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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 NOT	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
1(1)	Vol 1, LOEP, decomposition temperature	**NL:** August 2004 was quite some time ago, what is the status on the decomposition temperature study / information? (see also vol 3 of the DAR).	**RMS:** This study (de Ryckel, 2005) was submitted by FMC in June 2005 and accepted after EU peer review in September 2005. **NOT** Carbofuran boils at 254.1°C with no decomposition.	Addressed: Accepted by EPCO 35 (September 2005)
1(2)	Vol 3, B.2.2.19a, Diafuran 5G Shelf-life	**NL:** Please state what type of packaging was used for the shelf-life study.	**RMS:** Only FMC re-submitted a dossier for evaluation of carbofuran according to the accelerated procedure. Diafuran 5G was the representative formulation proposed by the other initial notifier Dianica SA (now Arysta LifeScience), who did not re-submit a dossier.	Addressed: The representative formulation of the resubmission is Furadan 5G only
1(3)	Addendum to Vol 3 B5, B.5.5.2	**NL:** It appears that the conclusion that a fully validated method for dry crops is not supported by the evaluation under B.5.2.1? The recoveries at 10xLOQ are not within acceptable range. Please also note that in the LOEP it is suggested that additional validation is required.	**RMS:** Sugar beet is only representative crop presented in the re-submission. Nevertheless, also in maize grain, recoveries of residues are within acceptable range (using LC-MS/MS method). No request for additional method validation is mentioned in LoEP. **NOT** Sugar beet is the only representative crop presented in the re-application of carbofuran under Regulation 33/2008/EC.	Addressed: The LC-MS/MS method was validated in maize grain and sugar beet

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 NOT	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
1(4)	Vol. 3, B.3.2.3, Rate of application	**NOT:**The DAR disagrees with the Risk assessment at reduced dose rate". However, the Article 15(1b) of Regulation 33/2008/EC states that "*The supported uses are the same as those that were the subject of the non-inclusion Decision. They 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*". Whilst we appreciate the efforts to calculate the Risk assessment at 600 g ai/ha, we introduced risk assessments at 60 g ai/ha (and also 400 g ai/ha) in order to increase the chances to identify a safe use scenario. The RA conducted by the RMS shows that while the risk to granular intake at 600 g ai/ha is acceptable according to the EPPO scheme, the risk to secondary poisoning via ingestion of treated seedlings, earthworms and/or arthropods needs further refinement. This suggests that a lower application rate should be considered for the risk assessements, as wisely foreseen by Article 15b of the Regulation. Should the EC decide that registration of carbofuran is possible only with limitation on its maximum applied dose rate, this issue would be dealt by FMC at national level. Indeed, we are confident that certain technologies are efficient at dose rate equal or lower to 60 g carbofuran/ha. We would like to stress that diuron was re-submitted for Annex I inclusion defending an application rate of 0.5 kg/ha, which is lower than the dose rate originaly submitted (2 kg/ha). Diuron has recently been voted positively for inclusion to Annex I on the basis of the 0.5 kg/ha safe use.	**RMS:** RMS has clearly explained his point of view as far as reduced dose is concerned in level 3 of the revised DAR. The PECsw and PECgw at 60 g/ha were included in Vol.3 (B8) of the revised DAR. We consider that this issue should be discussed by the WG legislation.	Addressed: The EFSA evaluation takes only the most critical scenario into account

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 NOT	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
1(5)	Vol 3, B.5.2.1, Method of analysis plant matrices, p.5-25	**EFSA:** The acceptability of the method developed and validated by Battelle (cf. report no. A-17-05-13 (Enriquez, 2006), sugar beet and maize) and of the ILV study by Zietz (2008) to be discussed in a meeting of experts in light of the modifications described in the ILV claimed to be necessary for robustness of the method	**RMS:** The validation by Battelle shows lower recoveries in some cases (in comparison with ILV by Zietz); however, these are within the acceptable range. **NOT:** The analysis of carbamates is known to be very difficult, especially at such low LOQ. It is not surprising that the same method may perform differently from one laboratory to another. The ILV by Zietz 2008 offers solutions to implement successfully the method by Enriquez 2006.	Open point: The acceptability of method A-17-05-13, validated by Battelle (Enriquez, 2006), and of the ILV study by Zietz (2008) to be discussed in a meeting of experts in light of the modifications described in the ILV claimed to be necessary for robustness of the method

2. Mammalian toxicology

Acute toxicity (B.6.2)				
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 NOT	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
2(1)	Vol. 3, B.6.2.2, Acute percutaneous toxicity, p. 18-19: classification	**EFSA:** It is noted that the final decision of the European Chemical Bureau (ECB) was not to classify carbofuran relating to the acute dermal toxicity based on both studies summarised in the original DAR. See Commission Directive 2009/2/EC of 15 of January 2009.	**RMS:** The discussion on the classification will not be re-opened anyway. However, it is proposed to maintain the relevant endpoints for dermal toxicity in the scientific conclusions and LoEP of the EFSA. **NOT:** We agree	Addressed.

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 NOT	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
2(2)	B.6.10.4; AOEL	**NL:** In PRAPeR TC 3 the AOEL was discussed. As the development of the brain in rats at PNF 11 reflects the development of the human brain in late pregnancy and occupational exposure of pregnant woman cannot be excluded, the AOEL was set at the same value as the ADI and AOEL, i.e. 0.00015 mg/kg bw/day	**RMS:** It is questionable whether PND11 rat brain development would be equivalent to that of human brain in the 3th trimester of human pregnancy. In open literature, estimates are not consistent. Some authors* estimate that the PND7 old pup is approximately equal to the human neonate in terms of brain growth rate, periventricular germinal matrix composition, neurochemical expression, EEG patterns and synapse formation. More relevant for the endpoint of AChE inhibition**, the timing of axonal outgrowth of AChE-positive nerve fibers was demonstrated just before birth in humans and perinatally (up to PND7) in the rat. On the contrary, in a more general neurodevelopmental model***, it was predicted that a PND14 old rat pup has a brain cortical development comparable to a human foetus 2 months before birth, possibly suggesting that human neonate neurodevelopment would be comparable to that in the weaned rat (however, the model is restricted to rat PND14 stage). In a recent paper ****, it was considered reasonable that the 2nd half of the brain growth spurt in the rat (PND11-21) corresponds in developmental time to a portion of the human brain postnatal growth spurt. Inspection of all the study results on PND11 or PND17 ♂rats moreover shows that brain AChE inhibition at 0.1 mg/kg was overall of about the same magnitude (33-40%),indicating that the rat neonate PND11 and PND17 were of equivalent sensitivity, and represent merely a human perinatal, and not a "third trimester embryo" situation. In any case, from the risk assessment point of view, it is not realistic that women in late pregnancy (approximately last month) would be representative for operators loading and applying Carbofuran. Therefore, it is not relevant to establish an AOEL on a pup toxicity NOAEL (0.015 mkd), and the adult NOAEL (0.03 mkd) is considered preferable. *References:* **Am J Physiol Regul Integr Comp Physiol, 282, 55-63, 2002; **in: Bjorklund, A, Hokfelt,T (Eds.) Handbook of Chemical Neuroanatomy, Elsevier, A'dam, 33-62, 1991; ***Neuroscience, 105, 7-17,2001; ****Toxicol Appl Pharmacol, 196, 287-302, 2004.* **NOT:** See also comment 2(5).	Open point: MSs to discuss the AOEL values in an expert meeting. See also comment 2(4)

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 NOT	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
2(3)	Vol. 3, B.6.10.2, ADI Vol. 3, B.6.10.3, ARfD	**DE:** It is proposed to support both the ADI and the ARfD of 0.001 mg/kg bw as derived by the 2008 JMPR. The 2008 JMPR has evaluated the same toxicological data as the RMS in the updated DAR of November 2008. The RMS established an ADI and an ARfD of 0.00015 mg/kg bw based on a LOAEL of 0.03 mg/kg bw and a safety factor of 200. The JMPR established an ADI and ARfD of 0.001 mg/kg bw based on the overall NOAEL of 0.03 mg/kg bw per day identified on the basis of inhibition of brain acetylcholinesterase activity in rat pups aged 11 days (PND 11) and a safety factor of 25. This NOAEL was supported by the $BMDL_{10}$ of 0.03 mg/kg bw extrapolated from data on inhibition of brain acetylcholinesterase activity in rat pups aged 11 days (postnatal day 11) from three studies. A safety factor of 25 was considered to be appropriate because the acute toxic effects of carbofuran are dependent on C_{max} rather than area under the curve of concentration–time (AUC) and data indicated that the sensitivity of humans and laboratory animals (rats, dogs) to inhibition of acetylcholinesterase activity by carbofuran was similar. A more detailed explanation is given in the JMPR Report 2008, pp.123-126 (carbofuran) and pp. 7-10 (Safety factors for acute C_{max}-dependent effects; specific considerations with respect to carbamates such as carbofuran).	**RMS:** The establishment of the ADI and of the ArfD of Carbofuran was agreed upon in TC 03. RMS took note of the position of the JMPR and the arguments to prefer an AF=100 were discussed at length in the addendum of the DAR. In short, it was explained why we would not ignore a statistically significant 20% decrease of AChE activity in the pups at 0.03 mkd in the main study, and the obvious trend in the pilot study. Finally, the BMD estimation, taking into account the two full NT studies (2005, 2007) support the 2× AF to extrapolate from the LOAEL to the NOAEL. **NOT:** we agree. This view is consistent with our position paper – which present also detailed analysis of the new acetylcholinesterase inhibition studies – and which also makes reference to the recent JMPR review. See also comment 2(5).	Addressed.

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 NOT	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
2(4)	Vol. 3, B.6.10.4, AOEL, p. 174	**EFSA:** A new AOEL of 0.00015 mg/kg bw/day was proposed for carbofuran during the PRAPeR teleconference TC04/09 on benfuracarb. As the RMS expressed a strong disagreement with this position after the teleconference, it is proposed to re-discuss this end-point.	**RMS:** As discussed in 2(2), it is not realistic that women in late pregnancy (approximately last month) would be representative for operators loading and applying Carbofuran. Therefore, it is too conservative to establish an AOEL on a pup toxicity NOAEL (0.015 mkd), and the adult NOAEL (0.03 mkd) is considered preferable. This may be discussed further. **NOT**: See comment 2(3) and 2(5)	See open point in comment 2(2)
2(5)	Vol3, B.6.10, ADI, ARfD and AOEL	**NOT:**We refer to our position papers with regard to the setting of the ADI, ARfD and AOEL on the basis of the new AChE inhibition studies. We believe that the true NOEL is at 0.03 mg/kg bw/day since AChE inhibition does not overtake the 20% threshold at this concentration and no clinical sign is observed at that concentration. Lower safety factor should be applied to the NOEL since 1) it is established on pups and 2) it measures a purely toxicokinetic phenomena (the inhibition of AChE) before it can trigger measurable toxicodynamic effect. We also refer to the recent WHO assessment of ADI and ARfD that took such consideration into account and concluded on an ADI and ARfD of 0.001 mg/kg bw/day.	**RMS:** The establishment of the ADI and of the ArfD of Carbofuran was agreed upon in TC 03. The arguments to prefer an AF=100 were discussed at length in the addendum of the DAR. In short, it was explained why we would not ignore a statistically significant 20% decrease of AchE activity in the pups at 0.03 mkd in the main study, and the obvious trend in the pilot study. Finally, the BMD estimation, taking into account the two full NT studies (2005, 2007) support the 2× AF to extrapolate from the LOAEL to the NOAEL (0.015 mkd). It is common sense to rely on the obtained lowest relevant NOAEL's of these NT studies to establish the reference doses (0.0003 mkd for the AOEL, and 0.00015 mkd for both the ADI and the ARfD). It was also of note that, besides the scientific uncertainties on the application of lower AF (25× i.o. 100×), the 100× AF was chosen for reasons of consistency in TC03, as this factor was used for all other NMC's evaluated so far..	Addressed.

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 NOT	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
2(6)	Vol.3 B6.12 b Dermal absorption	**FR:** we agree with the dermal absorption rate of 3 % retained by the RMS	**RMS:** Noted, see also 2(7).	See open point in comment 2(7)
2(7)	B.6.12.2b; dermal absorption, conclusion.	**NL:** RMS proposes a dermal absorption value for the concentrate of 3%, based on the amount 6.19 % absorbed after 24h at a relevant area dose in an *in-vivo* study in rats with carbofuran, and a correction factor of 2 based on an *in-vitro* study with rat and human skin. NL can agree with the correction factor but has doubts by the value for the *in-vivo* study. Urinary excretion shows significant further absorption after 24 h. Whether this is caused by a large available dermal depot or due to the fact that the skin was not washed after 6 or 24 hours is not clear. Therefore, NL proposes to use the more conservative value of 10% for *in-vitro* rat as s originally used. After correction for the in vitro study this result in a dermal absorption for the concentrate in humans of 5%.	**RMS:** The refinement consisted in comparing the *in-vivo* and the *in-vitro* (first study) absorption value at 6h post-application (see addendum p 188). In both cases the absorption rate was about 1-2%. This equivalence is an essential condition to make a bridging from *in-vivo* to *in-vitro*. Then, the rat/human proportion (2×) calculated on the data *in-vitro* was applied on the 24h absorption value (6%), leading to the 3% estimate. RMS considered it overly conservative to rely on an *in-vivo* value at >24h, as in a regular *in-vivo* study, the skin would have been swabbed to remove the excess of radioactivity. It is logic that extending the contact time without swabbing leads to a protracted skin absorption (although a plateau phase seems to be attained at 24h). In addition, using acetone to dissolve the a.s. is likely to enhance absorption, and a 80× more diluted substance was used *in-vivo* compared with *in vitro*. Thus, several parameters indicate that the *in-vivo* study approximated a worst-case condition. In conclusion, the 3% value was considered a reasonable approach, and not very different from the value proposed by NL (5%), taking into account the variation usually observed in this kind of studies.	Open point: MSs to discuss the dermal absorption value in an expert meeting. See also comments 2(6) and 2(8)
2(8)	Vol. 3, B.6.12.1b, *in vitro* comparative dermal absorption using rat and human skin, p. 187-188	**EFSA:** The validity of the study is in fact very limited due to discarding the 12 tape strips. It should be discussed if it brings enough evidence to decrease the 10 % default value to the proposed 3 %.	**RMS:** Actually, the numbers in table B.6.12b-1 (second *in-vitro* study) indicate that the radioactivity of 12 tape strips was negligible, as the value of the stratum corneum (**), containing the 10 lower tape strips, was <LOQ. Hence, the total radioactivity was restricted to the 2 upper strips, and this may effectively be discarded. Therefore, as explained above, the absorption value is valid.	See opent point in comment 2(7)

Exposure data (B.6.14)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the NOT	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
2(9)	Vol.3 B6.15.1 Estimation of operator exposure	**FR:** the operator exposure estimate should be re calculated with the new AOEL agreed for carbofuran of 0.00015 mg/kg bw/d during the focus peer review of benfuracarb (Jan 2009). However exposure will remain still acceptable with gloves when using UK POEM and with gloves and RPE when using the BBA model. But it will not be acceptable when using the PHED model.	**RMS:** if it is decided to maintain the currently proposed AOEL, a safe use is predicted in the PHED model. **NOT:** See comment 2(2) and 2(3) and 2(5)	Open point: Pending on the outcome of the discussion on the AOEL and dermal absorption values, RMS to provide new estimates of operator exposure risk assessment. MSs to discuss the model to be used in the operator exposure risk assessment in an expert meeting. See also comment 2(10)
2(10)	Vol. 3, B.6.15.1, Operator exposure	**EFSA:** Pending on the discussion on the AOEL and dermal absorption values, operator exposure might have to be revised.	**RMS:** noted. **NOT:** See comment 2(2) and 2(3) and 2(5)	See open point in comment 2(9)

3. Residues

Storage Stability (B.7.0)				
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 NOT	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	**FR:** Could you specified the owner of studies as in the other parts of the Vol.3, B.7 (before the studies of each owner)?	**RMS 03.2009:** The owner is indicated after the title of each study.	Addressed.
3(2)	Vol. 3, B.7.14, Storage stability of residue samples, FMC data	**FR:** How can you explain the different results from one study to another? Should one of these studies be invalidated In "Carbosulfan storage stability study in/on various crops – Burt J.E; 1982", the carbosulfan in green alfalfa is stable up to 12 months, at 21 months the stability is not demonstrated (percent recovery 69,5%). In "Cold storage Stability of Carbofuran and Its Carbamate Metabloites on Various Loboratory Fortified Crop and Animal Matrices – Shreier T.C., 1989", the carbosulfan in green alfalfa is stable up to 26 months. The both data are in contradiction. Same contradiction for corn forage?	**NOT:** Analysis of carbamates residue is uneasy, and variability may explain some descrepancies, especially in old studies that used older analytical technology. Besides, the newly submitted studies confirm the residue stability. **RMS 03.2009:** In the second study (Schreier T.C., 1989), the storage stability of Carbofuran, 3-keto-carbofuran and 3-OH-carbofuran was analysed. There is no storage stability data on Carbosulfan as mentioned in the comment from France. RMS agrees that there are some discrepancies with regards to the results on the storage stability period for Carbofuran in green alfalfa between the 2 studies. In the first study (Burt J.E., 1982), variability in the percent recoveries of Carbofuran was observed in green alfalfa (58%-3 months; 65%-6 months; 86%-12 months and 69.5%-21 months). Raw data did not provide any further clarification on such variability. The percentages of recoveries for Carbosulfan were acceptable in green alfalfa except at the time point of 21 months (69.9%). This study	Addressed: If the study by Burt J.E. (1982), is not considered valid it should be removed from the list of references relied on.

Storage Stability (B.7.0)				
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 NOT	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			cannot be considered as valid. There is no contradiction for corn forage. The recoveries for Carbofuran are acceptable in both the 2 studies.	

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 NOT	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
3(3)	Vol. 1, LoEP, p.74, Plant groups covered, FMC	**FR:** Foliar applications on sugar beet and on rice were not mentioned in the LoEP.	**NOT** Granular application at 60 – 600 g ai/ha on sugar beet is the representative use presented in the re-application of carbofuran under Regulation 33/2008/EC. We did not re-apply for any foliar uses. **RMS 03.2009:** Foliar treatment on sugar beet crop cannot be considered as covered since the metabolism of Carbosulfan in the roots was not depicted. The metabolism of Carbosulfan in rice grain after foliar application can be considered as sufficiently investigated. RMS will amend the LoEPs accordingly.	Addressed: Note: The LoEP should usually only contain reviewed and agreed data that is necessary to conclude on the risk assessment of the notified use.
3(4)	Vol. 1, LoEP, p.74, Plant groups covered, ARYSTA	**FR:** The metabolism study on cabbage should not be mentioned on the LoEP because the level of radioactive residues remains low and no clarification on the lack of TRR (-25%) was proposed by the NOT. This plant group (leafy vegetable) is not covered by the submitted study. Could you please mention in the LoEP	**RMS 03.2009:** RMS agrees although still it was specified in the LoEPs that FMC studies completely investigated the fate of Carbofuran only in potatoes and soybeans after soil application and that the ARYSTA studies did not	Addressed: Note: The LoEP should usually only contain reviewed and agreed data that is necessary to conclude on the risk assessment of the notified use.

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 NOT	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
		- The only valid metabolism study? - What active substance was radiolabelled? - What application method was used?	provide a complete picture of the degradation of Carbofuran in soybean, cabbage, maize and sugar beet. For further clarification, metabolism studies have been submitted on the following crops and were characterized as follows: FMC: Field corn: Carbofuran soil treatment. Metabolites identification was performed only in forage and silage but not in grain. Potato: Post-emergence Carbofuran treatment. The study could be considered as valid. Soybean: Carbofuran soil application. The study could be considered as valid. Sugar beet: Carbosulfan soil application. Poor metabolites identification occurred in sugar beet roots and tops/leaves. No metabolites identification in foliar treated sugar beet roots Rice: Carbosulfan/Carbofuran soil application. No metabolite identification was performed in	

Metabolism in plants (B.7.1)				
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			mature rice grain. The metabolism in foliar treated rice grain can be considered as sufficiently investigated. Arysta LifeScience (previously DIANICA): Soybean and mungbean: Carbofuran soil and foliar applications. Very poor identification of metabolites was observed. Cabbage: Benfuracarb soil application. No metabolites identification was carried out. Maize: Carbofuran soil treatment. Metabolites characterization was performed only on silage. Maize seedlings: Carbofuran soil treatment. This study could not be considered as representative of the residue profile in maize grain and silage at harvest. Metabolites identification occurred in leaves at 3 days, 1, 2 and 4 weeks after emergence. Sugar beet: Carbofuran soil treatment. The radioactive residues were only characterized in sugar beet roots and tops/leaves without any further identification.	

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 NOT	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			Sugar beet seedlings: Carbofuran soil treatment. This study could not be considered as representative of the residue profile in sugar beet roots and tops/leaves at harvest. Metabolites identification occurred in roots and cotyledons at 3 days, 1, 2 and 4 weeks after emergence. The LoEPs will be amended accordingly.	

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 NOT	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
3(5)	Vol.3, B.7.1.1 Metabolism in field corn (study by FMC)	**EFSA:** Page 7-3, 2nd paragraph: The statement that in grain 93.4% TRR remained as bound residues is in contradiction to what is reported in table B.7.1.1-1 (bound residue 31.1%). 93.4% were not solvent extractable, however succeeding acid hydrolysis released 61.1%. Was there any attempt made to identify compounds in this hydrolysed fraction?	**NOT**: The amount of residue (0.014 mg/kg) was insufficient to conduct a proper characterisation. Besides, the conclusion of the RMS is consistent with the known metabolism of carbofuran in plant. Eventually, this study does not apply to sugar beet (see comments 1(3) and 3(3)). **RMS 03.2009:** RMS agrees that the wording leads to some confusion. In grain, 6.6 % (0.002 mg/kg) of the TRR were extracted with Methanol/water and 93.4 % of the TRR (0.021 mg/kg) constituted the post extraction solids (PES) fraction. No solvent partitioning was applied on the extracted phase due to the very low level of recovered radioactivity in this phase. Further analysis for the determination of sugars was tentatively assessed on the PES fraction. Most of the radioactivity was likely incorporated into the sugar molecules that form corn starch. 61.3 % of the TRR (0.014 mg/kg) were released from the PES fraction by acid hydrolysis but without any further characterization. 32.1 % of the TRR (0.007 mg/kg) constituted the residual bound residues.	Addressed: To be amended and set out in a corrigendum/ revised DAR as appropriate
3(6)	Vol.3, B.7.1.3 Metabolism in maize and maize seedlings and Vol. 3, B. 7.1.4	**EFSA**: In these studies identification was not attempted on residues below 10% TRR or less than 0.01 mg/kg, however it should be noted that according to current guidance an	**NOT:** the metabolism pathway expressed in the analysed fractions is in accordance with the known metabolism of carbofuran. Altogether, these metabolism studies	Addressed: If the studies are destined to be used for the the birds and mammals risk assessment and not for the consumer

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 NOT	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
	Metabolism in sugar beet and sugar beet seedlings (studies by Arysta)	identification below the trigger is suggested for compounds with high toxicity (carbofuran is considered as such a compound). Moreover the number of reference standards used was very limited, and though these are new studies (2005/06) modern techniques such MS were not applied. In the sugar beet seedling study there were significant none-extractable fractions (70-92%) not further investigated. Altogether these new metabolism studies do not add any new information.	confirm that carbofuran + 3-OH-carbofuran remains the relevant residue definition in seedlings. It should also be noted that the pupose of those studies is to serve the birds and mammals RA, as opposed to the human RA. **RMS 03.2009:** -Carbofuran metabolism studies in maize and sugar beet: These studies were carried out at a normal and a high dose of application. No tentative characterization/identification of the radioactivity was attempted in the high dose treated matrices (maize grain, sugar beet and leaves). The notifier assumed that the requirements for acceptance of this study were met (TRR not exceeding the trigger value of 0.01 ppm). RMS considered that although a few reference standards were used in the experimental design, those were considered as the most toxicological relevant metabolites of Carbofuran. RMS agrees that these studies did not help to describe completely the metabolic pathway of Carbofuran in these crops. -Carbofuran metabolism studies in maize and sugar beet seedlings: RMS agrees with the notifier that the pupose of those studies was to serve the birds and mammals risk assessment, as opposed to the human risk	risk assessment, they should have been reported in the section B.9. The relevant chapters of the DAR including the lists of references relied on should be revised accordingly.

Metabolism in plants (B.7.1)				
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			assessment.	
3(7)	B.7.1.4 (Arysta), metabolism in sugarbeet, page 7-26	**NL:** In the text it is concluded that 600 g/ha is the normal dose. However, under point B.7.4 it is reported that this was the dose proposed in the original submission by FMC but that at re-submission a dose of 60 g as/ha was proposed. Hence, the normal dose of 600 g as/ha, would be no longer the normal dose, but 10N. There is no use pattern for Arysta reported, therefore, acceptability of the Arysta studies cannot be verified.	**NOT:** We agree that 60 g ai/ha should be considered. Indeed, if 600 g ai/ha would not meet the criteria to demonstrate a safe use, then the dose of 60 g ai/ha should be evaluated. **RMS 03.2009:** In his resubmission dossier, besides the GAP at 600 g a.s./ha (supported in the original dossier), FMC supported additionally a reduced dose rate of application of 60 g a.s./ha. RMS considered that the proposal for an additional risk assessment at a reduced granular dose rate corresponding to the doses used for seed treatment is not acceptable.	Addressed: Note: The critcal GAP should be assessed (as done by RMS), which is the application of 600 g ai/ha.
3(8)	Vol.3, B.7 General: Metabolism studies with soil application (both FMC and Arysta studies)	**EFSA:** In a number of studies there was a significant portion of the TRR released by acid and/ or enzymatic hydrolysis. Based on these findings the presence of numerous glycoside conjugates was suggested, but there was no reporting on identification in the hydrolysed fractions. Was there any attempt made to identify the released compounds (aglycon) in these hydrolysed fractions?	**NOT:** As a rule of thumb, FMC metabolism studies always attemp to characterize the bound residues released from performing Enzyme or Acid hydrolysis. The resulting hydrolyzates are extracted with organic solvents or solid phase, and the aglycones or aglyconic metabolites are identified (HPLC-TLC- MS etc). If the hydrolyzates are very polar degradates that have no single defined peaks, but rather an ubiquitous radioactive back ground, resulting from an array of multi-minor radioactive degradates, then a HPLC run is typically done on that polar fraction to prove that there is no one single component in the hydrolyzates accounting for more than 5% TRR or 0.01 mg/kg.	Addressed: It is again noted that for substances as carbofuran the trigger of 0.01 mg/kg might not be applicable. The presence of individual carbamate metabolites greater than 0.01 would anyway not have been expected in N rate studies, given the information available on carabamate residue behaviour upon soil application.

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 NOT	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			RMS 03.2009: RMS agrees with the notifier's comment. In most of the submitted studies (both FMC and ARYSTA), both the aqueous soluble fractions following solvent partitioning and the post extraction solids fraction were submitted to acid hydrolysis and enzymatic cleavage in order to release the metabolites from their conjugated forms. The released radioactivity was characterized by partitioning against solvents into organo soluble and aqueous soluble phase followed by tentative metabolites identification using TLC/HPLC co-chromatography with reference standards and to a minor extent Mass Spectrometry analysis. TLC analysis was used to characterized the radioactivity. Radioactivity remaining at the origin of the TLC plates was considered as bound radioactive residues. Undefined very polar radioactivity consisted of the radioactive fractions that eluted over the TLC without any defined spot. In that case, HPLC analysis were attempted to fractionate the radioactivity into distinct components with no further identification when each accounted for less than 0.01 mg/kg (below 10 % TRR).	

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 NOT	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
3(9)	Vol.3, B.7 General: Metabolism studies (Arysta)	**EFSA:** p.7-35 last paragraph on acceptance of plant metabolism studies. It is understood from this para that the studies conducted by Arysta are not considered acceptable to derive a metabolic pathway in the investigated crops. Can the RMS confirm this is correct?	**RMS 03.2009:** RMS confirms that it is correct.	Addressed: All concerned studies by Arysta should be removed from the list of references relied on.

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 NOT	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
3(10)	Vol. 3, B.7.11, Estimates of the potential and actual exposure through diet and other means	**NOT:** The consumer risk assessment according to the PSD model demonstrates that carbofuran residue intake via refined sugar is at maximum 0.00008 mg/kg bw/day (53.3% ADI). Besides, we also agree with RMS that the model overestimates the risk to consumer since the residue database demonstrates a non residue situation and since any theoretical carbamate residue would hydrolyse to phenolic metabolites. We agree that the use of the PSD model for assessing the acute and chronic exposure to consumer from the carbofuran use on sugar beet is relevant since refine sugar is the actual consumed commodity. However, the table on chronic dietary intake calculation by the PSD model sum up the intake from sugar beet root and refined sugar. The chronic intake of carbofuran residue via refined sugar only is at maximum 0.00008 mg/kg bw/day (53.3% ADI) for the toddlers and that of sugar beet is of 0.00056 mg/kg bw/day (373.3% ADI). Therefore, if the use on sugar beet is limited to roots intended for processing to refined sugar, then the risk to consumer is low.	**RMS 03.2009:** RMS notes the remark. The notifier referred to the consumers' exposure assessment according to the PSD's ten consumer Model in the DAR (the results are expressed in % of the ARfD and not in % of the ADI).	Addressed.

Metabolism in livestock (B.7.2)				
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 NOT	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
3(11)	Vol. 3, B.7.2.1 Cow metabolism	**EFSA:** Even if in the metabolism study on cows there was only milk analysed for the TRR and for quantification of metabolites that could possibly be useful information as to whether residue levels in the milk are linear dose correlated. This can not be concluded on the basis of the feeding study, but may be necessary information (see comment on expected residue levels in milk and RA)	**NOT:** The lactating cow feeding study shows that no amount of carbofuran residue, nor any of its metabolites, could be found in milk even at exaggerated dose rates. **RMS 03.2009:** RMS agrees that this information could not be extracted from the available feeding study since any residue of carbamates and phenolic metabolites was detected even at the highest dose levels: 10 and 50 mg/kg DM in the diet; i.e. 50 and 250 times the theoretical calculated dietary burden, respectively.	See open point in comment 3(25)

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 NOT	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
3(12)	Vol. B.7.3.1 Residue definition plant	**EFSA:** It was stated by the RMS in this chapter that *'metabolites formed were recovered as free and conjugated compounds'*. In the light of the decision to include conjugates of carbofuran/3-OH- carbofuran in the RA residue definition for soil treated brassica vegetable (benfuracarb dossier), supported by the JMPR evaluation on soil treated crops, and considering the limitations in the submitted studies in the carbofuran dossier in terms of	**NOT:** All metabolism studies consistently show that 3-OH-carbofuran is the only relvant metabolites that can represent a large portion of TRR. The other metabolites identified at significant amounts in plants are phenolic metabolites which are not toxicologically relevant. Phenolic metabolites appear down the metabolisation chain (compared to carbamates metabolites) since they lose the carbamates function. Degradation of these phenolic metabolites – or they evolution to bound residue - could	Open point: The residue definition in plant commodities both for monitoring and risk assessment should be discussed in a meeting of experts.

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 NOT	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
		identification in the hydrolysed fractions (see comment above), the residue definition for root crops should be discussed by experts.	not result in toxicologically relevant molecules. Therefore the sum of carbofuran and 3-OH-carbofuran – which is already below an LOQ of 0.01 mg/kg according to the new residue D-base - accounts for the relevant part of the residue. **RMS 03.2009:** RMS agrees that the residue definitions for monitoring and RA must be consistent with the residue definitions established for Carbofuran in the framework of Benfuracarb dossier. The available plant metabolism studies showed that Carbofuran and 3-OH-carbofuran were the most predominant compounds of the total residues. Considering the limited characterization of the glycosides and other conjugates in the acid hydrolysis released radioactivity, the following residue definitions are proposed for sugar beet: -**Monitoring**: carbofuran + 3-0H carbofuran expressed as carbofuran -**Risk assessment**: carbofuran + 3-0H carbofuran, both free and conjugated expressed as carbofuran; There is no need to include other carbamates metabolites (3-keto-carbofuran) and phenolic metabolites that are less toxic than Carbofuran and 3-OH-carbofuran. RMS proposes to discuss this point during	

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 NOT	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			the Expert meeting considering the JMPR Carbofuran evaluation.	
3(13)	Vol. 3, B.7.3.2, Definition of residue in animal products	**DE:** Given that Regulation (EC) No 396/2005 requires MRLs for each commodity listed in annex I thereto, a definition of residues is deemed necessary also for products of animal origin. Even though no residues can reasonably be expected in products of animal origin it seems nevertheless desirable, as there are MRLs for carbofuran in the Community legislation, to be prepared for an answer to the question: "0.1* mg/kg of what?". Livestock metabolism studies are available, so a residue definition for animal matrices should be provided.	**NOT:** We agree that no residue can be expected in animal food. If a residue definition needs to be given anyhow, we believe that 3-OH-carbofuran alone would be reasonable on the basis of the metabolism studies. **RMS 03.2009:** RMS also agrees that considering the available metabolism studies in livestock and the theoretical calculated dietary burden, no residue is expected in the animal matrices. -For ruminants'matrices, **3-OH-carbofuran both free and conjugated expressed as 3-OH-carbofuran** can be a valid indicator of the total residues in milk, liver and kidney and per default in muscle and fat characterized by extremely low levels of recovered radioactivity (<0.01-0.01 mg/kg). Indeed, a non negligible fraction of the radioactivity consisted of aqueous soluble residues/polar residues in all the matrices. The available analytical methods include an acid hydrolysis step to take into account the possible conjugates. HPLC-PCD methods were considered as suitable for the determination of the residues of Carbofuran, 3-OH-carbofuran and 3-keto-carbofuran in animal matrices with a LOQ for each analyte of 0.05 ppm (liver, muscle,	Open point: The residue definition in animal commodities both for monitoring and risk assessment should be discussed in a meeting of experts. 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 NOT	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			eggs), LOQ of 0.025 ppm (whole milk). Concerning kidney, fat and cream, insufficient data were available to establish a LOQ unequivocally. For poultry matrices, no residue is expected in any matrices considering the calculated dietary burden. No metabolism study was triggered. Therefore, a residue definition per default is proposed as **3-OH-carbofuran, free and conjugated expressed as 3-OH-carbofuran** although this metabolite was recovered only in egg yolk.	
3(14)	Vol. B.7.3.2 Residue definition animal products	**EFSA:** Since a ruminant study was triggered, and considering moreover the toxicological profile of carbofuran and its carbamate metabolites a residue definition for risk assessment in animal commodities should be proposed and discussed by experts.	**NOT**: see comment 3(12) **RMS 03.2009:** See comment 3(12).	See open point in comment 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 NOT	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
3(15)	B.7.4	**NL:** There is no use pattern for Arysta reported, therefore, acceptability of the Arysta studies cannot be verified.	**NOT:** FMC alone has re-applied for Annex I inclusion of carbofuran. FMC obtained a Letter of Access from the Arysta data package, which explains the submission of additional Arysta studies. **RMS 03.2009:** See notifier's comments.	Addressed.
3(16)	Vol. 3, B.7.6 Supervised residue trials- Analytical methods	**EFSA:** p.1-51 analytical methods: Unless reported in chapter B.5.2, the detailed validation data for method Nr.A-17-00-15 and A-17-96-02 should be reported in this chapter B.7.6. These methods used acid refluxing and acidic hydrolysis respectively. Was the hydrolysis validated to quantitatively release conjugates?	**NOT:** These methods are already referenced in the DAR under pages 5-17 and 5-30. The use of acid reflux or acid hydrolysis offers a worst case analysis in the sense that any conjugated residue of carbofuran or 3-OH-carbofuran that is practically extractable would be analysed together with the free carbamates. **RMS 03.2009:** These analytical methods are reported in chapter B.5.2.1. These methods were considered as suitable for the determination of carbofuran and 3-OH-carbofuran. RMS asks EFSA to clarify the question on the validation of the hydrolysis step to release the conjugates.	Open point: It should be clarified whether in the data generation methods (residue trials) the efficiency of the hydrolysis step was validated? See also comment in 3(17)

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 NOT	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
3(17)	Vol. 3, B.7.6 Supervised residue trials- Analytical methods	**EFSA:** p.1-52 analytical methods: Unless also reported in chapter B.5.2, the detailed validation data for method Nr.A-17-05-13 should be reported in this chapter B.7.6. This method used acid refluxing. Would this step be considered sufficient to quantitatively release conjugates?	**NOT:** This method is already referenced in the DAR under page 5-20. The use of acid reflux offers a worst case analysis in the sense that any conjugated residue of carbosuran or 3-OH-carbofuran that is practically extractable would be analysed together with the free carbamates. **RMS 03.2009:** This analytical method is reported in chapter B.5.2.1. These methods were considered as suitable for the determination of carbofuran and 3-OH-carbofuran. RMS asks EFSA to clarify the question on the validation of the hydrolysis step to release the conjugates.	See open point in comment 3(16)
3(18)	Vol. 3, B.7.6.1 Supervised residue trials- Sugar beet (FMC trials)	**EFSA:** The conclusion is not clear with regard to the number of trials reported (N-EU 4, S-EU 14). Why were the trials with carbosulfan not considered, while the introduction to this chapter highlighted that they could be because of the rapid degradation of carbosulfan to carbofuran.	**RMS 03.2009:** In the DAR under point B.7.6.1, both Carbosulfan and Carbofuran residue data were considered for MRL setting in sugar beet (See Residue trials added in November 2008 both for Carbosulfan and Carbofuran).	See open point in comment 3(19)
3(19)	Vol. 3, B.7.6.1 Supervised residue trials- Sugar beet (FMC trials)	**EFSA:** In one of the trials a result of 0.112 mg/kg was found in the root. As agreed in previous EPCO and PRAPeR meetings, values should not be deleted if they may be true values and no obvious error has occurred in a trial. The results in sugar beet (including Arysta	**NOT:** We agree with RMS that the 0.112 mg/kg result is an outlier from a statistical point of view. Indeed, the DAR references a new residue d-dase confirming that the residue remains below a LOQ of 0.01 mg/kg (as sum of carbofuran + 3-OH-carbofuran), Besides, this value refers to a very old	Open point: Upon a plant residue definition for risk assessment has been agreed, the available residue data should be reviewed and the appropriate data should be selected. (Consider also open point in comment 3(16))

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 NOT	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
		data) correlate well with the findings in brassica crops (benfuracarb dossier), that were merely below the LOQ but showed occasional low-level residues are possible with this type of application and substance (see also indication by rotational crop data).	residue trial (1973). Bearing in mind that (1) the quality of the analytical method was not as efficient as today's technology and (2) carbamates are known to be difficult to analyse, then there is a high likelyhood that this single result was a false positive. In contract, the new residue trials have been conducted using fully validated method. **RMS 03.2009:** One Carbosulfan trial (1980) on the complete residue database both for Carbosulfan and Carbofuran (40) covering Northern Europe showed a residue value of 0.112 mg/kg in sugar beet root. Looking more in detail to this trial, 2 tests were performed with Carbosulfan at 0.6 kg as/ha and 1.8 kg as/ka, respectively. *At 0.6 kg as/ha:* Carbosulfan: 2x<0.05 mg/kg Carbofuran: 2x<0.05 mg/kg 3-OH-carbofuran: <0.05-0.062 mg/kg *At 1.8 kg as/ha:* Carbosulfan: 2x<0.05 mg/kg Carbofuran: 2x<0.05 mg/kg 3-OH-carbofuran: 2X<0.05 mg/kg As mentioned in the Benfuracarb dossier, limited stability of 3-OH-carbofuran was observed in brassica matrices, increasing the difficulty to analyse the carbamates. Although it is likely that no error occurred in	See also comment in 3(18)

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 NOT	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			the biological part of the trial, this value may be a false positive value because of the limited stability of 3-OH-carbofuran. RMS disagrees with the comment that this positive residue value would correlate with the type of application and the substance. Indeed, the application consisted of a mechanical incorporation of the granules into the seed furrows. Soil is then folded over to cover before sowing. Finally, a complete residue database covering North and South of Europe on sugar beet was provided in the frame of the resubmission and showed a non-residue situation both in roots and leaves with tops. The analytical method was completely validated at a Limit of Quantification of 0.005 mg/kg for each analyte.	
3(20)	Vol. 3, B.7.6.2 Supervised residue trials- Maize and Vol. 3, B.7.6.3 - Sunflower	**EFSA:** These data were not reviewed by EFSA as they are not relevant to the notifed use in sugar beet.	**NOT:** We agree **RMS 03.2009:** Agree.	Addressed.

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 NOT	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
3(21)	Vol. 3, B.7.7.1, Effect on the nature of the residues, Table B.7.7.1-1	**FR:** All metabolites are quoted in a different order in pH 5.0 buffer, in pH 7.0 buffer and in pH 9.0 buffer. Is there a particular reason? For easier reading, could you please harmonise the order of the metabolites (name, percentage)?	**RMS 03.2009:** This table was amended accordingly in the Addendum to the DAR-B (7)-March 2009.	Addressed.
3(22)	Vol. 3, B.7.7.1, Effect on the nature of the residues	**FR:** Could you mention that none of the submitted studies are in conformity with the guideline 7035/VI/95 rev.5 of 22/7/1997 – Appendix E – Processing studies?	**RMS 03.2009:** The first study (El-Naggar S.F., Reynolds J.l., 1982) does not comply with the current guideline on processing studies. This study was not conducted according to the representative hydrolytic conditions of the guideline. In fact, the study was conducted at room temperature (T°: 25°C) not representative of the sugar beet processing. Moreover, this study performed with Carbosulfan did not investigate the hydrolysis of Carbofuran and 3-OH-carbofuran. The second study (Alvarez M., 1989b) was considered as acceptable (see Carbofuran DAR-Vol 3 B(2), point B.2.1.14). RMS still points out that processing studies were not triggered since no significant residues occurred in sugar beet roots (below 0.01 mg/kg).	Open point: The available processing data (nature and level) should be discussed by experts in terms of their suitability to conclude on residue behaviour under sugar beet processing/ sugar raffination See also comments in 3(23) and 3(24)

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 NOT	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
3(23)	Vol. 3, B.7.7.1 Nature of residue	**EFSA:** How relevant are the studies to reflect conditions of sugar beet processing, considering the tests were carried out at room temperature, the compound in one test was carbosulfan, and that alcaline pH was choosen in the test with carbofuran? As agreed in previous EPCO and PRAPeR meetings the design in the phys-chem hydolysis study is less useful to describe the fate of an active substance and its metabolite under much different processing conditions. The case made should be discussed by experts.	**RMS 03.2009:** See point 3(21).	See open point in comment 3(22)
3(24)	Vol. 3, B.7.7.2 Level of residue	**EFSA:** How relevant is this processing study when residues in the RAC were below the LOQ, as it was understood from the conclusion?	**NOT:** It is interesting to note that (1) residue in RAC was below the LOQ despite the fact that the sugar beet were treated at exaggerated dose (4.48 kg ai/ha) and (2) low residue (0.02 – 0.03 mg/kg) of 3-keto-7-phenol was recovered in molasses and sugar. This indicates that the non-detectable residue of carbamates have degraded to a phenolic metabolite (loosing the carbamate founction) through the sugar processing. This finding is consistent with the hydrolysis behaviour of carbamates. **RMS 03.2009:** RMS considers the notifier's comments and also refers to point 3(21).	See open point in comment 3(22)

Livestock feeding (B.7.8)				
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 NOT	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
3(25)	Vol.3, B.7.8 Livestock feeding	**EFSA:** Considering an N rate of around 120 when the estimated dietary burden is compared with the dose rate in the FMC goat metabolism study and provided carbofuran and 3-OH carbofuran were defined as the relevant residues in animal matrices, residues of 0.3 µg/kg would be expected in milk and kidney (assuming linearity in dose and recovered level) , resp. It is noted that in the risk assessment for compounds with very low tox reference values the 'usual' trigger does not apply. A feeding study (carbosulfan) with LOQs of 0.025 and 0.05 mg/kg and only analysis in samples of too high dose groups is not considered very useful to carry out an robust consumer risk assessment in terms of the notified use.	**NOT**: Running this extrapolation, 0.3 µg/L of 3-OH carbofuran would be expected in milk, and 0.03 µg/kg of 3-OH carbofuran would be expected in kidney. These levels are below the lowest achievable LOQ (5 µg/kg). A new study repeated at lower dietary intake would not bring any new valuable information. **RMS 03.2009:** RMS agrees that the available feeding study on ruminants cannot be used to perform a robust dietary risk assessment given the extremely low toxicological reference values for Carbofuran. Assuming linearity in dose and recovered residue levels in all the matrices, RMS proposed to carry out the consumer risk assessment considering the recovered residue values in the carbofuran metabolism study on lactating goats. To be consistent with the residue definition proposed for animal matrices (point 3(12)), the residue levels of 3-OH-carbofuran that would be expected are: 0.3 µg/L in milk, 0.3 µg/kg in kidney, 0.05 µg/kg in liver and 0.01µg/kg in muscle and fat.	Open point: Asssessment of residues in animal matrices, considering information available from all animal studies, to be submitted in an addendum and reviewed by the meeting of experts See also comment in 3(11)

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 NOT	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
3(26)	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 signifcant residues could be expected. This is in line with the conclusion by PRAPeR TC05 regarding carbofuran residues in rotated crops (considering JMPR evaluation). 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.	**NOT:** The amount of TRR found in the succeeding crops after 30 and 60 days (1) was too low to allow characterization, (2) is an order of magnitude lower to the TRR found in the metabolism studies and (3) demonstrates that an MRL of 0.01 mg/kg for the sum of carbofuran + 3-OH-carbofuran would not be overtaken in succeeding crops. Besides, if taking into account the known metabolism pathway of carbofuran in soil and plants, the low TRR observed in the succedding crops most likely accounts essentially for non toxic phenolic metabolites. **RMS 03.2009:** RMS considers that the longest DT90 (field) is 91 days for Carbofuran. The metabolites containing the carbamate moiety (3-OH-carbofuran and 3-keto-carbofuran) have DT90 ranging between 3.3 and 10 days. It is therefore obvious that the DT90 of Carbofuran does not trigger a rotational crop. RMS also assumed that the duration between carbofuran application (at sowing) and the rotated crops is more than 91 days for the supported use. In the new confined rotational crop study (Rosenwald J., 2008), residue levels above 0.01 mg/kg (0.031 mg/kg) were recovered in spinach leaves only at 30 days (simulating a crop failure). At the same worst-case time	Open point: The issue of residues in rotational crops should be discussed in a meeting of experts, taking into account the conclusion drawn on benfuracarb with regard to carbofuran residues and the interim results obtained in the new confined study (2008).

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 NOT	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			interval, no residues above 0.01 mg/kg were detected in radish roots and leaves and in cereals (straw, chaff and grain). The results of the investigation of the total residues in spinach leaves at 30 days are expected in the final report. However, even if uptake by rotational crops is at very low levels as observed in the study, an exceedance of the ARfD might still be expected if the trigger value of 0.01 mg/kg is applied to rotated crops. Since the confined rotational crop study was conducted in compliance with the supported use, RMS proposes to consider the actual residue levels recovered in the different rotated crops to perform the consumer dietary risk assessment. This approach is rather conservative since it does not consider the metabolisation of carbofuran into its other carbamates metabolites and into its phenolic metabolites that occur in soil before planting the rotational crops. This point should be discussed at the expert meeting.	

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 NOT	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
3(27)	Vol. 3, B.7.11, Consumer Risk Assessment	**DE:** it appears misleading to insert the MRL of 0.01* mg/kg for sugar beet. The UK model operates with an intake of 63,85 g sugar beet root per kg bw (calculated from the sugar intake and the amount of sugar beets needed to produce this amount of sugar); along with a body weight of 20.5 kg for an 4-6 y UK infant this means a consumption of 1.31 kg of sugar beet a day! This approach appears flawed because even if one assumes (which is highly unlikely) that the level of residues in the raw sugar beet root equals that in the sugar and no reduction of residues occurs during processing, the consumed amount of refined sugar should be about one fifth corresponding to the sugar content of the root (1.3 kg x 0.2). In addition, when taking into account the results of the (recent) residue trials and the DT_{50}/DT_{90} values in soil, and keeping further in mind that any residue that may be left in the roots is substantially reduced during production of sugar, the outcome of the model is clearly overly conservative. As this conclusion is also shared by the RMS this should be stated more clearly because it might easily be overlooked when just swiftly scanning the report (at the moment just one sentence in the conclusion).	**NOT:** We agree. See also comment 3(10). **RMS 03.2009:** RMS reported the following calculation in the Carbosulfan DAR. 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) are 1309 g/day and 1971 g/day of sugar beet root. If we assume that the sugar beet root contains approximately 16 % of sugar, the actual sugar consumption can be estimated to be 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. Moreover, considering the available residue database on sugar beet root with such a low Limit of quantification for carbofuran and 3-OH-carbofuran (0.005 mg/kg) and considering that processing into sugar will further lower this level of quantification, the dietary intake calculation according to EFSA PRIMo can be considered as highly conservative. This point should be discussed at the expert meeting.	Open point: Consumer intake assessment for sugar beet and whether any refinement is possible with the available data should be discussed in a meeting of experts.

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 NOT	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
3(28)	Vol. 3, B.7.11 Consumer Risk Assessment	**EFSA:** The risk assessment does not consider potential residues in animal commodities (in particular milk) and in rotational crops (study ongoing). It should be noted that the estimated residue level of only 0.3 µg/kg in milk fills the ARfD to 25% and the ADI to 8%for children (EFSA PRIMo). This is a significant contribution and should thus be considered in a sound assessment, and so should be rotational crop residues when data will be available.	**NOT:** These preliminary RA indicates acceptable risk for the consumer. If a RA should be conducted for assessing the succeeding crops as well, then proper assumption must be taken. Bearing in mind that TRR in succeeding crop is an order of magnitude lower than in metabolism studies, then a suragate residue of 0.001 mg/kg (10 x lower than LOQ) should be used for sum of carbofuran + 3-OH-carbofuran. This assumption is conservative as it does not consider the metabolisation to phenolic coumpounds happening in the soil before the succeeding crop is sowed. In these conditions, ADI consumed for all crop ranges between 3 and 18% (including milk consumption). This should be added to the 53.3 % ADI consumed by sugar intake (see comment 3(10)). ARfD consumption in these conditions is always below 100%, except potatoes that consums 102.5% of the ARfD. Please note that this evaluation takes into account the ADI/ARfD of 0.00015 mg/kg bw/day, which FMC disagrees with (see also comments 2(2), 2(3) and 2(5)). **RMS 03.2009:** RMS will perform the dietary intake calculation according to the UK model and the EFSA PRIMo. These calculations will be included in the Addendum to the DAR-March 2009.	Open point: The consumer risk assessment should be discussed in a meeting of expert, considering all relevant sources of exposure to carbofuran residues with respect to the notified use See also comments in 3(29) and 3(31)

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 NOT	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
3(29)	Vol. 3, B.7.11 Consumer Risk Assessment	**EFSA:** It is not agreed that the database showed a 'no residue situation' in sugar beet (leaves and root residues, see comment on trials). The acute risk assessment for sugar (beet) was carried out with 0.01 mg/kg while the highest residue was 0.112 mg/kg for carbofuran/3-OH carbofuran found in one trial with carbosulfan. However no refinement for sugar processing/raffination is possible due to lack of relevant data. The consumer risk assessment should be further discussed by experts.	**NOT:** We believe that 0.01 mg/kg (sum of carbofuran + 3-OH-carbofuran) should be entered in the UK model and refined sugar only should be the relevant commodity. **RMS 03.2009:** According to the PSD's ten Consumer Model, only refined sugar with the default residue level of 0.01 mg/kg should be taken into consideration for the consumer dietary intake assessment. The concern regarding the residue value of 0.112 mg/kg for carbofuran and 3-OH-carbofuran in sugar beet roots was already discussed (see point 3(18)). This residue value does not have to be included in the residue database. RMS agrees to discuss further this point with other experts.	See open point in comment 3(28)

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 NOT	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
3(30)	Vol. 3, B.7.12 MRLs	**EFSA:** It is noted that the proposed MRL will exceed the tox reference values in a consumer risk assessment.	**NOT:** see comments 3(28). Using the UK model for refined sugar, the worst case intakes represent 53.3% ADI and 37.7% ARfD. See also comment 3(27) if considering animal food and succedding crops. **RMS 03.2009:** According to the UK model, there is no chronic and acute intake concerns considering the refined sugar consumption data and the residue levels of 3-OH-carbofuran in animal commodities. According to EFSA PRIMo based on the sugar beet root consumption data and the residue levels of 3-OH-carbofuran in animal commodities, an exceedance of the ADI (152%) and ARfD (425%) is observed. These calculations will be included in the Addendum to the DAR-March 2009.	Open point: At the end of the discussion on carbofuran the meeting of experts may consider the MRLs (plants, animals) that should be proposed to risk managers

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 NOT	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
3(31)	Vol.3, B.7.15 Summary	**EFSA:** Consumer safety: EFSA does not agree with the RMS conclusion that there are no chronic and acute exposure concerns since: 1) current assessment indicates an exceedance of both ADI and ARfD for one MS and data do not allow for further refinement and 2) the assessment is not finalised as it does not consider all means of consumer dietary exposure related to the notified use (animal products, rotated crop residues, drinking water).	**NOT:** We disagree with EFSA because the EFSA model does not offer refine sugar intake figures whilst the UK model does. See also comment 3(29). See comment 3(27) if animal product and succeeding crops need to be assessed. **RMS 03.2009:** See comments 3(24), 3(25) and 3(29).	See open point in comment 3(28)

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 NOT	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(1)	Vol. 3, B.8.1, Route and rate of degradation	**FR:** p.22; Willems 2005, Study might be in rate section instead of route section.	**RMS:** this remark has no impact on the final risk assessment	Addressed
4(2)	Vol. 3, B.8.1, Route and rate of degradation	**FR:** p.23; for the carbufuran-3-hydroxy the geometric mean of 0.35 d might be inserted in an additional line in Table B.8.1.1.1-17 p8-26. same remark for geometric mean of 3.81 d calculated for carbufuran-3-keto in table Table B.8.1.1.1-19.	**RMS:** this remark has no impact on the final risk assessment	Addressed
4(3)	Vol. 3, B.8.1, Route and rate of degradation	**FR:** p.37. Rate of degradation, aerobic. Table B.8.1.2.1-6. presented data are unnormalized.	**RMS:** this remark has no impact on the final risk assessment; Normalized and unormalized values are presented in this table	Addressed
4(4)	Vol. 3, B.8.1, Route and rate of degradation	**FR:** p.37. When comparing Table B.8.1.2.1-6 and table Table B.8.1.2.1-7, in the study from Markle (1981a) there is one site on the first table (Barney) and then 2 sites (Berney and Nebraska).	**RMS:** The Table B.8.1.2.1-8 gives an overview of the DT50 that have been derived from the studies with carbosulfan as test item.	Addressed Note: DT_{50} for carbosulfan was calculated (but dismissed) for the Nebraska soil as well.
4(5)	Vol. 3, B.8.1, Route and rate of degradation	**FR:** p.38. General conclusion of the RMS on the degradation of an overall DT_{50} carbofuran. RMS considers that the overall mean values of 12.83 and 10.7 days are appropriate. Since this parameter is very sensitive for both PECgw and sw calculations then it should be clearly mentioned to use the worst case value.	**RMS:** The RMS considers that the overall DT50 is 12.83 days	See note in 4(7) and comment in Column 2 in 4(12).
4(6)	B.8.1.1	**NL:** In case of carbofuran-phenol a very low recovery was found. Because the metabolite has a Vp of 1.32 Pa, the volatility of this metabolite could be an important factor in the low mass balance. In the study summary the following is stated: 'Mean procedural recoveries were low (17-74%) at the LOQ and	**RMS:** It has been shown in the original submission that the metabolites of carbofuran were clearly not major (never at level above 5% at 2 sampling points): 3-OH-carbofuran (max 0.8%, once in 1 out of 5 soils), 3-keto-	Open point: MS experts to discuss whether is there any need for DegT50 value for carbofuran-phenol for the exposure

Route and rate of degradation in soil (B.8.1)				
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		20x LOQ level for all analytical series. However, even when a correction for this low recovery would be made, analytical results of the samples analysed within a few hours after spiking, would be <20% of applied. Hence, despite the low recoveries, the results do indicate rapid dissipation of carbofuran-phenol from soil with a half-life of <1 day. Carbofuran-phenol dissipated rapidly in soil with half-lives of <1 day in Speyer 2.2, Speyer 2.3 and Speyer 6S soils.' Nevertheless, the values are used as degradation parameters during the assessment. For modelling the consequence is that volatility is introduced in the models by the DisT50 and also by the vapour pressure. This is double counting of a loss process with impact on the predicted concentrations. No adequate DegT50 values of carbofuran-phenol are available in the dossier.	carbofuran (once at maximum level of 6.2% AR, in 1 out of 5 soils), carbofuran-phenol (=7-phenol) (max 2.1%, once in 1 out of 5 soils) (Arysta, FMC) However EPCO 31 agreed that 3-OH-carbofuran and 3-keto-carbofuran need to be further assessed as carbofuran metabolites containing the active carbamate moiety. Carbofuran-phenol does not contain the carbamate moeity. The notifer has provided DT50 (the 3 metabolites are not persistent) and Koc (Koc for modelling has been chosen according to a worst case approach) for the metabolites. Despite the choice of worst case input parameters assumptions, the PEC gw for the metabolites are clearly below the trigger of 0.1 µg/L. The RMS considers that this remark has no impact on the final risk assessment. **NOT:** The discussion is moot. Carbofuran-phenol does not contain a carbamate moiety and is orders of magnitude less potent than either 3-hydroxy carbofuran or 3-keto carbofuran	assessment or the available estimations using DisT50 are supported; and discuss moreover the vapour pressure used in the PEC calculations. Notes for the discussion: - carbofuran-phenol is regarded as minor metabolite in aerobic soil, but major in water/sediment system - carbofuran-phenol does not contain the carbamate moiety - the definition of residue regarding carbofuran-phenol might be changed - an open point is set for the discussion of the input parameters for modelling, however the degradation parameters and adsorption parameters

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 NOT	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
				were already agreed by the meeting of PRAPeR 62 - another Vp value for carbofuran-phenol is reported in B.8.4.6 of the addition report of carbofuran (0.28 Pa) See comment in Column 2 in 4(20), notes in 4(41) and open points in 4(39) and 4(44).
4(7)	Vol. 3, B.8.1.1 Route of degradation Conclusion of the study by Saxena) Page 8-8, Conclusion of the study by Schocken) Page 8-14	**EFSA:** It is stated for both studies that the study is not acceptable, but no detailed scientific argumentation is added for the exclusion. These studies were not regarded by the previous peer review as not acceptable; they are included in the EFSA conclusions on carbofuran, carbosulfan and benfuracarb. Moreover, the meeting of experts (PRAPeR 62, January 2009) of peer review on the resubmission of benfuracarb (2nd peer review) discussed and agreed to continue to accept this studies, and established a set of DT_{50} for carbofuran to be used further in the RA. For the set of DT_{50} see EFSA comment 4(6).	**RMS:** We consider that a detailed argumentation has been given in the DARs of benfuracarb and carbofuran to exclude the studies by Saxena and Schocken. The RMS disagrees with the conclusions of the PRAPER 62 meeting on this point and would like that his argumentation is taken on board in the conclusions of carbofuran. **Study by Saxena**: - In this study two soils were used, called as acidic and alkaline soil. The alkaline soil was prepared by adding lime to the collected sandy loam soil (acidic), by this the pH was modified from 5.7 to 7.7.	Addressed Note: this issue containing all the points listed in Column 3 was exhaustively discussed at the meeting of PRAPeR 62 (January 2009) with the participation of the RMS (see meeting report for benfuracarb). RMS may only raise this point (exclusion of these DT50s) at the meeting of experts for

Route and rate of degradation in soil (B.8.1)				
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			- The soil indeed seems to be dry if compared with e.g. the FOCUS default values for sandy loam, but the moisture holding capacity of the soil was determined in this GLP study and the actual moisture content was set for this (75% of 1/3 bar=4.05%) in accordance with EPA guidelines (Very often, degradation determined according EPA guideline is slower). - The microbial biomass was checked several times throughout the study and the results show that both soils were viable at the end of the study. - According to the RMS, one soil has been tested in this study (same soil properties, except pH, same microflora). It is therefore not valid to derive 2 DT50 in order to artificially increase the mean or the median DT50. **Study by Schocken**: - The pH of this sandy loam soil was also modified by lime from 5.8 to 7.1. The microbial activity of the soil was checked by measuring the evolved $^{14}CO_2$ from ^{14}C labelled glucose up to 57 days in a parallel experiment. The evolved CO_2 was continuously increasing and reached 62.3%	carbofuran, if the RMS includes a clear argumentation (in addition to what is already presented in the additional report for carbofuran and available documentation for benfuracarb as outlined in column 3) in an addendum. See also comment in Column 2 in 4(12).

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 NOT	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			by the end of this term. It was stated in the DAR that the carbofuran degradation in this study is occurring through a chemical rather than a microbial process (similar degradation rates under sterile and non-sterile conditions). Absence of mineralization is observed in this study The degradation of carbofuran has been determined under aerobic laboratory conditions with carbofuran, benfuracarb or carbosulfan as test substance (14 studies with DT50 ranging between 5.7 and 22.7 days) and under field conditions (5 studies with DT50 ranging between 1.3 and 27 days). Under anaerobic laboratory conditions, the DT50 in one soil is 7.6 days. The RMS considers that there are sufficient arguments that are indicating that the DT50 of 381, 174 days (actually one soil tested in Saxena 1994) and 444 days (one soil in Schocken, 1989) are not valid. The RMS is therefore of the opinion that the DT50 of 12.83 days is a reasonable estimate that can be used for PECgw and PECsw 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 NOT	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(8)	Vol. 3, B.8.1.1 Route of degradation Studies of: Willems, H., 2005 a,b,c	**EFSA:** Summaries of these studies were included in the additional report of benfuracarb (2008). Comments (from UK and EFSA) on these studies and the evaluation of these comments by the RMS and the NOT can be found in the reporting table (rev 1-0, 1-12-2008) of benfuracarb. Therefore further clarification is probably not necessary.	**RMS:** no comment	Addressed
4(9)	Vol. 3, B.8.1.1.1, Aerobic degradation in soil	**DE:** Page 8-9 (revised in Nov. 2008) *'The incubation under aerobic/anaerobic conditions cannot be used to determine a valid DT_{50}.'Could* you please give an explanation?	**RMS:** It means that the results under anaerobic conditions cannot be used for DT50 derivation.	Addressed
4(10)	Vol. 3, B.8.1.1.1, Aerobic degradation in soil	**DE:** RMS has excluded the aerobic soil metabolism study (Saxena A.M. et al., 1994) from the risk assessment although this study was considered of acceptable quality and taken into account in the original DAR. Please give a justification for the exclusion of the study.	**RMS:** See point 4.7	See note in 4(7).
4(11)	Vol. 3, B.8.1.1.3, Soil photolysis	**DE:** Page 8-31 (revised in Nov. 2008) The temperature of the soil during radiation must be kept at about 20°C. Furthermore the findings cannot be transferred to the North European conditions.	**RMS:** Soil photolysis is not an important route of degradation. Moreover, the a.s. is incorporated into the soil. **NOT:** Soil Photolysis is not an important route of carbofuran degradation and excluding the data should have neglible affect on RAs.	Open point: RMS to update the List of Endpoints by indicating the actual temperature or range of temperature used in the soil photolysis studies in the box of soil photolysis.

Route and rate of degradation in soil (B.8.1)				
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4(12)	Vol. 3, B.8.1.2 Rate of degradation, B.8.1.2.1 Aerobic degradation Page 8-33 – 8-39	**EFSA:** The relevant pages for the DT50 derivation for carbofuran (page 8-33 – 8-39) were already discussed in the meeting of experts for the benfuracarb 2nd peer review in January 2009 (PRAPeR 62). The meeting agreed that all the refitted DT50 and the normalisation procedure indicated on these pages are acceptable and should be used further in the RA. It was also agreed that 3 other DT_{50} values from the studies by Saxena and Schocken (see EFSA comment (1)) 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 DT_{50} values is 14 days.	**RMS:** See point 4.7 **NOT:** See 4(13). The Notifier has considered the revised DT50 value for the PECgw and PECsw risk assessments.	See note in 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 NOT	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(13)	Vol. 3, B.8.1.2 Rate of degradation, B.8.1.2.1 Aerobic degradation Page 8-39	**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 DT_{50} of 6.1 days. RMS please clarify it. 22.7 days should not be used as this is the average of the two DT_{50} values determined on the same soil at different temperatures. As input for PECgw and PECsw DT_{50} of 14d should be used. See also EFSA comment 4(13).	**RMS:** The PEC results that have been submitted by the notifier will be evaluated in an addendum. The RMS however confirms the conclusions that are presented by the notifier here below. The value of 6.1 days is probably a mistake. However, this value has not been included in the calculation of the overall DT50 of 12.83 days. It is not clear to the RMS why the DT50 of 22.7 days cannot be used. **NOT:** Considering the DT50 value of 14 days in the PECgw assessment results in a single passing scenario in PEARL and multiple passing scenarios In PELMO for the 0.6 kg ai/ha annual application. Considering DT50 of 14 days for the 0.06 kg ai/ha annual application succeeds 6 out of 9 scenarios using PEARL and all scenarios using PELMO.	Open point: RMS to include the evaluation of the PEC calculations, which considers the soil DT50 value of 14 days and the supported application rate in an addendum. Include in the addendum all the input parameters used, all the relevant results and examples of the output files of the models as well. Note that an open point is set for discussion of the input parameters for modelling in 4(39) of the reporting table. See also comment in Column 2 in 4(12).

Route and rate of degradation in soil (B.8.1)				
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4(14)	Vol. 3, B.8.1.3 Field studies Page 8-41 – 8-44 & B.8.3 PECsoil	**EFSA:** In the previous peer review of carbofuran, carbosulfan and benfuracarb for calculation of PECsoil, DT_{50} of 71.9 days was used from the field study by Taylor and Houseman. The validity of this DT_{50} was already discussed in the meeting of experts for the benfuracarb 2nd peer review in January 2009 (PRAPeR 62) (the previous peer review was not able to make a conclusion on the reliability of this DT_{50}). The meeting of experts (PRAPeR 62) agreed with the RMS that DT_{50} of 71.9 days is not relied on and for the PECsoil calculation, in line with this chapter, 27 days should be used (longest field dissipation data from the European sites from study by Mol, 2002). Therefore further clarification is probably not necessary.	**RMS:** no comment	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 NOT	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(15)	B.8.2.1 sorption metabolites 3-hydroxy-carbofuran	**NL:** In case of 3-hydroxy-carbofuran the soil used for risk assessment (lowest value) is not acceptable. Because only 2% has adsorbed after 6 hours according to OECD 106 no adequate Koc value can be derived. The Koc of 43 L/kg cannot be the result of 2% adsorption. Now it is assumed that the concentration decrease is due to adsorption (overestimation). The P criterion of 0.3 (OECD 106) is not met; p value of soil II is 0.2. Because the average recovery is 88% at least 12% loss can be due to degradation. Only 2 adequate values are available or the value of 43 L/kg should be corrected for degradation/recovery.	**RMS** See 4.6: the 3 metabolites are far from being major. The RMS considers that this remark has no impact on the final risk assessment. **NOT:** The notifer agrees that either approach is acceptable with correction for degradation/recovery likely the better of the two approaches. However, the overall impact of the change is neglible given that the PECgw and PECsw assessments are driven by parent concentrations.	Open point: MS experts to discuss the need of the correction for degradation/recovery of the Kdoc of 43 L/kg of the metabolite 3-hydroxy-carbofuran (sandy loam soil, Speyer 2.3) or alternatively should this value completely be excluded from the exposure calculations. Note that Kdoc of 55 L/kg for 3-hydroxy-carbofuran was agreed to be used in modeling by the meeting of PRAPeR 62. See comment in Column 2 in 4(20) and open point in 4(39).

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 NOT	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(16)	B.8.2.1 sorption metabolites 3-keto-carbofuran	**NL:** In case of 3-keto-carbofuran in only 2 soils 1/n values are presented. Two values of 1.144 and 0.489 are available. The low value is not acceptable. Below a 1/n of < 0.7 no freundlich sorption is applicable.	**RMS** See 4.6: the 3 metabolites are far from being major. The RMS considers that this remark has no impact on the final risk assessment.	See comment in Column 2 in 4(20). Note: the use of 1/n of 1 was agreed at PRAPeR 62 meeting for 3-keto-carbofuran.
4(17)	B.8.2.1 sorption metabolites carbofuran-phenol	**NL:** In case of carbofuran-phenol values of 0.4, 0.5 and 0.75 are available. The low values are not acceptable. Below a 1/n of < 0.7 no freundlich sorption is applicable. Moreover the metabolite has a Vp of 1.32 Pa, so the volatility of this metabolite could also be an explanation of the low mass balance.	**RMS** See 4.6: the 3 metabolites are far from being major. The RMS considers that this remark has no impact on the final risk assessment.	See comment in Column 2 in 4(20). Note: the use of 1/n of 0.9 was agreed at PRAPeR 62 meeting for carbofuran-phenol (PECsw/sed).
4(18)	Vol. 3, B.8.2.1 Adsorption and desorption of the active substance and relevant metabolites Page 8-49	**EFSA:** In the EFSA conclusions for carbofuran and benfuracarb, the mean Koc (KFoc) of 22 ml/g (17 – 28 mL/g) for carbofuran is included (data gap was identified in this field in the carbosulfan EFSA conclusion). For PECgw and PECsw calculations for carbofuran, KFoc of 22 with 1/n of 0.96 was used in the EFSA conclusion for benfuracarb (2006). This value is supported in the carbofuran EFSA conclusion (2006) as well. Now, 23.3 mL/g as mean KFoc and 0.89 as mean 1/n value is calculated. Could RMS please clarify what is the reason for this change (see also EFSA comment?	**RMS:** The derivation of the Koc derived from the entire database (3 study reports with low Koc) is more robust. Moreover, there are no differences between a Kfoc of 22 or 23, unless it is believed that it would worsen the PEC situation.	See open point in 4(19).

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 NOT	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(19)	Vol. 3, B.8.2.1 Adsorption and desorption of the active substance and relevant metabolites Study by Bradau E G, 1976b	**EFSA:** Results from the study by Bradau were ignored by the previous peer review, but it seems that now this study is considered as valid by the RMS. Maybe it is also true for the study by Daily D. Based on the EFSA conclusion; the only study considered valid by the previous peer review is Manouni A., 2002. Could the RMS please clarify on what bases he overruled the evaluation of the previous peer review (see also EFSA comment?) The results of this study (or studies) were not used regarding benfuracarb, the study (or studies) is not summarised in the benfuracarb documentation.	**RMS** see above	Open point: RMS to cancel all the values, which were not considered as valid by the previous peer review from the LoEP. For modeling KFoc of 22 with 1/n of 0.96 has to be used for carbofuran.
4(20)	Vol. 3, B.8.2.1 Adsorption and desorption of the active substance and relevant metabolites Studies of: Noorloos, B. van; Willems, H., 2005a, 2005b, 2005c	**EFSA:** Summaries of these studies were included in the additional report of benfuracarb (2008). Comments (from UK and EFSA) on these studies and the evaluation of these comments by the RMS and the NOT can be found in the reporting table (rev 1-0, 1-12-2008) of benfuracarb. The meeting of experts for benfuracarb (PRAPeR 62, January 2009) confirmed the values from these studies to use in the modelling. Therefore further clarification is probably not necessary.	**RMS:** No comment	Addressed See also open point in 4(15).
4(21)	Vol. 1, 2.5.2, Fate and behaviour in soil, Aerobic metabolism	**DE:** RMS has excluded the aerobic soil metabolism study (Saxena A.M. et al., 1994) from the risk assessment although this study was considered of acceptable quality and taken into account in the original DAR. Please give a justification for the exclusion of the study.	**RMS:** see point 4.7	See note in 4(7).

Adsorption,desroptionand 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 NOT	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(22)	Vol. 3, B.8.2, Adsorption, desorption and mobility in soil	**FR:** p.53, Since K_{OC} value of 55 cm3/g as been selected as worst case, then 1/n value of 1 should be selected as worst case to (using K_D assume linearity). Units from the metric system should be used (L instead of cm^3).	**RMS** See 4.6: the 3 metabolites are far from being major. The RMS considers that this remark has no impact on the final risk assessment.	See comment in Column 2 in 4(20) and open point in 4(15). Note: the use of 1/n of 1 has already been agreed by the PRAPeR 62 meeting for 3-keto-carbofuran and 3-hydroxy-carbofuran.
4(23)	Vol. 3, B.8.2, Adsorption, desorption and mobility in soil	**FR:** p.54, In Table B.8.2.1-12 it's mentioned a Kfoc value of 48 cm3/g for the soil I. Then in conclusion it's mentioned that "FMC has chosen the an extreme worst case K_{OC} of 47.5cm3/g as input". K_{OC} in the text should be corrected to $K_{FOC.}$ In addition, It makes sense to round up 47.5 to 48; still for a clear understanding it would be better to harmonized data (table/text).	**RMS** See 4.6: the 3 metabolites are far from being major. The RMS considers that this remark has no impact on the final risk assessment.	Addressed Note: Koc of 47.5 L/kg (or 48 L/kg) was derived from a Kd value.
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 and then if it's appropriate to calculate a mean value with such data distribution. Maybe it would be good to keep the worst case value.	**RMS** See 4.6: the 3 metabolites are far from being major. The RMS considers that this remark has no impact on the final risk assessment.	See comment in Column 2 in 4(20). Note: the use of 1/n of 0.9 was agreed at PRAPeR 62 meeting for carbofuran-phenol (PECsw/sed).

Adsorption,desroptionand 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 NOT	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.62 (and 66). Lysimeter leachate sampling: 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.	**RMS** The lysimeter studies have not been considered in the final risk assessmemnt	Open point: EFSA to emphasize in the EFSA conclusion that the leachate samples were collected in every 14 days in both studies and this might enhance the degradation in the leachate samples.
4(26)	Vol. 3, B.8.2, Adsorption, desorption and mobility in soil	**FR:** p.62, Extraction of radioactivity: the soil was shaken twice with methanol and once with water. After soil extraction with methanol (supposed to be harsher that with water) ; how may an additional extraction with water be useful.	**RMS** The lysimeter studies have not been considered in the final risk assessmemnt **NOT:** An extraction with water could be stronger than methanol for the polar/acidic metabolites also measured in the study.	Addressed

Adsorption,desroptionand 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 NOT	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(27)	Vol. 3, B.8.2, Adsorption, desorption and mobility in soil	**FR:** p.67, We agree with the RMS that both studies might be seen as additional information, and we would like to emphasized that extrapolation to these data might be done only with respect to the apparent dry conditions. In agreement with the conclusion of the RMS, we would like to mentioned that the low amounts of product leached through lysimeters may not necessarily be seen a low leaching potential for the active substance. Indeed, in Table B.8.2.4-11 provide accurate information. It emphasized that during the first months after application (from April to July), only few leachates were collected: 17 L and 12 L for lysimeters A and B respectively. It appears that degradation of the product was enhanced by dry conditions during the months following the application. Detailed information on precipitation (at least monthly or daily data) would be good for an accurate interpretation of leaching behavior. Then it should also be emphasized that from the 3rd.07.90 to the 28th.01.91 (7 months in total) no leaching samples were collected. For both lysimeters, the main leaching event seems to occur on the 12.03.91 (with respectively 21.4 and 17.8 L collected from lysimeters A and B respectively), so almost one year after application of the product. It's also clear that when leachate volumes increase (Mars 1991, one year after application), then total residues collected in leachate increase also significantly. So compounds still present in the lysimeter (degradation no that fast, maybe due to dry conditions) is still available for leaching. Extrapolation of such data for risk assessment purpose appears difficult.	**RMS** The lysimeter studies have not been considered in the final risk assessmemnt **NOT:** The results from lysimeter study are not needed to demonstrate a safe use. Revised modelling that considers all parameter inputs suggested by EFSA and the experts results in passing scenarios for both PEARL and PELMO at the 600 g ai/ha rate for an annual application. Even more scenarios succeed at the 60 g ai/ha for annual application.	Open point: EFSA to emphasize in the EFSA conclusion that the lysimeter studies were performed under similar experimental conditions and these conditions were dry (very low percolation).
4(28)	Vol. 3, B.8.2, Adsorption, desorption and mobility in soil	**DE:** Page 8-45 ff :It is observed that Kf-values had been determined and given as Kd-values. Please replace 'Kd' by 'Kf'.	**RMS:** the DAR has been amended **NOT:** The notifier agrees with DE response.	Addressed See also open point in 4(19). Note: the DAR has not been amended (March 2009).

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 NOT	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(29)	Vol. 3, B.8.4.2, Direct phototransformation	**DE:** RMS has excluded the aqueous photolysis study of FMC. Please give an explanation for the exclusion of the study.	**RMS:** this issue has not been challenged during the previous peer review. It can be expected that the study was clearly not acceptable. Additional information was deemed not necessary.	Addressed RMS to consider providing an explanation of deficiencies of this study in a corrigendum of the additional report.
4(30)	Vol. 3, B.8.4.4 Water/sediment study Page 8-73	**EFSA:** RMS should clearly state whether the RMS agree or disagree with the argumentation given in the position paper by Shaaban F. Elnaggar, 2005.	**RMS:** An explanation is given in the level 2 of the DAR; the metabolite is not relevant.	Open point: RMS to state and explain why they agree or disagree with the argumentation given in the position paper by Shaaban F. Elnaggar, 2005 in an addendum. Note: the explanation given in the level 2 of the DAR is the same text (copy) what can be found in level 3, on the same page.

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 NOT	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(31)	Vol. 3, B.8.4.4 Water/sediment study Page 8-80	**EFSA**: It is noted that DT_{50} values for carbofuran are available from the benfuracarb dossier as well (see additional report for benfuracarb). However, these values were calculated from studies where carbofuran was formed as metabolite of benfuracarb and the values are shorter than the value, which is chosen for PEC calculation in this additional report for carbofuran. RMS please clarify moreover, what is the difference between the systems Millstream (A) and Millstream (D) in the table B.8.4.4-11? If these different values come from the same system and same study, both of them are valid and can be used?	**RMS:** The application rate is different between the 2 Millstream systems. Worst case DT50 have been chosen for PEC calculations	Open point: For completeness, RMS to include in the LoEP those whole system DT50 values those come from the benfuracarb dossier and indicate that these values were derived from studies with benfuracarb. Indicate moreover that Millstream (A) and Millstream (D) is the same system, but different application rates were used in the experiments.

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 NOT	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(32)	Vol. 3, B.8.6.1, PECgw	**FR:** p.93, Regarding PECgw calculations performed for the metabolites 7-phenol-carbofuran, 3-hydroxy-carbofuran and 3-keto-carbufuran. It's mentioned that assuming worst-case scenarios few exceedances of the 0.1 µg/L trigger might be observed. Even if the RMS mentioned that these last are not a concern; it might be good to indicated if these metabolites have toxicological relevance or not (then no concern).	**RMS:** see point 4.6 **NOT** The molecule of risk is clearly carbofuran. 7-phenol carbofuran is not a carbamate and is not toxicologically relevant. The 3 keto and 3- hydroxy forms of carbofuran are formed in smaller quanities than the parent and have at most similar toxicity to the parent. The 0.1 ppm trigger is relevant for carbofuran, 3-hydroxy carbofuran, and 3-keto carbofuran.	Open point: RMS to include in an addendum that which metabolites have toxicological relevance and which one has not.
4(33)	Vol. 3, B.8.6.1, PECgw	**FR:** p.96, Table B.8.6.2-1; 2-5; 2-9 and 2-12 In table B.8.6.2-1, plant uptake value has been set to 0 as "default value". Since carbofuran is a systemic insecticide, 0 for plant uptake would be a worst-case option (default value is 0.5 for systemic compounds).	**NOT:** The notifer agrees but would like to point out passing scenarios even when the worst case is considered.	Addressed
4(34)	Vol. 3, B.8.6.1, PECgw	**FR:** p.96, Table B.8.6.2-5 and 2-9. For the Freundlich coefficient 1/n the value 0.9 is used as "default Focus value". The default worst-case value to be used should be 1 (already discussed in previous PRAPeR meeting). In addition, since the Koc value is used, then no information on linearity or non-linearity of the isotherm might be done and the worst case value of 1 (for 1/n) may be used.	**NOT:** A value of 0.96 was used in current modelling as mentioned in expert meetings.	See comment in Column 2 in 4(20) and open points in 4(15) and 4(19).
4(35)	B.8.6.1 PECgw	**NL:** The input values DT_{50} and Koc/Kom used are not acceptable for 3-hydroxy-carbofuran and carbofuran-phenol	**RMS:** see point 4.6 **NOT:** See comment 4(36)	See comment in Column 2 in 4(20) and open point in 4(15).

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 NOT	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(36)	B.8.6.1 PECgw	**NL:** For the metabolites no adequate 1/n values are available. According to the EFSA meetings if no adequate data is available a 1/n of 1 should be used. In PRAPeR 32 it was stated: The experts agreed that when soil adsorption was only measured at a single experimental concentration, so only a Kd value could be determined, subsequent FOCUS modelling simulations should be carried out using a 1/n value of 1 (as Kd estimations assume a linear isotherm). They agreed that in this situation a 1/n of 0.9 (FOCUS guidance default) should not be used. In case of 3-hydroxy-carbofuran only Kd values are available and no measured 1/n values. In case of 3-keto-carbofuran in only 2 soils 1/n values are presented. Two values of 1.144 and 0.489 are available. The low value is not acceptable. Below a 1/n of < 0.7 no freundlich sorption is applicable. In case of carbofuran-phenol values of 0.4, 0.5 and 0.75 are available. The low values are not acceptable. Below a 1/n of < 0.7 no freundlich sorption is applicable.	**RMS:** see point 4.6 **NOT:** The notifier understands the limitations within the current dataset for the carbofuran metabolites but would like to maintain that the metabolties of carbofuran are estimated to be orders of magnitude lower in modelling predictions than parent and these recommendations do not change that fact.	See comment in Column 2 in 4(20) and open point in 4(39).
4(37)	B.8.6.1 PECgw	**NL:**It is unclear if the new Q10 value has been used. According to the Scientific Opinion of the Panel on Plant Protection Products and their Residues on a request from EFSA related to the default Q10 value used to describe the temperature effect on transformation rates of pesticides in soil the median Ea value of 65.4 kJ mol-1 corresponding to a Q10 of 2.58 is the appropriate value.	**RMS:** According to the Commission, the new Q10 would be required under the new regulation. For the moment, the Commission requests therefore flexibility in this request	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 NOT	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(38)	B.8.6.1 PECgw	**NL:** The incorporation depth is unclear. 7 cm is mentioned in B.8 and 5 cm in the LoEP.	**NOT:** The incorporation depth was 7 cm.	Open point: RMS to amend the soil incorporation depth for PECgw to 7 cm in the LoEP.
4(39)	B.8.6.1 PECgw	**NL:** Based on 1/n values for metabolites of 1, the Q10 of 65.4 higher concentrations are predicted (7 cm incorporation). Even with the non agreed input data (e.g. DT_{50} and Kom, Vp 7-phenol) a safe use in sugar beets is very limited. An expert meeting on input data (e.g. DT50 and Kom, Vp 7-phenol) is recommended. For Sevilla the results are based on spring application and not autumn.	**RMS:** see point 4.6 **NOT:** The carbofuran metabolites as stated earlier are not the major driver in the modelling predictions. The 3 keto and 3-hydroxy metabolites are formed in small quanities and have similar to lesser toxicity when compared to the parent. The 7-phenol carbofuran which can be formed in larger quantities especially under neutral to alkaline conditions is not a carbamate is many orders of magnitude less potent than the parent.	Open point: MS experts to discuss the input parameters to be used for the modelling (PECgw, PECsw), taking into consideration that the degradation and the adsorption parameters were already discussed and agreed at the meeting of PRAPeR 62. For formation fraction of 3-keto-carbofuran and 3-hydroxy-carbofuran in soil 0.1 was accepted. See open points in 4(6), 4(13), 4(15), and 4(19). See also points 4(36), 4(40), 4(41) and 4(42).
4(40)	B.8.6.1 PECsw/sed	**NL**: The comments on input data regarding degradation and sorption in soil for the metabolites are also relevant for PECsw/sed.	**RMS:** see point 4.6 **NOT:** See comment 4(39)	See open point in 4(39)

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 NOT	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(41)	Vol. 3, B.8.6.1 PEC groundwater Table B.8.6.1-1	**EFSA:** The vapour pressure data of the metabolites used for the modelling seem to be higher than those were calculated by the QSAR methods (B.8.4.6). Carbofuran-7-phenol has a relatively high vapour pressure (calculated) and the used value is almost 5 times higher. The source of the used values is indicated as DAR, 2004 in the table B.8.6.1-1, but EFSA is not able to find these values in the original DAR. Please clarify this.	**RMS:** The RMS has requested the QSAR calculations in a later stage in the procedure. The RMS has considered, taking into account the properties of 7-phenol (metabolite without the carbamate moiety, very high Koc,…) that the discrepancy for the vapour pressure (0.28 of 1.3) was not important enough to request new PEC calculations	See open point in 4(39). Open point: RMS to amend the vapour pressure data of the metabolites in the relevant boxes of the LoEP. Notes: The use of 5 times higher Vp. value in the modeling can have a significant effect on the outcome in the higher range of Vp. The set of the other Vp. data (including the value of 1.32 Pa) originates from other QSAR estimations (see benfuracarb evaluation).

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 NOT	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(42)	Vol. 3, B.8.6.1 PEC groundwater Vol. 3, B.8.6.2 PEC Surface water and sediment	**EFSA:** The proper input parameters to be used for the FOCUS modelling for carbofuran and its metabolites were discussed on the bases of the same data set during the peer review of the resubmission of benfuracarb (meeting of experts held in January 2009). For the agreed values please consider the Report of PRAPeR expert meeting 62 (15 January 2009), especially where the simulations presented here used input parameters that represent a 'better case'. Moreover please see EFSA comments No 4(12), No 4(18) No 4(31) and No 4(45).	**RMS:** taking into account the differences in terms of databases available to the benfuracarb and carbofuran notifiers, we consider that the DT50 of 12.83 days that has been proposed by the notifier is a proper estimate of the DT50. As all endpoints, this estimate of the DT50 (geomean, median,..) has a statistical uncertainty. We still consider that the DT50 of 175-444 days are outliers that are used to artificially pull the DT50 to a higher level. The term "better case" used by EFSA is clearly misleading and does not reflect our evaluation. There is no significant difference between a DT50 of 12.83 or 14 d.	See open point in 4(39) Note: difference between DT50 values like 12.83 or 14 days can be extremely significant particularly in such a case like the current one.
4(43)	Vol. 3, B.8.6.2 PEC Surface water and sediment	**EFSA:** please indicate what the '*' mark means set for the Crop Wash-off Factor in the input data tables. Were any wash off from crop considered in the calculations where the application method is a soil incorporation? The simulations used should have resulted in all applied material reaching the soil. Please clarify.	**RMS:** see notifier's comment **NOT:** Crop wash off values were calculated, but are not relevant for soil incorporation treatments. The runs were carried out using the incorporation at 7 cm settings, so all the applied material did reach the soil in the simulations.	Addressed

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 NOT	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(44)	Vol. 3, B.8.10 Residue definition	**EFSA:** EFSA still agrees with the residue definition as it is stated in the carbofuran EFSA conclusion.	**RMS:** the RMS has explained in the DAR the reasoning behind the derivation of residue definitions **NOT:** The residue definition should not include 7 phenol carbofuran. As stated in earlier comments, the compound is not a carbamate and has many orders of magnitude lower toxicity than parent and the acidic metabolites consisting of 3 hydroxy and 3-keto carbofuran.	Open point: MS experts to discuss the definition of residue. See also open point in 4(6).

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 NOT	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(45)	Vol. 1, List of Endpoints	**EFSA:** please consider the following: - the 3 DT_{50} values from the studies by Saxena and Schocken should be added to the degradation box and the median of the whole dataset (14 days) should be presented (see EFSA comment 4(12)) - please check the normalization of the soil DT_{50} values of the metabolites of carbofuran (there are different values if they are compared with the values indicated in the benfuracarb LoEP - for Koc box please consider the EFSA comment No 4(19) - for the lysimeter studies some information about the results should be included - for input parameters for FOCUS calculations please consider EFSA comments No 4(41), No 4(42) and No 4(43) - for the definition of residue please consider that EFSA still agrees with the residue definition as it is stated in the carbofuran EFSA conclusion.	**RMS:** - Our argumentation on the 3 DT_{50} values from the studies by Saxena and Schocken is given under point 4.6 - The DT50 normalisation are evaluated under B.8.1.2.1 Aerobic degradation - Our comment on Koc is given under point 4.19 - The lysimeter studies are not valid. - Residue definition : see point 4.44	Open point: RMS to amend the LoEP in line with the discussion of the meeting of experts on carbofuran.

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 NOT	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(1)	Vol. 3, B.9.1	**FR:** FR agrees with overall conclusion of RMS for birds. In addition, FR also highlights that the data from SAGIR and WIIS well underestimated the real mortality as it is assumed that only a limited percentage of the dead animals are found.	**RMS (March 2009):** The RMS takes note of this.	Addressed.
5(2)	Vol. 3, B.9.1.1, Acute oral toxicity	**DE:** Study on effects of Furadan 4F on the AChE activity. Due to the poor test design (too short observation period, lack of clinical examination) the ecotoxicological relevance of the findings can be regarded as questionable.	**RMS (March 2009):** Please refer to comments 5(3) and 5(4). The study results were not used in the ecotoxicological risk assessment. **NOT:** See comment under 5(3) and 5(4).	Addressed.
5(3)	Vol. 3, B.9.1.1, AChE depression and recovery	**NOT:** It should be noted that the aim of this study was to achieve an AChE response in order to measure the rapidity of AChE depression after ingestion of carbofuran, and the time to recovery in all dose levels. Therefore, the test doses were purposely selected to allow for an effect dose. Therefore, neither a NOAEL nor LC_{50} could be derived from the study. Clinical observations were also not recorded since it was not considered part of the study objectives. The objective with this dose level selection was to achieve a relatively high level of cholinesterase depression and have the animals recover through the maximum time point of the study (6 hrs was selected as the maximum time point since was anticipated to cause a rapid onset of ChE depression and capture recovery at all dose levels). The low dose (0.75 mg a.i./kg body weight) was selected at approximately one-tenth of the oral LD_{50} and one-fourth the high dose to yield measurable differences in ChE inhibition and recovery time (a dose level that was practical for an accurate	**RMS (March 2009):** The RMS concluded on this study: "Neither the incidence nor the degree or kind of clinical signs was noted, precluding a full interpretation of the toxicological impact of the marked brain AChE inhibition observed at any dose. Whereas, based on current study results or existing literature, brain AChE inhibition of 50-90 % would be predictive of death inbirds, it remains unclear whether inhibition rates as low as 20-50 % may have a neurotoxicological impact of ecotoxicological relevance." Therefore, since it was not possible to relate the inhibition of AChE to clinical effects, the	See open point in comment 5(16)

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 NOT	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
		dosing). The relevant endpoints generated from this study are 1) that within 15 min measurable AChE depression in birds occurs after carbofuran ingestion and 2) AChE recovery is observed after 1.1 to 4.4 hours. This information is helpful when running a tier 3 risk assessment and supports the fact that birds that are acutely exposed to carbofuran do not die due to several biological mechanism that cause them to seize from feeding or reduce the toxicity of the test item. While we appreciate the effort from the RMS in calculating a BMD_{10} / $BMDL_{10}$, we disagree that such an endpoint would be relevant and should therefore not be included in the DAR for the following reason: 1) This method was adopted by US EPA in order to provide an additional level of safety in the evaluation of risk to humans. Ecotoxicological risk assessement aims to protect the wildlife population, as opposed to a Human Risk assessment that must protect the individual. Applying the similar level of safety in the ecotoxicological risk assessment would be an over conservatism. 2) A BMD_{10} / $BMDL_{10}$ set at an arbitrary value of 5-10% AChE inhibition is already an over protection for human and not considered applicable to birds. Indeed, as mentioned by the RMS, AChE inhibition above 50 to 90% is needed to observe death of birds. Ludke et al. (1975) proposed that brain ChE activity inhibition of 50% of avian control levels was a conservative predicator of death, while other research has shown that some avian species can tolerate more severe brain ChE inhibition than 50% (Hill 1988).	study results were not used in the ecotoxicological risk assessment.	

Birds and mammals (B.9.1 and B.9.3)				
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5(4)	Vol 3, B.9.1.1, AChE depression and recovery	**NOT:** We do not believe that increasing the duration of the study - in regards to avian mortality – would be relevant. It is well documented that carbofuran is an acute toxin and birds that have survived passed the initial hours are highly unlikely to die later on. Since no significant mortalities were observed in the high dose group (3.0 mg/kg bw) at study termination (6 hrs), it is very unlikely that more death would occur beyond this time. In addition, as noted in above point, birds do survive with no observable adverse effects at ChE inhibition of up to 90%, due to the rapid reversibility of ChE inhibition. At termination birds were below 50% inhibition.	**RMS (March 2009):** RMS takes note of this but refers to the conclusion in the DAR: "Animals died in the period 30'-360' post-dosing, and the incidence was equally spread during this period. As the observation was limited to 6h post-dosing, it is unclear if further fatalities would have been observed beyond this time-frame."	Addressed.

Birds and mammals (B.9.1 and B.9.3)				
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5(5)	Vol. 3, B.9.1.2, Acute dietary toxicity	**DE:** Regarding the sub-acute dietary toxicity study to the mallard duck only the 5-Day-LD_{50} was reported. Since mortality increased over time the 14-d median lethal value (LD_{50}) of 1.6 mg/kg bw/d (corresponding to 21 ppm) should be mentioned.	**RMS (March 2009):** Several studies with mallard duck were conducted, resulting in LC_{50} values after 5 days, respectively after 14 days. The endpoints are clearly listed in Table B.9.1.12-1. RMS calculated the risk assessment with the lowest endpoint (LC_{50} (14 d) = 1.6 mg a.s./kg b.w./day). **NOT:** The 21 ppm is presumably from the 4 week feeding study (NCT 429.69-02). The 21 ppm LC50 is based on mortality at 14 day but it does not report the effects at 5 days. Therefore it can not be concluded that mortality increases over time. This is uncharacteristic of carbamates. LC50 guidelines OECD 205 and OPPTS 850.2200 is based on a 5 day dietary exposure to obtain the avian LC50. Therefore, the notifier does not find it necessary to mention a 14 day value from a non-GLP study.	Addressed.

Birds and mammals (B.9.1 and B.9.3)				
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5(6)	B.9.1.3, Subchronic and reproductive toxicity Conclusions of the RMS on the recalculation of the reproductive bird endpoints	**NOT:** The issue of reduced ovary size was most certainly not a detrimental symptom. Any time birds are forced into 12 weeks of productivity, many birds in the study will experience reproductive exhaustion and ovarian or testicular regression (withdrawal from reproductive physiology). In the wild, northern bobwhite lay a clutch of eggs within approximately 14-days. They may lay a second clutch after completing the first brooding effort or after a nest failure. This is a far cry from 12 weeks of continuous egg laying. The avian reproductive toxicity test places tremendous physiological stress on the birds, especially the females. It is entirely predictable that some birds will display regressed ovaries or testes toward the end of the egg laying period. Reviewing the number of eggs layed per mating pair would show that the birds were productive.	**RMS (March 2009):** The RMS takes note of this. The RMS has considered that the study cannot be used to assess reproductive effects because the birds (males and females) were not in optimal reproductive conditions.	Addressed.
5(7)	Volume 3, B.9.1.10, Monitoring studies, reported cases	**FR:** Even if the studies on uses of carbofuran on rice/broadcast application (indicated p. 59) are not relevant for the supported uses, these studies should be kept as additional data to highlight that despite the application method, carbofuran is highly hazardous for birds.	**RMS (March 2009):** RMS agrees with the notifier that the risk assessment should be based on the in-furrow application method in sugar beet. The high toxicity of carbofuran to birds is also demonstrated by the laboratory studies. **NOT:** See comment in 5(8). Application method is considered highly relevant since it is a means of mitigation. Therefore the notifier does not agree with the comment made by France.	Addressed.

Birds and mammals (B.9.1 and B.9.3)				
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5(8)	B.9.1.10, Monitoring studies, reported cases *Examen spécial de l'insecticide carbofuran : Impact sur la faune avienne et valeur pour l'agriculture canadienne. (1993).*	**NOT:** Whilst we value the weight of evidence approach, we would like to stress that carbofuran is used in North America in conditions significantly different compared to the EU, in particular, dose rates applied are much higher in North America. Therefore, the incidence reports from EU MSs would provide a better reflection of the potential impact of carbofuran on avian populations as it is applied in the EU.	**RMS (March 2009):** Registered rates of application range from 0.225 to 5.5 kg a.i./ha in the study of Canada (0.6 kg a.s./ha is the supported use in the EU dossier). As mentioned in the DAR, the RMS considered this reports as supportive information.	Addressed.
5(9)	B.9.1.11 Evaluation of the risk assessment submitted by the NOT	**NOT:** RMS wrote that "*the risk assessments at 400 or 60 g a.s./ha do not comply with the GAP of 600 g a.s./ha that was proposed in the original DAR*". However, the Article 15(1b) of Regulation 33/2008/EC states that "*The supported uses are the same as those that were the subject of the non-inclusion Decision. They 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*". Whilst we appreciate the efforts to calculate the Risk assessment at 600 g ai/ha, FMC did submit valid risk assessments at 60 g ai/ha and 400 g ai/ha in order to demonstrate a safe use scenario that would be supported. The RA conducted by the RMS shows that while the risk to granular intake at 600 g ai/ha is acceptable according to the EPPO scheme, the risk to secondary poisoning via ingestion of treated seedlings, earthworms and/or arthropods needs further refinement. This suggests the value of the low dose rate risk assessements, as wisely foreseen by Article 15b of the Regulation. Should the EC decide that registration of carbofuran is possible only with limitation on its maximum applied dose rate, this issue would be dealt by FMC at a national level. We are confident that efficacy is achieved at a dose rate of 60 g carbofuran/ha. It should be noted that the 91/414/EEC revision introduced major changes in the way insecticides are used on the EU market.	**RMS (March 2009):** The RMS considers that the proposal for an additional risk assessment at a reduced granular dose rate (60 g a.s./ha) corresponding to the doses used for seed treatment is not acceptable. It is indeed very questionable whether such use can be considered as a representative use : - it is not representative for the use of a granular formulation as the dosage of 60 g carbofuran/ha is much lower than the authorized dosages. The GAPs for granule formulations that were authorized in 2002 in EU MS consisted in applications at sowing or transplant time, with incorporation in the furrow at maximum rate of 600-750 g a.s./ha. (Broadcast applications were performed at even higher dosages) - it is not representative for the use of a seed treatment formulation at similar rates of 60 g a.s./ha because the exposure routes and risk assessments are	Addressed.

Birds and mammals (B.9.1 and B.9.3)				
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		Therefore, a representative use of the late '90 will not necessarily be representative of the current market. In addition, we understand that the Regulators encourage the reduction in chemical use for agriculture. A supported reduction in the application rate of carbofuran contributes to this objective. We would also like to stress that diuron was re-submitted for Annex I inclusion defending an application rate of 0.5 kg/ha, which is lower than the dose rate originaly submitted (2 kg/ha). Diuron has recently been voted positively for inclusion to Annex I on the basis of the 0.5 kg/ha safe use.	not equivalent; for example, it is obvious that the exposures of the consumer, of the operator, of the birds and mammals will be significantly different if we compare a granular application to a seed treatment - the resubmitted dossier does not contain trials performed at 60 g a.s./ha in order to determine the residue levels in bird and mammal feed items (sugar beet seedlings, earthworms, arthropods).	
5(10)	B.9.1.11 Evaluation of the risk assessment submitted by the NOT, - Risk to granule intake	**NOT:** As mentioned, the risk to birds *accidentally* or *intentionally* ingesting Furadan 5G granules is low when calculated following the EPPO scheme. However, the RMS has voiced doubts about this evaluation since *'a small bird reaches its LD50 with one granule'.* We believe that the conclusion of the EPPO scheme is validated by the incident data and PRA submitted. Please see further explanation for comments on the size and weight of granules. **Size of granules.** The size of Furadan 5G granules is determined in the Vol 3 B2 as ranging from 0.4 to 0.85 mm. A slightly different range of 0.6-0.85 mm would only propose a worst case figure since larger granules would obviously carry more carbofuran. **Weight of granules** The weight of evidence from EU incident data shows that bird 'incidents' are due to intentional poisoning and not from use in accordance with the GAP. This therefore provides further supporting information that is in agreement with the EPPO	**RMS (March 2009):** **Size of granules:** The calculations for the probabilistic risk assessment have been performed for a size range of 0.4 to 0.85 mm. If however, the size range of the granules is 0.6 to 0.85 mm or even higher (see phys/chem chapter), then indeed the real situation (higher a.s. content) is not covered by the current risk assessment. **Weight of granules:** The granule weight of 0.37 mg is not substantially supported by data in the phys/chem section. From the efficiency trial, the value of 0.87 mg was derived as explained in column 2. RMS is of the opinion that a typing error could have occurred (0.87 mg was read as 0.37 mg). In the efficiency trial, the granules found on the soil surface were calibrated. It is possible	Point of clarification: Applicant to provide more detailed information on the size of the granules. Open point: MSs to discuss in an expert meeting whether the risk assessment covers also bigger granules (0.6-0.85 mm). See also open point in comment 5(24)

Birds and mammals (B.9.1 and B.9.3)				
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		assessment for the potential risk posed from granular intake. In addition, the PRA approach also shows a low risk to birds. Therefore, the conclusion that the risk from granular uptake is low is supported by three pieces of evidence: 1) EPPO scheme, 2) Incident data and 3) PRA. This therefore demonstrates, as the risk assessment is intended to do, that the hazard, i.e. a small bird reaching an LD_{50} from the ingestion of one granule, is not observed in the field and the risk is therefore acceptable. The values of 0.37 mg granule weight and the amount of 0.0185 mg a.s./granule are used throughout the DAR and are mentioned in the EFSA conclusion on carbofuran as well. Thus these values were used in the probabilistic risk assessment. The RMS calculated the weight of 0.87 mg per granule from the study of Knäbe et al. (2008). In that study, granules that had been applied to the field and were found on the surface were weighed. The RMS calculated a mean weight from these numbers and also calculated the amount of active substance in a granule from this number: 1143 granules/g 1 granule = 1/1143 = 0.8748 mg 5% ratio of active substance => 0.87 * 0.05 = 0.0437 mg a.s./granule In contrast to: 0.37 mg / granule ; 0.0185 mg a.s. / granule (=> DAR) It is questionable whether the weight of granules that have already been applied to the field and then collected from the field surface can be used to accurately calculate the amount of a.s. from it. It could, e.g., be possible that the granules have already taken up water from the field and thus they can have become heavier. But this would not have an impact on the amount of active substance in the granule. It appears to be more appropriate to use the laboratory data on granule weight and amount of a.s. per granule	that they were heavier due to uptake of water. If the notifier disagrees with 0.0437 mg a.s./granule, this should be supported by more data. The notifier should provide experimental data on the size and weight of granules.	

Birds and mammals (B.9.1 and B.9.3)				
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		that was provided in the DAR.		
5(11)	B.9.1.11 Evaluation of the risk assessments submitted by the NOT P 9-85 Risk to granule intake	**NOT:** It is written that: *"The TER that have been derived from this assessment were compared to the annual mortality rate of these birds. However, the annual mortality data should be recalculated for the relevant period of carbofuran application. Annual mortality for linnets is around 58.5 % anf for skylarks 44.75 %. It could be assumed that the granules are available for around 2 weeks after treatment.* *Recalculated mortality for linnets is then 2.25 % and for skylarks is 1.72 %. These results are almost in the range of the mortality figures obtained for scenario 1."* However, this only means that during the assumed time period of 2 weeks the mortality that might be caused by carbofuran is at a level comparable to the natural mortality. The impact on the population, however, has to be compared to the annual mortality: Carbofuran is applied once per year and thus the described effects only occur once a year. Using the numbers stated by the RMS, a simple calculation shows that the possible impact is minor. Scenario 1 is considered to be probably unrealistic as discussed in the report. However, using the 90th percentile effect probabilities from soil 3 (3.18%) and the random soil scenario (1.34%), see the following calculation: 58.5% + 3.18% = 61.68% 58.5% + 1.34% = 59.84% The "natural" annual mortality plus the effect possibly caused by carbofuran equals to 61.68% or 59.84%, respectively. These numbers represent the annual mortality of linnets including the possible effect of carbofuran. The annual mortality of linnets fluctuates between 53% and 64%. Thus the mortality is still within the normal range of the annual mortality (since 61.68% is smaller than 64%, and 59.84% < 64%, too). One has to keep in mind that these numbers hold for scenario 1, which is considered	**RMS (March 2009):** The interpretation of the effect probabilities is that birds (linnets) with an LD_{50} value < 0.42 mg/kg die with a probability of 3.18 % in soil 3 and 1.34 % in the random soil scenario. These probabilities are in the same range as the recalculated annual mortality of 2.25 % for a period of 2 weeks. This means that during 2 weeks, carbofuran has almost the same probability of killing birds than all other natural factors. The impact of carbofuran exposure (during 2 weeks) on the population cannot be simply extrapolated as proposed by the notifier (annual mortality + additional mortality of carbofuran). Please refer to comment 5(13).	See open point in comment 5(24)

Birds and mammals (B.9.1 and B.9.3)				
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		to be simplified but rather unrealistic since it overestimates the preference for the "end of row" zone (see discussion). This example shows that the potential effects caused by carbofuran are within the normal range of mortality fluctuations. The natural population fluctuations that the populations of linnets and skylarks have to cope with are higher than the possible effect of carbofuran.		
5(12)	B.9.1.11 Evaluation of the risk assessment submitted by the NOT - Secondary poisoning – higher tier risk assessment (tier 2)	**NOT:** We note that any PT factor was not considered in the tier 2 risk assessement, arguing that "*the PD determination is based on measurements of bird crop or faeces examination of birds commuting between treated fields and untreated areas. The PT factor is therefore already taken into account in the PD factor determination*". We disagree and believe that an additional PT value should be entered in the refined risk assessment. 1) Diet data based on crop contents or faecal samples provide useful information in determining an appropriate species-specific PD value for refining the risk calculation. PDs can be used in combination with a PT value, but not replace it. In the diet samples it is analyzed what the animals had ingested in a rather short time period before the sample had been taken (minutes to hours). Birds will take food in a rather limited area in this time. 2) The purpose of including a PT factor value allows for the inclusion of the bird's behavior in the RA e.g. a change in feeding ground over the period of weeks to month. Over the period of weeks to month a field will change e.g. its growth stage. This would render the site into a less (e.g. woodpigeon and Yellow wagtail) preferred feeding area. 3) Furthermore, it is appropriate to use a PT value in the tier 2 risk assessment since the SANCO guidance accepts the use of a PT in a first tier assessment. Therefore we maintain our proposal of a PT value for the focal species.	**RMS (March 2009):** The diet composition (PD) is derived from bird crop or faeces examination of birds commuting between treated fields and untreated areas. The PT contribution is already taken into consideration into the PD factor. The RMS considers that the PT "proportion of the diet obtained in the treated area" determination should be based on the acreage sugar beet fields in a specific region. We would welcome a discussion in the expert meeting on the PD and PT factors. What are acceptable PD and PT values for relevant bird species in sugar beet crop? How would you use the bird diet information that is proposed in the "bird bible – Buxton J. M., Crocker D. R., Pascual J.A., 1998" Please refer to comments 5(23), 5(26) and 5(70).	See open point in comment 5(23)

Birds and mammals (B.9.1 and B.9.3)				
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		FMC agrees that a conservative acute PT for a Tier II assessment can be set at 1. However, a PT of 1 does not accurately reflect a short or long-term exposure. The proposed PTs for the focal species is 0.3 (for woodpigeon, yellow wagtail and skylark). For a Tier II, conservative RA, blackbird PT feeding of earthworms was set at 1. However, we believe that the TER approach for earthworm eating birds is overly conservative since earthworms will continously produce slime and therefore eliminate residue from their surface. Dr. L. Brewer provides the following comment: *"While collecting earthworms during several pesticide field studies, conducted over a span of 20 years, it has been my observation that the body slime is constantly produced and soil or granules get sloughed off with the slime as the worms move forward. When earthworms have something sticking to them that is an irritant, they produce profuse amounts of slime to remove the irritant. I have conducted unofficial (undocumented) tests consisting of rolling worms in soil then putting them in a container to see how long it takes for them to slough the soil off. Generally, this took 1-2 minutes maximum, after which the earthworms were perfectly clean again when I picked them back out of the container with forceps."* This behavior of earthworms is consistent with the very rapid decline of carbofuran residue observed in the residue studies.		

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5(13)	B.9.1.11 Evaluation of the risk assessment submitted by the NOT, - Secondary poisoning – higher tier risk assessment (tier 3)	**NOT:** It is written that: *"Numerous sources of uncertainty are imbedded in the probabilistic risk assessment (beta distribution for PT values, gamma distribution for availability of granules in the field) which are not substantiated by experimental data."* The distributions used for various parameters are based on experimental data. The source of these distributions is provided in the diagram coming with the report (Fig. 1 in case of the PT; data source: field study of the Central Science Laboratory, UK); in case of the granule distribution in the field, the data from Knäbe et al. (2008) is used. An overview of the granule distribution is shown in Fig. 5 in the report by Bastiansen & Wang (2008; FMC Study # PC-0404). The field size distribution that was used is shown in Fig. 6; the size of grit particles taken up by the focal species is taken from de Leeuw et al. (1995), the data which the distribution is based on is shown in figures 2&3. Distributions representing the body weight of the focal species are based on data from standard literature (Cramp et al., 1998, Dunning, 1993). Concluding, 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-0404).	**RMS (March 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. We would welcome a discussion in the expert meeting on the applicability of probabilistic risk assessment.	See open points in comments 5(23 and 5(24))
5(14)	B.9.1.11 Evaluation of the risk assessment submitted by the NOT, - Secondary poisoning – higher tier risk assessment (tier 2)	**NOT:** It is agreed that the residue in seedlings should consist of the sum of carbofuran and 3-OH carbofuran (which is a major metabolite in plants). We also agree that the most valuable information comes from the decline curve residue trails (Waalkens and Baltussen, 2005 - France N&S). However, we disagree with the 6.13 extrapolation factor derived from the Zietz (2008) residue trails (see below for further rationale). Instead the extrapolation factor of 2.5 set in the benfuracarb DAR is more robust since it is derived from a metabolism study. Besides, using the same extrapolation factor will build up consistency across the dossiers. We propose to use the following residue endpoints for a risk assessment at 600 g ai/ha:	**RMS (March 2009):** RMS disagrees with the statement of the notifier that the residues will decline 10 times for the lower application rate of 60 g a.s./ha, compared to the applied 600 g a.s./ha. This extrapolation should be substantiated with data, e.g. residue trial conducted at 60 g a.s./ha. For the same reason, extrapolation of the factor 2.5 from the dossier of benfuracarb (cabbage) cannot be done to the dossier of carbofuran (sugar beet).	Open point: MSs to discuss in an expert meeting which residue values in seedlings should be applied in the refined risk assessment for birds. See also open point 5(42) Note: open points 5(14) and 5(42) should be

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		Acute toxicity: use 10.4 mg/kg. At this time point, no significant 3-OH-carbofuran metabolisation has started. **Short term toxicity**: use 6.6 x 2.5 = **16.5 mg/kg** (carbofuran + 3-OH-carbofuran) **Long term toxicity**: use TWA of 2.4 x 2.5 = **6 mg/kg** (carbofuran + 3-OH-carbofuran). Residue values will be 10 times lower when conducting the risk assessment at 60 g ai/ha. The residue by Zietz (2008) analysed for carbofuran + 3-OH-carbofuran by a method (hydrolysis extraction) that enables the release of the conjugated residues. The total residues were measured at BBCH equivalent to the early time points of the decline curve (Waalkens and Baltussen, 2005) residue trails. The residues found remained lower to similar to those observed in the decline curve (DC) confirming that these DC present protective results. DALA in the residue study by Zietz (2008) are high compared to the BBCH because the dry weather conditions made the seedlings emerge slowly. Therefore, more transformation of carbofuran to 3-OH-carbofuran had time to happen in these trials which explain the abnormally high ratios of 3-OH-carbofuran compared to carbofuran. Seedlings emerged quickly in the Decline Curve from France (Waalkens and Baltussen, 2005), therefore metabolisation of carbofuran to 3-OH-carbofuran should have been less extensive, which further support the use of the 2.5 transformation factor.		discussed together.

<table>
<tr><th colspan="5">Birds and mammals (B.9.1 and B.9.3)</th></tr>
<tr><td>No.</td><td>Column 1
Reference to DAR (vol., point, page)</td><td>Column 2
Comments from Member States or applicant</td><td>Column 3
Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the NOT</td><td>Column 4
Data requirement or Open point (if data point not addressed or fulfilled)</td></tr>
<tr><td>5(15)</td><td>B.9.1.11 Evaluation of the risk assessment submitted by the NOT, - Secondary poisoning – higher tier risk assessment (tier 2)</td><td>NOT: Residue in earthworms and beetles should only consider carbofuran. Indeed, 3-OH-carbofuran is a minor metabolite in soil (<5%: see B.8.1.1.1 of original DAR) and will therefore not contaminate insects and soil dwelling arthropods in any significant concentrations. This is confirmed in the DAR of benfuracarb where the NOT Otsuka analysed both carbofuran and 3-OH-carbofuran in earthworm. These data confirms the modest contribution of 3-OH-carbofuran to the carbofuran residue.
Proposed Residue values (normalized from the measured residue obtained from Brown et al (2007) at an app rate of 375 g as/ha):
Earthworm:
<table>
<tr><th>App rate [g as/ha]</th><th>Acute [DAT 1]</th><th>Short-term [DAT 5]</th><th>Long-term [twa]</th></tr>
<tr><td>600</td><td>0.128</td><td>0.224</td><td>0.128</td></tr>
<tr><td>400</td><td>0.085</td><td>0.149</td><td>0.085</td></tr>
<tr><td>60</td><td>0.0128</td><td>0.0224</td><td>0.0128</td></tr>
</table>
Arthropods:
<table>
<tr><th>App rate [g as/ha]</th><th>Acute [DAT 1]</th><th>Short-term [DAT 5]</th><th>Long-term [twa]</th></tr>
<tr><td>600</td><td>5.84</td><td>0.512</td><td>2</td></tr>
<tr><td>400</td><td>3.89</td><td>0.34</td><td>1.33</td></tr>
<tr><td>60</td><td>0.584</td><td>0.05</td><td>0.2</td></tr>
</table></td><td>RMS (March 2009):
In absence of actual residue concentrations in invertebrates at 0.6 kg a.s./ha, the residue values were extrapolated from an application rate of 0.375 to 0.600 kg a.s./ha, according to a RUD approach.

The 3-OH-carbofuran residues were not taken into account in the calculations of the RMS since the available data don’t allow taking into account the contribution of 3-OH-carbofuran.</td><td>Addressed.</td></tr>
<tr><td>5(16)</td><td>B.9.1.11 Evaluation of the risk assessment submitted by the NOT, -</td><td>NOT: The conclusion states that “considering the large uncertainties on the numerous factors (AVT, AVD, FPM, Conc. in food, bw, half-life of ADME process, LD50) that have to be</td><td>RMS (March 2009):
RMS would welcome a discussion in the expert meeting:</td><td>Open point:
MSs to discuss in an expert meeting the</td></tr>
</table>

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 NOT	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
	Secondary poisoning – higher tier risk assessment (tier 3)	*estimated on the basis of scarce scientific evidence, and the very high risk that has been identified in 1st and 2nd tier assessments, the RMS does not take the responsibility to support this type of approach for carbofuran*". We selected the PPR panel approach for assessing pirimicarb since it is, in our knowledge, the only recognised reference in EU for conducting a tier 3 assessment of an insecticide risk against birds and mammals. Since the tier 2 risk assessment concludes on the need for further refinements, then clarification is needed on the appropriate approach and acceptable input parameters into a tier 3 risk assessment. Considering the large uncertainties in the factors two points should be noted. -First, parameters have all been conservatively estimated. E.g. the FPM has been taken from situations in which the food supply was rather optimal compared with the situation on a sugar beet field. On a sugar beet field the food intake rate will probably be lower as assumed in the RA. The body weight is based on a considerable number of individuals. For the acute endpoint we calculated the HD5 which is an appropriate method to deal with uncertainties in the RA. -Second, to cover the uncertainties two calculations have been conducted. One, assuming always the worst-case number (highest food intake rate, lowest metabolism rate etc…) and one assuming an alternative more realistic situation. Even though it cannot be excluded completely that a single individual will behave according to the worst-case assumption it is certainly unlikely that all individual of a population will always behave according to the worst case assumption in reality.	Does the expert meeting consider that the "Opinion on pirimicarb" can be used to refine the risk assessment for other active substances? Under which conditions?	refined risk assessment for birds (3rd tier) based on the approach suggested for pirimicarb. It should also be discussed if the provided data are robust enough to support such a risk assessment approach. See also comments 5(3), 5(17), 5(18), 5(29) and open point in comment 5(35)

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 NOT	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(17)	B.9.1.11 Evaluation of the risk assessment submitted by the NOT, - Secondary poisoning – higher tier risk assessment (tier 3)	**NOT:** It is written that: *"Moreover, in the conclusions of his own risk assessment for an application rate of 400 g a.s./ha, the NOT recognizes that in the worst-case scenario, woodpigeons and wagtails may ingest a lethal carbofuran dose despite any ameliorative effects associated with ADME".* Birds may ingest a lethal dose only if all worst case assumptions fall together at the same time. It should be noted that this leads to a very unrealistic scenario. E.g., it appears that in the worst-case scenario for yellow wagtails, this bird may ingest slightly more than the lethal dose before they stop feeding. However, this seems unlikely because a yellow wagtail needs to feed at its maximum food intake rate only on contaminated insects without pause for more than half an hour. In reality a bird will feed with the maximum speed only for a couple of minutes. It will ingest contaminated and non contaminated arthropods (coming from adjacent fields and field margins). It appears that in the worst-case scenario, woodpigeons may ingest a lethal carbofuran dose. However, woodpigeons are known for their 'digestive bottleneck': a digestion rate of 0.5 g per min limits passage through the gut. The uptake of the active substance into the bird is therefore limited by digestion rate rather than by the food intake rate. Hence, the maximal food intake rate can realistically be assumed to be near 0.5 g/min. Therefore, the more favourable assumptions seem to represent a more realistic case.	**RMS (March 2009):** The RMS takes note of this.	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 NOT	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(18)	B.9.1.11 Evaluation of the risk assessment submitted by the NOT, - Secondary poisoning – higher tier risk assessment (tier 3)	**NOT:** It is written that: "*The brain AChE was meaningfully and dose-dependently decreased at all doses from 15' post-dosing time on, and was extensive until 90' (at 0.75 mg/kg b.w.), 4h (at 1.5 mg/kg b.w.) and until termination (at the top-dose). Based upon the extent of inhibition compared to the control group monitored at 5' post-dose, the maximum inhibition was attained at 30' post-dose for all dosing groups, and ranged from 64, 86, and 93% inhibition at the low- mid and top-dose, respectively. According to this study, the earliest symptoms of intoxication (AChE activity in the brains) could therefore occur at a later stage (15 min). Under those circumstances, birds could ingest a lethal dose before exhibiting symptoms of intoxication.*" Even though the brain AChE was measurably decreased from 15' post-dosing time the animal could have a sensation of poisoning before carbofuran reaches the brain. The mode of action of carbamates is not restricted solely to the brain. Acetylcholine has functions both in the peripheral nervous system and in the central nervous system. In the peripheral nervous system acetylcholine activates muscles, and it is a major neurotransmitter in the autonomic nervous system. The reaction to the toxin is almost immediately as shown by the studies in the RA.	**RMS (March 2009):** RMS agrees that N-methyl Carbamates have effect on more than one tissue: all nerve fibers containing AChE receptors may be adversely affected. Generally, clinical signs are recorded at a dose above that inhibiting AChE-levels in the brain. For this reason, brain is considered the primary target organ, and brain AChE-inhibition the most sensitive relevant toxicological endpoint. A drop of 64% of the AChE activity at the lowest dose indicates the absence of a NOAEL. There is no indication from the study that the animal could have a sensation of poisoning *before* carbofuran reaches the brain, but it is of course not excluded. The risk evaluation therefore remains unaltered. Please refer also to comments 5(3) and 5(4).	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 NOT	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(19)	Volume 3, B.9.1.12 (point 6) and B.9.3.2 (point 5),	**FR:** Risk assessments for consumption of contaminated drinking water (birds and mammals). Due to the high toxicity of the active substance to birds and mammals, a calculation could be done based on the new puddle calculation formulae proposed by EFSA (EFSA journal, July 2008).	**RMS (March 2009):** A calculation for the drinking water according to EFSA journal is presented in an addendum.	Open point: RMS to provide in an addendum a risk assessment for birds for the uptake of contaminated drinking water from puddles in line with the suggestion of the PPR opinion on the science behind the GD on risk assessment for birds and mammals (EFSA Journal, July 2008)
5(20)	Vol.1, LoE, and Vol. 3, B.9.1: endpoint from bird reproduction study	**NL:** We agree with RMS that the long-term mallard study can be used to assess the effect on reproductive parameters. To avoid confusion, it would be good to indicate in the LoEP that the long-term NOEC only includes reproductive parameters and not parental mortality. We do not understand why RMS indicates (e.g. in Table B.9.1.12-1 on page 9-91) that this NOEC of 10 ppm is based on adult mortality, as clear effects on adult mortality were seen at 2, 5 and 10 ppm.	**RMS (March 2009):** This is a typing error. Indeed, the NOEC (12 weeks pre-egg laying) = 1.5 mg a.s./kg b.w./day (10 mg a.s./kg feed) is based on reproductive effects. The DAR and the List of Endpoints are corrected accordingly.	Open point: RMS to indicate in the corrected DAR and in the LoEP that the long-term reproductive NOEC for birds of 10 ppm includes only reproductive effects but not parental mortality which was observed at concentrations of 2, 5 and 10 ppm.

Birds and mammals (B.9.1 and B.9.3)				
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5(21)	Vol. 3, B.9.1: long-term bird endpoint	**NL:** The endpoint used in the long-term risk assessment is the LC_{10} of 0.64 mg/kg bw/d. We wonder if this endpoint covers the effects seen in the reproduction study with the mallard. In that study, 16 out of 35 birds died at a concentration of 2 mg/kg feed. No information is available to recalculate this to daily dose, but it is probable that it would be lower than 0.64 mg/kg bw/d, as at 10 mg/kg feed the daily dose was 1.5 mg/kg bw/d.	**RMS (March 2009):** The RMS is of the opinion that the adult mortalities observed in the reproduction study are not relevant for the risk assessment (12 weeks exposure period is an overestimation of the exposure in the field). **NOT:** The longterm endpoint is in consideration of sensitive species by using the LC10. There is no evidence that the value is lower than 0.64 mg/kg bw/day, therefore it is not relevant to mention here.	Open point: MSs to discuss the long-term endpoint to be used in the risk assessment for birds.
5(22)	Vol. 3, B.9.1.12: Risk assessment birds, uptake of granules	**NL:** We agree with RMS that the risk to birds from uptake of granules is not acceptable considering the large likelyhood of effect from uptake of only one granule.	**RMS (March 2009):** The RMS takes note of this.	Addressed.
5(23)	Vol. 3, B.9.1.12: Risk assessment birds, uptake of other food items	**NL:** We agree with RMS that the risk to birds feeding on sugar beet seedlings, beetles and earthworms is not acceptable. Further insecurities in the calculations are: use of PT and PD refinements for acute exposure is generally not acceptable; the PD of 0.3 for sugar beet seedlings for woodpigeon is not sufficiently supported (by radiotracking data) and can not be used quantitatively; the PD of 0.7 for yellow wagtail is more a PT, but is anyway not sufficiently supported for quantitative refinement; PD refinements for skylark were not accepted for benfuracarb in Praper 63.	**RMS (March 2009):** The RMS fully agrees with the comment of the notifier below. Please refer to comments 5(26) and 5(70). **NOT:** PT and PD are referenced by the guidance document as acceptable refinement routes. If these refinements – and approach we proposed in our RA are rejected, then we would like to obtain a view on what refinement route is acceptable.	Open point: MSs to discuss in an expert meeting whether the quantitative refinement of PT and PD values are sufficiently supported by data. See also comments 5(12), 5(13), 5(26).

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 NOT	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(24)	Vol. 3, B.9.1.12, Summary of effects on birds –exposure and risk assessment for birds	**DE:** According to the EPPO risk assessment scheme the risk is considered to be low, if ETR-values are below 1. This approach cannot be accepted since no safety factors were used and lethal effects might occur following ingestion of one single granule.	**RMS (March 2009):** The RMS has already concluded in the DAR that no safety factor is used in the EPPO calculations. The RMS would welcome discussion in the expert meeting. Is the EPPO scheme for calculations of risk to granules still valid? Does the meeting whish to apply a supplementary safety factor in the calculations? Please refer also to comment 5(30). **NOT:** In this case, we believe the experts should provide a clear view on what safetyfactor would be appropriate.	Open point: MSs to discuss the risk assessment for birds for the uptake of granules. See also open point in comment 5(10) and comment 5(13)
5(25)	Vol. 3, B.9.1.12, Summary of effects on birds –exposure and risk assessment for birds	**DE:** We fully agree with the conclusions by the RMS on the outcome of the risk assessment for birds. Due to the shortcomings in the reported studies and doubtful interpretation of data the risk of Furadan 5G granules to birds cannot be regarded acceptable.	**RMS (March 2009):** The RMS takes note of this.	Addressed.
5(26)	Vol. 3, B.9.1.12, 7.2 Higher tier risk assessment for birds from uptake of contaminated feed items.	**EFSA:** The PD values suggested for wood pigeon, yellow wagtail and skylark were not sufficiently supported by data. The RMS assessed the PD values as being of use in a qualitative way only. However the PD refinement was included in the TER calculation. It was referred to the dossier for benfuracarb where similar PD values were suggested. These PD values were rejected in the peer-review (see PRAPeR 63 in January 2009). Therefore it is suggested not to use the PD values in the TER calculation.	**RMS (March 2009):** The calculations with PD = 1 are already performed in the first tier. The RMS would welcome a discussion in the expert meeting: As RMS, we consider that EFSA and MS	See open point 5(23)

Birds and mammals (B.9.1 and B.9.3)				
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			have discarded our proposals for PD/PT factors, however without proposing acceptable ways for refinement: According to our last information, the new guidance opinion on risk assesment is not yet in application. We therefore invite EFSA to propose its own evaluation and to explain clearly how to perform the risk assessment for birds and mammals on the basis of the available database. - Is the guidance document SANCO/4145/ 2000 (Sept 2002) still applicable? - What are acceptable PD and PT values for relevant bird species in sugar beet crop? How would you use the bird/mammal diet information that is proposed in the "bird/mammal bible – Crocker *et al*., 1998" - How to address the determination of an acute PD factor for an acutely toxic compound? - Which interesting results can be expected from a radio-tracking study? How many replicates? How to perform this study?	Notes: If there is time left in the expert meeting it is possible to discuss the general issues raised. -Yes, SANCO/4145/ 2000 (Sept 2002) is still applicable. -This needs to be investigated by the applicant. PD – the information must be relevant for the crop and time of the year when the product is applied. -It is very difficult to demonstrate that birds don´t feed only on one food type on the acute timescale. -Guidance on PT refinement is give in SANCO/4145/ 2000

Birds and mammals (B.9.1 and B.9.3)				
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			Please refer to comments 5(23) and 5(70). **NOT:** See comment 5(23)	(Sept 2002) and also in the PPR opinion on the science behind the GD on the risk assessment for birds and mammals.
5(27)	Vol. 3, B.9.1, Risk assessment for birds for the uptake of contaminated drinking water.	**EFSA:** Carbofuran residues may be found in puddles formed after heavy rainfall. A risk assessment for the uptake of contaminated drinking water should be performed. Such a risk assessment was considered necessary in the peer-review for benfuracarb (PRAPeR 63 in January 2009).	**RMS (March 2009):** Please refer to comment 5(19).	Addressed: See open point in comment 5(19).
5(28)	Vol. 3, B.9.1, Risk assessment for birds	**EFSA:** It should be discussed in an expert meeting whether the LC_{10} of 0.64 mg/kg bw/d from can be used in the risk assessment as a surrogate for the long-term NOEC from a reproduction study. (This discussion point was already identified in the peer-review for benfuracarb – see PRAPeR 63 in January 2009)	**RMS (March 2009):** Please refer to comment 5(21).	See open point in comment 5(28).
5(29)	Vol. 3, B.9.3.1, Effects on other terrestrial vertebrates	**DE:** We agree with the RMS that the 3rd tier risk assessment of the NOT includes a lot of uncertainties on the numerous factors (FPM, concentration in food, body weight, half-life of ADME process).	**RMS (March 2009):** The RMS takes note of this. RMS would welcome a discussion in the expert meeting: Does the expert meeting consider that the "Opinion on pirimicarb" can be used to refine the risk assessment for other active substances? Under which conditions? Please refer to comment 5(16). **NOT:** See comment 5(16)	See open point 5(16)

Birds and mammals (B.9.1 and B.9.3)				
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5(30)	Vol. 3, B.9.1.12: Risk assessment mammals, granules	**NL:** RMS has calculated ETR-values without considering a safety factor, which is not according to the EPPO-scheme (which states that either a 5th percentile of the toxicity distribution or a fixed extrapolation factor should be used).	**RMS (March 2009):** RMS has calculated the risk according to the EPPO scheme considering the respective safety factors: For acute risk birds: HD_5 = 0.42 mg a.s./kg b.w. For short-term risk birds: LC_{50} / 5.7 = 1.6 / 5.7 mg a.s./kg b.w./day For long-term risk birds: NOEC / 5.7 = 0.64 / 5.7 mg a.s./kg b.w./day For acute risk mammals: LD_{50} / 3.8 = 5.3 / 3.8 mg a.s./kg b.w. For short-term risk mammals: NOAEL / 3.8 = 5 / 3.8 mg a.s./kg b.w./day For long-term risk mammals: NOAEL / 3.8 = 0.71 / 3.8 mg a.s./kg b.w./day	See open point in comment 5(31)

Birds and mammals (B.9.1 and B.9.3)				
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5(31)	Vol. 3, B.9.3.2: Risk assessment mammals, granules	**NL:** For mammals the same conclusion can be drawn as for birds: there is a large likelyhood of effect from uptake of only one or a few granules. Therefore we wonder if the risk really is acceptable.	**RMS (March 2009):** According to the theoretical calculations based on the EPPO scheme, the risk to mammals *accidentally* ingesting Furadan 5G granules when seeking food, would be acceptable: ETR are 0.049, 0.010 and 0.039 respectively for the short-term, medium-term and long -term risk assessment. Where the ETR is < 1, the risk is considered to be low. These ETR are equivalent to TER values of respectively 21, 95 and 26 showing acceptable acute and long -term risk to mammals. RMS considered the risk to mammals acceptable since they do not consume grit. Please refer to comments 5(37) and 5(38).	Open point: MSs to discuss in an expert meeting the risk assessment for mammals for the uptake of granules. See also comments 5(30), 5(37), 5(38).

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 NOT	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(32)	Vol. 3, B.9.3.2: Risk assessment mammals, uptake of seedlings, earthworms and arthropods	**NL:** We agree with RMS that the risk to mammals feeding on sugar beet seedlings, arthropods and earthworms is not acceptable. A further insecurity in the calculations is that the use of PT and PD refinements for acute exposure is generally not acceptable.	**RMS (March 2009):** The RMS takes note of this. We would welcome a discussion in the expert meeting on the PD and PT factors. What are acceptable PD and PT values for relevant mammal species in sugar beet crop? How would you use the mammal diet information that is proposed in the "mammal bible – Gurney J. E. Perrett J., Crocker D. R., Pascual J.A., 1998" Please refer to comment 5(70). **NOT:** See comment 5(23)	Open point: MSs to discuss the PD/PT values suggested in the refined risk assessment for mammals. See also comments 5(34), 5(43), 5(46)
5(33)	B.9.3.1, Effects on other terrestrial vertebrates – Risk assessment presented by NOT	**NOT:** We believe that the granule weight of 0.37 mg is correct. **Size of granules.** The size of Furadan 5G granules is determined in the Vol 3 B2 as ranging from 0.4 to 0.85 mm. A slightly different range of 0.6-0.85 mm would only propose a worst case figure since larger granules would obviously carry more carbofuran. **Weight of granules** The values of 0.37 mg granule weight and the amount of 0.0185 mg a.s./granule are used throughout the DAR and are mentioned in the EFSA conclusion on carbofuran as well. Thus these values were used in the probabilistic risk assessment. The RMS calculated the weight of 0.87 mg per granule from the study of Knäbe et al. (2008). In that study, granules that had been applied to the field and were found on the surface were weighed. The RMS calculated a mean weight from these numbers and also calculated the amount of active	**RMS (March 2009):** Please refer to comment 5(10).	See point of clarification and open point in comment 5(10)

Birds and mammals (B.9.1 and B.9.3)				
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		substance in a granule from this number: 1143 granules/g 1 granule = 1/1143 = 0.8748 mg 5% ratio of active substance => 0.87 * 0.05 = 0.0437 mg a.s./granule In contrast to: 0.37 mg / granule ; 0.0185 mg a.s. / granule (=> DAR) It is questionable whether the weight of granules that have already been applied to the field and then collected from the field surface can be used to accurately calculate the amount of a.s. from it. It could, e.g., be possible that the granules have already taken up water from the field and thus they can have become heavier. But this would not have an impact on the amount of active substance in the granule. It appears to be more appropriate to use the laboratory data on granule weight and amount of a.s. per granule that was provided in the DAR.		

Birds and mammals (B.9.1 and B.9.3)				
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5(34)	B.9.3.1, Effects on other terrestrial vertebrates – Risk assessment presented by NOT	**NOT:** We note that RMS did not consider any PT factor in the tier 2 risk assessment, arguing that "*the PD determination is based on measurements of stomach contents or faeces examination of mammals commuting between treated fields and untreated areas. The PT factor is therefore already taken into account in the PD factor determination*". We disagree and believe that an additional PT value should be entered in the refined risk assessment. 1) Diet data based on stomach contents or faecal samples provide useful information in determining an appropriate species-specific PD value for refining the risk calculation. PDs can be used in combination with a PT value, but not replace it. In the diet samples it is analyzed what the animals had ingested in a rather short time period before the sample had been taken (minutes to hours). Mammals will take food in a rather limited area in this time. 2) The purpose of including a PT factor value allows for the inclusion of the focal species' behavior in the RA e.g. a change in feeding ground over the period of weeks to month. Over the period of weeks to month a field will change e.g. its growth stage. This would render the site into a less preferred feeding area. 3) Furthermore, it is appropriate to use a PT value in the tier 2 risk assessment since the SANCO guidance accepts the use of a PT in a first tier assessment. Therefore we maintain our proposal of a PT values for the focal species.	**RMS (March 2009):** Please refer to comments 5(12) and 5(70).	See open point in comment 5(32).

Birds and mammals (B.9.1 and B.9.3)				
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5(35)	B.9.3.1, Effects on other terrestrial vertebrates – Risk assessment presented by NOT	**NOT:** In its conclusion, the RMS states that "*Considering the large uncertainties on the numerous factors (FPM, Conc. in food, bw, half-life of ADME process, LD_{50}) that have to be estimated on the basis of scarce scientific evidence, the RMS does not take the responsibility to support this type of approach for carbofuran*". We selected the PPR panel approach for assessing pirimicarb since it is, in our knowledge, the only recognised reference in EU for conducting a tier 3 assessment of an insecticide risk against birds and mammals. Since the tier 2 risk assessment concludes on the need for further refinement for herbivore mammals, then clarification is needed on the appropriate approach and acceptable input parameters into a tier 3 risk assessment. Considering the large uncertainties in the factors two points should be noted. -First, parameters have all been conservatively estimated, e.g. the FPM has been taken from situations in which the food supply was rather optimal compared with the situation on a sugar beet field. On a sugar beet field the food intake rate will probably be lower as assumed in the RA. The body weight is based on a considerable number of individuals. -Second, to cover the uncertainties two calculations have been conducted. One, assuming always the worst-case number (highest food intake rate, lowest metabolism rate etc…) and one assuming an alternative more realistic situation. Even though it cannot be excluded completely that a single individual will behave according to the worst-case assumption it is certainly unlikely that all individual of a population will always behave according to the worst-case assumption in reality.	**RMS (March 2009):** Please refer to comment 5(16). RMS would welcome a discussion in the expert meeting: Does the expert meeting consider that the "Opinion on pirimicarb" can be used to refine the risk assessment for other active substances? Under which conditions?	Open point: MSs to discuss in an expert meeting the refined risk assessment for mammals based on the approach suggested for pirimicarb. It should also be discussed if the provided data are robust enough to support such a risk assessment approach. See also open point 5(16)
5(36)	B.9.3.2.1 Risk assessment presented by	**NOT:** RMS wrote that "*the risk assessments at 400 or 60 g a.s./ha do not comply with the GAP of 600 g a.s./ha that was proposed in the original*	**RMS (March 2009):** Please refer to comment 5(9).	Addressed.

Birds and mammals (B.9.1 and B.9.3)				
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	the RMS; Supported uses	*DAR*". However, the Article 15(1b) of Regulation 33/2008/EC states that "*The supported uses are the same as those that were the subject of the non-inclusion Decision. They 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*". Whilst we appreciate the efforts to calculate the Risk assessment at 600 g ai/ha, we submitted valid risk assessments at 60 g ai/ha and 400 g ai/ha in order to demonstrate a safe use scenario. The RA conducted by the RMS shows that while the risk to granular intake at 600 g ai/ha is acceptable according to the EPPO scheme, the risk to secondary poisoning via ingestion of treated seedlings, earthworms and/or arthropods needs further refinement. This suggests the value of the low dose rate risk assessements, as wisely foreseen by Article 15b of the Regulation. Should the EC decide that registration of carbofuran is possible only with limitation on its maximum applied dose rate, this issue would be dealt by FMC at national level. Indeed, we are confident that certain technologies are efficient at dose rate equal or lower to 60 g carbofuran/ha. It should be noted that the 91/414/EEC revision induced major changes in the way insecticides are used on the EU market. Therefore, a use representative of the late '90 will not necessarily be representative of the current market. Besides, we understand that the Regulators encourage agriculture to reduce its chemical input. A reduced application rate of carbofuran contributes to this objective. We would also like to stress that diuron was re-submitted for Annex I inclusion defending an application rate of 0.5 kg/ha, which is lower than the dose rate originaly submitted (2 kg/ha). Diuron has recently been voted positively for inclusion to Annex I on the basis of the 0.5 kg/ha safe use.		

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 NOT	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(37)	Vol. 3, B.9.3.2 – 4.2, Effects on other terrestrial vertebrates	**DE:** According to the EPPO risk assessment scheme the risk is considered to be low, if ETR-values are below 1. This approach cannot be accepted since no safety factors were used and lethal effects might occur following ingestion of one single granule.	**RMS (March 2009):** Please refer to comment 5(38). **NOT:** See comment 5(24)	See open point in comment 5(31)
5(38)	Vol. 3, B.9.3.2, Risk assessment presented by the RMS (points 4 and 9)	**FR:** It is unclear what are finally the conclusions about the risk from granule consumptions for mammals. Indeed a discussion of the results of the EPPO based assessment leads, for birds, to question its relevance to represent the level of risk (see page 110). So similarly, it remains difficult to understand why, considering that 0.24-6 granules correspond to the LD_{50} and NOAEL in a body weight of 15 to 50 g, in mammals, may be deduced from the EPPO approach.	**RMS (March 2009):** According to the theoretical calculations based on the EPPO scheme, the risk to mammals *accidentally* ingesting Furadan 5G granules when seeking food, would be acceptable: ETR are 0.049, 0.010 and 0.039 respectively for the short-term, medium-term and long -term risk assessment. Where the ETR is < 1, the risk is considered to be low. These ETR are equivalent to TER values of respectively 21, 95 and 26 showing acceptable acute and long -term risk to mammals. RMS considered the risk to mammals acceptable since they do not consume grit. Please refer to comment 5(31).	See open point in comment 5(31)
5(39)	Vol. 3, B.9.3.2, Risk assessment presented by the RMS (point 9)	**FR:** FR agrees with the conclusion of RMS for the risk via beet seedlings, earthworms and arthropods consumption for mammals.	**RMS (March 2009):** The RMS takes note of this.	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 NOT	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(40)	Vol.3, B.9.3	**NL:** Considering the specific characteristics of carbofuran, the setting of the long term mammalian endpoint is a complicated issue. RMS has taken the mean of a range of very different studies, which is generally not acceptable. Furthermore, new neurotoxicity studies with carbofuran have recently become available in the mamtox section, which lead to a long-term endpoint in the mamtox section ca. 10x as low as the one proposed here. We recommend a discussion on the ecologically relevant long-term mammalian endpoint in an expert meeting.	**RMS (March 2009):** The long term risk resulting from the use of carbofuran is not the most ecologically relevant: Main toxicological effects are related to the acute effects of cholinesterase inhibition. The exposure through crop seedlings or invertebrates is short lived as indicated in the residue trials. The RMS would welcome discussion in the expert meeting to decide on the appropriate NOAEL.	Open point: MSs to discuss in an expert meeting the endpoint to be applied in the long-term risk assessment for mammals. See also comment 5(45)
5(41)	Vol. 3, B.9.3.2, Effects on other terrestrial vertebrates	**DE:** The residue levels for carbofuran on earthworms and insects in the risk assessment for mammals are based on a field trial with a much lower application rate (0.375 kg as/ha) as the intended use (0.6 kg as/ha). Moreover the residue level does not include the contribution of 3-OH-carbofuran. Therefore they can not be used in the risk assessment.	**RMS (March 2009):** In absence of actual residue concentrations in invertebrates at 0.6 kg a.s./ha, the residue values were extrapolated from an application rate of 0.375 to 0.600 kg a.s./ha, according to a RUD approach. The 3-OH-carbofuran residues were not taken into account in the calculations of the RMS since the available data don't allow taking into account the contribution of 3-OH-carbofuran. Please refer to comment 5(15).	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 NOT	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(42)	Vol. 3, B.9.3.2, Effects on other terrestrial vertebrates	**DE:** The residues of carbofuran in food (sugar beet seedlings) do not include the contribution of 3-OH-carbofuran.	**RMS (March 2009):** The RMS indicated in the DAR (Table B.9.3.2-18) why the 3-OH-carbofuran residues were not taken into account in the calculations of the RMS. "RMS considers that too much uncertainty remains on the conversion factor and has therefore presented a TER assessment based on the measurement of carbofuran alone. This element must be taken into account in the interpretation of the final risk assessment."	Open point: MSs to agree on the residues in sugar beet seedlings used in the refined risk assessment for mammals. See also open point 5(14) and comment 5(48)
5(43)	Vol. 3, B.9.3.2 – 7.2, Effects on other terrestrial vertebrates	**DE:** Refined risk assessment for the hare. As the PD is already set at 0,4 for non-grass herbs, the PT can not be set at 0,33. The PT factor is already taken into account in the PD factor determination.	**RMS (March 2009):** The RMS indicated in the DAR (Table B.9.3.2-18) that a PT of 1 has been used. "The diet composition (PD) is derived from stomach contents or faeces examination of mammals commuting between treated fields and untreated areas. The PT contribution is already taken into consideration into the PD factor. The RMS considers that the PT "proportion of the diet obtained in the treated area" determination should be based on the acreage sugarbeet fields in a specific region." Please refer to comments 5(32) and 5(70).	See open point 5(32)
5(44)	Vol. 3, B.9.3,	**DE:** Due to the fact, that the refined acute TER for insectivorous	**RMS (March 2009):**	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 NOT	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
	Effects on other terrestrial vertebrates	mammals is 2.38 and the refined long-term TER is 0.97 as well as the refined acute TER for herbivorous mammals is 4.81 and the refined long-term TER is 3.53, the risk for mammals consuming sugar beet seedlings, earthworms and arthropods is not acceptable for the intended use.	The RMS takes note of this. This is in line with the conclusion of the RMS: "The risk of carbofuran to mammals consuming sugar beet seedlings, earthworms and arthropods is not acceptable for the intended use based on insufficient information on the actual residue levels in feed items." **NOT:** These TERs – calculated using highly conservative model - are not that low. Therefore, we believe that a refine risk assessment would result in TERs >5. The experts should define what refinement route is acceptable.	
5(45)	Vol. 3, B.9.3 Risk assessment for mammals	**EFSA:** It is not fully clear which studies were included in the calculation of the mean long-term NOAEL for mammals. Details on the effects observed in the different studies which were used to calculate the mean NOAEL should be provided. The endpoint for the long-term risk assessment should be discussed in an expert meeting. (This discussion point was already identified in the peer-review for benfuracarb – see PRAPeR 63 in January 2009).	**RMS (March 2009):** Following list of endpoints are the lowest NOAELs derived from the studies : 2 generation rat study : NOAEL parental tox = 1.169 mg carbofuran/kg b.w./day (Schardein, 1990) 3 generation rat study : NOAEL parental tox = 1.2 mg carbofuran/kg b.w./day (Goldenthal, 1979b) developmental rat study : NOAEL maternal tox = 0.3 mg carbofuran/kg b.w./day (Schardein, 1989) developmental rat study : NOAEL maternal tox = 0.1 mg carbofuran/kg b.w./day (Rao,	See open point in comment 5(40)t

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 NOT	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			1978a) developmental rat study : NOAEL maternal tox > 1.2 mg carbofuran/kg b.w./day (Rodwell, 1980) developmental rat study : NOAEL maternal tox = 1.47 mg carbofuran/kg b.w./day (Rodwell, 1981) developmental rat study : NOAEL maternal tox = 1.71 mg carbofuran/kg b.w./day (Ponnock, 1994) rabbit study (gavage) : NOAEL maternal tox = 0.2 mg carbofuran/kg b.w./day (Schardein, 1990) rabbit study (gavage) : NOAEL maternal tox = 0.6 mg carbofuran/kg b.w./day (Rao, 1978b) rabbti study (gavage) : NOAEL maternal tox = 0.5 mg carbofuran/kg b.w./day (Laveglia, 1981) 60-day rat study : NOAEL = 0.1 mg carbofuran/kg b.w./day (Pant *el al*., Human Exp. Toxicol., 1995, 14, 889-894) rat study (in utero and lactational exposure) : NOAEL = 0.2 mg carbofuran/kg b.w./day (Pant *et al*., Human Exp. Toxicol., 1997, 16, 267-272) reproductive toxicity in mice : NOAEL = 0.7 mg carbofuran/kg b.w./day (Baligar and Kaliwal, Indust. Health, 2002, 40, 345-352) developmental rat study : NOAEL maternal	

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 NOT	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			tox = 0.5 mg carbofuran/kg b.w./day (Courtney *et al.*, J. Environ. Sci. Health, 1985, B(20)4, 373-406) As a reasonable worst-case scenario the mean value of former NOAEL values was used for the long-term risk assessment, mean NOAEL = 0.71 mg carbofuran/kg b.w./day. Please refer to comment 5(40).	
5(46)	Vol. 3, B.9.3 Risk assessment for mammals	**EFSA:** The PD values for the refined risk assessment for hares were derived on general considerations of the food compostion of hares. The relevance with regard to hares feeding in sugar beet fields is unclear. Particularly the refinement of the acute risk with a PD of 0.4 is highly uncertain. The information provided does not allow concluding that a hare would not feed solely on sugarbeet seedlings on the acute timescale.	**RMS (March 2009):** We would welcome a discussion in the expert meeting on the PD and PT factors. What are acceptable PD and PT values for relevant mammal species in sugar beet crop? How would you use the mammal diet information that is proposed in the "mammal bible – Gurney J. E. Perrett J., Crocker D. R., Pascual J.A., 1998" Please refer to comment 5(32).	See open point 5(32)

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 NOT	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(47)	Vol. 3, B.9.3 Risk assessment for mammals for the uptake of contaminated drinking water	**EFSA:** Carbofuran residues may be found in puddles formed after heavy rainfall. A risk assessment for the uptake of contaminated drinking water should be performed. Such a risk assessment was considered necessary in the peer-review for benfuracarb (PRAPeR 63 in January 2009).	**RMS (March 2009):** A calculation for the drinking water according to EFSA journal is presented in an addendum.	Open point: RMS to provide in an addendum a risk assessment for mammals for the uptake of contaminated drinking water from puddles in line with the suggestion of the PPR opinion on the science behind the GD on risk assessment for birds and mammals (EFSA Journal, July 2008)
5(48)	B.9.3.2.2 Risk assessment presented by the RMS; Source of uncertainty in the RA	**NOT:** It is agreed that the residue in seedlings should consist of the sum of carbofuran and 3-OH carbofuran (which is a major metabolite in plants). We also agree that the most valuable information comes from the decline curve residue trails (Waalkens and Baltussen, 2005 - France N&S). However, we disagree with the 6.13 extrapolation factor derived from the Zietz (2008) residue trails. Indeed, we believe that the extrapolation factor of 2.5 set in the benfuracarb DAR is more robust since it is derived from a metabolism study, and using the same extrapolation factor will build up consistency across the dossiers. We propose to use the following residue endpoints for a risk assessment at 600 g ai/ha: **Acute toxicity: use 10.4 mg/kg**. At this time point, no significant 3-OH-carbofuran metabolisation has stared. **Short term toxicity**: use 6.6 x 2.5 = **16.5 mg/kg** (carbofuran + 3-OH-carbofuran) **Long term toxicity**: use TWA of 2.4 x 2.5 = **6 mg/kg** (carbofuran + 3-OH-carbofuran).	**RMS (March 2009):** Please refer to comments 5(14) and 5(42).	See open point in comment 5(42)

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 NOT	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
		Residue values will be 10 times lower when conducting the risk assessment at 60 g ai/ha. The residue by Zietz (2008) analysed for carbofuran + 3-OH-carbofuran by a method (hydrolysis extraction) that enables the release of the conjugated residues. The total residues were measured at BBCH equivalent to the early time points of the decline curve (Waalkens and Baltussen, 2005) residue trails. The residues found remained lower to similar to those observed in the decline curve (DC) confirming that these DC present protective results. DALA in the residue study by Zietz (2008) are high compared to the BBCH because the dry weather conditions made the seedlings emerge slowly. Therefore, more transformation of carbofuran to 3-OH-carbofuran had time to happen in these trials which explain the abnormally high ratios of 3-OH-carbofuran compared to carbofuran. Seedlings emerged quickly in the Decline Curve from France (Waalkens and Baltussen, 2005), therefore metabolisation of carbofuran to 3-OH-carbofuran should have been less extensive, which further support the use of the 2.5 transformation factor. Furthermore, the Residue part of the dossier (B7) presents 2 carbofuran metabolism studies on sugar beet and maize seedlings (Mamouni, 2006) that confirms the extrapolation factor of 2.5 after 2 weeks or more. At the very earliest stage, these metabolism data confirm that the residue is essentially carbofuran.		

<table>
<tr><th colspan="5">Birds and mammals (B.9.1 and B.9.3)</th></tr>
<tr><td>No.</td><td>Column 1
Reference to DAR (vol., point, page)</td><td>Column 2
Comments from Member States or applicant</td><td>Column 3
Evaluation by (RMS) rapporteur and
- if available - (Co-RMS) Co-rapporteur / response from the NOT</td><td>Column 4
Data requirement or Open point (if data point not addressed or fulfilled)</td></tr>
<tr><td>5(49)</td><td>B.9.3.2.2 Risk assessment presented by the RMS; Source of uncertainty in the RA
p-9-170</td><td>NOT: Residue in earthworms and beetles should only consider carbofuran. Indeed, 3-OH-carbofuran is a minor metabolite in soil (<5%) and will therefore not contaminate insect and soil dwelling arthropods in a significant manner. This is confirmed in the DAR of benfuracarb where the NOT Otsuka analysed both carbofuran and 3-OH-carbofuran in earthworm. This data confirms the modest contribution of 3-OH-carbofuran to the carbofuran residue.
Proposed Residue values (normalized from the measured residue obtained from Brown et al (2007) at an app rate of 375 g as/ha):
Earthworm:
<table>
<tr><th>App rate [g as/ha]</th><th>Acute [DAT 1]</th><th>Short-term [DAT 5]</th><th>Long-term [twa]</th></tr>
<tr><td>600</td><td>0.128</td><td>0.224</td><td>0.128</td></tr>
<tr><td>400</td><td>0.085</td><td>0.149</td><td>0.085</td></tr>
<tr><td>60</td><td>0.0128</td><td>0.0224</td><td>0.0128</td></tr>
</table>
Arthropods:
<table>
<tr><th>App rate [g as/ha]</th><th>Acute [DAT 1]</th><th>Short-term [DAT 5]</th><th>Long-term [twa]</th></tr>
<tr><td>600</td><td>5.84</td><td>0.512</td><td>2</td></tr>
<tr><td>400</td><td>3.89</td><td>0.34</td><td>1.33</td></tr>
<tr><td>60</td><td>0.584</td><td>0.05</td><td>0.2</td></tr>
</table></td><td>RMS (March 2009):
Please refer to comments 5(15) and 5(41).</td><td>Addressed</td></tr>
</table>

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 NOT	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(50)	Vol. 3, B.9.2. (p. 9-155) Risk assessment for aquatic organisms (sediment dwellers)	**EFSA:** The TER for *C. riparius* was below the trigger of 10 on the basis of FOCUS step1 PECsed values for carbofuran-phenol. It was concluded that the risk is acceptable. However the risk assessment should be conducted also with FOCUS step2 or step3 PECsed values in order to demonstrate that the trigger of 10 is exceeded.	**RMS (March 2009):** The risk for sediment dwelling organisms is considered acceptable since the calculations in surface water (TER = 155 in Table B.9.2.16.2-6) demonstrate acceptable risk. Moreover, this TER in sediment is based on a worst case endpoint (FOCUS step 1: maximum concentration achieved in sediment). **NOT:** TER is nearly at 10. Running step 2 and step 3 would certainly demonstrate acceptable risk.	Open point: RMS to present in an addendum the TER calculations for C. riparius based on refined PECsed values (FOCUS step2 and step3).

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 NOT	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(51)	Vol. 3, B.9.2.6, Acute toxicity to aquatic invertebrates	**FR:** The study "acute toxicity of 3-Keto-Carbofuran" (Sayers, 2007b, p. 136) is acceptable but due to the actual concentration below the LOQ at the end of the test the data are of poor quality. The need for a new study, i.e. a flow-through study, should be driven by the margin of safety achieved by TER calculations.	**RMS (March 2009):** We consider that a new study is not required and that the margin of safety is sufficient (TERs between 9608 and 81667 based on FOCUS step 3 calculations). There was a calculation error which is corrected in the updated DAR. **NOT:** Flow-through study with *C. dubia* is not feasible (too small). Besides, the study was conducted with all efforts to maximize stable concentrations and maximize the exposure *C. dubia* to carbofuran since 1) Test solutions were renewed daily and 2) were prepared in laboratory well water to reduce the pH of the solutions (and therefore, decrease the hydrolysis); 3) Animals were added to the test solutions as quickly as possible after solution preparation. The use of ½ the LOQ when concentration went down <LOQ is a conservative estimate in accordance to guidance provided by the OECD.	Open point: MSs to discuss in an expert meeting whether a new acute toxicity study with 3-keto-carbofuran and *Ceriodaphnia dubia* is 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 NOT	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(52)	Vol. 3, B.9.2.9, Effects on sediment dwelling organisms	**DE:** The analysis of the studies with sediment-dwelling organisms (effects of Carbofuran-7-phenol and effects on Carbofuran) are not correct. Although the amounts of the nominal concentrations after 28 days are just 23-46 (Carbofuran-7-phenol) and 44-53 (Carbofuran) %, the endpoints are based on the nominal concentrations. The endpoints must be based on mean measured concentrations.	**RMS (March 2009):** For the study with 7-phenol, the nominal concentration of 10 mg/L corresponds to the mean measured concentration of 5.34 mg/L. For the study with carbofuran, the nominal concentration of 0.004 mg a.s./L corresponds to the mean measured concentration of 0.0032 mg a.s./L. The TER calculations based on mean measured concentrations are presented in an addendum. The outcome of the risk assessment remains unchanged.	Open point : RMS to include the mean measured concentrations from the studies with sediment dwellers and carbofuran 7-phenol and carbofuran in the LoEP and in an addendum and to provide a revised risk assessment in an addendum and to update the LoEP
5(53)	Vol. 3, B.9.2.16.1, Risk assessment for the active substance	**FR:** Could you explain why the "risk is considered to be acceptable" since there is a TER value below the trigger value for *Ceriodaphnia dubia* (8.2) with the PECsw (Step 3) of the scenario D4 (Pond) in the Table B.9.2.16.1-3 (p. 152)? The figure should trigger the need for mitigation measures.	**RMS (March 2009):** The TER value of 8.2 (scenario D4 pond) is very close to the trigger. The other scenarios gave acceptable results (TER of 11, 76 and higher). If MS whish, recalculations of the PEC and TER values can in addition be performed at the MS level. **NOT:** Only one safe use needs to be demonstrated for the purpose of Annex I inclusion. Not all scenario needs to succeed as long as at least one does. Besides, the mentioned TER is closed to the trigger.	Addressed.

Bees and non-target arthropods (B.9.4 and B.9.5)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the NOT	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(54)	Vol. 3, B.9.4.4, Effects on bees of residues on crops	**FR:** Even if the determination of residues of carbofuran in maize pollen and nectar is not relevant for the evaluation since the intended use on maize is not supported anymore, it could be useful to have the opinion of the RMS on the acceptability and on the quality of the submitted data.	**RMS (March 2009):** The company Arysta submitted during the peer review process (2005) a determination of residues of carbofuran in pollen and nectar of maize. The use in maize is no longer supported by FMC. However, for completion, the RMS has presented a short description of the data available. Considering our workload, we believe that it is not necessary to evaluate crops that are not supported.	Addressed.
5(55)	Vol. 3, B.9.5.1, Effects of the active substance on non-target terrestrial arthropods	**FR:** FR considers that the studies on Rove Beetle (Schmuck R., 1993, p. 194-195 and Schmuck R., 1993, p. 201-203) and the study on Carabid Beetles (Schmuck, 1993, p 198-200) are not acceptable since no positive control was tested in these tests.	**RMS (March 2009):** An extensive database containing laboratory studies on numerous organisms and field studies has been evaluated. We believe that the three studies are acceptable. However, if the meeting would consider these 3 studies as not be acceptable, this would not change the outcome of the risk assessment.	Open point: MSs to discuss in an expert meeting whether the studies with Rove Beetle (Schmuck R., 1993, p. 194-195 and Schmuck R., 1993, p. 201-203) and the study on Carabid Beetles (Schmuck, 1993, p 198-200) are acceptable since no positive control was tested
5(56)	Vol. 3, B.9.5.2, Effects of the formulations on non-target terrestrial arthropods (laboratory, semi-field tests)	**DE:** In the study with the beetle *Poecilus cupreus* most animals were moribund directly after application, but 80 % recovered. Since in the field no moribund beetle would survive, the 20 % mortality value is considered to underestimate the effects of the test substance.	**RMS (March 2009):** We agree with the comment of DE, but the laboratory study with *Poecilus cupreus* is overruled by the field study (Brown K. C. *et al*., 2007) at 375 g a.s./ha.	Addressed.

Bees and non-target arthropods (B.9.4 and B.9.5)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the NOT	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(57)	Vol. 3, B.9.5.2	**DE:** Effects of the formulations on non-target terrestrial arthropods (laboratory, semi-field tests). In the extended lab test (dose-response) with the beetle *Aleochara bilineata* no data on adult mortality are reported.	**RMS (March 2009):** In the study with *Aleochara bilineata* (Bruhnke C., 2002a), only effects on reproduction were reported. However, this extended laboratory test is overruled by the field study (Brown K. C. *et al*., 2007) at 375 g a.s./ha.	Addressed.
5(58)	Vol. 3, B.9.5.2	**DE:** Effects of the formulations on non-target terrestrial arthropods (laboratory, semi-field tests). The extended laboratory toxicity test with *Poecilus cupreus* on Curaterr GR 5 Blau is not acceptable. The reference substance did not show toxic effects.	**RMS (March 2009):** The study with *Poecilus cupreus* and Curraterr GR 5 Blau (Schmuck R., 1991, p. 195-196) was not considered acceptable by the RMS due to shortcomings with the reference substance. Another study with *Poecilus cupreus* and Curaterr GR 5 Blau (Schmuck R., 1991, p. 196-197) was conducted in which the positive control showed toxic results.	Addressed.
5(59)	Vol. 3, B.9.5.4,	**DE:** Effects of the formulations on non-target terrestrial arthropods (laboratory, semi-field tests). The field study on the effects of Furadan 5G (Brown, Forster, Davies, 2007) does not fully cover the application rate of 0,600 kg as/ha in sugar beet and cannot be considered in the risk assessment for arthropods.	**RMS (March 2009):** The RMS did indeed conclude this in the DAR. The field study is valuable since it showed that effects occur and recovery is observed for all insects at an application rate of 375 g a.s./ha. However, this application rate does not cover the supported use of 0.600 kg a.s./ha in sugar beet.	Addressed.
5(60)	Vol. 3, B.9.5.4,	**DE:** Effects of the formulations on non-target terrestrial arthropods (laboratory, semi-field tests). The risk of carbofuran to non-target arthropods is not acceptable for the intended use of 0,600 kg as/ha.	**RMS (March 2009):** Please refer to comment 5(59).	Addressed.

Bees and non-target arthropods (B.9.4 and B.9.5)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the NOT	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(61)	Vol. 3, B.9.5.4, Summary of effects, exposure and risk assessment for non-target terrestrial arthropods	**FR:** FR agrees with overall conclusion of RMS for non-target terrestrial arthropods.	**RMS (March 2009):** The RMS takes note of this.	Addressed.

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 NOT	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(62)	Vol. 3, B.9.6.6, Summary and risk assessment for earthworms	**FR:** Could we consider the field study performed with a capsule suspension preparation (Strömel C. *et al*., 2002) reliable for the risk assessment of a granule preparation?	**RMS (March 2009):** The position paper of the notifier is presented on p. 240-241 of the DAR. The average actual concentration in the soil at day 0 was 2.8 mg carbofuran/kg wet soil. This test concentration covers the maximum PECsoil of 0.8 mg carbofuran/kg soil. **NOT:** We refer to our position paper that was part of the re-application dossier.	Open point: MSs to discuss in an expert meeting whether the field study performed with a capsule suspension preparation (Strömel C. *et al*., 2002) can be used to address t he risk from the granular formulation suggested in the representative use.

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 NOT	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(63)	Vol. 3, B.9.7, Effects on other soil non-target macro-organisms	**FR:** The conclusion of the RMS that the risk for the other soil non-target macro-organisms is not fully acceptable at the application rate of 600 g a.s./ha indicated in the Vol. 1 level 3 (3.1 Background of to the proposed decision, p. 132) should be also indicated in the Vol.3 B.9.7 (p. 246) for a better readability.	**RMS (March 2009):** The correction is made in the updated DAR.	Open point: RMS to include a statement in the updated DAR or in an addendum that the risk to other soil dwelling macro-organissm is not addressed for the use rate of 0.6 kg a.s./ha. See also comment 5(65)
5(64)	Vol. 3, B.9.7, Effects on other non target soil organisms	**DE:** The long-term risk of carbofuran to *Folsomia candida* is not acceptable. The field study of Brown, Forster and Davies (2007) does not fully address the proposed indication of 0,6 kg as/ha and can not be considered in the risk assessment.	**RMS (March 2009):** Please refer to comments 5(59) and 5(63).	Addressed.

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 NOT	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(65)	Vol. 3, B.9.7. Risk assessment for non-target soil macro-organisms	**EFSA:** The conclusion on the risk to soil-dwelling non-target macro-organisms is unclear. The TER trigger is breached for *Folsomia candida*. In the text it is said that the risk is acceptable referring to the field study of Brown, K.C., Forster A., Davies N. A. (2007). However significant effects on collembola were observed in this study from May until September suggesting a high risk.	**RMS (March 2009):** We agree with the comment of the notifier below (effects were observed for the positive control only). The field study is acceptable. Both pitfall trap samplings and soil core analysis show no statistically significant effects compared to the control. Recovery occurs for all invertebrate taxa (including Collembola) within 2 months after application of 375 g a.s./ha. This application rate does not fully cover the supported use of 0.600 kg a.s./ha in sugar beet. The risk of carbofuran to non-target arthropods is not acceptable for the intended use of 0.600 kg a.s./ha in sugar beet. **NOT**: No significant effect of carbofuran on collembola has been observed at any time point. In contrast, significant effect of the reference molecule (chlorpyrifos) has been observed in this study from May until September.	See open point in comment 5(63)

Earthworms and other soil non-target organisms (macro and micro) (B.9.6, B.9.7 and B.9.8)				
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5(66)	Vol. 1, 2.6.4	**FR:** It is unclear why the risk posed by carbofuran to earthworms in sugar beet is acceptable in the part 2.6.4.1 and not fully addressed in the part 2.6.4.2. In addition, no mention to the other soil non-target macro-organisms was found in this part. Could you please check this point?	**RMS (March 2009):** The conclusion for earthworms is mentioned in the part 2.6.4.1, stating that the risk to earthworms in sugar beet is addressed. Under part 2.6.4.2, the conclusion for soil non-target macro-organisms is: "The long-term risk of carbofuran to *Hypoaspis aculeifer* is acceptable. The long-term risk of carbofuran to *Folsomia candida* is not acceptable based on the laboratory study. However, the field study of Brown, K. C., Forster A., Davies N.A., 2007 shows that recovery occurs for all invertebrate taxa within 2 months after application of 375 g a.s./ha. This application rate does not fully cover the supported use of 0.600 kg a.s./ha in sugar beet." The corrections are made in Vol 1, level 2.	Addressed.

Other comments				
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5(67)	Volume 3, point B.9	**FR:** FR agrees with the RMS statement for the non inclusion of the reduced granular dose rate (60 g a.s./ha) in the risk assessment.	**RMS (March 2009):** The RMS takes note of this.	Addressed.

Other comments				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the NOT	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(68)	Vol. 1, level 2, List of Endpoints	**EFSA:** The TERs for *Hypoaspis aculeifer* and *Folsomia candida* were mixed up.	**RMS (March 2009):** The List of Endpoints is corrected accordingly.	Open point: RMS to correct in the LoEP the interchanged TER values for *Hypoaspis aculeifer* and *Folsomia candida.*
5(69)	Vol. 1, Level 4 Data gaps in ecotoxicology	**EFSA:** The refined risk assessment for birds and mammals resulted in TERs below the triggers. The data gap identified in level 4 states that more information is needed on residue levels in feed items. However it is not clear if such a refinement would be sufficient to demonstrate a low risk. Further refinement may be necessary. Therefore it is suggested to broaden the wording of the data gap to "further refinement of the risk assessment to birds and mammals for the uptake of carbofuran residues in feed items is needed".	**RMS (March 2009):** The RMS would welcome discussions in the expert meeting: As RMS, we consider that EFSA and MS have discarded our proposals for PD/PT factors, however without proposing acceptable ways for refinement: According to our last information, the new guidance opinion on risk assesment is not yet in application. We therefore invite EFSA to propose its own evaluation and to explain clearly how to perform the risk assessment for birds and mammals on the basis of the available database. - Is the guidance document SANCO/4145/ 2000 (Sept 2002) still applicable? - What are acceptable PD and PT values for relevant bird species in sugar beet crop? How would you use the bird/mammal diet	Addressed. Data gaps will be defined in the meeting of experts after discussion of the open points.

Other comments				
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			information that is proposed in the "bird/mammal bible – Crocker *et al*., 1998" - How to address the determination of an acute PD factor for an acutely toxic compound? - Which interesting results can be expected from a radio-tracking study? How many replicates? How to perform this study? Is the EPPO scheme for calculations of risk to granules still valid? Does the meeting whish to apply a supplementary safety factor in the calculations? We would welcome a discussion in the expert meeting on the applicability of probabilistic risk assessment. Does the expert meeting consider that the "Opinion on pirimicarb" can be used to refine the risk assessment for other active substances? Under which conditions? The RMS would welcome discussion in the expert meeting to decide on the appropriate NOAEL for the long-term risk to mammals.	

Other comments				
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			NOT: We believe that the evaluation should consider the RA at the application rate of 60 g ai/ha (see also Article 15 1b of regulation 33/2008/EC), and the experts should define what refinement route is acceptable. For example, how could the reversibility of the carbamates AChE depression be considered in the RA?	