PEER REVIEW REPORT ON **CARBOFURAN** 22 06 2009

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List of all reports from EPCO Expert Meetings

Date		Section
21-24 04 2009	PRAPeR expert meeting 66	Physical and Chemical Properties
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REPORT OF PRAPeR EXPERT MEETING 66

CARBOFURAN

Rapporteur Member State: BE

Specific comments on the active substance in the section

1. Physical and Chemical Properties

are already listed in the relevant reporting table. Comments submitted for this meeting are listed below.

1. Comments submitted for this meeting:

Date	Supplier	File Name
none		

2. Documents submitted for meeting:

Date	Supplier	File Name
200-04-14	BE	Carbofuran evaluation table rev1-0 (2009-04-14).doc
April 2009	BE	Carbofuran List of endpoints (April 2009).doc
2009-03-20	BE	Carbofuran reporting table rev 1-1 (2009-03-20).doc
March 2009	BE	Carbofuran revised DAR Vol1 (March 2009).doc

3. Documents tabled at the meeting:

Date	Supplier	File Name
none		

The conclusions of the meeting were as follows:

4. **Data on preparations:** Furadan 5 G

5. **Classification and labelling:** not discussed

6. **Recommended restrictions/conditions for use:** none

7. **Reference list:** Not discussed

Areas of concern: none

Appendix 1: Discussion table: CARBOFURAN

Appendix 2: Evaluation table

Appendix 1: Discussion Table, Carbofuran (In)

1. Physical and Chemical Properties

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	Open point: 1.1 The acceptability of method A-17-05-13, validated by Battelle (Enriquez, 2006), and of the ILV study by Zietz (2008) to be discussed in a meeting of experts in light of the modifications described in the ILV claimed to be necessary for robustness of the method See reporting table 1(5)	The acceptability of the method and the ILV was discussed by the meeting. The meeting concluded that modifying a method in the process of an ILV by changing the extraction procedure is a significant deviation from the proposed method and therefore biases the results of the ILV. The modified method could be accepted as primary method, but an ILV study is a data gap. Efficiency of the hydrolysis step in residue analysis must be demonstrated. Messages to residues: it should be noted that the monitoring method contains a hydrolysis step and therefore will also cover conjugated material. However Section 1 has identified a data gap in the residue method to validate the hydrolysis step (see open point 3.3. in the evaluation table). In case the method is used without hydrolysis step, it is considered valid for the determination of carbofuran but not for 3-hydroxycarbofuran.	Open point fulfilled. New data gaps proposed, see below.
	New data gap 1.1 identified at PRAPeR 66 meeting: ILV for modified method (Zietz (2008)) is needed		Data gap open.
	New data gap 1.2		Data gap open.

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	identified at PRAPeR 66 meeting Efficiency of hydrolysis step to be addressed		
	New open point 1.2: EFSA to amend residue definition in conclusions after residue meeting	Residue definition: does not comply with method of analysis and should be amended after the residues meeting Plant method: ILV open, hydrolysis of conjugates open Residue definition: a definition for body fluids and tissues should be included	Open point open.
	New data gap 1.3 identified at PRAPeR 70 meeting: The notifier 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.		

Appendix 2: Evaluation 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
	Section 1 Open points: ***1*** Points for clarification: ***0*** Data gaps: ***0***			Section 1 Open points: ***1*** Points for clarification: ***0*** Data gaps: ***3***
	Open point: 1.1 The acceptability of method A-17-05-13, validated by Battelle (Enriquez, 2006), and of the ILV study by Zietz (2008) to be discussed in a meeting of experts in light of the modifications described in the ILV claimed to be necessary for robustness of the method See reporting table 1(5)	**NOT**: we refer to RMS and applicant comment from the Reporting tables	**RMS:** The validation by Battelle shows lower recoveries in some cases (in comparison with ILV by Zietz); however, these are within the acceptable range.	PRAPeR 66 (21 – 24 April 2009): Open point fulfilled.
	New data gap 1.1 identified at PRAPeR 66 meeting: ILV for modified method (Zietz (2008)) is needed			PRAPeR 66 (21 – 24 April 2009): Data gap open.
	New data gap 1.2 identified at PRAPeR 66 meeting Efficiency of hydrolysis step to be addressed			PRAPeR 66 (21 – 24 April 2009): Data gap open.
	New open point 1.2:			PRAPeR 66 (21 – 24 April 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
	EFSA to amend residue definition in conclusions after residue meeting			Open point open.
	New data gap 1.3 identified at PRAPeR 70 meeting: The notifier 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.			PRAPeR 66 (21 – 24 April 2009): Data gap open.

REPORT OF PRAPeR EXPERT MEETING 67

CARBOFURAN

Rapporteur Member State: BE

Specific comments on the active substance in the section

4. Fate and behaviour in the environment

are already listed in the relevant reporting table. Comments submitted for this meeting are listed below.

1. Comments submitted for this meeting:

Date	Supplier	File Name
none		

2. Documents submitted for meeting:

Date	Supplier	File Name
2009-04-14	BE	Carbofuran evaluation table rev1-0 (2009-04-14).doc
April 2009	BE	Carbofuran List of endpoints (April 2009).doc
2009-03-20	BE	Carbofuran reporting table rev 1-1 (2009-03-20).doc
March 2009	BE	Carbofuran revised DAR Vol1 (March 2009).doc
March 2009	BE	Carbofuran_addendum_Vol3 B8 (March 2009).doc

3. Documents tabled at the meeting:

Date	Supplier	File Name
None		

The conclusions of the meeting were as follows:

4. Data on preparations: FURADAN 5G

5. Classification and labelling: candidate for R53

8. **Recommended restrictions/conditions for use:** only tri-annual use results in more than 1 FOCUS groundwater scenario with a predicted carbofuran groundwater concentration of < 0.1 µg/L.

9. Reference list: Not discussed

Areas of concern: high potential for groundwater contamination by parent carbofuran over a wide range of geo-climatic conditions

Appendix 1: Discussion table: CARBOFURAN

Appendix 2: Evaluation table

Appendix 1: Discussion Table, Carbofuran (In)

4. Fate and behaviour

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	Open point: 4.1 MS experts to discuss whether is there any need for DegT50 value for carbofuran-phenol for the exposure assessment or the available estimations using DisT50 are supported; and discuss moreover the vapour pressure used in the PEC calculations. Notes for the discussion: - carbofuran-phenol is regarded as minor metabolite in aerobic soil, but major in water/sediment system - carbofuran-phenol does not contain the carbamate moiety - the definition of residue regarding carbofuran-phenol might be changed	Reminder: In the new DAR (2008) also a seed treatment use of 60 g a.s./ha is supported – this is not considered for the current evaluation of the original GAP of 600 g a.s./ha as granule in sugar beet, but is to be kept in mind for future uses. Supported use in sugar beet considers a triennial application. The initial comment was that aerobic rate studies provide dissipation endpoints rather than degradation endpoints in view of the high Vp. However this is based on QSAR which might be reliable for vapour pressure but not for e.g., Henry constant since the molecule may be subject to dissociation. It has been decided (at open point 4.14) that carbofuran-phenol does not need a groundwater exposure assessment, therefore this point becomes obsolete for groundwater. As the metabolite is major in water/sediment study, surface water PEC calculations are needed and therefore the soil degradation endpoint can be necessary to account for the route via soil. However, in STEP 1 or 2 there is no double counting issue because volatilization is not modelled. If other routes of dissipation can be excluded, then in this case a soil dissipation estimate can be accepted. The meeting considers the point can be fulfilled. Note: The rejected Chang 1990 study dosed with radiolabelled carbofuran-phenol gives indication that the poor material balance might also be caused by incorporation into NER instead of volatility of carbofuran-phenol. This would mean that volatility may not be an issue.	Open point fulfilled.

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	- an open point is set for the discussion of the input parameters for modelling, however the degradation parameters and adsorption parameters were already agreed by the meeting of PRAPeR 62 - another Vp value for carbofuran-phenol is reported in B.8.4.6 of the addition report of carbofuran (0.28 Pa) See reporting table 4(6)		
	Open point: 4.2 RMS to update the List of Endpoints by indicating the actual temperature or range of temperature used in the soil photolysis studies in the box of soil photolysis. See reporting table 4(11)	The list of endpoints is updated. Open point fulfilled.	Open point fulfilled.
	Open point: 4.3 RMS to include the evaluation of the PEC calculations, which considers the soil DT50	The information provided by the notifier on the PECgroundwater is evaluated in the addendum (March 2009), using the median DT50 of 14 days. It is noted that no examples of the output files are provided in the available documentation. In the PRAPeR 62 on benfuracarb the consensus agreed was to use a median DT50 of 14 days for carbofuran. The endpoint was not agreed by the RMS. The inclusion of the long	Open point fulfilled.

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	value of 14 days and the supported application rate in an addendum. Include in the addendum all the input parameters used, all the relevant results and examples of the output files of the models as well. Note that an open point is set for discussion of the input parameters for modelling in 4(39) of the reporting table. See reporting table 4(13)	DT50 values (studies of Schocken and Saxena) are not considered valid by RMS as they might be considered outliers as presented in a statement by the RMS in the addendum of March 2009. In the benfuracarb evaluation these studies are included in the calculation of the carbofuran DT50 to be used for risk assessment. The consensus of this meeting is that the median DT50 of 14 days is appropriate as model input for carbofuran. RMS notes that the groundwater leaching models are very sensitive to small changes in DT50 values and therefore these considered outliers play a large role in the outcome. This is a well-recognized fact when using the available leaching models recommended for regulatory purposes. It is brought up by the experts that probably the (larger) change in 1/n from the old to the new dossier has a larger influence than the small change in median DT50 value. Because more parameters have been changed it is not possible to state that the failing of the scenarios is due to only the change in DT50 values. Open point fulfilled for providing new PEC groundwater calculations. The input parameters will be discussed at other open points.	
	Open point: 4.4 MS experts to discuss the need of the correction for degradation/recovery of the Kdoc of 43 L/kg of the metabolite 3-hydroxy-carbofuran (sandy loam soil, Speyer 2.3) or alternatively should this value completely be excluded from the exposure calculations. Note that Kdoc of 55 L/kg for 3-hydroxy-	This considers a minor metabolite with the carbamate moiety and therefore is assessed. In the benfuracarb discussion a Kdoc of 55 L/kg was agreed. The comment on the Kdoc of 3-hydroxy-carbofuran was not made for the benfuracarb dossier. A correction for degradation would probably lead to a lower Kdoc. Exclusion of this value from the data set would lead to a higher endpoint for exposure assessment (because then the lowest Koc of the two remaining values would be used). RMS acknowledges that the used Koc input value might be refined further but considers that because the issue relates to the minor metabolite 3-hydroxy-carbofuran and the assumptions were sufficiently worst-case in the model (i.e., formation fraction of 1, and a 1/n of 1 in the new calculations in the addendum) the Koc selected can be accepted. The experts agreed with the use of a Kdoc of 55 L/kg with an associated 1/n of 1. Open point fulfilled.	Open point fulfilled.

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	carbofuran was agreed to be used in modeling by the meeting of PRAPeR 62. See reporting table 4(15)		
	Open point: 4.5 RMS to cancel all the values, which were not considered as valid by the previous peer review from the LoEP. For modeling KFoc of 22 with 1/n of 0.96 has to be used for carbofuran. See reporting table 4(19)	The Loep was not yet updated. The new modelling was performed with the agreed value of 22 L/kg and an associated 1/n of 0.96 (in the addendum of March 2009). Only the Mamouni study was considered reliable in the first EFSA conclusion for carbofuran (and also for the resubmission dossier for benfuracarb, see PRAPeR 62). There appears to be no reason to reconsider this now in the absence of new argumentation. Open point still open for the LoEP to be updated.	Open point still open. The list of end points still needs to be amended.
	Open point: 4.6 EFSA to emphasize in the EFSA conclusion that the leachate samples were collected in every 14 days in both studies and this might enhance the degradation in the leachate samples. See reporting table 4(25)	The experts discussed the lysimeter studies available. RMS states that the lysimeter studies are not useful due to the low recharge water volumes and application rates used, so they should not be mentioned in the conclusion. However they were denominated by RMS as supplementary information in the original DAR. RMS agrees with this conclusion and that the information on the lysimeters should be deleted from the LoEP. Open point closed since no need for EFSA to include anything about the lysimeters in the conclusion as they are not relied on. New open point: RMS to update the LoEP by deleting all information on the lysimeters and stating: no reliable information available.	Open point closed. New open point proposed, see below.

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	New open point 4.16: RMS to update the list of end points by deleting all information on the lysimeters and stating: no reliable information available.		Open point open.
	Open point: 4.7 EFSA to emphasize in the EFSA conclusion that the lysimeter studies were performed under similar experimental conditions and these conditions were dry (very low percolation). See reporting table 4(27)	See above at OP 4.6. Open point closed.	Open point closed.
	Open point: 4.8 RMS to state and explain why they agree or disagree with the argumentation given in the position paper by Shaaban F. Elnaggar, 2005 in an addendum. See reporting table 4(30)	The position paper is included in the updated DAR of November 2008 but the RMS did not clarify their opinion. The position paper states that the observation of the 7-phenol as a major metabolite in sediment 'is a short-lived metabolite which is bound to the sediment matrix and further degraded to humic/fulvic compounds. Therefore no accumulation is expected'. This was submitted as reaction on a presumed pH dependency of the formation of this metabolite. This issue is not addressed at all. Step 1 calculations were done based on an observed percentage of 12 % (Diehl 2002) and acceptable TER values are calculated. However a maximum observed percentage (from the other available study by Saxena & Marengo 1994) of 17.6 % in the sediment combined with an observed 5.9 % in the surface	Open point redundant. New open point proposed, see below.

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
		water (a total % of 23.5 % for the whole system) should have been used for STEP 1 modelling. Open point redundant. New open point: recalculate STEP 1 with formation fraction derived from the maximum observed sum of water and sediment % AR indicate with a footnote in the LoEP that the formation of 12 % should be replaced with 23.5 % for the sum of the water and sediment compartments.	
	New open point 4.17: RMS to recalculate STEP 1 with formation fraction derived from the maximum observed sum of water and sediment % AR indicate with a footnote in the LoEP that the formation of 12 % should be replaced with 23.5 % for the sum of the water and sediment compartments.		Open point open.
	Open point: 4.9 For completeness, RMS to include in the LoEP those whole system DT50 values those come from the benfuracarb dossier and indicate that these values were derived from studies with	The benfuracarb dossier values for carbofuran are still missing. The RMS did not want to mix the dossiers due to the different ownership of the dossiers for benfuracarb and carbofuran. From a scientific point of view, there is no reason to keep the dossiers separate. Taking all available data together has been done for numerous other substances and also in the 2006 EFSA conclusions on carbofuran, carbosulfan and benfuracarb. Regarding the Millstream studies no indication has been made that it concerns the same systems with a different application rate.	Open point remains open.

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	benfuracarb. Indicate moreover that Millstream (A) and Millstream (D) is the same system, but different application rates were used in the experiments. See reporting table 4(31)	Open point remains open.	
	Open point: 4.10 RMS to include in an addendum which metabolites have toxicological relevance and which one has not. See reporting table 4(32)	A clarification has been provided in the addendum of March 2009. Open point fulfilled.	Open point fulfilled.
	Open point: 4.11 RMS to amend the soil incorporation depth for PECgw to 7 cm in the LoEP. See reporting table 4(38)	LoEP has been amended. Open point fulfilled.	Open point fulfilled.
	Open point: 4.12 MS experts to discuss the input parameters to be used for the modelling (PECgw,	The endpoints (as agreed in PRAPeR 62) to be used for groundwater modelling are: carbofuran DT50 soil 14 days (median of normalised values, only 2 incubations required temperature normalisation and these values did not effect the arithmetic for calculating the median)	Open point fulfilled for groundwater - for surface water see the row below.

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	PECsw), taking into consideration that the degradation and the adsorption parameters were already discussed and agreed at the meeting of PRAPeR 62. For formation fraction of 3-keto-carbofuran and 3-hydroxy-carbofuran in soil 0.1 was accepted. See reporting table 4(39)	Koc 22 L/kg 1/n 0.96 Vp: 8E-5 Pa at 25 °C 3-keto-carbofuran DT50 soil 3.01 days Koc 331 L/kg 1/n 1.0 Formation fraction 1 (modelling in carbofuran addendum March 2009) Vp 2.6E-3 Pa at 25 °C 3-hydroxy-carbofuran DT50 soil 0.41 days Koc 55 L/kg 1/n 1.0 Formation fraction 1 (modelling in carbofuran addendum March 2009) Vp 3.29E-3 Pa at 25 °C NB The revised DAR of November 2008 used other input values for Vp. This has no bearing on the results because the water solubility is so high that volatilization will be negligible (low Henry constant). Current modeling was already performed by the notifier using most of these agreed endpoints in the addendum of March 2009 (values which deviate are discussed under this point). It is noted that for groundwater modeling a formation fraction of 1 was used in the addendum assuming a sequential degradation scheme of parent-> 3-hydroxy-carbofuran -> 3-keto-carbofuran. However, in PRAPeR 62 parallel formation of both metabolites directly from parent carbofuran was assumed with a formation fraction of 0.1 (as a conservative estimation in view of the low % observed). So the approach differs and a direct comparison of the values of the formation fraction	

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
		approaches used for carbofuran and benfuracarb is not appropriate. To be more in line with the observed % in the soil route studies, a formation fraction of hydroxy-carbofuran of 0.5 is estimated during the meeting, followed by a formation fraction of 1 for 3-keto-carbofuran from hydroxyl-carbofuran (when modeled as sequential metabolite of hydroxyl-carbofuran). However since a formation fraction for both hydroxy-carbofuran and 3-keto-carbofuran of 1 is used at least the results are conservative. (If a refinement were ever needed for future exposure assessments, a kinetic fit of the formation fractions would be desirable.) Another difference is that the new Q10 of 2.58 was used in the model in the addendum of March 2009 while the old Q10 (2.2) was used to derive the normalized DT50 value for the compounds, and the Q10 of 2.2 was also used in the modeling in the revised DAR of November 2008. In this case, the inconsistency that results from the normalization of the lab data only concerns few values out of a large data set (for the a.s. this regards 2 out of 14 values and there is no issue for the metabolites), and therefore in this case new calculations are not deemed necessary as the median value was agreed for use (only the geomean would change slightly with introduction of temperature normalised values with an updated Q10). NB in general: the date of entry into force of the new Q10 value is 1 July 2008 and all dossiers submitted after this date should use it. If the original dossier is submitted before July 2008 the old Q10 value may be used. For resubmission dossiers submitted after July 2008 the new Q10 should be used for modelling and for normalisation of DT50 values. In some cases (renewals) the old Q10 value is still allowed; for further details see FOCUS website.	
	4.12 continued for surface water	The same input values as for groundwater were used with additional endpoints for: - Carbofuran DT50water (based on whole system value) of 15.3 days was used in the addendum to the additional report for carbofuran. (This originates from the benfuracarb additional report (as agreed at PRAPeR 62)). 70 days was used in the revised DAR for carbofuran of Nov 2008, based on a larger	Open point fulfilled.

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
		dataset (see table B.8.4.4-11 of the carbofuran revised DAR). DT50 sediment 1000 days (default). The correct values for carbofuran therefore are: DT50 water 70 days (longest available system DT50 after normalisation to 20°C from 25°C. Note this normalisation used utilised a Q10 of 2.58 and the system is acidic). DT50 sediment 1000 days default - 3-Hydroxy-carbofuran DT50 water 1000 days default DT50 sediment 1000 days default - 3-keto-carbofuran DT50 water 1000 days default DT50 sediment 1000 days default - Carbofuran(-7-)Phenol (water-sediment metabolite) DT50 soil 1 day Koc 1031 L/kg 1/n 0.9 DT50 water 9.9 days DT50 sediment 1000 days default The endpoints as used and presented above were agreed by the meeting as the appropriate values, however the modelling approach for carbofuran-7-phenol used was not appropriate as discussed below. It appears that the soil metabolites were modelled in FOCUS STEP1-2 calculator and STEP 3 with a formation fraction of 1 in the addendum of March 2009. This was agreed. It seems that the major water-sediment metabolite carbofuran-phenol was modelled as a	

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
		soil metabolite using a formation fraction of 1, which is not correct, certainly in view of the high Koc and low DT50soil, which would lead to almost no entry in the water system. It would be better to model the substance artificially as if it would enter the system via drift. The PECsw and PECsed of the metabolite are only about 1 % of the parent concentration, while 12 % in water and 18 % in sediment would be expected based on the observed % in the water-sediment studies. Standard STEP 2 cannot be used for PEC calculations because it is a granular application and there is no drift. It is recommended to use the STEP 3 PEC for parent carbofuran as a conservative estimate for carbofuran-phenol after a potential correction for molar weight and maximum occurrence. It was noted that a smaller crop canopy wash-off value than the default value was used. This was accepted as the application dates selected by the pesticide application timer (PAT) were before the emergence dates in the scenarios defined for sugar beet, so crop foliar interception was not simulated. The application method specified was incorporation. EFSA noted after the meeting that the new modelling for carbofuran in the addendum had used a water DT50 of 15.3 days when 70 days (after temperature normalisation with a Q10 of 2.58) was the appropriate value that had been used in the simulations of the additional report. It had not been requested consequent to comments on the additional report that any change be made to the value of 70 days. This will be indicated in the EFSA conclusion. See below for message to ecotox. Open point fulfilled.	
	Open point: 4.13 RMS to amend the vapour pressure data of	This has not been done yet. It should be indicated in the LoEP that the VP data for the metabolites are from the benfuracarb dossier.	Open point remains open.

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	the metabolites in the relevant boxes of the LoEP. Notes: The use of 5 times higher Vp. value in the modeling can have a significant effect on the outcome in the higher range of Vp. The set of the other Vp. data (including the value of 1.32 Pa) originates from other QSAR estimations (see benfuracarb evaluation). See reporting table 4(41)	Open point remains open.	
	Open point: 4.14 MS experts to discuss the definition of residue. See reporting table 4(44)	It was discussed whether should carbofuran-phenol be included in the residue definition for exposure assessment to groundwater and soil (assessments have been submitted by the notifier). Issues to consider: - no carbamate moiety - minor metabolite in aerobic studies in soil but major in anaerobic soil study It was considered that Willems (2005c) aerobic incubation with the phenol metabolite study might not have been suitable since volatilization was possible (high Vp based on QSAR). In all aerobic studies with parent carbofuran, the metabolite was minor. The route of degradation study with the parent showed a good material balance (based on sum of extractables and non-extractables), however non-identified volatiles were >10 % in one aerobic incubation, which could have been carbofuran-phenol.	Open point fulfilled

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
		The % identified carbofuran-phenol formed was clearly below 5 % in soil extracts so on that basis the trigger for groundwater and soil assessment was not exceeded. The material balance in the anaerobic study dosed with parent carbofuran (in which the metabolite was observed in major amounts) gives an indication of the degree of volatility: Recovery min. 91 % and max. observed in volatile traps < 1 % AR, which indicates that losses to the gas phase are minor. If this can be extrapolated to the aerobic study then losses to air could be neglected. On balance, the consensus of the experts at the meeting was that there is no need for a groundwater exposure assessment for carbofuran-phenol. This would be consistent with the benfuracarb conclusion. Residue definition (after having had the above discussion on carbofuran-phenol) Soil: carbofuran , 3-keto-carbofuran, 3-hydroxy-carbofuran Groundwater: carbofuran , 3-keto-carbofuran, 3-hydroxy-carbofuran Surface water: carbofuran, carbofuran-7-phenol, 3-keto-carbofuran, 3-hydroxy-carbofuran (both via soil) Sediment: carbofuran, carbofuran-7-phenol, 3-keto-carbofuran, 3-hydroxy-carbofuran (both via soil) Air: carbofuran (default) A note should be added that the minor soil metabolite 3-hydroxy-carbofuran is included in the 'residue definition for further assessment' because of its property (cholinesterase activity due to the carbamate moiety), 3-keto-carbofuran also contains the carbamate moiety but is a major soil metabolite in one soil incubation. Open point fulfilled.	
	Open point: 4.15 RMS to amend the LoEP in line with the	See above discussions. Open point remains open.	Open point remains open.

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	discussion of the meeting of experts on carbofuran. See reporting table 4(45)		
	Message from section 4 to section 5: The PECsurface water (and sediment) for carbofuran-7-phenol should be derived from the STEP 3 PEC values for carbofuran as calculated in addendum B.8 of March 2009, which might be corrected for molar weight and maximum occurrence (if required).	Message to ecotox: the PECsurface water (and sediment) for carbofuran-7-phenol should be derived from the STEP 3 PEC values for carbofuran as calculated in addendum B.8 of March 2009, which might be corrected for molar weight and maximum occurrence (if required).	

Appendix 2: Evaluation 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
	Section 4 Open points: ***15*** Points for clarification: ***0*** Data gaps: ***0***			Section 4 Open points: ***5*** Points for clarification: ***0*** Data gaps: ***0***
	Open point: 4.1 MS experts to discuss whether is there any need for DegT50 value for carbofuran-phenol for the exposure assessment or the available estimations using DisT50 are supported; and discuss moreover the vapour pressure used in the PEC calculations. Notes for the discussion: - carbofuran-phenol is regarded as minor metabolite in aerobic soil, but major in water/sediment system - carbofuran-phenol does not contain the carbamate moiety - the definition of residue regarding carbofuran-phenol might be changed - an open point is set for the discussion of the input parameters for modelling,		The RMS has requested the QSAR calculations in a later stage in the procedure. The RMS has considered, taking into account the properties of 7-phenol (metabolite without the carbamate moiety, very high Koc,…) that the discrepancy for the vapour pressure (0.28 of 1.3) was not important enough to request new PEC calculations	PRAPeR 67 (20 -24 April.2009): Open point fulfilled.

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
	however the degradation parameters and adsorption parameters were already agreed by the meeting of PRAPeR 62 - another Vp value for carbofuran-phenol is reported in B.8.4.6 of the addition report of carbofuran (0.28 Pa) See reporting table 4(6)			
	Open point: 4.2 RMS to update the List of Endpoints by indicating the actual temperature or range of temperature used in the soil photolysis studies in the box of soil photolysis. See reporting table 4(11)	**NOT:** As mentioned previously, soil photolysis is not a major route of carbofuran degradation.	The listing of endpoints has been amended.	PRAPeR 67 (20 -24 April.2009): Open point fulfilled.
	Open point: 4.3 RMS to include the evaluation of the PEC calculations, which considers the soil DT50 value of 14 days and the supported application rate in an addendum. Include in the addendum all the input parameters used, all the relevant results and examples of the output files of the models as well.		**RMS:** We consider that a detailed argumentation has been given in the DARs of benfuracarb and carbofuran to exclude the studies by Saxena and Schocken. The RMS disagrees with the conclusions of the PRAPER 62 meeting on this point and would like that his argumentation is taken on board in the conclusions of carbofuran. **Study by Saxena**:	PRAPeR 67 (20 -24 April.2009): Open point fulfilled.

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
	Note that an open point is set for discussion of the input parameters for modelling in 4(39) of the reporting table. See reporting table 4(13)		- In this study two soils were used, called as acidic and alkaline soil. The alkaline soil was prepared by adding lime to the collected sandy loam soil (acidic), by this the pH was modified from 5.7 to 7.7. - The soil indeed seems to be dry if compared with e.g. the FOCUS default values for sandy loam, but the moisture holding capacity of the soil was determined in this GLP study and the actual moisture content was set for this (75% of 1/3 bar=4.05%) in accordance with EPA guidelines (Very often, degradation determined according EPA guideline is slower). - The microbial biomass was checked several times throughout the study and the results show that both soils were viable at the end of the study. - According to the RMS, one soil has been tested in this study (same soil properties, except pH, same microflora). It is therefore not valid to derive 2 DT50 in order to artificially increase the mean or the median DT50. **Study by Schocken**: - The pH of this sandy loam soil was also modified by lime from 5.8 to 7.1. The microbial activity of the soil was checked by measuring the evolved $^{14}CO_2$	

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
			from ^{14}C labelled glucose up to 57 days in a parallel experiment. The evolved CO_2 was continuously increasing and reached 62.3% by the end of this term. It was stated in the DAR that the carbofuran degradation in this study is occurring through a chemical rather than a microbial process (similar degradation rates under sterile and non-sterile conditions). Absence of mineralization is observed in this study The degradation of carbofuran has been determined under aerobic laboratory conditions with carbofuran, benfuracarb or carbosulfan as test substance (14 studies with DT50 ranging between 5.7 and 22.7 days) and under field conditions (5 studies with DT50 ranging between 1.3 and 27 days). Under anaerobic laboratory conditions, the DT50 in one soil is 7.6 days. The RMS considers that there are sufficient arguments that are indicating that the DT50 of 381, 174 days (actually one soil tested in Saxena 1994) and 444 days (one soil in Schocken, 1989) are not valid.	

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 new PECgw and PECsw have been included in the addendum.	
	Open point: 4.4 MS experts to discuss the need of the correction for degradation/recovery of the Kdoc of 43 L/kg of the metabolite 3-hydroxy-carbofuran (sandy loam soil, Speyer 2.3) or alternatively should this value completely be excluded from the exposure calculations. Note that Kdoc of 55 L/kg for 3-hydroxy-carbofuran was agreed to be used in modeling by the meeting of PRAPeR 62. See reporting table 4(15)	**NOT:** The 3'OH-carbofuran metabolite is not the driver for the groundwater or surface water risk assessment. The notifier will refine assessment as necessary based upon outcome of expert meeting – should this be requested.	It has been shown in the original submission that the metabolites of carbofuran were clearly not major (never at level above 5% at 2 sampling points): 3-OH-carbofuran (max 0.8%, once in 1 out of 5 soils), 3-keto-carbofuran (once at maximum level of 6.2% AR, in 1 out of 5 soils), carbofuran-phenol (=7-phenol) (max 2.1%, once in 1 out of 5 soils) (Arysta, FMC) However EPCO 31 agreed that 3-OH-carbofuran and 3-keto-carbofuran need to be further assessed as carbofuran metabolites containing the active carbamate moiety. Carbofuran-phenol does not contain the carbamate moeity. The notifer has provided DT50 (the 3 metabolites are not persistent) and Koc (Koc for modelling has been chosen according to a worst case approach) for the metabolites. Despite the choice of worst case input parameters assumptions, the PEC gw for the metabolites are clearly below the trigger of 0.1 µg/L. The RMS considers that the change of the Koc figure has no impact on the final risk assessment.	PRAPeR 67 (20 -24 April.2009): Open point fulfilled.

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: 4.5 RMS to cancel all the values, which were not considered as valid by the previous peer review from the LoEP. For modeling KFoc of 22 with 1/n of 0.96 has to be used for carbofuran. See reporting table 4(19)		The mean Koc and mean 1/n factor have been recalculated considering the 3 acceptable adsorption/ desorption studies (Daly, 1988; Brandau,1976; Mamouni, 2000). The Koc values derived by Baumann (2002) were anomalously high and were withdrawn. There was no discussion in the previous PRAPER on the derivation of the Koc of 23.3 as proposed in the DAR of carbofuran. The RMS considers that the choice of the 3 studies (Daly, 1988; Brandau,1976; Mamouni, 2000) results in a worst case Koc. No discussion has taken place on the fact that the last study could be acceptable.	PRAPeR 67 (20 -24 April.2009): Open point still open. The list of end points still needs to be amended.
	Open point: 4.6 EFSA to emphasize in the EFSA conclusion that the leachate samples were collected in every 14 days in both studies and this might enhance the degradation in the leachate samples. See reporting table 4(25)	**NOT:** The notifier does not expect an impact to the resulting lysimeter study concentrations as carbofuran metabolites were also analyzed in the study.	The lysimeter studies have not been considered in the final risk assessmemnt	PRAPeR 67 (20 -24 April.2009): Open point closed. New open point proposed, see below.
	New open point 4.16: RMS to update the list of end points by deleting all information on the lysimeters and stating: no reliable			PRAPeR 67 (20 -24 April.2009): 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
	information available.			
	Open point: 4.7 EFSA to emphasize in the EFSA conclusion that the lysimeter studies were performed under similar experimental conditions and these conditions were dry (very low percolation). See reporting table 4(27)	**NOT:** The lysimeter studies were conducted under observed environmental conditions in Germany. This dry conditions do not discredit the validity of the study. The lower amounts of leachate water would potentially lead to slower degradation and higher observed average concentrations both of which did not occur. In all cases, concentrations were below the 0.1 ug/L trigger for relevant metabolites.	The lysimeter studies have not been considered in the final risk assessmemnt	PRAPeR 67 (20 -24 April.2009): Open point closed, see open point 4.6
	Open point: 4.8 RMS to state and explain why they agree or disagree with the argumentation given in the position paper by Shaaban F. Elnaggar, 2005 in an addendum. See reporting table 4(30)		The argumentation points that were available in the DAR have been repeated in an addendum Degradation studies of carbofuran and 7-phenol show that 7-phenol is a short-lived degradation product in/on soil/sediment environment. Carbofuran-phenol does not contain the carbamate moiety. Carbofuran-phenol is 4 orders of magnitude less toxic than carbofuran to aquatic organisms. This compound does not pose a risk to aquatic organisms.	PRAPeR 67 (20 -24 April.2009): Open point redundant. New open point proposed, see below.
	New open point 4.17: RMS to recalculate STEP 1 with formation fraction derived from the maximum observed sum of water and sediment % AR indicate with			PRAPeR 67 (20 -24 April.2009): 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
	a footnote in the LoEP that the formation of 12 % should be replaced with 23.5 % for the sum of the water and sediment compartments.			
	Open point: 4.9 For completeness, RMS to include in the LoEP those whole system DT50 values those come from the benfuracarb dossier and indicate that these values were derived from studies with benfuracarb. Indicate moreover that Millstream (A) and Millstream (D) is the same system, but different application rates were used in the experiments. See reporting table 4(31)		In order to avoid as much as possible confusion about data ownership and data protection between the 3 carbamates dossiers, the RMS has carefully tried to present each study at its right place and to avoid to mix up studies of different origins. The application rates in the Millstream systems have been added.	PRAPeR 67 (20 -24 April.2009): Open point still open.
	Open point: 4.10 RMS to include in an addendum that which metabolites have toxicological relevance and which one has not. See reporting table 4(32)	**NOT:** It is the Notifer's position that carbofuran and 3'OH carbofuran are the molecules of toxicological relevance as they have been identified in soil, water, and plant studies. 3'keto carbofuran is observed infrequently and at very low levels to be relevant.in the residue definition. 7-OH carbofuran phenol is not a relevant metabolite due to the absence of a carbamate moiety.	The relevance of the metabolites has been discussed in the addendum	PRAPeR 67 (20 -24 April.2009): Open point fulfilled.

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: 4.11 RMS to amend the soil incorporation depth for PECgw to 7 cm in the LoEP. See reporting table 4(38)		The incorporation depth has been changed in the listing of endpoints	PRAPeR 67 (20 -24 April.2009): Open point fulfilled.
	Open point: 4.12 MS experts to discuss the input parameters to be used for the modelling (PECgw, PECsw), taking into consideration that the degradation and the adsorption parameters were already discussed and agreed at the meeting of PRAPeR 62. For formation fraction of 3-keto-carbofuran and 3-hydroxy-carbofuran in soil 0.1 was accepted. See reporting table 4(39)		MS experts to discuss the input parameters to be used for the modelling (PECgw, PECsw)	PRAPeR 67 (20 -24 April.2009): Open point fulfilled.
	Open point: 4.13 RMS to amend the vapour pressure data of the metabolites in the relevant boxes of the LoEP. Notes: The use of 5 times higher Vp. value in the modeling can have a significant effect on the		The RMS has requested the QSAR calculations in a later stage in the procedure. The RMS has considered, taking into account the properties of 7-phenol (metabolite without the carbamate moiety, very high Koc,…) that the discrepancy for the vapour pressure (0.28 of 1.3) was not important enough to request new PEC calculations	PRAPeR 67 (20 -24 April.2009): Open point still 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
	outcome in the higher range of Vp. The set of the other Vp. data (including the value of 1.32 Pa) originates from other QSAR estimations (see benfuracarb evaluation). See reporting table 4(41)			
	Open point: 4.14 MS experts to discuss the definition of residue. See reporting table 4(44)	**NOT:** It is the Notifer's position that carbofuran and 3'OH carbofuran are the molecules of toxicological relevance as they have been identified in soil, water, and plant studies. 3'keto carbofuran is observed infrequently and at very low levels to be relevant.in the residue definition. 7-OH carbofuran phenol is not a relevant metabolite due to the absence of a carbamate moiety.	See residue definition proposal in the DAR.	PRAPeR 67 (20 -24 April.2009): Open point fulfilled.
	Open point: 4.15 RMS to amend the list of end points in line with the discussion of the meeting of experts on carbofuran. See reporting table 4(45)		-	PRAPeR 67 (20 -24 April.2009): Open point still open.
	Message from section 4 to section 5: The PECsurface water (and sediment) for carbofuran-7-			PRAPeR 67 (20 -24 April.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
	phenol should be derived from the STEP 3 PEC values for carbofuran as calculated in addendum B.8 of March 2009, which might be corrected for molar weight and maximum occurrence (if required).			

REPORT OF PRAPeR EXPERT MEETING 68

CARBOFURAN

Rapporteur Member State: BE

Specific comments on the active substance in the section

5. Ecotoxicology

are already listed in the relevant reporting table. Comments submitted for this meeting are listed below.

1. Comments submitted for this meeting:

Date	Supplier	File Name
none		

2. Documents submitted for meeting:

Date	Supplier	File Name
XXX		Carbofuran addendum Vol3 B9 (April 2009).doc
		Carbofuran evaluation table rev1-0 (2009-04-22).doc
		Carbofuran list of end points (2009-04-22).doc
		Carbofuran reporting table rev 1-1 (2009-03-20)
		Carbofuran-DAR_Vol3_ B9_part1_(rev April 2009).doc
		Carbofuran-DAR_Vol3_ B9_part1_(rev March 2009).doc
		Carbofuran-DAR_Vol3_ B9_part2_(rev April 2009).doc
		Carbofuran-DAR_Vol3_ B9_part2_(rev March 2009).doc
		Carbofuran-DAR_Vol3_ B9_part3_(rev April 2009).doc
		Carbofuran-DAR_Vol3_ B9_part3_(rev March 2009).doc
		Carbofuran_addendum_Vol B9_(March 2009) draft.doc

3. Documents tabled at the meeting:

Date	Supplier	File Name
none		

The conclusions of the meeting were as follows:

4. Data on preparations: Furadan 5G

5. Classification and labelling: N, R50/53

10. Recommended restrictions/conditions for use: none, no safe use demonstrated

11. Reference list: XXX

Areas of concern: birds, mammals, arthropods, earthworms, soil macro-organisms

The experts note that there is high concern in a number of areas and have strong doubts that further refinement can show a safe use, especially for birds. The risk of mortality is high from all exposure routes and it will be extremely difficult to avoid exposure to a sufficient extent (e.g. the risk of mortality is high after uptake of only one granule). Concerns were also expressed about the potential effects on nestlings.

Although not all field incidents can be directly linked to correct use of carbofuran, they provide evidence that carbofuran is of high risk to birds.

Appendix 1: Discussion table:CARBOFURAN

Appendix 2: Evaluation table

Appendix 1: Discussion Table, Carbofuran (In)

5. Ecotoxicology

	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
5.1	Point of clarification: Applicant to provide more detailed information on the size of the granules. See reporting table 5(10)	In the DAR, there were inconsistencies between different sections about size (0.4-0.85 or 0.6-0.85 mm?) and weight (0.37 or 0.87 mg?) of the granules. The notifier was asked to clarify but did not provide new studies. The correct values are still unclear. The risk assessment was performed based on the values of 0.4-0.85 mm and 0.87 mg. For grit loading (0.0437 mg as/granule) this is worst case, but it is not clear if this is a worst case approach for the probabilistic risk assessment (on granule size overlap with preferred grit particles). Also different species take up different grit sizes. Point of clarification not addressed.	Point of clarification not addressed. Applicant to provide more detailed information on the size and weight of the granules.
	Open point: 5.1 MSs to discuss in an expert meeting whether the risk assessment covers also bigger granules (0.6-0.85 mm). See reporting table 5(10)	The size range plays a role in identifying the overlap between soil particles and granules for specific birds (see page 75). It is difficult to predict what the influence is of a change in size range. For linnet it might not matter much, skylarks prefer smaller particles than 0.6 mm. The notifier should provide solid data on the granule size of Furadan, and provide not only a range, but also a distribution within this range. This type of data has been provided for other granular formulations. Might be a phys/chem requirement. Open point closed. See point of clarification 5.1 above.	Open point closed, see point of clarification 5.1
	Open point: 5.2 MSs to discuss in an expert meeting which residue values in seedlings should be applied in the refined risk assessment for birds. Note: open points	Residue trials were done with sugarbeet seedlings (at 600 g as/ha). Metabolite 3-OH was not included. The trials at 600 g as/ha were accepted by RMS for use in the risk assessment, noting that this is an underestimation because 3-OH was not included in the residue measurements. A correction factor of 6.1 was calculated to include 3-OH based on measurements on day 20 after application, but RMS did not use this in the risk assessment because the median value of 6.1 is very uncertain (large variability in 3-OH levels and measurements early in trial are missing, see page 39/40 of the DAR). For benfuracarb, better data were available and a correction factor of 2.5 for 3-OH was used. Notifier argued that this factor should also be used for carbofuran. RMS did not accept this because the factor was derived from trials on a different crop (cabbage). Also,	Open point fulfilled. New data gaps proposed, see below.

	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	5(14) and 5(42) should be discussed together. See reporting table 5(14)	the data for carbofuran on sugar beet indicate that the conversion factor is higher than 2.5. On page 104 of the DAR the notifier further supported the factor of 2.5: according to the notifier the conversion factor is 3.6 and 2.8 based on another residue trial (available in the residue section of the DAR) but RMS did not accept this. Notifier argued that the residue levels found at 600 g as/ha can be divided by 10 to obtain the level at 60 g as/ha based on comparison with two trials at 60 g as/ha. RMS did not agree with notifier because the linear extrapolation is only based on two trials, because in these two trials there was more than 50% variation and because the plant uptake curve is not known (maybe at 600 g as/ha a plateau value was already reached). In the standard RUD values in the GD for birds and mammals, linearity is assumed for residue values from spray application. Why is it different here? Not clear, it was discussed in this case with a residue expert. Considering the high toxicity of carbofuran, it is not accepted to include uncertainty about the residue values. If the notifier wants to show a safe use at 60 g as/ha, they should provide sufficient residue trials at 60 g as/ha. What is the efficacy at 60 g as/ha granular use, if they also support 600 g as/ha granular use? RMS discussed this at page 9-9 of the addendum: the 60 g as/ha granular use is not a representative use in Europe and the only two available residue trials at 60 g as/ha are insufficient because of the high toxicity of the compound (therefore high uncertainty with regard to residue levels is not acceptable, nor the extrapolation factor of 10 from the residue trials conducted at 600 g as/ha). RMS did therefore not evaluate the risk of the 60 g as/ha granular use. The meeting agrees with the RMS on this position. It is noted that the granular use of 60 g as/ha would not lead to an acceptable risk (see calculations of the notifier on page 9-8 of the addendum). For resubmissions, it is possible to change the rate of application, but not the type of application. For ecotox discussions, efficacy is not important (for procedural reasons). The notifier seems to want to use the 60 g as/ha as seed treatment at MS level. To support this different type of application however, different residue trials and a different risk assessment would be necessary.	

	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
		Conclusion on residue values on sugarbeets: Further trials at the correct application rate, according to GAP and at different field conditions (N and S-Eur) are necessary in which 3-OH should be included and measurements on carbofuran and 3-OH on different timepoints should be done. Residue values on invertebrates were also discussed by the meeting (reporting table 5(15), page 45 of the DAR). The trials were conducted at 375 g as/ha and 3-OH was not measured. RMS extrapolated to the 600 g as/ha use (indicating that some uncertainty remains) but considers that to support the 60 g as/ha use, trials at the correct GAP are necessary. Is is acceptable to extrapolate the residue values from 375 g as/ha to 600 g as/ha? For spray treatments this is easier than for granular formulations. Research has shown that the more active soil dwelling organisms are, the more residue they will contain. So behaviour of the organisms is of large influence in residue tests on soil organisms. Would soil organisms be affected already at 375 g as/ha? It was difficult to determine the initial effect, but recovery within two months was shown (page 204 -227 of the DAR). Behavioural observations of the individuals were not done. However, sampling was done by pitfall and other traps, so they must have been alive when walking in there. It was noted that dead arthropods might carry more residue. Since carbofuran is an insecticide, it can be expected that at least some species were killed by the application. Therefore the values found might not be worst case. The trial is used to calculate both initial and ftwa residue values. The maximum initial value was used for the acute, the mean initial for the short term and the mean twa for the long term from two trials. The approach i.e. derive graphically the long term residue value from the analysis of the curves, is unusual. But it is comparable to what is done in plant residue trials in the benfuracarb dossier (and also for carbosulfan). There is no information on the range of the values. Focus of the carbofuran risk assessment is on acute exposure. The uncertainty of 3-OH exposure is not taken into account, but mainly important for longer time exposure. The meeting feels that the use of the residue trial on arthropods is uncertain based on the available information. This uncertainty could be decreased by performing more arthropod residue trials at the right application rate, with behavioural observations, also including residues on dead arthropods.	

	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
		It is difficult to predict the change of behaviour of the organisms from 375 to 600 g as/ha. The meeting can accept the extrapolation of residue levels from 375 to 600 g as/ha. And agrees with RMS that extrapolation downwards to 60 g as/ha is not appropriate because the behaviour of the soil organisms might be different at the low dose. For another substance (carbofuran), the maximum PECsoil has been used for residue level on soil arthropods. Because of the high toxicity of carbofuran, it is important to decrease the uncertainty as much as possible. Conclusion on residue values on arthropods: the available field data are not acceptable. Further arthropod residue studies are necessary at the right application rate, with behavioural observations, also including residues on dead arthropods. Residue values in earthworms were determined in the same study as discussed above for arthropods. Exposure of birds via earthworms is very highly dependent on whether it rains after application or not. When it rains, the concentration in earthworms may be higher because of disintegration of the granules. From the DAR, it is not clear whether there was rain after application. The study was done in UK in May/June. The earthworms were rinsed after sampling and placed in a fridge for one night before measurements. This may have reduced the residue level. Many poisoning events have been seen in CH from birds eating earthworms with carbofuran residues. CH might be able to provide the articles (MS should ask CH by email). Poisoning events in FR were reported by SAGIR (these are included on page 63 of the DAR). The available residue values on earthworms are not considered worst case by the meeting. Data gap: Further residue trials with earthworms are necessary at the correct application rate and GAP, in which the issue of rainfall is addressed, 3-OH is measured, and carbofuran and 3-OH are followed over time. What is the behaviour of the granules in soil over time?	
	New data gap 5.1 identified at PRAPeR 68:		Data gap open.

	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	Further trials at the correct application rate, according to GAP and at different field conditions (N and S-Eur) are necessary in which 3-OH should be included and measurements on carbofuran and 3-OH on different timepoints should be done.		
	New data gap 5.2 identified at PRAPeR 68: Further arthropod residue studies are necessary at the right application rate and GAP, in which the issue of rainfall is addressed, with behavioural observations, also including residues on dead arthropods, and at different field conditions (N and S-Eur), in which 3-OH is measured, and carbofuran and 3-OH are followed over time.		Data gap open.

	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	New data gap 5.3 identified at PRAPeR 68: Further residue trials with earthworms are necessary at the correct application rate and GAP, in which the issue of rainfall is addressed, 3-OH is measured, and carbofuran and 3-OH are followed over time, and at different field conditions (N and S-Eur).		Data gap open.
	Open point: 5.3 MSs to discuss in an expert meeting the refined risk assessment for birds (3rd tier) based on the approach suggested for pirimicarb. It should also be discussed if the provided data are robust enough to support such a risk assessment approach. See reporting table 5(16)	Page 68-71 of the DAR. Considering the high uncertainty of the input parameters of the 'pirimicarb'-modelling of the risk of carbofuran, RMS feels that it is not appropriate to apply this model to carbofuran which has very low TER values in the first tier, unlike pirimicarb which had TER-values much closer to the trigger. The notifier used an application rate of 400 g as/ha instead of 600 g as/ha in the modelling. They concluded that their input parameters were worst case and that even though some individual birds might be affected, the population will not be. Many experts in the meeting feel that they are not sufficiently prepared/knowledgable to discuss the modelling in detail. However, the input parameters have to be all individually discussed (following Table B.9.1.11-2, page 70). <u>Yellow wagtail</u> RUD: Based on measured data from the residue trials in arthropods, corrected to 400 g as/ha. Highest measured level on beetles was 6.8 mg/kg and application rate is 600kg as/ha. Therefore this value is clearly not worst case. FPM: These rates were suggested by the PPR Panel in the pirimicarb opinion. Acceptable. Bw: Acceptable.	After the discussion the meeting concludes that because of all the uncertainties identified, the pirimicarb-approach is not accepted. Open point fulfilled.

	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
		T1/2: Based on a study on AChE levels in the brain of Bobwhite quail, see page 3 of the DAR. The toxicologist expert of the RMS evaluated this study and concluded that the study was not continued long enough (recovery was not demonstrated at the high dose) and that clinical effects should have been presented. Could the T1/2 anyway be used in the model? For methomyl, a T1/2 of 144 min was used, so the values for carbofuran seem comparable. However, to base T1/2 only on AChE levels is not enough, all four ADME parameters should be measured. The RMS gives reasons why the study cannot be used for this ecotoxicological risk assessment (see reporting table 5(3), (4) and (18)). The meeting agrees. Parameter not accepted. AVT: According to the pirimicarb opinion, the AVT should be between the NOEL and the LOEL (food intake). Here the 0.3xHD5 and the 0.8xHD5 were used, while the worst case should have been 0.9xHD5. The input is therefore not worst case. AVD: This parameter was based on studies which were not available to RMS. Therefore not acceptable. <u>Woodpigeon.</u> RUD: Based on measured data from the residue trials in seedlings, corrected to 400 g as/ha. Application rate is 600 g as/ha. Therefore this value is clearly not worst case. FPM: These rates were based on labstudies, while evidence suggests that the FPM in the field can be higher. Not worst case. The notifier further argues that the feeding of woodpigeon is limited by its crop size (bolus approach). But this approach is not supported by data and has not been accepted for methomyl. See above for other parameters. It is noted that even from the calculations of the notifier, a risk to birds is identified. The risk to nestlings is not covered by the above risk assessment. After the discussion the meeting concludes that because of all the uncertainties identified, the pirimicarb-approach is not accepted. Open point closed.	
	Open point: 5.4 RMS to provide in an addendum a risk assessment for birds for the uptake of	This was done in the addendum. TER 1.41. RMS considers the calculation unrealistic worst-case. The method used was developed for spray application. Could a run-off model from Focus be used for this granular application? Meeting agrees that this would be more realistic.	Open point fulfilled..

	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	contaminated drinking water from puddles in line with the suggestion of the PPR opinion on the science behind the GD on risk assessment for birds and mammals (EFSA Journal, July 2008) See reporting table 5(19)	From the fate section it appears that there is no run-off. The correct way to calculate drinking water exposure from granular applications is not known. A hypothetical puddle containing the worst case amount of granules found on the surface might be used as first tier. This would certainly lead to a risk and would need to be further addressed. Open point fulfilled.	
	Open point: 5.5 RMS to indicate in the corrected DAR and in the LoEP that the long-term reproductive NOEC for birds of 10 ppm includes only reproductive effects but not parental mortality which was observed at concentrations of 2, 5 and 10 ppm. See reporting table 5(20)	This was done. Open point fulfilled.	Open point fulfilled.
	Open point: 5.6 MSs to discuss the long-term endpoint to be used in the risk assessment for birds. See reporting table	The observed parental mortality in the reproduction study was not considered by RMS in the determination of the endpoint because exposure in the reproduction study is much longer than would be expected in the field and because mortality is the main effect of carbofuran. The first point is true for almost every a.s.. Usually mortality is included in the reproduction endpoint. The mamtox LoE mentions long-term endpoints based on testicular and sperm toxicity.	Open point fulfilled. New open point proposed, see below.

	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	5(21)	Therefore it is difficult to conclude that there is only an acute risk. The NOEL from the reproduction study could not be determined (adult mortality at lowest tested dose). Page 18 of the DAR: notifier concluded that it was possible to determine a NOEC based on reproductive effects only in the bird reproduction study. This approach is doubted considering that half of the test animals died. The guidelines specify a maximum allowed mortality of 5 or 10%. To test for reproduction effects only, the dose should have been lower. Conclusion: there is no long-term endpoint for risk assessment. Is a new study necessary? Preferably not for animal welfare reasons. NOEL acute study: 0.19 mg/kg bw (mallard) LC10 from a 14 day study is 0.64 mg/kg bw/d. This endpoint was based on mortality and was used by RMS in the long-term risk assessment. The LC50 of this study was 1.6, the NOEL was not determined as 20% corrected mortality occurred at the lowest tested dose of 17 ppm. An endpoint from a short-term study cannot be considered for long-term risk assessment with the normal trigger since it does not consider the longer exposure. The trigger could be increased. In the DAR, RMS used the normal trigger of 5. Often, the LC10 is lower than the NOEC. Meeting considers that in the specific case of carbofuran, the LC10 can be used with an increased trigger of 10, because the endpoint is based on a short term study. Open point closed. New open point: RMS to recalculate the risk with the trigger of 10. The long-term NOEC of 1.5 ppm will be removed from the LoE and the reproduction study from the list of studies relied on. The LC10 of 0.64 will be included in the LoE also as reproductive endpoint.	
	New open point 5.22: RMS to recalculate the risk with the trigger of 10. The long-term NOEC of 1.5 ppm will be		Open point open.

	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	removed from the LoE and the reproduction study from the list of studies relied on. The LC10 of 0.64 will be included in the LoE also as reproductive endpoint.		
	Open point: 5.7 MSs to discuss in an expert meeting whether the quantitative refinement of PT and PD values are sufficiently supported by data. See reporting table 5(23)	For carbofuran the same PD and PT refinements were used as for benfuracarb. In the PRAPeR meeting discussing benfuracarb, these values were not accepted for acute risk assessment and only in a qualitative way for short-term and long-term risk assessment. The notifier would like guidance on how to further refine the risk. It was noted that this is not the job of an expert meeting. Studies targeted at the specific use should be submitted. So here PT/PD should be investigated in fields with sugarbeet seedlings, since this is the use of concern. The seedlings do not have to be treated with the a.s. There are data available for sugarbeet in Austria but these are protected. Published UK data give PT values very close to 1. Extrapolation to other landscapes / agricultural uses should always be done with care. If PD data are derived from a study in which birds are visiting more than just ~~the~~ one field, PT should be considered carefully. The new draft GD gives more detailed guidance on the requirements for an acceptable radiotracking study than the current. The notifier should note: Since the acute effects are so high and we use an endpoint driven by mortality, it was questioned whether PD and PT refinements should be used for longer term risk characterization. Furthermore, the LoE shows that even including ~~PT and~~ PD refinements, TER values are below the triggers. PT and PD would have to be very low to get acceptable risk. Open point closed. New open point: RMS should indicate in the LoE that the ~~PT and~~ PD values used in the TER calculations are only for illustrative purposes.	Open point fulfilled. New open point proposed, see below.
	New open point 5.23:		Open point open.

	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	RMS should indicate in the LoE that the PT and PD values used in the TER calculations are only for illustrative purposes.		
	Open point: 5.8 MSs to discuss the risk assessment for birds for the uptake of granules. See reporting table 5(24)	The LD50 (the lowest available lab value) is reached by a small bird after consumption of only one granule. According to the EPPO scheme, the risk should then be considered further. RMS therefore calculated the risk from accidental and intentional uptake, which both indicate low risk. However, RMS doubts the applicability of the EPPO scheme for a compound like carbofuran. The only safety factor taken into account now is a division of the endpoints with 5.7 for medium and long-term following the EPPO scheme. For acute risk the HD5 (mean) was used without safety factor. Should the one-granule criterion be re-instated? This should be discussed at the revision of the GD for birds and mammals. For carbofuran there are many examples of poisoning in the field. E.g. ducks found dead in Switzerland recently because of direct poisoning. Also many cases from secondary poisoning via earthworms and for birds of prey. Were the incidences caused by misuse? Probably the secondary poisonings result from GAP use. Usually the reported incidents are only the tip of the iceberg. The notifier reported incidents under B.9.1.10. The RMS concluded that it is very difficult to link the incidents to the current risk assessment. The key question is whether we can accept that the LD50 is met with one granule, taking all the field evidence into account. If not, we might not have to discuss the risk assessment in detail. However, this has to be done. Granules might not all be incorporated. The notifier provided an incorporation efficiency study, which shows some spillage at row ends. This is already taken into account in the EPPO scheme. Incorporation efficiency: the ideal situation may differ from what happens in practice. In the study, no granules were found on the surface of the middle of the field.	Open point fulfilled. New data gap proposed, see below.

	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
		At row ends, the maximum number found was 243 granules/m row (after 3 days). For the PRA, the actual number of granules found in the field study was used as input (not clear from the DAR which values were used exactly, average of all days per field area, from Gamma distribution,…? RMS could check in the report). Few measurements of the granules on the soil surface were done, which increases uncertainty. Great variability was observed in the number of granules found on the surface. Spillages were not taken into account, although they had been found. This might be an underestimation considering that birds may be attracted mainly to the row end. The notifier similated exposure for two focal species based on incorporation efficiency at different parts of the field. Two scenarios were used: 1) equal probability to visit end, middle and other end; 2) probability to visit ends relative to size of end area. However, some birds may prefer the end of a field, others may prefer the middle. Therefore this approach is not accepted. Worst case would be to assume exposure only in the end area. The notifier did not provide an uncertainty analysis with the PRA. Parameters in the PRA are summarised ~~from~~ on page 80 ~~on~~ of the DAR. Four soil types were considered in the PRA, three real soils and one 'random' soil (mixture of the three real soils). The loading in the PRA was 0.0185 mg as/granule, whereas RMS would calculate with 0.0437 mg as/granule (this would be worse case). It is not clear what the 'effect %' in the PRA conclusion tables means. RMS explains: is chance that a bird dies, based on Monte Carlo simulation for 10000 birds. In the PRA, PT-values were used from a DEFRA project. These values were collected at a crop situation (established crop) so they are not appropriate for determining risk from grit uptake for granule use (bare soil). Furthermore, the PT should not be used in the acute exposure calculation. Fields just after sowing will probably be attractive for birds. The notifier compared the 'effect %' found in the PRA with the annual mortality of the two focal species. They conclude that the effect on carbofuran is negligible. RMS recalculated annual mortality to a period of two weeks and found that the effect of carbofuran could be equal to the normal mortality during two weeks of exposure to carbofuran. Furthermore it is unclear what caused the 'normal annual mortality'. Timing of application should be taken	

	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
		into account (application during breeding season would have a much higher impact than in winter; in this case carbofuran is applied in spring). This 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 takes only 1 visit per bird into account. RMS did not accept the PRA, because of uncertainty on weight of granule (and thus on loading), the lack of safety factor on the HD5 and other reasons. Meeting agrees that the uncertainties in the PRA are too high in this case. Conclusion: the risk from exposure to granules is not fully addressed. Data gap: notifier to address the risk to birds from exposure to granules, considering all comments of RMS and PRAPeR meeting. Concerns were raised in the meeting about the possibility to address the risk considering the high risk to birds after intake of only one granule.	
	New data gap 5.4 identified at PRAPeR 68: Notifier to address the risk to birds from exposure to granules, considering all comments of RMS and PRAPeR meeting. Concerns were raised in the meeting about the possibility to address the risk considering the high risk to birds after		Data gap open.
	Open point: 5.9 MSs to discuss in an	The LD50 is reached after uptake of 1 to 2 granules for a small mammal. This is refined according to the EPPO scheme for accidental ingestion only (mammals do not consume grit and the granules are not based on an organic carrier).	Open point fulfilled.

	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	expert meeting the risk assessment for mammals for the uptake of granules. See reporting table 5(31)	This refinement did include the worst case values regarding weight of granule (and size is not of influence). The meeting agrees with the risk assessment of the RMS. Open point closed.	
	Open point: 5.10 MSs to discuss the PD/PT values suggested in the refined risk assessment for mammals. See reporting table 5(32)	For benfurarb the same PT and PD values were used as proposed for carbofuran. In the PRAPeR meeting these were not accepted for acute risk. It is not clear whether for long-term risk they were only accepted for qualitative risk assessment or if they were quantitatively accepted. Literature data indicate that the proportion of ~~sugarbeet seedlings~~ dicotyledonous plants in the diet of the hare is at maximum 40%. Therefore for hare a PD of 40% for sugar beet seedlings (all dicots are assumed to be contaminated sugar beet seedlings) and 60% for monocotyledonous plants was used. The assumed residue level of the monocotyledonous plants is 0. RMS accepted this because there is no exposure of off-field, and weeds will be taken out (so the PD of 40% is a sort of PT). Is it too lenient to assume that all weeds are removed? We have not accepted this for other substances nor for other uses. Experience shows that weeds can be present in sugarbeet fields. Are the available literature data really convincing that a hare will never take more than 40% sugarbeet seedlings? The homerange of hares is large, but in its homerange all sugarbeet fields may be treated. The homerange approach was not accepted before? In Austria, a PT of 0.5 is usually used for hares. Do we have enough information to conclude on a PD/PT for hare? Meeting agrees that this is not possible. It is accepted that this conclusion is different from benfuracarb. It is noted that based on the 40%, TER values are already below the trigger, that 3-OH is not considered in the residue values and that the PD of 40% is not accepted. The feeding rate of the hare was considered by the notifier (see open point 5.11). Would the wood mouse be a better focal species? At the time of composing the DAR, the hare was certainly considered to be a reasonable focal species (it is 100% herbivorous).	Open point fulfilled. New data gap proposed, see below.

	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
		For earthworm-eating mammals a PD of 0.8 earthworms / 0.2 for arthropods was used for the focal species the shrew. The notifier states in the DAR that the shrew will avoid bare fields. Is it then a relevant focal species? In the draft GD for birds and mammals, the shrew is still indicated as a focal species even at low BBCH stages. The PD refinement is based on the Mammal Bible, but the underlying data are not conclusive. Is it realistic to assume only 0.2 for arthropods? The residue level in arthropods is higher than in earthworms. Even with the assumed PD of 0.2, the TER is below the trigger, and the PD is not confirmed. Furthermore the residue values in earthworms need further support. See open point 5.~~7~~ 2. Open point closed.	
	New data gap 5.5 identified at PRAPeR 68: The risk to mammals needs to be addressed further.		Data gap open.
	Open point: 5.11 MSs to discuss in an expert meeting the refined risk assessment for mammals based on the approach suggested for pirimicarb. It should also be discussed if the provided data are robust enough to support such a risk assessment approach. See reporting table	The input parameters have to be all individually discussed (following Page 156-158). <u>Hare</u> T1/2: should be confirmed by tox. FPM: Unclear how these were derived. Concentration in food: done for the wrong application rate (400 instead of 600 g as/ha). The endpoint used is slightly wrong (should be 5.3 instead of 5.5). Smaller animals are not addressed. Meeting agrees that the input parameters used in this approach are not worst case. A high risk to mammals cannot be excluded. Open point fulfilled.	Open point fulfilled.

	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	5(35)		
	Open point: 5.12 MSs to discuss in an expert meeting the endpoint to be applied in the long-term risk assessment for mammals. See reporting table 5(40)	RMS took the mean value of all long-term toxicology studies. Considering that these studies are all different, that the effects seen were different and that they were on different organisms, the meeting is not confortable with taking the mean. Based on the list of endpoints given now, it is difficult to decide on the relevant endpoint. Did the mamtox meeting confirm the long-term endpoints in the DAR or were they changed? This has to be checked. Conclusion: the relevant long-term ecological endpoint remains to be set awaiting the outcome of the mamtox meeting. However, even based on the NOAEL of 0.71, a risk is identified. Open point fulfilled. New open point: the relevant long-term endpoint for mammals has to be determined. When are developmental studies considered for ecotox? By AU only in first tier, in higher tier they look at ecological relevance.	Open point fulfilled. New open point: the relevant long-term endpoint for mammals has to be determined.
	New open point 5.24: the relevant long-term endpoint for mammals has to be determined.		Open point open.
	Open point: 5.13 MSs to agree on the residues in sugar beet seedlings used in the refined risk assessment for mammals. See reporting table 5(42)	See discussion for birds at open point 5.2.	Open point closed., see open point 5.2
	Open point: 5.14 RMS to provide in an	See discussion for birds at open point 5.4.	Open point closed., see open point 5.4

	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	addendum a risk assessment for mammals for the uptake of contaminated drinking water from puddles in line with the suggestion of the PPR opinion on the science behind the GD on risk assessment for birds and mammals (EFSA Journal, July 2008) See reporting table 5(47)		
	Open point: 5.15 RMS to present in an addendum the TER calculations for C. riparius based on refined PECsed values (FOCUS step2 and step3). See reporting table 5(50)	This was done. Low risk was found based on maximum PECs. Open point still open for RMS to check final PECs.	Open point still open for RMS to check final PECs.
	Open point: 5.16 MSs to discuss in an expert meeting whether a new acute toxicity study with 3-keto-carbofuran and *Ceriodaphnia dubia* is necessary.	At the end of the test, the concentrations were below the LOQ. The question was raised whether a flow-through study should be required. The notifier argued that this would be practically impossible for such a small species. The endpoint from the available study indicates a large margin of safety. RMS agreed with this. Open point closed. New open point: RMS to add a footnote to the LoE explaining why the study was accepted.	Open point fulfilled. New open point proposed, see below.

	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	See reporting table 5(51)		
	New open point 5.24: RMS to add a footnote to the LoE explaining why the study was accepted.		Open point open.
	Open point : 5.17 RMS to include the mean measured concentrations from the studies with sediment dwellers and carbofuran 7-phenol and carbofuran in the LoEP and in an addendum and to provide a revised risk assessment in an addendum and to update the LoEP See reporting table 5(52)	This was done. Low risk was found. Open point closed. New open point: in Step 1 calculation for 7-phenol, the carbofuran endpoint was used instead of 7-phenol endpoint, RMS should revise this in the LoE.	Open point fulfilled. New open point proposed, see below.
	New open point 5.25: I the Step 1 calculation for 7-phenol, the carbofuran endpoint was used instead of 7-phenol endpoint, RMS		Open point open.

	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	should revise this in the list of end points.		
	Open point: 5.18 MSs to discuss in an expert meeting whether the studies with Rove Beetle (Schmuck R., 1993, p. 194-195 and Schmuck R., 1993, p. 201-203) and the study on Carabid Beetles (Schmuck, 1993, p 198-200) are acceptable since no positive control was tested See reporting table 5(55)	Are the studies valid without positive control? Meeting agrees that in this case the studies can be accepted since clear effects of carbofuran compared to the untreated control were observed. Open point fulfilled. NB The studies are not critical for risk assessment since field trials are available.	Open point fulfilled.
	Open point: 5.19 MSs to discuss in an expert meeting whether the field study performed with a capsule suspension preparation (Strömel C. *et al*., 2002) can be used to address t he risk from the granular formulation suggested in the representative use. See reporting table	This concerns a field study on earthworms with a capsule suspension formulation. The concentration measured in the study (2.8 mg/kg) covers the expected PECsoil of the granular use (~~2.8 vs.~~ 0.8 mg/kg). Does the study also cover the possibly different type of release of the a.s. (faster or slower in granule?) and the different type of application (spraying of capsule suspension will not lead to homogeneously distribution over the field)?. The PECsoil calculated for the granular use is an average over the field, while in reality it will be high in-furrow and low outside the furrows. Notifier has provided argumentation that the exposure pattern in the field study with earthworms is comparable to that of the granular use on page 241 of the DAR. This seems contradictory. The mentioned Broadbent and Tomlin study has not been submitted. Concerns remain on the use of the field study. Open point closed. New data gap: Notifier to provide further details on this study	Open point fulfilled. New data gap proposed, see below.

	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	5(62)	(Broadbent and Tomlin) to support the use of the field study.	
	New data gap 5.6 identified at PRAPeR 68: Notifier to provide further details on this study (Broadbent and Tomlin) to support the use of the field study.		Data gap open.
	Open point: 5.20 RMS to include a statement in the updated DAR or in an addendum that the risk to other soil dwelling macro-organissm is not addressed for the use rate of 0.6 kg a.s./ha. See reporting table 5(63)	This was done in the updated DAR. Meeting agrees. Open point fulfilled.	Open point fulfilled.
	Open point: 5.21 RMS to correct in the LoEP the interchanged TER values for *Hypoaspis aculeifer* and *Folsomia candida.* See reporting table	This was done. Open point fulfilled.	Open point fulfilled.

	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	5(68)		
	Message from section 4 to section 5: The PECsurface water (and sediment) for carbofuran-7-phenol should be derived from the STEP 3 PEC values for carbofuran as calculated in addendum B.8 of March 2009, which might be corrected for molar weight and maximum occurrence (if required).		Noted.

Appendix 2: Evaluation 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
	Section 5 Open points: ***21*** Points for clarification: ***1*** Data gaps: ***0***			Section 5 Open points: ***6*** Data gaps: ***6***
5.1	Point of clarification: Applicant to provide more detailed information on the size of the granules. See reporting table 5(10)	**NOT:** **Size of granule:** the particle size distribution of Furadan 5G granule was determined by de Ryckel (2001) and reported already in the original DAR. The particle size distribution ranges from 0.4 – 0.85 mm. See point B2.2.26b in Vol. 3 of the new DAR. **Weight of granule:** Whilst 0.37 mg was mentioned in the original DAR, it is correct that FMC does not have data superseding the measurement from Knäbe *et al*. (2008), which indicates a weight of 0.87 mg per granule.	**RMS (April 2009):** No further comment.	PRAPeR 68 (4. – 8. May 2009) Point of clarification not addressed and changed into a data gap: Applicant to provide more detailed information on the size and weight of the granules.
	Open point: 5.1 MSs to discuss in an expert meeting whether the risk assessment covers also bigger granules (0.6-0.85 mm). See reporting table 5(10)		**RMS (April 2009):** The calculations for the probabilistic risk assessment have been performed for a size range of 0.4 to 0.85 mm.	PRAPeR 68 (4. – 8. May 2009) Open point closed, see point of clarification 5.1

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: 5.2 MSs to discuss in an expert meeting which residue values in seedlings should be applied in the refined risk assessment for birds. Note: open points 5(14) and 5(42) should be discussed together. See reporting table 5(14)	**NOT:** From the study of Zietz, E. (2008) there was a 10-fold difference in residues between applications at 600 g a.s./ha and 60 g a.s./ha (see Table B.9.1.8-2 from the revised assessment report). Levels of the metabolites were also reported.	**RMS (April 2009):** 1) RMS disagrees with the statement of the notifier that the residues will decline 10 times for the lower application rate of 60 g a.s./ha, compared to the applied 600 g a.s./ha. This extrapolation should be substantiated with data, e.g. residue trials conducted at 60 g a.s./ha. 2) For the same reason, extrapolation of the factor 2.5 from the dossier of benfuracarb (cabbage) cannot be done to the dossier of carbofuran (sugar beet). 3) The RMS indicated in the DAR (Table B.9.1.12-11) why the 3-OH-carbofuran residues were not taken into account in the calculations of the RMS. "RMS considers that too much uncertainty remains on the conversion factor and has therefore presented a TER assessment based on the measurement of carbofuran alone. This element must be taken into account in the interpretation of the final risk assessment. A copy of the statement of the notifier on the lowered dose rate of 60 g a.s./ha is included in the addendum. RMS	PRAPeR 68 (4. – 8. May 2009) Open point fulfilled. New data gaps 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
			maintains its position on this issue.	
	New data gap 5.1 identified at PRAPeR 68: Further trials at the correct application rate, according to GAP and at different field conditions (N and S-Eur) are necessary in which 3-OH should be included and measurements on carbofuran and 3-OH on different timepoints should be done.			PRAPeR 68 (4. – 8. May 2009) Data gap open.
	New data gap 5.2 identified at PRAPeR 68: Further arthropod residue studies are necessary at the right application rate and GAP, in which the issue of rainfall is addressed, with behavioural observations, also including residues on dead arthropods, and at different field conditions (N and S-Eur), in which 3-OH is measured, and carbofuran and 3-OH are followed over time.			PRAPeR 68 (4. – 8. May 2009) Data gap open.
	New data gap 5.3 identified at PRAPeR 68:			PRAPeR 68 (4. – 8. May 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
	Further residue trials with earthworms are necessary at the correct application rate and GAP, in which the issue of rainfall is addressed, 3-OH is measured, and carbofuran and 3-OH are followed over time, and at different field conditions (N and S-Eur).			Data gap open.
	Open point: 5.3 MSs to discuss in an expert meeting the refined risk assessment for birds (3rd tier) based on the approach suggested for pirimicarb. It should also be discussed if the provided data are robust enough to support such a risk assessment approach. See reporting table 5(16)	**NOT:** We refer to our comments in 5(16).	**RMS (April 2009):** The RMS would welcome discussion in the expert meeting: Does the expert meeting consider that the “Opinion on pirimicarb” can be used to refine the risk assessment for other active substances? Under which conditions?	PRAPeR 68 (4. – 8. May 2009) After the discussion the meeting concludes that because of all the uncertainties identified, the pirimicarb-approach is not accepted. Open point fulfilled.
	Open point: 5.4 RMS to provide in an addendum a risk assessment for birds for the uptake of contaminated drinking water from puddles in line with the suggestion of the PPR opinion on the science behind the GD on risk assessment for birds and mammals (EFSA Journal, July 2008)	**NOT:** It should be noted that granules are buried to a depth of ≥ 40 mm when applied in furrow with the seed. Stewardship of the product requires that exposed granules should be buried or removed. Therefore the presence of granules in drinking water puddles and the subsequent risk assessment may, when stewardship in line with the requirements of authorisation is undertaken, lead to a possible	**RMS (April 2009):** A calculation for the drinking water according to EFSA Journal is presented in an addendum (acute TER = 1.41). RMS agrees with the statement of the notifier that these calculations possibly overestimate the risk.	PRAPeR 68 (4. – 8. May 2009) Open point fulfilled.

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 5(19)	overestimate of the risk.		
	Open point: 5.5 RMS to indicate in the corrected DAR and in the LoEP that the long-term reproductive NOEC for birds of 10 ppm includes only reproductive effects but not parental mortality which was observed at concentrations of 2, 5 and 10 ppm. See reporting table 5(20)		**RMS (April 2009):** The DAR and the List of Endpoints are corrected accordingly.	PRAPeR 68 (4. – 8. May 2009) Open point fulfilled.
	Open point: 5.6 MSs to discuss the long-term endpoint to be used in the risk assessment for birds. See reporting table 5(21)	**NOT:** See comment 5(21)	**RMS (April 2009):** The RMS is of the opinion that the adult mortalities observed in the reproduction study are not relevant for the risk assessment (12 weeks exposure period is an overestimation of the exposure in the field).	PRAPeR 68 (4. – 8. May 2009) Open point fulfilled. New open point proposed, see below.
	New open point 5.22: RMS to recalculate the risk with the trigger of 10. The long-term NOEC of 1.5 ppm will be removed from the LoE and the reproduction study from the list of studies relied on. The LC10 of 0.64 will be included in the LoE also as reproductive endpoint.			PRAPeR 68 (4. – 8. May 2009) 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
	Open point: 5.7 MSs to discuss in an expert meeting whether the quantitative refinement of PT and PD values are sufficiently supported by data. See reporting table 5(23)	**NOT:** We believe that we are using appropriate values from the guidance document (see 5(23)).	**RMS (April 2009):** The calculations with PD = 1 are already performed in the first tier. The RMS would welcome discussion in the expert meeting. As RMS, we consider that EFSA and MS have discarded our proposals for PD/PT factors, however without proposing acceptable ways for refinement: According to our last information, the new guidance opinion on risk assessment is not yet in application. We therefore invite EFSA to propose its own evaluation and to explain clearly how to perform the risk assessment for birds and mammals on the basis of the available database. - Is the guidance document SANCO/4145/2000 (Sept 2002) still acceptable? - What are acceptable PD and PT values for relevant bird species in sugar beet crop? How would you use the bird/mammal diet	PRAPeR 68 (4. – 8. May 2009) Open point fulfilled. 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
			information that is proposed in the "bird/mammal bible – Crocker *et al*., 1998)"? - How to address the determination of an acute PD factor for an acutely toxic compound? - Which interesting results can be expected from a radio-tracking study? How many replicates? How to perform this study?	
	New open point 5.23: RMS should indicate in the LoE that the PT and PD values used in the TER calculations are only for illustrative purposes.			PRAPeR 68 (4. – 8. May 2009) Open point open.
	Open point: 5.8 MSs to discuss the risk assessment for birds for the uptake of granules. See reporting table 5(24)	**NOT:** See comments at 5(24)	**RMS (April 2009):** The RMS would welcome discussion in the expert meeting. Is the EPPO scheme for calculations of risk to granules still valid? Does the meeting whish to apply a supplementary safety factor in the calculations?	PRAPeR 68 (4. – 8. May 2009) Open point fulfilled. New data gap proposed, see below.
	New data gap 5.4 identified at PRAPeR 68: Notifier to address the risk to birds from exposure to granules, considering all comments of RMS and			PRAPeR 68 (4. – 8. May 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
	PRAPeR meeting. Concerns were raised in the meeting about the possibility to address the risk considering the high risk to birds after intake of only one granule.			
	Open point: 5.9 MSs to discuss in an expert meeting the risk assessment for mammals for the uptake of granules. See reporting table 5(31)	**NOT:** We agree with the comments of the RMS (5(31))	**RMS (April 2009):** According to the theoretical calculations based on the EPPO scheme, the risk to mammals *accidentally* ingesting Furadan 5G granules when seeking food, would be acceptable: ETR are 0.049, 0.010 and 0.039 respectively for the short-term, medium-term and long-term risk assessment. Where the ETR < 1, the risk is considered to be low. These ETR are equivalent to TER values of respectively 21, 95 and 26 showing acceptable acute and long-term risk to mammals. The RMS considers the risk to mammals acceptable since they do not consume grit.	PRAPeR 68 (4. – 8. May 2009) Open point fulfilled.
	Open point: 5.10 MSs to discuss the PD/PT values suggested in the refined risk assessment for mammals. See reporting table 5(32)	**NOT:** The feeding behaviour of mammals may show differences between MS due to different habitats because of differences in agronomic practices. For an Annex I inclusion of a representative use however, it appears appropriate to initially use robust representative	**RMS (April 2009):** The RMS would welcome discussion in the expert meeting. - What are acceptable PD and PT values for relevant bird species in sugar beet crop? How would you use the bird/mammal diet	PRAPeR 68 (4. – 8. May 2009) Open point fulfilled. New data gap 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
		values, e.g. the 'Mammal Bible', which may be refined within MS should an Annex I inclusion follow.	information that is proposed in the "bird/mammal bible – Crocker *et al*., 1998)"? - How to address the determination of an acute PD factor for an acutely toxic compound?	
	New data gap 5.5 identified at PRAPeR 68: The risk to mammals needs to be addressed further.			PRAPeR 68 (4. – 8. May 2009) Data gap open.
	Open point: 5.11 MSs to discuss in an expert meeting the refined risk assessment for mammals based on the approach suggested for pirimicarb. It should also be discussed if the provided data are robust enough to support such a risk assessment approach. See reporting table 5(35)	**NOT:** See comment at 5(35)	**RMS (April 2009):** The RMS would welcome discussion in the expert meeting: Does the expert meeting consider that the "Opinion on pirimicarb" can be used to refine the risk assessment for other active substances? Under which conditions?	PRAPeR 68 (4. – 8. May 2009) Open point fulfilled.
	Open point: 5.12 MSs to discuss in an expert meeting the endpoint to be applied in the long-term risk assessment for mammals. See reporting table 5(40)		**RMS (April 2009):** The long-term risk resulting from the use of carbofuran is not the most ecologically relevant: Main toxicological effects are related to the acute effects of cholinesterase inhibition. The exposure through crop seedlings or invertebrates is short-lived as indicated	PRAPeR 68 (4. – 8. May 2009) Open point fulfilled. 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
			in the residue trials. The RMS would welcome discussion in the expert meeting to decide on the appropriate NOAEL.	
	New open point 5.24: the relevant long-term endpoint for mammals has to be determined.			PRAPeR 68 (4. – 8. May 2009) Open point open.
	Open point: 5.13 MSs to agree on the residues in sugar beet seedlings used in the refined risk assessment for mammals. See reporting table 5(42)	**NOT:** See comment under open point 5.2.	**RMS (April 2009):** 1) RMS disagrees with the statement of the notifier that the residues will decline 10 times for the lower application rate of 60 g a.s./ha, compared to the applied 600 g a.s./ha. This extrapolation should be substantiated with data, e.g. residue trials conducted at 60 g a.s./ha. 2) For the same reason, extrapolation of the factor 2.5 from the dossier of benfuracarb (cabbage) cannot be done to the dossier of carbofuran (sugar beet). 3) The RMS indicated in the DAR (Table B.9.3.2-18) why the 3-OH-carbofuran residues were not taken into account in the calculations of the RMS. "RMS considers that too much uncertainty remains on the conversion factor and has therefore	PRAPeR 68 (4. – 8. May 2009) Open point closed., see open point 5.2

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
			presented a TER assessment based on the measurement of carbofuran alone. This element must be taken into account in the interpretation of the final risk assessment. A copy of the statement of the notifier on the lowered dose rate of 60 g a.s./ha is included in the addendum. RMS maintains its position on this issue.	
	Open point: 5.14 RMS to provide in an addendum a risk assessment for mammals for the uptake of contaminated drinking water from puddles in line with the suggestion of the PPR opinion on the science behind the GD on risk assessment for birds and mammals (EFSA Journal, July 2008) See reporting table 5(47)	**NOT:** See comment under open point 5.4.	**RMS (April 2009):** A calculation for the drinking water according to the EFSA Journal is presented in an addendum (acute TER = 20).	PRAPeR 68 (4. – 8. May 2009) Open point closed, see open point 5.4
	Open point: 5.15 RMS to present in an addendum the TER calculations for *C. riparius* based on refined PECsed values (FOCUS step2 and step3). See reporting table 5(50)		**RMS (April 2009):** The risk for sediment dwelling organisms is considered acceptable since the calculations in surface water (TER = 155 in Table B.9.2.16.2-6) demonstrate acceptable risk. Moreover, the TER of 2.11 in sediment is based on a worst-case endpoint (FOCUS step 1: maximum concentration achieved in	PRAPeR 68 (4. – 8. May 2009) Open point still open for RMS to check final PECs.

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
			sediment). The notifier provided new PECsw FOCUS step 3 calculations. The TER calculations of the RMS based on these new PECsw values are presented in an addendum. The risk of 7-phenol to sediment dwelling organisms is acceptable (TER > 680000).	
	Open point: 5.16 MSs to discuss in an expert meeting whether a new acute toxicity study with 3-keto-carbofuran and *Ceriodaphnia dubia* is necessary. See reporting table 5(51)	**NOT:** We agree with the RMS	**RMS (April 2009):** The RMS considers that a new study is not required and that the margin of safety is sufficient (TER values between 9608 and 81667 based on FOCUS step 3 calculations). There was a calculation error which is corrected in the updated DAR. The notifier provided new PECsw FOCUS step 3 calculations. The TER calculations of the RMS based on these new PECsw values are presented in an addendum. The risk of 3-keto-carbofuran to aquatic invertebrates is acceptable (TER > 6203).	PRAPeR 68 (4. – 8. May 2009) Open point fulfilled. New open point proposed, see below.
	New open point 5.24: RMS to add a footnote to the LoE explaining why the study was accepted.			PRAPeR 68 (4. – 8. May 2009) Open point open.
	Open point : 5.17 RMS to include the mean measured concentrations		**RMS (April 2009):** For the study with 7-phenol, the nominal concentration of 10 mg/L	PRAPeR 68 (4. – 8. May 2009) Open point fulfilled.

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
	from the studies with sediment dwellers and carbofuran 7-phenol and carbofuran in the LoEP and in an addendum and to provide a revised risk assessment in an addendum and to update the LoEP See reporting table 5(52)		corresponds to the mean measured concentration of 5.34 mg/L. For the study with carbofuran, the nominal concentration of 0.004 mg a.s./L corresponds to the mean measured concentration of 0.0032 mg a.s./L. The TER calculations based on mean measured concentrations are presented in an addendum. The List of endpoints is corrected accordingly. The outcome of the risk assessment remains unchanged.	New open point proposed, see below.
	New open point 5.25: I the Step 1 calculation for 7-phenol, the carbofuran endpoint was used instead of 7-phenol endpoint, RMS should revise this in the list of end points.			PRAPeR 68 (4. – 8. May 2009) Open point open.
	Open point: 5.18 MSs to discuss in an expert meeting whether the studies with Rove Beetle (Schmuck R., 1993, p. 194-195 and Schmuck R., 1993, p. 201-203) and the study on Carabid Beetles (Schmuck, 1993, p 198-200) are acceptable since no positive control was tested	**NOT:** In the absence of suitable information the studies may provide supplementary information to identify which terrestrial organisms may be at a potential risk following application of carbofuran granules in furrow. We agree with the RMS that should the studies not be acceptable the outcome of the risk assessment would not change because of the availability of field studies.	**RMS (April 2009):** An extensive database containing laboratory studies on numerous organisms and field studies has been evaluated. The RMS believes that the 3 studies are acceptable. However, if the meeting would consider these 3 studies as not acceptable, this would not change the outcome of the risk assessment.	PRAPeR 68 (4. – 8. May 2009) Open point fulfilled.

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 5(55)			
	Open point: 5.19 MSs to discuss in an expert meeting whether the field study performed with a capsule suspension preparation (Strömel C. *et al*., 2002) can be used to address the risk from the granular formulation suggested in the representative use. See reporting table 5(62)	**NOT:** We agree with the RMS that analytical measurements from the study demonstrated exposure of the test organisms to carbofuran at a higher concentration than that predicted following application in line with the proposed GAP (in-furrow application at 60 – 600 g a.s./ha).	**RMS (April 2009):** The position paper of the notifier is presented on p. 240-241 in the DAR. The average actual concentration in the soil at day 0 was 2.8 mg carbofuran/kg wet soil. This test concentration covers the maximum PECsoil of 0.8 mg carbofuran/kg soil.	PRAPeR 68 (4. – 8. May 2009) Open point fulfilled. New data gap proposed, see below.
	New data gap 5.6 identified at PRAPeR 68: Notifier to provide further details on this study (Broadbent and Tomlin) to support the use of the field study.			PRAPeR 68 (4. – 8. May 2009) Data gap open.
	Open point: 5.20 RMS to include a statement in the updated DAR or in an addendum that the risk to other soil dwelling macro-organisms is not addressed for the use rate of 0.6 kg a.s./ha. See reporting table 5(63)		**RMS (April 2009):** The statement is included in the updated DAR on p. 246.	PRAPeR 68 (4. – 8. May 2009) Open point fulfilled.

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: 5.21 RMS to correct in the LoEP the interchanged TER values for *Hypoaspis aculeifer* and *Folsomia candida.* See reporting table 5(68)		**RMS (April 2009):** The List of Endpoints is corrected accordingly.	PRAPeR 68 (4. – 8. May 2009) Open point fulfilled.
	Vol. 1, Level 4 Data gaps in ecotoxicology	**EFSA:** The refined risk assessment for birds and mammals resulted in TERs below the triggers. The data gap identified in level 4 states that more information is needed on residue levels in feed items. However it is not clear if such a refinement would be sufficient to demonstrate a low risk. Further refinement may be necessary. Therefore it is suggested to broaden the wording of the data gap to "further refinement of the risk assessment to birds and mammals for the uptake of carbofuran residues in feed items is needed".	**Comment of the reporting table added by RMS (April 2009):** The RMS would welcome discussions in the expert meeting: As RMS, we consider that EFSA and MS have discarded our proposals for PD/PT factors, however without proposing acceptable ways for refinement: According to our last information, the new guidance opinion on risk assesment is not yet in application. We therefore invite EFSA to propose its own evaluation and to explain clearly how to perform the risk assessment for birds and mammals on the basis of the available database. - Is the guidance document SANCO/4145/ 2000 (Sept 2002) still applicable? - What are acceptable PD and PT values for relevant bird species in sugar beet crop?	PRAPeR 68 (4. – 8. May 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
			How would you use the bird/mammal diet information that is proposed in the "bird/mammal bible – Crocker *et al*., 1998" - How to address the determination of an acute PD factor for an acutely toxic compound? - Which interesting results can be expected from a radio-tracking study? How many replicates? How to perform this study? - Is it necessary to request additional residue trials in beet seedlings, earthworms and arthropods (which GAP, in-furrow, at the plant hole, or seed treatment)? Is the EPPO scheme for calculations of risk to granules still valid? Does the meeting whish to apply a supplementary safety factor in the calculations? We would welcome a discussion in the expert meeting on the applicability of probabilistic risk assessment. Does the expert meeting consider that the "Opinion on pirimicarb" can be used	

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
			to refine the risk assessment for other active substances? Under which conditions? The RMS would welcome discussion in the expert meeting to decide on the appropriate NOAEL for the long-term risk to mammals. **NOT:** We believe that the evaluation should consider the RA at the application rate of 60 g ai/ha (see also Article 15 1b of regulation 33/2008/EC), and the experts should define what refinement route is acceptable. For example, how could the reversibility of the carbamates AChE depression be considered in the RA?	
	Message from section 4 to section 5: The PECsurface water (and sediment) for carbofuran-7-phenol should be derived from the STEP 3 PEC values for carbofuran as calculated in addendum B.8 of March 2009, which might be corrected for molar weight and maximum occurrence (if required).			PRAPeR 68 (4. – 8. May 2009) noted.

Report of PRAPeR Expert MEETING 69

CARBOFURAN

Rapporteur Member State: BE

Specific comments on the active substance in the section

2. Mammalian Toxicology

are already listed in the relevant reporting table. Comments submitted for this meeting are listed below.

1. Comments submitted for this meeting:

Date	Supplier	File Name
none		

2. Documents submitted for meeting:

Date	Supplier	File Name
2009-04-14	BE	Carbofuran evaluation table rev1-0 (2009-04-14).doc
April 2009	BE	Carbofuran List of endpoints (April 2009).doc
2009-03-20	BE	Carbofuran reporting table rev 1-1 (2009-03-20).doc
March 2009	BE	Carbofuran revised DAR Vol1 (March 2009).doc

3. Documents tabled at the meeting:

Date	Supplier	File Name
none		

The conclusions of the meeting were as follows:

4. **Data on preparations:** Furadan 5G

5. **Classification and labelling:** The proposed classification of carbofuran is 'VERY TOXIC' with the associated risk phrases [R26/28] 'Very toxic by inhalation and if swallowed', [R39/41] 'Danger of very serious irreversible effects/risk of serious damage to eyes' and [R21] 'Harmful in contact with skin'.

6. **Recommended restrictions/conditions for use:** To be used as a granule according to the intended use listed in the GAP table.

7. **Reference List:** Not discussed

Areas of concern: None

Appendix 1: Discussion table: CARBOFURAN

Appendix 2: Evaluation table

Appendix 1: Discussion Table, Carbofuran (In)

2. Mammalian toxicology

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	Open point: 2.1 MSs to discuss the AOEL values in an expert meeting. See reporting table 2(2)	Experts discussed whether the pup results at post natal day 11 (PND11) from the new set of rat acute neurotoxicity studies should be taken for the establishment of the AOEL or the results in the young adults relating to the observed reduction of the brain AChE. Pup toxicity (PND11) NOAEL = 0.015 mg/kg bw/day and young adult toxicity NOAEL = 0.03 mg/kg bw/day. RMS – presented the results summarised in the evaluation table and whether it is considered that PND11 rat brain development is equivalent to that of the human brain in the 3rd trimester (just before birth) and should be used to establish the AOEL. The RMS proposed to use the adult NOAEL to establish the AOEL based on the results presented in the studies, applying a safety factor 100, and considering that the effects obtained in PND 11-21 rats are representative for the human neonate. Due to the concerns regarding exposure experts discussed whether a restriction on the use could be specified (i.e. granules). Experts discussed whether agreed that the AOEL should be established based on hazard and not risk. Not considering the exposure risk assessment, the majority of experts agreed that the higher NOAEL value (in adults) should be used to establish the AOEL, however all experts agreed that a restriction on the use should be stressed (in the GAP table, granular application is the only intended use). Therefore, the agreed AOEL is 0.0003 mg/kg bw/day, considering a SF of 100 and no correction for oral absorption. Note - experts also agreed that as it is unlikely that woman in late stages of pregnancy would be exposed to carbofuran.	Open point fulfilled The AOEL is 0.0003 mg/kg bw/day

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
		Open point fulfilled.	
	Open point: 2.2 MSs to discuss the dermal absorption value in an expert meeting. See reporting table 2(7)	The RMS presented an Addendum to the DAR with refinement of the *in vivo* and *in vitro* dermal absorption studies (in comparing the absorption value at 6h post-application in both studies). The absorption rate was ~1-2% in both cases and the equivalence was considered essential to bridge the studies. The rat/human proportion (2x) calculated on *in vitro* was applied on 24h absorption value (6%) leading to 3% estimate. As some drawbacks were found in the *in vivo* study, mainly urinary excretion showing further absorption after 24 h., the experts agreed that as a precautionary principle a dermal absorption of 5 % should be used as proposed by the Netherlands in the Reporting table comment 2(7). Open point fulfilled.	Open point fulfilled. The dermal absorption value is 5 % for the concentrate and the dilution of the representative formulation
	Open point: 2.3 Pending on the outcome of the discussion on the AOEL and dermal absorption values, RMS to provide new estimates of operator exposure risk assessment. MSs to discuss the model to be used in the operator exposure risk assessment in an expert meeting. See reporting table 2(9)	Open point open – RMS to provide the information in an Addendum to the DAR using the PHED model. The list of endpoints to be updated including only the PHED model results as the UK and German models are not appropriate for this type of application.	Open point open

Appendix 2: Evaluation 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
	Section 2 Open points: ***3*** Points for clarification: ***0*** Data gaps: ***0***			Section 2 Open points: ***1*** Points for clarification: ***0*** Data gaps: ***0***
	Open point: 2.1 MSs to discuss the AOEL values in an expert meeting. See reporting table 2(2)	**NOT:** We refer to our position paper on the setting of the ADI, ARfD and AOEL; to DE comment 2(3) from the reporting table; to applicant comment 2(5) from the reporting table and to JMPR views on the setting of carbofuran ADI, ARfD and AOEL. We maintain that ADI, ARfD and AOEL should be set at 0.001 mg/kg bw/day.	**RMS:** It is questionable whether PND11 rat brain development would be equivalent to that of human brain in the 3th trimester of human pregnancy. In open literature, estimates are not consistent. Some authors* estimate that the PND7 old pup is approximately equal to the human neonate in terms of brain growth rate, periventricular germinal matrix composition, neurochemical expression, EEG patterns and synapse formation. More relevant for the endpoint of AChE inhibition**, the timing of axonal outgrowth of AChE-positive nerve fibers was demonstrated just before birth in humans and perinatally (up to PND7) in the rat. On the contrary, in a more general neurodevelopmental model***, it was predicted that a PND14 old rat pup has a brain cortical development comparable to a human foetus 2 months before birth, possibly suggesting that human neonate neurodevelopment would be comparable to that in the weaned rat (however, the model is restricted to rat PND14 stage). In a recent paper****, it was considered reasonable that the 2nd half of the brain growth spurt in the rat (PND11-21) corresponds in developmental time to a portion of the human brain postnatal growth	PRAPeR 69 (4. – 8. May 2009): Open point fulfilled The AOEL is 0.0003 mg/kg bw/day

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
			spurt. Inspection of all the study results on PND11 or PND17 ♂rats moreover shows that brain AChE inhibition at 0.1 mg/kg was overall of about the same magnitude (33-40%), indicating that the rat neonate PND11 and PND17 were of equivalent sensitivity, and represent merely a human perinatal, and not a "third trimester embryo" situation. In any case, from the risk assessment point of view, it is not realistic that women in late pregnancy (approximately last month) would be representative for operators loading and applying Carbofuran. Therefore, it is not relevant to establish an AOEL on a pup toxicity NOAEL (0.015 mkd), and the adult NOAEL (0.03 mkd) is considered preferable. *References:* **Am J Physiol Regul Integr Comp Physiol, 282, 55-63, 2002; **in: Bjorklund, A, Hokfelt,T (Eds.) Handbook of Chemical Neuroanatomy, Elsevier, A'dam, 33-62, 1991; ***Neuroscience, 105, 7-17,2001; ****Toxicol Appl Pharmacol, 196, 287-302, 2004.*	
	Open point: 2.2 MSs to discuss the dermal absorption value in an expert meeting. See reporting table 2(7)	**NOT:** We refer to RMS comments 2(7) and 2(8) from the reporting tables.	**RMS:** The refinement consisted in comparing the *in-vivo* and the *in-vitro* (first study) absorption value at 6h post-application (see addendum p 188). In both cases the absorption rate was about 1-2%. This equivalence is an essential condition to make a bridging from *in-vivo* to *in-vitro*. Then, the rat/human proportion (2×) calculated on the data *in-vitro* was applied on the	PRAPeR 68 (4. – 8. May 2009) Open point fulfilled. The dermal absorption value is 5 % for the concentrate and the dilution of the representative formulation

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
			24h absorption value (6%), leading to the 3% estimate. RMS considered it overly conservative to rely on an *in-vivo* value at >24h, as in a regular *in-vivo* study, the skin would have been swabbed to remove the excess of radioactivity. It is logic that extending the contact time without swabbing leads to a protracted skin absorption (although a plateau phase seems to be attained at 24h). In addition, using acetone to dissolve the a.s. is likely to enhance absorption, and a 80× more diluted substance was used *in-vivo* compared with *in vitro*. Thus, several parameters indicate that the *in-vivo* study approximated a worst-case condition. In conclusion, the 3% value was considered a reasonable approach, and not very different from the value proposed by NL (5%), taking into account the variation usually observed in this kind of studies.	
	Open point: 2.3 Pending on the outcome of the discussion on the AOEL and dermal absorption values, RMS to provide new estimates of operator exposure risk assessment. MSs to discuss the model to be used in the operator exposure risk assessment in an expert meeting.		**RMS:** agreement to make a new estimation of the operator exposure in case of an altered reference dose (AOEL) or if skin absorption is revised upwards.	PRAPeR 68 (4. – 8. May 2009) 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
	See reporting table 2(9)			

REPORT OF PRAPeR EXPERT MEETING 70

CARBOFURAN

Rapporteur Member State: BE

Specific comments on the active substance in the section

3. Residues

are already listed in the relevant reporting table. Comments submitted for this meeting are listed below.

1. Comments submitted for this meeting:

Date	Supplier	File Name
none		

2. Documents submitted for meeting:

Date	Supplier	File Name
2009-04-14	BE	Carbofuran evaluation table rev1-0 (2009-04-14).doc
April 2009	BE	Carbofuran List of endpoints (April 2009).doc
2009-03-20	BE	Carbofuran reporting table rev 1-1 (2009-03-20).doc
March 2009	BE	Carbofuran revised DAR Vol1 (March 2009).doc
April 2009	BE	Carbofuran_addendum_Vol3 B7 (April 2009).doc

3. Documents tabled at the meeting:

Date	Supplier	File Name
none		

The conclusions of the meeting were as follows:

4. **Data on preparations:** FURADAN 5G

5. **Classification and labelling:** none

6. **Recommended restrictions/conditions for use:** Rotational crop limited to cereals

7. **Reference List:** not discussed

Areas of concern: the intake assessment indicates a risk for consumers but could not be finalised with the data available

Appendix 1: Discussion table: CARBOFURAN

Appendix 2: Evaluation table

Appendix 1: Discussion Table, Carbofuran (In)

3. Residues

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	Open point: 3.1 The residue definition in plant commodities both for monitoring and risk assessment should be discussed in a meeting of experts. See reporting table 3(~~12~~ 11)	Metabolism studies using soil application were provided on many crops, the main metabolite detected being the 3-OH carbofuran, partly detected as conjugated. The proposed residue definition includes the parent and the 3-OH carbofuran, this metabolite being considered as toxic as the parent. The 7-phenol metabolite was considered of no particular toxicological concern (no carbamate structure). The experts were of the opinion that the 3-OH carbofuran conjugates have to be included in the residue definition for risk assessment. The meeting discussed on the need to include also these conjugates in the residue definition for monitoring, taking into account that the efficiency of the analytical methods to release all these conjugates still has to be demonstrated. Currently it is unclear if and to what extend the method determines conjugated 3-OH carbofuran. Finally the following residue definitions were agreed: Risk assessment: Sum of carbofuran + 3 OH-carbofuran both free and conjugated expressed as carbofuran Monitoring: Open (pending information whether the methods of analysis are able to release the conjugates i.e. demonstrate the efficiency of the hydrolysis step) Preferably, the residue definition defined for monitoring and risk assessment should be the same, i.e. include conjugated residues of carbofuran + 3 OH-carbofuran.	Open point fulfilled. Risk assessment: Sum of carbofuran + 3 OH-carbofuran both free and conjugated expressed as carbofuran Monitoring: Open (pending information on efficiency of the hydrolysis step in the analytical method) Preferably, the same as for risk assessment.
	Open point: 3.2 The residue definition in	Metabolism studies in ruminant and poultry are available but the animal residue intake needs to be verified (if effectively expressed on the DM basis). The metabolite	Open point fulfilled. Risk assessment: 3 OH-carbofuran

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	animal commodities both for monitoring and risk assessment should be discussed in a meeting of experts. See reporting table 3(~~13~~ 12)	identification was considered sufficient. In these studies samples were analysed using an analytical method including a hydrolysis step. Thus free and conjugated carbofuran and 3-OH carbofuran were taken into account but their respective ratio remains unknown. From the rat metabolism there are some indications that there is no accumulation of carbofuran and 3-OH carbofuran (table B.6.1-6 in B.6 section of the DAR) and that conjugates are present in urine in faeces (table B.6.1-8). On the basis of the available data the following residue definitions were agreed: Risk assessment: 3 OH-carbofuran free and conjugates expressed as carbofuran Monitoring: Preferably the same (but the efficiency of the analytical method to release the conjugates needs to be addressed)	free and conjugates expressed as carbofuran Monitoring: Preferably the same (pending information on efficiency of the hydrolysis step in the analytical method) Data gap (see below): Notifier to address the amount of conjugates in the livestock metabolism studies Data gap for section 1 (transferred to section 1): The notifier 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.
	New data gap 3.1 identified at PRAPeR 70 meeting: Notifier to address the amount of conjugates in the livestock metabolism studies		Data gap open
	Open point: 3.3 It should be clarified whether in the data generation methods (residue trials) the efficiency of the hydrolysis step was	Refer to discussion in OP 3.1	Open point fulfilled. Data gap (see below): The notifier to address the efficiency of the hydrolysis step to effectively release the carbofuran and 3 OH-

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	validated? See reporting table 3(16)		carbofuran conjugates in the methods of analysis used in the supervised residue trials.
	New data gap 3.2 identified at PRAPeR 70 meeting: The notifier to address the efficiency of the hydrolysis step to effectively release the carbofuran and 3 OH-carbofuran conjugates in the methods of analysis used in the supervised residue trials.		Data gap open
	Open point: 3.4 Upon a plant residue definition for risk assessment has been agreed, the available residue data should be reviewed and the appropriate data should be selected. (Consider also open point in comment 3(16)) See reporting table 3(19)	As long as the efficiency of the analytical method to analyse the conjugates is unknown, the acceptability of the residue trial results is pending and a reliable consumer risk assessment can not be performed.	Open point open.
	Open point: 3.5	Some hydrolysis studies were provided but performed with carbosulfan, at 25°C and not in	Open point fulfilled.

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	The available processing data (nature and level) should be discussed by experts in terms of their suitability to conclude on residue behaviour under sugar beet processing/ sugar raffination See reporting table 3(22)	compliance with the guidelines. They were considered as not acceptable to address sugar beet processing. Sugar beet processing being conducted at higher temperatures and at a pH of about 11, a more rapid degradation is expected. However, the experts do not expect any new metabolites other than that recovered in the plant metabolism. In the submitted sugar beet processing study, no carbamate residues above the LOQ of 0.01 mg/kg for each carbamate (3 compounds) were recovered (neither in roots nor in processed products). A processing factor could not be derived from the study.	The experts do not expect any new metabolites other than that recovered in the plant metabolism. A processing factor could not be derived from the sugar beet processing study.
	Open point: 3.6 Assessment of residues in animal matrices, considering information available from all animal studies, to be submitted in an addendum and reviewed by the meeting of experts See reporting table 3(25)	The ruminant feeding study was performed at a 250N dose rate but was not used to derive residue levels for the risk assessment since the LOQs were considered not acceptable (0.05 and 0.025 mg/kg for tissues and milk respectively) with regard to the low tox reference values of carbofuran/ 3 OH-carbofuran. For this reason the animal metabolism studies were evaluated according to the livestock dietary burden. The recovered residue levels in the metabolism study should be reconsidered in the light of the conjugates (see Open point 3.2). Nevertheless these levels were used to conduct a provisional consumer risk assessment. Post meeting note: Livestock dietary intake estimates should also take into account residues in rotational crops (see OP 3.7 and 3.9). If crop rotation were restricted to cereals residues in maize silage, cereal straw and grain should be considered in the livestock dietary burden estimates, and residues in food of animal origin have to be assessed accordingly.	Open point fulfilled. New open point (see below): Estimates of residue levels in animal products to be reconsidered in the light of the conjugates issue (see Open point 3.2).
	New open point 3.11 Estimates of residue levels in animal products to be reconsidered in the light		Open point open

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	of the conjugates issue (see Open point 3.2).		
	Open point: 3.7 The issue of residues in rotational crops should be discussed in a meeting of experts, taking into account the conclusion drawn on benfuracarb with regard to carbofuran residues and the interim results obtained in the new confined study (2008). See reporting table 3(26)	In the fate section, it was concluded that more than 10% of carbamate residues were present in soil after 100 days in a number of available studies (considering the total, carbofuran, 3 OH carbofuran and 3 keto carbofuran, field study or extractable radioactivity lab incubations). A confined accumulation rotational crop study (interim report) was provided. Application was at 0.6 kg as/ha as recommended in the GAP. TRR in green parts of plants exceeded 0.01 mg/kg, but no information was provided on the nature of the residues. A final conclusion can not be drawn for the time being. A new data gap was identified.	Open point fulfilled. New data gap (see below): Data on further identification of residues in rotational crops has to be provided.
	New data gap 3.3 identified at PRAPeR 70 meeting: Data on further identification of residues in rotational crops has to be provided.		Data gap open
	Open point: 3.8 Consumer intake assessment for sugar beet and whether any refinement is possible with the available data should be discussed in a meeting of experts.	Based on the available data no refinement is possible. The approach using the EFSA PRIMo model leads to an exceedance due to the conservative sugar beet (raw) consumption figure of 1.3 kg used for the UK children. Processing factors for sugar processing could not be established. However, considering the crystallisation step in the sugar beet processing, no residues are expected in sugar. The majority of the experts were of the opinion that it would be acceptable to use the input value “0” for sugar beet/sugar in the intake assessment.	Open point fulfilled. The majority of the experts were of the opinion that it would be acceptable to use the input value “0” for sugar beet/sugar in the intake assessment.

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	See reporting table 3(27)		
	Open point: 3.9 The consumer risk assessment should be discussed in a meeting of expert, considering all relevant sources of exposure to carbofuran residues with respect to the notified use See reporting table 3(28)	RMS performed a calculation including the TRR values observed in the rotational crop study (see Addendum of April 2009). Using such values, the ARfD is significantly exceeded for a lot of crops. Considering this calculation, a proposal to overcome the problem might be to restrict the crop rotation to cereals since there is no scientific ground for any further refinement of the RA at the moment. In addition, a leaching of carbofuran was identified in several focus scenarios and the possible intake through drinking water should be considered in addition to the intake through food. Post meeting note: Livestock dietary intake estimates should also take into account residues in rotational crops. If crop rotation were restricted to cereals residues in maize silage, cereal straw and grain should be considered in the livestock dietary burden estimates, and residues in food of animal origin have to be assessed accordingly.	Open point fulfilled. The provisionally estimated intakes, considering all relevant sources of exposure to carbofuran residues indicate a risk for consumers.
	Open point: 3.10 At the end of the discussion on carbofuran the meeting of experts may consider the MRLs (plants, animals) that should be proposed to risk managers See reporting table 3(30)	No MRLs can be proposed for plant and animal commodities due to the outstanding data (points 3.1 and 3.2)	Open point still open. For the time being, no MRLs can be proposed for plant and animal commodities
	New open point : The list of endpoints to be updated in accordance with the decisions of the	List of endpoints to be updated	Open point still open.

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	meeting		

Appendix 2: Evaluation table

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: ***10*** Points for clarification: ***0*** Data gaps: ***0***			Section 3 Open points: ***3*** Points for clarification: ***0*** Data gaps: ***3***
	Open point: 3.1 The residue definition in plant commodities both for monitoring and risk assessment should be discussed in a meeting of experts. See reporting table 3(~~12~~ 11)	**NOT**: We refer to RMS and applicant comment 3(12) from the reporting tables. The residue definition in plant should be maintained as carbofuran + 3-0H carbofuran, both free and conjugated expressed as carbofuran.	**RMS 04.2009:** RMS agrees that the residue definitions for monitoring and RA in plant commodities must be consistent with the residue definitions established for Carbofuran in the framework of Benfuracarb dossier. The available plant metabolism studies showed that Carbofuran and 3-OH-carbofuran were the most predominant compounds of the total residues. Considering the limited characterization of the glycosides and other conjugates in the acid hydrolysis released radioactivity, the following residue definitions are proposed for sugar beet: -**Monitoring**: **carbofuran + 3-0H carbofuran expressed as carbofuran** **-Risk assessment: carbofuran + 3-0H carbofuran, both free and**	PRAPeR 70 (4 – 8 May.2009): Open point fulfilled. Risk assessment: Sum of carbofuran + 3 OH-carbofuran both free and conjugated expressed as carbofuran Monitoring: Open (pending information on efficiency of the hydrolysis step in the analytical method) Preferably, the same as for risk assessment.

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 expressed as carbofuran. There is no need to include other carbamates metabolites (3-keto-carbofuran) and phenolic metabolites that are less toxic than Carbofuran and 3-OH-carbofuran. RMS proposes to discuss this point during the Expert meeting considering the JMPR Carbofuran evaluation that is presented in the Addendum to the DAR-April 2009.	
	Open point: 3.2 The residue definition in animal commodities both for monitoring and risk assessment should be discussed in a meeting of experts. See reporting table 3(~~13~~ 12)	**NOT**: We refer to RMS and applicant comment 3(13) from the reporting tables. 3-0H carbofuran, both free and conjugated expressed as 3-OH-carbofuran would be the appropriate residue definition in animal commodities – if such residue definition is required.	**RMS 04.2009:** RMS also agrees that considering the available metabolism studies in livestock and the theoretical calculated dietary burden, no residue is expected in the animal matrices. -For ruminants'matrices, **3-OH-carbofuran** can be a valid indicator of the total residues in milk, liver and kidney and per default in muscle and fat characterized by extremely low levels of recovered radioactivity (0.01 µg/kg). Indeed, a non negligible fraction of the radioactivity consisted of aqueous soluble residues/polar residues in all the matrices. The available analytical methods for	PRAPeR 70 (4 – 8 May.2009): Open point fulfilled. Risk assessment: 3 OH-carbofuran free and conjugates expressed as carbofuran Monitoring: Preferably the same (pending information on efficiency of the hydrolysis step in the analytical method) Data gap (see below): Notifier to address the amount of conjugates in the livestock metabolism studies Data gap for section 1 (transferred to section 1): The notifier to address the efficiency of the

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 determination of the carbamate metabolites (carbofuran, 3-OH-carbofuran and 3-keto-carbofuran) include an acid hydrolysis step to take into account the possible conjugates. HPLC-PCD methods were considered as suitable for the determination of the residues of Carbofuran, 3-OH-carbofuran and 3-keto-carbofuran in animal matrices with a LOQ for each analyte of 0.05 ppm (liver, muscle, eggs), LOQ of 0.025 ppm (whole milk). Concerning kidney, fat and milk cream, insufficient data were available to establish a LOQ unequivocally. For poultry matrices, no residue is expected in any matrices considering the calculated dietary burden that did not trigger a metabolism study. The metabolite 3-OH-metabolite was detected only in egg yolk. Therefore, a general residue definition is proposed for animal matrices: -**For monitoring: 3-OH-carbofuran** **-For risk assessment: 3-OH-carbofuran, free and conjugated expressed as 3-OH-carbofuran.**	hydrolysis step to release the 3 OH-carbofuran conjugates in animal matrices in the method of analysis for monitoring.
	New data gap 3.1 identified at PRAPeR 70 meeting:			PRAPeR 70 (4 – 8 May.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
	Notifier to address the amount of conjugates in the livestock metabolism studies			Data gap open
	Open point: 3.3 It should be clarified whether in the data generation methods (residue trials) the efficiency of the hydrolysis step was validated? See reporting table 3(16)	**NOT:** We refer to the metabolism data which demonstrates that solven and acid hydrolysis extraction release any free and conjugated residue while enzyme extraction release the bound residue (compounds incorporated to natural plant constituents). Therefore, the hydrolysis extraction step is validated by the metabolism data for its efficiency at releasing conjugated 3-OH-carbofuran.	**RMS 04.2009:** The efficiency of the hydrolysis step in the analytical method referenced A-17-05-13 was validated through the validation data package of this method under chapter B.5.2.1, Table B.5.2.1-9b regarding the recovery and precision of the analytical method for 3-OH-carbofuran. Indeed at fortification levels of 0.005 and 0.05 mg/kg with this metabolite, the recoveries accounted for 107 % and 92 %, respectively. The complete validation data package for the analytical method No A-17-05-13 is reported in the Addendum to the DAR-April 2009.	PRAPeR 70 (4 – 8 May.2009): Open point fulfilled. Data gap (see below): The notifier to address the efficiency of the hydrolysis step to effectively release the carbofuran and 3 OH-carbofuran conjugates in the methods of analysis used in the supervised residue trials.
	New data gap 3.2 identified at PRAPeR 70 meeting: The notifier to address the efficiency of the hydrolysis step to effectively release the carbofuran and 3 OH-carbofuran conjugates in the methods of analysis used in the supervised residue trials.			PRAPeR 70 (4 – 8 May.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
	Open point: 3.4 Upon a plant residue definition for risk assessment has been agreed, the available residue data should be reviewed and the appropriate data should be selected. (Consider also open point in comment 3(16)) See reporting table 3(19)		**RMS 04.2009:** A complete residue database covering North and South of Europe on sugar beet was provided in the frame of the resubmission and showed a non-residue situation both in roots and leaves with tops. The analytical method was completely validated at a Limit of Quantification of 0.005 mg/kg for each analyte.	PRAPeR 70 (4 – 8 May.2009): Open point open
	Open point: 3.5 The available processing data (nature and level) should be discussed by experts in terms of their suitability to conclude on residue behaviour under sugar beet processing/ sugar raffination See reporting table 3(22)	**NOT:** For recall, the processing study was run at exaggerated dose rate (4.48 g ai/ha) and showed 0.02 – 0.03 mg/kg of 3-keto-7-phenol in molasses and sugar while no carbamates residue was recovered. This confirms that any carbamate residue would convert to phenolic metabolite through the processing of roots to sugar. We believe that this data could support a 3 x residue degradation factor in processing, considering the worst case assumption that 0.03 mg/kg of carbamate degraded to 0.02 mg/kg of phenoilic metabolite and 0.01 mg/kg of carbamate (0.01 mg/kg being the LOQ of carbamates residue in the processing study).	**RMS 04.2009:** The first study (El-Naggar S.F., Reynolds J.L., 1982) was not conducted according to the representative hydrolytic conditions of processing according to the current guideline. In fact, the study was conducted at room temperature (T°: 25°C) and at pH values of 5.0, 7.0 and 9.0. Processing operations typically involve higher T° but for much shorter periods and for more extreme pH values. Moreover, this study performed with Carbosulfan did not investigate the hydrolysis of Carbofuran and 3-OH-carbofuran. Although the second study (Alvarez M.,	PRAPeR 70 (4 – 8 May.2009): Open point fulfilled. The experts do not expect any new metabolites other than that recovered in the plant metabolism. A processing factor could not be derived from the sugar beet processing study.

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
			1989b) was considered as acceptable (see Carbofuran DAR-Vol 3 B(2), point B.2.1.14), this study cannot be considered as valid to describe the fate of Carbofuran and its metabolites under the different processing conditions. With regard to the residue levels in processed sugar beet commodities, the study (Stearns J.W., 1986) consisted of a soil treatment at an exaggerated dose rate of 4.48 kg as/ha. No residues of carbamates metabolites were recovered in the roots, cossettes, molasses and sugar (<0.01 mg/kg). It is therefore not possible to calculate a processing factor. Only low residue levels of 3-keto-7-phenol (0.02-0.03 mg/kg) were recovered in molasses and sugar suggesting that all the carbamates have been degraded totally in to the phenolic metabolites through sugar processing.	
	Open point: 3.6 Asssessment of residues in animal matrices, considering information available from all animal studies, to be	**NOT:** We refer to applicant comment 3(28) from the Reporting table.	**RMS 04.2009:** RMS agrees that the available ruminants' feeding study presented in the DAR (point B.7.8.1) was not suitable to perform a robust dietary	PRAPeR 70 (4 – 8 May.2009): Open point fulfilled. New open point (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
	submitted in an addendum and reviewed by the meeting of experts See reporting table 3(25)		intake risk assessment with LoQs of 0.025 mg/kg and 0.05 mg/kg in whole milk and tissues, respectively provided the extremely low toxicological reference values of Carbofuran. Therefore, assuming linearity in dose and recovered residue levels in all the matrices, RMS proposed to carry out the consumer risk assessment considering the recovered residue values in the carbofuran metabolism studies performed on lactating goats and laying hens. To be consistent with the residue definition proposed for animal matrices (open point 3.2), the residue levels of 3-OH-carbofuran that would be expected are listed as follows considering the **120 N** and **2500 N** rates for ruminants and poultry, respectively and the recovered residue levels in the different animal matrices (see tables B.7.2.1-3 and B.7.2.2-3 in the DAR): -0.3 µg/L in milk, -0.3 µg/kg in kidney, -0.05 µg/kg in liver , -0.01µg/kg in muscle and fat, -0.01µg/kg in eggs. The assessment of the residue levels	Estimates of residue levels in animal products to be reconsidered in the light of the conjugates issue (see Open point 3.2).

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
			in the animal matrices were reported in the Addendum to the DAR-April 2009. These values were considered as inputs in the EFSA PRIMo and UK model to carry out the dietary risk assessment.	
	New open point 3.11 Estimates of residue levels in animal products to be reconsidered in the light of the conjugates issue (see Open point 3.2).			PRAPeR 70 (4 – 8 May.2009): Open point open
	Open point: 3.7 The issue of residues in rotational crops should be discussed in a meeting of experts, taking into account the conclusion drawn on benfuracarb with regard to carbofuran residues and the interim results obtained in the new confined study (2008). See reporting table 3(26)	**NOT:** We refer to applicant comment 3(26) from the Reporting table. If a consumer risk assessment for succeeding crops should be considered, we then propose to consider that 10% of the TRR in succeeding crop expressed carbofuran + 3-OH-carbofuran (both free and conjugated). This would still be an extreme worst case assumption (1) since all metabolism data show that less than 10% of the TRR in consumable parts – at harvest – accounts for carbofuran and + 3-OH-carbofuran (both free and conjugated); and (2) since it does not takes into account the degradation of carbofuran to phenolic metabolites happening in	**RMS 04.2009:** DT_{50} lab Carbofuran: 1.3-27 days. DT_{90} Carbofuran field (Netherlands, Spain, Italy) on bare soil: 4.4-91 days. . DT_{50} lab 3-OH-carbofuran: 0.22-0.3 days DT_{50} lab 3-keto-carbofuran: 1.54-8.12 days DT_{50} lab carbofuran-phenol: 0.3 day RMS disagrees on the conclusions that were drawn on Benfuracarb to require additional rotational crops since the longest DT_{90} (field) is 91 days for Carbofuran. The 2 other metabolites containing the carbamate moiety have DT_{90} ranging between 1 and 26 days. It	PRAPeR 70 (4 – 8 May.2009): Open point fulfilled. New data gap (see below): Data on further identification of residues in rotational crops has to be provided.

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 soil in the time interval between 2 crops.	is therefore obvious that less than 10% of the total relevant residue (carbofuran and carbamate metabolites) can be found in soil at 100 days. In the new confined rotational crop study (Rosenwald J., 2008), the uptake of Carbofuran by all plant parts at all ageing periods was very low and the level of total radioactive residues did not exceed the trigger value of 0.01 mg/kg, except for spinach leaves at 30-day interval (0.031 mg/kg at harvest). The notifier mentioned that no further investigation of the TRR in spinach leaves will be undertaken because of the low levels of total recovered residues. In order to perform the dietary risk assessment, the total radioactive residues values reported for the edible parts of the rotated crops at the 30-day interval were used as inputs in the EFSA PRIMo although these residue levels are largely overestimated with regards to the most valid indicators of the total residues in crops, i.e. Carbofuran and 3-OH-carbofuran. Moreover, this approach is rather conservative as it does not consider	

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 further degradation of these carbamate metabolites into the phenolc compounds occurring into the soil before the rotated crop is sown. These inputs in the EFSA PRIMo were : -0.006 mg/kg fort the root vegetables rotated crops, -0.001 mg/kg for the small grain rotated crops, -0.03 mg/kg for the leafy rotated crops.	
	New data gap 3.3 identified at PRAPeR 70 meeting: Data on further identification of residues in rotational crops has to be provided.			PRAPeR 70 (4 – 8 May.2009): Data gap open
	Open point: 3.8 Consumer intake assessment for sugar beet and whether any refinement is possible with the available data should be discussed in a meeting of experts. See reporting table 3(27)	**NOT:** we refer to RMS and applicant comment 3(30) from the reporting tables. The use of refine sugar consumption intake from the UK model is appropriate to reflect impact of the sugar beet use of carbofuran. See also Open point 3.5 for another refinement on the basis of the processing study.	**RMS 04.2009:** EFSA PRIMo: The maximum food intake reported at the 97.5th percentile for the UK 4-6 year old child (20.5 kg bw) and for the UK adult (76 kg bw) accounted for 1309 g/day and 1971 g/day of sugar beet root, respectively. If we assume that the sugar beet root contains approximately 16 % of sugar, the actual sugar consumption can be estimated to raise 209 g/day for the UK	PRAPeR 70 (4 – 8 May.2009): Open point fulfilled. The majority of the experts were of the opinion that it would be acceptable to use the input value “0” for sugar beet/sugar in the intake assessment.

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
			4-6 year old child and 315 g/day for the UK adult. The recommended maximum sugar intake for an adult and a 4-6 year old child are 50 g/day and 40 g/day of sugar, respectively. In addition, when taking into account the no-residue situation in sugar beet root characterized by an extremely low Limit of Quantification (0.005 mg/kg for each analyte), the soil DT_{90} values respectively for Carbofuran and 3-OH-carbofuran and assuming that any residue that may be left in the roots is substantially reduced during production of sugar, the outcome of this model can be considered as clearly conservative. With regard to the rotational crops, the input values in the EFSA PRIMo corresponded to the amount of TRR found in the succeeding crops after 30 days (simulating a crop failure). This approach is rather conservative since the residue levels of Carbofuran and 3-OH-carbofuran are lower than the TRR values (see available plant metabolism studies performed with Carbosulfan and Carbofuran) considering the $DT_{50/90}$ values of Carbofuran and 3-OH-carbofuran and also the metabolisation	

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
			of Carbofuran into its other carbamate and phenolic metabolites that occurs in soil before planting the succeeding crops. RMS presented the consumer risk assessment considering all the sources of exposure to carbofuran according to the EFSA PRIMo. UK model was also used since the refined sugar consumption data is more appropriate to refine the impact of the sugar beet use of carbofuran on the consumer safety.	
	Open point: 3.9 The consumer risk assessment should be discussed in a meeting of expert, considering all relevant sources of exposure to carbofuran residues with respect to the notified use See reporting table 3(28)	**NOT:** See our comments under Open points 3.6, 3.7 and 3.8.	**RMS 04.2009:** The consumer dietary risk assessment including all means of consumer dietary exposure (animal products, rotated crops) was performed according to EFSA PRIMo and the UK model and is presented in the Addendum to the DAR-April 2009.	PRAPeR 70 (4 – 8 May.2009): Open point fulfilled. The provisionally estimated intakes, considering all relevant sources of exposure to carbofuran residues indicate a risk for consumers.
	Open point: 3.10 At the end of the discussion on carbofuran the meeting of experts may consider the MRLs (plants, animals) that		**RMS 04.2009:** RMS agrees.	PRAPeR 70 (4 – 8 May.2009): Open point open. For the time being, no MRLs can be

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
	should be proposed to risk managers See reporting table 3(30)			proposed for plant and animal commodities
	New open point 3.12 The list of endpoints to be updated in accordance with the decisions of the meeting of experts PRAPeR 70			PRAPeR 70 (4 – 8 May.2009): Open point open.