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0. General

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
	Section 0 Open points: ***1*** Points for clarification: ***0*** Data gaps: ***0***			
	Open point: 0.1 The new template for the list of end points should be used. See reporting table 0(1)			

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

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
	Section 1 Open points: ***3*** Points for clarification: ***0*** Data gaps: ***1***			Section 1 Open points: ***3*** Points for clarification: ***0*** Data gaps: ***2***
	Open point: 1.1 EFSA to explain the issues with the 5-chlorocarbofuran in the conclusion and propose a maximum level for this impurity. See reporting table 1(3)		**RMS 08.2009:** No further comments	Written procedure The issues with 5-chlorocarbofuran impurity is dealt with in the conclusion.
	Open point: 1.2 EFSA to ensure that the relevant impurities are taken account of in the list of end points. See reporting table 1(5)		**RMS 08.2009:** No further comments	Written procedure The relevant impurities have been taken account of in the end points
	Data gap: 1.1 Shelf life with analysis of 5-chlorocarbofuran and N-nitrosodibutylamine See reporting table 1(9)	**NOT:** We refer to RMS and notifier comments under point 1(9) of the Reporting tables.	**RMS 08.2009:** No further comments	Written procedure Data gap remains

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
	Open point: 1.3 The methods submitted in this dossier are the same as submitted for carbofuran EFSA should ensure that the conclusion is in line with that for carbofuran. See reporting table 1(13)	**NOT:** We refer to notifiers comments under points 3(9) and 3(10) of the Reporting tables.	**RMS 08.2009:** No further comments	Written procedure This issue is addressed in the conclusion and is inline with carbofuran.

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
	New data gap 1.2 identified at PRAPeR TC 21 meeting on residues: Applicant to address the efficiency of the hydrolysis step to release the 3 OH-carbofuran conjugates in animal matrices in the method of analysis for monitoring. (refer to data gaps 3.1 and 3.2)		**RMS September 2009 (after TC 21):** One ideal way to address the efficiency of the hydrolysis step would be a method validation experiment in which samples are spiked with isolated (e.g. via preparative analysis) and well-defined conjugates of the analytes. The other possible way to address this point is to compare the recoveries obtained in the performed validation experiment (in which non-conjugated reference standards were used for spiking) with the recoveries obtained when analysing the samples from the metabolism studies (performed with the radio-labelled active substance). Though, in making this comparison, one would be assuming that the total residues are under their conjugated form in those samples. However, it was concluded in the residue section that "based on the available data a reliable factor to describe the ratio between free and conjugated 3-OH-carbofuran cannot be established."	Written procedure This issue is addressed in the conclusion and is inline with carbofuran.

2. Mammalian toxicology

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
	Section 2 Open points: ***0*** Points for clarification: ***0*** Data gaps: ***0***			Section 2 Open points: ***0*** Points for clarification: ***0*** Data gaps: ***0***
	New open point: 2.1 identified at PRAPeR TC 21 meeting on residues: It is necessary to check if NDBA is not formed in the environment and present in the ground water. RMS has to check if this point has been considered by the tox and fate section for the potential leaching of NDBA in the ground water. (refer to open points 3.2 and 3.7)		**RMS September 2009 (after TC 21):** PEC gw DBA=0 µg/L in all scenarios. There is no data on the PEC gw NDBA in the e-fate section. However, considering the absence of DBA in ground water and the non polar character of the NDBA molecule, it is assumed that the potential leaching of NDBA in groundwater is not relevant. The tox meeting also considered the question and concluded this point as not an area of concern.	Written procedure: This question has been considered in the additional report; no concern has been identified over NDBA, although NDBA is a relevant impurity.

3. Residues

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
	Section 3 Open points: ***6*** Points for clarification: ***0*** Data gaps: ***3***			Section 3 Open points: ***3*** Points for clarification: ***0*** Data gaps: ***4***
	Open point: 0.1 The new template for the list of end points should be used. See reporting table 0(1)		**RMS September 2009 (after TC 21):** The template (EPCO manual –Part E, No E 4, revision 5) was included and fulfilled according to the decisions of the PRAPeR TC 21 meeting).	PRAPeR TC 21 (14 September 2009): Open point still open. Moreover, the list of endpoints should be updated in accordance with the decisions of the PRAPeR TC 21 meeting. Written procedure Open point fulfilled
	Open point: 3.1 RMS to check the raw data in the goat metabolism study in terms of the respective ratio between free and conjugated Carbofuran and 3-OH-carbofuran See reporting table 3(3)	**NOT:** see comment data gap 3.1	**RMS 08.09:** In the goat metabolism study (Curry S.J. and Weintraub R.A., 1996), the extraction procedure showed that acid hydrolysis step was applied on the aqueous soluble phases. Enzymatic digestion and acid hydrolysis were also performed on the non extractable radioactive residues in order to release additional radioactivity. Muscle and fat were not further analysed for metabolites identification due to the very low levels of recovered residues (0.006 and 0.0105 mg/kg, respectively). Phenyl label treated milk, liver and	PRAPeR TC 21 (14 September 2009): Open point fulfilled. Based on the available data a reliable factor to describe the ratio between free and conjugated 3-OH-carbofuran cannot be established. It is therefore recommended to maintain the proposal for inclusion of conjugated 3-OH-carbofuran also in the residue definition for monitoring.

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
			kidney were analysed for metabolites identification. Both in the 3 matrices, Carbosulfan and Carbofuran were not detected or detected at a trace level (0.1-0.2 % of TRR). Based on the reported goat metabolism study in the revised DAR and the detailed extraction procedure outlined in the addendum to the DAR-August 2009, if it is assumed that in liver and kidney, the polar metabolites recovered in the non organo soluble phase are conjugates, a ratio between free and conjugated 3-OH-carbofuran can be approximately derived. A clear picture is given based on the available goat metabolism study ((Hoffman and Robinson, 1994a) reported in the JMPR 1997 report-see Addendum to the DAR-August 2009. Indeed, in this study, Carbofuran was detected at a trace level in milk only. 3-OH-carbofuran was recovered at a level around 10 % of TRR in milk and kidney and at a level of 4% TRR in liver. The information was given that in milk, 10 % of the TRR occurred as free 3-OH-carbofuran only. In liver, the 4 % of the total residues included 2.2% conjugated 3-OH-carbofuran, released by protease	

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
			treatment. While in kidney, 11 % of the total residues included 8.2% conjugated 3-OH-carbofuran, released by protease treatment. There is no indication whether the aqueous fractions resulting from the mild/strong acid hydrolysis were further characterized.	
	Data gap: 3.1 The available method of analysis for monitoring to determine the residues of 3-OH-carbofuran and its conjugates in animal matrices includes a hydrolysis step. The efficiency of this step to release the 3-OH-carbofuran conjugates should be addressed. See reporting table 3(3)	**NOT:** In Curry and Weintraub, 1996, acid hydrolysis extraction was used as the last step to realese bound residue that could not be released by other means. The results indicate that less than 13% of the TRR remained unextracted. This indicates this high efficientcy of the acid hydrolysis to release conjugated residue.	**RMS 08.09:** RMS agrees that the efficiency of the hydrolysis step to release the 3-OH-carbofuran conjugates should be addressed. It is the RMS understanding that the extraction procedures used in the livestock metabolism studies should be compared to the extraction step in the analytical method for monitoring to determine the residues of 3-OH-carbofuran and its conjugates in animal matrices (see Vol 3 B(5)-&B.5.2.2) in order to determine the efficiency of the acid hydrolysis step. Based on the available goat metabolism study reported in the revised DAR, April 2009, -Milk/liver: Enzymatic hydrolysis with β-glucuronidase. No acid hydrolysis step. -Liver NER/kidney/kidney NER:	PRAPeR TC 21 (14 September 2009): Data gap open. Requirement is referred to section 1 on Phys-Chem. properties.

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			Enzymatic digestion (pronase-E) and acid hydrolysis steps are combined. RMS proposes to discuss a general approach to define the efficiency of the hydrolysis step of an analytical method both in plants and animal matrices since a spiking with conjugated 3-OH-carbofuran standards to determine the recoveries is not possible and considering also that there are different types of conjugates (proteins/sulphates conjugates) recovered in animal matrices that might be quite resistant to acid hydrolysis.	
	Open point: 3.2 Experts to discuss whether it would be necessary to consider the following issue for the consumer risk assessment of carbosulfan: DBA is certainly less toxic than carbosulfan itself, but it may be a precursor of NDBA in acidic conditions and/or at higher temperature, conditions as present under crop processing. See reporting table 3(5)	**NOT:** the crop metabolism study reveals that no DBA must be expected in the sugar beet roots	**RMS 08.09:** For the consumers, no major risk of Dibutylnitrosamine intake is expected from food ingestion. From the metabolism study in sugar beet (Robinson R.A., 1982), where the metabolic profile of the ^{14}C-Dibutylamine moiety was investigated (worst-case foliar application 1 kg a.s./ha, greenhouse conditions), it appeared that no relevant residue level (0.014 mg/kg) was observed in the 30 - day sugar beet root sample. After soil incorporation at similar dose (1.1 kg a.s./ha), the total radioactive residues at harvest (130 days) accounted for 0.02 ppm in both sugar beet leaves and roots, indicating a very low	PRAPeR TC 21 (14 September 2009): Open point fulfilled. Due to the processing conditions during sugar refining it was considered unlikely that NDBA will be present in refined sugar. New open point proposed, see below.

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
			potential exposure of the consumers to DBA residues when consuming sugar beet roots (mainly sugar after crystallization process). Drinking water is not expected to contain Dibutylnitrosamine after Carbosulfan application by soil incorporation since Dibutylamine has no leaching potential into the groundwater. RMS considers that no risk is expected for the consumers to both DBA and DBNA when carbosulfan is applied to the soil.	
	New open point: 3.7 RMS to check if the issue on NDBA has been considered by the tox and fate section (for the potential leaching of NDBA in the ground water).		**RMS September 2009 (after TC 21):** PEC gw DBA=0 µg/L in all scenarios. There is no data on the PEC gw NDBA in the e-fate section. However, considering the absence of DBA in ground water and the non polar character of the NDBA molecule, it is assumed that the potential leaching of NDBA in groundwater is not relevant. The tox meeting also considered the question and concluded this point as not an area of concern.	PRAPeR TC 21 (14 September 2009): Open point open. Written procedure Open point fulfilled
	Open point: 3.3 For a toxicologically relevant compound consumer exposure (amounts occurring) should be considered to conclude	**NOT:** the metabolism studies show that the formation of 3-keto-carbofuran in plants remains one order of manitude lower than carbofuran + 3-OH carbofuran. Furthermore, the residue d-base shows that no residue	**RMS 08.09:** The available plant and animal metabolism studies reported in the revised DAR, April 2009 showed that the metabolite 3-keto-carbofuran is not a relevant metabolite of the total	PRAPeR TC 21 (14 September 2009): Open point fulfilled. The meeting agreed to include 3-keto

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	whether it is relevant for consumer risk assessment. The issue to be discussed by experts. It was agreed in the first peer review on carbofuran that all metabolites with carbamate moiety (including the 3-keto) are toxicologically relevant. The 3-keto-carbofuran is classified with T, R25. Tox data for the metabolite are very limited, however it is very likely that the reference values of carbofuran will cover the toxicity of the metabolite. See reporting table 3(6)	of carbofuran nor 3-OH carbofuran can be quantified at 0.005 mg/kg. Therefore, adding 3-keto-carbofuran to the residue definition would not add any valuable information. Carbosuran and 3-OH-carbofuran are effective tracers that demonstrate the absence of residue at harvest.	residues occurring in the edible parts of the crops or in animal matrices after Carbosulfan soil application. -Sugar beet crop metabolism: 3-keto-carbofuran was recovered at a level of 0.0045 mg/kg in leaf (30 days after application) and at 0.0014 mg/kg in root (60 days after application). -Livestock matrices: 3-keto-carbofuran was recovered at a trace level considering the calculated dietary burden. RMS considers that including this metabolite in the residue definition for risk assessment won't contribute significantly to the toxicological burden.	carbofuran in the residue definition for risk assessment for both plant and animal matrices. Residue definition for risk assessment in plants: 1) Carbosulfan 2) Carbofuran, 3-OH carbofuran and 3-keto-carbofuran, including their conjugates expressed as carbofuran Residue definition for risk assessment in livestock: 1) Carbosulfan 2) 3-OH carbofuran and 3-keto-carbofuran, including their conjugates expressed as carbofuran
	Data gap: 3.2 The efficiency of the hydrolysis step in the analytical method (plant matrices- supervised residue trials and monitoring) to release all the conjugates of carbofuran and 3-OH-carbofuran must be demonstrated See reporting table 3(9)	**NOT:** The acid hydrolysis step was used in all crop metabolism studies in order to realease residue that could not be fully extracted by solvent means. The results show that on the crop samples where parent and early metabolites are expected, the % of TRR extracted is very high and concur with significant findings of carbofuran and 3-OH-carbofuran. This would not be the case if the acid hydrolysis step was unable to eficiently release the	**RMS 08.09:** See data gap 3.1. RMS has some reserve regarding the determination of the efficiency of the hydrolysis step based on the available plant matrices from the metabolism studies. Can we assume that all the residues present in the plant samples at harvest will be under their conjugated form when Carbosulfan is applied at pre-planting ?	PRAPeR TC 21 (14 September 2009): Data gap open. See also data gap 3(1). Written procedure Data gap open.

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
		conjugated carbofuran and 3-OH-carbofuran.	The available data in the Benfuracarb/Carbofuran dossier showed that this was not the case. In the 1997 JMPR evaluation (reported in the Benfuracarb updated addendum to the DAR -January 2009) based on metabolism studies performed on corn, potato and soya plants using soil application, it was shown that carbofuran, 3-keto carbofuran, 3-OH carbofuran and the phenol metabolites and their conjugated forms were present at non negligible levels at longer sampling intervals and at harvest. This point should be discussed further.	
	Open point: 3.4 RMS to check analytical reports of the field trials 'Trial F006 7903/2' and 'Trial F006 7907' (carbosulfan in roots) for validity / acceptability. See reporting table 3(11)	**NOT:** We refer to RMS and notifier comments under point 3(11) of the Reporting tables.	**RMS 08.09:** RMS did not find the original analytical reports. These were asked to the applicant. An additional comment on these reports will be sent before the TC.	PRAPeR TC 21 (14 September 2009): Open point fulfilled. The meeting agreed not to take into account these two trials in the assessment (i.e. trials not acceptable).
	Data gap: 3.3 Data to address residues in rotational crops, in particular further metabolite identification in the edible parts of the rotational crops is required.	**NOT:** We refer to RMS and notifier comments under point 3(15) of the Reporting tables.	**RMS 08.09:** In the PRAPeR Expert Meeting 70 on Carbofuran, it was concluded that more than 10 % of the carbamate residues were expected in soil after 100 days in a number of available studies (considering the total	PRAPeR TC 21 (14 September 2009): Data gap open. Written procedure Data gap open.

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
	See reporting table 3(15)		Carbofuran, 3-OH-carbofuran and 3-keto-carbofuran). A confined rotational crop study was reported in the revised DAR, April 2009. TRR in green parts of the plants after 30 days exceeded 0.01 mg/kg but no data was provided on the nature of the residues. -In a confined Carbofuran rotational crop study (JMPR 1997 report) and reported in the addendum to the DAR-August 2009, Phenyl-^{14}C-Carbofuran was applied directly to the soil at a rate of 3.4 kg a.s./ha. Wheat, soya beans and sugar beet were sown in the treated soil 4 and 12 months after treatment. The phenolic metabolites (3-OH-7-phenol, 3-keto-7-phenol and 7-phenol) were the main degradation products recovered in the rotated crops while the carbamates (carbofuran, 3-OH-carbofuran, 3-keto-carbofuran) constituted less than 10 % of the TRR in any crop sown at 4 and 12 months. However, this study did not address the situation of short plant back intervals. -In the reported plant metabolism studies in the revised DAR, only in sugar beet root and in soya bean plants, the level of the carbamates metabolites was below 10 % of TRR.	

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			In rice and corn grains, no metabolite identification was investigated. RMS is of the opinion that the approach as suggested by the applicant to consider 10 % TRR as carbamates in the rotational crops for the consumer risk assessment calculation is border line. Considering the extremely low toxicological reference values of Carbofuran and 3-OH-carbofuran, the trigger value of 0.01 mg/kg is not applicable and further metabolite identification in the edible parts of the rotational crops is necessary. Nevertheless, it has to be noted that RMS performed a consumer risk assessment including the TRR values from the rotational crops (see Carbofuran Addendum –April 2009). Using such values, the ARfD was significantly exceeded for leafy and root crops but not in succeeding cereals crops. A proposal to overcome the problem might be to restrict the crop rotation to cereals.	
	Open point: 3.5 Experts may consider whether the approach as suggested by the applicant is justified to consider 10% TRR in rotational crops in the	**NOT:** We refer to RMS and notifier comments under point 3(15) of the Reporting tables.	**RMS 08.09:** See Data gap: 3.3	PRAPeR TC 21 (14 September 2009): Open point fulfilled. The default 10% TRR for carbamate

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
	consumer risk assessment See reporting table 3(15)			compounds in leafy, root and oilseed crops is not supported by the available studies.
	Open point: 3.6 Combined risk assessment should be conducted considering the same mode of action (cholinesterase inhibition) but the different tox potency of carbofuran (plus 3-OH carbofuran) and carbosulfan. See reporting table 3(18)		**RMS 08.09:** Under point B.7.11 in the revised DAR, April 2009, a combined dietary intake risk assessment was performed using the sum of the LoQs for Carbofuran and 3-OH-carbofuran, respectively. Carbosulfan was not included in this risk assessment calculation since the metabolism data showed that it was hydrolysed directly into carbofuran and Dibutylamine.	PRAPeR TC 21 (14 September 2009): Open point fulfilled. New open point proposed, see below.
	New open point: 3.8 raised by experts during PRAPeR TC 21 meeting: RMS to compile an overview table with the levels of the individual carbamate metabolites to be considered in the risk assessment. It should be checked whether sufficient data are available on 3-keto carbofuran to be used in the consumer RA.		**RMS September 2009 (after TC 21):** RMS compiled the recovered levels of carbofuran, 3-OH-carbofuran and 3-keto-carbofuran metabolites in both plant and animal matrices and was provided to EFSA by e-mail after the TC 21. The data were considered as sufficient in sugar beet (although the recovered levels of the carbamates in sugar beet roots/leaves were not provided at harvest) and soybean after soil application. There is no data on the level of carbamates metabolites in corn and rice grain. In poultry and ruminants matrices, 3-keto-carbofuran was recovered at non detectable levels.	PRAPeR TC 21 (14 September 2009): Open point open. Written procedure An overview table was compiled by RMS. It has to be discussed and concluded whether the available data nd information is sufficient to derive reliable factors to be used in the consumer risk assessment Open point open.

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
	New open point: 3.9 raised by experts during PRAPeR TC 21 meeting: The presumed residue level of carbamate residues of "zero" (PRAPeR 70) in refined sugar has to be reconsidered. Is for sugar the use of a "zero" value for the risk assessment really justifed?		**RMS September 2009 (after TC 21):** RMS agrees.	PRAPeR TC 21 (14 September 2009): Open point fulfilled. New data gap proposed, see below.
	New data gap: 3.4 identified at PRAPeR TC 21 meeting: Applicant to address the residue levels of the carbamate metabolites in sugar.		**RMS September 2009 (after TC 21):** RMS agrees.	PRAPeR TC 21 (14 September 2009): Data gap open. Written procedure Data gap open.

4. Environmental fate and behaviour

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
	Section 4 Open points: ***3*** Points for clarification:- Data gaps:***2***			Section 4 Open points: ~~***4***~~ ***1*** Points for clarification:- Data gaps:~~***2***~~ ***1***
	Open point 4.1: RMS to clarify whether significant volatility could happen in this study and whether the results of this study can be regarded as DegT50s or DisT50 values. See reporting table 4(6) Note: see moreover the notes in comment 4(7) below	**NOT:** Whiles DBA has a relatively high vapor pressuer (0.2 Pa), it also has a very high water solubility (4 g/l). The Henry constant of DBA is therefore low (0.0065 $Pa.m^3.mol^{-1}$) indicating low potential for volatility from the environment. Furthermore, its Koc of 409 ml/g indicates that it binds to the organic matter of the soil more than it solubilises in the water phase, further decreasing the portion of DBA available for volatilisation.	**RMS 08.2009:** No further comments	September 2009 Open point open Issue was not sufficiently clarified. EFSA noted this issue in the conclusion.
	Data gap 4.1: for derivation of the DT50 values of dibutylamine (study by Völkel, 2007) based on the recommendations of FOCUS kinetic guidance and calculate the geomean of the new values. Notes: EFSA notes that due to the non-persistence of this metabolite in soil, even if the new geomean (expected to be longer than the existing one) was used, no significant	**NOT:** We agree with EFSA and RMS that DBA is not persistent and recalculation of its DT50 according to the Focus Kinetic requierement will not impact the Risk asessment.	**RMS 08.2009:** No further comments	September 2009 Data gap open

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
	increase would be expected in the PEC values (PECgw, PECsw, PECsed). With the available calculations, which used a wrongly calculated geomean value of the set of uncertain DT_{50} (might be $DisT_{50}$, see comment in 4(6) above), the risk to groundwater or water living organisms is low. See reporting table 4(7)			
	Open point 4.2: EFSA to highlight in the EFSA conclusion that based on the tentative structure of the major unidentified metabolite in the W/S study (unknown metabolite 3) was regarded as an intermediate transformation product between carbosulfan and carbofuran. Due to rapid degradation of carbosulfan in soil, this compound might not reach the SW as far as the application method is soil incorporation (furrow application). Note that as a consequence,	**NOT**: we agree.	**RMS 08.2009:** No further comments	September 2009 Open point fulfilled.

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	the exposure and risk assessments for this unidentified compound are deemed as not necessary at EU level. See repoting table 4(29)			
	Open point 4.3: EFSA to highlight in the EFSA conclusion that the PECsw/sed calculations are valid only when the granules are applied into the furrows, as indicated in the GAP table. See reporting table 4(34)	**NOT:** We agree.	**RMS 08.2009:** No further comments	September 2009 Open point fulfilled.
	Data gap 4.2: for Atkinson calculation for the parent molecule. Note: regarding the applied for representative use of the PPP, the data gap might be regarded as not essential for the finalisation of the evaluation of carbosulfan at EU level. See reporting table 4(38)	**NOT:** We agree with EFSA and RMS that the Atkinson calculation is not essential for the Risk assessment of the prososed safe use.	**RMS 08.2009:** No further comments	September 2009 Data gap open October 2009 RMS clarified in their comment to the draft EFSA conclusion that the requested information is included in the B.2 chapter of the DAR. Data gap fulfilled.
	New open point: 4.4 identified at PRAPeR TC 21 meeting			

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	on residues: It is necessary to check if NDBA is not formed in the environment and present in the ground water. RMS has to check if this point has been considered by the tox and fate section for the potential leaching of NDBA in the ground water. (refer to open points 3.2 and 3.7)			September 2009 Open point fulfilled. EFSA fate and behaviour experts considered this point and concluded that NDBA was unlikely to be present in groundwater. Text to this effect was added to the conclusion in section 3.1.1.

5. Ecotoxicology

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
	Section 5 Open points: ***13*** Points for clarification: ***0*** Data gaps: ***1***			Section 5 Open points: ***8*** Points for clarification: ***0*** Data gaps: ***1***
	Open point: 0.1 The new template for the list of end points should be used. See reporting table 0(1)			PRAPeR TC 22 (14 September 2009): Open point closed.
	Open point: 5.1 RMS to amend in the DAR and the LoEP the long-term endpoint for the metabolite carbofuran in accordance with the outcome of the expert discussion on carbofuran (PRAPeR 68 in May 2009). (The LC10 (14d) = 0.64 was suggested to be used in the risk assessment together with an increased safety factor of 10). See reporting table 5(1)	**NOT:** We agree with the selection of the LC10 (14d) of 0.64 mg/kg bw/day for the metabolite carbofuran. However, we stress that the use of the LC10 in itself contains already a safety factor. Besides, the residue declines rapidly, so that a continued exposure of 14 days represents a worst case scenario. Therefore increasing the Safety factor to 10 in the Risk assessment is very conservative.	**RMS (August 2009):** The updated DAR August 2009 (p. 94; p. 99-101) and the List of endpoints have been revised.	PRAPeR TC 22 (14 September 2009): Open point open. RMS to amend the LoEP with substance (carbosulfan/carbofuran) details. Written procedure: Open point still open.
	Open point: 5.2 RMS to indicate in the LoEP that the PD/PT values suggested in the refined risk assessment are based on	**NOT:** A PT of 1 represents a worst case estimate rather than a reasonable estimate for the long term risk assessment, since it is not possible to use a higher value. Residues in insects	**RMS (August 2009):** The updated DAR August 2009 (p. 99) and the List of endpoints has been revised. In principle, we agree with the notifier that PT of 1 overestimates the	PRAPeR TC 22 (14 September 2009): Open point open.

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	general considerations of diet composition and that they are not appropriate to be used in a quantitative risk assessment. See reporting table 5(2)	have been shown to decline very rapidly with time. Therefore, a PT value of 1 overestimates the number of contaminated insects likely to be found. With regard to moribund insects: (1) the non-target arthropod field trials show a rapid recovery of the surface dwelling insects (that will be part of the diet) indicating that toxic effects on this important guild of insects which make up the diet are not long lasting, i.e. only short-term duration; and (ii) as foliage density increases then any affected insects would become increasingly difficult to find in the crop. Both observations add weight to the argument that the portion of the diet from the treated area is only likely to be contaminated for a short period of time.	risk. However, a quantification of the PT value is not possible based on the available information.	RMS to add footnote to the LoEP that the LD50 5th-percentile (5.32 mg a.s/kg bw) has been used in the risk assessment. Written procedure: Open point still open.
	Open point: 5.3 RMS to update the evaluation of the residue trial with insects and earthworms as discussed in the expert meeting (PRAPeR 68, May 2009) in the context of the refined risk assessment for carbofuran. See reporting table 5(3)	**NOT:** we agree However note that 3-OH-carbofuran was not measured in these residue trials. However, as highlighted in the Environmental Fate Section of the DAR, 3-OH-carbofuran is a minor and transient metabolite in soil. Therefore, the contribution of 3-OH to the residue in earthworms and arthropods is expected to be modest. This conclusion is confirmed in practice by	**RMS (August 2009):** The residue trials in both dossiers are not the same. In the carbofuran DAR, residue trials were conducted with carbofuran; in the carbosulfan DAR, residue trials were conducted with carbosulfan. The residue trial (carbosulfan) in sugar beet seedlings was made at both application rates (100 and 750 g a.s./ha) and measurements of	PRAPeR TC 22 (14 September 2009): Open point open. RMS to update the DAR to explain that the residue studies with earthworms were not used in the risk assessment and why the studies were not accepted. RMS furthermore to update the DAR (Table B.9.1.12-13) to leave out the recommendation on residue measurement

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
		the earthworm/insect residue trials that were reported in the benfuracarb DAR, where 3-OH-carbofuran was measured and found to contribute only modestly to the overall residue.	carbosulfan, carbofuran and 3-OH-carbofuran were made. The residue trial (carbosulfan) in beetles and earthworms was made only at the application rate of 750 g a.s./ha and measurements of carbosulfan and carbofuran were made. (no measurements of 3-OH-carbofuran). However, the same shortcomings as in the carbofuran dossier apply leading to an underestimation of the residues (p. 31 of updated DAR August 2009). The notifier has also submitted an "Updated and comparative risk assessment of the carbosulfan use on sugar beet at 100 g ai/ha versus 750 g ai/ha." RMS disagrees with the statement of the notifier that the residues will decline 7.5 times for the lower application rate of 100 g a.s./ha, compared to the applied 750 g a.s./ha. This extrapolation should be substantiated with data, e.g. residue trials conducted at 100 g a.s./ha. A copy of the statement of the notifier on the lowered dose rate of 100 g a.s./ha is included in the addendum (p. 10-15). RMS maintains its position on this issue.	after BBCH 12. Written procedure: Open point closed.
	Open point: 5.4	**NOT:** We refer to our comment under	**RMS (August 2009):**	PRAPeR TC 22 (14 September 2009):

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
	RMS to update in an addendum to the DAR and in the LoEP the risk assessment for mammals and carbofuran with the NOAEL of 0.1 mg carbofuran/kg bw/d. See reporting table 5(5)	point 5(5) of the Reporting Tables.	The updated DAR August 2009 (p. 163-172) and the List of Endpoints have been revised.	Open point open. RMS to indicate the origin of the medium-term mammal endpoint (28 day NOAEL = 2.2 mg a.s./kg bw/day) in the LoEP. Written procedure: Open point still open.
	Open point: 5.5 RMS to indicate in an addendum to the DAR and in the LoEP that the suggested refinement of PD for hare and shrew are uncertain since they were not derived from targeted studies in sugarbeet fields. See reporting table 5(6)		**RMS (August 2009):** The updated DAR August 2009 (p. 167 and 172) and the List of Endpoints have been revised.	PRAPeR TC 22 (14 September 2009): Open point fulfilled.
	Open point: 5.6 MSs to discuss in an expert meeting the probabilistic risk assessement for birds from uptake of granules as grit. See reporting table 5(13)	**NOT:** the proposed PRA meets the conclusion of the RA for granule intake as according to the EPPO subscheme. Indeed, both evaluations independently conclude that the chance for a bird to intake a few numbers of granules is very low. Hence to risk to birds is acceptable.	**RMS (August 2009):** The RMS has the same reservations for the probabilistic risk assessment with Marshal 10G (carbosulfan) as for Furadan 5G (carbofuran). The PRA for carbofuran was discussed in PRAPeR 68 and the meeting agreed with the RMS that too many uncertainties remained. For the PRA of carbosulfan, the RMS	PRAPeR TC 22 (14 September 2009): Open point open. EFSA to highlight in the conclusion that the risk is potentially high and precautions are needed to avoid spill of granules. Written procedure: This was highlighted in the EFSA

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			recalculated the annual mortality for a period of 2 weeks and found that the effect of carbosulfan could be equal to the normal mortality during 2 weeks (estimated exposure period to carbosulfan). Furthermore, it is unclear what caused the annual mortality. The timing of application should be compared to the breeding season. The current PRA approach considers population effects, but should not individual deaths be of concern also? What is the protection goal? There might be a cumulative effect, while the PRA now only takes 1 visit per bird into account. The PRA is based on HD_5 = 3.179 mg a.s./kg b.w./day, with an uncertainty factor of 1 (no margin of safety even if an endpoint based on mortality is used).	conclusion.
	Open point: 5.7 MSs to discuss in an expert meeting the applicability of the avoidance study with house sparrow and granules. See reporting table 5(16)	**NOT:** The initial assessment indicates that 11 carbofuran granules are sufficient to kill a small bird. Since sufficient granules to kill a bird were potentially available, then the results suggest that either (1) the birds quickly metabolised carbosulfan and suffered no harm, or most likely (2) the birds do not take the granule because, it is proposed, they do not resemble grit. The latter reduces exposure and is consistent with the results of the EPPO	**RMS (August 2009):** The conclusion of the RMS on the acceptance study is on p. 19 of the updated DAR August 2009. RMS considers that the results of this study cannot be easily extrapolated to the actual field situation.	PRAPeR TC 22 (14 September 2009): Open point fulfilled. The cage study was not considered a worst case situation and was not accepted.

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
		scheme risk assessment. Furthermore the notifier believes that the house sparrow is an appropriate species of choice for this study because the granule size range overlaps the grit size range for the species of interest. Best and Gionfriddo (1991) reported the mean gizzard grit size for house sparrows (*Passer domesticus*) to be 0.7 mm (range of 0.25 to 1.6 mm). Marshal® 10G granule size range is 0.3 to 1.0 mm (de Ryckel, 1999a), which overlaps the range for house sparrow. With house sparrows being a readily available granivore that has been used in laboratory settings, it was the most reliable species to evaluate the potential avoidance of Marshal granules to small granivores that would seek grit particles of the same size.		
	Open point: 5.8 MSs to discuss in an expert meeting the refined acute risk assessment based on body burden modelling according to the PPR opinion on pirimicarb.	**NOT:** the pirimicarb approach has the merit to consider the rapid metabolisation and the reversibility of the AChE inhibition – which are inherent properties of carbosulfan and carbofuran.	**RMS (August 2009):** The PPR panel approach for assessing pirimicarb was also used for the carbofuran dossier and discussed during PRAPeR 68. The parameters used in the carbosulfan dossier are the same as in the carbofuran dossier, except for the residues in arthropods	PRAPeR TC 22 (14 September 2009): Open point fulfilled. The pirimicarb approach was not considered valid for carbosulfan.

<table>
<tr><th>No.</th><th>Column A
Conclusions from the Reporting Table</th><th>Column B
Comments from the notifier / applicant</th><th>Column C
Rapporteur Member State comments on the notifier / applicant comments</th><th>Column D
Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure</th></tr>
<tr><td></td><td>See reporting table 5(21)</td><td></td><td>and sugar beet seedlings. The conclusion of the PRAPeR 68 meeting was :
For the yellow wagtail: $T_{1/2}$, AVT and AVD were not accepted; for woodpigeon: FPM, $T_{1/2}$, AVT and AVD were not accepted. The meeting concluded that, because of all the uncertainties identified, the pirimicarb-approach is not accepted.</td><td></td></tr>
<tr><td></td><td>Open point: 5.9
RMS to update the aquatic risk assessment with the new PECsw values.

See reporting table 5(29)</td><td>NOT: New highest PECsw at max application rate of 750 g ai/ha for carbosulfan and its metabolite, carbofuran, are 0.0 and 0.0658 ug/L for the Run off and drainage respectively, in all simulated scenarios using FOCUS Step 3.
The revised aquatic TERs based on toxicity endpoint reported in the carbofuran Dossier are in the Table below.
<table>
<tr><td>Lepomis macrochirus</td><td>96 h</td><td>180 ug/L</td><td>2736</td></tr>
<tr><td>Cyprinodon variegatus</td><td>35 d</td><td>6 ug/L</td><td>91</td></tr>
<tr><td>Daphnia magn</td><td>48 h</td><td>2.05 ug/L</td><td>31</td></tr>
</table></td><td>RMS (August 2009):
The revised TER calculations (750 g a.s./ha) are presented in an addendum (p. 2-7) and the List of Endpoints has been revised.</td><td>PRAPeR TC 22 (14 September 2009):

Open point open.

RMS to update Chironomus endpoint as mean measured value in the LOEP.

Written procedure:
Open point fulfilled.</td></tr>
</table>

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure

a				
Ceriodaphnia dubia	7 d	0.16 ug/L	2.4	
Chironomus riparius	28 d	4.0 ug/L	61	
Pseudokirchneriella subcapitata	72 h	6500 ug/L	98784	

All of the TERs represent an acceptable risk, except for *Ceriodaphnia dubia.*

Open point: 5.10

MSs to discuss in an expert meeting whether the aquatic risk assessment should be based on the NOAEC of 0.4 µg a.s./L together with an uncertainty factor of 4. The resulting EAC of 0.1 µg a.s./L would drive the aquatic risk assessment.

RMS to update the LoEP accordingly.

NOT: We agree.

RMS (August 2009):

The updated DAR August 2009 (p. 140, 144) and the List of Endpoints have been revised.

The results of the mesocosm study can be used to refine the risk assessment for aquatic invertebrates :

NOAEC = 0.4 µg carbosulfan/L

EAC = 0.1 µg carbosulfan/L

Complete recovery of the population of *Ceriodaphnia* occurred after 40 days at 0.4 µg carbosulfan/L.

The refined risk assessment for

PRAPeR TC 22 (14 September 2009):

Open point fulfilled.

MS experts agreed on the RAC of 0.1 µg a.s./L based on the mesocosm study available.

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	See reporting table 5(30)		*Daphnia magna* and *Ceriodaphnia dubia* is presented in an addendum (p. 7) and in the List of Endpoints.	
	Open point: 5.11 MSs to discuss in an expert meeting whether new studies with fish are necessary. See reporting table 5(32)	**NOT:** We refer to RMS and notifier comments under point 5(32) of the Reporting tables.	**RMS (August 2009):** Only the acute toxicity studies with carbosulfan were considered of low quality, not the studies with the metabolites. We agree with the view of the notifier. **NOT (reporting table):** A sufficient number of studies are available to adequately determine risk to aquatic species including fish and invertebrates. The current risk assessment passes at Step 3 and generation of new data would not change the overall risk conclusions derived in the surface water risk assessments.	PRAPeR TC 22 (14 September 2009): Open point open. RMS to add the following footnote in the LOEP “no analytical measurements were available which add some uncertainty”. Written procedure: Open point still open.
	Open point: 5.12 MSs to discuss in an expert meeting whether new studies with daphnids are necessary. See reporting table 5(33)	**NOT:** We refer to RMS and notifier comments under point 5(33) of the Reporting tables.	**RMS (August 2009):** Only the acute toxicity studies with carbosulfan were considered of low quality, not the studies with the metabolites. We agree with the view of the notifier. **NOT (reporting table):** See comment in 5(32).	PRAPeR TC 22 (14 September 2009): Open point open. RMS to add the following footnote in the LOEP “no analytical measurments were available which provide some uncertainty”. Written procedure: Open point fulfilled.
	Data gap: 5.1 Applicant to submit the study	**NOT:** Addressed. This publication has been submitted to RMS in the	**RMS (August 2009):** The notifier submitted the publication	PRAPeR TC 22 (14 September 2009):

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	of Broadbent and Tomlin (1982). Please note that according to regulation 1095/2007 no new studies can be taken into account in the peer review. Therefore this point was identified as a formal data gap. See reporting table 5(36)	meanwhile.	and the RMS has evaluated this in an addendum (p. 8-9). The RMS has reservations towards this study due to several shortcomings (low number of earthworms found, measurements after 22 weeks when residues had fallen to 0 mg/kg). Therefore, based on this publication, RMS cannot conclude on the comparison of exposure via in-furrow or via broadcast application.	Data gap open.
	Open point: 5.13 RMS to correct in the LoEP the endpoints for *Hypoaspis* and *Folsomia* (they are inverted). See reporting table 5(37)		**RMS (August 2009):** The List of Endpoints has been revised.	PRAPeR TC 22 (14 September 2009): Open point fulfilled.