TABLE OF CONTENTS

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

Other comments				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
1(1)	Vol. 1, Level 2, Appendix 1 - List of endpoints	DE: For body fluids and tissues the residue definition for monitoring purposes is missing. We agree that the relevant residue for monitoring should be carbofuran.	**Comments from notifier (Nov 2008):** no comments **RMS:** For other dossiers, the RMS was asked to include these data in the LoEP and to remove them a few months after, because it was not allowed according to the official LoEP.	Addressed.
1(2)	Vol. 1, 1.1, purpose	Notifier:In general the notifier is pleased with the DAR and acknowledges the overall conclusions. The comments here given are limited and do not affect the overall conclusions. With respect to ecotox (birds) the notifier whishes to highlight differences between the submitted dossier and DAR, especially concerning the choice of ecotoxicological relevant toxicity endpoints and PD refinements used in the risk assessment.	**RMS:** We acknowledge the notifier's comment.	Addressed.

2. Mammalian toxicology

Other toxicological studies & Medical data (B.6.8-B.6.9)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
2(1)	B.6.8.1.1 Toxicity studies on metabolites – carbofuran, p. 6-73 & Table p. 6-74, short term toxicity	EFSA: It is understood that the 60-day gavage study in rat and the 10-week dietary study also in rat are new studies, not referred in the carbofuran's DAR or respective addendum; therefore a more detailed assessment should be made available.	**Comments from notifier (Nov 2008):** No comments. Action RMS. **RMS (Nov 2008):** The study was fully evaluated at the occasion of the resubmission of Carbofuran, and RMS refers to this DAR. In summary, it was concluded that in the new study, slight testicular effects were observed at the dietary top dose (180 mkd). In the gavage study, no histopathological effects were observed at 0.8 mg/kg b.w.. The effects were considered insufficient to support classification for reprotoxicity. The outcome of the study was without effect on the determination of the reference doses (cfr. 2(2)).	Open point: RMS to transfer the detailed evaluation of the new studies from the carbofuran dossier to an addendum to the benfuracarb resubmission dossier to be discussed in an expert's meeting.

Other toxicological studies & Medical data (B.6.8-B.6.9)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
2(2)	B.6.8.1.1 Toxicity stud on metabolites carbofuran, p. 6- maternal NOAEL fr developmental studies rat	EFSA: Another rat developmental study assessed in the DAR on carbofuran (Rao, 1978a FMC) presented a maternal LOAEL of 0.3 mg/kg bw/day and a NOAEL of 0.1 mg/kg bw/day that were considered relevant for risk assessment. Therefore, this overall maternal NOAEL for rat developmental toxicity studies of 0.1 mg/kg bw/day should be referred as well.	**Comments from notifier (Nov 2008):** No comments. Action RMS. **RMS (Nov 2008):** Fully agreed. However, this study was not considered to drive the reference doses any more. Indeed, the notifier submitted new acute neurotoxicity studies (on both adult and rat pups) which were considered relevant to derive lower reference doses than those initially established. RMS refers to the DAR of Carbofuran. In short, the ARfD and the ADI were lowered to 0.00015 mg/kg b.w./d, and the AOEL to 0.0003 mg/kg b.w./d.. The relevant NOAEL's were based upon significant (≥ 20%) decreases of brain AChE after single administration.	Rat developmental study: Addressed: RMS to consider in a revised DAR of corrigendum. Rat acute neurotoxicity studies with carbofuran: Open point: As these studies appear to present more critical results, RMS to present its assessment in an addendum to the resubmission report of benfuracarb.

Other toxicological studies & Medical data (B.6.8-B.6.9)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
2(3)	B.6.8.1.1 Toxicity studies on metabolites – carbofuran, p. 6-80, metabolites of carbofuran	EFSA: Depending on the fate assessment of ground water metabolites, it should be discussed further if data on genotoxicity of carbofuran (mainly *in vivo* tests) are applicable to 3-OH carbofuran metabolite.	**Comments from notifier (Nov 2008):** No risk for leaching of carbofuran metabolites. **RMS (Nov 2008):** The FOCUS-PEARL simulations, considering yearly applications indicated that in all scenarios, the estimated 80th percentile concentrations in groundwater were <0.0001 µg/L for Benfuracarb and its metabolites (carbofuran-phenol, carbofuran-3-keto and carbofuran-3-hydroxy). Thus, the 3-OH carbofuran has been shown an unlikely candidate to leach into the groundwater, and was not considered environmentally relevant.	Open point: Pending on the outcome of the environmental fate and behaviour section discussion, MSs to discuss genotoxicity of carbofuran's metabolite 3-OH in an expert's meeting.

Other toxicological studies & Medical data (B.6.8-B.6.9)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
2(4)	B.6.8.1.1 Toxicity studies on metabolites – carbofuran, p. 6-82, ADI and ARfD	EFSA: At the time of finalization of the carbofuran conclusion, at the EFSA Evaluation Meeting in June 2006, it was noted that a new study on spermatogenesis in rat had been provided to the RMS and also to ECB for consideration as part of the classification process. The results of this study have not been considered or peer reviewed within the risk assessment process under Directive 91/414/EEC and would support a confirmation of the reference values i.e ADI and ARfD that were provisionally agreed at EPCO 33 (Mammalian toxicology experts' meeting). Therefore it would be useful to assess this study to set an ADI and ARfD for carbofuran and to agree on the withdrawal of the provisional statement.	**Comments from notifier (Nov 2008):** No comments. Action RMS. **RMS (Nov 2008):** As discussed in 2(2), it is proposed to lower the reference doses based upon the newly submitted acute neurotoxicity studies on Carbofuran. The outcome will be of importance for the discussion of the three carbamates Carbofuran, Carbosulfan and Benfuracarb, as they all have the same metabolite.	Open point: MSs to discuss the reference values (ADI and ARfD) of carbofuran in an expert's meeting.

Toxicity of the product(s) (B.6.11)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
2(5)	Vol. 3, B.6.11.5, Eye irritation	DE: A tabular summary of individual scores of the eye irritation study should be given. Reversibility was not controlled later than 72 h. Nevertheless, the study is considered acceptable by the RMS. Iris scores are 1 for all animals at 24 and 48 h and 1 for 5/6 animals at 72 h which is just below the threshold for classification. Moreover, a clear tendency of reversibility was not shown. It should be discussed at the expert meeting, whether this study is acceptable.	Notifier: 1. A tabular summary of individual scores of the eye irritation should be given. □ Such a table is included in the report (page 16); indeed not in the summary of the DAR. 2. Reversibility was not controlled later than 72 h. □ 48h and 72h after administration no eye effects was observed in any animal (score 0.0) . According to the guideline, the study can be terminated at 72 h in case no effects are observed at that time point. Therefore the study could be terminated after 72 hours (and control of reversibility was not relevant). (1987, OECD 405: "If there is no evidence of irritation after 72 hours, the study may be ended). (2002, OECD 405:"animals that do not develop ocular lesions may be terminated not earlier than 3 days post instillation. Animals with mild to moderate lesions should be observed until the lesions clear, or for 21 days, at which time the study is terminated"). 3. Iris cores are 1 for all animals at 24 and 48 hours, and 1 for 5/6 animals at 72 hours (which is just below the threshold for classification). □ Iris scores are 0 for any animal on any	Addressed: To be considered at MSs level.

Toxicity of the product(s) (B.6.11)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			time point. Only very mild scores for redness and chemosis of conjunctivae are observed at 0h and 24h (which all disappeared at 48h). □ Treshold for classification is far above the eye effects observed in the study. 4. Moreover, a clear tendency of reversibility was not shown. □ Reversibility is not relevant since all effects disappeared at 48 (and 72) hours. 5. It should be discussed at the expert meeting, whether this study is acceptable. □ As explained above, this study does fully meet the requirements, hence is acceptable. **RMS (Nov 2008):** RMS does not understand the explanation of the notifier: there were ocular effects up to and including 72h (maybe notifier was referring to the data of the skin irritation experiment?). The values in the 6 rabbits on the relevant time points are as follows (page 13 of the report): **time (h)** **erythema** 24 2 2 2 2 2 2 48 2 1 1 1 1 1 **72 2 1 0 1 1 0** **chemosis**	

Toxicity of the product(s) (B.6.11)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			24 2 2 1 1 2 2 48 2 1 1 0 1 2 **72 2 1 1 0 0 1** **iris** 24 1 1 1 1 1 1 48 1 1 1 1 1 1 **72 1 1 0 1 1 1** **cornea** 24 2 0 0 0 2 2 48 1 0 0 0 0 2 **72 1 0 0 0 0 0** RMS recognises that no reversibility has been demonstrated. In a worst-case (even if not very plausible) it could not be excluded that lesions (for instance iris lesions) would still be present on d21. Although overall, the test on the formulation was below the threshold for classification, this may be overruled if irreversible effects would be present on later stages. Therefore, classification Xi; R36 could be proposed. A new test was not warranted based upon animal welfare considerations.	

Exposure data (B.6.14)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
2(6)	Vol. 3, B.6.14, Exposure data	DE: Operator exposure is calculated using 0.086 kg as/ha by the RMS. According to the summary of representative uses the application rate is 1.0 kg as/ha.	**Comments from notifier (Nov 2008):** The calculation according to PHED model as presented in the DAR is correct. We have verified the calculation. Probably in the table it should be mentioned that the application rate is 1 kg a.s./ha to avoid confusion **RMS (Nov 2008):** The RMS confirms that the calculations were performed taking into account an application rate of 1 kg a.s./ha, and not 0.086 kg a.s./ha.	Addressed: Application rate of 1.0 kg as/ha has been considered in the peer-review of benfuracarb for operator exposure risk assessment.

Other comments				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
2(7)	Vol. 1, List of endpoints, Impact on human and animal health, Vol. 3, B.6.12, Dermal absorption	DE: In the endpoint list in Vol. 1, a 100 % default value for dermal absorption is mentioned. In contrast, 10 % is given in Vol. 3 without any justification. Based on physico-chemical properties (as laid down in the EU Guidance document), we support 100 %. This assumption should be used for the exposure calculations.	**Comments from notifier (Nov 2008):** the additional report contains calculations for both 10% and 100% dermal absorption. At 100% dermal absorption, the use is safe provided gloves and respiratory equipment are used. This was also the conclusion in the EFSA report of July 28, 2006 (page 2). **RMS (Nov 2008):** Agreed. In the DAR, calculations are conducted with both a 10% and a 100% absorption rate. In the PHED model, an acceptable exposure would be expected using both gloves and RPE.	Addressed: 100 % dermal absorption has been agreed during the peer-review of benfuracarb and has been used in the operator exposure risk assessment.

Other comments				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
2(8)	Vol. 1, 2.1.4, Classification and Labelling of Oncol 8.6 G	DE: Data on acute inhalation toxicity are not provided for Oncol 8.6 G. Therefore, according to Directive 1999/45/EC classification of the preparation with Xn, R20 is necessary based on the concentration of benfuracarb (> 3 %).	**Comments from notifier (Nov 2008):** no comments. DE comments is correct. This has no further effects on the dossier. **RMS (Nov 2008):** This is formally correct. However, both for Carbofuran and Carbosulfan products, which are comparable formulations (gr) and have similar ways of application, inhalation tests on the formulations were not submitted, and no classification proposed. This is also the case for the Benfuracarb formulation. As it was shown that the dustiness of the preparation was low, the waiving seems acceptable. -The dust content of Oncol 8.6 G was determined gravimetrically in accordance with CIPAC MT 171 (i.e. method recommended by FAO/WHO manual) and the preparation was found << 1%w/w , i.e. 'nearly dust-free' (see Vol.3 B.2.2.27). -The attrition resistance was determined to be 99.82% (by using CIPAC MT 178), which is above the generally used minimum limit of 98%. -The dust content (particles < 150 µm) was determined to be 0.1 % w/w (by dry sieve analysis CIPAC MT 58).	Addressed: To be considered at MSs level.

3. Residues

Metabolism in plants (B.7.1)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
3(1)	Vol.3 B.7.1.3 bis Metabolism in cabbage	EFSA: It is not clear what is meant by *"high variability in the total recovered radioactive residues"*. Does this statement refer to the observed increase of TRR with sampling time? Isn't an increase even expected to occur when seedlings/ young plants are growing due to a high availability of the substance in soil and an increasing capacity of the developing root system for uptake of compounds from soil?	**Comments from notifier (Nov 2008):** In our interpretation it refers to the high recovery (179%) for the day 3 sample. So the statement does not refer to the observed increase of TRR, which is indeed quite possible. **RMS (Nov 2008):** The statement referred to the observation that the total radioactive residues increased from 4.2 mg/kg after 3 days to 319 mg/kg after 2 weeks and decreased again to 188 mg/kg after 3 weeks. Unexpectedly, the residue levels were higher again in the PHI 4 weeks' samples. The variability in those results was assumed to be due to the homogenisation of only a small amount of seedlings leaves. The second point highlighted in the DAR was the unrealistic high recovery of radioactivity in the acetonitrile/n-Ethylmaleimide extraction phase of the PHI 3 day-samples (173 % of the TRR-7.3 mg/kg). According to the notifier, the high recovery in this sample was probably related to the very low radioactivity of the samples hampering	Addressed RMS to consider adding the clarification included in column 3 in a corrigendum or addendum to the additional report

Metabolism in plants (B.7.1)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			accurate measurement of the total radioactivity in those extracts.	
3(2)	Vol.3 B.7.1.3 bis Metabolism in cabbage	EFSA: It is stated that in the sample preparation of the 4 week samples acidic hydrolysis was conducted to release conjugated residues from the aqueous soluble phase. It was noted by the RMS that carbofuran (17.2% TRR), carbofuran-3-keto (2.7%) and carbofuran-3-OH (6.1%) were released from conjugates, it however not clear how these findings were reflected in table B.7.1.3 bis-2. Considering the increase of radioactivity recovered in the aqueous soluble phase over the test period from 3 to 28 days a progressive formation of conjugated residues can be assumed until harvest of the mature crop. Has the RMS thought about of whether conjugates of carbofuran /carbofuran-3-OH/ carbofuran-3-keto might have to be included in the residue definition for risk assessment for the use in cabbage?	**Comments from notifier (Nov 2008):** It was agreed that the metabolism study in sugar beet (leaves) was also applicable to cabbage. In this study, at harvest, indeed a significant polar fraction was present. However it was also demonstrated that this fraction, at harvest, did not release carbofuran/3-keto-carbofuran/3-OH-carbofuran upon de-conjugation (enzymatic/acid/base hydrolysis). It was demonstrated that the polar fraction (at harvest) does contain larger MW compounds. We conclude that during the initial phases of metabolism indeed carbofuran/3-keto-carbofuran/3-OH-carbofuran conjugates exist, however they are further transformed to large MW compounds or non-recognisable polar conjugates. Therefore these conjugates are not to be included in the residue definition for human risk assessment. They are however included for the RA of birds/mammals which feed on seedlings. **RMS (Nov 2008):**	Open point A new data requirement to address brassica metabolism was agreed in EPCO 34. Now, that new data in sugar beet and brassica is available, a re-discussion by experts is suggested to agree whether the data available is sufficient to establish a final residue definition in brassica crops. See also comments in 3(4)-3(6)

Metabolism in plants (B.7.1)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			See Addendum November 2008_Vol 3 (B7).	

Residue definition (B.7.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
3(3)	Vol.3 B.7.3.1 Residue definition	EFSA: We don't agree with the RMS statement *"None of the metabolite formed […] was of particular toxicological concern as they were generally also produced by the rat"*. Separate toxicological studies with the benfuracarb metabolites carbofuran, carbofuran-3-OH and carbofuran-3-keto exist, and it has been shown that they are of higher toxicity than benfuracarb and therefore they are residues of particular concern. The statement is incorrect and misleading, and should hence be revised.	**Comments from notifier (Nov 2008):** Based on the metabolism study in sugar beet leaves the metabolites are not expected at harvest (not as free metabolite, nor as conjugated metabolite). The proposed residue definition "carbofuran + 3-OH-carbofuran" is appropriate for RA. The fact that these metabolites are formed in rat does mean their toxicity is included in studies with carbofuran and benfuracarb. **RMS (Nov 2008):** It is known that Carbofuran together with 3-OH-carbofuran are the active intermediates of Benfuracarb and show an acute toxicity much higher than Benfuracarb. RMS agrees that this statement should be	Addressed RMS to consider adding the clarification included in column 3 in a corrigendum or addendum to the additional report

Residue definition (B.7.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			rephrased as follows: "All the metabolites of Benfuracarb recovered in the available plant metabolism studies were also recovered in the rat metabolism and their toxicity is therefore covered by the studies provided in the Mam Tox section and performed both with Benfuracarb and Carbofuran."	
3(4)	Vol.3 B.7.3.1 Residue definition	EFSA: The provisionally established plant residue definition for risk assessment for the representative use (brassicas, soil treatment) has been pending clarification on the full picture of residues the consumer can be exposed to. The new metabolism study in cabbage indicates that conjugated metabolites might be of significance in brasscia crops. Whether of not it is necessary to consider these compounds in the risk assessment should be further elaborated by the RMS and possibly discussed in a meeting of experts.	**Comments from notifier (Nov 2008):** See our comments on 3(2) and 3(3) above. **RMS (Nov 2008):** See comments under points 3(2) and 3(3). The EFSA comment should be corrected as follows: "The new metabolism study in cabbage seedlings indicated that conjugated metabolites might be of significance." The metabolism pathway of Benfuracarb in cabbage seedlings does not reflect the metabolism of Benfuracarb in brassica crops at harvest. At the EPCO expert meeting 34, it was	See open point in comment 3(2) **Note:** In the meeting of expert EPCO 34, it was not concluded that the metabolism study on sugar beet sufficiently addressed the metabolism of benfuracarb in brassica crops. The meeting concluded *"although this sugar beet study may have addressed metabolism in brassicas, the study did not sufficiently identify potentially relevant metabolites for the supported brassica uses"*, and identified a new data requirement.

Residue definition (B.7.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			concluded that the metabolism study on sugar beet was acceptable and sufficiently addressed the metabolism of Benfuracarb in *brassica* crops.	
3(5)	Vol. 3, B.7.3.1, Definition of the residue in plant products	FR: None of the metabolism studies provided in the first version of the DAR seems to be acceptable. Among the new studies of the revised DAR only two (sugar beet and apples) are acceptable. FR agrees with RMS conclusion about the study conducted on cabbage : "the validity of this study is borderline". Thus as only two metabolisms are acceptable and as none of these two studies has been conducted on leafy crops (representative of the intended use on cabbage) no sufficient data are available to set a reliable residue definition. In practice, it seems that residue definition should be linked to the one of carbofuran.	**RMS (Nov 2008):** RMS disagrees. At the EPCO expert meeting 34, it was concluded that the metabolism study on sugar beet (Haynes L.M., 2003) with further fractionation and characterization of the polar fraction T1 recovered in the sugar beet leaves at harvest was acceptable and sufficiently addressed the metabolism of Benfuracarb in *brassica* crops. Sufficient reliable data are available to set a residue definition in brassica crops.	See open point in comment 3(2)

Use pattern, critical GAP, residues trials (B.7.4 to B.7.6)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
3(6)	Vol.3. B.7.6 Residue trials - Methods	EFSA: The analytical methods include an extraction procedure with acetonitril/water In the light of the analysis steps carried out in the metabolism study in terms of the conjugated residues, are the methods used in the residue trials deemed to sufficiently extract all residues of carbofuran /carbofuran-3-OH/ carbofuran-3-keto present in the crops in both free and conjugated form?	**Comments from notifier (Nov 2008):** See our comments on (2) and (3) above. **RMS (Nov 2008):** See comments 3(2) and 3(3).	See open point in comment 3(2) By the response in column 3 it has not been clarified whether or not the analytical method does determine free and potential conjugated residues.

Use pattern, critical GAP, residues trials (B.7.4 to B.7.6)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
3(7)	Vol.3. B.7.6 Residue trials - Methods	EFSA: It is noted that in some trials the LoQ of the validated method (0.005 mg/kg) for carbofuran 3-OH could not be reached, since even the detection limit (LoD) was higher when analysing the cauliflower samples. Is it really considered appropriate to define in these trials a new LOQ of 0.01 mg/kg while the LoD was already up to 0.009 mg/kg? Shouldn't the validation have been repeated at the same day and under the same conditions when the samples were analysed?	**Comments from notifier (Nov 2008):** This seems to be a misunderstanding. Indeed in some trials the validated LOQ for 3-OH-carbofuran was not reached during sample analysis, however this applies to trials which used a **different** method (NOTOX report 465154) than the final validated method used in all 2007 trials (NOTOX report 485369). With the latter method (485369), the validated LOQ was always met during sample analysis, without problems. The trials with increased LOQ were not further used (for MRL calculation), as for all other trials with a too high LOQ. Theoretically the samples could have been reanalysed, however as this was not done, we have increased the LOQ in the residue table overview and as a result could not use these trials for MRL setting. **RMS (Nov 2008):** Clarification on this point is presented in the Addendum November 2008_Vol 3 (B7).	Addressed. From the presentation of data it is not clear which values were actually used for MRL proposal and risk assessment, RMS may consider to present these values in bold in a revision of Table B.7.6.1-1 in a corrigendum or addendum to the additional report, as appropriate

Use pattern, critical GAP, residues trials (B.7.4 to B.7.6)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
3(8)	Vol.3. B.7.6 Residue trials - Methods	EFSA: If reaching the LoQ for carbofuran 3-OH had already been a problem in supervised trials, isn't there good reason to believe that in routine monitoring it will become difficult to reach this LoQ of 0.005 mg/kg for carbofuran 3-OH and to be able to monitor the proposed MRL of 0.01 mg/kg for the sum of carbofuran and carbofuran-3-OH? Given the acute risk linked to carbofuran /carbofuran-3-OH (see comment 10 below), does the RMS agree that it is essential that laboratories are able to routinely reach the LoQ?	**Comments from notifier (Nov 2008):** See comment (6) above. The final validated method (incl ILV) does function well, without problems and reaches the validated LOQs easily. This method has been used continuously with success for all 2007 trials (on which MRL proposal was based). This method can be used to routinely monitor carbofuran and 3-OH-carbofuran at the appropriate levels ! **RMS (Nov 2008):** For MRL setting and consumer dietary risk assessment, RMS considered all the trials performed using the analytical method-NOTOX report 485369 intended for post-registration control and monitoring of Carbofuran and 3-OH-carbofuran at the validated LoQs of 0.0015 mg/kg and 0.003 mg/kg, respectively for Carbofuran and 3-OH-carbofuran. In the table B.7.6.1-1 in the DAR, the residue values of 0.0043 mg/kg must be corrected into 0.0045 mg.kg.	Addressed. RMS to consider adding the clarification included in column 3 in a corrigendum or addendum to the additional report

Use pattern, critical GAP, residues trials (B.7.4 to B.7.6)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
3(9)	Vol.3. B.7.6 Residue trials	EFSA: The meeting of experts EPCO 34 has required a complete set of residue trial data and concluded that due to the toxicological properties of benfuracarb and its metabolites it was not possible to flexible on the minimum number of trials. The decline studies and occasional positive findings at harvest in the available data set for brassica indicate that we cannot consider this a 'classical no-residue situation'. If the RMS has a differing view this should be (re-)discussed in a meeting of experts.	**Comments from notifier (Nov 2008):** We support the position of the RMS. The following argument was provided to the RMS (March 2008, statement 5, rev. 3): "A complete database with the most sensitive analytical method is available for head and flowering brassica. For benfuracarb 21 trials in N.E. and 12 trials in S.E. are available. For carbofuran and 3-OH-carbofuran 8 trials with sufficiently low LOQ are available in Northern and Southern Europe. Residues at harvest were always <LOQ in both Northern and Southern European trials, except for "carbofuran+3-OH-carbofuran" in one trial on broccoli in Northern Europe (Residue value of 0.0102 mg/kg). A similar residue situation was further confirmed in residue trials in leafy Brassica (3 in Northern Europe and 3 in Southern Europe) also performed with the most sensitive analytical method. In all trials residues were <LOQ except for "carbofuran+3-OH-carbofuran" in one trial on kale in Northern Europe (0.0086 mg/kg). The comprehensive dataset does not indicate differences between Northern and Southern Europe, nor between head and flowering brassica and leafy brassica. Therefore it is appropriate to calculate the MRL based on all available field trials. For benfuracarb, the MRL is set at the LOQ of 0.05 mg/kg. For "carbofuran + 3-OH-carbofuran" the calculated MRL according to 7039/VI/95 (Lundehn, Appendix I) was 0.008 (method I, n=22) and 0.009 (method II, n=22). The MRL was rounded to 0.01 mg/kg." Further, our arguments were not based on a non-residue situation but on comparable residues in a large number of trials (n=22). Adding two more leafy brassica trials will not change the MRL proposals. **RMS (Nov 2008):** agrees with the notifier's comments.	Open point It should be agreed by experts whether the decision of EPCO 34 for requiring a full database should no longer be applicable, based on the case made by the applicant in column 3 of the reporting table **Note:** Extrapolation from head cabbage and cauliflower to flowering and head brasscia group – 8 trials <u>on each</u> (16 trials) are required

Succeeding/Rotational crops (B.7.9)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
3(10)	Vol.3. B.7.9 Rotational crops	EFSA: RMS has argued that upon re-evaluation of the study by Taylor and Houseman (1982), considered valid and acceptable by the peer review in 2005, the DT50 for carbofuran from this study is no longer appropriate, and therefore a rotational crop study is not triggered. However, a transparent evaluation, giving the reasons why the study previously considered acceptable is revoked as inappropriate, is missing. Moreover, it is noted that the referred to inappropriate DT50 value is still included in the List of endpoints. As long as this hasn't been clarified the data gap for a rotational crop study previously identified should be maintained.	**Comments from notifier (Nov 2008):** We agree with the position of the RMS. The DT50 of 71.9 days should be removed from the LoEP. [Even with a DT50 of 71.9 days, residues in rotational crops are no concern, see open point 7 rev 1 submitted to RMS in March 2008]. **RMS (Nov 2008):** The laboratory DT50 of benfuracarb (geomean DT50, at reference temperature and moisture conditions: 0.31 d) and its active metabolite carbofuran (geomean DT50, at reference temperature and moisture conditions : 10.73 d, range: 6.1-17.4 d). On this basis, further rotational crop studies are not required. Moreover, rotational crop metabolism data for representative use on brassica with soil application can usually be covered by the primary crop metabolism data (brassica seedlings, sugar beet leaves and roots). Although the cereals as rotated crop are not covered by the primary metabolism studies, no residues above the LoQ are expected considering the very low residue levels recovered in the primary brassica crops.	Open point A new data requirement was agreed in EPCO34 to address carbofuran residues in succeeding crops. No new data is available but a case was made on a new DT50 (still to be confirmed by fate and behaviour) and on extrapolation to rotated cereal crops (not assessed in the additional report). A discussion by experts is suggested.

MRLs related issues and Consumer Risk Assessment (B.7.10 to B.7.15)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
3(11)	Vol.3 B.7.11 Exposure assessment	EFSA: For the sake of transparency it had been helpful to clarify/ justify the input parameters used (MRL, HR, STMR, highest LoQ in new trials) before presenting the results of the calculation of the exposure and risk assessment.	**Comments from notifier (Nov 2008):** No comments. Possibly use our reply to open point 5 rev. 3 of March 2008 (dietary risk assessment) which lists all the input parameters for the calculations. **RMS (Nov 2008):** See Addendum November 2008_Vol 3 (B7) for the dietary intake risk assessment considering the following input parameters in the EFSA model rev.2A: -HR (LoQ of the validated analytical method (report n° 485369)) for Benfuracarb: 0.05 mg/kg for all brassica crops. -HR (LoQ of the validated analytical method (report n° 485369)) for the sum of Carbofuran and 3-OH-carbofuran: 0.0045 mg/kg for head cabbage and leafy cabbage. -HR value for cauliflower: 0.01 mg/kg -HR value for broccoli: 0.0102 mg/kg. -HR value for kale: 0.0086 mg/kg. -Revised Carbofuran toxicological end points: ADI/ARfD: 0.00015 mg/kg bw/day (Acute rat neurotoxicity study, Assessment factor: 200) (cf. Carbofuran DAR – Mam Tox section, revised in November 2008).	Addressed. RMS to consider adding the clarification included in column 3 in a corrigendum or addendum to the additional report
3(12)	Vol.3 B7.13 Proposed	EFSA: Given the residue trial results for	**Comments from notifier (Nov 2008):**	Addressed.

MRLs related issues and Consumer Risk Assessment (B.7.10 to B.7.15)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
	MRLs	cauliflower for carbofuran /carbofuran-3-OH (HR 0.0101, LOQ in 2 trials 0.015 mg/kg) the proposed MRL should be at least 0.01 mg/kg (without asterisk) for flowering brassica if not even 0.015 mg/kg. It is acknowledged that the next "regular" MRL proposal would be 0.02 mg/kg, however with this MRL for carbofuran /carbofuran-3-OH in cauliflower/ broccoli the ARfD would be exceeded for both crops (132% and 116% ARfD for BE and NL child, resp).	See answer comment (6) and (7) above. We are aware that the two trials with LOQ 0.015 (measured with a **different** method than the proposed method for monitoring) cannot be used for assessment of consumer risk because LOQ is too high, but that is the case for a number of (older) trials. Therefore these trials were replaced by a sufficient number of trials (2007) with appropriate LOQ. We have proposed an MRL of 0.01 mg/kg (for carbofuran + 3-OH-carbofuran) (without asterisk) (see our reply to open point 5 rev. 3 of March 2008). **RMS (Nov 2008):** RMS agrees to propose 0.01 mg/kg (without asterisk) for flowering and head *brassica*. See also comments 3(7), 3(8) and 3(11).	RMS to consider correction of Table B.7.13 on 'Proposed MRLs' in a corrigendum or addendum to the additional report
3(13)	Vol.3 B.7.15 Summary and evaluation of residue behaviour	EFSA: RMS stated that from the available livestock data no animal residue definition could be concluded. At the end of the chapter it reads that "the contribution of animal products [to	**Comments from notifier (Nov 2008):** No residues will be transferred to animal products, hence no exposure for	Addressed. RMS to consider adding the clarification included in column 3 in a corrigendum or addendum to the additional report

MRLs related issues and Consumer Risk Assessment (B.7.10 to B.7.15)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
		consumer exposure] was not considered since no residue definition was proposed. This could be misunderstood in the context of what has been concluded before and should be made clear. With regard to the available goat metabolism study (B.7.2.1) it would help to enhance understanding and increase transparency if the residue levels (TRR) in the analysed tissues (i.e. LoD/LoQ of the method) had been reported.	consumer. Indeed, this is the reason contribution of animal products is not considered (not the fact that no residue definition could be set). **RMS (Nov 2008):** RMS proposes to delete the sentence: "The contribution of animal products was not considered since no residue definition was proposed" and to replace by the following sentence: "No residue of Benfuracarb and its metabolites carbofuran and 3-OH-carbofuran are expected in the animal matrices. Their contribution to the consumer dietary intake risk assessment is not considered". In the available goat metabolism study (Spare W.C., 1983), the Limit of Detection of the method was : 0.16 (Low dose)-2.0 (high dose) mg/kg (muscle/fat); 0.051 (LD)-0.74 (HD) mg/kg (liver, kidney, brain, heart).	

Other comments				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
3(14)	Vol.3 B.7 Appendix C Residue trials	EFSA: From the table of critical residue data it appears from the RMS remarks that for some of the trials it might be unclear whether they are supported by storage stability data over the whole duration of storing the samples. Can the RMS please clarify the status of those data?	**Comments from notifier (Nov 2008):** Please refer to page 7-39 of the DAR (conclusion). **RMS (Nov 2008):** Based on the available storage stability data, RMS concluded that the residues of Benfuracarb, Carbofuran and 3-OH-carbofuran were stable over a period of 10 months in cauliflower and cabbage and 6 months in maize. All the trials used for MRL setting were characterized by a maximum period of frozen storage of 56 days.	Addressed. RMS to consider adding to the residue table in Appendix C the clarification included in column 3 in a corrigendum or addendum to the additional report
3(15)	Vol. 1, 2.3.6.4, consumer	Notifier: clarification: the reported % ARfD are based on IESTI 1 calculation of the EFSA model	**RMS (Nov 2008):** RMS notes the remark.	Addressed.
3(16)	Vol. 1, 2.4.2, consumer	Notifier: clarification: the reported % ARfD are based on IESTI 1 calculation of the EFSA model	**RMS (Nov 2008):** RMS notes the remark.	Addressed.
3(17)	Vol . 1, appendix I, LoEP	Notifier: footnote 1 under box on page 61 should be removed. Residue values at harvest were below LOQ for all components of the residue definition (report Feb 2008).	**RMS (Nov 2008):** RMS notes the remark.	Addressed. RMS to consider correction, if appropriate, in a corrigendum or addendum to the additional report

Other comments				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
3(18)	Vol. 3, appendix C, residue data	Notifier: correction: on page 68 and 69, "in progress" is entered in the table for 42 day results. Actually, the report submitted by the notifier within the timelines of the Regulation did contain data for this timepoint. Trial AF/12036/OT-1: all residues in seedlings <LOQ at day 42 and for trial AF/10236/OT-2: residues in seedlings at 42 days <LOQ (BFC), 0.0242 (CF) and 0.0793 (3-OH-CF) mg/kg. This has no further effect on the risk assessment.	**RMS (Nov 2008):** RMS notes the remark.	Addressed. RMS to consider correction, if appropriate, in a corrigendum or addendum to the additional report

4. Environmental fate and behaviour

Route and rate of degradation in soil (B.8.1)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(1)	Vol. 3, B.8.1, Route and rate of degradation Willems, H., 2005a, Willems, H., 2005b, Willems, H., 2005c	EFSA: In the degradation studies of the carbofuran metabolites (carbofuran-3-hydroxy, carbofuran-3-keto and carbofuran-phenol) there were too few sampling points to derive reliable DT50 values (based on FOCUS kinetics), in addition some samples had been lost or <LOQ or <LOD increasing further the uncertainty. Recoveries of the studies were also below the acceptable range. However these compounds seem to be indeed inpersistent in aerobic soil.	**Comments from notifier (Nov 2008):** (1) indeed two samples were lost from one soil with carbofuran-3-keto. One of these samples was the T=0 sample. The other two soils showed good recovery at T=0 (97 and 101%). These soils were spiked at the same moment from the same spike solution using the same equipment as the missing soil. Therefore it can be assumed that the soil with the missing T=0 sample was also spiked correctly. (2) only for the carbofuran-phenol study recoveries were poor. (3) values below LOQ or LOD do not invalidate the studies, especially considering that the LOD is <1% of applied and LOQ was ~6% of applied. Hence degradation beyond the DT90 could be measured. **RMS (Nov 2008):** We consider that the minor deficiencies of the degradation studies with metabolites do not preclude to use them in the final	Addressed. Note: these compounds seem to be indeed inpersistent in aerobic soil (DT_{50} < 1 day).

Route and rate of degradation in soil (B.8.1)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			assessement.	
4(2)	Vol. 3, B.8.1, Route and r of degradation Willems, H., 2005c	EFSA: Further argumentation would need to justify the significant loss of carbofuran-phenol at the study initiation. No clear decay seems on the basis of the data after 1 d, however these data are below LOQ.	**Comments from notifier (Nov 2008):** carbofuran-phenol most likely undergoes rapid reaction with organic matter resulting in bound residue formation (by covalent bonds). These residues are not extractable and lead to low recoveries. Such interaction between phenolic compounds and organic matter is well known. **RMS (Nov 2008):** We agree with the notifier's explanation. Moreover, the DT50 is < 1 day	Addressed.
4(3)	Vol. 3, B.8.1, Route and r of degradation	EFSA: RMS please clarify the normalisation of DT50 values came from the new study by Noorloos, B. van; Brands C. In the Table B.8.1.1-1-22 two water holding capacity (are they MWHC?) values are reported for a single soil. Two (or a range) of water content at MWHC are reported (45-61%) as well, they may be refer to the experiments at different temperatures or different way of determination of MWHC (difference between the results is significant). Soil moisture is reported to be 26.3 % w/w in Table B.8.1.1.1-25 may be	**Comments from notifier (Nov 2008):** the actual moisture content of the soil during incubation was 26.3% (dry weight) (at both 10 and 20°C). This value was compared with the reference soil moisture content for this soil texture (according to FOCUS gw guidance) and a correction factor derived (indeed only the 20°C results were used to determine the DT50 for modelling). Depending on which MWHC determination was taken, a value of 45 or 61% of MWHC was calculated (OECD guideline	Open point RMS to correct the List of End Points. 40% MWHC of the clay loam soil should be changed to 45% or 61%, the one which is more realistic/was measured in the same laboratory.

Route and rate of degradation in soil (B.8.1)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
		referring to the experiment at 20°C, only. In the LoEP 40% of MWHC is indicated.	recommends 40-60% MWHC), but this does not affect the correction factor. **RMS (Nov 2008):** As indicated in the DAR, the two figures are MWHC that have been determined by two laboratories. Depending on which MWHC determination was taken, a value of 45 or 61% of MWHC was calculated.	
4(4)	Vol. 3, B.8.1, Route and r of degradation	EFSA: RMS please indicate whether the DT_{50} values from Noorloos, B. van; Brands C study based on the HPLC or TLC analysis and which kinetic was used with an argument why this was chosen.	**Comments from notifier (Nov 2008):** HPLC and TLC results were very simi therefore both data sets were combined an DT50 was calculated for the combined dataset **RMS (Nov 2008):** Both data sets were similar and were combi for the SFO DT50 calculations.	Addressed RMS to consider adding the clarification included in column 3 in a corrigendum or addendum to the additional report.
4(5)	Vol. 3, B.8.1, Route and rate of degradation Page 8-17	EFSA: Only four DT_{50} values (belonging to two studies) have already been peer reviewed. The 5th value (0.13 d) comes from a newly submitted study on alkaline soil. Please clarify it this is correct as it is stated 5 values were all peer reviewed.	**Comments from notifier (Nov 2008):** no comment **RMS (Nov 2008):** No comment	Addressed.
4(6)	Vol. 3, B.8.1, Route and rate of degradation Table B.8.1.1.1-25 & LoEP	EFSA: There are slight differences in case of some DT_{50}/DT_{90} values of carbofuran reported in this Table and LoEP of the additional report compared with the	**Comments from notifier (Nov 2008):** Original DT_{50}/DT_{90} values (d) are: silt loam 15.1/50.1 (instead of 15/50), sandy loam	Open point RMS to update the list of endpoints with the values listed in column 3 of the reporting table that are not in brackets.

Route and rate of degradation in soil (B.8.1)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
		original DAR/EFSA conclusion of carbofuran.	9.5/31.5 (instead of 9.5/32), clay loam 15.8/52.3 (instead of 15.8/52), loam 19.4/64.7 (instead of 19.3/65). differences because of rounding. **RMS (Nov 2008):** Differences because of rounding	
4(7)	Vol. 3, B.8.1, Route and rate of degradation Page 8-17 last paragraph	EFSA: EFSA confirms that the lab. DT_{50} values that originate from the carbosulfan dossier should not be used, as the peer review of carbosulfan concluded these values were unreliable.	**Comments from notifier (Nov 2008):** no comment **RMS (Nov 2008):** No comment – addressed	Addressed.
4(8)	Vol. 3, B.8.1, Route and rate of degradation Page 8-18 – 8-20	EFSA: The data set included in the Table B.8.1.1.1-26 was peer reviewed during the carbofuran peer review. The three carbofuran DT_{50} values (norm. 175, 381, 444 d) originated by FMC, were considered reliable by the carbofuran peer review, while other data considered by this peer review disregarded as unreliable. The RMS conclusion on this studies deviates from the conclusion of the previous peer review. Until a detailed re-evaluation of these experiments by the RMS is made available, the existing conclusion of the peer review of MSs should not be changed/overruled and the accepted DT_{50} values should be used in the RA. The argument presented in the	**Comments from notifier (Nov 2008):** we agree with the position of the RMS. The arguments presented by the RMS seem very plausible. The applicant has no access to the study reports so we cannot provide a more detailed assessment. This could be part of the additional report on carbofuran. **RMS (Nov 2008):** We have received 3 dossiers submitted by several notifiers on a timespan of 6 months. We have tried, as best as we could, to give a comprehensive and balanced evaluation of the 3 dossiers together, and in the same time to avoid "protection claims" conflicts. We consider that our choice of the studies is reasonable and take into account the entire	Open point RMS to provide clear, independent summaries and assessments of the studies Saxena *et al*., 1994 (laboratory degradation study in acid soil and alkali soil) and Schocken, 1989 in an addendum to support discussion of a meeting of experts. Information on soil pH, soil moisture content and microbial activity to be clearly presented.

Route and rate of degradation in soil (B.8.1)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
		additional report of August 2008 is insufficient to conclude if changing the previous assessment is justified.	database. We expect therefore some flexibility from EFSA, at least at administrative level.	
4(9)	Vol 3, B.8.1.1 additional data on aerobic degradation	UK: All 3 new study summaries in B.8.1.1 are quite brief (especially methods of analysis) but indicate fairly rapid degradation of the metabolites	**Comments from notifier (Nov 2008):** the analytical method is presented in more detail in section B.5, appendix (page 5-38). **RMS (Nov 2008):** The analytical methods are presented in section B.5	Addressed. RMS to consider adding a cross reference to section B.5 in a corrigendum or addendum to the additional report.
4(10)	Vol 3, B.8.1.1 additional study aerobic degradation benfuracarb at 10 and 20C in alkaline soils	UK: Brief study summary (especially methods of analysis) but indicates similar degradation rates to acidic/neutral soils.	**Comments from notifier (Nov 2008):** no comments **RMS (Nov 2008):** See previous point	Addressed. RMS to consider adding a cross reference to section B.5 in a corrigendum or addendum to the additional report.
4(11)	Vol 3, B.8.1.1. Degradation of carbofuran in soil at low temps	UK: Please can the RMS clarify if/where these data have been evaluated to address this outstanding point as we were unable to identify any relevant studies here.	**Comments from notifier (Nov 2008):** -It is concluded that for benfuracarb, the default Q10 value applies (based on a newly submitted study which was included in the additional report). The first step in the degradation pathway of benfuracarb is hydrolysis to form carbofuran. - The first step in the degradation of carbofuran is (a) hydrolysis of the carbamate function or (b) oxidation (microbially mediated) of the ring to form hydroxy or keto carbofuran. As	Open point MS to discuss in a meeting of experts if there is any need to require additional data on carbofuran degradation in soil at 10°C or whether the use of a standard Q10 is supported.

Route and rate of degradation in soil (B.8.1)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			demonstrated for benfuracarb, the default Q10 factor should also be applicable to the hydrolysis reaction of carbofuran. The microbially mediated degradation should be covered by the large database which has been used to derive the default Q10 value. For pirimicarb and carbaryl, both also carbamates, a Q10 of 2.2 was used. **RMS (Nov 2008):** The following new study has been submintted and evaluated in the DAR: Determination of the aerobic degradation rate of benfuracarb in alkaline soil at 10ºC and 20ºC. (Noorloos, B. van; Brands, C.)	
4(12)	Volume 3, point B.8.1.1 route of degradation	FR : does the formulation type has any influence on the dissipation time of the substance in soils, and further on the occurrence time of the degradation products ? this issue is linked with modelling hypothesis as well as with further exposure hypothesis used to discuss delayed effects in aged residue studies with soil organisms. It also conditions the relevance of study protocols in soil ecotoxicology studies that investigate effects of the formulated product on earthworms.	**Comments from notifier (Nov 2008):** in a soil under normal moisture conditions the release of benfuracarb from granules is immediate. Upon release benfuracarb is rapidly transformed to carbofuran. Indirect evidence comes from the field residue trials in which seedlings were investigated. Residues in seedlings are already present from day 0-1 onwards, maximum between 3-21 and <LOQ from day 21-42 onwards. **RMS (Nov 2008):** As indicated by the notifier (and substantiated by	Addressed. RMS to consider adding the clarification included in column 3 in a corrigendum or addendum to the additional report.

Route and rate of degradation in soil (B.8.1)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			the indirect evidence of field residues trials with seedlings), it can be expected that the release of benfuracarb from granules is immediate, with rapid transformation to carbofuran. Most of the ecotox studies on soil organisms were performed with the relevant formulation. - soil-dwelling arthropods studies were performed with the relevant granular formulation. - The LC50 of the acute tox studies with benfuracarb and its formulation were similar (equivalent to 29 and 34 mg a.s./kg). We consider that further field study should be performed with the relevant formulation. -The effects on soil micro-organisms are evaluated at levels equivalent to 1 and 5 times the initial carbofuran PEC assuming full conversion of the a.s. to carbofuran.	
4(13)	Vol 3, B.8.1.1.1, aerobic degradation in soil – determination of DT50s for modelling	UK: The DT50 values of 175 and 444 days for carbofuran are presented in the agreed list of end points for carbofuran so the UK considers they cannot be ignored (if the studies are generally considered invalid the DT50 values should not be listed in the endpoints). Unless the DT50 values are removed from the endpoints the risk assessment should take account of them.	**Comments from notifier (Nov 2008):** these DT50 are not reliable and should not be considered. We agree with the explanation of the RMS in the additional report and the by the RMS proposed LoEP. **RMS (Nov 2008):** The DT50 values of 175 and 444 are not appropriate and will be removed from the	See open point in comment 4(8)

Route and rate of degradation in soil (B.8.1)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			LoEP of carbofuran when revising it.	
4(14)	Vol. 3, B.8.1.3, Field studies	EFSA: Field DT50 of 71.9 d was used for PECsoil in the carbofuran DAR/EFSA conclusion for carbofuran. Whilst RMS stated he reassessed the study and concluded it was of limited quality. The reasons why the study is too deficient to be relied on are not explained adequately for others to tell if they would agree with the RMS position. As far as agreed lab. DT_{50} values are > 60 d (see EFSA comment No 8), field dissipation experiments are required and field DT_{50} should be used for PECsoil calculation. (Note: PECsoil of carbofuran in this additional Report is based on the worst case, not normalised lab DT_{50} of 19.4 d. This seems to be inappropriate)	**Comments from notifier (Nov 2008):** we are of the opinion that DT50 lab values are <60 days hence no field studies are required (see also reply to comment (8) above). The DT50 has no influence on the initial PEC value in soil used in the RA. As far as we know, DT50 are not yet normalised for PECsoil calculations (as is done for PECgw and PECsw) . Normalisation would lead to a lower DT50. A DT50 of 19.4 days seems at least a realistic value, also considering that DT50 field values are between 1.3 and 27 days (as was also stated by the RMS, page 8-18). **RMS (Nov 2008):** The laboratory DT50 of benfuracarb (geomean DT50, at reference temperature and moisture conditions : 0.31 d) and its active metabolite carbofuran (geomean DT50, at reference temperature and moisture conditions : 10.73 d, range: 6.1-17.4 d) are less than 60 days. On this basis, further field dissipation studies are not required. The	Open point a) RMS to provide a clear summary and assessment of the study by Taylor and Houseman, 1982 in an addendum to support discussion of a meeting of experts on the validity of this study and also report the Terry A. 2005 analysis if this is relevant. b) degradation endpoint used in the PECsoil calculation to be discussed in a meeting of experts

Route and rate of degradation in soil (B.8.1)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			endpoints determined in the Otsuka laboratory studies are taken into account for the PEC assessment. The FMC report Carbosulfan and carbofuran: analysis of Nether Poppleton field dissipation investigation (Terry A. 2005) clearly demonstrated that the carbofuran data are not reliable.	

Adsorption, desorption and mobility in soil (B.8.2)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(15)	Vol 3, B.8.2.1 additional data on adsorption	UK: Studies conducted to OECD guidelines, and are acceptable for risk assessment. Some kocs have a fairly wide range around the averages eg average 330 mL/g but range from 48 – 504 mL/g.	**Comments from notifier (Nov 2008):** no comment **RMS (Nov 2008):** No comment	Addressed.

Adsorption, desorption and mobility in soil (B.8.2)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(16)	Vol. 3, B.8.2.1, Adsorption, desorption and mobility Noorloos, B. van; Willems, H., 2005a, Noorloos, B. van; Willems, H., 2005b,	EFSA: It is agreed that worst case Koc (Kfoc only for 2 solis) values should be taken into account for average calculation, but as 1/n 1 (or 1.144 for carbofuran-3-keto as worst case) should be used. In fact it seems that the equilibrium was not perfectly reached within the 6 hours and Freundlich isotherm could not be establish. For the two soils where Kfoc were determined 1/n values are far from each other (1.144 and 0.489).	**Comments from notifier (Nov 2008):** we agree that the 1/n value could be set at 1. On the other hand, the default value of 0.9 might be equally applicable for these metabolites. We have rerun FOCUS-PEARL calculations with a 1/n value of 1. For all metabolites the same results were obtained (i.e. <0.0001 µg/L) as presented in the benfuracarb dossier. Results can be submitted if requested. **RMS (Nov 2008):** We consider that the outcome of the calculations with another 1/n factor will not be changed.	See open point in comment 4(23).
4(17)	Vol. 3, B.8.2.1, Adsorpti desorption and mobility Noorloos, B. van; Wille H., 2005c	EFSA: RMS please give more details which clarifies that if carbofuran-phenol was classified as "stable", from where come from the significant difference in adsorption by 6 or 24 hrs. In the conclusion of this study 1031 cm^3/g should be read as Kfoc instead of Koc.	**Comments from notifier (Nov 2008):** Carbofuran-phenol is classified as stable in pure $CaCl_2$ solution. In the presence of soil, this is apparently not the case (possibly because of degradation) . This is also why the equilibrium period was reduced to 6 hours (in order to avoid degradation) **RMS (Nov 2008):** We agree with the explanation given by the notifier. The DT50 is clearly below 1 day.	Addressed.

PEC in surface water and in ground water (B.8.6)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(18)	Vol 3, B.8.6.1 new gw modelling	UK: Carbofuran exceeds 0.1µg/L in 4/7 spring scenarios and 3/5 summer scenarios using Pearl. Although carbofuran only exceeds 0.1µg/L in 1/12 scenarios using PELMO, we would normally take account of results using both models. There is also the strong possibility of carbofuran exceeding 0.1µg/L in more scenarios after taking account of the longer DT50s mentioned above.	**Comments from notifier (Nov 2008):** (1) see comment above on DT50s, (2) for Annex I inclusion it is sufficient that safe scenarios exist and (3) PECgw for metabolites (<0.001 µg/L) are already worst-case as they were based on a maximum occurrence of 10%, whereas they never exceeded 10% in laboratory studies (aerobic, 20°C). Considering the low DT50 they will never exceed 0.1 µg/L. **RMS (Nov 2008):** We consider that the PECgw have been properly calculated and that a sufficient number of acceptable scenarios exists in order to include the a.s. on Annex I.	See open point in comment 4(22).

PEC in surface water and in ground water (B.8.6)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(19)	Vol. 3, B.8.6.1 PEC groundwater	EFSA: It is not clear how mean formation 0.86 relates to the maximum formation of 0.846 and how and why was ff establish for carbofuran from carbofuran DAR. This needs to be clarified.	**Comments from notifier (Nov 2008):** 0.846 (84.6%) is the maximum % of carbofuran observed in a soil degradation study. In the model it was entered as the formation fraction. This maximum % of formation was considered as a realistic estimate for the formation fraction. This was confirmed by FMC report where the ffM (obtained from the same studies) was modelled and found to be 0.86. **RMS (Nov 2008):** See following point	See open point in comment 4(20).

PEC in surface water and in ground water (B.8.6)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(20)	Vol. 3, B.8.6.1 P groundwater Page 8-46	EFSA: EFSA agrees that the formation fraction of carbofuran used in the modelling is too low, but contrary to the opinion of the RMS, a proper ground water modelling with an appropriately derived kinetic formation fraction is necessary.	**Comments from notifier (Nov 2008):** We have rerun FOCUS-PEARL calculations with a 1/n value of 1 (for the parent, see comment below) and a formation fraction of 0.86 (for carbofuran). For the parent the results are the same (i.e. <0.0001 µg/L) as presented in the benfuracarb dossier. For carbofuran, the PECgw increased with <0.001 to 0.02 µg/L. The number of safe scenarios did not change as a result of this adjustment. The conclusion from the RMS that this has no significant input on the outcome is correct. Results can be submitted if requested. **RMS (Nov 2008):** We consider that these minor changes (formation fraction, 1/n value,…) have no impact on the final outcome of the evaluation, namely that benfuracarb, 3-keto-carbofuran, 3-OH-carbofuran and carbofuran-phenol do not leach to groundwater. Carbofuran is the only metabolite that could leach to some extent , however, a sufficient number of safe scenarios has been identified, allowing annex I inclusion.	Open point MSs to discuss in a meeting of experts the proper formation fraction to be used for the PECgw calculation for carbofuran. See also comment 4(19).

PEC in surface water and in ground water (B.8.6)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(21)	Vol. 3, B.8.6.1 PEC groundwater, Table B.8.6.1-1 PEC surface water, Table B.8.6.2-3	EFSA: for benfuracarb as 1/n of 1 should be used as HPLC method was used for the estimation of Koc.	**Comments from notifier (Nov 2008):** See comment 4(20) above. **RMS (Nov 2008):** We consider that the outcome of the calculations with another 1/n factor will not be changed.	See open point in comment 4(23)
4(22)	Vol. 3, B.8. PEC groundwater Table B.8.6.1-2 PEC surface water Table B.8.6.2-5 Page 8-56 regard PECsw/sed carbofuran-phenol	EFSA: For carbofuran, for derivation of soil degradation input parameter all the endpoints from accepted lab. experiments from the peer review of benfuracarb and carbofuran should be used, as no new data or re-evaluation of the existing data is available.	**Comments from notifier (Nov 2008):** we see no need to change the DT50 for carbofuran. (see comment (8) above) **RMS (Nov 2008):** We have revised the databases of benfuracarb, carbofuran and carbosulfan. We consider that our choice of the studies is reasonable and take into account the entire database.	Open point MSs to discuss in a meeting of experts the proper degradation endpoint to be used for the PECgw and PECsw calculations for carbofuran. See also open point in comment 4(8) and 4(18).
4(23)	Vol. 3, B.8.6.1 PEC groundwater Table B.8.6.1-7, Table B.8.6.1-8	EFSA: for 3-keto-carbofuran and 3-hydroxy-carbofuran as 1/n of 1 should be used. See EFSA comment No.10.	**Comments from notifier (Nov 2008):** We have rerun FOCUS-PEARL calculations with a 1/n value of 1. For all metabolites the same results were obtained (i.e. <0.0001 µg/L) as presented in the benfuracarb dossier. **RMS (Nov 2008):** We consider that the outcome of the calculations with another 1/n factor will not be changed.	Open point MSs to discuss in a meeting of experts the appropriate 1/n value to be used for benfuracarb and its metabolites. See also comments 4(16) and 4(21).

PEC in surface water and in ground water (B.8.6)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(24)	Vol. 3, B.8.6.1 PEC groundwater	EFSA: RMS pls. clarify the application times used for the modelling. According to FOCUS GW cabbage can be planted in the Summer for areas represented by Thiva and Jokoinen scenarios, but not in Spring time. Moreover in the output tables some dates are not in the range as indicated in the text before (e.g. Thiva (spring appl., 22/08)).	**Comments from notifier (Nov 2008):** this is an error from our part. "Spring" should read "Summer" for Jokoinen and Thiva. The reported dates are correct. **RMS (Nov 2008):** This is a minor issue. The reported dates are correct.	Addressed. RMS to consider adding the correction in column 3 in a corrigendum to the additional report.
4(25)	Vol. 3, B.8.6.1, PEC gw and Vol. 3, B.8.9, Definition of the residues	DE: As a result of the groundwater assessment carbofuran is most critical for leaching. PECgw simulations for carbofuran resulted in concentrations of > 0.1 µg/L in some scenarios. In case of a normal soil metabolite showing this behaviour an assessment of the relevance of this metabolite would be necessary to be documented in the DAR. Carbofuran is an active substance on itself that was not addressed in the DAR of benfuracarb. However, a note should be added that with respect to groundwater assessment carbofuran should be treated as an active substance.	**Comments from notifier (Nov 2008):** no further comment. We agree that carbofuran should be treated as an active substance and hence that the groundwater limit of 0.1 µg/L applies. This was also the approach in the DAR and the submitted dossier. **RMS (Nov 2008):** It is obvious that carbofuran is an active substance. Carbofuran and its own metabolites have been extensively addressed in the benfuracarb DAR.	Addressed. All agree carbofuran is a pesticide and 0.1 µg/L in groundwater applies.

PEC in surface water and in ground water (B.8.6)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(26)	Vol. 3, B.8.6.2 PEC surface water Page 8-39	EFSA: It is still not perfectly clear how DT_{50}/DT_{90} values were derived for the different compartments of the compounds. Could RMS pls. give more details (e.g. the individual measurements involved, graphical presentation, if possible) about these calculations?	**Comments from notifier (Nov 2008):** we have submitted the excel sheets with the calculations to the RMS. **RMS (Nov 2008):** The Excel sheets can be submitted.	RMS to provide complete details (e.g the individual measurements involved, graphical presentation) about the calculations used to derive the DT50/DT90 values for the different compartments of the compounds in the surface water study.

Fate and behaviour in air and PEC in air (B.8.7-8.8)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(27)	Volume 3, point B.8.8 PEC in ground water	FR: from the results of both modelling and leaching studies, recommendation for MS to protect ground water from transfer of benfuracarb residues will have to be reported in the review report	**Comments from notifier (Nov 2008):** no comment **RMS (Nov 2008):** The PECgw calculations show that carbofuran is the only "metabolite" likely to be detected at significant level in groundwater.	Addressed. France should make this request again to the Commission when the EFSA conclusion is finalised.

Definition of the residues (B.8.9)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(28)	Vol 3, B.8.9, definition of residue	UK: Due to time and resource constraints we have focussed our attention to the key concern that prevented Annex I listing so have not reconsidered the residue definitions. We note there are additional data in the toxicology section that relate to the relevance of environmental metabolites.	**Comments from notifier (Nov 2008):** no comment **RMS (Nov 2008):** No comment	See open point in comment 4(29).
4(29)	Vol. 3, B.8.9 Residue definition	EFSA: EFSA still agrees with the residue definition as it is stated in the befuracarb EFSA conclusion.	**RMS (Nov 2008):** Numerous studies an risk assessement on the a.s. and its metabolites have been included in the DAR. This new information has been taken into account in the revision of the residue definitions that are presented in the DAR.	Open point MSs to discuss in a meeting of experts the residue definition for the environment. See also comments 4(28) and 4(30).

Definition of the residues (B.8.9)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(30)	Volume 3, point B.8.9 residue definition	FR: despite not expected at high concentration level in groundwater fro the use of benfuracarb granules on cabbage, the degradation products 3-OH carbofuran, 3-keto carbofuran and carbofuran phenol are to be considered relevant as they bear the active moety. They should be kept in the residue definition.	**Comments from notifier (Nov 2008):** carbofuran-phenol does not contain the active moiety. **RMS (Nov 2008):** The PECgw calculations show that carbofuran is the only "metabolite" likely to be detected at significant level in groundwater. The RMS considers it is useless to include metabolites that are absent in the PECgw in the residue definition.	See open point in comment 4(29).

Other comments				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(31)	Vol. 3, B.8.10 References relied on	EFSA: RMS pls. include the studies of Yamasaki, 1999 and Hayashi, 1999 into the list of studies relied on.	**Comments from notifier (Nov 2008):** they are included in phys-chem section. **RMS (Nov 2008):** they are included in phys-chem section.	Addressed.

Other comments				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(32)	Vol. 3, B.8.10 Referen relied on	EFSA: In the References relied on studies under reference numbers of IIA, 7.2.1.2/01 and IIA, 7.2.1.2/02 are not summarised in the additional report. RMS pls. clarify it.	**Comments from notifier (Nov 2008):** see comment above **RMS (Nov 2008):** they are included in phys-chem section.	Addressed. RMS to consider deleting these references from section B.8.10 in a corrigendum or amended DAR.
4(33)	Dossier	EFSA: The CADDY-dossier submitted to EFSA does not contain PEC calculations, document KIIIA for Environmental fate and behaviour is completely missing.	**Comments from notifier (Nov 2008):** The PEC calculations were included in the M-III document of the CADDY dossier. They have therefore not been included in the KIII section. The PEC calculations were also reported in our replies to the EFSA open points. Print outs of the model runs were submitted to the RMS (jan 2008). **RMS (Nov 2008):** See notifier's comment	Point of clarification to the applicant to update the dossier provided to the MSs and EFSA with models used for the PEC calculations and transparent model reports.

Other comments				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(34)	Vol. 1, Level 4, 4.8 and 4.9	DE: DE suggests adding a note that the contamination of non-target areas and organism via dust drift during application needs to be considered on Member state level. This Exposure route depends on the application technology. The recent experience on exposure of non target areas by dust drift during sowing of treated seeds should Member states make aware of this possible exposure route also for application of a granular formulation.	**Comments from notifier (Nov 2008):** No comments at this moment. We will consider this in Annex III dossiers as suggested by DE. **RMS (Nov 2008):** The attrition properties and dust content of the granules have been evaluated appropriately according to requirements of the directive (see chapter B.2). We disagree to the arbitrary addition of recommendations in the benfuracarb evaluation, based on accidents that occured with other substances and other types of formulations,… Moreover these accidents at local level were probably due to an inadequate formulation. The need of a new specific guidance for the RA for dust drift should be discussed in the appropriate forum	Addressed.
4(35)	Vol. 1, 2.5.1, Definition of the residues	Notifier: correction second and last paragraph on page 34: carbofuran-phenol does *not* contain the active carbamate moiety	**RMS (Nov 2008):** We confirm that the carbofuran-phenol does *not* contain the active carbamate moiety	Addressed.
4(36)	Vol. 1, 2.5.1, Definition of the residues	Notifier: addition first paragraph on page 35: FOCUSgw calculations have indicated a number of safe scenarios (e.g. FOCUS-PELMO: 11 out of 12 safe scenarios, see Vol 3 B8.6.1 page 46)	**RMS (Nov 2008):** We confirm that safe PECgw scenarios have been identifed for benfuracarb, carbofuran and the other metabolites.	Addressed.

Other comments				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(37)	Vol. 1, 2.5.2, Fate and behaviour in soil	Notifier: correction 5th paragraph under 2.5.2 on page 35: carbofuran-phenol does *not* contain the active carbamate moiety	**RMS (Nov 2008):** We confirm that the carbofuran-phenol does *not* contain the active carbamate moiety	Addressed.

5. Ecotoxicology

Birds and mammals (B.9.1 and B.9.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(1)	Vol. 3, B.9.1.8, Residue content in food items table B.9.1.8-1	NL : Why starts the table with 7 days after planting and not earlier?	**Notifier :** day 3 was not analysed due to low residues at that time point. See also residue section (plant metabolism). **RMS (nov 2008) :** RMS agrees with the notifier. Moreover, in Table B.9.1.8-4 it is shown that in 6 out of 8 trials, the highest residue value was observed after 7 days and later.	Addressed.
5(2)	Vol. 3, B.9.1.8, Resi content in food items	NL : It is stated that field studies indicate that the highest residues are found between day 4 and 14. This is not totally right because in several studies already at day 3 the highest residue was found (see table B.9.1.8-4). Further it is stated that the 14 day residue situation is considered representative for the risk assessment for birds/mammals as it also represents the situation when residue levels are highest. This is not right; in most field studies the highest residue was found at day 3 or 7 (see again table B.9.1.8-4).	**Notifier :** remark is correct, highest residues are found between 3 and 21 days and the statement that residues are highest on day 14 is indeed not always true. These inaccuracies do not affect the choice of the conversion factor of "2.5" or "1.4" (as proposed on page 9-15). The results on page 9-14 are used to propose a conversion factor in order to include the polar, conjugated fraction in the dietary risk assessment for birds/mammals. As a matter of fact, at day 7 the polar fraction is "zero" and the conversion factor would be "1.3" (formula 1, page 9-15) or "1" (formula 2 page 9-15). Based on day 21 results, the conversion factor would be "4" and "1.8". The proposed conversion factor	Addressed.

Birds and mammals (B.9.1 and B.9.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			of "2.5" and "1.4", based on day 14 results are an appropriate realistic worst-case value for the entire sampling period. It should also be noted that the whole polar fraction was considered for exposure, whereas e.g. at day 28, only 60% of the polar fraction consists of relevant conjugates. Hence also from this perspective the proposed conversion factors are conservative. **RMS (nov 2008) :** RMS agrees with the notifier. The data from the study (Van Noorloos B., 2006) are used to calculate a conversion factor, taking into account the polar fraction. The conversion factors are then applied to the residue data of different field studies, from which the worst-case residue values were used for the risk assessment for birds and mammals.	

Birds and mammals (B.9.1 and B.9.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(3)	Vol. 3, B.9.1.8, Resi content in food items	NL: The 90th percentile residue level is set to a level of 3.92 mg/kg. Because there are only 8 measurements, the 90th percentile should be the maximum residue form these measurements, in this case 10.566 mg/kg.	**Notifier :** (1) the result of 10.566 is not reliable and is also an outlier (see earlier comments by notifier). In the notifiers opinion this study should not be included and if expert meetings will take place we hope the position of the notifier will be carefully considered. (2) the DAR makes it clear that the 87.5th percentile is being used (7th maximum value out of 8), presumably as this is the nearest (and reasonable) estimate. To suggest that as there are not 10 values, the 90th percentile cannot be estimated in this way and that a worst-case value i.e. the maximum residue level should be used, is wholly inappropriate. It does not make use of the available data and the assessment of variability it provides i.e. it is an unrealistic worst-case. **RMS (nov 2008) :** RMS agrees with the notifier. The 87.5th percentile is the closest to the 90th percentile.	Open point: MSs to discuss in an expert meeting whetheher the maximum measured residue value should be used in the refined risk assessment for birds and mammals or the 90th percentile value from the 8 residue trials. Furthermore it should be discussed if the residue trial of Beaufort (2006) should not be included in the risk assessment. See also comment 5(4)

Birds and mammals (B.9.1 and B.9.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(4)	Vol. 3, 9.1.8, residue content in food items	Notifier: In the table on page 17, the RMS has included two trials not used by the notifier. The notifier accepts the inclusion of the Montserrat 2005 trial by the RMS. The notifier disagrees with the inclusion of the Beaufort 2006 trial (see justification under further explanations). When omitting this trial the acute PECseedling becomes 3.3 mg/kg, the short-term PECseedling 2.01 mg/kg and the long-term PECseedling 0.79 mg/kg. Hence, the notifier is of the opinion that the RMS has overestimated the residue intake (birds and mammals) through seedlings by 20% (acute), 35% (short term) and 31% (long-term) (RMS values see page 18). The DAR (final sentence 1st paragraph page 19), makes reference to ruling out potential outliers but this does not appear to have been done (and in any case only applies to the acute exposure).	**RMS (nov 2008) :** The study of Beaufort (2006) is valid since it is conducted according to the GAP. In relation to former comment 5(3), the value of 3.92 mg carbofuran equivalents/kg cabbage seedlings is a good choice for the acute risk assessment based on a weight of evidence approach.	See open point in comment 5(3)
5(5)	Vol. 3, 9.1.8, residue content in food items	Notifier: correction table page 25. See B.7 residues comment 3(18). This has no impact on the risk assessment.	**RMS (nov 2008) :** RMS took note of the corrections in the table of residues. This has no impact on the risk assessment.	Addressed.

Birds and mammals (B.9.1 and B.9.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(6)	Vol. 3, B.9.1.9 Habitation and feeding behaviour of birds in treated areas, 3.1 Crested lark	NL: 61% weeds as proposed by the notifier seems to be a very high percentage. It is concluded by the RMS that a PD of 33% for cabbage seedlings is acceptable. Where is this figure based on? Has not by mistake the PD-value for woodpigeon been taken here?	**Notifier :** (1) Abs (1963) gives 62.3% for weed seeds. So this value is not impossible. (2) No, data for woodpigeon were not taken **RMS (nov 2008) :** Please refer to DAR, p. 9-36; PD is based on studies of Green (1978, 1980) and Donald *et al*. (2001b). This factor has been determined according to a weight of evidence approach and is only likely to help on a qualitative basis.	Open point MSs to discuss in an expert meeting the PD values suggested in the refined risk assessment for crested lark. See also open points 5(7) and 5(9)

Birds and mammals (B.9.1 and B.9.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(7)	Vol. 3, B.9.1.9 Habitat and feeding behaviour birds in treated areas, Wood pigeon	NL: Why not taken 40% for cabbage seedlings as worst case, based on the figures in table B.9.1.9-11, and then 51% for weed seeds?	**Notifier :** the 40% value is for total plant material. The RMS proposed PD of 33% would mean 83% of leaves intake comes from cabbage, which seems still a high value. We see no need to increase the PD to 40%. [the value of PD = 33% for wood pigeons and cabbage seedlings, is a judgment based on the available information taking into account seasonal changes in diet and making an appropriate distinction between plant leaves in general and cabbages seedlings in particular. The use of the worst-case value for PD of 40% is unnecessarily simplistic]. **RMS (nov 2008) :** Please refer to DAR, p. 9-38; a PD factor of 33 % or 40 % will not substantially change the calculations and has no impact on the risk assessment.	Open point: MSs to discuss in an expert meeting the PD values suggested in the refined risk assessment for wood pigeon. See also open points in comments 5(6) and 5(9)
5(8)	Vol. 3, B.9.1.9 Habitat and feeding behaviour birds in treated areas, PT determination	NL: What is exactly the conclusion of the RMS with respect to the PT determination? This is not clear from the text.	**Notifier :** we suggest the conclusion is that a realistic PT refinement will lead to acceptable TERs. The RMS is perfectly clear about the assessment of PT. Detailed information about crop production in a region of high cabbage availability is presented. This provides the basis for demonstration of an acceptable risk to birds from the use of benfuracarb under realistic conditions (for Annex I inclusion) but also	Open point The refined risk assessment (without a reduced PT) resulted in TERs below the trigger. Therefore it should be discussed in an expert meeting whether the information presented in the DAR allows a quantitative PT refinement or if a data gap remains. See also comments 5(10) and 5(13) and open point in comment 5(39)

Birds and mammals (B.9.1 and B.9.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			makes the point that a single definitive assessment is not appropriate and needs to be considered on a national basis. While this does not provide the simplistic single number values that the comment clearly requires, it is actually a more appropriate basis for the risk assessment. **RMS (nov 2008) :** RMS has presented a very clear risk assessment, argumentation was provided why certain parameters were chosen (PD, residue values, toxicological endpoints, focal species…). The RMS has presented a detailed PT evaluation based on the cabbage production in a region where this crop is very important. The RMS has indicated that the PT factor was not yet taken into account in the risk assessment in order to highlight the attention of other MS that the risk refinement is still possible on that basis. The RMS is of the opinion that the PT issue is a risk management decision that has to be taken at national level.	

Birds and mammals (B.9.1 and B.9.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(9)	Vol. 3, 9.1.9, feeding behaviour birds	Notifier: clarification: the RMS has selected a PD of 33% for the skylark (page 36). This is the maximum observed from three locations over a 2.5 year study period. This should be considered an extreme worst-case value and not "representative" as claimed (page 36 last paragraph). For the location with the highest % seedlings in the skylark diet from which the 33% value was taken, the 2.5 year mean value is ~8% and median only ~ 4%. The notifier has used a PD of 10% for the skylark in the submitted risk assessment. The same applies to the PD for earthworms in the black-headed gull diet (page 39) which is also extreme worst-case.	**RMS (nov 2008) :** Comment related to skylark : refer to comment 5(6). Comment related to the black-headed gull : PD = 92 % is indeed a worst-case approach, that has been proposed by the notifier in his original dossier.	Open point: MSs to discuss in an expert meeting the PD values suggested in the refined risk assessment for black headed gull.
5(10)	Vol. 3, 9.1.9, feeding behaviour birds	Notifier: clarification: under conclusion of the RMS on page 40 the RMS states that the notifier has back calculated the PT factor to achieve an acceptable TER. This was in fact done to demonstrate the principle that a realistic PT refinement will lead to acceptable TERs. Such a refinement is MS specific and will be included at MS level.	**RMS (nov 2008) :** Please refer to comment 5(8).	See open point 5(8)

Birds and mammals (B.9.1 and B.9.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(11)	Volume 3, point B.9.1.10 Monitoring data	FR: FR agrees with the RMS, any demonstration of a safe use for substances that have shown to be implicated in incidents should be discussed in light of monitoring feed back and relevant literature. This is as most important as a safe use is not identified from the refined risk assessment available for birds.	**Notifier :** no comments on the statement made by RMS under B.9.1.10. We note the two incidents reported were because of abuse. The RMS refers to the use of Oncol. However, also other products containing carbofuran may have been on the market in the UK. **RMS (nov 2008) :** Incidents reported were related to abuse. RMS indicated that these data cannot be used in the risk assessment for benfuracarb according to the GAP.	Addressed.

Birds and mammals (B.9.1 and B.9.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(12)	Vol. 3, B. 9. 1.11. Risk assessment for birds	EFSA: It is noted that the risk assessment for birds from uptake of granules was conducted with extrapolated HC5 values (in appendix 1 to B.9). Such an approach would need further discussion in an expert meeting. It may be beneficial to present a more standard risk assessment with the observed endpoints and the trigger values of 10 and 5.	**Notifier :** This is not correct. The use of extrapolated HC5 values to conduct the risk assessment for birds from uptake of granules relates to the Notifier's response to EFSA Open Point 11, which is included in Appendix 1 to B.9 (although this does actually follow the EPPO scheme). In the actual DAR, the most severe endpoints were used in the assessment i.e. the acute LD_{50} and the dietary LC_{50} of benfuracarb for the most sensitive species (*Anas platyrhynchos*) and the reproductive NOEC for *Colinus virginianus* (19.8 m/kg bw, 15 mg/kg bw/d and 8.93 mg/kg bw/d, respectively). **RMS (Nov 2008) :** RMS agrees with the notifier. The RMS did not use HC_5 values in its risk assessment, but worst-case LD_{50}, LC_{50} and NOEC values. Please refer to DAR, p. 9-45 and p. 9-49.	Open point RMS to include in an addendum an evaluation of the risk assessment for birds for the uptake of granules. MSs to discuss in an expert meeting the risk assessment for birds for the uptake of granules. Note to the RMS – no full risk assessment for the uptake of granules was provided in the main text of Vol. 3. There is only a reference to the Annex 1 to B.9 where the risk assessment of the applicant is presented. It seems that in the conclusion of the main text (Vol.3, B.9 on page 9-50) there is a misinterpretation of the EPPO risk assessment scheme for granules. The EPPO scheme uses the "1granule" criteria to identify a high risk but not to identify a low risk. If one or a few granules lead to mortality than it is evident that there is a high risk but the risk assessment needs to proceed further if more than a few granules lead to mortality.
5(13)	Vol. 3, B. 9. 1.11. Risk assessment for birds	EFSA: The refined risk assessment for birds resulted in TERs below the triggers of 10 and 5. A data gap should be set for further refinement of the risk assessment for birds (e.g. by reliable estimates of the PT values).	**Notifier :** The RMS has performed a deterministic worst case risk assessment as required in the current guidance documents. However, it is made clear that the calculated TERs should be read in a balanced way considering the various sources of uncertainty of the input parameters and the worst case assumptions that were used. In doing this, it is made clear that the TER values are below the	Addressed.

Birds and mammals (B.9.1 and B.9.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			triggers of 10 and 5. However, it is also pointed out that additional refinements of the risk such as the revision of the acute dose, the PT factor determined in a region of high cabbage production, the proportion of fields at the critical growth stage (seedlings at BBCH 12-19, with potentially high residue level) could be envisaged. This information was not taken into account for the TER calculations as the RMS is of the opinion that such information can only be used as a weight of evidence approach, rather than for a quantitative risk assessment. This type of refinement could be envisaged at MS level in a region with high cabbage production. This higher tier assessment is entirely appropriate and any data requirement should be clearly expressed in this context. **RMS (nov 2008) :** RMS has presented a very clear risk assessment, argumentation was provided why certain parameters were chosen (PD, residue values, toxicological endpoints, focal species…). The RMS has presented a detailed PT evaluation based on the cabbage production in a region where this crop is very important. The RMS has indicated that the PT factor was not yet taken into account in the risk assessment in order to highlight the attention	

Birds and mammals (B.9.1 and B.9.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			of other MS that the risk refinement is still possible on that basis. The RMS is of the opinion that the PT issue is a risk management decision that has to be taken at national level. The RMS considers that full information is available to define a PT factor and further data requirement is not necessary.	
5(14)	Volume 3, point B.9.1.11 Risks from the consumption of drinking water (birds and mammals)	FR: due to the high toxicity of the active substance and its main metabolite to birds, a calculation could be done based on the new puddle calculation formulae proposed by EFSA (EFSA journal, July 2008).	**Notifier :** we suggest this recent guidance should not be considered (it is also not yet approved for use), but could be included in Annex III dossiers. **RMS (Nov 2008) :** This recent guidance should not be considered (it is also not yet approved for use), but could be included in Annex III dossiers.	Open point MSs to discuss in an expert meeting whether a risk assessment should be conducted for birds and mammals for the uptake of contaminated drinking water.

Birds and mammals (B.9.1 and B.9.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(15)	Vol. 3, B.9.1.11 Summary of effects on birds, 1.2 Long-term endpoint	NL: The LC10 of 0.64 mg carbofuran/kg bw/d has been taken as the relevant long-term endpoint. Why the LC0 of 0.12 mg carbofuran/kg bw/d has not been taken as the relevant endpoint?	**Notifier :** (1) the LC10 value is appropriate because also the control in this study showed 10% mortality (which is within OECD 205 guideline criteria). This is explained on page 9-48 of the DAR. (2) The LC_{10} is usually accepted as an appropriate dose response value for use as a surrogate NOEC. It is actually not clear how an LC_0 value has been derived using a probit model as statistically this cannot be obtained. In any case, the confidence limits at the extremes of the fitted model are usually so wide as to make the value virtually meaningless. **RMS (Nov 2008) :** In former dossier it was agreed to set LC_{10} = NOEC.	Open point: MSs to discuss in an expert meeting the long-term endpoint for carbofuran used in the risk assessment.
5(16)	Vol. 3, B.9.1.11 Summary effects on birds, Higher tier assessment; refinement	NL: RMS has accepted PD-refinements for acute risk calculation. However, we doubt that the available data really show that at the acute feeding scale (1 feeding bout), an animal would still divide its food in different categories. Therefore, 100% feeding on the food item with the highest residues should be assumed for acute risk assessment.	**Notifier :** in statement 13 of the resubmission dossier a calculation was presented under 4.1.3.2 which demonstrated that a bird of 300 g would have to consume 765 g to reach the LC50 (i.e. ~2.5 times it's body weight). This seems not realistic. We realise this is based on the use of the LC50 instead of the LD50 for the acute RA. In the notifiers opinion the LC50 can be used for acute RA and if expert meetings will take place we hope the position of the notifier	Open point: MSs to discuss in an expert meeting the applicability of the suggested PD to refine the acute risk assessment for birds.

Birds and mammals (B.9.1 and B.9.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			will be carefully considered. (1) we have consulted bird experts (Rifcon GmbH) and they confirmed that PD refinements can also apply to the acute time scale. Therefore PD refinements can be considered at MS level also for the acute time scale (2) the current SANCO birds and mammals guidance document (SANCO/4145/2000, September 2002) makes it clear that exposure should be expressed as a daily dose for all time scales. It goes on to refer to the use of PT and PD as possible refinements where TER_a, TER_{st} or TER_{lt} are less then the Annex VI threshold values. This seems appropriate as the initial worst-case ETE calculation are based on intake over one day. **RMS (Nov 2008) :** The risk assessment has been refined using PD factors as proposed in the guidance document (SANCO/4145/2000, September 2002). These PD determinations are substantiated by the available literature studies. The use of PD = 100% is a first tier approach, which is also included in the DAR.	

Birds and mammals (B.9.1 and B.9.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(17)	Vol. 3, B.9.1.11 Summary of effects on birds, 6.2 Higher tier risk assessment; PT refinement	NL: RMS mentions a 'weight of evidence' PT refinement which can be applied on MS level. We doubt that this would be applicable on the acute scale, as a bird can fulfill its entire food demand of one feeding bout on one field. Furthermore, there is not necessarily a connection between a low percentage of cabbage fields in an area and low feeding of birds on those fields.	**Notifier :** we suggest the conclusion is that a realistic PT refinement will lead to acceptable TERs. See also comment (8) above. **RMS (Nov 2008) :** See comments 5(8) and 5(13).	See open point in comment 5(8)
5(18)	Vol. 3, B.9.1.11 Summary of effects on birds, 6.2 Higher tier risk assessment	NL: Under Conclusions of the RMS a NOEC value of 0.74 mg carbofuran/kg bw/d is mentioned. According to subchapter 1.2. of this chapter this value should be 0.64 mg carbofuran/kg bw/d.	**Notifier :** calculations were performed with 0.64 mg/kg bw/d. No need to revise calculations. **RMS (Nov 2008) :** Typing error will be corrected.	Addressed.
5(19)	Vol. 3, B.9.1.11, summary of effects on birds	Notifier: (page 46-49) Acute toxicity endpoints for birds: the notifier is of the opinion that the LD_{50} can be substituted with the LC_{50} for acute risk assessment (in line with EFSA opinion on pirimicarb). Full argumentation is provided in the benfuracarb dossier (IIIA Section 6 page 6) and in the DAR B.9 page 47) Short-term LC_{50}: see comment 5(38).	**RMS (Nov 2008) :** RMS does not agree, see DAR, p. 9-48.	Addressed.

Birds and mammals (B.9.1 and B.9.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(20)	Vol. 3, B.9.1.11, summary of effects on birds	Notifier: (page 51-59) The presented risk assessment is extreme worst-case in terms of PECfood (see comments 5(4), toxicity endpoints (see comments 5(38) and 5(19) and PD factors (see comment 5(9)) and does not include a PT refinement. Realistic worst-case inputs and realistic PT refinements will lead to acceptable TER values. A refined risk assessment is included in the dossier (IIIA, section 6, 10.1).	**RMS (Nov 2008) :** RMS has presented a worst-case risk assessment, indicating that the parameters should be read in a balanced way, taking into account the uncertainties and variabilities.	Addressed.
5(21)	Vol. 3, B. 9.3. Risk assessment for mammals	EFSA: It is noted that the risk assessment for mammals from uptake of granules was conducted with extrapolated HC5 values (in the appendix 2 to B.9). Such an approach would need further discussion in an expert meeting. It may be beneficial to present a more standard risk assessment with the observed endpoints and the trigger values of 10 and 5.	**Notifier :** This is not correct. The use of extrapolated HC5 values to conduct the risk assessment for birds from uptake of granules relates to the Notifier's response to EFSA Open Point 15, which is included in Appendix 2 to B.9 (although this does actually follow the EPPO scheme). In the actual DAR, the most severe endpoints are used the acute LD_{50} and the reproductive NOAEL for the rat (205 mg/kg bw and 1.2 mg/kg bw/d, respectively). **RMS (Nov 2008) :** The RMS agrees with the notifier. RMS did not use HC_5 values in its risk assessment, but worst-case LD_{50} and NAOEL values. Please refer to DAR, p.9-89 and p. 9-92.	Open point: RMS to include in an addendum an evaluation of the risk assessment for mammals for the uptake of granules. MSs to discuss the risk assessment for mammals for the uptake of granules. See also open point in comment 5(12)

Birds and mammals (B.9.1 and B.9.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(22)	Vol. 3, B. 9.3. Risk assessment mammals	EFSA: The suggested refinement of PD for herbivorous and earthworm-eating mammals is based on general observations on the food composition of mammals. There is no specific investigation of the food uptake in the vicinity of treated fields where cabbage is grown. Benfuracarb acts predominantly as an acute toxin. The suggested PD may be sufficiently supported on the chronic time scale but the data do not provide evidence that herbivorous mammals or earthworm-eating mammals would not consume more than 26% and 80% of only one food type (cabbage or earthworms) on the acute time scale.	**Notifier :** It is stated in the DAR that the PD determination was based on an extensive literature search that has been performed in order to determine the composition of the diet of the 2 focal species. It is pointed out that the available information is derived from stomach or faeces examination of mammals commuting between treated fields and untreated areas and so the determination of an accurate PD factor is difficult and only helpful on a qualitative level. However, the acute ETE calculation is based on daily uptake and on this basis it is reasonable to assume that herbivorous or earthworm-eating mammals would consume a variety of food items over this time period. See also answers to Dutch comments with respect to PD refinement for the acute time scale 5(16). **RMS (Nov 2008):** See comment 5(16)	Open point: MSs to discuss in an expert meeting the PD values suggested to refine the acute and long-term risk to mammals. See also comments 5(26), 5(27), 5(29)

Birds and mammals (B.9.1 and B.9.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(23)	Vol. 3, B. 9.3. Risk assessment for mammals	EFSA: It is not fully clear which studies were included in the calculation of the mean long-term NOAEL for mammals. Were the same effects observed in the different studies which were used to calculate the mean NOAEL?	**Notifier :** action for RMS **RMS (Nov 2008):** RMS clearly explained in the DAR which tests were used. An overall endpoint was chosen taking into account reprotoxic effects.	Open point: RMS to provide in an addendum a comprehensive explanation on how the mean NOAEL (carbofuran) for the long-term mammal risk assessment was derived. See also comment 5(25) and 5(28)
5(24)	Vol. 3, B.9.3 Effects on other terrestrial vertebrates	NL: Comments 5(1), 5(2), 5(3), 5(16) and 5(17) are also applicable to this chapter.	**Notifier and RMS (Nov 2008) :** see other answers	Addressed.

Birds and mammals (B.9.1 and B.9.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(25)	Vol. 3, B.9.3 Effects on ot terrestrial vertebrates	NL: The mean value of former NOAEL values is used for the long-term risk assessment (mean NOAEL = 0.71 mg carbofuran/kg bw/d), but this is not in agreement with the LoEP of carbofuran, in which a NOEL of 0.1 mg/kg bw/d is mentioned.	**Notifier :** the RMS states that as a reasonable worst-case scenario the mean value of the NOAEL values presented was used for the long-term risk assessment i.e. mean NOAEL = 0.71 mg carbofuran/kg b.w./day. This seems to be an appropriate judgment, which has been made in the context of carbofuran (although it is not entirely clear how this mean value was obtained i.e. which studies were included). In addition, as carbofuran is also being re-submitted it does not seem appropriate to refer to its LoEP as this is sill being evaluated and so an independent judgment is necessary (although clearly there should be coordination between the two re-submissions). **RMS (Nov 2008) :** Carbofuran is under evaluation and the endpoint setting of carbofuran in the dossier benfuracarb and carbofuran is in correlation. In the meantime, the notifier agrees with the setting of the long term endpoint by RMS.	See open point in comment 5(23)

Birds and mammals (B.9.1 and B.9.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(26)	Vol. 3, B.9.3 Effects on ot terrestrial vertebra 6.2.4 Higher tier T calculations	NL: Table B.9.3-11: A PD value of 0.8 is used for risk assessment. But PD must always be summed up to 1. What is the remaining 20% and could this 20% be contaminated with carbofuran?	**Notifier :** intake of plant material can be considered minimal. Other food items are woodlice, spiders, slugs, snails and insects which should not contain carbofuran as explained in 6.2.1 (9-94). **RMS (Nov 2008) :** The data were retrieved from the mammal bible and this information does not directly provide one PD value for a certain food item. RMS made a reasonable estimate of PD.	See open point in comment 5(22)
5(27)	Vol. 3, B.9.3 Effects on ot terrestrial vertebra 7.2.2 Determination of proportation of food t in the diet (PD value)	NL: The PD value of 0.25 for cabbage seedlings seems to be quite arbitrary. The height of this value is dependant on the availability of different food items. In our opinion a more conservative PD value is necessary to cover all situations (e.g. a PD value of 0.5).	**Notifier :** the PD value of 0.25 used for the hare is not arbitrary, rather the basis is clearly presented in the DAR: "Hares feed predominantly on monocotyledonous plants (Poaceae 50-70 %) but several dicotyledonous plant species (from the families of Fabaceae, Asteraceae, Brassicaceae and Plantaginaceae) may also form part of the diet over the course of the year (Niethammer J. and Pegel M., 2003; Zörner H., 1990). In a study from Schleswig-Holstein, Germany, the proportion of dicotyledonous plants was greatest in spring with 40-60 % (Brüll U., 1973; Brüll U., 1976). Hence, for the long-term risk assessment a reduction of PD to at least 50 % can be made on the basis of this information.	See open point in comment 5(22)

Birds and mammals (B.9.1 and B.9.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			A further reduction can be made on the basis of studies that analyzed individual food items in the stomach of hares. Plant parts from the genus Brassica (including unidentified food items) amount to 17.1 % stomach content annual average in Austria (Onderscheka *et al*., 1981 in Zörner H., 1990). Homolka (1987) found in eastern Bohemia that plant parts from the genus Brassica (including unidentified food items) amount to only 6 % stomach volume annual average. Hence a further reduction to 25 % (PD = 0.25 for cabbage seedlings) is justified." Further information is provided by the RMS and the PD value of 0.25 is accepted. **RMS (Nov 2008) :** Justification of RMS is presented in the DAR, p. 9-101.	

Birds and mammals (B.9.1 and B.9.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(28)	Vol. 3, B.9.3, effect on other terrestrial vertebrates	Notifier: on page 91, second paragraph on long-term endpoint, the RMS disagrees with the proposed endpoint by the notifier because it "should be based on reproductive toxicity and teratogenicity studies". However, the notifier proposed ecotoxicological long-term endpoint is based on a 3-generation rat study. It seems the argumentation of the RMS is not valid. Justification of the proposal of the notifier is given in the DAR on page 90.	**RMS (Nov 2008) :** In the meantime, the notifier agrees with setting of the long-term of the RMS.	See open point in comment 5(23)
5(29)	Vol. 3, B.9.3, effect on other terrestrial vertebrates	Notifier: clarification (page 94-95): the earthworm PD of 80% is the maximum observed in any month from a total of 5 studies (this value is based on the proportion of earthworms in the diet of the common shrew inhabiting a watercress bed in July, which seems of little relevance for the intended use of benfuracarb). A more realistic worst-case PD factor would be the 90th percentile value (i.e. 28%) for the months February-August form the other three more relevant studies. On this basis, the selected PD by the RMS of 80% is clearly an extreme worst-case.	**RMS (Nov 2008) :** Please refer to comment 5(26).	See open point in comment 5(29)

Bees and non-target arthropods (B. 9.4 and B.9.5)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(30)	Volume 3, point B.9.4 Risk to bees	FR: a Spe8 phrase should be proposed in order to limit exposure of bees to flowering adventices growing on contaminated soils in the crop, in the case where flower removal would not be the rule.	**Notifier :** no comment **RMS (nov 2008) :** Flower removal **is** the rule.	Open point: MSs to discuss in an expert meeting whether risk mitigation measures should be proposed for bees.
5(31)	Volume 3, point B.9.5.Risk to non target arthropods	FR: numerous studies are available in the scientific literature for side-effects of carbofuran on non target species (IOBC publications). This valuable information should be added in the risk assessment for benfuracarb as it fits with current guidelines for testing.	**Notifier :** IOBC data to assess the effects of pesticides on beneficial arthropods is primarily intended to provide advice to growers but has been used in the past for regulatory submissions, particularly pre-ESCORT. However, it should be treated with caution as the methodology is generally not of a regulatory standard and in particular the older data was produced on the basis of maximum application concentrations (not rates) and so could not be interpreted in a risk-based context. In addition, higher tier data was not often produced (i.e. only worst-case Tier 1 studies). Carbofuran does not appear in the 2nd to 9th Joint Testing Programmes. **RMS (nov 2008) :** A complete database performed according to approved guidelines has been provided by the notifier. We consider that the evaluation of literature studies (what about protocol, application rate, agricultural conditons,.. ?) is out of the scope of this assessment.	Addressed.
5(32)	Vol. 3, B.9.5.2	EFSA: In the aged residue study with	**Notifier :** see extract from the report below.	Open point:

Bees and non-target arthropods (B. 9.4 and B.9.5)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
	Effects of the formulation on non-target arthropods	*Aleochara bilineata* (Geuijen I., 2005a) an increase of adverse effects were observed with the duration of ageing of residues (>50%). This was explained as not being related to the exposure situation in the test. However the observed increase in mortality was not fully explained and it is questionable if the study can be considered as valid.	This explanation is acceptable, the reduced response for the positive control is because of the dose. Therefore at the last time point the dose was increased, resulting in a sufficient response of the positive control. Therefore it can be concluded that with respect to the control and positive control the validity of the study is demonstrated. The increased mortality at DAT 119 is random (when performing many assays the statistical probability to have a positive result increases) and not treatment related (as was also explained by simulations of carbofuran concentrations in the test medium which is included in the DAR). This answer may also be useful for the comment of MS France on the same study. **RMS (Nov 2008) :** Please refer to comment 5(33).	MSs to discuss in an expert meeting the validity of the aged residues study with *A. bilineata*. See also comment 5(33)
5(33)	Volume 3, point B.9.5.2 aged residue study with Aleochara bilineata	FR: the acceptability of risks relies on acceptable effects on the soil staphylinid *Aleochara bilineata* in an aged residue study, where acceptable effects were observed even after 0 day aging at a rate of 1.0 kg a.s./ha. This result is not consistent with the effects observed in the extended laboratory study (no aging) at a rate of 1 kg a.s./ha. In addition, the increased toxicity at 119 days post-treatment is proposed to be not treatment-related, based on time-dependent release of	**Notifier :** see comment 5(32). Please also note that on page 9-121 a simulation was performed based on a release period from granules of 42 days (which is really long considering the first remark). **RMS (Nov 2008) :** 6 + 1 studies were conducted with *Aleochara bilineata* with fresh and aged residues. From these	See open point in comment 5(32)

Bees and non-target arthropods (B. 9.4 and B.9.5)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
		benfurabarb from granules. This should be cross validated by information of efficacy (duration of protection and mode of protection) as well as with relevant fate data on the formulated product.	7 studies, mortality and reproduction were slightly above 50 % trigger effect for 2 trials. RMS considers therefore that enough information is available in the DAR.	

Earthworms and other soil non-target organisms (macro and micro) (B. 9.6, B.9.7 and B.9.8)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(34)	Volume 3, point B.9.6 Risk to earthworms	FR: we agree with the RMS that the risk to earthworms is not sufficiently assessed. The field study presents deficiencies among which the lack of effects of the reference substance. In addition, due to a possible delayed release of the active substance from granules, chronic studies are particularly of interest in this case.	**Notifier :** see notifiers reply in commenting table sent to RMS/EFSA. With respect to delayed release see first comment Env Fate. **RMS (Nov 2008) :** The notifier communicated that testing is ongoing.	Open point: MSs to discuss in an expert meeting whether a data gap remains with regard to the risk to earthworms. See also comment 5(41)
5(35)	Vol. 3, B.9.6.2, sublethal effects on earthworms	Notifier: see comment 5(41).	**RMS (Nov 2008) :** Please refer to respective comment.	Addressed.
5(36)	Vol. 3, B.9.6.6, summary and risk assessment for earthworms	Notifier: see comment 5(41).	**RMS (Nov 2008) :** Please refer to respective comment.	Addressed.

Other comments				
No.	Column 1 Reference to DAR (vol.,point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(37)	Vol. 1, LoEP Risk assessment for birds and mammals	EFSA: Only the number of granules which are needed to reach the LC/LD 50 and NOEC are reported but no risk assessment for birds and mammals was included for the uptake of granules. The TERs for this exposure route should be included in the LoEP.	**Notifier :** It is not correct to state that no risk assessment was included for birds and mammals for the uptake of granules. It is not appropriate to assess the risk arising from the uptake of granules using the TER approach due to the discrete nature of the exposure from individual granules. Accordingly, the SANCO Birds and Mammals Guidance Document refers to the EPPO scheme, which has been used in the DAR. Thus, in the DAR it states that according to the EPPO scheme, further risk assessment for ingestion on granular formulation is necessary when only one or a few granules would be sufficient to achieve a lethal dose. The risk for birds consuming granules containing benfuracarb as grit or accidentally has been considered acceptable since at least 24-54 granules are necessary to reach the relevant toxicological endpoints in the case of a bird weighting 15 g (and more for larger birds). This would require sustained daily consumption at this rate in the case of the long-term risk. **RMS (Nov 2008) :** RMS has conducted a risk assessment from uptake of granules. This was based on LD_{50}, LC_{50} and NOEC values, being recalculated in the number of granules a bird/mammal with a certain body weight has to consume before an effect will occur. According to EPPO guidance, the risk assessment is finalised unless one or a few granules are sufficient to achieve the dose with	Open point: RMS to include details on the risk assessment for birds and mammals for the uptake of granules in the LoEP. See also open points in comments 5(12), 5(21)

Other comments				
No.	Column 1 Reference to DAR (vol.,point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			effects. Since this is not the case for benfuracarb, the risk assessment from uptake of granules is finalised.	
5(38)	Vol. 1, 2.6.1.1, Effects on birds	Notifier: (page 84) the notifier disagrees with the choice of toxicological endpoint for the Tier I short-term risk assessment (carbofuran). The proposed endpoint comes from a non-standard 14 day duckling study. It is more appropriate to use the endpoint from the standard 5 day dietary study in mallard duck for short term exposure (LC_{50} 10 mg/kg bw/d), especially considering that maximum residue levels in food - which are used in the short term RA – are only present for a few days.	**RMS (Nov 2008) :** The RMS has presented a full explanation on the choice of the endpoint in the DAR, p. 9-46 and p. 9-47.	Open point: MSs to discuss in an expert meeting the long-term endpoint (carbofuran) used in the short-term risk assessment for birds.
5(39)	Vol. 1, 2.6.1.1, Effects on birds	Notifier:(page 85) the RA performed by the RMS deviates from the submitted RA by the notifier. The RA performed by the RMS appears to be an extreme worst-case scenario (accumulation of worst-case residue values, worst-case toxicological endpoints and worst-case PD factors, no PT factor). See also comments 5(38), 5(4), 5(9), 5(10), 5(19) and 5(20).	**RMS (Nov 2008) :** RMS acknowledges the comment of the notifier. However, in the risk assessment of the RMS it is clearly stated that the worst-case choice of the parameters should be read in a balanced way.	Open point: RMS to present in an addendum the refined risk assessment for birds suggested by the applicant (including the justification for the proposed refinements) to be discussed in an expert meeting.

Other comments				
No.	Column 1 Reference to DAR (vol.,point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(40)	Vol. 1, 2.6.1.2, Effects on other terrestrial vertebrates	Notifier: the RA performed by the RMS deviates from the submitted RA by the notifier. The RA performed by the RMS appears to be an extreme worst-case scenario (accumulation of worst-case residue values and worst-case PD factors, no PT factor). See also comments 5(28) and 5(29).	**RMS (Nov 2008) :** RMS acknowledges the comment of the notifier. However, in the risk assessment of the RMS it is clearly stated that the worst-case choice of the parameters should be read in a balanced way.	Addressed.
5(41)	Vol. 1, 2.6.4.1, Earthworms	Notifier: in relation to current guidance the data on earthworm fulfil all criteria of 91/414/EEC and demonstrate an acceptable risk to earthworms (TERacute > 10, DT50f <100 days and single application). It is considered that any sublethal effects will be reversible (typical for carbamate acetylcholinesterase inhibition) and so any effects will not persist and will not affect earthworm populations.	**RMS (Nov 2008) :** RMS maintains the data requirement set in the DAR, p. 9-137 and p. 9-138.	See open point in comment 5(34)
5(42)	Vol. 1, Appendix 1, LoEP	Notifier: page 84: see comment 5(38) above.	**RMS (Nov 2008) :** See relevant points above	Addressed.
5(43)	Vol. 1, Appendix 1, LoEP	Notifier: page 85-86: see comment 5(39) and 5(40) above.	**RMS (Nov 2008) :** See relevant points above	Addressed.
5(44)	Vol. 1, level 4, 4.9.6	Notifier: see comment 5(41) above.	**RMS (Nov 2008) :** See relevant points above	Addressed.