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2. Mammalian toxicology

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations PRAPeR Expert Meeting / Conclusions of the Evaluation Meeting
	Section 2 Open points: ***4*** Points for clarification: ***0*** Data gaps: ***0***			Section 2 Open points: ***0*** Points for clarification: ***0*** Data gaps: ***0***
	Open point: 2.1 RMS to transfer the detailed evaluation of the new 60-day gavage study in rat and the new 10-week dietary study in rat from the carbofuran dossier to an addendum to the benfuracarb resubmission dossier to be discussed in an expert's meeting. See reporting table: 2(1)	Applicant: no comment. Action for RMS.	**RMS 01.2009:** The study was fully evaluated at the occasion of the resubmission of Carbofuran, and RMS refers to this DAR. In summary, it was concluded that in the new study, slight testicular effects were observed at the dietary top dose (180 mkd). In the gavage study, no histopathological effects were observed at 0.8 mg/kg b.w.. The effects were considered insufficient to support classification for reprotoxicity. The outcome of the study was without effect on the determination of the reference doses. See addendum.	PRAPeR TC 4 (13 January 2009) In the 60-day, gavage part of the rat study with carbofuran, the agreed NOAEL is 0.2 mg/kg bw/day; In the 10-week dietary administration part of the study, the agreed NOAEL is 3 mg/kg bw/day. No classification is proposed for reproductive toxicity. Open point fulfilled.
	Open point: 2.2 As the new rat acute neurotoxicity studies on carbofuran appear to present more critical results, RMS to present its assessment in an addendum to the resubmission report of benfuracarb.	Applicant: We were informed by the RMS that the safety factor used to derive the ADI/ARfD for carbofuran should still be discussed between experts. We refer to the discrepancy between the proposed safety factor by the JMPR (October 2008) and safety factor used by the RMS. The applicant supports the JMPR proposed ADI/ARfD	**RMS 01.2009:** RMS refers to Addendum. In short, the ARfD and the ADI were lowered to 0.00015 mg/kg b.w./d, and the AOEL to 0.0003 mg/kg b.w./d.. The relevant NOAEL's were based upon significant (³ 20%) decreases of brain AChE after single administration. It is of note that the CF notifier disagreed with the	PRAPeR TC 4 (13 January 2009) The new acute neurotoxicity study in rat with carbofuran resulted in a LOAEL of 0.03 mg/kg bw in pups (from which a NOAEL of 0.015 mg/kg bw is estimated); In adults the NOAEL is 0.03 mg/kg bw. Open point fulfilled.

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	See reporting table: 2(2)	of 0.001 mg/kg.	proposed pup LOAEL and with the AF of 200 to derive the ARfD.	
	Open point: 2.3 Pending on the outcome of the environmental fate and behaviour section discussion, MSs to discuss genotoxicity of carbofuran's metabolite 3-OH in an expert's meeting. See reporting table: 2(3)	Applicant: 3-OH-carbofuran dose not leach to groundwater (all FOCUS PECgw calculations <0.001 µg/L)	**RMS 01.2009:** The metabolite is of no environmental relevance.	PRAPeR TC 4 (13 January 2009) Open point fulfilled.
	Open point: 2.4 MSs to discuss the reference values (ADI and ARfD) of carbofuran in an expert's meeting. See reporting table: 2(4)	Applicant: see open point 2.2 above.	**RMS 01.2009:** Agreed to discuss the ADI and the ARfD.	PRAPeR TC 4 (13 January 2009) The ADI for carbofuran is 0.00015 mg/kg bw/day. The ARfD for carbofuran is 0.00015 mg/kg bw. Open point fulfilled

3. Residues

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations PRAPeR Expert Meeting / Conclusions of the Evaluation Meeting
	Section 3 Open points: ***3*** Points for clarification: ***0*** Data gaps: ***0***			Section 3 Open points: ***1*** Points for clarification: ***0*** Data gaps: ***2***
	Open point: 3.1 A new data requirement to address brassica metabolism was agreed in EPCO 34. Now, that new data in sugar beet and brassica is available, a re-discussion by experts is suggested to agree whether the data available is sufficient to establish a final residue definition in brassica crops. See reporting table: 3(2)	Applicant: Indeed a new data requirement was identified by EPCO meeting 34. The new requirement was that additional information on metabolite fraction T1 was required. This information was submitted by the applicant as part of the resubmission dossier and evaluated by the RMS in the additional report. See also the comment of the RMS in the reporting table 3(5).	**RMS 01.2009:** RMS agrees to discuss the metabolism and the final residue definition in brassica crops (Head and flowering/leafy brassica) with reference to the open points 3(2), 3(3), 3(4), 3(5) and 3(6) in the reporting tables. Open points 3(2), 3(3) and 3(6) were also discussed in the Addendum to the DAR-B(7)-(January 2009). **RMS 01.09 (after PRAPeR TC 5):** RMS agrees with the new residue definition for the risk assessment as Benfuracarb; and Carbofuran + 3-OH-carbofuran, both free and conjugated expressed as carbofuran.	PRAPeR TC 5 (13 January 2009) Open point fulfilled. Taking into account the metabolism studies in the DAR and the 1997 JMPR evaluation the meeting agreed a new residue definition for risk assessment.
	Open point: 3.2 It should be agreed by experts whether the decision of EPCO 34 for requiring a full	Applicant: please refer to the reporting table for our position.	**RMS 01.2009:** RMS agrees to discuss this point. See also open points 3(7) and 3(8) of	PRAPeR TC 5 (13 January 2009) Open point fulfilled. New data gap proposed, see below.

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	database should no longer be applicable, based on the case made by the applicant in column 3 of the reporting table See reporting table: 3(9)		the reporting tables and discussed in the Addendum to the DAR-B(7)-(January 2009).	
	New data gap: 3.1 Identified at PRAPeR TC 5 meeting. Residue trials data in head brassica, flowering brassica and leafy brassica in compliance with the new residue definition for risk assessment have to be submitted. If, in the light of the acute risk assessment for flowering and leafy brassica, the applicant decided to only continue with the use on head brassica, a full data set for head cabbage in compliance with the new residue definition for risk assessment has to be submitted (8 northern and 4 southern trials).		**RMS 01.09 (after PRAPeR TC 5):** -RMS considers that it makes no sense to request new trials on flowering and leafy brassica in compliance with the new residue definition for risk assessment if it is not possible to lower the Limit of Quantification of the analytical method for the determination of both carbofuran and 3-OH-carbofuran in the light of the acute exposure calculations made for these crops (Dietary intake risk assessment in the addendum to the DAR – January 2009). Moreover, as mentioned by RMS during the teleconference, lowering further the LOQ of the analytical method is not realistic on an analytical point of view. -RMS specifies that the current variability factor for head lettuce and head cabbage is 3 (JMPR report 2002). The acute dietary intake for head cabbage is borderline, the conjugates not yet included, (95% of the ARfD),	PRAPeR TC 5 (13 January 2009) Data gap open.

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			considering the variability factor of 3 and the total LOQ of 0.0045 mg/kg for carbofuran and 3-OH-carbofuran. -RMS disagrees on the request made by the meeting for conducting trials on the variability of the residues in head cabbage in order to refine the variability factor (3 or below) because of the no or the very low residue situation observed in head cabbage. In order to proceed further with head cabbage (head brassica), RMS agrees that further residue trials should be conducted in compliance with the new residue definition for risk assessment (4 northern and 2 southern if the situation of no residue is confirmed). In a general way with regard to the supported use on brassica, RMS is convinced that the exceedance of the ARfD for the brassica crops is a "theoretical problem" considering the very low LoQ of the analytical method and the extremely low values of the toxicological end points established for carbofuran.	
	Open point: 3.3 A new data requirement was agreed in EPCO34 to address carbofuran residues in succeeding crops. No new	Applicant: please refer to the reporting table for our position.	**RMS 01.2009:** RMS agrees to discuss this point. At EPCO 34, the data requirement to address the residues of Carbofuran in	PRAPeR TC 5 (13 January 2009) Open point fulfilled.

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	data is available but a case was made on a new DT50 (still to be confirmed by fate and behaviour) and on extrapolation to rotated cereal crops (not assessed in the additional report). A discussion by experts is suggested. See reporting table: 3(10)		succeeding crops referred to the inappropriate DT50 value of 71.9 days for Carbofuran.	
	New data gap: 3.2 Identified at PRAPeR TC 5 meeting. If the new residue data as discussed under open point 3.2 demonstrated that the exposure of the consumer to head cabbage residues would be acceptable, additional rotational crop studies according to the OECD guidelines should be provided.		**RMS 01.09 (after PRAPeR TC 5):** RMS disagrees. RMS considers that the longest DT90 (field) is 91 days for Carbofuran. The 3 relevant metabolites containing the carbamate moiety have DT90 values ranging between 3.3 and 10 days. It is therefore obvious that the DT90 of Carbofuran does not trigger a rotational crop. Nevertheless, potentially adverse data were effectively provided in a confined crop rotation study (JMPR report 1997). Therefore, if the acute exposure of the consumers to the head cabbage residues is acceptable, RMS proposes to waive a new rotational crop study considering the available soil	PRAPeR TC 5 (13 January 2009) Data gap open.

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			application metabolism studies performed with carbofuran in primary crops (see DAR carbofuran, 2004).	
	New open point: 3.4 Identified at PRAPeR TC 5 meeting. LoEP to be amended in order to reflect the outcome of the discussion.		**RMS 01.09 (after PRAPeR TC 5):** The LoEPs was amended accordingly.	PRAPeR TC 5 (13 January 2009) Open point open.

4. Environmental fate and behaviour

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	Section 4 Open points: ***10*** Points for clarification: ***1*** Data gaps: ***0***			Section 4 Open points: ***3*** Points for clarification: ***0*** Data gaps: ***0***
	Open point: 4.1 RMS to correct the List of End Points. 40% MWHC of the clay loam soil should be changed to 45% or 61%, the one which is more realistic/was measured in the same laboratory. See reporting table: 4(3)	Applicant: no comment. Action for RMS.	The listing of endpoints has been modified.	PRAPeR 62 (13 – 15 January 2009) Open point fulfilled.
	Open point: 4.2 RMS to update the list of endpoints with the values listed in column 3 of the reporting table that are not in brackets. See reporting table: 4(6)	Applicant: no comment. Action for RMS.	Differences because of rounding. The listing of endpoints 0has been modified.	PRAPeR 62 (13 – 15 January 2009) Open point fulfilled.
	Open point: 4.3 RMS to provide clear, independent summaries and assessments of the studies	Applicant: no comment. Action for RMS.	In order to ease the work of the experts participating to the PRAPER meeting, the assessment of the 2 studies has been transferred from the DAR	PRAPeR 62 (13 – 15 January 2009) Open point fulfilled. New open point proposed, see below.

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations PRAPeR Expert Meeting / Conclusions of the evaluation group
	Saxena *et al*., 1994 (laboratory degradation study in acid soil and alkali soil) and Schocken, 1989 in an addendum to support discussion of a meeting of experts. Information on soil pH, soil moisture content and microbial activity to be clearly presented. See reporting table: 4(8)		carbofuran in an Addendum	
	New open point: 4.11 Identified at PRAPeR 62 meeting. RMS to update the list of endpoints lab DT50 values in line with the discussion table. Non linear fitting of the degradation of carbofuran from the studies by Saxena, 1994 and Schocken, 1989 and the appropriate normalization of the resulting DT50 values should be included in an addendum. FOMC fitting of the degradation of benfuracarb from the study by Noorloos, B. van; Brands, C. and the			PRAPeR 62 (13 – 15 January 2009) Open point open.

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	appropriate normalization of the resulting DT50 values should be included in an addendum.			
	Open point: 4.4 MS to discuss in a meeting of experts if there is any need to require additional data on carbofuran degradation in soil at 10°C or whether the use of a standard Q10 is supported. See reporting table: 4(11)	Applicant: please refer to our argumentation in the reporting table	The following new study has been submitted and evaluated in the DAR: Determination of the aerobic degradation rate of benfuracarb in alkaline soil at 10ºC and 20ºC. (Noorloos, B. van; Brands, C.)	PRAPeR 62 (13 – 15 January 2009) Open point fulfilled.
	Open point: 4.5 a) RMS to provide a clear summary and assessment of the study by Taylor and Houseman, 1982 in an addendum to support discussion of a meeting of experts on the validity of this study and also report the Terry A. 2005 analysis if this is relevant. b) degradation endpoint used in the PECsoil calculation to be discussed in a meeting of experts See reporting table: 4(14)	Applicant: please refer to our argumentation in the reporting table	In order to ease the work of the experts participating to the PRAPER meeting, the assessment of the Taylor and Houseman, 1982 has been transferred from the DAR carbofuran in an Addendum	PRAPeR 62 (13 – 15 January 2009) Open point fulfilled. New open point proposed, see below.

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	New open point: 4.12 Identified at PRAPeR 62 meeting. RMS to calculate new PEC soil for carbofuran using a single first order DT50 of 27 days and include in an addendum.		**RMS: 20 January 2009** The original PECsoil have been based on the worst case lab DT50 (19 d) that have been submitted by the notifier of benfuracarb. The RMS has calculated the PEC soil for the DT50 of 27 days (see LoEP), even if it is clear that both values are in the same range and that the initial PEC is the most relevant endpoint.	PRAPeR 62 (13 – 15 January 2009) Open point open. RMS recalculated the PEC soil as it was requested in the LoEP. No calculations were performed in an addendum.
	Open point: 4.6 MSs to discuss in a meeting of experts the proper formation fraction to be used for the PECgw calculation for carbofuran. See also comment 4(19). See reporting table: 4(20)	Applicant: please refer to our answer in the reporting table. See also "point of clarification" (last row of this section).	We consider that these minor changes (formation fraction, 1/n value,…) have no impact on the final outcome of the evaluation, namely that benfuracarb, 3-keto-carbofuran, 3-OH-carbofuran and carbofuran-phenol do not leach to groundwater. Carbofuran is the only metabolite that could leach to some extent , however, a sufficient number of safe scenarios has been identified, allowing annex I inclusion.	PRAPeR 62 (13 – 15 January 2009) Open point fulfilled.
	Open point: 4.7 MSs to discuss in a meeting of experts the proper degradation endpoint to be used for the PECgw and PECsw calculations for carbofuran. See also open	Applicant: please refer to our answer in the reporting table	See open point 4.6	PRAPeR 62 (13 – 15 January 2009) Open point fulfilled. New open point proposed, see below.

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations PRAPeR Expert Meeting / Conclusions of the evaluation group
	point in comment 4(8) and 4(18). See reporting table: 4(22)			
	New open point: 4.13 Identified at PRAPeR 62 meeting. New groundwater simulation required the input parameters of: DT50 ff Koc 1/n Benfuracarb 0.42 - 9100 1 Carbofuran 14 1 22 0.96 3-OH carbofuran 0.41 0.1 55 1 3-keto carbofuran 3.01 0.1 331 1 should be used for these new groundwater simulations to be provided by the RMS in an addendum. New surface water simulation required the input parameters of: Soil DT50 ff Koc 1/n		**RMS: 20 January 2009** The RMS does not fully agree with the inclusion in the DT50 database of carbofuran of 2 FMC studies with extremely long DT50 that can be considered as outliers (very dry soil for one of the studies, no microbial degradation in one of the studies). However, the RMS could agree with the input parameters for the new groundwater simulations. They are indeed very close to the endpoints that have been proposed in the DARs of benfuracarb and carbofuran. Benfuracarb: the new DT50 is 0.42 d, to be compared with the original figure of 0.31 d. (No reason has been given on the fact that the original value is not appropriate).The RMS considers that such minor changes are useless and time consuming. Carbofuran: the new DT50 is 14 d, to be compared with the original figure of 10.73 d (DAR benfuracarb) or 12.82 d	PRAPeR 62 (13 – 15 January 2009) Open point open. RMS included new PEC calculations as requested in an addendum. The PECgw calculations were performed only with FOCUS PELMO, FOCUS PEARL simulations were not repeated. The updated PECgw calculations for the metabolites were not included in an addendum.

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	Benfuracarb 0.42d - 9100 1 Carbofuran 14d 1 22 0.96 Carb phenol 1d 0.14 1031 0.9 water DT50 sed DT50 Benfuracarb 1000d 15 hours Carbofuran 15.3d 1000d Carb phenol 1000d 9.9d should be used for these new surface water simulations to be provided by the RMS in an addendum.		(DAR carbofuran) Minor changes of the 1/n factor and formation fractions have been proposed by the expert meeting as slightly more conservative values. New PECgw (PELMO) and PECsw have been included in an addendum The TER aquatic have been amended accordingly.	
	Open point: 4.8 MSs to discuss in a meeting of experts the appropriate 1/n value to be used for benfuracarb and its metabolites. See also comments 4(16) and 4(21). See reporting table: 4(23)	Applicant: please refer to our answer in the reporting table. See also “point of clarification” (last row of this section).	See open point 4.6	PRAPeR 62 (13 – 15 January 2009) Open point fulfilled. For new Open point for new simulations see Open point 4.7 above.
	Open point: 4.9 RMS to provide complete	Applicant: no comments. Action for RMS.	In order to ease the work of the experts participating to the PRAPER meeting,	PRAPeR 62 (13 – 15 January 2009) Open point fulfilled.

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	details (e.g the individual measurements involved, graphical presentation) about the calculations used to derive the DT_{50}/DT_{90} values for the different compartments of the compounds in the surface water study. See reporting table: 4(26)		the recalculation of the relevant endpoints has been put in an Addendum	
	Open point: 4.10 MSs to discuss in a meeting of experts the residue definition for the environment. See reporting table: 4(29)	Applicant: no comments. The applicant supports the conclusions of the RMS.	No comment	PRAPeR 62 (13 – 15 January 2009) Open point fulfilled.
4.1	Point of clarification to the applicant: The applicant to update the dossier provided to the MSs and EFSA with the models used for the PEC calculations and transparent model reports. See reporting table: 4(33)	Applicant: Several Appendices containing the FOCUS-PEARL and PELMO reports have been added to the PECgw calculations as submitted to the RMS with the resubmission dossier. The PECgw calculations and appendices have been distributed to RMS and all appropriate MS contact points by courier in the week of 15-19 December 2008.	No comment	PRAPeR 62 (13 – 15 January 2009) Point of clarification addressed.

5. Ecotoxicology

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	Section 5 Open points: ***18*** Points for clarification: ***0*** Data gaps: ***0***			Section 5 Open points: ***7*** Points for clarification: ***0*** Data gaps: ***3***
	Open point: 5.1 MSs to discuss in an expert meeting whether the maximum measured residue value should be used in the refined risk assessment for birds and mammals or the 90th percentile value from the 8 residue trials. Furthermore it should be discussed if the residue trial of Beaufort (2006) should not be included in the risk assessment. See reporting table: 5(3)	Applicant: we refer to the evaluation table points 5 (3) column 3 and 5(4) column 2. Please also see further justification included in the applicant's comments on the DAR (of 18 September 2008) and repeated below:. 1 The field growing period was too long. The crop variety Aviso has an average growing period of 72 days. The growing period in this trial was 130 days, which indicates the growth was retarded. 2 The crop was planted too late in the season. The planting date of this trial was 4th August. However, the variety Aviso is an early autumn cauliflower. Early autumn varieties are planted at the end of June/ beginning of July. 3 No duplicate samples on 7, 14, 21 and 28 days after application could be taken because of too little plant material. Outlier samples could therefore not be re-analyzed by means of the spare sample analysis.	**RMS (January 2009) :** RMS agrees to discuss this point in an expert meeting.	PRAPeR 63 (13 – 15 January 2009) Open point fulfilled. The RMS's assessment was confirmed.

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations PRAPeR Expert Meeting / Conclusions of the evaluation group
		4 According to the Dixons test, the value of 10.566 mg/kg carbofuran + 3-OH-carbofuran at day 14 after application should be considered as an outlier (in comparison with the observed maximum residue values in the other trials). [the Q-value is 0.649. The critical value at n=8 is 0.526 for Dixon's Q-test at 95% confidence level. The Q-value is higher than the critical value. Therefore the residue value of 10.566 should be considered as an outlier.		
	Open point: 5.2 MSs to discuss in an expert meeting the PD values suggested in the refined risk assessment for crested lark. See reporting table: 5(6)	Applicant: please refer to our answer in the reporting table.	**RMS (January 2009) :** RMS agrees to discuss this point in an expert meeting.	PRAPeR 63 (13 – 15 January 2009) Open point fulfilled.
	5.1. New data gap identified at PRAPeR 63: The risk to birds needs to be further addressed.		**RMS (after PRAPER 63) :** No comment.	PRAPeR 63 (13 – 15 January 2009) Data gap open.
	Open point: 5.3 MSs to discuss in an expert meeting the PD values suggested in the refined risk assessment for wood pigeon.	Applicant: please refer to our answer in the reporting table.	**RMS (January 2009) :** RMS agrees to discuss this point in an expert meeting.	PRAPeR 63 (13 – 15 January 2009) Open point fulfilled.

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations PRAPeR Expert Meeting / Conclusions of the evaluation group
	See reporting table: 5(7)			New data gap proposed, see data gap 5.1
	Open point: 5.4 The refined risk assessment (without a reduced PT) resulted in TERs below the trigger. Therefore it should be discussed in an expert meeting whether the information presented in the DAR allows a quantitative PT refinement or if a data gap remains. See reporting table: 5(8)	Applicant: please refer to our answer in the reporting table.	**RMS (January 2009) :** RMS agrees to discuss this point in an expert meeting. Please also refer to open point 5.18.	PRAPeR 63 (13 – 15 January 2009) Open point fulfilled.
	Open point: 5.5 MSs to discuss in an expert meeting the PD values suggested in the refined risk assessment for black headed gull. See reporting table: 5(9)	Applicant: please refer to our answer in the reporting table.	**RMS (January 2009) :** RMS agrees to discuss this point in an expert meeting.	PRAPeR 63 (13 – 15 January 2009) Open point fulfilled. New open point proposed, see below.
	New open point 5.19: RMS to calculate the acute TER with a PD of 1		**RMS (after PRAPER 63) :** The acute TER with PD = 1 were already calculated in the first tier. The listing of endpoints has been amended accordingly.	PRAPeR 63 (13 – 15 January 2009) Open point open. Open point fulfilled after written procedure
	Open point: 5.6	Applicant: please refer to our answer in	**RMS (January 2009) :**	PRAPeR 63 (13 – 15 January 2009)

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	RMS to include in an addendum an evaluation of the risk assessment for birds for the uptake of granules. MSs to discuss in an expert meeting the risk assessment for birds for the uptake of granules. See reporting table: 5(12)	the reporting table.	The evaluation is presented in an addendum. RMS agrees to discuss this point in an expert meeting.	Open point fulfilled. New open point proposed, see below.
	New open point 5.20: RMS to provide new calculations without the DT50 value. RMS to clarify the GAP (are the granules covered by the soil?). RMS to update the LoE including the EPPO scheme calculations.		**RMS (after PRAPER 63) :** RMS provided new calculations with f_{TWA} = 1, presented in the addendum of January 2009, update. Soil incorporation of the granules is the GAP, therefore the risk of consumption of granules is acceptable. The list of endpoints has been amended accordingly.	PRAPeR 63 (13 – 15 January 2009) Open point open. Open point fulfilled after the written procedure.
	Open point: 5.7 MSs to discuss in an expert meeting whether a risk assessment should be conducted for birds and mammals for the uptake of contaminated drinking water. See reporting table: 5(14)	Applicant: please refer to our answer in the reporting table. We support the position of the RMS.	**RMS (January 2009) :** RMS agrees to discuss this point in an expert meeting.	PRAPeR 63 (13 – 15 January 2009) Open point fulfilled. New open point proposed, see below.
	New open point 5.21: RMS to provide a risk		**RMS (after PRAPER 63) :** RMS provided the calculations for drinking water and the list of endpoints	PRAPeR 63 (13 – 15 January 2009) Open point open.

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	assessment for the uptake of drinking water and to update the list of end points.		has been amended accordingly.	Open point fulfilled after the written procedure.
	Open point: 5.8 MSs to discuss in an expert meeting the long-term endpoint for carbofuran used in the risk assessment. See reporting table: 5(15)	Applicant: please refer to our answer in the reporting table. We support the position of the RMS.	**RMS (January 2009) :** RMS agrees to discuss this point in an expert meeting.	PRAPeR 63 (13 – 15 January 2009) Open point open **pending** on the outcome of the carbofuran peer review.
	Open point: 5.9 MSs to discuss in an expert meeting the applicability of the suggested PD to refine the acute risk assessment for birds. See reporting table: 5(16)	Applicant: please refer to our answer in the reporting table.	**RMS (January 2009) :** RMS agrees to discuss this point in an expert meeting.	PRAPeR 63 (13 – 15 January 2009) Open point fulfilled. Refer to point 5.2, 5.3, 5.5.
	Open point: 5.10 RMS to include in an addendum an evaluation of the risk assessment for mammals for the uptake of granules. MSs to discuss the risk assessment for mammals for the uptake of granules. See reporting table: 5(21)	Applicant: please refer to our answer in the reporting table.	**RMS (January 2009) :** The evaluation is presented in an addendum. RMS agrees to discuss this point in an expert meeting.	PRAPeR 63 (13 – 15 January 2009) Open point fulfilled. see open point 5.20

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	Open point: 5.11 MSs to discuss in an expert meeting the PD values suggested to refine the acute and long-term risk to mammals. See reporting table: 5(22)	Applicant: please refer to our answer in the reporting table.	**RMS (January 2009) :** RMS agrees to discuss this point in an expert meeting.	PRAPeR 63 (13 – 15 January 2009) Open point fulfilled. New open point proposed, see below.
	New open point 5.22: RMS to update the acute risk assessment for mammals. (without PD refinement).		**RMS (after PRAPER 63) :** The acute TER with PD = 1 were already calculated in the first tier. The listing of endpoints has been amended accordingly.	PRAPeR 63 (13 – 15 January 2009) Open point open. Open point fulfilled after the written procedure.
	Open point: 5.12 RMS to provide in an addendum a comprehensive explanation on how the mean NOAEL (carbofuran) for the long-term mammal risk assessment was derived. See reporting table: 5(23)	Applicant: no comments, action for RMS.	**RMS (January 2009) :** RMS agrees to discuss this point in an expert meeting.	PRAPeR 63 (13 – 15 January 2009) Open point open **pending** on carbofuran peer review.
	Open point: 5.13 MSs to discuss in an expert meeting whether risk mitigation measures should be proposed for bees.	Applicant: no comments.	**RMS (January 2009) :** RMS agrees to discuss this point in an expert meeting. **RMS (after PRAPER 63) :** Clarification : flowering brassicas = broccoli + cauliflower, see also the	PRAPeR 63 (13 – 15 January 2009) Open point fulfilled. The meeting agreed restrict the use to non flowering brassicae plants.

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	See reporting table: 5(30)		residue section. Conclusion : the GAP does not include flowering brassica plants like oilseed rape, mustard, … and therefore the risk to bees is acceptable (no exposure).	Flowing plants/weeds should be removed or exposure should be avoid (Sp8).
	Open point: 5.14 MSs to discuss in an expert meeting the validity of the aged residues study with *A. bilineata*. See reporting table: 5(32)	Applicant: please refer to our answer in the reporting table. We support the conclusion of the RMS.	**RMS (January 2009) :** RMS agrees to discuss this point in an expert meeting.	PRAPeR 63 (13 – 15 January 2009) Open point fulfilled. New data gap proposed, see below..
	5.2 New data gap identified at PRAPeR 63: The risk to *Aleochara* needs to be further addressed.		**RMS (after PRAPER 63) :** Clarification of RMS : only carbofuran is present, the degradation products of carbofuran (3-OH-carbofuran, 7-phenol) are degrading faster than carbofuran (see section on fate and behaviour).	PRAPeR 63 (13 – 15 January 2009) Data gap open.
	Open point: 5.15 MSs to discuss in an expert meeting whether a data gap remains with regard to the risk to earthworms. See reporting table: 5(34)	Applicant: in relation to current guidance the data on earthworm fulfil all criteria of 91/414/EEC and demonstrate an acceptable risk to earthworms (TERacute > 10, DT50f <100 days and single application). It is considered that any sublethal effects will be reversible (typical for carbamate acetylcholinesterase inhibition) and so any effects will not persist and will not affect earthworm populations. The	**RMS (January 2009) :** RMS agrees to discuss this point in an expert meeting.	PRAPeR 63 (13 – 15 January 2009) Open point fulfilled. New data gap proposed, see below.

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		applicant will confirm this by additional experiments (confirmatory data at MS level) if required.		
	5.3 New data gap identified at PRAPeR 63: The risk to earthworms need to be further addressed.		**RMS (after PRAPER 63) :** No comment.	PRAPeR 63 (13 – 15 January 2009) Data gap open.
	Open point: 5.16 RMS to include details on the risk assessment for birds and mammals for the uptake of granules in the LoEP. See reporting table: 5(37)	Applicant: please refer to our answer in the reporting table. We support the conclusion of the RMS.	**RMS (January 2009) :** No changes since August 2008. **RMS (after PRAPER 63) :** The list of endpoints has been amended accordingly.	PRAPeR 63 (13 – 15 January 2009) See open point 5.6 and 5.10 Open point fulfilled after the written procedure.
	Open point: 5.17 MSs to discuss in an expert meeting the long-term endpoint (carbofuran) used in the short-term risk assessment for birds. See reporting table: 5(38)	Applicant: please refer to our answer in the reporting table. We welcome the discussion.	**RMS (January 2009) :** RMS agrees to discuss this point in an expert meeting.	PRAPeR 63 (13 – 15 January 2009) Open point open **pending** on the carbofuran peer review.
	Open point: 5.18 RMS to present in an addendum the refined risk assessment for birds suggested by the applicant (including the justification for the proposed refinements) to	Applicant: please refer to our answer in the reporting table. We welcome the discussion.	**RMS (January 2009) :** The information is presented in an addendum. RMS agrees to discuss this point in an expert meeting.	PRAPeR 63 (13 – 15 January 2009) Open point fulfilled.

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	be discussed in an expert meeting. See reporting table: 5(39)			