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0. General

General				
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0(1)	Vol. 1, List of end points	DE: The RMS should consider to use the current harmonised version of the list of end points. Data on hydrolysis, photostability and quantum yield are still given.	**RMS 07.2009:** The data on hydrolysis, photostability and quantum yield were not removed from the physchem part of the LoEP during preparation of the revised DAR, in order to avoid that possibly some relevant information would be completely excluded from the LoEP. The full use of the new template will be considered for revisions of list of end points in the future.	Open point: The new template for the list of end points should be used.
0(2)	Vol. 3, 3.2.3	DE: A rate of 100 g as/ha for granules can be effective on some pest insects of sugar beet, if row treatment is used. Test with LD_{90} values of carbosulfan applied in soil (not topical application as mentioned under 3.2.3) showed clear activity to Diabrotica larvae. More than 1 ppm in soil will be present if row application of 100 g is used.	**NOT**: We agree. *[with comment DE]* **RMS 07.2009:** The RMS considers that insufficient information was provided to demonstrate the representativeness of the proposed altered GAP at 100 g a.s./ha in sugar beet under practical conditions. See Vol.1 level 2, point 2.1.3.	Addressed: The RMS has not considered the 100 g/ha rate. See also 1(11)

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

Identity (B.1, Annex C)				
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 / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
1(1)	Vol 4, general	EFSA: The applicant has proposed a new specification supported by new methods and batch analysis. According to Article 15 1a of Regulation 33/2008 this active substance is not eligible for submission under the accelerated procedure.	**NOT**: the specification of carbosulfan was one of the reasons of the non-inclusion. Indeed, the Non-inclusion Directive wrote „*Furthermore, technical material (that is, the active substance as sold in the market) contains relevant impurities, of which at least one (N-nitrosodibutylamine) is carcinogenic. This impurity is found in the technical material at levels which raise concerns. The data lodged by the notifier within the legal deadlines did not provide sufficient information to resolve these concerns*“ We repeated the 5-batches analyses in order to demonstarte that we can now produce carbosulfan technical with concentration of N-nitrosodibutylamine below 1 mg/kg. Furthermore, the former 5-batches analysis was very old and its analytical method was not completely validated. Eventually, FMC produces now carbosulfan technical in Mexico. Repeating the 5-batches at the new source closes all those open points. The change of specification is the consequenec of the new 5-batches. The minimum purity has not changed however. **RMS 07.2009:** A new batch analysis was at least needed to address the potential concern of the *N*-nitrosamine impurity in the technical material (see comment	Addressed: The applicant has chosen to address a tox requirement by changing the specification. The commission has seen these comments and has not raised any issue with this active being considered under the accelerated procedure. See also 1(2)

Identity (B.1, Annex C)				
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			1(2)). A full new batch analysis was provided, because it concerned technical carbosulfan from a different manufacturing source than that initially assessed. As a consequence, the proposal of a new specification, accounting for potential differences in analytical profile between the new source and the old (unsupported and unaccepted) source, was considered by the RMS to be logic and in accordance with the approach of assessing technical specifications. Furthermore, it should be noted that the original specification as a whole was regarded by EFSA as being provisional (cf. EFSA Scientific Report (2006) 91, 1-84), due to missing validation data for the impurity methods. Additional validation data were therefore provided and only a few new (or updated) methods were used in the new 5-batch analysis study. Taking into account the elements outlined above, the RMS considers it to be appropriate and justified to have re-assessed the specification as a whole, based on the toxicological and additional analytical information provided by the applicant.	
1(2)	General	DE: Could the RMS please explain why a new specification is proposed? It seems that this approach is not in compliance with the substantive and procedural requirements of Article 15 of	**NOT**: Please see comment 1(1) **RMS 07.2009**: - In the Commission Decision of non-inclusion of carbosulfan (2007/414/EC, OJ L 156,	See comment in 1(1)

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		Regulation 33/2008 where it is clearly stated that "…the specification of the active substance is the same as was the subject of the non-inclusion Decision. It may only be changed insofar as this is necessary, in the light of the reasons which gave rise to the non-inclusion Decision, to permit inclusion of that substance in Annex I to Directive 91/414/EEC;…" It should be clarified whether the explanation/justification given in Volume 4 (pages 22/23) is generally acceptable to amend the specification even if the specification was not an issue with respect to the non-inclusion of the substance.	16.6.2007), it is clearly stated that the presence of the relevant impurity NDBA (*N*-nitrosodibutylamine) in the technical material was a critical issue from the toxicological point of view, and was thus a main reason for non-inclusion: *"Furthermore, technical material (that is, the active substance as sold in the market) contains relevant impurities, of which at least one (N-nitrosodibutylamine) is carcinogenic. This impurity is found in the technical material at levels which raise concerns. The data lodged by the notifier within the legal deadlines did not provide sufficient information to resolve these concerns."* - The applicant has attempted to resolve the above-mentioned concern by providing a new 5-batch analysis study, of technical material from another manufacturing source than that originally assessed. Thus, it was demonstrated by the applicant that the level of NDBA was <1 mg/kg in the new commercial 5-batch, contrarily to what was previously submitted (levels up to 26 mg/kg). As the applicant made efforts to improve the purity of the a.s., this should be taken into account in the evaluation during	

Identity (B.1, Annex C)				
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			re-submission. **NOT:** *[...]* We repeated the 5-batches analyses in order to demonstrate that we can now produce carbosulfan technical with concentration of N-nitrosodibutylamine below 1 mg/kg. Furthermore, the former 5-batches analysis was very old and its analytical method was not completely validated. Eventually, FMC produces now carbosulfan technical in Mexico. Repeating the 5-batches at the new source closes all those open points. The change of specification is the consequence of the new 5-batches. The minimum purity has not changed however.	

Identity (B.1, Annex C)				
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 / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
1(3)	Vol 4, C.1.2.2, new specification	EFSA: 5-chlorocarbofuran is a relevant impurity and it should have a numerical value in the specification.	**NOT**: 5-chlorocarbofuran could not be detected in the 5-batches analysis. Therefore, no specification was proposed for it. We analysed this impurity only because it could have form (theoretically), but he 5-batches results show that it doesnot form in practice. If a numerical value needs to me mentioned anyway, we propose 0.03% w/w, which is the lowest recovery level tested in the validation of the method. **RMS 07.2009**: This impurity was analysed for, but it was not detected in any of the provided batch analyses of technical carbosulfan (MUP). The limit of detection (LOD) of the method applied was estimated to be approximately 0.01 g/kg (based on S/N = 3). The validated limit of quantification (LOQ) was 0.33 g/kg (see C.1.2.4). The impurity was also not detected in the formulation Marshal 10 G, analysed before and after storage for 14 days at 54°C (see B.2.2.15b). Therefore, the RMS considered it to be justified not to include this impurity into the technical specification. It is the understanding of the RMS that by excluding the impurity from the specification, the trigger value of 1 g/kg would apply as maximum level for 5-chlorocarbofuran in the technical material. **NOT:** 5-chlorocarbofuran could not be detected in the 5-batches analysis. Therefore, no specification was proposed for it. We analysed this impurity only because it could have form (theoretically), but the 5-batches results show that it does not form in practice. If a numerical value needs to me	Open point: EFSA to explain the issues with the 5-chlorocarbofuran in the conclusion and propose a maximum level for this impurity.

Rapporteur:

Identity (B.1, Annex C)				
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 / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
1(4)	Vol 4, table C.1.2.3-4, tox batch	EFSA: This batch has N-Nitroso-dibutylamine at levels above 1 mg/kg. Is this batch a commercial batch manufactured by the current method of manufacture?	**NOT:** This batch is not typical of a carbosulfan production for the reason mentioned in the new DAR (see page 27 of Vol 4). **RMS 07.2009**: The applicant provided an argumentation, which was summarised in the conclusion below table C.1.2.3-4: *"[…] this may be due to the fact that the sample analysed was unstabilized (commercial production of batch 637 had to be interrupted/stopped to remove the 1 kg unstabilized sample) and had been stored frozen for approximately two years prior to its analytical determination by Wang (2008)."* The tox batch constitutes a worst-case compared to the technical grade active ingredient for which authorisation is being sought.	Addressed: The batch is not considered representative of current production.
1(5)	Vol. 1, 1.3.10	DE: Relevant impurities should not be regarded as confidential.	**RMS 07.2009**: RMS agrees. However, the relevant impurities are mentioned in the list of endpoints.	Open point: EFSA to ensure that the relevant impurities are taken account of in the list of end points.
1(6)	Vol. 4, C.1.2.4.1-2,	**Notifier**:	**RMS 07.2009**:	Addressed:

Identity (B.1, Annex C)				
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	Validation for impurities	Method precision/repeatability of method APG468 and APG 470 for impurities 3,4,5,6 and 22 is also addressed by the good linear fit of the calibration curve and the good recoveries in the accuracy test. Good results under linearity would not be possible if the system is non repeatable, and the accuracy results indicate recoveries with a decent range. Therefore, this demonstrates, on top of the replicated injection, the system repeatability.	We agree with the applicant that the (instrument) system precision/repeatability for those impurities was sufficiently addressed with acceptable RSD values in the range of 0.38 - 1.58%. However, this validation approach does not account for the effect of repeated sample preparations and was therefore considered to be not fully in accordance with the provisions of SANCO/3030/99 rev.4. However, it is acknowledged that the sample preparation procedure of the methods APG 468 and APG 470 is relatively simple (weighing of technical material aliquot and simple dissolution in solvent before analysis) and therefore, it can be expected that the method precision will be acceptable as well. Moreover, impurities 4, 5 and 6 were found to be not significant in technical carbosulfan (MUP) (see C.1.2.3, levels ≤ 0.5 g/kg) and were therefore not included in the technical specification. Taking also this into account, we agree that the validation data provided for those impurities is sufficient and that further data on (method) precision are not absolutely necessary.	The method validation for the impurities is acceptable.

Identity (B.1, Annex C)				
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1(7)	Vol. 4, C.1.2.4.1-2, Validation for impurities	**Notifier**: Spiked level of impurities 13 and 14 were indeed lower than the expected level in the 5-batches. However, as it is more difficult to validate a method at lower concentration. Therefore we argue that the validation results cover the 5-batches analysis and the toxicological batches analysis.	**RMS 07.2009**: The validation data provided did not demonstrate good accuracy of method APG 466 for determining impurities 13 and 14 at levels appropriate to the technical material profile/specification (cf. SANCO/3030/99 rev.4).	Addressed: The validation data for impurities 13 and 14 are sufficient as they are validated at a lower level than necessary and therefore they will work at the higher level found in the batch analysis.
1(8)	Vol. 4, C.1.2.4.1-2, Validation for impurities	**Notifier**: Samples are diluted before analysis when the pre-test show that their level in one impurity will be outside the corresponding linear range tested. Therefore, impurity 10 analysis is covered by the linear range validated.	**RMS 07.2009**: The clarification of the applicant is acceptable. We consider the point to be fulfilled.	Addressed: If the level is outside the linear range the samples are diluted.

Physical, chemical and technical properties of the formulation (B.2.2)				
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 / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
1(9)	Vol 3, B.2.2.19b, shelf life	EFSA: This is still a data gap shelf life with analysis of 5-chlorocarbofuran and N-nitrosodibutylamine	**NOT:** This shelf life is still ongoing. The accelerated storage stability replaces it in the meanwhile. **RMS 07.2009**: RMS refers to the data gap identified in the DAR April 2009, Vol.1 level 4, 4.2. With respect to *N-nitrosodibutylamine* content in the formulation, only an accelerated storage stability study (6 weeks at 45°C or 8 weeks at 40°C) was provided. The missing shelf life study has been announced for May 2010. However, with respect to the impurity *5-chlorocarbofuran*, the RMS deems further data on content of this impurity in the formulation to be not required (see also comment 1(3)). Furthermore, the content of *carbofuran* in the formulation before and after storage (accelerated and long-term) had indeed already been addressed by the applicant (see B.2.2.15b and B.2.2.19b).	Data gap: Shelf life with analysis of 5-chlorocarbofuran and N-nitrosodibutylamine

Physical, chemical and technical properties of the formulation (B.2.2)				
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 / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
1(10)	Vol. 3, B.2.2-b, Summary and conclusion	**Notifier**: We disagree that DBA is a relevant impurity and refer to the evaluation conducted by RMS in the Vol 3 B6, which acknowledges that DBA itself is not toxic. We understand the view of the RMS that DBA is the precursor of NDBA, which is a relevant impurity, however only NDBA itself is relevant. The relevant information is whether NDBA level will increase upon storage or not. In this regard, we fully agree with RMS conclusion that NDBA will remain below the trigger of 1 mg/kg as long as Marshal 10G is not stored under high temperature conditions.	**RMS 07.2009**: There is no statement in the DAR indicating that DBA would be toxicologically irrelevant, as it is harmful. It is certainly less toxic than CS itself, but it may be a precursor of NDBA in acidic conditions. Further, the level of DBA was 2.4 g/kg in the tox batches and thus it was considered that the toxicity of the TC was covered. Overall, RMS agrees that the monitoring of NDBA in the formulation is more relevant than that of DBA.	Addressed: DBA is not a relevant impurity as long as the NDBA is controlled.

Further information (B.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 / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
1(11)	Vol.3, B.3.2.3, Rate of application	**Notifier:** FMC statement that carbosulfan will exhibit biological efficacy at 100 g ai/ha – if incorporated sufficiently close to seed – is supported by the seed treatment registration that use to be registered before the non-Annex I inclusion of carbosulfan. See for example 'Combocoat CBS' under the 'list of authorized uses' on page 128. 100 g carbosulfan/ha represents a maximum loading for this type of use. Whilst we appreciate the efforts to calculate the Risk assessment at 750 g ai/ha, we introduced risk assessments at 100 g ai/ha in order to increase the chances to identify a safe use scenario.	**RMS 07.2009**: See comment 0(2).	See comment 0(2)

Classification and labelling (B.4)
For comments on classification and labelling see the relevant sections.

Methods of analysis (B.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 / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
1(12)	Vol. 3, B5.5.1, method for formulation	**Notifier:** No method for determination of DBA in Marshal 10G is necessary because DBA is not a relevant impurity. See also comment 1(10) under B2.2.	**RMS 07.2009**: DBA is certainly less toxic than carbosulfan itself, but it may be a precursor of NDBA in acidic conditions and/or at higher temperature. The hydrolysis of carbosulfan into carbofuran and DBA is thus relevant, but RMS agrees that the monitoring of NDBA in the formulation is more relevant than that of DBA.	Addressed: DBA is not a relevant impurity therefore a method of analysis in the formulation is not needed.
1(13)	Vol. 3, B.5.5.2, new plant method	EFSA: These are the same studies as seen for carbofuran so the out come of the carbofuran peer review will have to be taken in to account.	**RMS 07.2009**: RMS agrees. During the peer review of carbofuran (cf. PRAPeR 66), it was concluded that the modified method (Zietz, 2008) could be accepted as primary method, but that an ILV study was still required. A second data gap was set: Notifier to demonstrate the efficiency of the hydrolysis step (cf. determination of conjugates). A similar data gap was identified for the animal matrices method: "The notifier to address the efficiency of the hydrolysis step to release the 3 OH-carbofuran conjugates in animal matrices in the method of analysis for monitoring."	Open point: The methods submitted in this dossier are the same as submitted for carbofuran EFSA should ensure that the conclusion is in line with that for carbofuran.

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 / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
2(1)	Vol. 3, B.6.8.1.1, toxicity of dibutylamine	EFSA: It is noted that the experts at EPCO 33 required a full *in vitro* data package on the metabolite dibutylamine, however only an Ames test was provided. It should be further discussed if the data requirement is fulfilled.	**NOT**: It should be noted that confusion around this impurity rose from the fact that FMC had wrongly submited – during the first evaluation - a genotoxicity study on a substance with an FMC code number very close to that of DBA (see page 6-85 in the new DAR). The new Ames test (negative) confirms that DBA itself carries not genotoxic potential. **RMS 07.2009**: The result from the Ames-test demonstrated that DBA is not inducing gene mutations in bacteria. In the light of its structure, it is unlikely that this metabolite would present a genotoxic potential. Most importantly, it was also demonstrated by the notifier that the level of Dibutylnitrosamine was <1 ppm in the commercial 5-batch, contrarily to what was previously submitted. Therefore, the data requirement is considered fulfilled.	Addressed: In the EFSA conclusion, this impurity will be referred as non relevant as it is less toxic than the parent and the fact that it is a precursor of a relevant impurity does not make it relevant.

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 / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
2(2)	Vol. 3, B.6.8.1.1 Toxicity of dibutylamine	**Notifier:** The evaluation conducted by RMS actually demonstrates that DBA is not a relevant impurity since it has no genotoxic potential and has acute toxicity less severe than carbosulfan. Whilst it is a precursor to NDBA, only NDBA itself remains the relevant impurity. As a metabolite, we agree with RMS that no risk to human nor environment will happen due to DBA.	**RMS 07.2009:** The conclusion of the rapporteur was *not* that DBA is toxicologically irrelevant, but that there is no concern for both the consumer and the operator, taking into account the expected levels which are generated. As explained above (phys-chem section), the potential reaction product DBNA should be monitored in the TC.	Addressed: See comment 2(1) above

Summary of mammalian toxicology and setting of ADI, AOEL and ARfD (B.6.10)				
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 / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
2(3)	Vol. 3, B.6.10.2, ADI	EFSA: It is noted that the JMPR assessment is still using the 2-year rat study as a basis for the ADI setting, even when the acute neurotoxicity study was available. Therefore it might be useful to indicate that this was also considered to enhance transparency.	**NOT**: We agree. See also 2(4). **RMS 07.2009:** As explained in the DAR, and in the light of the evaluation of the main metabolite Carbofuran, the derivation of the reference doses should be based upon the most sensitive endpoint. As the acute NT study with Carbosulfan was the lowest one, it is appropriate to establish the ADI on this basis. In addition, the acute NT study was conducted by gavage, while in the chronic toxicity study, the a.s. was administered via the diet. Finally, brain AChE levels were not monitored in the latter. In conclusion, the chronic toxicity study was considered but not deemed the most appropriate study to derive the reference doses.	Addressed: This comment has been adequately considered, it is in line with the approach previously agreed for carbofuran, and therefore no further discussion is necessary in relation to this endpoint.
2(4)	Vol. 3, B.6.10, setting ADI and ARfD	**Notifier:** We believe that carbosulfan ADI and ARfD should be set respectively at 0.01 mg/kg bw/d and at 0.08 mg/kg bw/day. We refere to our position paper, provided in the DAR on page 6-135	**RMS 07.2009:** The opinion of the notifier was considered, but reference doses were established otherwise, for the reasons explained in the DAR and summarised in point 2(3).	Addressed: See also comment 2(3)
2(5)	Vol. 3, B.6.10, setting ADI, ARfD and AOEL	**Notifier** FMC refers to its comments made in the form of the carbofuran evaluation with regard to establishment of the ADI, ARfD and AOEL of carbofuran. We maintain that it sould be set at 0.001 mg/kg bw/day.	**RMS 07.2009:** The opinion of the notifier was considered, but reference doses of the main metabolite Carbofuran were established otherwise, for the reasons explained in the DAR. The endpoints were discussed and agreed upon in various expert TC/meetings.	Addressed: See also comment 2(3)

Dermal absorption (B.6.12)				
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 / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
2(6)	Vol. 3, B.6.12.2, comparative dermal absorption *in vitro*	EFSA: According to the guidance document on dermal absorption, when only an *in vitro* study is available, the results with human skin should be preferred, however in this case where a lower recovery was obtained with human skin, the use of the rat dermal absorption values is agreed. However it might be considered to use a rounding to 1 % when such low results are found (< 1 %). This approach would also account for a slightly lower total recovery than 100 %. Given the operator exposure assessment presented with the PHED model, even if this proposal is agreed, this is not expected not alter significantly the outcome of the overall risk assessment.	**RMS 07.2009:** Agrees with the remark in general. The current proposal for skin absorption is 0.2%, thus the adoption of a 1% estimation would rise the operator exposure to 50% of the AOEL, in the presence of PPE. As this is still acceptable, the overall risk assessment remains unaltered.	Addressed: This is a general discussion, not specific to this a.s. In the EFSA conclusion and LOEP, the dermal absorption can be referred as ≤ 1 %, without having a major impact on the risk assessment.

3. Residues

Storage Stability (B.7.0) B.7.14 in carbosulfan DAR				
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 / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
3(1)	Vol.3, B.7.14, Storage stability of residue samples (p87)	FR: It is written that 3-keto-carbofuran was shown to be stable for 11 months in sugar beet tops instead of 26 months as for other compounds, however average percent of recovered 3-keto-carbofuran is only at 47% after a storage period of 11 months, which is not between 70 and 110%. Its stability is not essential as this metabolite is not included in the residue definition.	**RMS 07.2009:** RMS notes the remark.	See open point in 3(6) 3-keto-carbofuran is toxicologically relevant. If storage stability of 3-keto-carbofuran in residue trial samples is not supported by valid data, the respective residue data could not be used to assess potential consumer exposure to 3-keto-carbofuran, if necessary.

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 / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
3(2)	Vol.3, B.7.1 Plant metabolism -general	EFSA: It is noted that previous comments and decisions with regard to metabolism studies other than sugar beet (1st peer review 2005/2006) still apply. The EFSA comments on the resubmission will focus only on the notified use, i.e. sugar beet with soil application.	**RMS 07.2009:** RMS notes the remark.	Addressed The resubmission review will focus only on the notified use, i.e. sugar beet with soil application. In terms of other uses, previous comments and decisions (EPCO 34) may still apply.

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 / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
3(3)	Vol. B.7.3.1 Residue definition plant	EFSA: Though there might be limitations in the submitted soil applied metabolism studies, it is agreed that, given the similarity of the notified use compared to the assessed uses for benfuracarb (soil treated brassica vegetable) and carbofuran (soil treated sugar beet) the same residue definition with regard to the carbosulfan metabolite carbofuran should apply (carbofuran/3-OH- carbofuran and their conjugates).	**RMS 07.2009:** The reported carbosulfan metabolism studies on sugar beet (Robinson R.A., 1982) and rice (Capps T.M., 1980) were common to the additional reports of Carbosulfan and Carbofuran. Metabolism studies on oranges, corn, soybean plants and alfalfa were also reported in the DAR of Carbosulfan. All these studies demonstrated a similar degradation pathway of Carbosulfan supporting the same residue definition as proposed for Carbofuran dossier (see PRAPeR Expert Meeting 70).	Addressed The resubmission review will focus only on the notified use, i.e. sugar beet with soil application. In terms of other uses, previous comments and decisions (EPCO 34) may still apply.
3(4)	Vol. B.7.3.2 Residue definition animal products	EFSA: Given the data gaps identified in the meeting PRAPeR 70 with regard to conjugated residues in animal products, is there any more information to address the issue to be retrieved from the available animal studies with carbosulfan?	**NOT**: The analytical method used includes an acid hydrolysis step, which releases the conjugated 3-OH-carbofuran. Therefore, the animal feeding study has determined both free and conjugated residue. Besides, the feeding studies and the metabolism studies demonstrate that the residue in animal tissues is expected to be very low (≤ 0.00043 mg/kg) when the animals are feeded with treated commodity. **RMS 07.2009:** The following data gaps were identified at PRAPeR 70: a) the expression of the animal dietary intake on a "DM basis" or "as received". In the Carbosulfan dossier, it seems that the dietary	Open point RMS to check the raw data in the goat metabolism study in terms of the respective ratio between free and conjugated Carbofuran and 3-OH-carbofuran Data gap: The available method of analysis for monitoring to determine the residues of 3-OH-carbofuran and its conjugates in animal matrices includes a hydrolysis step. The efficiency of this step to release the 3-OH-carbofuran conjugates should be addressed.

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 / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			intake is expressed as received both for the poultry and ruminant metabolism studies. b) the respective ratio between free and conjugated Carbofuran and 3-OH-carbofuran should be provided in the animal matrices. In the addendum-July 2009 to the additional report, the carbosulfan poultry metabolism study (Markle J.C.; 1982) was reported. Acid hydrolysis was performed on the post extraction solids and on the polar aqueous fractions of thigh muscle and liver for additional release of conjugated metabolites (Table B.7.2.1.2' in the addendum). In this table only a ratio between the polar and non polar fractions could be established since carbofuran and 3-OH-carbofuran were not detected in the non polar phase. RMS still has to check the raw data in the goat metabolism study (Curry S.J.; 1996). c) the available method of analysis for monitoring to determine the residues of 3-OH-carbofuran and its conjugates includes a hydrolysis step. The efficiency of this step to release the 3-OH-carbofuran conjugates should be addressed. It has to be highlighted that considering the calculated dietary burden (point B.7.8) for poultry and ruminants, no residue is expected in the animal matrices.	
3(5)	Vol. B.7.3. Residue definition –tox relevance	EFSA: Nitrosamine structures may be generated from dibutylamine (DBA), one	**NOT**: In our dossier, we presented cases demonstrating that: • dibutylamine is a molecule occurring	Open point: Experts to discuss whether it would be necessary to consider the following issue

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 / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
	of metabolites in plants and livestock	of the major metabolites of carbosulfan. In a previous meeting EPCO 34, it was agreed, that DBA should also be considered as a candidate component for both plant and animal residue definition for risk assessment purposes. There should be some more elaboration on the potential of the generation of nitrosamines from DBA.	naturally; • dibutylamine will not lead to N-nitrosodibutylamine formation in the soil condition characteristic for growing sugar beet; Beside, the metabolism data shows that no dibutylamine is translocated to the root of sugar beet 60 days after treatment. Therefore, no residue of dibutylamine (nor any subsequent metabolite) would be found in sugar beet root. With regard to dibutylmamine residue in food of animal origin, the calculation based on the animal, feeding studies and the animal dietary burden show that only a very modest dibutylamine residue, far below the LOQ, would be expected in food of animal origin. Since dibutylamine is naturally occurring, is a mammalian metabolite of carbosulfan, is not toxic, and does not quantitavely lead to a significant residue, there is no reason to include dibutylamine in the carbosulfan residue definition neither for risk assessment nor for monitoring. **RMS 07.2009:** RMS agrees with the notifier's comments. Moreover, in EPCO 34, a data requirement concerning the potential genotoxicity of Dibutylamine (DBA) was proposed by the EPCO Meeting on toxicology (EPCO 33). Therefore, the DBA metabolite was considered as a candidate	for the consumer risk assessment of carbosulfan: DBA is certainly less toxic than carbosulfan itself, but it may be a precursor of NDBA in acidic conditions and/or at higher temperature, conditions as present under crop processing. See also comment in 3(14)

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 / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			component for both plant and animal residue definition. An Ames test was provided which showed negative results demonstrating that DBA was devoid of genotoxicological potential in bacterial cells. It was also demonstrated that the level of Dibutylnitrosamine (DBNA) was below 1 ppm in the commercial 5-batch, contrarily to what was previously submitted. For the consumers, no major risk of Dibutylnitrosamine intake is expected from food ingestion. From the metabolism study in sugar beet (Robinson R.A., 1982), where the metabolic profile of the ^{14}C-Dibutylamine moiety was investigated (worst-case foliar application 1 kg a.s./ha, greenhouse conditions), it appeared that no relevant residue level (0.014 mg/kg) was observed in the 30 -day sugar beet root sample. After soil incorporation at similar dose (1.1 kg a.s./ha), the total radioactive residues at harvest (130 days) accounted for 0.02 ppm in both sugar beet leaves and roots, indicating a very low potential exposure of the consumers to DBA residues when consuming sugar beet roots (mainly sugar after crystallization process). Drinking water is not expected to contain Dibutylnitrosamine after Carbosulfan application by soil incorporation since Dibutylamine has no leaching potential into the groundwater. RMS considers that no risk is expected for the	

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 / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			consumers to both DBA and DBNA when carbosulfan is applied to the soil.	
3(6)	Vol. B.7.3. Residue definition –tox relevance of metabolites in plants and livestock	EFSA: It is mentioned that 3-keto-carbofuran is less toxic than carbofuran. This statement is contradictory to previous decisions of the toxicology meeting were it was agreed that, in analogy to 3-OH carbofuran, the reference values of carbofuran should apply for 3-keto-carbofuran. Clarification on this issue is needed.	**RMS 07.2009:** RMS disagrees. At the PRAPeR Expert meeting 69 on Toxicology-Carbofuran, the metabolite 3-keto-carbofuran was not discussed at all. RMS asks EFSA to clarify the source of its comment.	Open point: For a toxicologically relevant compound consumer exposure (amounts occurring) should be considered to conclude whether it is relevant for consumer risk assessment. The issue to be discussed by experts. It was agreed in the first peer review on carbofuran that all metabolites with carbamate moiety (including the 3-keto) are toxicologically relevant. The 3-keto-carbofuran is classified with T, R25. Tox data for the metabolite are very limited, however it is very likely that the reference values of carbofuran will cover the toxicity of the metabolite. See also comment in 3(1)

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 / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
3(7)	Vol. 3, B.7.3, Definition of the residue (p34)	FR: residue definition has to be consistent with the residue definition of carbofuran and benfuracarb, in the framework of the dossier of these a.i.	**RMS 07.2009:** RMS agrees.	Addressed In the framework of the peer review of the notified uses for the carbamates (soil applied root and brassica crops) the same residue definition should apply.
3(8)	Vol. 3, B.7.3.1, Definition of the residue in plant products (p34 and 97)	FR : proposed metabolism pathway for plants does not correspond exactly to explanations in B.7.3.1. "3-OH-carbofuran was reduced into 3-keto-carbofuran and further hydrolysed into carbofuran-3-OH-7-phenol;" Metabolism pathway shows that it is in carbofuran-3-keto-7-phenol instead of carbofuran-3-OH-7-phenol.	**NOT**: 3-OH-carbofuran can be directly hydrolysed to carbofuran-3-OH-7-phenol which is then oxydized to carbofuran-3-keto-7-phenol. Or 3-OH-carbofuran can be oxidized to 3-keto-carbofuran, which is then hydrolysed to carbofuran-3-keto-7-phenol. **RMS 07.2009:** RMS agrees.	Addressed If appropriate any clarification/ amendments may be done in a revised assessment 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 / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
3(9)	Vol. 3, B.7.3.1, Definition of the residue in plant products (p35)	FR: The efficiency of the analytical method to release all the carbofuran and 3OH-carbofuran conjugates has to be demonstrated as these compounds are included in the residue definition of plants and animals for enforcement purposes	**NOT**: Every analytical method used for residue determination includes an acid hydrolysis extraction in order to release the 3-OH-carbofuran bound residue. Efficiency of this extraction procedure is demonstrated by the crop metabolism studies, where the acid hydrolysis extraction was used successfully to characterize the nature of the conjugated residues. Therefore, the residue trials demonstrate that no residue above 0.005 mg/kg (LOQ of the method), nor conjugated residue, are formed in sugarbeet root after treatment of 750 g carbosulfan/ha. **RMS 07.2009:** In line with the conclusions of PRAPeR 70, the efficiency of the hydrolysis step to release all the conjugates of Carbofuran and 3-OH-carbofuran must be demonstrated.	Data gap The efficiency of the hydrolysis step in the analytical method (plant matrices-supervised residue trials and monitoring) to release all the conjugates of carbofuran and 3-OH-carbofuran must be demonstrated See also comment 3(10)

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 / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
3(10)	Vol. 3, B.7.6 Supervised residue trials- Analytical methods	EFSA: Was the hydrolysis step used in the methods in residue trials with carbosulfan validated to quantitatively release / determine conjugates?	**NOT**: It is actually impossible to obtain sufficient recoveries of 3-OH-carbofuran without the hydrolysis step because this metabolite forms quickly conjugates. The validation data presented shows that the method achieves acceptable extraction of 3-OH-carbofuran thanks to the hydrolysis step. The metabolism data demonstrates also the efficiency of the hydrolysis step to release conjugated residue. **RMS 07.2009:** The analytical methods BATTELLE N°A-17-05-13 (M. Enriquez, 2006) and N°17-03-25 (N. Ginzburg, 2003) were used for the determination of the residues of Carbosulfan, Carbofuran and 3-OH-carbofuran in the residue trials on sugar beet. Both the 2 methods include a hydrolysis step. These are reported in the Carbosulfan additional report (revised April 2009-Chapter B.5.2.1) and in the Addendum-July 2009.	See data gap in comment 3(9)
3(11)	Vol. 3, B.7.6.1 Supervised residue trials-Sugar beet	EFSA: Three results found in sugar beet residue trials were deleted as outliers, of them two in the same set of data . If at all, only one figure being significantly different from the rest of the data set may possibly be considered an outlier, but stepwise elimination of more than one result is not intended by this 'rule'. As	**NOT**: these results were observed in a very old report (1980); not carried out under GLP, at a time the analytical method on carbamates was not as performent as the newly validated HPLC-MS-MS method. It should be noted that residue was observed in some control samples within that old report, which demonstrate the ineficiency of the method to prevent false positive. On the other hand, the DAR presents 5 new residue trials that	Open point RMS to check analytical reports of the field trials 'Trial F006 7903/2' and 'Trial F006 7907' (carbosulfan in roots) for validity / acceptability. See also comment in 3(13)

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 / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
		agreed in previous EPCO and PRAPeR meetings, values should not be deleted if no obvious error has occurred in the trial because these results may be true values. If a trial is found not valid (as apparently the trial that comes to the result of 0.112 mg/kg in roots), the result should not be called an outlier. Any such explanation on the results from the other trials (0.248 and 0.063 mg/kg) is missing.	confirm the residue in root was below 0.005 mg/kg for each analyte of the residue definition. The results of 0.112 mg/kg relate to the finding of 0.062 mg/kg 3-OH-carbofuran (+ 0.05 mg/kg LOQ of carbofuran) and is discussed in the DAR. The results of 0.248 and 0.063 mg/kg relate to the carbosulfan analyte only. Such findings are very unlikely when considering the short half life of carbosulfan in soil. Beside, one would expect to find carbofuran and 3-OH-carbofuran residue aside carbosulfan residue, which is not the case in these samples. Again, the new residue trails at lower LOQ do not confirm such finding. **RMS 07.2009:** -The residue value **0.112** mg/kg (Trial F001 7903/2) representing the sum of carbofuran and 3-OH-carbofuran in the root is not acceptable since the field trial (1980) showed positive results of 3-OH-carbofuran in the control samples and no validation data of the analytical method was reported. The value of 0.112 mg/kg relates to the finding of 0.062 mg/kg for 3-OH-carbofuran and <0.05 mg/kg for Carbofuran in the root. -RMS has still to check in detail the analytical reports of the field trials corresponding to the residue values of **0.248** mg/kg (Trial F006 7903/2) and **0.063** mg/kg (Trial F006 7907) for Carbosulfan in the roots. However, RMS has to point out that a complete	

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 / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			residue database reported in the additional report, April 2009 and covering both Northern and Southern Europe showed a no residue situation both in sugar beet roots and leaves for Carbosulfan, Carbofuran and 3-OH-Carbofuran. RMS also agrees with the notifier's comments.	
3(12)	Vol. 3, B.7.6.2 to Vol. 3, B.7.6.4 -Supervised residue trials- Maize, cotton, citrus	EFSA: These data were not reviewed by EFSA as they are not relevant to the notified use in sugar beet. Previous comments and decisions with regard to these trials (EPCO 34) still apply.	**RMS 07.2009:** RMS notes the remark.	Addressed Data on Maize, cotton, citrus are not reviewed, as they are not relevant to the use in sugar beet notified for the resubmission procedure. Previous comments and decisions (EPCO 34) may still apply.
3(13)	Vol. 3, B.7.6.1., Residues resulting from supervised trials – sugar beet (p43)	FR: There is an explanation about the residue value 0.112 mg/kg which is considered as an outlier but not concerning 0.248 and 0.063mg/kg, which are also considered as outliers according to the DIXON Q-Test. Justification for these 2 outliers should be provided.	**NOT**: See 3(11) **RMS 07.2009:** See point 3(11).	See open point in comment 3(11)

Processing (B.7.7)				
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 / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
3(14)	Vol. 3, B.7.7.1 Nature of residue and Vol. 3, B.7.7.2 Level of residue	EFSA: The relevance of the studies to reflect conditions of sugar beet processing is questionably, considering the tests were carried out at room temperature. The conclusions of PRAPeR 70 may apply with regard to the fate of the carbofuran part of the molecule, however the potential to generate degradation / conversion products of DBA that could be of concern (nitrosamine structure), is not considered as addressed by the available data.	**NOT**: The metabolism study on sugar beet show that no residue of DBA can be expected at maturity in sugar beet roots from the carbosulfan use. Besides, the environmental fate section shows that DBA has a very short half life in soil. We also refer to the RMS general conclusion on DBA under B6.8.1.2.2 in the DAR. **RMS 07.2009:** No risk is expected for the consumers to both DBA and DBNA when carbosulfan is applied to the soil (see point 3(5)).	See open point in 3(5)

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 / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
3(15)	Vol.3, B.7.9 Rotational crops	EFSA: The position paper summarised here does not address a situation of short plant back intervals. Moreover does the new confined study indicate significant residues could be expected. This is in line	**NOT:** If a consumer risk assessment for succeeding crops should be considered, we then propose to consider that 10% of the TRR in succeeding crop expressed carbofuran + 3-OH-carbofuran (both free and conjugated). This would still be an extreme worst case assumption (1)	Data gap: Data to address residues in rotational crops, in particular further metabolite identification in the edible parts of the rotational crops is 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 / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
		with the conclusion by PRAPeR TC05 and PRAPeR 70 regarding carbofuran residues in rotated crops . It is again noted that in the light of the toxicological properties and low reference values for the carbofuran and 3-OH metabolite the trigger of 0.01 mg/kg is not applicable, as a consumer risk may be identified with even lower residue levels. Further data is expected.	since all metabolism data show that less than 10% of the TRR in consumable parts – at harvest – accounts for carbofuran and + 3-OH-carbofuran (both free and conjugated); and (2) since it does not takes into account the degradation of carbofuran to phenolic metabolites happening in the soil in the time interval between 2 crops. This is confirmed by a rotational crop study presented in the addendum of carbosurna DAR, where it is said that the ‚carbamates (carbofuran, 3-OH-carbofuran and 3-keto-carbofuran) constituted a small portion of the total radioactivity residues (<10% of the TRR in any crop sown at 4 and 12 months). Eventually, the residue in a rotated crop cannot be higher than the residue in the crop of the same group that was exposed to regular treatment. **RMS 07.2009:** At the PRAPeR 69 (e-fate), it was concluded that more than 10% of the carbamate residue were present in the soil after 100 days considering total Carbofuran, 3-OH-carbofuran and 3-keto-carbofuran. With regard to the confined rotational crops (Rosenwald J., 2008), RMS agrees that the trigger value of 0.01 mg/kg is not applicable in the case of such low toxicological reference values and that further metabolite identification in the edible parts of the rotational crops must be investigated.	Open point: Experts may consider whether the approach as suggested by the applicant is justified to consider 10% TRR in rotational crops in the consumer risk assessment See also comment in 3(16) and 3(20)

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 / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
3(16)	Vol. 3, B.7.9, Residues in succeeding or rotational crops	FR: In the framework of the carbofuran dossier, a new rotational crop study for this substance is still on going. Therefore rotational crops that can be planted after beetroots have, for the time being, to be limited to cereals.	**NOT**: see 3(15) **RMS 07.2009:** Considering the dietary intake risk assessment performed using the TRR values reported for the edible parts of the rotational crops as inputs in the EFSA PRIMo Model and the toxicological reference values of Carbofuran and 3-OH-carbofuran, an acute intake concern was detected for the leafy and root crops (point B.7.11 of the additional report, April 2009). PRAPeR 70 agreed to restrict the crop rotation to cereals since no further refinement of the dietary intake calculation is possible based on the available data.	See data gap in comment 3(15)

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 / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
3(17)	Vol. 3, B.7.11 Consumer Risk Assessment	EFSA: EFSA: Consumer safety: EFSA does not agree with the RMS conclusion that there are no chronic and acute exposure concerns since current assessment indicates an acute risk for consumers related to the notified use. Available data	**NOT**: The risk assessment presented by RMS shows a safe use for sugar beet rotated with cereals. Furthermore, root vegetable could be rotated too if considering that only 10% (maximum) of the TRR in rotated crops represents carbamate residue (see also 3(15)).	Addressed PRAPeR 70 conclusion on carbofuran will apply. A safe use would only be possible if risk mitigation measures (limiting crop rotation) are applied. Unmitigated the notified use cannot be considered safe.

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 / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
		do not allow for further refinement. Further data are required, but for the time being the identified risk could only be mitigated by imposing restrictions to the notified use.	**RMS 07.2009:** RMS agrees with the recommended restrictions for the rotational crops limited to cereals. The dietary intake risk assessment performed in the additional report, revised in April 2009 (see point B.7.11 – B)) is rather conservative considering the following points: -*Sugar beet root*: The maximum food intake reported at the 97.5th percentile for the UK 4-6 year old child (20.5 kg bw) and for the UK adult (76 kg bw) accounted for 1309 g/day and 1971 g/day of sugar beet root, respectively. If we assume that the sugar beet root contains approximately 16 % of sugar, the actual sugar consumption can be estimated to raise 209 g/day for the UK 4-6 year old child and 315 g/day for the UK adult. The recommended maximum sugar intake for an adult and a 4-6 year old child are 50 g/day and 40 g/day of sugar, respectively. In addition, when taking into account the no-residue situation in sugar beet root characterized by an extremely low Limit of Quantification (0.005 mg/kg for each analyte), the soil DT_{90} values of Carbofuran and 3-OH-carbofuran and assuming that any residue that may be left in the roots is substantially reduced during production of sugar by crystallization, the outcome of the model can be considered as clearly conservative.	Acceptability of proposed mitigation measure to **be decided by risk managers.**

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 / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			-*Rotational crops*: The input values in the EFSA PRIMo corresponded to the amount of TRR found in the succeeding crops after 30 days (simulating a crop failure). This approach is rather conservative since the residue levels of Carbofuran and 3-OH-carbofuran are lower than the TRR values (see available plant metabolism studies performed with Carbosulfan and Carbofuran) considering the DT50/90 values of Carbofuran and 3-OH-carbofuran and also the metabolisation of Carbofuran into its other carbamate and phenolic metabolites that occurs in soil before planting the succeeding crops. Considering the crystallization process of the sugar beet roots, no residues are expected in sugar and the value "0" should be used as input for the risk assessment calculation.	
3(18)	Vol. 3, B.7.11 Consumer Risk Assessment	EFSA: New residue trial data clearly indicate the presence of carbosulfan, carbofuran and 3-OH carbofuran residues in sugar beet though at levels below the lowest validated level of quantification (see Table B.7.6.1-1) Given all 3 compounds have the same mode of action (cholinesterase inhibition) a combined exposure / risk assessment, should be conducted considering the different tox potency of carbofuran (plus 3-OH carbofuran) and carbosulfan.	**NOT**: The risk assessment presented by the RMS considers the LOQ, which are higher than the numbers presented in table 7.6.1-1. These results could offer some refinement to the for the RA if necessary. **RMS 07.2009:** RMS agrees but the methodology on how to perform a combined dietary intake risk assessment should be clearly set.	Open point Combined risk assessment, should be conducted considering the same mode of action (cholinesterase inhibition) but the different tox potency of carbofuran (plus 3-OH carbofuran) and carbosulfan

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 / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
3(19)	Vol. 3, B.7.12 MRLs	EFSA: It is noted that the proposed MRL for sugar beet will exceed the tox reference values in a consumer risk assessment (considering residue level equal to the MRL). Should the setting of MRLs for food of animal origin be considered (reference is made to PRAPeR 70 decision)?	**RMS 07.2009:** According to the current guidance document 7031/VI/95 rev.4, no livestock feeding study for ruminant and poultry were required and therefore no MRL should be set for the animal matrices. The available ruminants' feeding study (Chen A.W., 1995) reported in the Carbosulfan DAR (point B.7.8.1) was not suitable to perform a realistic dietary intake risk assessment with Limits of Quantification of 0.025 mg/kg and 0.05 mg/kg in whole milk and tissues, respectively provided the very low toxicological values of Carbofuran and 3-OH-carbofuran. From the rat metabolism data there are some indications that no accumulation of Carbofuran and 3-OH-carbofuran occurred (Table B.6.1-6 in the DAR). Therefore, the linearity dose-response can be assumed and the residue levels in the Carbosulfan metabolism studies were considered according to the calculated dietary burden and in compliance with the agreed residue definition in animal matrices (these levels should be reconsidered in the light of the conjugates – see point 3(4)). These values as inputs in the EFSA PRIMo model were reported in the Carbosulfan additional report, April 2009 under point B.7.11-B)). RMS is of the opinion that MRLs for food of animal origin cannot be set since the recovered residue levels in the metabolism studies are so low	Addressed PRAPeR 70 decision will apply. However, RMS is of the opinion that MRLs for food of animal origin cannot be set since the recovered residue levels in the metabolism studies are so low that no monitoring is possible with the available methods. This issue has **to be considered by risk managers.**

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 / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			that no monitoring is possible.	
3(20)	Vol. 3, B.7.11, Consumer Risk Assessment	**Notifier:** FMC agrees with the Risk assessment conducted by RMS and with its conclusion. Regarding the RA for the rotational crop, it should be added that further refinement is possible if considering that only a portion of the TRR is identified as carbofuran and 3-OH-carbofuran in the harvest samples from the metabolism studies.	**RMS 07.2009:** RMS agrees.	See open point in comment 3(15)

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 / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(1)	Vol. 3, B.8.1.2. Rate of degradation, Table B.8.1.2.1-5 and B.8.1.1.1 Aerobic degradation in soil, Study by Baumann J., 2002	EFSA: The soil classification of the soil called St. Amand is different in the different chapters of the additional report (wrong in the study description). It is a silt loam soil under the USDA classification scheme (if data in the Table B.8.1.1.1-1 are correct). No clay-silt soil considered under FOCUS guidelines. Please check this and check the normalization of the DT50 value derived from this soil.	**NOT**: The soil characteristics of St. Amand (sand, silt, clay percentages, and OM content) would suggest that the soil would be considered a silt loam under OECD soil classification. **RMS 07.2009**: The updated additional report has been amended appropriately. It is well a silt loam under USDA classification. DT50 are normalized according to this USDA classification.	Addressed
4(2)	Vol. 3, B.8.1.2. Rate of degradation, B.8.1.1.1 Aerobic degradation in soil, Study by Baumann J and Ferreira J., 2001	EFSA: The soil is called as St. Amand however it seems that under B.8.1.2 it has another name which appears not clarified in the study description. Please clarify this. The soil is classified under the German textural class as silt loam soil; however for the procedure of the DT50 normalization, the standard soil moisture value at pF2 for silt loam soil classified under the USDA classification scheme was used. Please clarify this, check the soil classification and check the normalization of the DT50 value derived from this soil.	**RMS 07.2009**: Under B.8.1.2, St. Amand has another name (VS 236). RMS confirms that it is the same soil (a silt loam under USDA classification). As discussed in Comment 4(8), the DT50 value for carbosulfan is no more taken into account in the geomean value.	Addressed

Rapporteur:

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 / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(3)	Vol. 3, B.8.1.1.1 Aerobic degradation in soil, Study by Baumann J and Ferreira J., 2001	EFSA: Either the DT50 or the DT90 value or the used kinetic reported in the conclusions is wrong (or all of them). Please clarify. Moreover the new sentence in the conclusions is not clear.	**RMS 07.2009**: DT50 and DT90 were not calculated according to the FOCUS kinetics guideline. The notifier has submitted a more recent kinetic analysis according to the FOCUS kinetics guideline with the study by Price O. (2007), but the results of this analysis is no more taken into account for the geomean calculation (see Comment 4(8)).	Addressed
4(4)	Vol. 3, B.8.1.1.1 Aerobic degradation in soil Studies of: Willems, H., 2005a, Willems, H., 2005b, Willems, H., 2005c	EFSA: Summaries of these studies were included in the additional report of benfuracarb (2008) and additional report of carbofuran (2008). Comments from several MSs and EFSA on these studies had already been evaluated by the RMS; the critical issues regarding these studies and the endpoints to be used had been discussed and agreed in the meetings of experts (see Report of PRAPeR expert meeting 62 and 67, 2009). Therefore further clarification is probably not necessary.	**RMS 07.2009**: No comment.	Addressed
4(5)	Vol. 3, B.8.1.1.1 Aerobic degradation in soil, Study by Völkel, 2007, Table B.8.1.1.1-29	EFSA: The same value is reported for OC% and OM% content for the sand soil. Please clarify this. Check and confirm (or clarify) moreover please the CaCO3 content of the silt loam soil.	**RMS 07.2009**: The organic matter has been checked and amended in the updated additional report. The CaCO3 content of the silt loam soil has been checked, and is the same in the study.	Addressed

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 / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(6)	Vol. 3, B.8.1.1.1 Aerobic degradation in soil, Study by Völkel, 2007	EFSA: It is stated in the 'Findings' that the low recoveries (reported values were normalized to time 0) of the experiments are due to the rapid and strong binding to soil, however from the study description of the adsorption/desorption study of dibutylamine the rapid and strong binding is not that evident. After clarification of that what is the proper vapour pressure and water solubility of this metabolite (see relevant EFSA comment on PECsw and PECsed) RMS please consider whether the results of this study can be regarded as DegT50s or DisT50 values.	**NOT**: The water solubility of DBA is indeed important (4.4 g/L), but the DT50 value provided in the DAR comes from laboratory studies where volatility and degradation are the 2 only possible route for the substance to disappear. The likelihood of DBA being removed by volatility is low due to its high water solubility. **RMS 07.2009**: RMS is of the opinion that this metabolite is not persistent.	Open point RMS to clarify whether significant volatility could happen in this study and whether the results of this study can be regarded as DegT50s or DisT50 values. Note: see moreover the notes in comment 4(7) below
4(7)	Vol. 3, B.8.1.1.1 Aerobic degradation in soil, Study by Völkel, 2007	EFSA: It seems that the determination of the degradation rate parameters of dibutylamin did not follow the recommendations of the FOCUS kinetic guidance. Based on FOCUS kinetics the degradation/dissipation of dibutylamin (DT50 / DT90) might be longer than indicated in the Table B.8.1.1.1-31 and kinetics might not be SFO. Please check this and calculate the DT50 values based on the recommendations of the FOCUS kinetic guidance and report the LOQ and LOD values of this study. The geomean of	**NOT**: We agree that the persistence of DBA is very short and even using the longest value of the three listed would no significantly impact risk conclusions for DBA. **RMS 07.2009**: RMS is of the opinion that this metabolite is not persistent.	Data gap for derivation of the DT50 values of dibutylamine (study by Völkel, 2007) based on the recommendations of FOCUS kinetic guidance and calculate the geomean of the new values. Notes: EFSA notes that due to the non-persistence of this metabolite in soil, even if the new geomean (expected to be longer than the existing one) was used, no significant increase would be expected in the PEC values (PECgw, PECsw, PECsed). With the available calculations, which used a wrongly calculated geomean

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 / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
		0.06, 0.58 and 2.13 is not 0.46 as indicated. However it seems that dibutylamin is not persistent in aerobic soil. The LoEP might need to be corrected accordingly.		value of the set of uncertain DT_{50} (might be $DisT_{50}$, see comment in 4(6) above), the risk to groundwater or water living organisms is low.
4(8)	Vol. 3, B.8.1.2 Rate of degradation, B.8.1.2.1 Aerobic degradation Table B.8.1.2.1-8, (determination of degradation endpoint for carbosulfan and formation fraction for carbofuran)	EFSA: The derivation of the values marked with two stars (**) is not clear like the 4th column (Average DT50) of the table. Please clearly clarify how these values were derived. If these values were the combination of two values from two studies why the formation fractions were not combined as well (St. Amand soil)? EFSA is of the opinion that the value from the study by Baumann J and Ferreira J., 2001 (10°C study) should not be used. RMS please provide the visual assessments of the fits from the Barney soils and reconsider the combination of the two values if necessary or use only the SFO DT50 from this data set (7.87 d). Please check whether the star (*) for the 7.87 d is correct. Please clarify moreover that fit from which study is acceptable for the Nebraska soil	**NOT**: We agree that the lower temperature study should not be used to derive a DT50 value. **RMS 07.2009**: Excluding the results from the study by Baumann and Ferreira 2001 (10°C study), the DT50 geomean for Carbosulfan becomes 4.81 d and the arithmetic mean of the formation fraction becomes 0.68. The table is adapted in the updated additional report and the general conclusions of the RMS at page 8-28 are amended appropriately. Barney soils: The visual assessments of the fits from the Barney soils are provided in the updated additional report. The FOMC model gives a much better fit to the 1981a data (chi square error = 1.71%), while there is little difference between SFO and FOMC for the 1981b data. This is also evident from the visual fits. The SFO DT50 for 1981a is 2.55 days so the DT50 back calculated from the FOMC DT90 provides a conservative value	Addressed Note: it is noted that RMS supports the use of the formation fraction derived from the Nebraska soil (Markle 1981a) based on the visual fit which was not included in any of the versions of the additional report. It seems that this formation fraction is derived from a fit where the fit for the parent was not accepted. However, the formation fraction derived from this experiment is in line with the other available data, it is higher than the average of the remaining data set (realistic worst case). Moreover, ff of 1 was used in the FOCUS PEC calculations.

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 / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
		and the reason of the refuse of the fit for carbosulfan from the other study (data sets are similar, acceptable X2 values are reported in table B.8.1.2.1-4). Clarify moreover that which fit was used for the derivation of the formation fraction for carbofuran from the Nebraska soil. From the Table B.8.1.2.1-8 it seems that for this fit, the measured degradation for carbosulfan from the study by Markle 1981b was combined with the degradation of carbofuran observed in the study by Markle 1981a. Is it correct?	also. It is valid to average (geometric mean) the DT50 values for the Barney soil as 90% was degraded in the experimental period for the FOMC fit. The star (*) for the 7.87 d is indeed not correct. The table is corrected in the updated additional report. Nebraska soils – fit acceptability: The fit for Markle (1981b) is acceptable. Although the chi-square error for 1981a was good, the kP parameter was unreliable (P=0.455), so the fit for 1981a was not acceptable. Further clarification about the fit used for the derivation of the formation fraction for carbofuran from the Nebraska soil: Incorrect. The formation fraction for carbofuran was calculated using carbosulfan and carbofuran data from the 1981a study. The visual fit in CEA.244 shows the same carbosulfan degradation as the parent only fit for the same study. 1981b did not have carbofuran.	

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 / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(9)	Vol. 3, B.8.1.2 Rate of degradation, B.8.1.2.1 Aerobic degradation Page 8-22 – 8-27	EFSA: The relevant pages for the DT50 derivation for carbofuran (page 8-22 – 8-27) were already discussed in the meetings of experts (PRAPeR 62 and PRAPeR 67) for the benfuracarb and carbofuran 2nd peer review in January and April 2009. The meetings agreed that all the refitted DT50 and the normalisation procedure for carbofuran indicated on these pages are acceptable and should be used further in the exposure assessment. It was also agreed that 3 other DT50 values from the studies by Saxena and Schocken should be added to the data set and that for Bretagne soil (study by Völkl) only the value from the experiment conducted at 20°C should be used. The resulting data set to be used is: 17.87, 14.01, 7.71, 13.56, 17.25, 6.92, 9.39, 11.46, 22.54, 22.19, 5.7, 20.39, 10.39, 11.69, 151, 54.6, 387 days. The median of these normalized SFO DT50 values is 14 days. The LoEP needs to be corrected accordingly.	**RMS 07.2009**: RMS agrees with the EFSA comment. The LoEP is amended appropriately. The general conclusions on the derivation of an overall DT50 carbofuran at page 8-28 are also adapted appropriately in the updated additional report.	Addressed

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 / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(10)	Vol. 3, B.8.1.2 Rate of degradation, B.8.1.2.1 Aerobic degradation Page 8-28	EFSA: from the data set sorted in the General conclusions of the RMS on the derivation of an overall DT50 carbofuran it is not clear where the 6.1 days came from as in the individual reports there is no DT50 of 6.1 days. This should not be used as well as 22.7 days should not be used as this is the geomean of the two DT50 values determined on the same soil at different temperatures. As input for PECgw and PECsw DT50 of 14d should be used. See also EFSA comment (9).	**RMS 07.2009**: RMS agrees with the EFSA comment. This mistake is corrected in the updated additional report. (see also Comment 4(9)).	Addressed
4(11)	Vol. 3, B.8.1.2 Rate of degradation, B.8.1.2.1 Aerobic degradation Page 8-28	EFSA: The geomean of 3.81 d of 3-keto-carbofuran as reported in the General conclusions of the RMS on the derivation of DT50 for the metabolites is might be the geomean of the non-normalized values. The geomean of the normalized values is 3.01 d. The endpoints for 3-keto-carbofuran, 3-OH-carbofuran and carbofuran phenol to be used in the exposure assessment had been discussed and agreed in the meetings of experts (see Report of PRAPeR expert meeting 62 and 67, 2009). For dibutylamin see EFSA comments (5), (6) and (7). The LoEP needs to be corrected accordingly.	**RMS 07.2009**: RMS agrees with the EFSA comment. The DT50 are amended in the updated additional report and the LoEP. For dibutylamine, see Comments 4(6) and 4(7).	Addressed See moreover the data gap in comment 4(7).

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 / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(12)	Vol. 3, B.8.1.3 Field studies & B.8.3 PECsoil	EFSA: Meetings of experts (PRAPeR 62, PRAPeR 67) already agreed with the RMS that DT50 of 71.9 days for carbofuran is not relied on and for the PECsoil calculation for carbofuran, 27 days should be used (longest field dissipation data from the European sites from study by Mol, 2002). Therefore further clarification on this is probably not necessary. However the statement in the last paragraph of the point B.8.1.3, as the DT50 values which were chosen for PECsoil are considered as extreme worst case, is disagreed.	**RMS 07.2009**: The term "extreme worst case" is replaced by "worst case" in the updated additional report.	Addressed
4(13)	Vol. 3, B.8.1, Route and rate of degradation	FR: p.8-14; For the studies added in April 2009 (Willems, H., 2005a ; 2005b ; 2005c) RMS mentioned in conclusion the values to be used as inputs for further calculations. It should be clearly stated that corresponding studies are deemed acceptable.	**RMS 07.2009**: The studies are acceptable.	Addressed
4(14)	Vol. 3, B.8.1, Route and rate of degradation	FR: p.8-17; in accordance with the text, the geometric mean calculated for carbufuran-3-keto (3.81 d) might be inserted in an additional line in Table B.8.1.1.1-26 p8-18. Same remark for geometric mean of 0.3 d calculated for carbufuran-phenol in table B.8.1.1.1-28.	**RMS 07.2009**: The updated additional report is amended appropriately.	Addressed

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 / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(15)	Vol. 3, B.8.1, Route and rate of degradation	FR: p8.22. It's mentioned that data on anaerobic degradation in soil are not required based on the proposed uses. Then it's indicated "(granular application, foliar spraying)". That's the treatment timing and not the formulation which is important to expect (or not) for anaerobic conditions. By the way the formulation assessed is only Granular (foliar spraying should be taken away).	**NOT**: We agree that foliar spraying should be removed and the expected rate of degradation should preclude any issue concerning anaerobic conditions developing based upon application timing. **RMS 07.2009**: The term "foliar spraying" is removed in the updated additional report. No anaerobic conditions are expected, sugar beets seeds do not germinate at anaerobic conditions at the moment the application takes place.	Addressed
4(16)	Vol. 3, B.8.1, Route and rate of degradation	FR: p8-29. Field studies are performed with Granular and Capsule suspension formulated preparations. It is obvious that corresponding DT50 are correlated to the formulation type; DT50 of the granular form being >> DT50 from CS. Granular formulation might be seen as slow release formulation according to 95/36/CE. The worst case value for PECsoil calculations might be the geometric mean of the Granular formulation only.	**RMS 07.2009**: The max. DT50 field soil values for the PECsoil are the worst case.	Addressed

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 / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(17)	Vol. 3, B.8.1, Route and rate of degradation	FR. P.8-29. If data from Nether Poppleton are not used for risk assessment purpose then they should be taken off table 8.1.3-1.	**NOT**: We agree that trhe Nether Poppleton soil information should be removed from the table. **RMS 07.2009**: An argumentation is developed in the additional report to effectively not consider the data from this study. The LoEP is up to date.	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 / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(18)	Vol. 3, B.8.2.1.1, Table B.8.2.1.1-2	EFSA: It is noted that the 'Mean' in the last column means arithmetic mean.	**NOT**: We agree. **RMS 07.2009**: The updated additional report is amended appropriately.	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 / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(19)	Vol. 3, B.8.2.1.2	EFSA: For carbofuran adsorption/desorption, the only study considered valid by the 1st and the 2nd peer reviews of carbofuran and benfuracarb is Manouni A., 2002. A data gap was identified in this field in the carbosulfan EFSA conclusion. The other studies were not accepted. No new study or re-evaluation of the existing studies is submitted. For PECgw and PECsw calculations for carbofuran, KFoc of 22 with 1/n of 0.96 have to be used, based on the Manouni study.	**NOT**: We agree. **RMS 07.2009**: We agree. The notifier has proposed new PEC calculations taking into account the agreed KFoc and 1/n values for carbofuran. These PEC's are evaluated in the updated additional report. The LoEP is amended appropriately.	Addressed
4(20)	Vol. 3, B.8.2.1.3	EFSA: The advanced test was performed up to 48 hours, please provide argumentation what was the reason for this. This metabolite seems to be volatile (see EFSA comments (31) and (6) and this could have affected the results of the study and the Koc and 1/n derivation from the results, especially with this prolonged equilibrium time. RMS please comment this issue. Note: neither the volatility nor the water solubility is clear from the additional report.	**NOT**: The high water solubility of DBA should preclude any loss via volatility. See Comment 4(6). **RMS 07.2009**: We have considered that the adsorption reaches its plateau after 48h. Moreover, we believe that this study is sufficient to derive the Koc of this metabolite.	Addressed Note: EFSA will highlight in the EFSA conclusion that the adsorption potential of the DBA, therefore the calculated PECsw/sed and PECgw are uncertain, if no satisfying information is available on the volatility and the water solubility of this metabolite. See moreover the notes in comment 4(7).

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 / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(21)	Vol. 3, B.8.2.1.4, B.8.2.1.5, B.8.2.1.6	EFSA: Summaries of these studies were included in the additional report of benfuracarb (2008) and additional report of carbofuran (2008). Comments from several MSs and EFSA on these studies had already been evaluated by the RMS; the critical issues regarding these studies and the endpoints to be used had been discussed and agreed in the meetings of experts (see Report of PRAPeR expert meeting 62 and 67, 2009). Therefore further clarification is probably not necessary.	**NOT**: We agree. **RMS 07.2009**: We agree.	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 / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(22)	Vol. 3, B.8.2.4	EFSA: A data gap was set by the previous peer review for the determination of the levels of dibutylamine in the available lysimeter study. This data gap is still not fulfilled in the additional report. However the data gap might be regarded as obsolete as new information is available for the mobility (adsorption to soil) of this metabolite. The two lysimeter studies for carbofuran (Scholz, 1993, 1992) were already discussed at the meeting of experts from Member States for carbofuran (PRAPeR 67) and it was agreed that these studies do not provide valuable information regarding the mobility of carbofuran or its metabolites. It was agreed moreover that the relevant box of the LoEP should contain 'Non reliable information available'.	**NOT**: We agree that sufficient information is available to predict environmental concentrations for DBA without the need to consider the lysimeter studies. **RMS 07.2009**: The LoEP is updated.	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 / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(23)	Vol. 3, B.8.2, Adsorption, desorption and mobility in soil	FR: p.53, As already discussed in previous PRAPeR meeting, since K_{OC} values as been selected as worst case for 3-keto-carbofuran and 3-hydroxy-carbofuran, then 1/n value of 1 should be selected as worst case to (using K_D assumes isotherms linearity).. Rq. ; Unit from the metric system should be used (L instead of cm^3).	**NOT**: We agree. **RMS 07.2009**: As discussed in previous PRAPeR meetings (62 and 67), the agreed input parameters for carbofuran and its metabolites to be used in PECsw and PECgw are : DT50 ff Koc 1/n Carbofuran 14 1 22 0.96 3-OH CF 0.41 0.1 55 1 3-keto CF 3.01 0.1 331 1 7 phenol CF 1 0.14 1031 0.9	Addressed Notes: ff of 1 for carbofuran refers to carbofuran formed from benfuracarb. For ff of the metabolites 3-OH CF and 3-keto CF see Column 2 in 4(32).
4(24)	Vol. 3, B.8.2, Adsorption, desorption and mobility in soil	FR: p.55, 1/n values calculated for carbofuran-phenol adsorption test for 3 soils range from 0.407 to 0.751 (the third value being 0.516). We wonder why there is such difference between soils. Taking the worst case value would have been conservative,	**NOT**: The absence of a carbamate moiety on carbofuran phenol makes the issue moot as carbofuran phenol is an insignificant risk contributor to surface water and groundwater risk assessments. **RMS 07.2009**: See Comment 4(23).	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 / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(25)	Vol. 3, B.8.2, Adsorption, desorption and mobility in soil	FR: p.53 (and 66). Lysimeter leachate sampling (Sholtz, 1993 and 1992): It's mentioned that the leachate were collected every 14 days (as available). It should be empathized that this method might enhanced degradation in the leachate sample since time delay of 14 days (max. possible) might occur between leaching event and analysis.	**NOT**: The lysimeter studies should be viewed as supplemental information. **RMS 07.2009**: For lysimeters, it was concluded that non reliable information are available (see Comment 4(22).	Addressed See EFSA comment in 4(22)
4(26)	Vol. 3, B.8.2, Adsorption, desorption and mobility in soil	FR: p.54, RMS indicates that both studies (lysimeters) might be seen as additional information. It should be emphasized that extrapolation from these data might be done only with respect to the apparent dry conditions. Since these data are not useful for risk assessment because of the observed discrepancies, the acceptability of these studies is then questionable..	**NOT**: See Comment 4(25) **RMS 07.2009**: See Comment 4(25)	Addressed See EFSA comment in 4(22)

PEC in soil (B.8.3)				
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 / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(27)	Vol. 3, B.8.3, PECsoil	EFSA: The 'kinetic' PECsoil calculation for the metabolites which is performed in the additional report is a novel kind of calculation. Please provide all the relevant details regarding how these calculations were performed. EFSA notes that following the usual calculation method the max. PECsoil for the metabolites would be higher. Further PEC calculations (by the 'usual' way) therefore appear to be necessary.	**RMS 07.2009**: New PECsoil calculations are performed in the updated additional report by the 'usual' way. The LoEP is updated.	Addressed

Fate and behaviour in water and impact on water treatment procedures (B.8.4-B.8.5)				
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 / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(28)	Vol. 3, B.8.4.2, Photolysis	EFSA: It is noted that major fraction(s) of degradation products were not identified. However this is not an essential issue at EU level regarding the applied for representative use of the PPP.	**RMS 07.2009**: No Comment.	Addressed
4(29)	Vol. 3, B.8.4.4, Water/sediment study	EFSA: It is noted that a major unidentified metabolite (unknown metabolite 3) was found in the sediment phase (max 16.53%AR, 20°C). This should be	**NOT**: From the water/sediment study, it appears clearly that this metabolite forms in the few first days and degrades completely in a period of 20 – 50 days. Therefore, the carbosulfan studies on sediment dwellers	Addressed Open point EFSA to highlight in the EFSA conclusion

Fate and behaviour in water and impact on water treatment procedures (B.8.4-B.8.5)				
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 / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
		included in the residue definition for sediment. It would appear that an exposure and risk assessment for this metabolite is necessary.	organisms cover this metabolite as well. Besides, the PECsw calculation shows that there is no contamination of carbosulfan in surface water, therefore, this metabolite cannot contaminate surface water either. Eventually, this is a new question from data already evaluated during the first peer review. **RMS 07.2009**: The tentative determination of the structure of this metabolite shows that it is an intermediate between carbosulfan and carbofuran. Due to rapid degradation of carbosulfan in soil, the only compound reaching surface water is carbofuran which is further degraded in soil to 3-keto CF, 3-OH CF, 7-phenol CF and dibutylamine. It is therefore unlikely that this unknown metabolite 3 occurs in surface water. Moreover, it is assumed that the risk related to this metabolite is covered by the assessment that has been performed for the substances with the carbamate moiety.	that based on the tentative structure of the major unidentified metabolite in the W/S study (unknown metabolite 3) was regarded as an intermediate transformation product between carbosulfan and carbofuran. Due to rapid degradation of carbosulfan in soil, this compound might not reach the SW as far as the application method is soil incorporation (furrow application). Note that as a consequence, the exposure and risk assessments for this unidentified compound are deemed as not necessary at EU level.

Fate and behaviour in water and impact on water treatment procedures (B.8.4-B.8.5)				
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 / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(30)	Vol. 3, B.8.4.4 Modelling endpoints derived from the water/sediment studies Page 8-71	EFSA: It is noted that DT50 values for carbofuran and 7-phenol carbofuran are available from the benfuracarb dossier as well (see additional report for benfuracarb). However, these values were calculated from studies where 7-phenol carbofuran and carbofuran was originated from benfuracarb and the values are shorter than the value, which is chosen for PEC calculation in this additional report for carbosulfan (the use of the DT50 of 70.07 for carbofuran in the PEC calculations is agreed and regarded as worst case). For completeness please amend the LoEP with the values from the experiments dosed with benfuracarb.	**NOT**: As mentioned in 4(24), 7 phenol carbofuran estimated concentrations are not relevant to risks posed by either carbosulfan or carbofuran. We agree that benfuracarb degradation would be considered worst case regarding degradation for a PEC calculation. **RMS 07.2009**: The LoEP have been amended with the data from the Benfuracarb dossier.	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 / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(31)	Vol. 3, B.8.6.1 PEC Surface water and sediment and B.8.6.2 PEC groundwater	EFSA: Many parameters used in the Focus modelling (for both GW and SW/sed) are disagreed. Please note that most of the parameters had already been agreed (on	**RMS 07.2009**: The notifier has proposed new PEC calculations taking into account the End Points proposed in Praper meeting. These	Addressed Notes: RMS did not provide detailed information about the sources, quality and

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 / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
	Input parameters	the bases of the same data set) during the peer reviews of the resubmission of benfuracarb and cabofuran (please consider the Report of PRAPeR expert meeting 62 and 67). Please note moreover that some other parameters depend on the outcome of the comments in this table. The following parameters need to be changed (or reconsider) (proposed values in brackets; some represents 'better case', some 'worst case' comparing with the value used in the additional report): - carbosulfan • DT_{50} in water (1000 d) • DT_{50} in sediment (5.57 d) • DT_{50} in W/S (5.57 d) • soil DT_{50} (5 d), see EFSA comment (9) • temperature for the solubility (25°C) - carbofuran • soil DT_{50} (14 d) • Koc (22 mL/g) • Kom (12.76 mL/g) • Freundlich exponent (0.96) • Formation fraction in soil (0.73) - 3-keto-carbofuran • soil DT_{50} (3.01 d)	PEC's are evaluated in the updated additional report.	acceptability of the vapour pressure and water solubility data of the metabolites used in the PEC calculations. Please see EFSA note in 4(20) and EFSA comment in 4(32). Soil DT_{50} of 5 days regarding carbosulfan is in contrast with the RMS conclusion for comment 4(8), (DT_{50} of 4.8d should have been used). This difference can have effect on the results of the metabolites; however seems not to be significant. Moreover as formation fraction for the soil metabolites, the worst case value of 1 was used. For Koc of 3-OH-CF 43 ml/g was used (instead of the agreed 55 ml/g) which is a worst case value. For DT_{50} of dibultilamin 0.46 d was used (see data gap in 4(7)).

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 / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
		• Koc (331 mL/g) • Kom (192 mL/g) • Freundlich exponent (1.0) - 3-OH-carbofuran • Koc (55 mL/g) • Kom (31.9 mL/g) • Freundlich exponent (1.0) (would be appropriate if Step 3 or 4 calculated) - carbofuran phenol • PEC SW/Sed: meeting of PRAPeR 67 recommended to use the STEP 3 PEC for carbofuran as a conservative estimate for carbofuran-phenol after a potential correction for molar weight and maximum occurrence (for details see the Report of PRAPeR expert meeting 67). This might be appropriate here as well. • PEC GW: not needed (this metabolite was not in the residue definition for soil or ground water, this metabolite do not contain the carbamate moiety) - dibutylamin • soil DT_{50} (0.42 d), see EFSA comment (8) • for Koc/Kom and 1/n please see EFSA comment (17)		

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 / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
		• significantly different data were used for vapour pressure and water solubility in PEC SW/Sed and PECgw calculations. The wash-off factor depends on the water solubility. Please clearly clarify the sources of these data, the quality and acceptability of these data and indicate which should be used and why. The other parameters included in the relevant tables of the input parameters (page 8-73 – 8-76 and 8-81) are agreed, but please consider the EFSA comment No (25) below beside the other relevant comments of this table. The FOCUS calculations should be repeated based on information/comments above (and below). The LoEP needs to be updated.		
4(32)	Vol. 3, B.8.6.1 PEC Surface water and sediment and B.8.6.2 PEC groundwater	EFSA: Regarding FOCUS PEC calculations, RMS please consider and comment these: • It is noted that for carbofuran metabolites different data set for vapour pressure is available and used.	**RMS 07.2009**: The notifier has proposed new PEC calculations taking into account the End Points proposed in Praper meetings (62 and 67). These PEC's are evaluated in the updated additional report.	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 / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
		Please comment which Vp data set are more realistic. • It is not clear what is indicated for the formation fraction in sediment in the tables for input parameters (value: 0, reference: Not major metabolite in water sediment) especially in case of carbofuran and carbofuran phenol • Please check the temperature used in the calculations for the water solubility, somewhere 20°C somewhere else 25°C is indicated for the same value • It is noted that the agreed soil DT50 for 3-OH-carbofuran is 0.41 d, however 0.35 d can be accepted as well (for details see LoEP for carbofuran) • If PECgw are calculated for carbofuran phenol (not necessary) for 1/n 0.9 should be used. The agreed value for soil DT50 is 1 d, however 0.3 d can be accepted as well (for details see LoEP for carbofuran) • A formation fraction (in soil) of hydroxy-carbofuran of 0.5 (from carbofuran) was estimated during the	The new PEC calculations are performed with the lowest Vp data and the formation fractions in water/sediment system are amended.	

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 / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
		meeting of PRAPeR 67 (on carbofuran resubmission), followed by a formation fraction of 1 for 3-keto-carbofuran from hydroxyl-carbofuran. It was noted also that if a refinement were ever needed for future exposure assessments, a kinetic fit of the formation fractions would be desirable.		
4(33)	Vol. 3, B.8.6.1 PEC Surface water and sediment and B.8.6.2 PEC groundwater	EFSA: Please amend the soil incorporation depth for PECgw and PECsw to 7 cm in the LoEP.	**RMS 07.2009**: The LoEP is corrected.	Addressed.
4(34)	Vol. 3, point B.8.6.1, PECs surface water	DE: PECs in surface water/sediment were calculated for granular application and soil incorporation at -7 cm. In FOCUS PRZM the chemical application method No. 8 (CAM 8) was chosen. This virtually excludes entry from run-off and consequently all PECs for the run-off scenarios at FOCUS Step 3 are zero. However, a single run-off event can contribute significantly to the PEC_{sw}. Therefore, FOCUS Step 3 calculations should be repeated with CAM 4 or CAM 5.	**RMS 07.2009**: CAM 4 and CAM 5 do not represent the supported use of granular application in the furrow at incorporation depth of 7 cm.	Addressed Note: CAM 8 has already been used for the evaluation of related compounds (benfuracarb, carbofuran; both already peer reviewed) with similar application methods. CAM 8 indeed assumes no pesticide available for runoff (if DEPI>2cm), which is in line with the applied for representative uses for EU. Open Point EFSA to highlight in the EFSA conclusion that the PECsw/sed calculations are valid only when the granules are applied into the furrows, as indicated in the GAP table.

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 / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(35)	Vol. 3, B.8.6.1, PECsoil	FR:, p.61. Since the representative use to be assessed at EU level is a granular application in the seed furrow then PECsoil should be calculated specifically for the furrow zone to account for exposure of soil macro-organisms (especially when dealing with nematicide). As performed in previous risk assessment (i.e. cadusafos), PECsoil in the furrow zone might be easily calculated by using a "concentration factor" (area represented by the furrow compared to the whole area) to accurately assess the exposure.	**RMS 07.2009**: The PECs have been calculated according to the conventional methodology. There are no guideline to define the appropriate depth and width of the furrow. Moreover it is not clear how to calculate reasonable TER for earthworms/other soil organisms that are in the furrow or in the non treated soil between the furrows.	Addressed Note: PECs calculated according to the conventional methodology have already been used for the evaluation of related compounds (benfuracarb, carbofuran; both already peer reviewed) with similar application methods. MSs might whish to calculate PECs using a "concentration factor" for MS level evaluation.
4(36)	Vol. 3, B.8.6.1, PECgw	FR: p.83, Regarding PECgw calculations performed for the metabolites and more specifically 3-keto-carbufuran, few exceedances of the 0.1 µg/L trigger are observed when assessing the representative use. For other uses and other rates at MS level PECgw concentrations above 0.1µg/L might be observed and raise the question of the toxicological relevance of such metabolite (Sanco221/2000). More information on this specific point might be needed.	**RMS 07.2009**: Data on the relevance of the metabolites that were already available in the DAR of November 2008 are proposed in the additional report.	Addressed Note: Information regarding the toxicological relevance of the metabolites of concern are included in the Addendum to Vol. 3 B.8 (March 2009) for carbofuran.
4(37)	Vol. 3, B.8.6.1, PECgw	FR:, see previous comment on Freundlich coefficient 1/n.	**RMS 07.2009**: See Comment 4(32).	Addressed

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 / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(38)	Vol. 3, B.8.7, Fate and behaviour in the air	EFSA: The Atkinson calculation is missing from the additional report, please provide this in an addendum and include the concentration of atmospheric hydroxyl radicals used in the calculation in the LoEP.	**RMS 07.2009**: Due to the mode of application (granular incorporation), atmospheric contamination is unlikely.	Data gap for Atkinson calculation for the parent molecule. Note: regarding the applied for representative use of the PPP, the data gap might be regarded as not essential for the finalisation of the evaluation of carbosulfan at EU level.

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 / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(39)	Vol. 3, B.8.9 The definition of the residue	EFSA: It is several times indicated in this chapter that carbofuran phenol contains the carbamate moiety, please confirm that not this is the case. Considering all the information available (1st and 2nd peer-review of carbosulfan, carbofuran and benfuracarb) the proposal for the definition of residue for risk assessment is: - soil: carbosulfan, carbofuran, 3-keto-carbofuran, 3-OH-carbofuran, dibutylamine Notes: 3-OH-carbofuran and 3-keto-carbofuran are minor in soil studies dosed with carbosulfan and 3-OH-carbofuran might be regarded as transient in nature, but both contain the carbamate moiety; no PECsoil are available for this metabolites - GW: carbosulfan, carbofuran, 3-keto-carbofuran, 3-OH-carbofuran, dibutylamine - SW&Sed: carbosulfan, carbofuran, 3-keto-carbofuran, 3-OH-carbofuran, carbofuran phenol, dibutylamine, Unknown metabolite 3 - air: carbosulfan	**NOT**: We agree with the comments with the exception of including carbofuran phenol in the SW and sediment compartments. The metabolite can be considered detoxified after removal of the carbamate moiety. **RMS 07.2009**: RMS confirms that carbofuran phenol doesn't contain any carbamate moiety. The definition of residue is amended in the updated additional report and the LoEP. No PECsoil have been calculated for 3-keto-carbofuran, 3-OH-carbofuran and carbofuran-phenol since an argumentation is given in B.8.9 2nd paragraph for 3-keto-CF and the 2 last metabolites are considered to be transient (DT50 < 1 day).	Addressed Note: considering the assessment to the comment in 4(29) EFSA considers to leave out Unknown metabolite 3 from the residue definition for SW&Sed.

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 / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(40)	General for fate	EFSA: there are three different studies in the section of environmental fate and behaviour performed by Völkel 2007. These should have been distinguished	**RMS 07.2009**: The additional report is amended.	Addressed
4(41)	Vol. 3, B.8.1.1.1, B.8.2.1.1, B.8.2.1.3, Studies by Völkel, 2007	EFSA: The three studies by Völkel 2007 used partly the same soils. The names and a part of the soil parameters are the same, but some other parameters are different among these studies conducted by the same author in the same year. Please make sure that the reported soil parameters are correct and the Koc values were calculated using the correct OC content of the relevant soils.	**RMS 07.2009**: The additional report is amended. The Koc values were calculated using the correct OC content of the relevant soils.	Addressed
4(42)	Vol. 1, List of Endpoint	EFSA: Essential data are missing from the LoEP. Please amend the LoEP and for this please consider all the comments of the reporting table.	**RMS 07.2009**: The LoEP is amended appropriately.	Addressed
4(43)	Vol. 3, general comment, active substance	DE: Carbosulfan was rapidly degraded to carbofuran under aerobic conditions (DT_{50soil} < 1 day). Carbofuran is intended to none inclusion in Annex I (91/414/EWG) by RMS Belgium.	**RMS 07.2009**: No comment.	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 / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(1)	Vol. 3, B.9.1.3 Subchronic and reproductive effects on birds	EFSA: The long-term endpoint for the metabolite carbofuran should be amended in accordance to the outcome of the expert discussion on carbofuran (PRAPeR 68 in May 2009). (The LC10 (14d) = 0.64 was suggested to be used in the risk assessment together with an increased safety factor of 10).	**RMS (July 2009):** The DAR and the List of Endpoints have been revised.	Open point: RMS to amend in the DAR and the LoEP the long-term endpoint for the metabolite carbofuran in accordance to the outcome of the expert discussion on carbofuran (PRAPeR 68 in May 2009). (The LC10 (14d) = 0.64 was suggested to be used in the risk assessment together with an increased safety factor of 10). See also comment 5(10).
5(2)	Vol. 3, B.9.1.7 Higher tier risk assessment for birds	EFSA: The PD/PT values suggested in the refined risk assessment are based on general considerations of diet composition. This was not agreed to be used in a quantitative risk assessment for benfuracarb and carbofuran. It is proposed to indicate this in the LoEP (as was done for benfuracarb and carbofuran).	**RMS (July 2009):** The List of Endpoints has been revised. **NOT:** see 5(19).	Open point: RMS to indicate in the LoEP that the PD/PT values suggested in the refined risk assessment are based on general considerations of diet composition and that they are not appropriate to be used in a quantitative risk assessment. See also 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 / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(3)	Vol. 3, B.9.1.8 Residue levels in food items	EFSA: The residue trial with insects and earthworms was discussed in the context of the refined risk assessment for carbofuran. The measured residues potentially underestimate the real exposure under field situations. The risk assessment/evaluation of the residue trials should be updated in accordance to the outcome of the expert discussion on carbofuran.	**RMS (July 2009):** The DAR has been revised. **NOT:** see 5(18).	Open point: RMS to update the evaluation of the residue trial with insects and earthworms as discussed in the expert meeting (PRAPeR 68, May 2009) in the context of the refined risk assessment for carbofuran. See also comment 5(11)
5(4)	Vol. 3, B.9.1.8 Residue levels in food items	EFSA: The earthworms were rinsed and stored overnight before analysis. This treatment has most likely reduced the residue levels in earthworms.	**RMS (July 2009):** Noted. Please also refer to comment 5(11).	See open point in comment 5(3).
5(5)	Vol. 3, B.9.3.2 Risk assessment for mammals	EFSA: The NOAEL of 0.1 mg carbofuran/kg bw/d was agreed in the meeting on carbofuran. The risk assessment for mammals needs to be updated accordingly.	**RMS (July 2009):** The DAR and the List of Endpoints have been revised. **NOT:** The NOAEL of 0.1 mg/kg bw/d is very conservative for determining risk to wild mammals. This value was derived from mammalian toxicological studies designed to detect very low levels of cholinesterase inhibition via oral gavage introduction. The typical feeding pattern of mammals (timeframe) of consumption is very important considering that the inhibitory effects of carbofuran are rapidly reversible. These studies are available in the toxicological section of the DAR.	Open point: RMS to update in an addendum to the DAR and in the LoEP the risk assessment for mammals and carbofuran with the NOAEL of 0.1 mg carbofuran/kg bw/d. See also comment 5(7).

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 / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(6)	Vol. 3, B.9.3.2 Risk assessment for mammals	EFSA: The suggested refinement of PD for hare and shrew are uncertain since they were not derived from targeted studies in sugarbeet fields. This should also be highlighted in the LoEP.	**RMS (July 2009):** The List of Endpoints has been revised.	Open point: RM to indicate in an addendum to the DAR and in the LoEP that the suggested refinement of PD for hare and shrew are uncertain since they were not derived from targeted studies in sugarbeet fields.
5(7)	Vol. 3, B.9.3.2 Risk assessment for mammals	EFSA: If the new (agreed endpoint) long-term endpoint of 0.1 mg carbofuran/kg bw/d is used in the mammal risk assessment then the TER trigger would not be met (TER = 2, including the PD refinement). Therefore the long-term risk to herbivorous mammals would need to be addressed further. It should also be considered that shortcomings of the residue trials with sugarbeet seedlings were identified by the RMS and that there are uncertainties with regard to the suggested PD refinements.	**RMS (July 2009):** Noted. **NOT:** See comment in Section 5(5).	See open point in comment 5(5).

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 / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(8)	Vol. 3, B.9.1, Effects on birds	DE: In order to reduce the risk to birds, application in plant hole at lower dosage is proposed by the RMS to reduce the amount of active substance used per hectare. However, the notifier has not yet demonstrated the feasibility of this technique. For that reason, as well as due to the high toxicity to terrestrial vertebrates and due to insufficient data on residue levels in feed items, the refinement of the risk assessment should not be transferred to national level.	**RMS (July 2009):** Noted. Please also refer to comment 0(2). **NOT:** See comment 0(2). Carbosulfan will indeed control some pest when applied as spot application close to the seed. Applicator exist on the market that allow such granular local treatment. See for example web site http://www.sembdner.com/main.htm.	Addressed. This is a valid comment. However, only the applied for representative use is evaluated in the peer-review and will be included in the EFSA conclusion.
5(9)	Vol. 3, B.9.3, Effects on mammals	DE: In order to reduce the risk to mammals, application in plant hole at lower dosage is proposed by the RMS to reduce the amount of active substance used per hectare. However, the notifier has not yet demonstrated the feasibility of this technique. For that reason, as well as due to the high toxicity to terrestrial vertebrates and due to insufficient data on residue levels in feed items, the refinement of the risk assessment should not be transferred to national level.	**RMS (July 2009):** Noted. Please also refer to comment 0(2). **NOT:** See 5(8).	Addressed. This is a valid comment. However, only the applied for representative use is evaluated in the peer-review and will be included in the EFSA conclusion.

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 / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(10)	Vol 9, point B.9.1.3: conclusions of the RMS on the recalculation of the reproductive bird endpoints, page 9-13	FR: we agree with the reasoning about the selection of endpoints for long term effects and risk assessment.	**RMS (July 2009):** Please refer to comment 5(1).	See open point in comment 5(1).
5(11)	Vol 9, point B.9.1.8: residue in earthworms and beetles, page 9-28 and page 9-33	FR: from the description of the study protocol, residues in earthworms have been quantified after a rinsing of earthworms. Residue quantification might then not be representative of residue to which birds may be exposed in the field. Was the soil content in gut extracted as well?	**RMS (July 2009):** The study reports "Earthworm samples were placed in a refrigerator until the following day to allow worms to void their guts. Please refer also to comment 5(3) and 5(4). **NOT:** Rinsing is the only process that earthworms underwent when collected on the field, therefore, earth contained in the gut was analysed together with the earthworms.	See open point in comment 5(3). .
5(12)	Vol 9, point B.9.1.3.9.3 determination of the proportion of different food types in the diet of the focal species, page 9-9-43	FR: we agree with the reservations about the refinements, values retained by the RMS seem reasonable.	**RMS (July 2009):** Please refer to comment 5(2).	See open point in comment 5(2).
5(13)	Vol 9, point B.9.1.11, probabilistic risk assessment, pages 9-56 to 9-77	FR: the hypothesis behind the risk assessment proposed may miss some key issues somewhere, as it is strange that one could conclude to acceptable risks based on "% effects" close to 0% for a compound for which several granules may suffice to reach a lethal dose or a dose affecting reproduction (from table B.9.1.12-7, page	**RMS (July 2009):** The RMS has the same reservations for the probabilistic risk assessment with Marshal 10G (carbosulfan) as for Furadan 5G (carbofuran). The PRA for carbofuran was discussed in PRAPeR 68 and the meeting agreed with the RMS that too much uncertainties remained. For the PRA of carbosulfan, the RMS recalculated	Open point: MSs to discuss in an expert meeting the probabilistic risk assessement for birds from uptake of granules as grit. See also comments 5(14), 5(17), 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 / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
		9-85). In addition, ends of row may display the highest granule density so that birds living in vegetated area close to end row may in fact be very exposed. In general the same reservations as for the risk assessment that was proposed for carbofuran should be taken into account.	the annual mortality for a period of 2 weeks and found that the effect of carbosulfan could be equal to the normal mortality during 2 weeks of exposure to carbosulfan. Furthermore, it is unclear what caused the annual mortality. The timing of application should be compared to the breeding season. The current PRA approach considers population effects, but should not individual deaths be of concern also? What is the protection goal? There might be a cumulative effect, while the PRA now only takes 1 visit per bird into account. The PRA is based on HD_5 = 3.179 mg a.s./kg b.w./day, with an uncertainty factor of 1 (no margin of safety even if an endpoint based on mortality is used).	
5(14)	Vol 9, point B.9.3.2, risk assessment for ingestion of granules, pages 9-157 to 9-165	FR: the same reservations as for birds apply (from 1.3 to 2.2 granules suffice to reach the NOEL for reproductive effects, which questions the EPPO approach and further refinement. See also comment 5(13).	**RMS (July 2009):** Noted.	See open point in comment 5(13).
5(15)	Vol 9, point B.9.3.2, refined risk assessment	FR: the risk assessment should be checked to be in line with expert agreements for carbofuran.	**RMS (July 2009):** Please refer to former comments related to birds, mammals and carbofuran.	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 / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(16)	Vol. 3, B.9.1.6, Acceptance of granules	**Notifier:** The initial assessment indicates that 11 carbofuran granules are sufficient to kill a small bird. Since sufficient granules to kill a bird were potentially available, then the results suggest that either (1) the birds quickly metabolised carbosulfan and suffered no harm, or most likely (2) the birds do not take the granule because, it is proposed, they do not resemble grit. The latter reduces exposure and is consistent with the results of the EPPO scheme risk assessment.	**RMS (July 2009):** The conclusion of the RMS on the acceptance study is on p. 9-19 of the revised DAR. RMS considers that the results of this study cannot be easily extrapolated to the actual field situation.	Open point: MSs to discuss in an expert meeting the applicability of the avoidance study with house sparrow and granules.

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 / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(17)	Vol. 3, B.9.1.8, Residue content in food items – availability of granules	**Notifier:** The conclusion on page 9-24 is incorrect in the sense that no spills were found outside the sampling area since there was no spill after 0.5 m beyond the field boundaries. Every granule observed on the surface has been taken into account in this study.	**RMS (July 2009):** This comment was made to the RMS before introducing the DAR and RMS has amended the DAR already before submission in April 2009 (p.9-20 to 9-24 of the revised DAR); "granule spillage was measured up to 0.5 m beyond the field boundaries." However, additionally to the sampling areas, 4 spills outside the defined sampling area were found for treatment T1 and 10 spills for treatment T2. These spills were not taken into account for the number of granules on the soil surface and can be considered as an underestimate of the exposure level. Moreover, the number of granules remaining on the soil surface, resulting from the efficiency incorporation trial, were used as input for the probabilistic risk assessment. In stead of 5 m end of row with the availability of granules on the soil surface according to the "end of row", the notifier proposed to have 1 m end of row with the availability of "end of row" and the remaining 4 m with the availability of "start of row", which is much lower and thus underestimates the risk.	See open point in comment 5(13).

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 / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(18)	Vol. 3, B.9.1.8, Residue content in food items – residue in earthworms and beetle	**Notifier**: 3-OH-carbofuran was not measured in these residue trials. However, as highlighted in the Environmental Fate Section of the DAR, 3-OH-carbofuran is a minor and transient metabolite in soil. Therefore, the contribution of 3-OH to the residue in earthworms and arthropods is expected to be modest. This conclusion is confirmed in practice by the earthworm/insect residue trials that were reported in the benfuracarb DAR, where 3-OH-carbofuran was measured and found to contribute only modestly to the overall residue.	**RMS (July 2009):** The notifiers statement that residues in earthworms and beetles should only consider carbofuran (3-OH-carbofuran residues are negligible) is based on the benfuracarb dossier. If data from the benfuracarb dossier are used, this should be accompanied by a letter of access.	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 / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(19)	Vol. 3, B.9.1.9.3, Portion of diet obtained in treated area	**Notifier**: A PT of 1 represents a worst case estimate rather than a reasonable estimate for the long term risk assessment, since it is not possible to use a higher value. Residues in insects have been shown to decline very rapidly with time. Therefore, a PT value of 1 overestimates the number of contaminated insects likely to be found. With regard to moribund insects: (1) the non-target arthropod field trials show a rapid recovery of the surface dwelling insects (that will be part of the diet) indicating that toxic effects on this important guild of insects which make up the diet are not long lasting, i.e. only short-term duration; and (ii) as foliage density increases then any affected insects would become increasingly difficult to find in the crop. Both observations add weight to the argument that the portion of the diet from the treated area is only likely to be contaminated for a short period of time.	**RMS (July 2009):** Noted. However, this weight-of-evidence based information will not allow deriving a quantitative PT value. The RMS considers that the PT determination should be based on the acreage sugar beet fields in a specific region.	Addressed. The argumentation may be taken up in a weight of evidence approach.

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 / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(20)	Vol. 3, B.9.1.10, Monitoring studies – reported cases	**Notifier**: From the way that the WIIS Scheme is run, it might be possible that if mortality was in line with the PRA and the pirimicarb approach RA (for secondary poisoning), then this level of mortality may not be identified. However, what the results of the scheme do demonstrate is that significant bird mortality (i.e.: significant numbers of carcasses) is not being found, in line with expectations based on the deterministic risk assessment.	**RMS (July 2009):** The conclusion of the RMS is on p. 9-50 of the revised DAR. Considering the very limited use of Furadan 5G (carbofuran) and Marshal 10G (carbosulfan), the low number of poisoning incidents due to the approved use cannot be considered as an indication that the actual risk to birds is low.	Addressed.
5(21)	Vol. 3, B.9.1.11, Evaluation of the risk assessment submitted by the notifier	**Notifier**: We selected the PPR panel approach for assessing pirimicarb since it is, to our knowledge, the only recognised reference in the EU for conducting a Tier 3 risk assessment for birds and mammals. Since the Tier 2 risk assessment concludes the need for further refinement, then clarification is needed concerning an appropriate approach and acceptable input parameters for a Tier 3 risk assessment. When conducting the Risk Assessment, 2 scenarios (a worst case and a favorable case) have been assessed to limit the uncertainties.	**RMS (July 2009):** Noted. The PPR panel approach for assessing pirimicarb was also used for the carbofuran dossier and discussed during PRAPeR 68. The parameters used in the carbosulfan dossier are the same as in the carbofuran dossier, except for the residues in arthropods and sugar beet seedlings. The conclusion of the PRAPeR 68 meeting was : For the yellow wagtail: $T_{1/2}$, AVT and AVD were not accepted; for woodpigeon: FPM, $T_{1/2}$, AVT and AVD were not accepted. The meeting concluded that, because of all the uncertainties identified, the pirimicarb-approach is not accepted.	Open point: MSs to discuss in an expert meeting the refined acute risk assessment based on body burden modelling according to the PPR opinion on pirimicarb.

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 / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(22)	Vol. 3, B.9.1.11, Evaluation of the risk assessment submitted by the notifier	**Notifier:** Since carbosulfan is applied maximum once a year, the annual mortality due to carbosulfan is equal to the effect of carbosulfan granules in the first 2 weeks after application – when granules can still be found on the surface. The estimated effect of carbosulfan on bird populations is very low compared to their natural mortality.	**RMS (July 2009):** Please refer to comment 5(13).	See open point in comment 5(13)
5(23)	Vol. 3, B.9.1.11, Evaluation of the risk assessment submitted by the notifier	**Notifier:** All of the distributions used to represent the respective parameters are based on experimental data and provided as part of the report (FMC Study # PC-0403).	**RMS (July 2009):** The RMS agrees that the distributions used are based on experimental data. However, no margins of safety are applied in this probabilistic risk assessment, even if an endpoint based on lethal effects is used. Please refer also to comment 5(13).	See open point in comment 5(13)
5(24)	Vol. 3, B.9.1.12, Risk assessment for birds – consumption of contaminated drinking water	**Notifier:** We agree the puddle scenario overestimates the risk. Granules are buried, therefore the carbofuran metabolite will be less available at the soil surface than would be the case following a foliar treatment – as assumed by the puddle scenario.	**RMS (July 2009):** Noted.	Addressed.
5(25)	Vol. 3, B.9.1.12, Risk assessment for birds – Higher tier RA - Residue in seedling	**Notifier:** Actual contribution of the 3-OH-carbofuran metabolite to the residue in seedling was measured in the reported seedling residue trials.	**RMS (July 2009):** Noted. However, RMS listed this in the recommendations for submitting new information.	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 / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(26)	Vol. 3, B.9.1.12, Risk assessment for birds – Higher tier RA - Residue in earthworms and insect	**Notifier:** 3-OH-carbofuran was not measured in these residue trials. However, the Environmental fate section highlights that 3-OH-carbofuran is a minor – and transient – metabolite in soil. Therefore, its contribution to the residue in earthworms and arthropods is expected to be modest. This conclusion is confirmed by earthworms/insects residue trails reported in the benfuracarb DAR where 3-OH-carbofuran was measured and contributed only modestly to the overall residue. See also comment 5(18).	**RMS (July 2009):** Please refer to comment 5(18).	Addressed.
5(27)	Vol. 3, B.9.1.12, Risk assessment for birds – Higher tier RA - Completeness of residue d-base	**Notifier**: To ensure consistency of the review, it is proposed that the DAR should indicate other substances for which the same extensive request (statistical distribution in number of field conditions, evaluation of ratio parent/metabolite through time) was made with regard to residue in seedlings, earthworms and arthropods.	**RMS (July 2009):** The request with new information is in line with the dossier of carbofuran.	Addressed.
5(28)	Vol. 3, B.9.3.2, Risk assessment for mammals	**Notifier**: The risk assessment conducted by the RMS indicates a low risk for mammals except insect eating mammals, where the acute and chronic TER are 6.63 and 2.69 respectively. However, these TERs are very close to the respective trigger values of 10 and 5. This indicates that further refinement, for example using the pirimicarb approach, will allow a safe use to be identified for these non-target organisms.	**RMS (July 2009):** Please refer to comment 5(5) and 5(7). **NOT:** See comment in Section 5(5).	Addressed.

Aquatic organisms (B. 9.2)				
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 / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(29)	Vol. 3, point B.9.2.16, Exposure and risk assessment for aquatic organisms	DE: In case that surface water PECs need to be revised (in order to take into account entry via run-off), the aquatic risk assessment requires revision too. Current aquatic TERs are near to the trigger values in some cases (e.g. for *Ceriodaphnia dubia*) and increased PECs would indicate risk.	**RMS (July 2009):** New PECsw are awaited. The new TER calculations will be presented in an addendum and the List of Endpoints will be revised accordingly.	Open point: RMS to update the aquatic risk assessment with the new PECsw values.
5(30)	Vol. 3, point B.9.2.16, Exposure and risk assessment for aquatic organisms	DE: The mesocosm with a low value for the EAC (0.1µg/L; not 0.4 µg/L) is not considered in the aquatic risk assessment, because a need was denied for formal reasons. However, since the validity of the EAC from the mesocosm was confirmed after the request by the EFSA SR (2006), this endpoint can not be ignored. Carbofuran could not be quantified in the mesocosm study. Nevertheless, the EAC should be related to the (revised) carbofuran PEC_{sw}.	**RMS (July 2009):** Please refer to comment 5(31).	Open point: MSs to discuss in an expert meeting whether the aquatic risk assessment should be based on the NOAEC of 0.4µg a.s./L together with an uncertainty factor of 4. The resulting EAC of 0.1 µg a.s./L would drive the aquatic risk assessment. RMS to update the LoEP accordingly. See also comment 5(31)

Aquatic organisms (B. 9.2)				
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 / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(31)	Vol. 3, B.9.12, Microcosm and mesocosm study	FR: A reassessment of the results of the mesocosm study as been done. We agree with the conclusions of the recommendations, i.e. a NOEAEC of 0.4 µg/L, leading to an EAC of 0.1 µg/L with an AF of 4. We wonder why the RMS has set an EAC of 0.4 µg/L, which we disagree with. We therefore are in favour of a risk assessment conducted with the EAC of 0.1 µg/L and a LoEP amended with this EAC instead of 0.4 µg/L.	**RMS (July 2009):** The NOEAEC and EAC terminology were mixed up. The reassessment of the mesocosm study and recalculation of the relevant ecotoxicological endpoints confirm that the NOEAEC of 0.4 µg carbosulfan/L (initial residue) is still valid. With an assessment factor of 4 this leads to an EAC = 0.1 µg carbosulfan/L. The DAR and the List of Endpoints have been revised.	See open point in comment 5(30)
5(32)	Vol. 3, B.9.2.15, Summary of effects, Table B.9.2.15-1 Vol. 1, LoEP, endpoints on acute toxicity to fish	FR: In Vol. B.9, all acute toxicity studies to fish were considered of poor quality, essentially due to lack of analytical measurements. FR agrees with RMS. Nevertheless, these endpoints are included in the LoEP. We consider that these endpoints should be removed from the LoEP and a gata gap should be set as no reliable data are available for the acute toxicity to fish.	**RMS (July 2009):** Only the acute toxicity studies with carbosulfan were considered of low quality, not the studies with the metabolites. We agree with the view of the notifier. **NOT:** A sufficient number of studies are available to adequately determine risk to aquatic species including fish and invertebrates. The current risk assessment passes at Step 3 and generation of new data would not change the overall risk conclusions derived in the surface water risk assessments.	Open point: MSs to discuss in an expert meeting whether new studies with fish are necessary.

Aquatic organisms (B. 9.2)				
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 / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(33)	Vol. 3, B.9.2.15, Summary of effects, Table B.9.2.15-2 Vol. 1, LoEP, endpoints on acute toxicity to daphnids	FR: In Vol. B.9, all acute toxicity studies to daphnids were considered of poor quality, essentially due to lack of analytical measurements. FR agrees with RMS. Nevertheless, these endpoints are included in the LoEP. We consider that these endpoints should be removed from the LoEP and a gata gap should be set as no reliable data are available for the acute toxicity to daphnids.	**RMS (July 2009):** Only the acute toxicity studies with carbosulfan were considered of low quality, not the studies with the metabolites. We agree with the view of the notifier. **NOT:** See comment in 5(32).	Open point: MSs to discuss in an expert meeting whether new studies with daphnids are necessary.
5(34)	Vol. 3, B.9.2.15, Summary of effects, Table B.9.2.15-5 Vol. 1, LoEP, endpoints on the mesocosm study	FR: Considering our comment no 5(31), either replace the value of 0.4 µg/L by 0.1µg/L, or replace the term EAC by NOEAEC.	**RMS (July 2009):** The List of Endpoints has been revised.	See open point in comment 5(31)
5(35)	Vol. 3, B.9.2.16.1, Risk assessment for the active substance	FR: Considering our comments no 5(32) and 5(33), the endpoints for acute toxicity to fish and daphnids can not be used for the risk assessment, and values should be removed from Tables B.9.2.16.1-1, B.9.2.16.1-2 and B.9.2.16.1-3.	**RMS (July 2009):** Please refer to comment 5(32) and 5(33). **NOT:** See comment in 5(32).	Addressed. The LoEP has to be updated according to the outcome of the discussions in open points 5(30), 5(32) and 5(33).

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 / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(36)	Vol. 3, B 9.6.5 Field test with earthworms	EFSA: The study of Broadbent and Tomlin (1982) was considered as key information to address uncertainties with regard to differences in effects on earthworm populations from different exposure patterns (local exposure from in-furrow treatment versus even distribution of the active substance). The study should have been submitted and summarized in the DAR. A data gap for submission of this study was identified in the meeting of experts in the discussion on carbofuran.	**RMS (July 2009):** The notifier submitted the publication and the RMS has evaluated this in an addendum. The RMS has reservations towards this study due to several shortcomings (low number of earthworms found, measurements after 22 weeks when residues had fallen to 0 mg/kg). Therefore, based on this publication, RMS cannot conclude on the comparison of exposure via in-furrow or via broadcast application.	Data gap: Applicant to submit the study of Broadbent and Tomlin (1982). Please note that according to regulation 1095/2007 no new studies can be taken into account in the peer review. Therefore this point was identified as a formal data gap.
5(37)	Vol. 1, LoEP, Endpoints on soil macro-organisms	FR: The NOEC values expressed as active substance for *Hypoaspis* and *Folsomia* are inverted.	**RMS (July 2009):** The List of Endpoints has been revised.	Open point: RMS to correct in the LoEP the endpoints for *Hypoaspis* and *Folsomia* (they are inverted).
5(38)	Vol. 3, B.9.6.6, Risk assessment for earthworms Vol. 1, LoEP, Field studies on earthworms	FR: The risk assessment is based on a PECsoil calculated for the whole surface. As mentioned in our comment no 4(35) in the e-fate section, as the representative use to be assessed at EU level is a in-furrow granular application, the PECsoil should be calculated specifically for the furrow zone to account for exposure of soil macro-organisms. New calculations should therefore be conducted in order to compare the application rate of the field study to this new PEC, and verify if the	**RMS (July 2009):** RMS is of the opinion that the real risk is in between the risk assessed with the conventional PECsoil and an in-furrow PECsoil. However, no guidance is available on how to calculate an in-furrow PECsoil. Please refer to comments 4(35) and 5(36). The vision of RMS is that new information in the ecotox section should be submitted to compare exposure via in-furrow or via broadcast application in the field situation, rather than calculating conventional TER based on in-furrow	See data gap in comment 5(36) and comment 4(35).

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 / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
		field study really covers the exposure of earthworms in the furrow. The conclusion has also to be revised in view of this assessment. The LoEP has to be amended also.	PECsoil. New conventional PECsoil was calculated for the metabolites and the DAR and List of Endpoints have been revised accordingly. (initial PECsoil = 0.581 mg carbofuran/kg; initial PECsoil = 0.340 mg dibutylamine/kg).	