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

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Comments on the Draft Assessment Report on diflubenzuron (EAS)

RMS SE

End of commenting period: 21 February 2006 (MS, NOT)

Date	Supplier	File
14.02.2006	Denmark	01 diflubenzuron comments DK 2006-02-14.doc
17.02.2006	Germany	02 diflubenzuron comments DE 2006-02-17.doc
17.02.2006	The Netherlands	03 diflubenzuron comments NL 2006-02-17.doc
17.02.2006	United Kingdom	04 diflubenzuron comments UK 2006-02-17.doc
21.02.2006	Austria	05 diflubenzuron comments AT 2006-02-21.doc
21.02.2006	Notifier	06 diflubenzuron comments NOT 2006-02-21.doc
03.04.2006	EFSA	07 diflubenzuron comments EFSA 2006-04-03.doc

1. Physical/Chemical Properties; Details of Uses and Further Information; Methods of Analysis (B.1-B.5)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS>>: <<comment>>	

section 2 – Mammalian toxicology

2. Mammalian toxicology (B.6)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca. 10 lines)	Column 3 Further explanations
(1)	**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 concurrent control are seen in lower doses than the allocated NOAEL's. These findings are considered to be adverse.	
(2)	Vol. 3, B.6.10.9, AOEL	DK: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.	
(3)	Vol. 3, B.6.12.1, Dermal absorption	DK: We do not agree that residues in skin should not be included. The study was 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.	

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section 3 - Environmental fate and behaviour (B.8)

3. Environmental fate and behaviour (B.8)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	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.	

section 3 - Environmental fate and behaviour (B.8)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(2)	Comments on the Diflubenzuron end-point list (Vol. 1)	Page 83: Relevant metabolites, DFBA: …at day 6-13 (n=3)…please correct to: …at day 3-13 Anaerobic degradation: 35% NER and 20% mineralization should preferably be corrected to: 6,4% NER and 2,77% mineralization Soil photolysis: 6,4 % NER should be 35% NER Page 85: PEC (soil), parent, two appl. Actual, 28 d: according to volume 3 this figure should be 0,008 instead of 0,017 Page 86: PEC (soil), metabolite DFBA, multiple appl.: the figures are not the same as in volume 3 table 8.3.b Page 88: The crop interception is missing for PECsw parent – orchard.	

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section 5 - Ecotoxicology (B.9)

4. Ecotoxicology (B.9)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	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
(2)	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.	
(3)	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.
(4)	Comments on the Diflubenzuron end-point list (Vol. 1)	Page 100: The application rate in forestry is not 0,48 kg as/ha but 0,048 kg as/ha. Page 103: The table "Effects on other arthropod species" mentions dose in kg as/ha, but the values are given in g as/ha.	

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5. Physical/Chemical Properties; Details of Uses and Further Information; Methods of Analysis (B.1-B.5)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	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.	
(2)	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.
(3)	Volume 1, Level 2, point 2.2.3, Analytical methods for residue analysis	DE: It should be added that validated confirmatory methods for diflubenzuron and relevant metabolites in soil, water and air are missing.	The specifity of LC-MS/MS methods has to be confirmed by using two transitions for validation.
(4)	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.	

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(5)	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 specifity of LC-MS/MS methods must be confirmed by using two transitions for validation.
(6)	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.
(7)	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.
(8)	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.
(9)	Volume 3, point B.5.3.4, Analytical method for the determination of residues in air	DE: A validated confirmatory method for the quantification of diflubenzuron in air metabolites is missing.	
(10)	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.

6. Environmental fate and behaviour (B.8)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	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.	

7. Ecotoxicology (B.9)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca. 10 lines)	Column 3 Further explanations
(1)	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.
(2)	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.
(3)	Volume 3, point B.9.5, Effects on other arthropod species	DE: The data set provided is not fully in 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.
(4)	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.	

8. Physical/Chemical Properties; Details of Uses and Further Information; Methods of Analysis (B.1-B.5)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 1, appendix 3, Listing of endpoints, FAO specification	NL: FAO specification is available, LOEP should be adapted	
(2)	Vol. 3, B.2.1.5.1.3, UV/VIS spectrometry	NL: It is unclear if there is any absorption above 290 nm	
(3)	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
(4)	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 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
(5)	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

section 1 - Physical/Chemical Properties; Details of Uses and Further Information; Methods of Analysis (B.1-B.5)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(6)	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	
(7)	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	
(8)	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.	
(9)	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
(10)	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
(11)	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	
(12)	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
(13)	Vol.1, level 4, 4.5 Method of analysis	The complete validation data of each impurity should be given in a table. Validation data should confirm the claimed LOQ's for each impurity.	

section 1 - Physical/Chemical Properties; Details of Uses and Further Information; Methods of Analysis (B.1-B.5)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(14)	Vol.3, B.5.3.1, Analytical method for the determination of residues in soil	NL: type of soil should be reported	
(15)	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.	
(16)	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	
(17)	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.	
(18)	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

9. Mammalian toxicology (B.6)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca. 10 lines)	Column 3 Further explanations
(1)	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.	

section 3 - Residues (B.7)

10. Residues (B.7)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(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.	
(2)	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. NL calculated a dietary intakeof 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.	
(3)	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.	
(4)	Vol. 3 Table 7.2.1.5 (metabolism laying hen)	NL: It is not stated whether results reflect the 1 mg/kg bw/d or 10 mg/kg bw/d dose.	

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section 3 - Residues (B.7)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(5)	Vol. 3 Table 7.2.1.6 (metabolism laying hen)	NL: It is not stated whether results reflect the 1 mg/kg bw/d or 10 mg/kg bw/d dose.	
(6)	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.	
(7)	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	

section 3 - Residues (B.7)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(8)	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. 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, NL propse 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).	

section 3 - Residues (B.7)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(9)	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 tgherefoe 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.	
(10)	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 of 2 weeks yield the same final residue as an application interval of 4 weeks. RMS is invited to give its opinion on this.	
(11)	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.	
(12)	B.7.12 (MRL calculation	NL: For the data set of Northern Europe, NL 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	

section 3 - Residues (B.7)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(13)	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)	

section 4 - Environmental fate and behaviour (B.8)

11. Environmental fate and behaviour (B.8)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	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.	
(2)	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.	
(3)	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.	
(4)	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.	

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section 4 - Environmental fate and behaviour (B.8)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(5)	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 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.	
(6)	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.	
(7)	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 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.	

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section 4 - Environmental fate and behaviour (B.8)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(8)	Vol. 1, LoEP	NL: For PECgw calculation the geo-mean of DT50 and Koc should be used according to the LoEP template.	
(9)	Vol. 1, LoEP	NL: Please delete the 3rd column in the PECgw modelling results.	

section 5 - Ecotoxicology (B.9)

12. Ecotoxicology (B.9)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	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?	
(2)	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 exposure to surface water can be considerable. Maybe it must be considered as a MS-issue.	
(3)	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?	
(4)	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?	

* When mentioning page numbers of the DAR in your comments, **the page numbers should refer to the pdf-version** (not the WORD-version) of the DAR to ensure consistency among the Member States.

13. Physical/Chemical Properties; Details of Uses and Further Information; Methods of Analysis (B.1-B.5)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol 3, B.5.1.2, analytical methods for determination of impurities	UK: TLC method BAI 42004 used for impurities B & E in technical material: were method details and validation data supplied? No data appears to be mentioned in the DAR and both impurities are listed in the tech spec.	

14. Mammalian toxicology (B.6)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca. 10 lines)	Column 3 Further explanations
(1)	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.	
(2)	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.	
(3)	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.)	
(4)	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.	

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca. 10 lines)	Column 3 Further explanations
(5)	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.	
(6)	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.	
(7)	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.	
(8)	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.	
(9)	Vol. 3, B.6.14.1.3, Table B.6.14.1.3-1 and following conclusion.Estimation of exposure in a greenhouse - mushrooms	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 bw/day should be 0.018 mg/kg bw/day (equivalent to 54% of the AOEL).	

section 2 - Mammalian toxicology (B.6)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca. 10 lines)	Column 3 Further explanations
(10)	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.	
(11)	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.	
(12)	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.	

15. Residues (B.7)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca. 10 lines)	Column 3 Further explanations
(1)	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.	
(2)	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. 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?	
(3)	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.	
(4)	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.	
(5)	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.	

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16. Environmental fate and behaviour (B.8)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol 3, B.8.2, adsorption, desorbtion 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.	

section 4 - Environmental fate and behaviour (B.8)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(2)	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 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.	

section 4 - Environmental fate and behaviour (B.8)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(3)	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.	
(4)	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.	

17. Ecotoxicology (B.9)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca. 10 lines)	Column 3 Further explanations
(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 LC50 value for the active substance than the toxic standard (p6). We propose that this information is included.	
(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.	
(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).	
(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.	

section 5 - Ecotoxicology (B.9)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca. 10 lines)	Column 3 Further explanations
(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.	
(6)	Vol 3, B.9.2.9, summary of toxicity studies on aquatic organisms	UK: It would be helpful if the values in the summary tables that are to be used in the risk 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.	
(7)	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.	

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section 5 - Ecotoxicology (B.9)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca. 10 lines)	Column 3 Further explanations
(8)	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.	
(9)	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 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.	

18. Physical/Chemical Properties; Details of Uses and Further Information; Methods of Analysis (B.1-B.5)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 3, B.2.2.2.2 oxidising properties	AT: A complete test according to EEC/A17 is required.	
(2)	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.	
(3)	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 product.	
(4)	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 missing.	
(5)	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.	
(6)	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.	

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section 1 - Physical/Chemical Properties; Details of Uses and Further Information; Methods of Analysis (B.1-B.5)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(7)	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.	
(8)	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.	
(9)	Vol. 3, B.5.3.4 air	AT: The unit of the concentrations used for the calibration curve (µg/m3) seems unreliable.	
(10)	Vol. 4, C.1.2.3.1 5-batches	AT: The closures of the a.i. and the impurities are missing.	
(11)	Vol. 4, C.1.2.4 determination of the impurities	AT: Specificity: Methods for the (initial) identification of the impurities must be reported.	

section 2 - Mammalian toxicology (B.6)

19. Mammalian toxicology (B.6)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/notifier>>: <<comment>>	

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section 3 - Residues (B.7)

20. Residues (B.7)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	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”.	

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section 4 - Environmental fate and behaviour (B.8)

21. Environmental fate and behaviour (B.8)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/notifier>>: <<comment>>	

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section 5 - Ecotoxicology (B.9)

22. Ecotoxicology (B.9)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	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 amendments should be made in volume 1.	
(2)	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.	
(3)	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.	
(4)	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.	

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section 5 - Ecotoxicology (B.9)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(5)	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.	
(6)	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.	
(7)	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.	
(8)	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.	
(9)	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.	
(10)	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).	

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section 5 - Ecotoxicology (B.9)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(11)	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.	
(12)	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.	

Volume 1

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
1	Vol. 1, Level 1: page 10 Table 1.5.3b	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).	
2	Vol. 1, Level 1: page 10 Table 1.5.3b	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).	
3	Vol. 1, Level 2: page 26 – 75	Headings not correct: Page 26-66 = Level 2 Page 67-75 = Appendix 1	
4	Vol. 1, Level 2: page 27	Last sentence: EC_{50} mentioned here is incorrect. It should be: EC_{50} = 2.6 µg/L (see also page 56)	
5	Vol. 1, Level 2: page 29 2.2.1 Methods of analysis	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.
6	Vol. 1, Level 2: page 30 2.2.3 Analytical methods for residue analysis	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.	
7	Vol. 1, Level 2: page 31: 2.3.1.1.2 Acute toxicity	The word "oral" should be replaced by "dermal": "The acute dermal LD_{50} of diflubenzuron was >10000 mg kg^{-1} bw in rats.	

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No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
8	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 conclusion reached having regard to established or proposed CAC MRLs	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 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!	
9	Vol. 1, Level: page 50+51 2.5.3.2 Predicted environmental concentrations in surface water and sediment	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.
10	Vol. 1, Level 2: page 56 Table 2.6.2.b Aquatic invertebrates	The quahogs NOEC = 320 (removal of "1ª" mentioned after it).	

Volume 1

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
11	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	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 based on the recovery of sensitive non-target aquatic invertebrates demonstrated in several outdoor field studies.
12	Vol. 1, Level 2: page 62 2.6.3.1 Risks assessments to honeybees	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.	
13	Vol. 1, Level 2: page 81 Appendix 3. Listing of endpoints Table: Forestry and woody ornamentals – aerial application (ULV) *[2] Mushrooms	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).	

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No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
14	Vol. 1, Level 2: page 81 Appendix 3. Listing of endpoints Table: Mushrooms	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).	
15	Vol. 1, Level 2: page 94 Appendix 3. Listing of endpoints Table: PEC_{sw} Parent – Forestry	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.
16	Vol. 1, Level 2: page 100 Appendix 3. Listing of endpoints	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.	
17	Vol. 1, Level 3: page 114 3.1 Background to the proposed decision	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.	

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
18	Vol. 1, Level 3: page 114 3.1 Background to the proposed decision	The word "oral" should be replaced by "dermal": "The acute dermal LD_{50} of diflubenzuron was >10000 mg kg^{-1} bw in rats.	
19	Vol. 1, Level 3: page 118 3.1 Background to the proposed decision	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.	The 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.
20	Vol. 1, Level 3: page 118 3.1 Background to the proposed decision	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.	

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
21	Vol. 1, Level 3: page 119 3.2 Proposed decision concerning inclusion in Annex 1	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.
22	Vol. 1, Level 3: page 119 3.2 Proposed decision concerning inclusion in Annex 1	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!

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
23	Vol. 1, Level 3: page 119 3.3 Rationale …..	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 aquatic and terrestrial non-target arthropods for both the forestry and orchard uses.	
24	Vol. 1, Level 4: page 120 4.5 Methods of analysis: 1st and 3rd paragraph	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.	
25	Vol. 1, Level 4: page 120 4.5 Methods of analysis	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.	
26	Vol. 1, Level 4: page 121 4.7 Residue data	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 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.

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
27	Vol. 1, Level 4: page 121 4.8 Environmental fate and behaviour 4.9 Ecotoxicology	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 both aquatic and terrestrial non-target arthropods for the proposed forestry and orchard uses.	

23. Physical/Chemical Properties; Details of Uses and Further Information; Methods of Analysis (B.1-B.5)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
1	Vol. 3, Annex B3: page 9 Data on application and further information B.3.2.4 Table B.3.2.6 Method of application	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).	
2	Vol.3, Annex B4: page 3 B.4.1 Proposals for classification and labelling of the active substance	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.	
3	Vol. 3, Annex B5: page 4 B.5.1.2 Analytical Methods for the determination of the impurities in the active substance as manufactured	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 included in the updated summary dossier.
4	Vol. 3, Annex B5, page 12 B.5.3.4 Analytical Methods for the determination of residues in air	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.	

* When mentioning page numbers of the DAR in your comments, **the page numbers should refer to the pdf-version** (not the WORD-version) of the DAR to ensure consistency among the Member States.

24. Mammalian toxicology (B.6)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
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	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.	
2	Vol. 3, Annex B.6: page 24 B.6.3.1.1 Oral 28-day study (rat)	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}.	
3	Vol. 3, Annex B.6: page 35 B.6.3.1.3 Oral 90-day toxicity (mouse) Table B.6.3.1.3-1	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).
4	Vol.3, Annex B.6: page 69 B.6.5.2 Carcinogenicity study in rats	Table B.6.5.2-1 Haemoglobin content should be expressed as g/dL (and not as mg/dL).	
5	Vol. 3, Annex B.6: page 110 B.6.10 Summary of mammalian toxicology and proposed ADI etc.	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.”	

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25. Residues (B.7)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
1	Vol. 3, Annex B.7: page 40 B.7.5 Identification of Critical GAPs	Table: The rate per treatment for the application in mushroom must be 1 g as/m^2 (the value 0.25 is incorrect).	
2	Vol. 3, Annex B.7: page 42 B.7.5 Identification of Critical GAPs	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).	

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
3	Vol. 3, Annex B.7: page 56-57 B.7.6, Mushroom residue trials	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 UK 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, 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.

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
4	Vol. 3, Annex B.7: page 57 B.7.6, Mushroom residue trials	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 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!
5	Vol. 3, Annex B.7: page 57 B.7.6, Mushroom residue trials	The notifier contests that the possible underestimated PCA residues in mushrooms are a valid reason to ask for additional residue trials.	The 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 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.

26. Environmental fate and behaviour (B.8)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
1	Vol. 3, Annex B.8: page 2 B.8.1.1 Aerobic degradation	According to our calculations the test concentration should be 0.98 kg diflubenzuron per ha and not 0.49.	
2	Vol.3, Annex B.8: page 46 B.4.4 Summary of studies on fate and behaviour in water	In the first sentence the word “methyl” should be deleted.	
3	Vol. 3, Annex B.8: page 61 B.8.6.2 Predicted environmental concentrations in surface water	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.

27. Ecotoxicology (B.9)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
1	Vol. 3, Annex B9: page 30 B.9.2.4.1, Acute toxicity to aquatic invertebrates	Materials and methods: Dose range values reported under the treatments are mean measured in stead of nominal values as is suggested.	
2	Vol. 3, Annex B9: page 32 B.9.2.4.1, Acute toxicity to aquatic invertebrates	In table 9.2.4.1.f, left column: Mean measured concentration (mg/L) should be replaced by Nominal concentration (mg/L).	
3	Vol. 3, Annex B9: page 40-41 B.9.2.6.1 Effects on algal growth and growth rate – Active ingredient	In the materials and methods section on page 40 and on the top of page page 41: The nominal concentration tested in this test is 0.20 mg/L in stead of 20 mg/L as suggested.	
4	Vol. 3, Annex B9: page 59, 68, 89, 93-95 and 98-99 B.9.2.8/9 Higher tier studies	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 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.

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
5	Vol. 3, Annex B9: page 95 B.9.2.10: Risk assessment for aquatic organisms	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.
6	Vol. 3, Annex B9: page 110 B.9.4.4 Summary and risk assessment for honeybees	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.	

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
7	Vol. 3, Annex B9: page 140-141 B.9.5.3 Summary and risk assessment for non-target arthropod species other than bees	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.

section 1 - Physical/Chemical Properties; Details of Uses and Further Information; Methods of Analysis (B.1-B.5)

28. Physical/Chemical Properties; Details of Uses and Further Information; Methods of Analysis (B.1-B.5)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	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.	
(2)	Vol. 1, Appendix 3 list of end points, dissociation constant	EFSA: Solubility in water is not a criteria for requiring the test to be done.	
(3)	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.	
(4)	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 %.	
(5)	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 %.	
(6)	Vol. 3, B.2.1.8, Partition coefficient	EFSA: The case presented by the rapporteur should be considered at a meeting of experts.	
(7)	Vol. 3, B.2.1.9.4	EFSA: Solubility in water is not a criteria for requiring the test to be done.	
(8)	Vol. 3, B.2.1.11.1/2, flammability and auto flammability.	EFSA: The material tested is not representative of technical material.	
(9)	Vol 3, B.2.1.13, explosive properties.	EFSA: The material tested is not representative of technical material.	

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section 1 - Physical/Chemical Properties; Details of Uses and Further Information; Methods of Analysis (B.1-B.5)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(10)	Vol. 3, B.2.1.15, oxidising properties	EFSA: The material tested is not representative of technical material.	
(11)	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.	
(12)	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.	
(13)	Vol. 3, B.5.2 Method in plants	EFSA: The applicability of a multi-residue method such as DFG S19 must be addressed.	
(14)	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.	

section 2 - Mammalian toxicology (B.6)

29. Mammalian toxicology (B.6)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	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.	
(2)	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.	
(3)	Vol. 3 B.6.14.1.3 Estimation of operator exposure in greenhouse using mushroom grower	EFSA: the operator exposure estimate reported in the DAR does not appear fully reliable; some details (e.g. the reduction of the treated area to 0.15 ha/day) need to be further explained.	

section 3 - Residues (B.7)

30. Residues (B.7)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	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	
(2)	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 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.	
(3)	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.	

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section 3 - Residues (B.7)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(4)	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.	
(5)	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.	
(6)	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.	
(7)	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.	

section 3 - Residues (B.7)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(8)	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 (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)	
(9)	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 97.5^{th} percentile of the consumption. For the other commodities, the mean consumption value should be taken.	
(10)	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.	

section 4 - Environmental fate and behaviour (B.8)

31. Environmental fate and behaviour (B.8)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(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 CO2 may need to be justified.	
(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 this residues. It would be helpful to have the results of this investigation summarized in the DAR.	
(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.	
(4)	Vol 3. B.8.2.3. Summary and assessment of adsoption, desroption 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.	

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section 4 - Environmental fate and behaviour (B.8)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(5)	Vol 3. B.8.2.3. Summary and assessment of adsoption, desroption and mobility in soil. p. 27	EFSA: Koc derived with the software PCKocWin v1.66 from EPA or by estimation form log Pow data have been only accepted when the substance is not stable under the experimental conditions necessary to performe the batch adsorption/desorption experiments. Otherwise a Koc = 0 has been normally used for the risk assessment.	
(6)	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).	
(7)	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 readily biodegradable.	
(8)	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.	
(9)	B.8.4.6.1. $PEC_{GW.}$ 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.)	

* When mentioning page numbers of the DAR in your comments, **the page numbers should refer to the pdf-version** (not the WORD-version) of the DAR to ensure consistency among the Member States.

section 4 - Environmental fate and behaviour (B.8)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(10)	B.8.6.2 PEC SW Wanner, U. (2004). p 54.	EFSA: The selection of the relevant FOCUS PEC SW scenarios is not dicussed in the DAR. At least the general criteria used should be explained (or appropriate reference to FOCUS guidance quoted).	
(11)	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 orchads and tractor mounted sprayer in forest needs to be provided.	

* When mentioning page numbers of the DAR in your comments, **the page numbers should refer to the pdf-version** (not the WORD-version) of the DAR to ensure consistency among the Member States.

section 5 - Ecotoxicology (B.9)

32. Ecotoxicology (B.9)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	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.	
(2)	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.	
(3)	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.	
(4)	Vol. 3. B.9.2. Aquatic risk assessment metabolites CPU, DFB, DFBA	EFSA: Some argumentation should be provided to address the risk of bioconcentration of the metabolites CPU, DFB, DFBA (log Pow < 3?, more polar than the parent?…)	
(5)	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.	
(6)	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.	

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section 5 - Ecotoxicology (B.9)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(7)	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.	
(8)	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?	
(9)	Vol. 3. B.9.10 Risk assessment for biological methods of sewage treatment	EFSA: no study summary is provided in the DAR.	
(10)	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.	