in the guidelines and one transition in LC-MS/MS together with retention time is still a good proof of specificity. Also, this has been confirmed at an expert-meeting (PRAPeR 01).	The methods are specific only one transition is required. See also 1(48), 1(49), 1(50), 1(51), 1(52), 1(53), 1(54)
1(48)	Volume 1, Level 3, point 3.1, Background to the proposed decision	DE: It should be added that a more sensitive method for quantification of diflubenzuron and relevant metabolites in surface water is required. Additionally validated confirmatory methods for diflubenzuron and relevant metabolites in soil, water and air are missing.	RMS: See 1(46, 47).	See data gap in 1(46) and also comment 1(47).
1(49)	Volume 1, Level 4, point 4.5, Methods of analysis	DE: It should be added that a more sensitive method for quantification of diflubenzuron and relevant metabolites in surface water is required. Additionally validated confirmatory methods for diflubenzuron and relevant metabolites in soil, water and air are required on Member State level The most sensitive aquatic organism is *Daphnia magna* with an NOEC of 0.04 µg/L. In contrast the validated LOQ of the proposed method for surface water is 0.1 µg/L and exceeds this NOEC value. The specificity of LC-MS/MS methods must be	RMS: See 1(46, 47).	See data gap in 1(46) and also comment 1(47).

Methods of analysis (B.5)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data gap or Open point (if data point not addressed or fulfilled)
		confirmed by using two transitions for validation.		
1(50)	Volume 3, point B.5.3.1, Analytical methods for the determination of residues in soil	DE: A validated confirmatory method for the quantification of diflubenzuron including the relevant metabolites is missing. Monitoring of a single transition from the precursor ion to the product ion by LC/MS/MS is not considered as highly specific. Validation data of a second transition are required.	RMS: Only single transition in this method is stated in the DAR. About single transition and requirements see above, 1(47).	See comment 1(47)
1(51)	Volume 3, point B.5.3.2, Analytical method for the determination of residues in surface water	DE: A more sensitive method for quantification of diflubenzuron and relevant metabolites in surface water is required. The most sensitive aquatic organism is *Daphnia magna* with an NOEC of 0.04 µg/L. In contrast the validated LOQ of the proposed method for surface water is 0.1 µg/L and exceeds this NOEC value.	RMS: See 1(46)	See data requirement in comment 1(46)
1(52)	Volume 3, point B.5.3.2, Analytical method for the determination of residues in surface water	DE: A validated confirmatory method for the quantification of diflubenzuron including the relevant metabolites is missing. Monitoring of a single transition from the precursor ion to the product ion by LC/MS/MS is not considered as highly specific. Validation data of a second transition are required.	RMS: That only a single transition is used in this method is stated in the DAR. About single transition and requirements see above, 1(47).	See comment 1(47)
1(53)	Volume 3, point B.5.3.4, Analytical method for the	DE: A validated confirmatory method for the quantification of diflubenzuron in air	RMS: The validation of this method was considered incomplete in the DAR. RMS	See comment 1(47)

Methods of analysis (B.5)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data gap or Open point (if data point not addressed or fulfilled)
	determination of residues in air	metabolites is missing.	proposes that an evaluation of an additional study that the notifier has reported is included in an addendum to the DAR, see also 1(56).	
1(54)	Volume 3, point B.5.5, Evaluation and assessment	DE: It should be added, that a more sensitive method for quantification of diflubenzuron and relevant metabolites in surface water is required. Additionally validated confirmatory methods for diflubenzuron and relevant metabolites in soil, water and air are missing. The most sensitive aquatic organism is *Daphnia magna* with an NOEC of 0.04 µg/L. In contrast the validated LOQ of the proposed method for surface water is 0.1 µg/L and exceeds this NOEC value. The specifity of LC-MS/MS methods has to be confirmed by using two transitions for validation.	RMS: See 1(46) and 1(47).	See data gap in 1(46) and also comment 1(47).
1(55)	Vol. 3, Annex B5: page 4 B.5.1.2 Analytical Methods for the determination of the impurities in the active substance as manufactured	NOT: A new method for one of the impurities was submitted to the RMS during the evaluation phase to replace the method described by Kampen and Thus (DI-9427), which was not fully validated. This new method by Riggs (2003) (DI-11742) has been fully validated according to SANCO guidelines. The new method uses HPLC with UV detection and external standard quantification. The new study has been	RMS: RMS proposes that an evaluation of the new method is included in an addendum to the DAR.	See data gap in comment 1(28).

Methods of analysis (B.5)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data gap or Open point (if data point not addressed or fulfilled)
		included in the updated summary dossier.		
1(56)	Vol. 3, Annex B5, page 12 B.5.3.4 Analytical Methods for the determination of residues in air	NOT: The new study for the determination of residues in air was delayed, but has been completed now. The study report will be provided when it is finalized.	RMS: RMS proposes that an evaluation of the new study that has been reported is included in an addendum to the DAR.	Data gap: Analytical method for air. See also 1(58), 1(61)
1(57)	Vol. 1, Level 2: page 29 2.2.1 Methods of analysis	NOT: There is no need to send calculations on the technical accuracy of one of the impurities, because a new method for analysis was submitted to the RMS during the evaluation phase to replace the method described by Kampen and Thus (DI-9427), which was not fully validated. This new method by Riggs (2003, DI-11742) has been fully validated according to SANCO guidelines. The new method uses HPLC with UV detection and external standard quantification. The new study has been included in the updated summary dossier.	RMS: RMS proposes that an evaluation of the new method is included in an addendum to the DAR.	See data gap in comment 1(28).
1(58)	Vol. 1, Level 2: page 30 2.2.3 Analytical methods for residue analysis	NOT: The new study for the determination of residues in air was delayed, but has been completed now. The study report will be provided when it is finalized.	RMS: RMS proposes that an evaluation of the new method is included in an addendum to the DAR.	See data gap in comment 1(56).
1(59)	Vol. 1, Level 3: page 114 3.1 Background to the proposed decision	NOT: A new method for analysis was submitted to the RMS during the evaluation phase to replace the method described by Kampen and Thus (DI-9427),	RMS: RMS proposes that an evaluation of the new method is included in an addendum to the DAR.	See data gap in 1(28).

Methods of analysis (B.5)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data gap or Open point (if data point not addressed or fulfilled)
		which was not fully validated. This new method by Riggs (2003, DI-11742) has been fully validated according to SANCO guidelines. The new method uses HPLC with UV detection and external standard quantification. The new study has been included in the updated summary dossier.		
1(60)	Vol. 1, Level 4: page 120 4.5 Methods of analysis: 1st and 3rd paragraph	NOT: A new method for analysis of the impurity mentioned in the DAR was submitted to the RMS during the evaluation phase to replace the method which was not fully validated. This new method has been fully validated according to SANCO guidelines. For this reason calculations or data on accuracy of the old method are not necessary.	RMS: RMS proposes that an evaluation of the new method is included in an addendum to the DAR.	See data gap in 1(28).
1(61)	Vol. 1, Level 4: page 120 4.5 Methods of analysis	NOT: The new study for the determination of residues in air was delayed, but has been completed now. The study report will be provided when it is finalized.	RMS: RMS proposes that an evaluation of the new method is included in an addendum to the DAR.	See data gap in comment 1(56).

Comments received on reporting table, section Physical/Chemical Properties; Details of Uses and Further Information; Methods of Analysis (B.1- B.5)			
Reference to reporting table	MS / Notifier	Comment	EFSA response
0(2)	NOT	Explanation of the difference between diflubenzuron technical concentrate (VC-90) and diflubenzuron technical: The FAO specification 2005 is for diflubenzuron technical concentrate. This is a 90% pre-concentrate, not equal to diflubenzuron technical (purity > 95%) included in our EU-dossier. This 90% technical concentrate is used, instead of diflubenzuron technical, in some fomulated products, but not for the representative formulation in the EU-dossier, the WG-80.	Noted this should be addressed to the evaluation table.
1(1)	NOT	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. Chemtura is of the opinion that we have provided ample data to maintain the specification as submitted. These certified limits have been submitted and accepted by many regulatory agencies across the globe.	This should be directed to point 1(2) and not 1(1). When the QC data are in an addendum they can be considered by a meeting of experts.
1(4)	NOT	RMS: The applicant could not explain the discrepancy in the certified limits The remark from the RMS is not correct. Our answer in the reporting table was that the certified limits are the same, but were expressed in different units. The limits mentioned on pages 14 and 15 were expressed in % w/w or ppm (4-chloroaniline), whereas on page 10 and 11 they are expressed in g/Kg. In the result tables there are some incorrect values, the correct values are: The 'Certified Limit' (% w/w) in Results Table 3 should be as follows: Sulphated Ash = 2.0 Loss on Drying = 0.5	Noted this should be addressed to the evaluation table.
1(16)	AT	The test substance was considered to be an oxidiser using EEC/A17 (Kempen, A.) In case that a false positive result was obtained the test should be repeated with an inert material like kieselguhr. [To investigate oxidising/reducing properties (Friedlander, B.) does not address this annex point].	Noted reporting table changed to an open point for discussion ina meeting of experts.

Comments received on reporting table, section Physical/Chemical Properties; Details of Uses and Further Information; Methods of Analysis (B.1- B.5)			
Reference to reporting table	MS / Notifier	Comment	EFSA response
1(19)	NOT	New shelf-life study (4-chloroaniline should be measured before and after storage period) It is not clear from the reporting table if the issue will be discussed at an expert meeting or that the reasoning from the RMS is accepted or that the study should be done anyhow. Please clarify	Either a study should be produced or a case should be made which should be presented in an addendum by the rapporteur.
1(20)	AT	Source is the Manual on the development and use of FAO specifications for plant protection products (Fourth Edition) where is written: *The normal requirement is that there is a maximum of 25 ml of foam after 1 min when applying MT 47 and 60 ml when applying MT 47.2.* The use of an oil-based adjuvant in forestry must be stated on the label.	Noted this issue will be discussed by a meeting of experts.
1(28)	NOT	New 5 batch data with fully validated methods of analysis is required. A new 5-batch study is in progress and will be submitted to the RMS at the end of September 2007.	Noted
1 (30)	NOT	The applicability of a multi-residue method such as DFG S19 must be addressed. As already demonstrated to the RMS available multi-residue methods are unsuitable for diflubenzuron residue analysis	Noted the rapporteur should produce an addendum.
1(40)	AT	Editorial point: The comment was made by AT.	Noted reporting table corrected.
1(41)	NOT	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. Further explanation: we agree with RMS comments. The ILV study employs LC-MS/MS as a confirmatory technique. In the original report (Thus and Allan) the LOQ was estimated to be at least 10 times lower than the lowest fortification level of 0.1 mg/kg.	No it is a different detector. Meeting of experts will consider this .
1(42)	NOT	See open point in comment 1(41) Further explanation: the ILV was conducted at 0.01 and 0.1 mg/kg, which confirmed that the LOQ (0.01 mg/kg) of the original method was achievable, and with good accuracy and precision, as demonstrated with the ILV data.	Noted see 1(41) above

Comments received on reporting table, section Physical/Chemical Properties; Details of Uses and Further Information; Methods of Analysis (B.1- B.5)			
Reference to reporting table	MS / Notifier	Comment	EFSA response
1(46)	NOT	As the LOQ for surface water is not low enough given the current NOEC a new method for surface water is required. It is not clear from the reporting table whether the issue will be discussed at an expert meeting, that the reasoning from the RMS is accepted or that the study should be repeated. A clarification is required. We maintain that the EAC in the aquatic environment can be set at 0.7 µg/L.We have provided detailed risk assessments, taking into account diflubenzuron's specific mode of action, it's environmental fate profile as well as all relevant environmental toxicity data from laboratory, semi-field & field studies to support this endpoint. This endpoint is clearly well above the LOQ in the submitted method of analysis and should allow adequate monitoring of this active substance in the surface water!	It is a data gap because of the current NOEC. Of course if the NOEC is changed the data gap may become void.

2. Mammalian toxicology

Toxicokinetics (B.6.1)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data gap or Open point (if data point not addressed or fulfilled)
2(1)	Vol. 3, Annex B.6: page 5 & 7 B.6.1.1-2, Single and repeated dose (low dose level) and single (high dose) in rats	NOT: The table B.6.1.1-2 (Cumulative recovery of total radioactivity after single and multiple oral dose of [^{14}C]-dilfubenzuron) given on page 5 should be deleted in this section and included in the next section B.6.1.2 on page 7 above the Conclusions. The table should be renumbered as B.6.1.2-1.	RMS: We don't agree. The Table B.6.1.1-2 on the DAR presents data from the study Dunsire *et al.* 1990. Cameron *et al* 1990 have studied the metabolism of diflubenzuron and not the tissue distribution.	Addressed

Acute toxicity (B.6.2)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data gap or Open point (if data point not addressed or fulfilled)
2(2)	Vol. 3, B.6.2 Acute toxicity	EFSA: for some studies the purity level is not mentioned or batches with much lower purity than the recommended one have been used. RMS to provide an explanation on the reliability of the conclusions drawn.	RMS: We have received a document from the Notifier called "Acute tox purity levels for tech.doc", with data on purity levels of batches used. It will be added to the addendum. (All batches had a high purity of Diflubenzuron)	Open point The acute toxicity to be agreed on in an experts' meeting considering the different batches tested
2(3)	Vol. 1, Level 2: page 31: 2.3.1.1.2 Acute toxicity	NOT: The word "oral" should be replaced by "dermal": "The acute dermal LD_{50} of diflubenzuron was >10000 mg kg^{-1} bw in rats.	RMS: Agree. It will be amended in the revised DAR.	Addressed RMS to consider in a revised DAR or corrigendum
2(4)	Vol. 1, Level 3: page 114 3.1 Background to the proposed decision	NOT: The word "oral" should be replaced by "dermal": "The acute dermal LD50 of diflubenzuron was >10000 mg kg-1 bw in	RMS: Agree. It will be amended in the revised DAR.	Addressed RMS to consider in a revised DAR or corrigendum

Acute toxicity (B.6.2)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data gap or Open point (if data point not addressed or fulfilled)
		rats.		

Short-term toxicity (B.6.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data gap or Open point (if data point not addressed or fulfilled)
2(5)	Vol 3, B.6.3.1.4, oral 90-day and 1 year toxicity - Dog	UK: Derivation of a NOAEL versus NOEL in the 90 day dog study of Greenbough et al, 1985 Justification is required for the assumption that increases in methaemoglobin at 10 mg/kg bw/day, which are statistically significant, are not toxicologically significant.	RMS: We agree the changes in methaemoglobin is considered an adverse effect on a long term basis as an increase in MetHb levels is possible only when the capacity of the reducing mechanisms is exceeded (RIVM report 601516007, 2001). Therefore, we propose the NOAEL/NOEL for the study to 2 mg kg^{-1} bw day^{-1}. It will be amended in the revised DAR.	Open point The toxicological relevance of increased methaemoglobin to be discussed in a meeting of experts. Open point was set after comments on the reporting table have been received.
2(6)	Vol. 3, Annex B.6: page 24 B.6.3.1.1 Oral 28-day study (rat)	NOT: The dose rates in several semi chronic and chronic studies are given as kg^{-1}bw day^{-1}, this should be mg kg^{-1}bw day^{-1}.	RMS: Agree. It will be amended in the revised DAR.	Addressed RMS to consider in a revised DAR or corrigendum

Short-term toxicity (B.6.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data gap or Open point (if data point not addressed or fulfilled)
2(7)	Vol. 3, Annex B.6: page 35 B.6.3.1.3 Oral 90-day toxicity (mouse) Table B.6.3.1.3-1	NOT: Salient findings on haematological parameters: The percentage Reticulocytes (%RBC) for the females are cited incorrectly from Table 5 of the original report. The values were taken from the values reported for Red Blood Cells and not from Reticulocytes. The following values should be used: Reticulocytes (% RCB) for Females Control: 2.6 (not 8.81); 16 ppm: 3.5 (not 8.70); 50 ppm: 3.0 (not 8.70); 400 ppm: 3.4 (not 8.19); 2000 ppm: 6.7 (not 7.72); 10000 ppm: 9.2 (not 8.30) and 50000 ppm: 8.5 (not 7.78).	RMS: Agree. The new figures in Table B.3.1.3-1 in females should be: Reticulocytes (% RCB), females Control 2.6 16 ppm 3.5 50 ppm 3.0 400 ppm 3.4 2000 ppm 6.7* 10000 ppm 9.2* 50000 ppm 8.5* It will be amended in the revised DAR.	Addressed RMS to consider in a revised DAR or corrigendum

Long-term toxicity and carcinogenicity (B.6.5)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data gap or Open point (if data point not addressed or fulfilled)
2(8)	Vol.3, Annex B.6: page 69 B.6.5.2 Carcinogenicity study in rats	NOT: Table B.6.5.2-1 Haemoglobin content should be expressed as g/dL (and not as mg/dL).	RMS: Agree. It will be amended in the revised DAR.	Addressed RMS to consider in a revised DAR or corrigendum

Summary of mammalian toxicology and setting of ADI, AOEL and ARfD (B.6.10)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data gap or Open point (if data point not addressed or fulfilled)
2(9)	Vol 3, B.6.10.8 and B.6.10.9 derivation of ADI and AOEL	UK: Derivation of ADI and AOEL need to be discussed at the expert meeting. If the NOEL from the dog study is considered appropriate for the derivation of the ADI, then it should also be relevant in the derivation of the AOEL.	RMS: We agree with UK. The NOAEL/NOEL of 2 mg kg^{-1} bw day^{-1} from the dog studies should be used both for ADI and AOEL derivation. (The effects of increased methaemoglobin and sulfhaemoglobin are initiated by shorter term exposure but become evident in more chronic toxicity studies and dog is the most sensitive relevant species, that's the reason for choosing the one year dog study also for the AOEL estimation.) It will be amended in the revised DAR.	Open point Reference values to be agreed on at an experts' meeting See also 2(5)
2(10)	Vol 1, Endpoints table: ADI and AOEL	UK: The short term oral NOAEL/NOEL should be amended. In order to ensure transparency, this section should include sufficient information to understand the basis of the derivation of the ADI and AOEL. (I.e. at current the ADI is based on a NOAEL of 2 mg/kg bw and the AOEL on a NOEL of 10 mg/kg bw – these values are not included in the short term toxicity endpoints.)	RMS: See response to comment 2(9). The study is listed in the summary table of studies suitable for estimation of ADI and AOEL.	See open point in comment 2(9) See also 2(5)
2(11)	Vol. 3, B.6.10.10 Acute Reference Dose	EFSA: methaemoglobinemia can be in principle considered as an acute effect: a comment on the non relevance of such an effect for setting the ARfD should be provided by the RMS.	RMS: We agree that Methaemoglobin can be an acute effect. However, Diflubenzurone has very low acute toxicity when given by various routs (oral, dermal, inhalation). There are recovery systems for increase in methaemoglobin so most likely one single acute dose is not critical but it is the repeated doses that overwhelm the reducing system and affects the whole body that is critical.	See open point in comment 2(9) See also 2(5)

Summary of mammalian toxicology and setting of ADI, AOEL and ARfD (B.6.10)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data gap or Open point (if data point not addressed or fulfilled)
			Thus according to the toxicological profile of Diflubenzuron the RMS suggest that establishing an ARfD is unnecessary. On the other hand if an ARfD should be established it should be based on the 28-day study in rat by Palmer et al 1977. The NOAEL of the study was 80 mg kg^{-1} bw day^{-1} and the **ARfD 0.8 mg kg^{-1} bw day^{-1}** using a safety factor of 100. The new ARfD will be included in the revised DAR/addendum together with a document from the notifier called "Rationale in Support of the Removal of the Acute Reference Dose (ARfD)".	
2(12)	Vol. 3, B.6.10.9, AOEL	UK:We do not agree that NOAEL's found in short term studies are around 10 mg/kg bw day (se our overall comment). We suggest that the AOEL is derived from the 1 year study in dogs in which we find that the NOAEL should be established to 2 mg/kg bw/day.	RMS: See response to comment 2(9).	See open point in comment 2(9) See also 2(5)
2(13)	Vol. 3, Annex B.6: page 110 B.6.10 Summary of mammalian toxicology and proposed ADI etc.	NOT: The last sentence "It was maternal or any evidence of embryotoxicity." should be replaced by "No maternal toxicity or any evidence of embryo toxicity was found."	RMS: Agree. It will be amended in the revised DAR.	Addressed RMS to consider in a revised DAR or corrigendum

Dermal absorption (B.6.12)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data gap or Open point (if data point not addressed or fulfilled)
2(14)	Vol3, B.6.12.1, dermal absorption	NL: RMS proposes a dermal absorption of 0.5 % based on an in vivo study in the rat. However, in our opinion the conduct of the study does not allow this conclusion. The animals were killed immediately after 1, 4 or 10 h of exposure. At these time points a significant amount of label is still present in the exposed skin. Since urine was not collected during at least a few days after the end of the exposure, the conclusion of RMS about serial non detects is not correct. Furthermore, for the low dose label is still excreted in urine at the end of the 10 h exposure period. Therefore, the amount in the skin should be considered as potentially absorbed. Based on this study the dermal absorption should be about 6%. This is supported by a 21 day dermal dermal toxicity study in rats in the NL dossier on diflubenzuron from the same notifier, which is not included in the DAR (Goldenthal, E.I.1996). In this study significant anaemia was found at doses of 500 mg/kg bw/d and higher indicating a dermal absorption of at least several percent.	RMS: Agree. The dermal absorption should be 6%. The limit values will be recalculated and the DAR revised. (The Goldenthal, E.I. 1996 study is included in the dossier.)	Open point Dermal absorption to be confirmed in an experts' meeting
2(15)	Vol. 3, B.6.12.1, Dermal absorption	DK: We do not agree that residues in skin should not be included. The study was	RMS: see comment 2(14).	See 2(14)

Dermal absorption (B.6.12)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data gap or Open point (if data point not addressed or fulfilled)
		terminated after 10 hours which is not sufficient time to be conclusive about the fate of residues in skin. At least for the 0.5 mg group it is not true that absorption did not increase from 1 to 10 hours. Absorption was almost 2 fold after 10 hours than after 1 hour.		

Exposure data (B.6.14)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data gap or Open point (if data point not addressed or fulfilled)
2(16)	Vol. 3, B.6.14, Table B.6.14-1., Exposure data	UK: It is likely that forestry and woody ornamentals may also be treated using ground-based equipment (both tractor-mounted/trailed sprayers and hand-held sprayers) and the GAP table refers to the use of such equipment (B.3.2.4). If these uses are intended, appropriate exposure estimates should be presented.	RMS: According to the GAP, applications to forestry may be made by tractor mounted equipment and hand-held equipment and so exposure with these methods of applications for forestry needs to be addressed. However, since the application rate on forestry (48 g a.s./ha) is much lower than for pome fruit (180 g a.s./ha) and since work rates and the method of application for both crops would be comparable, operator exposure when applying 'Dimilin' WG-80 to forestry will be lower than from applications to pome fruit. Therefore, the worst-case is already covered in the DAR. Nevertheless, estimates of exposure are submitted for completeness and appropriate calculations will be provided. RMS has received a document called "Additional risk assessments for operator, worker	Point of clarification (for formal reason, already submitted by the applicant) Applicant to provide further exposure details based on the intended uses Open point Operator, worker and bystander exposure to be confirmed at a meeting of experts.

Exposure data (B.6.14)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data gap or Open point (if data point not addressed or fulfilled)
			and bystander exposure for the EU-review of diflubenzuron" from the Notifier, it will be added to the addendum together with the calculation performed by RMS.	
2(17)	Vol. 3, B.6.14.1.1, estimation of operator exposure in orchards	UK: It is incorrectly stated that the UK POEM does not contain relevant data to evaluate the use of 'Dimlin WG-80' on pome fruit through tractor-mounted/trailed sprayers. The current version of the UK POEM (updated in early 2003) contains appropriate data and should be used.	RMS: Agree. The new calculation will be provided on an addendum.	See 2(16)
2(18)	Vol. 3, B.6.14.1.1, estimation of operator exposure in orchards	UK: The UK POEM should not be used to evaluate the use of 'Dimlin WG-80' on pome fruit through hand-held sprayers as this model has no data relating to the use of knapsack sprayers on high crops.	RMS: Agree. The figures will be deleted from the Table on the revised DAR.	Addressed
2(19)	Vol. 3, B.6.14.1.1, Table B.6.14.1.1-1 and following conclusion. estimation of operator exposure in orchards	UK: The values quoted for '% of AOEL' appear to be 10x too great.	RMS: Agree. There will be new calculations in the addendum.	Addressed
2(20)	Vol. 3, B.6.14.1.2, Table B.6.14.1.2-1 and following conclusion. Estimation of operator exposure in forestry	UK: The German model calculation for exposure during mixing and loading appears to be incorrect. The quoted systemic exposure value of 0.014 mg/kg bw/day should be 0.012 mg/kg bw/day.	RMS: We don't agree. The systemic exposure is calculated using a body weight of 60 kg which we consider more relevant than 70 kg. There will be new calculations in the addendum.	See 2(16)
2(21)	Vol. 3, B.6.14.1.3, Table B.6.14.1.3-1 and following conclusion.Estimation of	UK: The German model calculation for exposure during mixing and loading appears to be incorrect. The quoted systemic exposure value of 0.0031 mg/kg	RMS: see comment 2(20).	See 2(16)

Exposure data (B.6.14)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data gap or Open point (if data point not addressed or fulfilled)
	exposure in a greenhouse - mushrooms	bw/day should be 0.018 mg/kg bw/day (equivalent to 54% of the AOEL).		
2(22)	Vol. 3, B.6.14.1.3 Estimation of exposure in a greenhouse - mushrooms	UK: No attempt has been made to estimate the levels of operator exposure when treating the casing medium using hand-held equipment. Although neither the UK POEM nor the German model has data on indoor applications, the EUROPOEM database contains exposure values for the use of hand-held glasshouse spraying equipment which are appropriate to use in this situation.	RMS: There will be new calculations in the addendum. (The exposure is not acceptable).	See 2(16)
2(23)	Vol. 3, B.6.14.2, bystander exposure	UK: The bystander exposure estimate does not consider inhalation exposure to spray drift. Also, the assumption that normal clothing will provide 100% protection against contamination of the covered area is unrealistic.	RMS: RMS: There will be new calculations in the addendum.	See 2(16)
2(24)	Vol. 3, B.6.14.3.1, worker exposure in orchards	UK: The worker exposure estimate for pome fruit assumes an initial DFR of 1µg/cm/kg a.s./ha rather than the value of 3 µg/cm/kg a.s./ha proposed in EUROPOEM. Also, as pome fruit may be treated more than once, it may be appropriate to base a worst case estimate on the maximum total dose to account for the possible build up dislodgeable foliar residues.	RMS: A new calculation will be provided in the addendum.	See 2(16)
2(25)	Vol. 3 B.6.14.1.3 Estimation of operator	EFSA: the operator exposure estimate reported in the DAR does not appear fully	RMS: We have got the following information from the Notifier: A treated area of 0.15 ha	See 2(16)

Exposure data (B.6.14)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data gap or Open point (if data point not addressed or fulfilled)
	exposure in greenhouse using mushroom grower	reliable; some details (e.g. the reduction of the treated area to 0.15 ha/day) need to be further explained.	mushrooms/day (equal to the maximum area grown on the very largest mushroom farms across 3 or 4 mushroom houses) with hand-held equipment is considered to be much a worst-case as most mushroom farmers grow considerably smaller areas than this (typically 300 to 400 m2). Furthermore, a spray volume of 1.5 L/m2 (15,000 L/ha) requires an operator to handle 2250 L water per day, whereas 400 L water/day (as assumed in the UK model for hand-held applications) is probably a more realistic handling capacity. The product is prepared and used by each mushroom grower on his own farm and applications are not made at several mushroom farms by spray contractors. A new calculation will be provided	

Other comments				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data gap or Open point (if data point not addressed or fulfilled)
2(26)	**Overall comment**	DK:We agree in the overall conclusion that diflubenzuron should not be classified R48 on haemolytic anaemia. We however disagree to most of the NOAEL's established in the short and long term studies. In most studies considerable increases in methemoglobin and sulfhemoglobin compared to the	RMS: See comment 2(5). After having gone through the studies once more looking for signs of anemia we suggest that Diflubenzuron should be classified R48 on hemolytic anemia, see revised DAR. Diflubenzuron has been discussed on an ECB meeting (TC C&L meeting in nov. 2006) where it was not classified but that was with other basic	See 2(5) All the reference values will be revised at the experts' meeting.

Other comments				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data gap or Open point (if data point not addressed or fulfilled)
		concurrent control are seen in lower doses than the allocated NOAEL's. These findings are considered to be adverse.	data where increase in methaemoglobin and sulfhaemoglobin was not regarded as adverse effects and where anemic effects was not considered.	

Comments received on reporting table, section Mammalian Toxicology (B.6)			
Reference to reporting table	MS / Notifier	Comment	EFSA response
General	NL	No comments, agree with open points to be discussed in an expert meeting.	Noted
2(5)	NOT	RMS: Therefore, we propose the NOAEL/NOEL for the study to 2 mg kg-1 bw day-1. We do not agree with this proposal: the study of Greenough (1985) is referring to the 1-year dog study not the 90-day study. An exposure of 1 year in dogs is not a short term exposure (short term: 28 – 90 days), the duration of this study is approximately 4 times the 90-day study. The effects seen in both the 90-day and 1-year dog study are not biologically relevant and certainly not adverse. ➢ In the 90-day study (Versendaal, 1983) the NOEL is 4 mg/kg bw/day and the NOAEL is 50 mg/kg bw/day! The effects at 50 mg/kg bw/day are minor and not adverse: The value of MetHb was < 1% at 50 mg/kg bw/day which is the standard value presented in ECB's document (ECBI/07/03 Add.11). In the 1-year dog study (Greenough, 1985) the level of MetHb was < 1% at the NOAEL of 10 mg/kg bw/day. The 2 mg/kg is equal to the NOEL but is not relevant for the NOAEL. The NOAEL should be **10 mg/kg bw/day** based on the increase in spleen weight, which is a secondary effect.	New open point set on the toxicological relevance of increased methaemoglobin.
2(9)	NOT	RMS: We agree with UK. The NOAEL/NOEL of 2 mg kg-1 bw day-1 from the dog studies should be used both for ADI and AOEL derivation. We do not agree with the NOAEL of 2 mg/kg bw/days as proposed by the RMS for use in the derivation of the ADI and AOEL. The NOAEL used for the ADI & AOEL should be **10 mg/kg**	Noted

Comments received on reporting table, section Mammalian Toxicology (B.6)			
Reference to reporting table	MS / Notifier	Comment	EFSA response
		bw/day based on the increase in spleen weight, which is a secondary and certainly not an adverse effect. The effects seen at 10 mg/kg bw/day are minor and not biologically relevant, the values of MetHb are below the 1% value that is mentioned as a standard value in the ECB document (ECBI/07/03 Add.11).	
2(9)	UK	The RMS agreed with the UK in that it was appropriate to use the NOAEL/NOEL of 2 mg/kg bw/day from the dog study in the derivation of both the ADI and the AOEL. However, in the updated list of endpoints the NOAEL for the chronic mouse study has been reduced from 6.4 to 1.2 mg/kg bw/day, and this NOAEL, rather than that from the dog study, is used in the derivation of the ADI. Further explanation is required for the reduction of the NOAEL in the mouse study and its use in the ADI derivation.	Noted
2(11)	NOT	RMS: We agree that Methaemoglobin can be an acute effect Methaemoglobinemia is not an acute effect for diflubenzuron, since this effect isn't observed in the acute studies. Only in the short term and chronic studies the levels of methaemoglobinemia are increased. However these effects are mild and are reversible and compensatable, therefore there are certainly no scientifically sound reasons to establish an ArfD!	Noted
2(26)	NOT	RMS: See comment 2(5). After having gone through the studies once more looking for signs of anemia we suggest that Diflubenzuron should be classified R48 on hemolytic anemia, see revised DAR. We disagree with the statement of the RMS that there is "other basic data" on toxicology, no additional data of diflubenzuron on human toxicity has been provided. The RMS switched opinion on the basis of the same toxicological data package as presented in the submitted dossier and evaluated in the DAR. The RMS has changed some NOEAL/NOEL values in the List of end-points and based them on studies "of restricted quality". We certainly disagree and such studies should not be used for determining end-points. They should only be used as complementary. In general, the conclusions of these complementary studies were: No NOEAL/NOEL could be established. But still the RMS did use some values for that purpose.	Noted

Comments received on reporting table, section Mammalian Toxicology (B.6)			
Reference to reporting table	MS / Notifier	Comment	EFSA response
		In the section critical effects of the List of Endpoints, dated December 2006, there are effects mentioned that weren't even caused by diflubenzuron, *e.g.* chronic hepatitis. In the 2 studies were chronic hepatitis was observed the chronic hepatitis also occurred in the control group, thus this wasn't caused by the diflubenzuron. This is supported by the fact that, apart from these 2 studies mentioned, chronic hepatitis didn't occur in any other study. We do not agree with the recommended R48 classification, the effects on haematological parameters are not meeting the criteria as mentioned in ECB (ECBI/07/03 add.11) and therefore the R48 classification is not warranted. The toxicology package for diflubenzuron was assessed in association with ECBI/07/03 Add. 11 (Proposal for criteria to be used in the classification of R48 for hemolytic anemia in repeated dose toxicity studies). The treatment related effects seen in the toxicity studies with diflubenzuron are not indicative of serious adverse effects. The assessment concluded that the classification of R48 is not warranted for diflubenzuron. A separate document with our detailed assessment will be sent to the rapporteur. No serious systemic effects were demonstrated in any toxicity studies with diflubenzuron. Repeated dose studies with diflubenzuron in the diet, by oral bolus dose in the form of a capsule, by inhalation or by dermal exposure, have not resulted in any deaths related to treatment. Dietary treatment levels were up to 100,000 ppm for 9 weeks in rats (corresponding to 7801 & 8539 mg/kg bw/day fors males & females, respectively) (Hunter 1979). Clinical signs were not observed during dosing in any study. No decrease in life span for any animal species was noted in any repeated dose study. This demonstrates that the haematological effects as a result of diflubenzuron treatment do not result in a decrease in overall health of the treated animal. Repeated dose administration of diflubenzuron resulted in sub-clinical expression of anaemia, which was most likely due to extracellular hemolysis. The level of anaemia can be classified as sub-clinical because of the lack of clinical symptoms associated with treatment. The decrease in haemoglobin (Hb) levels was not below the designated adverse level of 10% of in any of the studies. Methemoglobin (MetHb) levels were only above the level of concern (4% in rats, 2% in mice) at extremely high doses (400 ppm in mice and 100,000 ppm in rats). Furthermore, chronic administration of diflubenzuron resulted in a reduction in the expression of anaemia compared to those evident upon sub-chronic treatment. The increase in liver and spleen weight is a secondary effect which is attributable to the deposition of pigment from damaged erythrocytes. Diflubenzuron affects the circulatory system through	

Comments received on reporting table, section Mammalian Toxicology (B.6)			
Reference to reporting table	MS / Notifier	Comment	EFSA response
		mild, subclinical extravascular hemolytic anemia. The effects seen are reversible and compensatable as demonstrated by the toxicological database of diflubenzuron.	

3. Residues

Metabolism in plants (B.7.1)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data gap or Open point (if data point not addressed or fulfilled)
3(1)	Vol. 3, B7.1.2, Table 7.1.2.2	NL: In the heading of the metabolism study in orange, a limit of determination of 0.001 mg/kg is given for metabolite PCI. In Table B7.2.1.2.2 it is shown that the recovery of PCI is only 62.5% at 0.001 mg/kg and not the required ≥ 70%. This is not in coherent.	RMS: Aniline-type molecules have a tendency to bind to the plant components (lignin,cellulose, etc). The limit of detection of the metabolite 4-chloroaniline (PCA) is very low, 0.001 mg/kg. For most substances the LOD is 0.01 mg/kg. We therefore argue that 62,5% recovery of a substance with LOD of 0.001 mg/kg is acceptable. **The notifier states** that Table B7.1.2.2 in DAR shows that the recovery of PCA at the usual LOD, 0.01 mg/kg, is ≥ 70%. The researchers were aware of the needs and concerns of the regulatory community and included additional data indicating a lower recovery at an order of magnitude lower concentration.	Addressed.
3(2)	Vol. 3 B.7.2, Animal metabolism (laying hens)	EFSA: For the laying hen study, information should be given on the evolution of the residue levels in eggs, reflecting the accumulation capacity of diflubenzuron	RMS: In eggs diflubenzuron residues are present in egg yolk (0.81-5.65 mg/kg diflubenzuron equivalents). Agrees with following statement from notifier. **The notifier states** although not mentioned in the DAR, plateau levels are mentioned in the original dossier, updated summary dossier (see document MIIA 6, page 17) and the report (see document KIIA 6.2/01a, page 29-31). It should be noted that the total recovery of radioactivity in egg yolk accounted for only ca. 0.4% of the total administered doses, which were 1 & 10 mg/kg.day for a period of 20 days.	Addressed. RMS to consider in a revised DAR or a corrigendum.

Metabolism in plants (B.7.1)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data gap or Open point (if data point not addressed or fulfilled)
			Doc MIIA 6, page 17: "There was some evidence of accumulation of radioactivity in egg yolks and levels reached a plateau after the fifteenth dose for both groups" **Doc KIIA 6.2/01a, page 29-30**: Group 2 (low dose level: 1 mg/kg/day): "Analysis of eggs indicated low levels of radioactivity associated with egg whites (Table 6). Mean levels of radioactivity in egg whites plateaued at 29 ng equiv.g^{-1} after the fifth dose and remained constant thereafter. Higher levels of radioactivity were detected in egg yolk (Table 7) and these increased steadily from a mean of 1 ng equiv.g^{-1} Post Dose 1 to 769 Post Dose 15 and thereafter remained constant. However, the total recovery of radioactivity in egg yolk accounted for only ca. 0.4% of the total administered dose." Group 3 (high dose level: 10 mg/kg.day): "Analysis of eggs indicated low levels of radioactivity associated with egg whites (Table 13). Mean levels of radioactivity reached a plateau of 0.2 µg equiv. g^{-1} following administration of the fifth dose. Higher levels of radioactivity were detected in egg yolks (Table 14) and these increased steadily from 0.3 µg equiv. g^{-1} Post Dose 3 to 7.3 µg equiv. g^{-1} Post Dose 15 and thereafter remained constant. This was also observed in the low dose group. The total recovery of radioactivity in egg yolk	

Metabolism in plants (B.7.1)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data gap or Open point (if data point not addressed or fulfilled)
			accounted for only ca. 0.4% of the total administered dose."	
3(3)	Vol. 3, B7.2.2 (Metabolism in laying hens: livestock dietary burden calculation)	NL: It is calculated that dietary intake for dairy cattle and beef cattle is 0.016 mg/kg bw/d and 0.056 mg/kg bw/d, respectively. It is concluded that therefore the trigger value for performing feeding studies is not exceeded. However, the trigger value should be expressed as mg/kg dry feed. XX calculated a dietary intake of 0.44 mg/kg dry feed and 1.30 mg/kg dry feed for dairy cattle and beef cattle, respectively. The trigger value for performing livestock feeding studies is clearly exceeded.	RMS: If we use the instructions and calculation given in guideline 7031/VI/95 rev. 4, p.4 and 5 the total dietary intake for dairy cattle will be 0.016-mg/kg bw/day (using proposed MRL for apple 1 mg/kg). In this instruction there is no clear indication that the total diet should be expressed as mg/kg dry feed p. 2. If we use the calculation NL proposes the figures are changing from below the trigger value of the guideline to above the trigger value in the guideline. The need of feeding studies were discussed with notifier during the completeness check; RMS argued that considering the potential use within EU and the products solubility in fat, feeding studies should be submitted. However, feeding studies were not submitted **Notifiers comment**: We do not agree with NLand RMS that a new feeding study is needed. **Calculation method**: In the procedure of determining the exposure to livestock there are several moments that worse case assumptions are done. By stacking up all these worse case assumptions on top of each other to our opinion we end up in a situation which is unrealistic. Worse case assumption no 1: In the residue trials used for determination of the residue on the apple and processed apple fractions (B7.7.1) the number of applications are more than the GAP, 4x versus 2x in the GAP, and therefore there is an over-	See open point in comment 3(29)

Metabolism in plants (B.7.1)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data gap or Open point (if data point not addressed or fulfilled)
			estimation of the amount of residue in apple and apple pomace. Worse case assumption no 2: By choosing from the above mentioned over-estimated residue values the highest concentration factor found for Worse case assumption no 3: Assuming that 10% or 15% of the daily dry feed, for respectively dairy and beef cattle, consists of fruit pomace is an over-estimation, it will be much less in real practise. The composition of the animal feed varies from one country to another, for sure there are even countries in which cattle do get fed any fruit pomace at all! Worse case assumption no 4: Assuming that all the fruit pomace consists of apple pomace is yet another over-estimate. In practise also other fruits will be used. Worse case assumption no 5: Calculating the STMR (and MRL) from the current residue trials (see point 1; 4 applications versus 2 applications) results again in an over-estimation. Worse case assumption no 6: Using residue trials from Northern countries only gives again an over-estimation of the STMR (and MRL) values for the whole EU. **Values used in the calculation**: We do not agree with the values used by the RMS for the STMR and the transfer factor. The chosen STMR is not based on all trials within the EU and should be 0.38 mg/kg and for the transfer factor the mean value of 2.3 should have	

Metabolism in plants (B.7.1)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data gap or Open point (if data point not addressed or fulfilled)
			been taken instead of the maximum value. This is as indicated in the guidance document of the FAO* *FAO manual on the submission and evaluation of pesticide residues data for the estimation of maximum residue levels in food and feed. 2nd Edition. Food and Agricultural Organisation of the United Nations, Rome, 2002. Rome, 2002.) When using these values and correcting* for the remainder of the diet not containing diflubenzuron residue, the exposure for diary cattle is **0.26** and for beef cattle is **0.54** mg/kg dry feed. For calculation see document: 072.doc (title: Revised calculations for dietary exposure of cattle and comparison with data found in the lactating goat study), it will be send to the RMS. *Corrections should be made for the rest of the dry feed that doesn't contain diflubenzuron residues, because apple pomace is only a small part of the diet. **RMS comment to notifier on values used in the calculation**; agrees with the use of STMR and transfer factor in the dietary intake calculation. We maintain that the value of STMR should be 0.41 (based on trials from N-EU) worst case rule. We agree on the reasoning about value of transfer factor.	

Metabolism in livestock (B.7.2)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data gap or Open point (if data point not addressed or fulfilled)
3(4)	Vol. 3, B.7.2.1 (metabolism laying hen)	NL: The feeding level in the header is expressed in mg/kg feed/day. This should be: mg/kg dry feed.	RMS: According guideline 7031/VI/95 rev.4 we are uncertain about this.	Addressed.
3(5)	Vol. 3 Table 7.2.1.5 (metabolism laying hen)	NL: It is not stated whether results reflect the 1mg/kg bw/d or 10 mg/kg bw/d dose.	RMS: The target doses for the study were 1 and 10 mg/kg bw/day, but as there was insufficient radioactive material the high doses were reduced to about 8 mg/kg bw. In the column Dose level in Table 7.2.1.5 **low** means **1 mg/kg bw/day** and high means **8 mg/kg bw/day**. Thus, both doses are included. The figures for low and high dose respectively, will be included in the table in the revised DAR.	Addressed. RMS to consider in a revised DAR or a corrigendum.
3(6)	Vol. 3 Table 7.2.1.6 (metabolism laying hen)	NL: It is not stated whether results reflect the 1mg/kg bw/d or 10 mg/kg bw/d dose.	RMS: Please see comment 3 (5).	Addressed. RMS to consider in a revised DAR or a corrigendum.
3(7)	Vol. 3, Table 7.2.17, B.7.2.1.8 and B.7.2.1.9	NL: Storage stability data in the tables should not only be given in mg/kg but also in also in percentage of the starting value.	RMS: The percentage of the starting value is not included in the table 7.2.1-7 but it is reported in the text of section **comments**	Addressed. RMS to consider in a revised DAR or a corrigendum.
3(8)	Vol. 3 B.7.2.1 metabolism in laying hens, page 27, last strophe)	NL: Dietary burden is well below 0.1 mg/kg dry feed instead of 0.1 mg/kg bw/d	RMS: Please see comment 3 (4).	Addressed
3(9)	Vol. 3, Table B.7.2.2.2 (metabolism lactating goat)	NL: Goats are dosed with 0.2 and 5 mg/kg bw/d, corresponding to (assuming a body weight of 45 kg and feed consumption of 2 kg dry feed/day) 4 and 100 mg/kg dry feed.	RMS: Goats is a dairy cattle for which NL calculated at dietary burden of 0.44 mg/kg dry feed (please see, comment 3.3). Therefore following the argument of NL the lowest dose group (4 mg/kg dry feed) is a 10 N dose. If	See open points in comments 3(12) and 3(29)

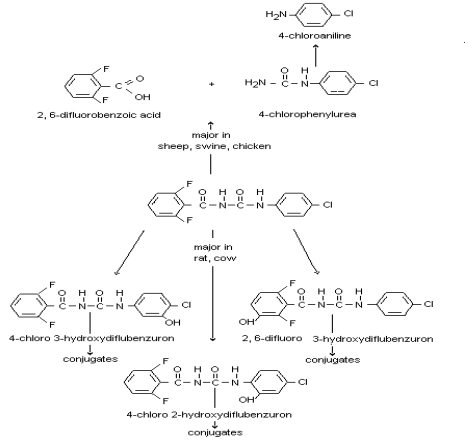
Metabolism in livestock (B.7.2)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data gap or Open point (if data point not addressed or fulfilled)
		NL calculated a dietary burden of 1.30 mg/kg dry feed maximal (beef cattle). Therefore, the lowest dose group (4 mg/kg dry feed) is a 3N dose. TRR in liver and kidney accounted for 0.26 and 0.019 mg/kg at the low dose. This is a 3 fold overdose. If linearity is assumed (and it is), then 0.086 and 0.006 mg/kg is expected in liver and kidney at a 1N dose. Most of the residue is not identified and its toxicity is unknown. Therefore, XX propose to compare goat metabolism and rat metabolism. If they are similar, it is proposed to take TRR into account as the relevant residue for risk assessment. **If so, following these results, MRLs should be set at least for liver (at 0.1 mg/kg) and kidney (at 0.01 mg/kg).**	linearity is assumed, then 0.026 and 0.0019 mg/kg is expected in liver and kidney respectively, at a 1N dose which is below 0.05 mg/kg, the trigger value for identifying residue compounds, according to guideline 7030/VI/95-Rev 3 At a 10 N overdose DFBA (2,6-difluorobenzamide) and CPU 4-chlorophenylurea are present in amounts of (0.011 mg/kg (0.03mg/kg) respectively in liver from goat. The submitted data from goat metabolism in the dossier does not include a study with different metabolites in the urine. Therefore it is not possible to make a comparison between rat metabolism and goat metabolism. The conclusion in the Tox dossier is that neither 4-chloroaniline (PCA), 4-chlorophenylurea (CPU) nor their n-hydroxyl derivatives were found in rat urine at a limit of detection of 0.4 ppb. PCA is only present as an intermediate compound in rat metabolism. **Notifers comment:** We agree with the RMS about the 10 N dose. See 3(3). According to our calculations the STMR should be 0.38 mg/kg and the transfer factor should be 2.3. Using these values, and a correction for the remaining part of the diet not containing diflubenzuron, the exposure for diary cattle is **0.26** mg/kg dry feed.	

Metabolism in livestock (B.7.2)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data gap or Open point (if data point not addressed or fulfilled)
			A document with our calculations will be sent to the RMS and is called "Revised calculations for dietary exposure of cattle for EU-review diflubenzuron and comparison with data found in the lactating goat study	

Residue definition (B.7.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data gap or Open point (if data point not addressed or fulfilled)
3(10)	Vol 3, B.7.3.residue definition in plants	UK: DFBA was not analysed for in the mushroom trials, although for mushrooms it is the main metabolite. This is acceptable provided toxicologists are content that DFBA is of no tox significance.	RMS: No tox data was included of DFBA in the dossier, and therefore its toxicological relevance was not evaluated separately. However Cameron *et al.* 1990 (section B.6.1.2 in dossier) reported that 2,6-difluorobenzoic acid was detected at significant levels in urine from rat, after receiving diflubenzuron. This means that DFBA is covered by toxicological studies of diflubenzuron in rat. JMPR concluded in Toxicological evaluation 2001 and in Residue evaluation 2002, that DFBA was of no toxicological concern. **Notifiers comment**: concurs with the position of RMS	See open point in comment 3(11).
3(11)	Vol. 3, B.7.3, Residue definition in plants	EFSA: RMS should provide an evaluation of the existing data from available reports and publication on metabolites of diflubenzuron (CPU, DFBA and PCA) and suggest which end-points could be used to	RMS: DFBA is covered by toxicological studies of diflubenzuron in rat. CPU and PCA have the same end-points as diflubenzuron (liver, spleen and methaemoglobinaemia) and are in addition carcinogenic. PCA is for instance carcinogenic in	Open point. MS to discuss the residue definition for plant commodities in an expert meeting. See also comments 3(10) and 3(14).

Residue definition (B.7.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data gap or Open point (if data point not addressed or fulfilled)
		characterise their toxicological properties (same end points as diflubenzuron or other end points). On the basis of that evaluation, the residue definition for risk assessment should be re-examined in particular for mushrooms.	male rates with rare tumours of the spleen. A TDI of 2 µg/kg body weight per day (un extra uncertainty factor 10) was set by International Programme on Chemical Safety (IPCS) 1994 for PCA. EPA concluded in Federal register 2001, vol. 66 and No 241 that " by association with PCA, CPU has carcinogenic potential and the same carcinogenic potency as PCA. PCA is used as an intermediate in the production of several urea herbicides and insecticides (e.g.monuron, diflubenzuron and monolinuron) azo dyes and pigments. Therefore it is possible that food products will be contaminated with PCA from other sources than diflubenzuron. The recommendation from IPCS INCHEM is that residual level of PCA in consumer products should be reduced or entirely eliminated (CICADS 48, 2003). **Notifiers comment**; As noted in the review of PCA toxicology (Freeman, E, Toxicological Evaluation of 4-Chloroaniline (PCA): A Minor Impurity in Technical Diflubenzuron, September 5, 2006) PCA is a threshold carcinogen with clear carcinogenic results in only one species, at a dose that causes overt systemic toxicity. CPU was associated with PCA and assigned the same carcinogenic potential based on structural similarities and metabolic conversion of CPU to PCA. In contrast to the EPA statement in the Federal Register, the Health Effects Division (HED) Metabolism Assessment Review Committee (MARC) concluded in a memorandum	

Residue definition (B.7.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data gap or Open point (if data point not addressed or fulfilled)
			of their review (Diflubenzuron. Residues of Concern for Cancer Risk Assessment, Document D272976, Submission S590172, 2001) CPU should not be included in the cancer risk assessment since high doses of CPU do not cause methemoglobinemia and CPU is not metabolized to PCA in rats (Gay, M. et al. Metabolism of [U-14C-Phenyl]-4-Chlorophenylurea by Male Fisher Rats, Chemtura Study no. 98203, 2001).	
3(12)	Vol. 3, B.7.3, Residue definition in animals	EFSA: For ruminants it is difficult to conclude on a residue definition as residues were identified only in milk and liver. Meat and fat were not investigated although the metabolism in hens demonstrated a lipophilic behaviour of diflubenzuron. A new metabolism study should be requested unless clear evidence can be supported that the exposure of ruminants leads to a no-residue situation in ruminant tissues or unless based on expert judgment it could be considered that the residue definition proposed by the RMS, including parent and CPU is safe for the consumer.	RMS: Please see comment 3(9). In the presented metabolism study from lactating goat the only marker residue present > 10% is CPU in liver and milk. The exposure in other organs is very low (table 7.2.2-4 at a 10N overdose e.g. kidney 0.016-0.019 mg/kg) but there is not a no-residue situation. However, JMPR have presented the following animal metabolism pattern	Open point. MS to discuss the residue definition in animal commodities in an expert meeting. See also comment 3(9) and 3(13).

Residue definition (B.7.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data gap or Open point (if data point not addressed or fulfilled)
			 **Figure 1. Animal metabolism of diflubenzuron.** Showing that in sheep, swine and chicken CPU and PCA are formed. www.inchem.org/documents/jmpr/jmpmono/v081pr05.gif. **Notifers comment**; In the lactating goat study, other organs or tissues (kidney, spleen, fat, muscle, bile, intestinal wall & contents, carcass) and blood were also monitored for radioactivity and thus residues. Residues in the meat (muscle) and fat of the lactating goat were both below the limit of quantification. Below the relevant pages of the DAR are mentioned for more detail. - **DAR, Vol. 3, B.7.3**, page 29-36:	

Residue definition (B.7.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data gap or Open point (if data point not addressed or fulfilled)
			In the presented tables (B.7.2.2-1 until B.7.2.2-7) radioactivity levels and thus residues of all investigated substrates are mentioned: liver, kidney, spleen, fat, muscle, bile, intestinal wall & contents, carcass and blood / milk / plasma / faeces / urine. - **DAR, Vol. 3, B.7.2.4**, page 37 (chapter Metabolism, distribution and expression of residues in livestock - summary and conclusion): "In lactating goat residues were below limit of quantification in muscle and fat." Additional metabolism studies are not needed. At the highly exaggerated doses used in the goat metabolism study, TRR in edible tissues exceeded 0.05 mg/kg in liver and kidney. In the spleen and fat TRR exceeded 0.05 mg/kg only at 5 mg/kg bw/day. Similarly, TRR in milk was <0.01 mg/kg at the low dose, 0.2 mg/kg bw/day, and reached a plateau of 0.2 mg/kg at the high dose, 5 mg/kg be/day. At the calculated maximum dietary exposure (1N), levels of individual residues will be at or below the LOD. Including any residue other than parent and CPU would not promote safety. While concentration in fat and yolk was observed in hens it was not observed in goats. There is no scientific basis for additional livestock metabolism studies and no further animal testing is justified. The relevant pages of the DAR are: -DAR, Vol.3,B.7. pages 27-36: In the tables B.7.2.2.-1 until B.7.2.2.-7 TRR in all collected	

Residue definition (B.7.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data gap or Open point (if data point not addressed or fulfilled)
			samples. –DAR, Vol.3,B.7.2.4 page 37: "In lactating goat residues were below the limit of quantitation in muscle and fat.	
3(13)	Vol. 3, B.7.3 Residue definition in livestock	NL: The only marker residue present > 10% is CPU in liver and milk. Therefore, the residue definition for monitoring is CPU. Most of the residue is not identified and therefore of unknown toxicity. When goat metabolism is similar of that of rat, the toxicity of the metabolites are taken into account and a conversion factor of 7 might be proposed (liver and kidney) to include all metabolites in risk assessment.	RMS: Please see comment 3 (12) **Notifers comment;** CPU is the appropriate residue definition for monitoring milk. At 10N the calculated maximum dietary exposure, the highest TRR in milk was 0.009 mg/kg and 35% of that was CPU. Assuming linearity between dose and residues, the TRR and concentrations of CPU will be in the parts per trillion range at a 1N dose. Minor metabolites at such low levels are not relevant.	See open point in comment 3(12)

Use pattern, critical GAP, residues trials (B.7.4 to B.7.6)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data gap or Open point (if data point not addressed or fulfilled)
3(14)	Vol 3, B.7.6, residues from supervised trials	UK: Please provide clarification on the proposed residue definition in plants for risk assessment and monitoring. PCA is cited as a possible carcinogen, which would seem to make reliable measurement of residues in mushroom important, yet elsewhere it is said to be of no toxicological relevance to consumers.	RMS: A TDI of 2 µg/kg body weight per day (an extra uncertainty factor 10) was set for PCA by International Programme on Chemical Safety (IPCS) 1994. The mushroom metabolism studies in the DAR revealed PCA residues in between 0.01-0.16 mg/kg with casing treatment with a dosage 5 times GAP. Assuming a linear relationship	See open point in comment 3(11).

Use pattern, critical GAP, residues trials (B.7.4 to B.7.6)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data gap or Open point (if data point not addressed or fulfilled)
		However, if PCA data is not in fact needed for risk assessment does it matter that we have no reliable PCA data for mushroom trials?	between residues and dosage rate of Diflubenzuron at only 1 time GAP dosage (1g/m^2) would result in 0.002-0.032 mg/kg of PCA. Considering the low consumption of mushrooms in the WHO, German and xx PDS diet 0.004, 0.003 and 0.0289 (Adult), 0,0141 (Child), 0.017 (Toddler) (kg/person/day) we argued that PCA is of no toxicological relevance due to the low exposure (5, 1.8, 3.2, 2.58, 9.215% of TDI) respectively via consumption of mushrooms (*treated with Diflubenzuron 5 times GAP*). In this conclusion the exposure from PCA in other pesticides, azo dyes and pigments is not considered. However if the intended use is broadened this conclusion indeed must be reconsidered. **Notifiers comment:** We agree with the RMS in that mushrooms form a very small portion of the diet and thus the exposure is very low. There are reliable data for PCA levels in treated mushrooms. As noted in 3(1), compounds like PCA bind to matrix components. As shown in tables B.7.1.1-3 and J B.7.1.3-2, PCA added to apples and mushrooms, respectively, immediately before assay was not quantitatively recovered. This is not the usual "instability." Hydrolysis, oxidation, and metabolism are not involved. Just as most of the added PCA cannot be recovered after 1 month storage, any PCA present from metabolic processes will rapidly bind to the	

Use pattern, critical GAP, residues trials (B.7.4 to B.7.6)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data gap or Open point (if data point not addressed or fulfilled)
			matrix and be unavailable for both assay and intoxication. Also see 3(16).	
3(15)	Vol 3, B.7.6, residues from supervised trials	UK: Please also clarify why the US trials are not acceptable: use of different formulation types may be acceptable provided that the EU and US GAPs in terms of rates and timings were equivalent.	RMS: Agrees, according to guideline 7525/VI/95-rev 7, different types of formulations may be acceptable provided that the EU and US GAPs in terms of rates and timing were equivalent. The rates in US GAP is 4 g Dimilin WP 25/m^2 or 2 g Dimilin 4L/m^2, equivalent to 1 and 0.8 g a.s. /m^2. The EU GAP is 1 g as/m^2 .**Thus the rates in EU GAP and US GAP are similar**. **The timing in the EU and US trials are both at casing**. Furthermore mushrooms are grown in dark cells, where no seasonal influences are envisaged. The cells are kept under constant moisture and temperature. It is not to expect that differences in this technology, as used in different countries will affect the residue behaviour. It will be corrected in the revised DAR	Open point. RMS to report the US trials on mushrooms in an addendum for consideration in expert meeting.
3(16)	Vol 3, B.7.6, residues from supervised trials	UK: We agree that it does appear to be case that storage periods of trial samples for parent and CPU are not supported by freezer storage stability data.	RMS: Agrees, PCA was found to be unstable in mushroom under freezer storage. The maximum storage period in residue trial and level of residues may be underestimated. In the US trials no storage condition data is given. Storage data, in particular from PCA, are therefore requested. **Notifiers comment**: Additional storage stability data are not needed. In a memorandum (document number DP# 321623) the US EPA concluded that while CPU was not stable during storage in a few commodities and PCA was not stable in many commodities, HEED has determined that	See data requirement in comment 3(17)

Use pattern, critical GAP, residues trials (B.7.4 to B.7.6)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data gap or Open point (if data point not addressed or fulfilled)
			correction of CPU and PCA residues for degradation during storage would not have a significant effect on the results of submitted field trials because individual residues of the metabolites in/on treated RAC samples were generally below the respective LOQs. Also rapid degradation to LOD levels with an additional 6 months of storage does not seem realistic. Tables 6.2-1 to 6.2-3 demonstrate that DFB and CPU are stable during storage for 18 and 19 months, respectively, and PCA is not stable. Additional storage studies will not alter these findings. As noted by the RMS (See 3(1)) compounds like PCA bind to plant components (See also 3(14 & 16)). Therefore, this is not a stability issue and the observed results reflect the concentration of available PCA residues in mushrooms.	
3(17)	Vol. 3, B.7.6, Residue trials	EFSA: Although BFDA appeared as the major compound in mushrooms in metabolism studies it was not analysed in the residue trials. Depending on its toxicological relevance, further trials should be carried out in mushrooms. The RMS is also requesting further residue trials in mushrooms for other reasons.	RMS: However Cameron *et al*. 1990 (section B.6.1.2 in dossier) reported that 2,6-difluorobenzoic acid was detected at significant levels in urine from rat, after receiving diflubenzuron. This means that DFBA is covered by toxicological studies of diflubenzuron in rat. JMPR concluded in Toxicological evaluation 2001 and in Residue evalutation 2002, that DFBA was of no toxicological concern. **Notifiers comment**; DFBA is of no toxicological relevance, see JMPR tox. eval. 2001, res. eval. 2002, and therefore not further discussed. For	Data gap. Notifier to submit further residue data in mushrooms taking into account the storage stability of compounds to be determined. See also comments 3(16), 3(23), 3(25), 3(35), 3(36) and 3(37). See comments received from the notifier on the reporting table.

Use pattern, critical GAP, residues trials (B.7.4 to B.7.6)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data gap or Open point (if data point not addressed or fulfilled)
			non-relevant metabolites, no toxicology data have to be included in the dossier. See **DAR, Vol. 1**, page 44: "In mushrooms DFBA is the main residue (98%) followed by CPU (8%), PCA (0,6%), and parent (0,5%) in casing treatment. In view of that DFBA is not a residue of particular toxicological concern and that the intakes of mushrooms is very low in Europe nor DFBA or CPU should be included in the residue definition for apples/pears and mushrooms." **DAR, Vol.3, B.7.,** page 15 (Comments RMS): "DFBA is the main metabolite of diflubenzuron in mushrooms, but of no toxicological concern and therefore not considered for inclusion in the residue definition of plants (JMPR tox eval. 2001, res. eval. 2002)". Residue trails in mushrooms: Four residue trials were performed in 2002 (2 trials in the UK and 2 trials the Netherlands). From these trials, residue data have been provided from in total **14 flushes**, which should be considered more than adequate to support an EU MRL for a minor crop. The notifier does not agree with the conclusion of the RMS in the DAR that for proposing an EU-MRL in mushrooms 3 additional residue trials are needed. The magnitude of residue trials for mushrooms cannot be considered as residue decline studies, considering the growth conditions of	

Use pattern, critical GAP, residues trials (B.7.4 to B.7.6)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data gap or Open point (if data point not addressed or fulfilled)
			mushrooms. Flushes of mushrooms should be considered as separate (complete) harvests of mushrooms.	
3(18)	Vol. 3, B.7.6, Residue trials	EFSA: The issue of setting MRLs on wild fruits or wild mushrooms resulting from the forestry application is an issue to be dealt with at management level. In case MRLs are not fixed and residues in wild varieties are not considered in risk assessment, measures should be taken to avoid the presence or residues or to prevent the harvest of those varieties.	RMS: Agrees **Notifers comment**: Based on the overall toxicity data package of diflubenzuron and its formulations there is no reason to expect any acute or long term risks to people eating occasionally wild berries or wild mushrooms from Dimilin treated forests. In order to reach the acute oral LD50 of 4640 mg/kg body weight a person should eat more than 2320 kg of wild berries and/or wild mushrooms per kg body weight, based on a very conservative residue level of 2 mg diflubenzuron/kg! For chronic exposure this would relate to eating every day more than 10 g of wild berries and/or wild mushrooms per kg body weight based on the ADI (Acceptable Daily Intake) of 0.02 mg diflubenzuron/kg body weight. The WHO has indicated that consumption of wild berries and/or wild mushrooms within the European diet is about 0.004 kg per person, resulting in 0.007 g per kg body weight. Therefore it is extremely unlikely that the ADI can be reached by eating wild berries and/or wild mushrooms from Dimilin treated forests.	Addressed.
3(19)	Vol3. B7.6, Table B.7.6.3 Residue trials with apple	NL: It is remarkable that the main residue is assumed to be diflubenzuron parent, that the residue is not dissipated after 4 weeks, but, however, that an application interval	RMS; According to section B7.1.1 metabolism studies in apples show that diflubenzuron do not metabolize to any large extent as 97 % of TRR was diflubenzuron.	Addressed.

Use pattern, critical GAP, residues trials (B.7.4 to B.7.6)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data gap or Open point (if data point not addressed or fulfilled)
		of 2 weeks yield the same final residue as an application interval of 4 weeks. RMS is invited to give its opinion on this.	After application of ^{14}C Diflubenzuron to fruits and leaves of apple trees, at a level of 1-3 mg/kg (1-3 times proposed MRL), 99,4% of applied radioactivity was recovered from the fruits 9 weeks after the treatment. From applied 104.5µg applied to each fruit 101.1 µg was recovered (97%) as diflubenzuron. Diflubenzuron showed very limited absorption and translocation in plants. **Notifers comment**: The results clearly show that diflubenzuron is not metabolized or translocated appreciably following application to apples and leaves. In two of three washing studies, residues were reduced by about 50% indicating that much of the residue is on the surface. A surface residue that does not wash off with pure water and/or is exposed to minimal rain will remain constant. While this behaviour is unusual, it is not unique or remarkable	
3(20)	Vol. 3, B.7.6, forestry	AT: since the active substances is to be applied in forestry, corresponding residue trials with respect to wild berries has been made available; the results were considered in the risk assessment only. However, a MRL for “wild berries” and “wild mushrooms” has to be set. If this is not possible (due to limited information of the reports provided), the use on forestry cannot regarded as “safe”.	RMS; please see comment 3 (18). **Notifers comment**: See 3(18)	This issue is to be dealt with at management level.
3(21)	Vol. 3, Annex B.7: page 40	NOT: Table: The rate per treatment for the application in mushroom must be 1 g	RMS; Agrees it will be corrected in the revised DAR.	Addressed. RMS to consider in a revised DAR or a

Use pattern, critical GAP, residues trials (B.7.4 to B.7.6)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data gap or Open point (if data point not addressed or fulfilled)
	B.7.5 Identification of Critical GAPs	as/m^2 (the value 0.25 is incorrect).		corrigendum.
3(22)	Vol. 3, Annex B.7: page 42 B.7.5 Identification of Critical GAPs	NOT: Table: The spray volume in forestry for ULV should be 3-5 “water + oil” in stead of “oil” (the oil is added to the water to prevent evaporation). The maximum* application rate for mushrooms should be “1 g a.s./m2” (= 10.000 g a.s./ha)” (* is in fact not relevant considering the typical growing conditions).	RMS; Agrees, it will be corrected in the revised DAR.	Addressed. RMS to consider in a revised DAR or a corrigendum.
3(23)	Vol. 3, Annex B.7: page 56-57 B.7.6, Mushroom residue trials	NOT: The notifier does not agree with the conclusion in the DAR that there are insufficient residue trials to support an EU MRL in mushrooms Four residue trials were performed in 2002 (2 trials in the xx and 2 trials the Netherlands, treated with Dimilin SC-48 and/or Dimilin WG-80). From these trials, residue data have been provided from in total 14 flushes, which should be considered more than adequate to support an EU MRL for a minor crop! In these four trials, residue samples from a total of 3 flushes (harvests) were analysed after application with Dimilin WG-80 and samples from 11 flushes (harvests) were analysed after application with Dimilin SC-48. Diflubenzuron residues were found in the same order of magnitude (SC-48: 5 x <0.01,	RMS; Agrees, please see also comment 3(15).	See data requirement in comment 3(17).

Use pattern, critical GAP, residues trials (B.7.4 to B.7.6)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data gap or Open point (if data point not addressed or fulfilled)
		3x 0.01 and 3x 0.02; WG-80: 1x 0.01 and 2x 0.02). These data clearly demonstrate that the level of residue found after application of Dimilin SC-48 or WG-80 at similar treatment rates on casing can be considered substantially similar, considering the normal variation expected for residue levels close to level of quantification (LOQ). This can be supported by the fact that efficacy data from trials with both formulations show similar results, the particle size of the active ingredient in both formulations is identical and both product formulations are applied similarly, dispersed in water. Also comparative residue trials on apples between Dimilin WP-25 and Dimilin WG-80 have proven the similarity of different sprayable formulations of Dimilin. In conclusion, residue data obtained with Dimilin SC-48 and Dimilin WG-80 are interchangeable. Therefore the notifier maintains its position that the existing residue trials for mushrooms fully support the proposed EU MRL of 0.05 mg/kg.		
3(24)	Vol. 3, Annex B.7: page 57 B.7.6, Mushroom residue trials	NOT: The notifier does not agree with the conclusion in the DAR that the residue trials are decline studies. The magnitude of residue trials for mushrooms cannot be considered as residue decline studies, considering the	RMS; Mushrooms are grown on compost in cells. After inoculation, application and harvesting the compost is discarded and completely renewed. Therefore, under practical conditions it is not relevant with a pre-harvest interval. The question mark in the DAR was due to that all residue data presented in the dossier are from 19 days until	Addressed.

Use pattern, critical GAP, residues trials (B.7.4 to B.7.6)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data gap or Open point (if data point not addressed or fulfilled)
		specific growth conditions of mushrooms. Flushes of mushrooms should be considered as separate (complete) harvests of mushrooms. Detailed information was provided to the RMS on typical mushroom growing practices. Furthermore, the suggestion made in the DAR that a proposal for a pre-harvest interval cannot be made is not relevant, considering the mushroom growing practices!	maximum 41 days after final application. We were asking for residue data previous to 19 days after final application. This is to confirm that residues are not particularly high if the mushrooms are harvested before 19 days after treatment. **Notifers comment**: The mushrooms were harvested according to commercial practice. First harvesting will occur once enough mushrooms have developed in the bed. Normally this occurs in week 4 of the growing cycle	
3(25)	Vol. 3, Annex B.7: page 57 B.7.6, Mushroom residue trials	NOT: The notifier contests that the possible underestimated PCA residues in mushrooms are a valid reason to ask for additional residue trials. e PCA analyses from the above-mentioned residue trials have not indicated its presence above the level of quantification. In the metabolism study for diflubenzuron in mushrooms, it has been clearly demonstrated that the main residue component is DFBA. PCA was only found in extremely low amounts, i.e. well below 1% of the TRR. PCA is therefore not considered a relevant residue in this minor crop (with a corresponding very low food factor). As proposed, and in line with what has been established by the JMPR in 2002, only the parent compound diflubenzuron should be included in the residue definition. A discussion on the low	RMS; please see comment 3 (14), 3(15) and 3 (16). **Notifiers comment:** PCA residues were not underestimated. As noted in 3(1), 3(14) and 3(16), this is not a storage stability issue. PCA added to apple or mushroom samples immediately before assay cannot be adequately recovered. PCA binds to the matrix and is no longer present as a free metabolite or residue. This also occurs with the incurred PCA residues, and thus, the measured values do in fact measure the available PCA residue.	See data requirement in comment 3(17).

Use pattern, critical GAP, residues trials (B.7.4 to B.7.6)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data gap or Open point (if data point not addressed or fulfilled)
		recoveries of PCA upon storage is therefore considered not relevant and should not be used as an argument to invalidate our magnitude or residue trials and establishment of an EU MRL for diflubenzuron.		

Processing (B.7.7)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data gap or Open point (if data point not addressed or fulfilled)
3(26)	Vol. 3, B.7.7.1, Effect of processing on the nature of residue	EFSA: No study was provided on the effect of processing on the nature of residues under representative hydrolysis conditions.	RMS: It is reported in in KEMPEN, A. VAN, FEENSTRA-BIELDERS, G., THUS, J. (1995)SOLUBILITY OF DIFLUBENZURON xx PH 4, 7 AND 10 REPORT SOLVAY DUPHAR B.V., THE NETHERLANDS NO.56830/46/1994 DI - 9167 (physical and chemical properties from the Dossier) that Diflubenzuron was hydrolytically stable under acidic and neutral conditions. The solubility of diflubenzuron in buffer pH 4, 7, and 10 at 25°C was found 0.10 mg/L at pH 4 (coefficient of variation = 13%) 0.08 mg/L at pH 7 (coefficient of variation = 12%)0.32 mg/L at pH 10 (coefficient of variation = 16%) after 180 days. It is therefore assumed that Diflubenzuron is hydrolytically stable and that such processing conditions will not significantly alter the nature of the residues of Diflubenzuron. **Notifiers comment**; The representative hydrolytic conditions following industrial processing of	Open point. MS to consider whether hydrolysis studies reflecting the effect of processing on the nature of residues is needed in an expert meeting.

Processing (B.7.7)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data gap or Open point (if data point not addressed or fulfilled)
			fruits are heating to 90ºC for 20 minutes at pH 4 (pasteurisation). For more detail see Updated summary dossier: Doc MIIA 2, page 13-14: In a study investigating the hydrolysis rate, diflubenzuron demonstrated to be hydrolytically stable at pH 5: less than 10% of the added diflubenzuron was hydrolysed after 4 weeks. The half-life of diflubenzuron at pH 5 is greater than 180 days. The hydrolysis rate constant Kobs at pH 5 is 0.693/T1/2, i.e. less than 0.004 days-1.	
3(27)	Vol. 3, B.7.7.1, Effect of processing on the level of residue	EFSA: For mushrooms, apparently one processing study for canned mushrooms is available (study AF/6263/UR/1). In the list of end points, it is mentioned that 5 studies are available, this should be clarified.	RMS: Only one processing study is available (study AF/6263/UR/1) but the project AF/6263/UR consists of 5 separate studies (field trials). It will be corrected in the revised list of endpoints.	Addressed. RMS to consider in a revised DAR or a corrigendum.
3(28)	Vol. 3, B.7.7.1, Table B7.7.1.1 (processing of apple)	NL: It is recommended to include an extra column in the table for the processing factors of each processing measurement.	RMS: Agrees, it will be corrected in the revised DAR.	Addressed. RMS to consider in a revised DAR or a corrigendum.

Livestock feeding (B.7.8)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data gap or Open point (if data point not addressed or fulfilled)
3(29)	Vol. 3, B.7.8, Feeding studies	EFSA: The argumentation provided by the RMS for not requiring feeding studies should be reconsidered. The calculation of the expected exposure of livestock	RMS has performed a calculation of expected exposure of livestock according to XX and used the transfer factor from fresh fruit (3.8) and STMR (0.41). The exposure as mg/kg diet is then	Open point. MS to discuss the need for a feeding study in lactating cows in an expert meeting.

Livestock feeding (B.7.8)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data gap or Open point (if data point not addressed or fulfilled)
		(expressed as mg/kg diet) is not found in the DAR. A calculation was provided under point 7.2 (animal metabolism) but contains inadequacies (the transfer factor from fresh fruits to pomace was not considered and the STMR should have been used instead of the MRL as highest residue likely to occur)	0.68 for Dairy Cattle and 2.03 for Beef cattle. Thus the trigger value for performing livestock feeding study (0.1 mg/kg of total diet received) is clearly exceeded and feeding studies are required. If the calculation is performed according to guideline 7031/VI/95 rev.4 the values for Dairy cattle will be 0.024 mg/kg bw/day and 0.087 mg/kg bw/day. If transfer factor 2.3 proposed by notifier and confirmed by RMS (061030) is used the values become even lower. Thus trigger value 0.1 mg/kg of total diet is not exceeded and feeding studies are not required. **Notifers comment:** see 3(3)	See also comment 3(3) and 3(9).

MRLs related issues and Consumer Risk Assessment (B.7.10 to B.7.15)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data gap or Open point (if data point not addressed or fulfilled)
3(30)	Vol 3, B.7.15.2, overall assessment of dietary exposure	UK: We would not normally consider pomace consumption for infants and toddlers, so the RMS is correct to state that this exposure level is not realistic and is overestimated.	RMS: Agrees, it will be corrected in the revised DAR.	Addressed.
3(31)	Vol. 3, B.7.15, Intake calculations	EFSA: As far as the intake calculations for British sub-populations are concerned, the practice is to consider that only 2 commodities (those resulting in the highest intakes) can be together consumed at the 97.5th percentile of the consumption. For the other commodities, the mean	RMS: It is stated in the DAR that only the high exposure values have been considered and therefore that the exposure level is overestimated illustrating worst case. Using only 2 commodities (those resulting in the highest intakes) at the 97.5th percentile of the consumption and the other commodities as mean consumption, the intakes becomes different and more correct. The	Addressed. RMS to consider in a revised DAR or a corrigendum.

MRLs related issues and Consumer Risk Assessment (B.7.10 to B.7.15)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data gap or Open point (if data point not addressed or fulfilled)
		consumption value should be taken.	contribution to the proposed ADI of 0.02 mg/kg/bw/day will the become 7.6% for adults, 10.1% for school children, 6.2% for toddlers and 19.1% for infants. The values will be corrected in the revised DAR.	
3(32)	Vol. 3, B.7.15, Intake calculations	EFSA: The calculations provided under table B.7.15-8 are irrelevant as apple pomace is not a commodity for human consumption. This should be deleted from the DAR.	RMS; Agrees, it will be corrected in the revised DAR	Addressed. RMS to consider in a revised DAR or a corrigendum.
3(33)	B.7.12 (MRL calculation	NL: For the data set of Northern Europe, XX calculated different values of R max = 0.77 mg/kg and a Rber (2x0.75) = 0.98 mg/kg. However, it is rounded to the same MRL value of 1.0 mg/kg	RMS; According to guideline 7039/VI/95 EN 22/7/1997 the maximum residue levels of classes are; 0.01, 0.02, 0.05, 0.1, 0.2, 0.3, 0.5 1.0, 2.0, 3.0 etc. Thus, there is no class in between 0.5 and 1.0. Both Rmax and Rber is closer to 1.0 than to 0.5 and therefore 1.0 was chosen as MRL value.	Addressed. RMS to consider in a revised DAR or a corrigendum.
3(34)	B.7.15.1, Table B.7.15.8 (estimation of TMDI)	NL: the header of the table suggests that calculation is made on intake of PCA (chloroaniline). However, this is misleading since the calculation reflects the risk assessment based on diflubenzuron data only. Risk assessment on PCA is already waived in B7.3 (residue definition in plants)	RMS: Please see comment 3 (14).	Addressed. RMS to consider in a revised DAR or a corrigendum.
3(35)	Vol. 1, Level 2: Page 45-46 2.4.4 Proposed EU-MRLs and compliance with existing MRL's. 2.4.6 Basis for differences, if any, in	NOT: The notifier does not agree with the conclusion of the RMS that there are insufficient residue trials to support an EU MRL in mushrooms. Flushes of mushrooms should be considered as separate (complete) harvests of mushrooms. Four residue trials were	RMS; Please see comment 3 (15).	See data requirement in comment 3(17).

MRLs related issues and Consumer Risk Assessment (B.7.10 to B.7.15)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data gap or Open point (if data point not addressed or fulfilled)
	conclusion reached having regard to established or proposed CAC MRLs	performed in 2002 (2 trials in the UK and 2 trials the Netherlands). From these trials, residue data have been provided from in total 14 flushes, which should be considered more than adequate to support an EU MRL for a minor crop!		
3(36)	Vol. 1, Level 3: page 119 3.2 Proposed decision concerning inclusion in Annex 1	NOT: The notifier does not agree with the conclusion of the RMS that for proposing an EU-MRL in mushrooms 3 additional residue trials are needed. The magnitude of residue trials for mushrooms cannot be considered as residue decline studies, considering the growth conditions of mushrooms. Flushes of mushrooms should be considered as separate (complete) harvests of mushrooms. Four residue trials were performed in 2002 (2 trials in the UK and 2 trials the Netherlands). From these trials, residue data have been provided from in total 14 flushes, which should be considered more than adequate to support an EU MRL for a minor crop!	RMS; Agrees, please see comment 3 (15).	See data requirement in comment 3(17).
3(37)	Vol. 1, Level 4: page 121 4.7 Residue data	NOT: The notifier does not agree with the conclusion of the RMS that there are insufficient residue trials to support an EU MRL in mushrooms. The magnitude of residue trials for mushrooms cannot be considered as residue decline studies, considering the growth conditions of mushrooms. Flushes	RMS; Agrees, please see comment 3(15)	See data requirement in comment 3(17).

MRLs related issues and Consumer Risk Assessment (B.7.10 to B.7.15)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data gap or Open point (if data point not addressed or fulfilled)
		of mushrooms should be considered as separate (complete) harvests of mushrooms. **The four residue trials performed in 2002 in the UK and The Netherlands provide residue data from in total 14 flushes, which should be considered sufficient to support an EU MRL for a minor crop.**		

Comments received on reporting table, section Residues (B.7)			
Reference to reporting table	MS / Notifier	Comment	EFSA response
3(4)	NL	RMS finds some uncertainty in guideline 7031/VI/95 rev.4 with regard to the trigger values for performing livestock metabolism and feeding studies. To our understanding, the guidelines mention a trigger value of 0.1 mg/kg total diet (7030/VI/95 rev. 3) or mg/kg of total diet as received (3031/95 rev.4). 'As received' is the difficult part. However, in Expert Meetings of the section Residues it is generally agreed on that the trigger value of '0.1' refers to the residue intake expressed per total dry feed, and not: the residue expressed as mg/kg fresh feed, mg/d, mg/kg bw/d, etc. NL recommend to put this explanation in a special worksheet regarding 'working compromises and agreements'	Noted. The need for a feeding study in lactating cows will be discussed in expert meeting (open point in comment 3(29).
3(17)	NOT	Notifier to submit further residue data in mushrooms taking into account the storage stability of compounds to be determined The initial reason of the RMS to ask for more residue trials was that the rapporteur thought that not enough residue trials in mushrooms were submitted. But after understanding how the growing cycle and harvesting in mushrooms takes place, the RMS accepted the number of trials as	Noted. Cross reference to this comment in the reporting table.

Comments received on reporting table, section Residues (B.7)			
Reference to reporting table	MS / Notifier	Comment	EFSA response
		sufficient. Thus this point is addressed. Residues in mushroom: ➢ See 3(16): Correction of CPU and PCA residues for degradation during storage would not have a significant effect on the results of submitted field trials because individual residues of the metabolites in/on treated RAC samples were generally below the respective LOQs. Also rapid degradation to LOD levels with an additional 6 months of storage does not seem realistic. Tables 6.2-1 to 6.2-3 demonstrate that DFB and CPU are stable during storage for 18 and 19 months, respectively, and PCA is not stable. Additional storage studies will not alter these findings. ➢ DFBA: DFBA is of no toxicological relevance. For non-relevant metabolites, no toxicology data have to be included in the dossier. As the RMS already stated in the reporting table: Cameron et al. 1990 (section B.6.1.2 in dossier) reported that 2,6-difluorobenzoic acid was detected at significant levels in urine from rat, after receiving diflubenzuron. This means that DFBA is covered by toxicological studies of diflubenzuron in rat. JMPR concluded in Toxicological evaluation 2001 and in Residue evaluation 2002, that DFBA was of no toxicological concern. PCA (see 3(25): PCA residues were not underestimated. As noted in 3(1), 3(14) and 3(16), this is not a storage stability issue. PCA added to apple or mushroom samples immediately before assay cannot be adequately recovered. PCA binds to the matrix and is no longer present as a free metabolite or residue. This also occurs with the incurred PCA residues, and thus, the measured values do in fact measure the available PCA residue.	

4. Environmental fate and behaviour

Route and rate of degradation in soil (B.8.1)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data gap or Open point (if data point not addressed or fulfilled)
4(1)	Vol. 3, B.8.1.1 Aerobic degradation, Walstra, P., Joustra, K.D. (1990); Gaaw Van Der, A. (2003)	EFSA: The identity of the volatiles trapped in the alkaline trap was not checked or is not explained in the DAR. Presumption that all volatiles were CO_2 may need to be justified.	RMS: The use of alkaline traps is a standard method for collecting evolved carbon dioxide, and it is considered reasonable to assume that the recovery in the traps consisted of CO_2. Organic volatiles are usually trapped in ethylene glycol or other organic solvents. No further action considered necessary.	Open point 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.
4(2)	Vol. 3, B.8.1.1 Aerobic degradation, Gaaw Van Der, A. (2003)	EFSA: Results of the investigation on the nature of the NER are not reported in the DAR. However, it is reported that harsh extraction methods were employed with late samples in order to investigate these residues. It would be helpful to have the results of this investigation summarized in the DAR.	RMS: On p 6 in the result section the results from the harsh extractions is summarised in the text. For further clarification a table will be included in an amended DAR.	Addressed RMS to consider in an amended DAR or corrigendum.
4(3)	Vol. 3, B.8.1.2. Anaerobic degradation, Thus, J.L.G. et al. (1991)	EFSA: Whereas the study is presented in the soil section the study design corresponds better to a water sediment study.	RMS: The RMS considers that the study fulfils the data requirement for anaerobic degradation in soil. The anaerobic conditions were maintained using a water layer and flushing with nitrogen gas as described for anaerobic transformation in soil OECD 307. No further action considered necessary.	Addressed
4(4)	Vol. 3, Annex B.8: page 2 B.8.1.1 Aerobic degradation	NOT: According to our calculations the test concentration should be 0.98 kg diflubenzuron per ha and not 0.49.	RMS: Assuming a a default soil density of 1.5 g /cm^3 ha and incorporation in a 5 cm layer the concentration will be 0.52 kg diflubenzuron. This will be corrected in the amended DAR.	Addressed RMS to consider in an amended DAR or corrigendum.

Adsorption,desroptionand mobility in soil (B.8.2)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data gap or Open point (if data point not addressed or fulfilled)
4(5)	Vol 3, B.8.2, adsorption, desorption and mobility in soil	UK: We note that the Koc for the major metabolite DFBA has been estimated using two QSAR approaches. In general the DAR lacks any detailed assessment of the applicability of these QSARs to the chemical class to which DFBA belongs e.g. organic acid. In order to have confidence that the QSARs are valid, it would be useful to include more detailed information on the QSARs used. In the absence of information, since the batch sorption study indicated minimal sorption of DFBA, the UK would prefer a conservative assessment of groundwater leaching potential to be performed assuming a Koc of 0 ml/g in the first instance, before the results of QSARs are used to refine the assessment.	RMS: Agree. The notifier will be asked to provide conservative first tier FOCUSgw simulation based on Koc =0 , to be included in an Addendum to the DAR.	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 OP in 4(6) and comments 4(7), 4(10) and 4(20).
4(6)	Vol 3. B.8.2.3. Summary and assessment of adsoption, desorption and mobility in soil. p. 27	EFSA: The report containing the calculation is not quoted in the DAR. If the value of Koc = 23.2 mL/g is used in the risk assessment the calculation should be properly reported and quoted.	RMS: The reference to the dossier report will be included in the revised DAR. However see also comment # 4(5). 9	Open point 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 DR in 4(5). See also comment in 4(10)
4(7)	Vol 3. B.8.2.3. Summary and assessment of	EFSA: Koc derived with the software PCKocWin v1.66 from EPA or by	RMS: The notifier will be asked to provide a new FOCUSgw simulation for DFBA based on Koc =0, to be included in an Addendum to	See point of clarification in 4(5)

Adsorption,desroptionand mobility in soil (B.8.2)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data gap or Open point (if data point not addressed or fulfilled)
	adsoption, desorption and mobility in soil. p. 27	estimation from log Pow data have been only accepted when the substance is not stable under the experimental conditions necessary to perform the batch adsorption/desorption experiments. Otherwise a Koc = 0 has been normally used for the risk assessment.	the DAR. See also point 4(5).	
4(8)	B.8.2.2. Leaching studies, p.25.	EFSA: The assumption that DFBA would be extracted with diethyl ether is disputable. No experimental details are given (eg. if pH was adjusted before extraction).	RMS: The leachate was extracted several times and for two extractions the pH was adjusted with sulphuric acid. This will be clarified in the amended DAR However, the conclusions of the risk assessment do not depend on the outcome of this study.	Addressed RMS to consider in an amended DAR or corrigendum.
4(9)	Vol. 3, B.8.2.1, adsorption/desorption	NL: Nederhorst den berg is one village and there are two soil types mentioned. How is this possible please explain.	RMS: No further information is given in the study report regarding this issue. However, the notifier states that the two soils were collected from the same village. Furthermore, the results from the soils from Nederhorst den berg were not used for the risk assessment. No further action considered necessary.	Addressed.
4(10)	Vol. 1, LoEP	NL: The Koc value for DFBA included in the endpoints list summary table is the value that was used for modelling purposes, half of the average value derived with PCKocWIN and logPow estimations. The	RMS: Agree, the LOEP will be amended, however see also comment #4(5) and 4(7)..	See point of clarification in 4(5) and open point 4(6).

Adsorption,desroptionand mobility in soil (B.8.2)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data gap or Open point (if data point not addressed or fulfilled)
		original values should be included here instead. The reported values with supporting argumanetation should be included with the data used for groundwater and surface water modelling.		

PEC in soil (B.8.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data gap or Open point (if data point not addressed or fulfilled)
4(11)	Vol. 3, B.8.3, PECsoil	NL: For the calculation of PECs for the metabolite DFBA it is written a worst case DT_{50} at 24ºC was used. The study by v.d.Gaauw however was performed at 20ºC. The study by Willems performed at 24ºC was considered supplementary.	RMS: This is an error in the summary, the results from the study conducted at 24 ºC was not used fort he assessment, only results from the study by Gaauw (2003) was used. The DAR will be amended accordingly.	Addressed RMS to consider in an amended DAR or corrigendum.

Fate and behaviour in water and impact on water treatment procedures (B.8.4-B.8.5)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data gap or Open point (if data point not addressed or fulfilled)
4(12)	Vol 3, B.8.4.3, Ready biodegradability	UK: We note that the RMS considers diflubenzuron as "ready biodegradable" on the basis of the results of the study of Laan and Thus (1993). The UK is of the opinion that substances should only be considered readily biodegradable in such studies if they meet the	RMS: We agree, and the DAR will be amended accordingly (B8, B4, vol1 and LOEP),.This will result in an alteration of the proposed classification. Since DFB is not readily biodegradable and the DT_{50} of diflubenzuron and its classifiable metabolite CPU (96h-LC50 for fish	Open point RMS to provide the re-evaluation of the ready biodegradability study in an addendum and to amend the list of end points accordingly.

Fate and behaviour in water and impact on water treatment procedures (B.8.4-B.8.5)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data gap or Open point (if data point not addressed or fulfilled)
		pass criteria with regards theoretical CO2 production as stipulated in the OECD guidelines. The UK considers that such studies should be a measure of ultimate biodegradation (i.e. mineralisation) and as 50% of the initial applied diflubenzuron appeared to remain as metabolite CPU after 28 d, we consider it unlikely that the test actually met the pass criteria under OECD 301B.	70 mg CPU/L;whole system water/sediment DT50= 37.6 d) is > 16 days the RMS considers that diflubenzuron should be classified as R53 in addition to R50.	See comment in 4(14) and 4(17) To discuss applicant's comment (in table of comments to the RT) during the expert's meeting.
4(13)	Vol 3, B.8.4.3.2, Degradation in water sediment systems	UK: In the study of Voelkel (1999) the UK notes that dissipation rates for the metabolites DFBA and CPU have been derived. However we consider that insufficient information has been provided in order for these dissipation rates to be fully validated. For example, it is not clear if rates have been determined from the peak occurrence onwards, or if kinetic modelling software has been used. In the table for CPU reference is made to 'consecutive reactions' which suggests a compartment model has been used but no further details are provided. The UK is aware of the difficulties in generating valid dissipation rates for metabolites from water-sediment studies. Further details of the assumptions used to derive these degradation rates would help clarify the validity of the values presented.	RMS: The rate of disappearance of DFBA was calculated by applying a non-linear first-order model and the dissipation rates in whole system and water phase was determined from the peak occurrence. The rate of disappearance of CPU was calculated by kinetic modelling with the degradation of parent and formation phase of the metabolite included in the model (i.e. a series of first order reactions). Hence the rate calculated for the whole system can be regarded as a degradation rate while for the water phase only the dissipation rate was calculated for CPU. This will be clarified in an in an amended DAR.	Open point 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.
4(14)	B.8.4.3.1 Ready biodegradation. Laan, J.M.T Van der and Thus, J.L.G. (1993).	EFSA: Results of the ready biodegradability study need to be discussed in an experts' meeting. Data provided in table 8.4.3.1.a do not seem to support that this product is	RMS: See comment # 4 (12), the RMS agrees and the DAR will be amended.	See open point in 4(12)

Fate and behaviour in water and impact on water treatment procedures (B.8.4-B.8.5)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data gap or Open point (if data point not addressed or fulfilled)
		readily biodegradable.		
4(15)	B.8.4.3.2. Degradation in water sediment system. Thus, J.L.G., Laan J.M.T. Van Der (1994).	EFSA: Nature of light (natural, artificial, kind of lamp, wave lengths?) is not explained in the DAR.	RMS: 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.	Open point 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 comment in 4(16)
4(16)	Vol. 3, B.8.4.4, Summary of studies on fate and behaviour in water	NL: Why is the water/sediment study under light/dark regime not included. Under the comments of the study it is said that results are comparable to the dark study and it is not stated that the results cannot be used for risk assessment.	RMS: The RMS does not consider that the study should be used for modelling since it does not follow standard guidelines and is conducted under partly illuminated conditions. However, it will be included in the summary in the amended DAR since it supports the results from the dark-study and indicates that photolytical breakdown is of less importance compared to biological degradation	See open point in 4(15)
4(17)	Vol. 3, B.8.4.3.1, Ready biodegradability	DK: It seems that the study only demonstrates primary degradation and not ultimate biodegradation. The amount of evolved CO_2 after 4 weeks was only 24.7% and not ≥60% as required in OECD 301 B. Therefore we find that diflubenzuron is not readily biodegradable.	RMS: See comment # 4 (12), the RMS agrees and the DAR will be amended.	See open point in 4(12).
4(18)	Vol.3, Annex B.8: page	NOT: In the first sentence the word "methyl"	RMS: The DAR will be amended accordingly.	Addressed

Fate and behaviour in water and impact on water treatment procedures (B.8.4-B.8.5)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data gap or Open point (if data point not addressed or fulfilled)
	46 B.4.4 Summary of studies on fate and behaviour in water	should be deleted.		RMS to consider in an amended DAR or corrigendum.

PEC in surface water and in ground water (B.8.6)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data gap or Open point (if data point not addressed or fulfilled)
4(19)	Vol 3, B.8.6.2, predeicted environmental concentrations in surface water	UK: Reference is made to deriving PECsw values following the aerial applications of diflubenzuron in forestry. However the UK could not locate such PECsw values presented in the DAR (Volume 3). The UK considers that only the hand-held applications in forestry have been adequately assessed. Please can the RMS confirm which uses have been fully assessed to assist the National authorisation of products containing diflubenzuron.	RMS: PECsw values for aerial application in forestry is presented in table 8.6.2.h. However, see also comment # 4(28) – new PECsw for the forest use have been submitted by the notifier and will be evaluated in an Addendum to the DAR.	See open point in 4(28)
4(20)	B.8.6.1. $PEC_{GW.}$ p 48	EFSA: PEC gw are estimated using only a FOCUS GW model. Results with two models should be provided (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.)	RMS: This recommendation was published after the deadline for submission of the dossier of diflubenzuron. Further, in the available FOCUS model simulation the resulting 80%ile PEC were <0.001ug/L, or a factor of 100 lower than the trigger for further action. Furthermore, it is stated in the opinion that crucial differences between models remain, "however, especially at concentrations near the regulatory trigger value (0.1 µg/L)". Hence the RMS considers that no further	Since new FOCUS GW need to be calculated, two models should be used in this case. See point of clarification in 4(5)

PEC in surface water and in ground water (B.8.6)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data gap or Open point (if data point not addressed or fulfilled)
			action is required.	
4(21)	B.8.6.2 PEC SW Wanner, U. (2004). p 54.	EFSA: The selection of the relevant FOCUS PEC SW scenarios is not discussed in the DAR. At least the general criteria used should be explained (or appropriate reference to FOCUS guidance quoted).	RMS: The RMS do not understand the comment, please clarify.	Addressed
4(22)	B.8.6.2 PEC SW	EFSA: Data gap identified for parent and metabolites FOCUS $PEC_{SW/SED}$ calculation for hand held sprayer application in orchards and tractor mounted sprayer in forest needs to be provided.	RMS: The notifier has not provided any PECsw for hand held application in orchards, but has at a late stage agreed to provide it. In the updated summary dossier the notifier calculated the PECsw for forestry *ground* application. Spray-drift values for ground applications in forestry were based on drift values for single (90^{th} percentile) late applications to vineyards using conventional spray equipment (i.e. 8.02% for 3 m buffer). The calculations were carried out according to draft EU working document 7193/VI/99 rev. 0 (09/08/99), assuming spray drift to a 30 cm deep water body. Hence the notifier seems to suggest that the spray drift resulting from hand held as well as from tractor mounted spraying equipment in forests can be assumed to be similar to spray drift in vineyards. However, no rational for this approximation was given in the dossier. In the DAR the RMS accepted this modelling for the forestry hand held application scenario since the application in vineyards has the	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.

PEC in surface water and in ground water (B.8.6)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data gap or Open point (if data point not addressed or fulfilled)
			same spray drift values as for hand held application on crops > 50 cm in Rautmann (1999). The RMS consider it reasonable that no FOCUS simulations for the application in forestry has been carried out, since no standard scenario for forests is available and since runoff and drainage is of minor importance compared with spray drift. However, the RMS considers that spraydrift following tractor mounted application in forests cannot be approximated with spray drift resulting from application in vineyards, but would rather be approximated with the spray drift resulting from late application in pome/stone fruit. MS are asked to respond to this during the written procedure. In conclusion, the RMS would suggest that PECsw/sed following tractor mounted spray in forests should be provided and that FOCUS $PEC_{SW/SED}$ should be provided for hand held application in orchards as well as aquatic risk assessments for these new PEC values.	
4(23)	Vol. 3, B.8.5, Impact on water treatment procedures	NL: RMS states that from the information provided in the previous section, it can be concluded that the product is in compliance with Annex VI, Part C, point 2.5.1.2 (b), i.e. that the lower limit concentrations laid down by the	RMS: Agree the DAR will be corrected and "previous section" will be changed to "below"	Addressed RMS to consider in an amended DAR corrigendum.

PEC in surface water and in ground water (B.8.6)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data gap or Open point (if data point not addressed or fulfilled)
		Commission are not exceeded under relevant field conditions. Probably it is meant that the trigger value of 0.1 µg/L is not exceeded. However, PEC calculations are part of B.8.6. Therefore the proposed conclusion cannot be true.		
4(24)	Vol. 3, B.8.6.2, PECsw	NL: It is not correct to state that exposure to surface water from mushroom rearing facilities can be considered to be negligible. The Netherlands has an assessment procedure for mushrooms. This procedure comes to a calculation of 78 times the dose for worst case direct exposure of surface water with just a local settlement tank and 51 times the dose for exposure via waste water treatment plant.	RMS: No agreed model is available for the assessment of environmental exposure from mushroom cultivations. The reviewer is asked to provide a more detailed proposal, to be discussed at an expert meeting.	Open point 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.
4(25)	Vol. 1, LoEP	NL: For PECgw calculation the geo-mean of DT50 and Koc should be used according to the LoEP template.	RMS: Agree that the geo-mean should be used according to the LoEP, however since the difference is only slight (i.e. DT_{50} of 3.4 days has been used instead of the geo-mean of 3.7 d) and since all scenarios resulted in a PEC <0.001 µg DFB/L the RMS believes that this inconsistency will not affect the final outcome. This is also stated in the "comments" to the study in the section B8 of the DAR. A clarification will be included in the LoEP.	Open point Arithmetic mean Koc should be used for calculation of FOCUS PEC GW. List of end points to be amended accordingly.

PEC in surface water and in ground water (B.8.6)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data gap or Open point (if data point not addressed or fulfilled)
4(26)	Vol. 1, LoEP	NL: Please delete the 3rd column in the PECgw modelling results.	RMS: This will be done in the revised LoEP.	Addressed However, LoEP will need to be updated with new calculations if reliable.
4(27)	Volume 3, point B.8.6.2, PECs in surface water	DE: PECs for orchard application were calculated for buffer zones of up to 30 m. However, safe use could not be demonstrated. FOCUS Step-4 calculations for larger buffer zones should be provided. Additionally, PECs for aerial application in forests considering buffer zones need to be estimated.	RMS: The notifier has not provided step-4 calculations for larger buffer zones since they disagree with the risk assessment for aquatic ecosystems made by the RMS. The notifier claim that buffer zones of 10 m would be enough for an acceptable risk for aquatic ecosystems. The aquatic risk assessment will most likely be discussed at the ecotox-expert meeting, and hence pending the outcome of this meeting further FOCUS step-4 modelling may be requested from the notifier. The notifier has provided new data on spray drift at aerial application. This data will be evaluated and summarised in an Addendum.	Open point RMS to summarize and assess in an addendum FOCUS PEC sw/sed for aerial application. See 4(19), 4(28), 4(29) and 4(30).
4(28)	Vol. 3, Annex B.8: page 61 B.8.6.2 Predicted environmental concentrations in surface water Vol. 1, Level 2: page 50+51 2.5.3.2 Predicted environmental concentrations in surface	NOT: The notifier does not agree with the spray drift value of 33.2% for aerial application as used by the RMS. In the Updated Summary Dossier the exposure estimates for the aerial application in forestry have been re-evaluated using the orchards crop scenario in FOCUS dossier (report U. Wanner: DI-11811). In the worst case scenario a maximum spray drift of 0.73% was found. This maximum spray drift value was	RMS: The new information will be evaluated and summarised in an Addendum to the DAR. See also comment # 4 (27).	See open point in 4(27)

PEC in surface water and in ground water (B.8.6)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data gap or Open point (if data point not addressed or fulfilled)
	water and sediment Vol. 1, Level 2: page 94 Appendix 3. Listing of endpoints Table: PEC_{sw} Parent – Forestry	determined by AGDISP, a dedicated aerial spray simulation model used to calculate spray drift of pesticides in forestry uses, developed and distributed by the US Department of Agriculture.		
4(29)	Vol. 1, Level 3: page 118 3.1 Background to the proposed decision	NOT: The notifier does not agree with the buffer zones as proposed by the RMS. These buffer zones are the result of calculations that are determined by the choice of the spray drift value. The notifier does not agree with the spray drift value used by the RMS for the calculations. In the Updated Summary Dossier the exposure estimates for the aerial application in forestry have been re-evaluated using the orchards crop scenario in FOCUS. In the worst case scenario a maximum spray drift of 0.73% was found.	RMS:. The notifier has provided new data on spray drift at aerial application. This data will be evaluated and summarised in an Addendum See also comment # 4 (28).	See open point in 4(27)
4(30)	Vol. 1, Level 4: page 121 4.8 Environmental fate and behaviour 4.9 Ecotoxicology	NOT: The notifier does not agree with the conclusions of the RMS that no acceptable risk was found for some of the proposed uses in orchards and forestry. We refer to the risk assessments provided in the updated summary dossier. We do not agree with the spray drift value chosen by the RMS to evaluate the aerial application in forestry and have the opinion that there's enough evidence for recovery of	RMS: The new information will be evaluated and summarised in an Addendum to the DAR. This issue needs further discussion at an expert meeting.	See open point in 4(27).

PEC in surface water and in ground water (B.8.6)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data gap or Open point (if data point not addressed or fulfilled)
		both aquatic and terrestrial non-target arthropods for the proposed forestry and orchard uses.		

Other comments				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data gap or Open point (if data point not addressed or fulfilled)
4(31)	General	NL: The format for study summaries used by RMS is different from standard. We think it important to have a general agreement about the format used for DARs to keep the consistency in the reports among member states.	RMS: We took notice for future DARs, but see no need to change the report already finalised.	Addressed
4(32) Comment copied from the ecotox section (see 5(20))	Vol. 3, B.9.2.10 Risk assessment for aquatic organisms	NL: A drift value of 33.2% for aerial application is mentioned. Where does this value come from?	RMS: From p 24 in the "FOCUS surface water scenarios in the EU evaluation under 91/4§4/EEC" (SANCO/4802/2001-rev1). No further action considered necessary.	Addressed

Comments received on reporting table, section Environmental fate and behaviour (B.8)			
Reference to reporting table	MS / Notifier	Comment	EFSA response
General	NL	We agree on the data requirements and open points set.	Noted.

Rapporteur: SE

Comments received on reporting table, section Environmental fate and behaviour (B.8)			
Reference to reporting table	MS / Notifier	Comment	EFSA response
General	NL	NL comments are addressed adequately	Noted.
4(5)	UK	We support the inclusion of the data requirement to further assess the groundwater leaching potential of metabolite DFBA using a more conservative Koc value.	Noted.
4(5) Column 1	FI	Typing error: desorbtion should read desorption.	Thanks, corrected.
4(5)	NOT	New FOCUS GW using Koc = 0 for metabolite DFBA. Two models should be used A report with this information has already been sent to the RMS on 27 February 2007, called doc "4(5) 4(7) PEC GW DFBA orchard(Koc = 0) Chemtura.pdf". Two models have been used in these calculations, namely FOCUS PELMO 3.3.2 and FOCUS PEARL 3.3.3. Even when using this, **unrealistic**, worse-case scenario, the following results were obtained: The PECs of all relevant locations were calculated to be less than 0.1 µg/L. Therefore, there can be confidence that DFBA will not exceed 0.1 µg/L in groundwater following the use of Dimilin® WG-80 in orchards.	Noted, information included in the RT.
4(7) Column 1	FI	Typing error: desroption should read desorption.	Thanks, corrected.
4(7) Column 2	FI	Typing error: form should read from, performe should read perform.	Thanks, corrected.
4(9) Column 1	FI	Typing error: predeicted should read predicted.	Predeicted not found in 4(9).
4(12)	NOT	RMS to provide the re-evaluation of the ready biodegradability study in an addendum and to amend the list of end points accordingly. The outcome of the "modified Sturm test", is not the only criterion used for determining if an active substance is "ready biodegradable". The properties of the metabolites should also be	Noted. Comment to be considered during the expert's meeting discussion.

Comments received on reporting table, section Environmental fate and behaviour (B.8)			
Reference to reporting table	MS / Notifier	Comment	EFSA response
		considered. In the water/sediment study the whole system DT50 of CPU was 37.6 days and of DFBA 2.7 days (geometric means). The DT50 of diflubenzuron is only 4.5 days. We disagree with the use of the DT50 of CPU for the whole system, the properties of CPU are totally different from diflubenzuron, *e.g.* water solubility, log Pow & toxicity to aquatic invertebrates; see below. Higher-tiered experiments proved that diflubenzuron and its degradation products CPU& DFBA degrade rapidly in natural aquatic environments. CPU & DFBA have characteristics, *e.g.* log Pow, water solubility and toxicity to aquatic invertebrates, which are entirely different from those of diflubenzuron. Hence, it is required to **assess each compound individually**! The bioconcentration factor of diflubenzuron is well below a level of concern. Based on the log Pow and water solubility of CPU & DFBA, it is very obvious that the BCF of these two degradation products are even of lesser concern. Whereas diflubenzuron has to be classified as "very toxic to the aquatic environment", the classification of two degradation products CPU & DFBA is "harmful to the aquatic environment". Based on all of these data, diflubenzuron and its degradation products CPU & DFBA do not cause any long-term effects in the aquatic environment. Therefore, the risk phrase R53 should not be applied!	
4(15)	DE	Although a thorough assessment of the light source with respect to respect to natural light at different latitudes is considered scientifically interesting, we would like to emphasise that, regardless of the results of such an analysis, inclusion of degradation/dissipation parameters from irradiated water/sediment studies in PEC modelling is not supported.	Noted
4(20)	NL	We agree with RMS that in this case where for all scenarios the 80th percentile is <0.001µg/L it is a waste of time to calculate with a second model. Only for the metabolite with regard to data requirement 4(5) new calculations should be required.	Noted
4(21) Column 2	FI	Typing error: dicussed should read discussed.	Thanks, corrected.
4(22)	AT	We agree to the proposal of the RMS concerning the PECsw/sed calculations following tractor	Noted, comment to be

Comments received on reporting table, section Environmental fate and behaviour (B.8)			
Reference to reporting table	MS / Notifier	Comment	EFSA response
		mounted application in forest (using the crop: late application in pome/stone fruit). We also agree to the arguments concerning the acceptance of the PECsw/sed calculations for forestry hand held application (vines, late application and hand held application, crop>50 cm, respectively). We suggest to calculate FOCUS step 3 and step 4 PECsw/sed for aerial application in forestry using the crop/technique "aerial application" (spray drift value of ~25 %).	considered by the experts' meeting.
4 (22)	DK	We agree with RMS that spray drift from tractor mounted application in forestry should preferably be approximated by spray drift from application in pome/stone fruit. Furthermore we find that the relevancy of hand held equipment in forestry should be discussed.	Noted, comment to be considered by the experts' meeting.
4(22)	UK	We note that the RMS has requested that MS respond to the question of selection of appropriate spray drift values for tractor mounted applications in forestry. The UK agrees that this point requires further consideration. We are of the opinion that the level of spray drift will be highly dependent on the pest to be controlled, the growth stage of the 'crop' and the application equipment used. For example if tractor mounted equipment is used on young forestry transplants, it is possible that short horizontal boom sprayers will be used over the top of the transplants. This may result in drift rates lower than the corresponding values for vineyard sprayers In more mature trees, it is clear that some form of air blast spray technology would be used to ensure application up into the canopy. This may result in drift rates closer to those found in orchards. The UK considers that the exposure assessment should be appropriate to cover the range of proposed application equipment and that the DAR should be clear on what types of application are or aren't assessed as acceptable.	Noted, comment to be considered by the NOT in its calculation and the experts' meeting.
4(22)	NOT	PECsw/sed following tractor mounted spray in forests and hand held application in orchards should be provided. Before we can do such calculations we must know if the scenario "late application in pome fruit" is accepted by the RMS and other member states for use in these calculations. (See remark of the rapporteur in column 3: ""However, the RMS considers that spray drift following tractor mounted application in forests cannot be approximated with spray drift resulting from application in	Noted, see MS's comment above.

Comments received on reporting table, section Environmental fate and behaviour (B.8)			
Reference to reporting table	MS / Notifier	Comment	EFSA response
		vineyards, but would rather be approximated with the spray drift resulting from late application in pome/stone fruit. MS are asked to respond to this during the written procedure.")	
4(24) Column 4	FI	We agree with the RMS that no agreed scenario is available for mushroom raring facilities. However, all available information should be considered and the open point should be discussed in an expert meeting. NL should provide more information about the Dutch assessment procedure.	Noted.
4(24)	UK	We note the open point regarding possible assessment in mushroom production. Since there has been no formal agreement of an assessment scheme for glasshouses at EU level it seems highly unlikely that agreement would be reached on how to assess exposure from mushroom production either. Since the EFSA PPR Panel is due to consider the issue of exposure from glasshouses in the future, and the NL seems to have made progress on a National assessment scheme, we would propose that these issues be considered by the EFSA panel rather than the PRAPeR meeting alone.	Noted. MS's consider forwarding the issue of mushroom production assessment to PPR Panel.
4(25) Column 4	FI	We believe that the open point should read: Geometric mean Koc should be used for calculation of Focus PEC GW. We agree with the RMS that there is no need to recalculate PECgw with geo-mean DT50. However, Koc from reliable studies (average 4609 ml/g, geo-mean 3990 ml/g) is half of the Koc 9148 ml/g used in the modelling. In our opinion a new PECgw calculation with lower Koc from reliable studies should be done. In the DAR vol.3 Tables 8.2.1.f. and 8.2.3.a. state that the Koc in sandy clay soil is 1938. In the LoEP Koc is stated to be 1983. The geo-mean with Koc 1938 is 3990. LoEP should be corrected accordingly.	Disagree, for Koc the arithmetic mean is used for FOCUS modelling.
4(25)	NL	We agree that no recalculation is required, just an update of the LoEP is enough.	Noted

5. Ecotoxicology

Birds and mammals (B.9.1 and B.9.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data gap or Open point (if data point not addressed or fulfilled)
5(1)	Vol 3, B.9.1.2/B.9.1.3, short term dietary toxicity/ subchronic toxicity and reproduction	UK: It is useful to present full details of the conversion from mg/kg feed to mg/kg bw/day so that it is clear exactly how the values have been derived. We also consider that it is more important to include the LC_{50} value for the active substance than the toxic standard (p6). We propose that this information is included.	RMS: The food consumption and body weight data for the highest dose will be included in the amended DAR. Since no mortalities occurred at the highest concentration tested LC50 could not be calculated, but the results are given as LC50 >1206 mg/kg bw d and these figures are already presented in the results-section.	Open point RMS to include the food consumption and body weight data for short-term dietary and reproduction studies with birds in a revised DAR.
5(2)	Vol 3, B.9.1.3, subchronic toxicity and reproduction	UK: Generally results of the reproductive parameters are given in full (often tabulated) as this gives more confidence in the end point chosen.	RMS: The exposure only caused very slight effects on reproductive performance and hence RMS did not considered it necessary to tabulate all endpoints and only endpoints were effects where observed were reported in detail in the DAR However, if it is considered necessary tables with the full results of the test can be included in an addendum	Open point 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.
5(3)	Vol 3, B.9.1.5, risk assessment for birds	UK: Clarification of the LD50 value used in the risk assessment is required as this does not tie in with the values presented in the summary (Table 9.1.4) i.e. 3762 compared with >5000. Similarly please clarify why different reproductive NOECs are used for forestry and orchard use (Table 9.1.5).	RMS: >5000 should be used in the risk assessment, the value 3762 came from a study not considered as reliable. This will be corrected in the amended DAR (B9, Vol.1 and LoEP)	Addressed
5(4)	Vol 3, B.9.3.1, acute oral and long term toxicity - mammals	UK: It would be useful to indicate the values used in the risk assessment in terms of mg/kg bw/day in the summary tables at the start of this section.	RMS: The LD50 for the acute toxicity studies is given in the table 9.3.1.a, however the unit is wrong and will be changed from mg/kg to mg/kg bw. The value used for the long term	Addressed RMS to provide the correct units for the acute and long-term toxicity to mammals in the summary tables of the risk

Birds and mammals (B.9.1 and B.9.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data gap or Open point (if data point not addressed or fulfilled)
			risk assessment is given in the text but will also be given in the table in the amended DAR.	assessment section in a revised DAR.
5(5)	Vol 3, B.9.3.2, risk assessment for mammals	UK: We believe that SANCO/4145/2000 indicates that the interception value for insecticides is 40% (deposition = 60%) and it appears that these values have been transposed in the risk assessment. However, we also consider that potential refinement of these values is possible in line with the crop growth stage and the crop interception values given in FOCUS groundwater scenarios in the EU review of active substances Sanco/312/2000. We would also be interested to know the standard interception value that is generally used for forests.	RMS: On page 12 in SANCO/4145/2000 it is stated that: "For "orchard/vine/hops" it is assumed that these cultures have ground vegetation which is represented by the category "short grass". In case of insecticides and fungicides, but not for herbicides, it is assumed that 40 % of the applied amount reaches the ground." The RMS is not aware of a standard interception factor for forestry use but the RMS considered the interception factor of 50 % as being reasonable, since it is less than the standard factor for orchard use. No further action considered as necessary.	Open point 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.
5(6)	Vol. 3, B.9.1. Risk assessment for birds	EFSA: No risk assessment was conducted for birds for the uptake of contaminated drinking water. No argumentation was provided to exclude exposure via drinking water.	RMS: A risk assessment for birds for uptake via contaminated drinking water will be carried out and included in the addendum. For use in orchards birds will be 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 will 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	Point of clarification for the applicant: A risk assessment for birds from uptake of contaminated drinking water according to SANCO 4145/2000 is needed.

Birds and mammals (B.9.1 and B.9.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data gap or Open point (if data point not addressed or fulfilled)
			aerial application will result in puddles of spray liquid)	
5(7)	Vol. 3, B.9.3 Risk assessment for mammals	EFSA: No risk assessment was conducted for mammals for the uptake of contaminated earthworms and fish and no risk assessment was conducted for the uptake of contaminated drinking water.	RMS: A risk assessment for mammals for uptake via contaminated drinking water will be carried out and included in the addendum. For use in orchards birds will be 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 will 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.	Point of clarification for the applicant: A risk assessment for earthworm- and fish-eating mammals and from uptake of contaminated drinking water according to SANCO 4145/2000 should be conducted.
5(8)	Vol. 3, B.9.1.5: Risk assessment for birds	AT: For the acute risk assessment the LD_{50} of 3762 mg/kg bw from a study with black birds was used. However the RMS stated on page 2 of section B.9 that this study would not be used in the risk assessment. This inconsistency in the DAR should be clarified and if the study is used in the risk assessment than it should also be stated in the list of endpoints. Respective	RMS: See comment #5(3), this will be corrected in the amended DAR.	See comment 5(3)

Birds and mammals (B.9.1 and B.9.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data gap or Open point (if data point not addressed or fulfilled)
		amendments should be made in volume 1.		
5(9)	Vol. 3, B.9.1.5: Risk assessment for birds	AT: In Table 9.1.5.c in the NOEC column the value 49.9 should read 42.7. However, the TER value of 7.9 was calculated with the correct NOEC value. Respective corrections should be made in volume 1, table 2.6.1.b.	RMS: This will be corrected in the amended DAR	Addressed RMS to correct the NOEC value in table 9.1.5.c
5(10)	Vol. 3, B.9.1.5: Risk assessment for birds	AT: Secondary poisoning, fish eating birds: The TER for use in forestry should read 119 instead of 15 (42.7/(0.00531*320*0.21) = 120). Respective corrections should be made in volume 1.	RMS: This will be corrected in the amended DAR	Open point RMS to correct the TER values for fish-eating birds in a revised DAR.
5(11)	Vol. 3, B.9.3.2: Risk assessment for mammals	AT: In table 9.3.2.c the estimated daily intake values for long-term exposure should read as follows: 5.6 instead of 10.64, 0.27 instead of 0.51 and 1.34 instead of 2.53. However, respective TER values were calculated with the correct daily intake values. These corrections should also be made in table 2.6.1.c in volume 1.	RMS: This will be corrected in the amended DAR	Open point RMS to correct the daily intake values for long-term exposure of mammals in a revised DAR.

Aquatic organisms (B. 9.2)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data gap or Open point (if data point not addressed or fulfilled)
5(12)	Vol 3, B.9.2.9, summary of toxicity studies on	UK: It would be helpful if the values in the summary tables that are to be used in the risk	RMS: Values used for the aquatic risk assessment will be given in bold in the amended DAR.	Open point RMS to correct the endpoint for fish to 106

Aquatic organisms (B. 9.2)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data gap or Open point (if data point not addressed or fulfilled)
	aquatic organisms	assessment are given in bold. For instance we were unclear where the fish value of >106 mg.as./L was derived from as we could not see it in Table 9.2.9a.	The reason for not finding the 106 mg/L in the table is due to a typo by the RMS, the correct value for the risk assessment is 102 mg/L, which can be found in the table. This will be corrected in the amended DAR .	mg/L in Table 9.2.9a (Vol. 3) in a revised DAR.
5(13)	Vol 3, B.9.2.10, risk assessment for aquatic organisms	UK: It is currently considered that the NOAEC from the littoral study is used with an uncertainty factor of 10. We propose that this is considered in more detail in an expert meeting. We appreciate that it may be necessary to include a level of uncertainty here, however it also needs to be remembered that this is a higher tier refined study. Detailed summaries of the various studies are already given. However, it may be possible to aid the discussions by the collation of all the key results from each of the refined studies, together with any problems etc. into a single table.	RMS: RMS agrees to discuss the aquatic risk assessment at an expert meeting. In the addendum the weight of evidence approach is further clarified which hopefully will aid the discussion during the expert meeting. See also comments 5(25), 5(28), 5(29), 5(30)	Open point MSs to discuss the aquatic risk assessment in an expert meeting. See also comments 5(25), 5(28), 5(29), 5(30), 5(33)
5(14)	Vol. 3. B.9.2. Aquatic risk assessment for the metabolite DFB	EFSA: No higher tier risk assessment was presented for the metabolite DFB – some argumentation should be provided if it is assumed that the risk is covered by the risk assessment for the parent.	RMS: An acceptable risk for all metabolites (DFBA and CPU) was identified using the PEC from FOCUS Step 2. It seems as if EFSA has mistaken DFB for a metabolite, it is however the active substance and a higher tier risk assessment for the parent DFB has been provided. No further action considered necessary.	Addressed
5(15)	Vol. 3. B.9.2. Aquatic risk assessment	EFSA: Some argumentation should be provided to address the risk of	RMS: The log Pow of CPU is 1.14 and of DFBA -0.02 (this information will be included in an addendum to B.2.), hence the risk of	Open point RMS to evaluate and include the log Pow

Aquatic organisms (B. 9.2)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data gap or Open point (if data point not addressed or fulfilled)
	metabolites CPU, DFB, DFBA	bioconcentration of the metabolites CPU, DFB, DFBA (log Pow < 3?, more polar than the parent?…)	bioconcentration of these metabolites is low. This rational will be included in the amended DAR.	values for CPU and DFBA in an addendum to the DAR to address the risk of bioconcentration.
5(16)	Vol. 3. B.9.3. Aquatic risk assessment: BCF trigger of 1000	EFSA: It is not clear from the results of the modified Sturm test presented in the DAR if the substance meets the criteria for ready biodegradable substances. In case that diflubenzuron is not ready biodegradable the trigger should be 100.	RMS: RMS agrees with comments regarding the biodegradability of diflubenzuron for the fate section and will alter the conclusion in the DAR, i.e. diflubenzuron is **not** biodegradable. 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 now 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: is or will be provided in the amended DAR - Biomagnification in aquatic food-chains:	Open point 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.

Aquatic organisms (B. 9.2)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data gap or Open point (if data point not addressed or fulfilled)
			is not needed since the BCF< 1000 and DT90< 100 days.	
5(17)	Vol.3, Annex B4: page 3 B.4.1 Proposals for classification and labelling of the active substance	NOT: The intrinsic toxicity to the waterflea Daphnia magna (48 h – EC_{50} 0.0026 µg/L….). This is incorrect and should be 2.6 µg/L.	RMS: This will be corrected in an amended DAR	Open point 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.
5(18)	Vol. 3, B.9.2.9 Summary of the toxicity studies on aquatic organisms	NL: For the chronic toxicity on fish there is only a 21-day study available. Is 21 days really long enough to show all the relevant effects?	RMS: In the aquatic guidance document in the section concerning long-term fish tests it is stated that ", the study should have a 28 day exposure duration and include survival, growth and behaviour as endpoints. In order to avoid unjustified animal testing, existing valid studies conducted in accordance with OECD 204 but lasting only 21 days can also be used to fulfil the data requirement." In order to avoid unnecessary animal testing the RMS considers that the 21-day study fulfils the data requirement of chronic test, since no indication of effects on mortality, growth and behavior were observed in the test. No further action considered necessary.	Addressed
5(19)	Vol. 3, B.9.2.10 Risk assessment for aquatic organisms	NL: It is stated that exposure to surface water from mushroom rearing facilities is considered to be negligible. In The Netherlands exposure to surface water from this use is taken into account. There is a model developed for this use and the	RMS: Agree that this should be considered at an MS level. No further action considered necessary.	Addressed Since the Dutch exposure model is not agreed by all MSs this can be left to MSs level. However it would be beneficial in future DARs to include a risk assessment based on the Dutch exposure model for the

Aquatic organisms (B. 9.2)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data gap or Open point (if data point not addressed or fulfilled)
		exposure to surface water can be considerable. Maybe it must be considered as a MS-issue.		MSs which accept the Dutch approach.
5(20)	Vol. 3, B.9.2.10 Risk assessment for aquatic organisms	NL: A drift value of 33.2% for aerial application is mentioned. Where does this value come from?	RMS: From p 24 in the "FOCUS surface water scenarios in the EU evaluation under 91/4§4/EEC" (SANCO/4802/2001-rev1). No further action considered necessary.	Comment included in the fate section, see 4(32).
5(21)	Vol. 1, Level 2, LOE, Toxicity data for aquatic species	AT: Typing error in the 3rd line of the table: DBF should be DFB. In general a short explanation of the used abbreviations would be helpful.	RMS: This will be corrected in a revised List of Endpoints. The full names of parent and metabolites has been included in all places where it has been feasible in the revised LoEP	Addressed
5(22)	Vol. 1, Level 2, LOE, Toxicity data for aquatic species	AT: The toxicity data for the formulation for fish, daphnids and algae should also be mentioned.	RMS: Agree, this will be included in the revised List of Endpoints	Open point RMS to include the toxicity data for the formulation for fish, daphnids and algae in the List of Endpoints.
5(23)	Vol. 1, Level 2, LOE, TER for aquatic species	AT: Application in pome fruit: The footnotes (1 – 3) in the headline of the table should be deleted.	RMS: This will be corrected in the revised List of Endpoints.	Open point 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.
5(24)	Vol. 1, Level 2, LOE, TER for aquatic species	AT: For application in pome fruit the first tier TER calculations (with FOCUS Step 1 and 2) should also be included.	RMS: TER values for the most sensitive organism using PEC from FOCUS step 2 will be included in the revised LoEP.	Open point RMS to include the TERvalues for the most sensitive organism with PECsw from FOCUSstep2 in a revised List of Endpoints.

Aquatic organisms (B. 9.2)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data gap or Open point (if data point not addressed or fulfilled)
5(25)	Volume 3, point B.9.2.8, Higher tier studies, point B.9.2.9, Summary of the toxicity studies on aquatic organisms and point B.9.2.10, Risk assessment for aquatic organisms	DE: The littoral enclosure study did not correspond to state-of-the-art methods and did not cover the intended use in orchards (2 x 0.18 kg as/ha, 14 days interval): The interval between the two applications in the enclosure study was 33 days and the duration of the study was too short to demonstrate recovery of the most sensitive species. A NOEAEC for zooplankton and aquatic invertebrates could not be determined and, hence, an EAC can not be derived. The conclusions of the RMS, who considers the NOEAC for zooplankton to be 0.7 µg as/L, are not fully comprehensible. The weight of evidence approach should be made more transparent. The same applies for the derivation of the EAC of 0.07 µg as/L.	RMS: RMS agrees to discuss the aquatic risk assessment at an expert meeting. In the addendum the weight of evidence approach is further clarified which hopefully will aid the discussion during the expert meeting See also comment 5(13) and 5 (28)	See open point 5(13)
5(26)	Vol. 3, B.9.2.6.1, Effects on algal growth, Berends & Thus, 1992	DK: In three places a printer's error has occurred; 20 mg/l should probably be 0.2 mg/l instead. The same applies for Table 9.2.9.c	RMS: This will be corrected in the amended DAR	Addressed RMS to correct the concentrations in the algae study of Berends & Thus (1992).
5(27)	Vol. 3, B.9.2.6.1, Effects on algal growth, Thompson & Swigert 1993	DK: (Anabaena flos-aquae) It could be discussed if the study is valid as the cell counts vary considerably within each replicate and as the growth is not exponential.	RMS: Agree, the counts vary considerably and the study should not have been considered as acceptable. This will be corrected in an amended DAR. This will however not affect the conclusion of the risk assessment since results from tests using S. capricornutum was used for the risk assessment.	Open point 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.

Aquatic organisms (B. 9.2)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data gap or Open point (if data point not addressed or fulfilled)
5(28)	Vol. 3, B.9.2.8, Higher tier studies,	DK: We do not agree with a NOEAEC of 0.7 µg/L to be used in the risk assessment. The littoral enclosure study demonstrates effects on cladocerans, copepods, and amphipoda at 0.7 µg/L and no NOEC can be established for Ephemeroptera and Odonata due to high variation/low statistical power. No recovery is demonstrated after 2 applications. These results should not be overruled by a literature review. Furthermore we do not find that the literature review addresses a NOAEC for insects. We would recommend a discussion of the literature review and the littoral enclosure study at an expert meeting.	RMS: The RMS suggests that the risk assessment for aquatic organisms should be discussed at an expert meeting. In the addendum the weight of evidence approach is further clarified which hopefully will aid the discussion during the expert meeting See also comment 5(13), 5(25)	See open point 5(13)
5(29)	Vol. 3, Annex B9: page 59, 68, 89, 93-95 and 98-99 B.9.2.8/9 Higher tier studies	NOT: The notifier does not agree with the safety factor of 10 as proposed by the RMS and refers to our most recent aquatic risk assessment. The argumentation is presented in the reports of Wyness & Pijst (2004 & 2005, DI-11802), these reports have been included in the updated summary dossier (Annex IIIA, section 6, point 10.2.2). The impact of diflubenzuron on non-target aquatic populations and communities has been intensively studied in outdoor field studies in various aquatic environments. These studies demonstrate that recovery	RMS: The RMS suggests that the risk assessment for aquatic organisms should be discussed at an expert meeting. A summary of the notifiers argumentation presented in the reports of Wyness & Pijst (2005, DI-11802) will be presented in an addendum, a summary of the report by Pijst and Wyness ("Risk assessment on aquatic organisms with particular emphasis on aquatic invertebrates) was included in the original DAR. See also comment 5(13), 5(25), 5(28).	Open point RMS to include an evaluation of the reports of Wyness & Pijst (2005, DI-11802 in an addendum to the DAR. See open point 5(13)

Aquatic organisms (B. 9.2)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data gap or Open point (if data point not addressed or fulfilled)
		will occur and that there are no indications that Amphipods are more sensitive than Cladocera. The notifier proposes an EAC = 0.7 µg/L based on the recovery of sensitive non-target aquatic invertebrates demonstrated in several outdoor field studies.		
5(30)	Vol. 3, Annex B9: page 95 B.9.2.10: Risk assessment for aquatic organisms	NOT: The notifier does not agree with the spray drift value of 33.2% for aerial application as used by the RMS. In the Updated Summary Dossier the exposure estimates for the aerial application in forestry have been re-evaluated using the orchards crop scenario in FOCUS dossier (report U. Wanner: DI-11811). In the worst case scenario a maximum spray drift of 0.73% was found. This maximum spray drift value was determined by AGDISP, a dedicated aerial spray simulation model used to calculate spray drift of pesticides in forestry uses, developed and distributed by the US Department of Agriculture.	RMS: The PECsw following aerial application will be discussed at the fate expert meeting and pending the outcome of this meeting a new risk assessment for aquatic organisms may be necessary.	Open point The aquatic risk assessment needs to be updated according to the outcome of the discussion in the fate section.
5(31)	Vol. 1, Level 2: page 27	NOT: Last sentence: EC_{50} mentioned here is incorrect. It should be: EC_{50} = 2.6 µg/L (see also page 56)	RMS: This will be corrected in the revised List of Endpoints.	Open point 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: EC_{50}

Aquatic organisms (B. 9.2)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data gap or Open point (if data point not addressed or fulfilled)
				mentioned here is incorrect. It should be: EC_{50} = 2.6 µg/L (see also page 56))
5(32)	Vol. 1, Level 2: page 56 Table 2.6.2.b Aquatic invertebrates	NOT: The quahogs NOEC = 320 (removal of "1[a]" mentioned after it).	RMS: This will be corrected in the revised List of Endpoints.	Open point 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 "1[a]" mentioned after it).
5(33)	Vol. 1, Level 2: page 60+61 2.6.2 Effects on aquatic organisms. Literature review 2.6.2.1 Risk assessments for aquatic organisms	NOT: The notifier does not agree with the safety factor of 10 as proposed by the RMS. The argumentation is presented in the reports of Wyness & Pijst (2004 & 2005, DI-11802), these reports have been included in the updated summary dossier (Annex IIIA, section 6, point 10.2.2). The impact of diflubenzuron on non-target aquatic populations and communities has been intensively studied in outdoor field studies in various aquatic environments. These studies demonstrate that recovery will occur and that there are no indications that Amphipods are more sensitive than Cladocera. The notifier proposes an EAC = 0.7 µg/L	RMS: The RMS suggests that the risk assessment for aquatic organisms should be discussed at an expert meeting. A summary of the notifiers argumentation presented in the reports of Wyness & Pijst (2005, DI-11802) will be presented in an addendum, a summary of the report by Pijst and Wyness ("Risk assessment on aquatic organisms with particular emphasis on aquatic invertebrates" was included in the original DAR. See also comment 5(13), 5(25), 5(28), 5(29).	See open point 5(13)

Aquatic organisms (B. 9.2)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data gap or Open point (if data point not addressed or fulfilled)
		based on the recovery of sensitive non-target aquatic invertebrates demonstrated in several outdoor field studies.		
5(34)	Vol. 1, Level 2: page 100 Appendix 3. Listing of endpoints	NOT: The application rates given for forestry in the TER table are 10-times too high. It should be 0.048 kg as/ha. Also the toxicity to algae in the bottom table is not cited correctly, this should be 80 mg/L and not >0.3.	RMS: This typing error will be corrected in the revised LoEP. The toxicity value for the formulation i.e. EC50 > 80 mg/ L is include in the revised LoEP .	Open point 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).

Bees and non-target arthropods (B. 9.4 and B.9.5)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data gap or Open point (if data point not addressed or fulfilled)
5(35)	Vol 3, B.9.4, effects on bees	UK: We agree that use should be limited to use on non-flowering crops at this stage with the information provided. Additional warning phrases as per Annex V phrases may also need to be considered at Member State level.	RMS: An additional report from a field study has been submitted by the notifier (S.Beuschel (2005): Dimilin WG 80: Assessment of Side Effects to the Honey Bee (Apis mellifera L.) in the Field Following Application during Bee-Flight in Germany 2005). This will be evaluated and summarised in an addendum. See also comment 5 (39) 5(40-42).	Open point 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 comments 5(38), 5(39), 5(40), 5(41), 5(42)
5(36)	Vol 3, B.9.5, effects on other arthropod species	UK: we agree that it is inappropriate to use a Hazard Quotient approach for this insect growth regulator. Also we agree that it is necessary to cover appropriate life stages where effects of chitin inhibition could be exhibited as well as the need to consider	RMS: We agree to discuss the assessment at an expert meeting. See also comment 5 (36), 5(37), 5 (45), 5 (47), 5(49), 5 (50)	Open point MSs to discuss the risk assessment for other non-target arthropods including risk mitigation measures in an expert meeting. See also comments 5(37), 5 (45), 5 (47),

Bees and non-target arthropods (B. 9.4 and B.9.5)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data gap or Open point (if data point not addressed or fulfilled)
		oral consumption. We note that the RMS has considered these elements in their risk assessment. Due to the complexity of the assessment it is considered appropriate to discuss this at an expert meeting.		5(49), 5 (50)
5(37)	Vol. 3. B.9.5. Effects on other non-target arthropods	EFSA: EFSA supports the statement of the RMS that the risk assessment for non-target arthropods (including the use of the literature review) should be discussed in an expert meeting.	RMS: We agree to discuss the assessment at an expert meeting. See also comment 5 (36), 5(37), 5 (45), 5 (47), 5(49), 5 (50)	See open point 5(36)
5(38)	Vol. 1, Level 2, LOE, Effects on Honey bees	AT: In the LOE an acute oral toxicity of > 25 µg/bee and an acute contact toxicity of > 30 µg/bee are stated (both values are stated to be literature data). However, in the information and study summaries provided in Vol. 3, B.9.4 "Effects on bees" these values can not be found. Please indicate from which studies the values given in the LOE were taken.	RMS: These values are from the same literature review as the values given in table 9.4.1.a for larvae, the values for adult honey bees should also have been included in the table in B.9., this will be corrected in the revised DAR. The use of literature data for the risk assessment may need to be discussed at an expert meeting (see also comment # 5 (39)). However, in the Guidance Document on Terrestrial Ecotoxicology Under Council Directive 91/414/EEC (SANCO/10329/2002) it is stated that "If toxicity to honeybee broods can already be predicted from the mode of action of the compound, testing may immediately start with cage/tent/tunnel or field trials". Thus, the RMS considers that the lack of laboratory studies conducted according to standardised guidelines on the sensitivity of adults and larvae is acceptable given that the notifier has submitted field trials to assess the risk to honey bees.	See open point 5(36)

Bees and non-target arthropods (B. 9.4 and B.9.5)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data gap or Open point (if data point not addressed or fulfilled)
5(39)	Volume 3, point B.9.4, Effects on bees	DE: If not derived from studies performed according to standardised guidelines, literature data from laboratory tests are not considered appropriate for a comprehensive risk assessment (see Table B.9.4.1.a). No final conclusions on risks of diflubenzuron on bees can be drawn since the results of a field study performed in 2005 are not provided yet.	RMS: Agree to discuss the quality of the data for honey bee risk assessment at an expert meeting. However, in the Guidance Document on Terrestrial Ecotoxicology Under Council Directive 91/414/EEC (SANCO/10329/2002) it is stated that "If toxicity to honeybee broods can already be predicted from the mode of action of the compound, testing may immediately start with cage/tent/tunnel or field trials". Thus, the RMS considers that the lack of laboratory studies conducted according to standardised guidelines on the sensitivity of adults and larvae is acceptable given that the notifier has submitted field trials to assess the risk to honey bees. The report from the field study has been submitted by the notifier (S.Beuschel (2005): Dimilin WG 80: Assessment of Side Effects to the Honey Bee (Apis mellifera L.) in the Field Following Application during Bee-Flight in Germany 2005). The results of the field study will be evaluated and summarised in the addendum.	See open point 5(35)
5(40)	Vol. 3, Annex B9: page 110 B.9.4.4 Summary and risk assessment for honeybees	NOT: A new field trial in apple orchards was initiated in spring 2005 to assess the effects of diflubenzuron on bee brood. This trial has been finalized and no adverse effects were found, confirming the earlier field trials performed in 1995. Preliminary	RMS: We have received the report (S.Beuschel (2005): Dimilin WG 80: Assessment of Side Effects to the Honey Bee (Apis mellifera L.) in the Field Following Application during Bee-Flight in Germany 2005). The results of the field study will be evaluated and	See open point 5(35)

Bees and non-target arthropods (B. 9.4 and B.9.5)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data gap or Open point (if data point not addressed or fulfilled)
		results have been included in the updated summary dossier. The final report is expected in the beginning of 2006. Based on the results of this trial, the notifier recommends the removal of the restriction for using the product to non-flowering stages.	summarised in the addendum.	
5(41)	Vol. 1, Level 2: page 62 2.6.3.1 Risks assessments to honeybees	NOT: A new field trial in apple orchards was initiated in spring 2005 to assess the effects of diflubenzuron on bee brood. This trial has been finalized and no adverse effects were found, confirming the earlier field trials performed in 1995. Preliminary results have been included in the updated summary dossier. The final report is expected in the beginning of 2006. Based on the results of this trial, the notifier recommends the removal of the restriction for using the product to non-flowering stages.	RMS see comment #5(40)	See open point 5(35)
5(42)	Vol. 1, Level 3: page 118 3.1 Background to the proposed decision	NOT: A new field trial in apple orchards was initiated in spring 2005 to assess the effects of diflubenzuron on bee brood. This trial has been finalized and no adverse effects were found, confirming the earlier field trials performed in 1995. Preliminary results have been included in the updated summary dossier. The final report is expected in the beginning of 2006. Based on the results of this trial, the notifier	RMS: see comment #5(40)	See open point 5(35)

Bees and non-target arthropods (B. 9.4 and B.9.5)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data gap or Open point (if data point not addressed or fulfilled)
		recommends the removal of the restriction for using the product to non-flowering stages.		
5(43)	B.9.5.3 Summary and risk assessment for non-target arthropod species other than bees	NL: Under 'Evaluation of the proposed first tier risk assessment by RMS' it is mentioned between brackets that at this stage of the assessment normally LR50 for 6 species should be available. Where is this number of 6 based on?	RMS: The figure is based on a statement in the Guidance document on terrestrial ecotoxicology where it is stated that "data on two sensitive standard species as well as data on two crop relevant species are required. If effects are observed with species relevant to the proposed use then further testing may be required. Annex III of 91/414/EEC states that where significant effects have been observed the toxicity of the product to two additional species must be investigated." This will then sum up to six species in total. However, according to the ESCORT II "the indicator species affected in the Tier 1 testing should be tested in higher-tiered tests. Where for one or both indicator species the HQ for the in-field risk assessment is greater than or equal to 2, testing of one additional species is required. If the HQ for the off-field hazard assessment is also greater than or equal to 2, one further additional species has to be tested." Thus, according to ESCORT II, for a substance where higher tier tests indicate a risk four species should have been tested in order to lower the safety factor. Maybe it should have been stated in the DAR that normally LR50 of more than 2 (or 4-6?) species should be available. Nevertheless, the	See open point 5(36)

Bees and non-target arthropods (B. 9.4 and B.9.5)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data gap or Open point (if data point not addressed or fulfilled)
			point is that the RMS considers it appropriate to use a safety factor of 10 at this stage of the assessment since only data for 2 species were available. No further action considered necessary.	
5(44)	Vol. 1, Level 2, LOE, Effects on other arthropod species	AT: First laboratory test on *Aphidius rhopalosiphi:* Please indicate in a footnote that from this study no interpretation of effects on reproduction can be made (to provide here as well the information given in the comment of the RMS to this study on page 111-112 of Vol.3, B.9.5.1).	RMS: This will be done in the revised List of Endpoints.	See open point 5(36)
5(45)	Vol. 3, B.9.5 Effects on other arthropod species	AT: The RMS based the higher-tier risk assessment on a literature review provided by the notifier. The RMS has not evaluated the original papers cited in this review. We suggest discussing this procedure as a general point in an expert meeting.	RMS: We agree to discuss the assessment at an expert meeting. See also comment 5 (36), 5(37), 5 (45), 5 (47), 5(49), 5 (50)	See open point 5(36)
5(46)	Vol. 3, B.9.5 Effects on other arthropod species	AT: Buffer zones were included in the risk assessment as risk mitigation measures. Although buffer zones are mentioned in ESCORT II as possible risk mitigation measures we think that they should not be included in a risk assessment because their applicability in agricultural practice is questionable. We suggest using instead drift reduction measures in the risk assessment.	RMS: Other MS are invited to comment on this generic issue during the written procedure and thereafter this issue can be discussed at the expert meeting.	See open point 5(36)
5(47)	Volume 3, point B.9.5,	DE: The data set provided is not fully in	RMS: According to the Terrestrial guidance	See open point 5(36)

Bees and non-target arthropods (B. 9.4 and B.9.5)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data gap or Open point (if data point not addressed or fulfilled)
	Effects on other arthropod species	agreement with the requirements stated in the Terrestrial Guidance Document, e.g. at tier I not enough species have been tested. The literature review on field studies is also not sufficient since the risk to the most sensitive group (foliar dwelling predators) is not comprehensively discussed, e.g. by conducting a weight-of-evidence approach concerning the potential for recovery. Safe use has not fully been demonstrated as on the one hand, an acceptable in-field risk for foliage dwelling arthropods depends on a re-colonisation from the off-crop area, but on the other hand, acceptable risk in the off-crop area is only reached with extensive buffer zones (10 - 40 m, depending on crop). It might be, however, assumed that the use of diflubenzuron following hand application in forests at application rates of 48 g as/ha (buffer zone: 10 m) might be acceptable if the respective data (i.e. from a field study) or a reasonable weight-of-evidence approach on the recovery potential of sensitive species are provided. Only when this information is available, an expert meeting might be useful.	document and ESCORT 2, data for two species is needed for tier 1, hence the RMS considers that enough species have been tested for tier 1 (LR50 available for *E. balteus* and *C. septempunctata*) The RMS considers that if acceptable risk off-field can be obtained using (extensive) buffer-zones then the risk in-field can be acceptable given the potential for recolonisation from off-field areas. . We agree to discuss the assessment at an expert meeting. See also comment 5 (36), 5(37), 5 (45), 5 (47), 5(49), 5 (50).	
5(48)	Comments on the Diflubenzuron end-point list (Vol. 1)	DK: Page 100: The application rate in forestry is not 0,48 kg as/ha but 0,048 kg as/ha.	RMS: This typing error will be corrected in the revised List of Endpoints.	Open point RMS to correct the application rate in the LoEP for forestry (it should read 0.048 kg

Bees and non-target arthropods (B. 9.4 and B.9.5)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data gap or Open point (if data point not addressed or fulfilled)
		Page 103: The table "Effects on other arthropod species" mentions dose in kg as/ha, but the values are given in g as/ha.		a.s./ha) and the heading in the table with non-target arthropods (g a.s./ha instead of kg a.s./ha).
5(49)	Vol. 3, Annex B9: page 140-141 B.9.5.3 Summary and risk assessment for non-target arthropod species other than bees	NOT: The notifier does not agree with the buffer zones as proposed by the RMS to mitigate the risks for ground and foliar dwelling predators. We refer to the risk assessment provided in the updated summary dossier (DI-11801). In the risk assessment it is concluded that : - The laboratory and field results are consistent in demonstrating a general lack of adverse effects on non-target arthropods at application rates below and above those recommended for use with DIMILIN WG-80 - None of the field studies report adverse effects on non-target arthropod populations of greater than 50% at application rates close to or above the maximum application rate for DIMILIN WG-80 use in orchards and forests. -Consistent with the recommendations of ESCORT 2 for IGRs, an evaluation of higher-tier field data has been carried out in relation to the recommended application rate of DIMILIN WG-80 for use in orchards and forests. The conclusion is that the risks to non-target arthropods, both in-field and off-field, are acceptable following the use of DIMILIN WG-80.	RMS: No new information or any new lines of reasoning for the risk assessment were provided in the updated summary dossier and hence the basis for the discussion should be the information in the original DAR (a summary of the notifier's argumentation was presented in the original DAR). The notifier maintains that the information in the literature review demonstrates that the risk to non-target terrestrial arthropods is acceptable off-field without buffer zones. The RMS does not share this view and welcomes a discussion on the risk assessment during the expert meeting. See also comment 5 (36), 5(37), 5 (45), 5 (47), 5(49), 5 (50). Furthermore, for an acceptable off-field risk following aerial application in forests buffer zones is needed; however no such calculation was provided by the notifier.	See open point 5(36)

Bees and non-target arthropods (B. 9.4 and B.9.5)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data gap or Open point (if data point not addressed or fulfilled)
5(50)	Vol. 1, Level 3: page 119 3.2 Proposed decision concerning inclusion in Annex 1	NOT: The notifier does not agree with the buffer zones as proposed by the RMS to mitigate the risks for ground and foliar dwelling predators. We refer to the risk assessment provided in the updated summary dossier (DI-11801). In the risk assessment it is concluded that : - The laboratory and field results are consistent in demonstrating a general lack of adverse effects on non-target arthropods at application rates below and above those recommended for use with DIMILIN WG-80 - None of the field studies report adverse effects on non-target arthropod populations of greater than 50% at application rates close to or above the maximum application rate for DIMILIN WG-80 use in orchards and forests. -Consistent with the recommendations of ESCORT 2 for IGRs, an evaluation of higher-tier field data has been carried out in relation to the recommended application rate of DIMILIN WG-80 for use in orchards and forests. The conclusion is that the risks to non-target arthropods, both in-field and off-field, are acceptable following the use of DIMILIN WG-80.	RMS: see comment # 5 (49)	See open point 5(36)
5(51)	Vol. 1, Level 3: page 119 3.3 Rationale …..	NOT: The notifier does not agree with the conclusions of the RMS that no acceptable risk was found for some of the proposed	RMS: The selection of spray drift value for the use in forestry will be discussed at a fate expert meeting, and the risk assessment of	Addressed

Bees and non-target arthropods (B. 9.4 and B.9.5)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data gap or Open point (if data point not addressed or fulfilled)
	Vol. 1, Level 4: page 121 4.8 Environmental fate and behaviour 4.9 Ecotoxicology	uses in orchards and forestry. We refer to the risk assessments provided in the updated summary dossier. We do not agree with the spray drift value chosen by the RMS to evaluate the aerial application in forestry and have the opinion that there's enough evidence for recovery of aquatic and terrestrial non-target arthropods for both the forestry and orchard uses.	the terrestrial and aquatic non-target arthropods will be discussed at the ecotox expert meeting. The new information provided by the notifier will be summarised and evaluated in an addendum.	

Earthworms and other soil non-target organisms (macro and micro) (B. 9.6, B.9.7 and B.9.8)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data gap or Open point (if data point not addressed or fulfilled)
5(52)	Vol. 3. B . 9.7. Risk to	EFSA: the DT90f of the soil metabolite CPU is 111 days which would require testing with soil non-target macro-organisms. Some argumentation should be provided why this testing is not necessary.	RMS: 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. No further action considered necessary.	Open point MSs to discuss in an expert meeting whether testing with the soil metabolite CPU and soil non-target macro-organisms is required.
5(53)	Vol. 3. B.9.8 Effects on other soil non-target micro-organism	EFSA: it is not clear from the study summaries to which of the tested dose rates the observed effects relate to. Did only the highest tested dose lead to the reported effects?	RMS: In the study by Thus et al. 1995 the effects on nitrogen turn over was concentration independent (as stated in the summary). In one soil the deviation from control was 40 % regarding the ammonium content at the	Open point 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

Earthworms and other soil non-target organisms (macro and micro) (B. 9.6, B.9.7 and B.9.8)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data gap or Open point (if data point not addressed or fulfilled)
			highest concentration and 23 % at the lowest concentration. In the other soil the percent deviation from control in the nitrate content was 23 % for the highest treatment rate and 28 % for the lowest. Therefore a study (Keetelaar-Jansen et al. 1995) investigating the effects over a longer time period was performed and in this study no effects above 25 % was observed on sampling occasions one month or longer after application. This information is already included in the DAR and therefore no further action considered necessary.	application rates below the rate suggested in the GAP.

Other non-target organisms (flora and fauna), sewage treatment (B.9.9 and B.9.10)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data gap or Open point (if data point not addressed or fulfilled)
5(54)	Vol. 3. B.9.10 Risk assessment for biological methods of sewage treatment	EFSA: no study summary is provided in the DAR.	RMS: A study summary is provided under B. 9.10.1 on page 152 in the DAR (word version). No further action considered necessary.	Addressed
5(55)	Volume 3, point B.9.9, Effects on other non-target organisms	DE: The RMS refers to herbicide screening data when assessing the risk to plants, but no data are provided.	RMS: The notifier provided data in a tabulated form which is summarised in the text on page 153 (B9). The summary of the result from the biological screening tests on higher plants indicated that none of the tested plant species were affected by post-emergence application of 10 kg/ha or pre-emergence application of	Addressed More detailed summaries of the studies should be given in future DARs to aid transparency.

Other non-target organisms (flora and fauna), sewage treatment (B.9.9 and B.9.10)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data gap or Open point (if data point not addressed or fulfilled)
			20 kg/ha. The RMS considers that this information is sufficient to conclude that the risk to non-target plants will be low. No further action is considered necessary.	

Other comments				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data gap or Open point (if data point not addressed or fulfilled)
5(56)	Vol. 3. B.9. References relied on and List of information, test and studies	EFSA: The following reference: Dykstra, A.C., Lewis, G., Mackay, N. (2003) is listed in the list of references relied on and in the List of information, tests and studies but DAR (Vol. 3. B9.) but the reference cannot be found in the text of the DAR.	RMS: This literature review contains a similar material as the more recent review "RISK ASSESSMENT OF DIFLUBENZURON ON AQUATIC ORGANISMS WITH PARTICULAR EMPHASIS ON AQUATIC INVERTEBRATES" by Pijst H.L.A., Wyness, L. (2004). The notifier claim that this report was prepared at an earlier stage with the aid of another expert consultancy firm and that it supports the more recent risk assessment in their dossier. Therefore they consider that it should be included in the lists. However, since the information given is similar to the second literature review the RMS suggests deleting it from the lists.	Open point 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.

Comments received on reporting table, section Ecotoxicology (B.9)			
Reference to reporting table	MS / Notifier	Comment	EFSA response
5(5)	UK	It is noted that the SANCO 4145/2000 guidance is inconsistent with regard to the actual deposition value that should be used stating on P 12 that deposition is 40% whilst on page 15 (footnote to Table 4) it is stated that the deposition is 60%. This issue should be addressed when this guidance document is revised. In the meantime values for interception could be used that are in line with 'Generic Guidance for FOCUS groundwater scenarios' Version 1.1 April 2002. The growth stage of the crop could etc can be considered in deciding on the appropriate interception and hence deposition value. With regard to forests, a value of 50% interception would be in line with that for apples (focus groundwater) however please also see the points raised at point 4(22) regarding the type of sprayer etc.	Noted The statement should be considered in the expert meeting.
5(6)	NOT	Data requirement: Applicant to submit a risk assessment for birds from uptake of contaminated drinking water according to SANCO 4145/2000. Puddles will not occur due to spraying, because spraying stops before runoff. It's uneconomic to spray till the product drips of the leaves, because you will loose product, the amount of residue on the leaves will be less, resulting in reduced efficacy. Furthermore, the toxicity of diflubenzuron to birds is very low (see below) and as the concentrations of diflubenzuron in drinking water will never even approach the high dosages used in the acute tests on birds, we really question the need for such an additional assessment. Acute oral toxicity to bird LD50 >5000 mg/kg b.w. (mallard duck and bobwhite quail) Dietary toxicity to birds LD50 >1206 mg/kg b.w./day (bobwhite quail, 8 d)	Noted For information: in previous expert-meeting it was agreed that an acute risk assessment should be conducted for all cases where exposure to contaminated drinking water cannot be excluded.
5(7)	NOT	Data requirement: Applicant to submit a risk assessment for earthworm- and fish-eating mammals and from uptake of contaminated drinking water according to SANCO 4145/2000. Puddles will not occur due to spraying, because spraying stops before runoff. It's uneconomic to spray till the product drips of the leaves, because you will loose product, the amount of residue on the leaves will be less, resulting in reduced efficacy. Furthermore, the toxicity of diflubenzuron to mammals is very low (see below) and as the concentrations of diflubenzuron in drinking water	Noted For information: in previous expert-meeting it was agreed that an acute risk assessment should be conducted for all cases where exposure to contaminated

Comments received on reporting table, section Ecotoxicology (B.9)			
Reference to reporting table	MS / Notifier	Comment	EFSA response
		will never even approach the high dosages used in the acute tests on mammals, we really question the need for such data. Acute oral toxicity to mammals LD50 > 4 640 mg/kg (mice and rat)	drinking water cannot be excluded.
5(20) and 5(30)	FR	About drift values for use on forest: in case that applications are intended by aircraft (aerial applications) a recent review in France on the potential risk related to aerial applications indicated that in the case of applications by aircraft (http://www.afsse.fr/index.php?pageid=706&parentid=424), which is expected in the case of forest, the aim is to enhance the drift in order to limit the number of pass of the aircraft. In such cases, drift is likely to be important and close to 100%.	Noted The information should be considered in an expert meeting
5(46)	FR	We note that buffer zones may be difficult to implement in MS. We would like to add that the use of drift reducing technologies is neither generalized in France so that its account in mitigation measures also is of limited interest. In addition, specific precautionary sentences (see Annex 5 of Dir 91/414/EC) are available for buffer zones to protect insects and non target arthropods while there is no harmonized sentence for drift reducing technologies.	Noted The information should be considered in an expert meeting
5(46)	UK	Risk mitigation measures vary between Member States and therefore we consider that it is inappropriate for specific measures such as drift reduction to be included.	Noted The information should be considered in an expert meeting
5(53) Column 4	FI	Because the effects were < 25 % after 2 months, we consider the risk is acceptable and no further action is required.	Noted