PEER REVIEW REPORT ON **CARBOSULFAN** 05 10 2009

TABLE OF CONTENTS

	Document	**File Name**
00	Cover page	00 carbosulfan cover
01	**All comments received on the DAR**	**01 carbosulfan all comments**
02	Reporting table all sections	02 carbosulfan rep table rev 1-1
03	All reports from PRAPeR Expert Meetings	03 carbosulfan all reports.
04	Evaluation table	04 carbosulfan eval table rev 2-1

Comments on the Draft Assessment Report on carbosulfan (EAS - Resubmission)

RMS BE

End of commenting period: 15.06.2009 (MS, NOT)

Date	Supplier	File
12.06.2009	Notifier	01 carbosulfan comments NOT (2009-06-12).doc
12.06.2009	France	02 carbosulfan comments FR (2009-06-12).doc
15.06.2009	EFSA	03 carbosulfan comments EFSA (2009-06-15).doc
15.06.2009	Germany	04 carbosulfan comments DE (2009-06-15).doc

1. Physical/Chemical Properties; Details of Uses and Further Information; Methods of Analysis (B.1-B.5)

Identity (B.1, Annex C)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 4, C.1.2.4.1-2, Validation for impurities	**Notifier**: Method precision/repeatability of method APG468 and APG 470 for impurities 3,4,5,6 and 22 is also addressed by the good linear fit of the calibration curve and the good recoveries in the accuracy test. Good results under linearity would not be possible if the system is non repeatable, and the accuracy results indicate recoveries with a decent range. Therefore, this demonstrates, on top of the replicated injection, the system repeatability.	
(2)	Vol. 4, C.1.2.4.1-2, Validation for impurities	**Notifier**: Spiked level of impurities 13 and 14 were indeed lower thant the expected level in the 5-batches. However, as it is more difficult to validate a method at lower concentration. Therefore we argue that the validation results cover the 5-batches analysis and the toxicological batches analysis.	
(3)	Vol. 4, C.1.2.4.1-2, Validation for impurities	**Notifier**: Samples are dilluted before analysis when the pre-test show that their level in one impurity will be outside the corresponding linear range tested. Therefore, impurity 10 analysis is covered by the linear range validated.	

Physical and chemical properties of the active substance (B.2.1)

No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/notifier>>: <<comment>>	

Physical, chemical and technical properties of the formulation (B.2.2)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 3, B2.2-b, Summary and conclusion	**Notifier**: We desagree that DBA is a relevant impurity and refer to the evaluation conducted by RMS in the Vol 3 B6, which acknowledges that DBA itself is not toxic. We understand the view of the RMS that BDA is the precursor of NDBA, which is a relevant impurity, however only NDBA itself is relevant. The relevant information is whether NDBA level will increase upon storage or not. In this regard, we fully agree with RMS conclusion that NDBA will remain below the trigger of 1 mg/kg as long as Marshal 10G is not stored under high temperature conditions.	

Further information (B.3)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol.3, B3.2.3, Rate of application	**Notifier:** FMC statement that carbosulfan will exhibit biological efficacy at 100 g ai/ha – if incorporated sufficiently close to seed – is supported by the seed treatment registration that use to be registered before	It should be noted that FMC resubmitted an additional dose rate of 100 g ai/ha applied as a granule, with application machinery able to concentarte the granules close to the seeds. We would like to stress that:

Further information (B.3)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
		the non-Annex I inclusion of carbosulfan. See for example 'Combocoat CBS' under the 'list of authorized uses' on page 128. 100 g carbosulfan/ha represents a maximum loading for this type of use. Whilst we appreciate the efforts to calculate the Risk assessment at 750 g ai/ha, we introduced risk assessments at 100 g ai/ha in order to increase the chances to identify a safe use scenario.	1) 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*". 2) 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.

Methods of analysis (B.5)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 3, B5.5.1, method for formulation	**Notifier:** No method for determination of DBA in Marshal 10G is necessary because DBA is not a relevant impurity. See also comment (1) under B2.2.	We refer to our position papers demonstrating that it is not intrinsically toxic and is furthermore a naturaly accuring molecule happening via degradation of proteins. We understand the view of the RMS that it is the precursor of NDBA, which is a relevant impurity, however only NDBA itself is relevant.

Other comments			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/notifier>>: <<comment>>	

2. Mammalian toxicology (B.6)

Toxicokinetics (B.6.1)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/notifier>>: <<comment>>	

Acute toxicity (B.6.2)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/notifier>>: <<comment>>	

Short-term toxicity (B.6.3)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/notifier>>: <<comment>>	

Genotoxicity (B.6.4)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/notifier>>: <<comment>>	

Section 2 - Mammalian toxicology (B.6)

Long-term toxicity and carcinogenicity (B.6.5)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/notifier>>: <<comment>>	

Reproductive toxicity (B.6.6)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/notifier>>: <<comment>>	

Neurotoxicity (B.6.7)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/notifier>>: <<comment>>	

Other toxicological studies & Medical data (B.6.8-B.6.9)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 3, B.6.8.1.1 Toxicity of dibutylamine	**Notifier:** The evaluation conducted by RMS actually demonstrates that DBA is not a relevant impurity	

Other toxicological studies & Medical data (B.6.8-B.6.9)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
		since it has no genotoxic potential and has acute toxicity less severe than carbusulfan. Whilst it is a precursor to NDBA, only NDBA itself remains the relevant impurity. As a metabolite, we agree with RMS that no risk to human nor environment will happen due to DBA.	

Summary of mammalian toxicology and setting ADI, AOEL, ARfD (B.6.10)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 3, B.6.10, setting ADI and ARfD	**Notifier:** We believe that carbosulfan ADI and ARfD should be set respectively at 0.01 mg/kg bw/d and at 0.08 mg/kg bw/day. We refere to our position paper, provided in the DAR on page 6-135	
(2)	Vol. 3, B.6.10, setting ADI, ARfD and AOEL	**Notifier** FMC refers to its comments made in the form of the carbofuran evaluation with regard to establishment of the ADI, ARfD and AOEL of carbofuran. We maintain that it sould be set at 0.001 mg/kg bw/day.	

Toxicity of the product(s) (B.6.11)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations

Section 2 - Mammalian toxicology (B.6)

Toxicity of the product(s) (B.6.11)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/notifier>>: <<comment>>	

Dermal absorption (B.6.12)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/notifier>>: <<comment>>	

Toxicity of non-active substances (B.6.13)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/notifier>>: <<comment>>	

Exposure data (B.6.14)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/notifier>>: <<comment>>	

Section 2 - Mammalian toxicology (B.6)

Other comments			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/notifier>>: <<comment>>	

3. Residues (B.7)

Storage Stability (B.7.0)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/notifier>>: <<comment>>	

Metabolism in plants (B.7.1)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/notifier>>: <<comment>>	

Metabolism in livestock (B.7.2)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/notifier>>: <<comment>>	

Residue definition (B.7.3)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/notifier>>: <<comment>>	

Section 3 - Residues (B.7)

Use pattern, critical GAP, residues trials (B.7.4 to B.7.6)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/notifier>>: <<comment>>	

Processing (B.7.7)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/notifier>>: <<comment>>	

Livestock feeding (B.7.8)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/notifier>>: <<comment>>	

Succeeding/Rotational crops (B.7.9)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/notifier>>: <<comment>>	

Section 3 - Residues (B.7)

MRLs related issues and Consumer Risk Assessment (B.7.10 to B.7.15)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 3, B.7.11, Consumer Risk Assessment	**Notifier:** FMC agrees with the Risk assessment conducted by RMS and with its conclusion. Regarding the RA for the rotational crop, it should be added that further refinement is possible if considering that only a portion of the TRR is identified as carbofuran and 3-OH-carbofuran in the harvest samples from the metabolism studies.	The metabolism studies report the following concentration of carbofuran + 3OH carbofuran expressed as % TRR: Robinson R.A., 1982 (sugar beet) reports 1.4% of TRR at 60 days in the roots and 3.3 % of TRR at 30 days in the leaves; Bixtler T.A.; 1983 (corn) reports 11.8% of TRR at harvest in husks; Reynolds J.L., 1983 (soybean) reports 0.5% of TRR at harvest in mature soybeans; Capps T.M. 1980 (rice) reports 21.4% of TRR 30 days after treatment in immature rice plants (TRR was not characterized at harvest in grain);

Other comments			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/notifier>>: <<comment>>	

4. Environmental fate and behaviour (B.8)

Route and rate of degradation in soil (B.8.1)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/notifier>>: <<comment>>	

Adsorption, desorption and mobility in soil (B.8.2)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/notifier>>: <<comment>>	

PEC in soil (B.8.3)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/notifier>>: <<comment>>	

Fate and behaviour in water and impact on water treatment procedures (B.8.4 – B.8.5)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/notifier>>: <<comment>>	

Section 4 - Environmental fate and behaviour (B.8)

PEC in surface water and ground water (B.8.6)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/notifier>>: <<comment>>	

Fate and behaviour in air and PEC in air (B.8.7 – B.8.8)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/notifier>>: <<comment>>	

Definition of the residues (B.8.9)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/notifier>>: <<comment>>	

Other comments			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/notifier>>: <<comment>>	

5. Ecotoxicology (B.9)

Birds and mammals (B.9.1 and B.9.3)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 3, B.9.1.6, Acceptance of granules	**Notifier:** The initial assessment indicates that 11 carbofuran granules are sufficient to kill a small bird. Since sufficient granules to kill a bird were potentially available, then the results suggest that either (1) the birds quickly metabolised carbosulfan and suffered no harm, or most likely (2) the birds do not take the granule because, it is proposed, they do not resemble grit. The latter reduces exposure and is consistent with the results of the EPPO scheme risk assessment.	
(2)	Vol. 3, B.9.1.8, Residue content in food items – availability of granules	**Notifier:** The conclusion on page 9-24 is incorrect in the sense that no spills were found outside the sampling area since there was no spill after 0.5 m beyond the field boundaries. Every granule obverved on the surface has been taken into account in this study.	
(3)	Vol. 3, B.9.1.8, Residue content in food items – residue in earthworms and beetle	**Notifier**: 3-OH-carbofuran was not measured in these residue trials. However, as highlighted in the Environmental Fate Section of the DAR, 3-OH-carbofuran is a minor and transient metabolite in soil. Therefore, the contribution of 3-OH to the residue in earthworms and arthropods is expected to be modest. This conclusion is confirmed in practice by the earthworm/insect residue trials that were reported in the benfuracarb DAR, where 3-OH-carbofuran was	

Birds and mammals (B.9.1 and B.9.3)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
		measured and found to contribute only modestly to the overall residue.	
(4)	Vol. 3, B.9.1.9.3, Portion of diet obtained in treated area	**Notifier**: A PT of 1 represents a worst case estimate rather than a reasonable estimate for the long term risk assessment, since it is not possible to use a higher value. Residues in insects have been shown to decline very rapidly with time. Therefore, a PT value of 1 overestimates the number of contaminated insects likely to be found. With regard to moribund insects: (1) the non-target arthropod field trials show a rapid recovery of the surface dwelling insects (that will be part of the diet) indicating that toxic effects on this important guild of insects which make up the diet are not long lasting, i.e. only short-term duaration; and (ii) as foliage density increases then any affected insects would become increasingly difficult to find in the crop. Both observations add weight to the argument that the portion of the diet from the treated area is only likely to be contaminated for a short period of time.	
(5)	Vol. 3, B.9.1.10, Monitoring studies – reported cases	**Notifier**: From the way that the WIIS Scheme is run, it might be possible that if mortality was in line with the PRA and the pirimicarb approach RA (for secondary poisoning), then this level of mortality may not be identified. However, what the results of the scheme do demonstrate is that significant bird mortality (i.e.: significant numbers of carcasses) is not being found, in line with expectations based on the deterministic	

Birds and mammals (B.9.1 and B.9.3)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
		risk assessment.	
(6)	Vol. 3, B.9.1.11, Evaluation of the risk assessment submitted by the notifier	**Notifier**: We selected the PPR panel approach for assessing pirimicarb since it is, to our knowledge, the only recognised reference in the EU for conducting a Tier 3 risk assessment for birds and mammals. Since the Tier 2 risk assessment concludes the need for further refinement, then clarification is needed concerning an appropriate approach and acceptable input parameters for a Tier 3 risk assessment. When conducting the Risk Assessment, 2 scenarios (a worst case and a favorable case) have been assessed to limit the uncertainties.	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 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*". With regard to the degree of uncertainty, two points in particular should be noted. 1. Input parameters were conservatively estimated, e.g., the FPM was taken from situations in which the food supply was rather optimal compared with the situation in a sugar beet field. In a sugar beet field the food intake rate is more likely to be probably 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 cover uncertainties in the RA. 2. Two calculations were conducted to account for uncertainties, namely one which assumed the worst case number (highest food intake rate, lowest metabolism rate, etc…) and one which alternatively assumed a more realistic exposure. While it cannot be definitively excluded that a single individual bird may behave according to the worst case assumption, it is considered improbable that all individuals in a population will behave according to the worst case assumption.

Birds and mammals (B.9.1 and B.9.3)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(7)	Vol. 3, B.9.1.11, Evaluation of the risk assessment submitted by the notifier	**Notifier:** Since carbosulfan is applied maximum once a year, the annual mortality due to carbosulfan is equal to the effect of carbosulfan granules in the first 2 weeks after application – when garnules can still be found on the surface. The estimated effect of carbosulfan on bird populations is very low compared to their natural mortality.	It is written that: "*The TER values 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 carbosulfan/carbofuran application. Annual mortality for linnets is around 58.5 % and 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: Carbosulfan 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 (6.00%) and the random soil scenario (1.61%), see the following calculation: 58.5% + 6.00% = 64.5% 58.5% + 1.61% = 60.11% The "natural" annual mortality plus the effect possibly caused by carbosulfan equal to 61.68% or 59.84, respectively. These numbers represent the annual mortality of linnets including the possible effect of carbosulfan. The annual mortality of linnets fluctuates between 53% and 64%. Thus the mortality is still within the normal range of the annual mortality (60.11% and 64.5% versus 64%). One has to keep in mind that these numbers hold for scenario 1, which is considered to be simplified but rather unrealistic since it overestimates the preference for the "end of row" zone (see discussion).

Birds and mammals (B.9.1 and B.9.3)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
			This example is supposed to show that the effect that is possibly caused by carbosulfan is 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 carbosulfan.
(8)	Vol. 3, B.9.1.11, Evaluation of the risk assessment submitted by the notifier	**Notifier:** All of the distributions used to represent the respective parameters are based on experimental data and provided as part of the report (FMC Study # PC-0403).	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-0403). 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).
(9)	Vol. 3, B.9.1.12, Risk assessment for birds – consumption of cotaminated drinking water	**Notifier:** We agree the puddle scenario overestimates the risk. Granules are buried, therefore the carbofuran metabolite will be less available at the soil surface than would be the case following a foliar treament – as assumed by the puddle scenario.	
(10)	Vol. 3, B.9.1.12, Risk assessment for birds – Higher tier RA - Residue in seedling	**Notifier:** Actual contribution of the 3-OH-carbofuran metabolite to the residue in seedling was measured in the reported seedling residue trials.	

Section 5 - Ecotoxicology (B.9)

Birds and mammals (B.9.1 and B.9.3)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(11)	Vol. 3, B.9.1.12, Risk assessment for birds – Higher tier RA - Residue in earthworms and insect	**Notifier:** 3-OH-carbofuran was not measured in these residue trials. However, the Environmental fate section highlights that 3-OH-carbofuran is a minor – and transient – metabolite in soil. Therefore, its contribution to the residue in earthworms and arthropods is expected to be modest. This conclusion is confirmed by earthworms/insects residue trails reported in the benfuracarb DAR where 3-OH-carbosuran was measured and contributed only modestly to the overall residue. See also comment (3).	
(12)	Vol. 3, B.9.1.12, Risk assessment for birds – Higher tier RA - Completeness of residue d-base	**Notifier**: To ensure consistency of the review, it is proposed that the DAR should indicate other substances for which the same extensive request (statistical distribution in number of field conditions, evaluation of ratio parent/metabolite through time) was made with regard to residue in seedlings, earthworms and arthropods.	
(13)	Vol. 3, B.9.3.2, Risk assessment for mammals	**Notifier**: The risk assessment conducted by the RMS indicates a low risk for mammals except insect eating mammals, where the acute and chronic TER are 6.63 and 2.69 respectively. However, these TERs are very close to the respective trigger values of 10 and 5. This indicates that further refinement, for example using the pirimicarb approach, will allow a safe use to be identified for these non-target organisms.	

Section 5 - Ecotoxicology (B.9)

Aquatic organisms (B.9.2)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/notifier>>: <<comment>>	

Bees and non-target arthropods (B.9.4 and B.9.5)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/notifier>>: <<comment>>	

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 draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/notifier>>: <<comment>>	

Other non-target organisms (flora and fauna), sewage treatment (B.9.9 and B.9.10)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/notifier>>: <<comment>>	

Other comments

Section 5 - Ecotoxicology (B.9)

No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/notifier>>: <<comment>>	

6. Residues (B.7)

Storage Stability (B.7.0)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol.3, B.7.14, Storage stability of residue samples (p87)	FR: It is written that 3-keto-carbofuran was shown to be stable for 11 months in sugar beet tops instead of 26 months as for other compounds, however average percent of recovered 3-keto-carbofuran is only at 47% after a storage period of 11 months, which is not between 70 and 110%. Its stability is not essential as this metabolite is not included in the residue definition.	

Residue definition (B.7.3)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 3, B.7.3, Definition of the residue (p34)	FR: residue definition has to be consistent with the residue definition of carbofuran and benfuracarb, in the framework of the dossier of these a.i.	
(2)	Vol. 3, B.7.3.1, Definition of the residue in plant products (p34 and 97)	FR : proposed metabolism pathway for plants does not correspond exactly to explanations in B.7.3.1. "3-OH-carbofuran was reduced into 3-keto-carbofuran and further hydrolysed into carbofuran-3-OH-7-phenol;" Metabolism pathway shows that it is in carbofuran-3-keto-7-phenol instead of carbofuran-3-OH-7-phenol.	
(3)	Vol. 3, B.7.3.1, Definition of the residue in plant products (p35)	FR: The efficiency of the analytical method to release all the carbofuran and 3OH-carbofuran conjugates has to be demonstrated as these compounds are included in the residue definition	

Section 3 - Residues (B.7)

Residue definition (B.7.3)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
		of plants and animals for enforcement purposes	

Use pattern, critical GAP, residues trials (B.7.4 to B.7.6)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 3, B.7.6.1., Residues resulting from supervised trials – sugar beet (p43)	FR: There is an explanation about the residue value 0.112 mg/kg which is considered as an outlier but not concerning 0.248 and 0.063mg/kg, which are also considered as outliers according to the DIXON Q-Test. Justification for these 2 outliers should be provided.	

Residues in succeeding or rotational crops (B.7.9)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 3, B.7.9, Residues in succeeding or rotational crops	FR: In the framework of the carbofuran dossier, a new rotational crop study for this substance is still on going. Therefore rotational crops that can be planted after beetroots have, for the time being, to be limited to cereals.	

7. Environmental fate and behaviour (B.8)

Route and rate of degradation in soil (B.8.1)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 3, B.8.1, Route and rate of degradation	FR: p.8-14; For the studies added in April 2009 (Willems, H., 2005a ; 2005b ; 2005c) RMS mentioned in conclusion the values to be used as inputs for further calculations. It should be clearly stated that corresponding studies are deemed acceptable.	
(2)	Vol. 3, B.8.1, Route and rate of degradation	FR: p.8-17; in accordance with the text, the geometric mean calculated for carbufuran-3-keto (3.81 d) might be inserted in an additional line in Table B.8.1.1.1-26 p8-18. Same remark for geometric mean of 0.3 d calculated for carbufuran-phenol in table B.8.1.1.1-28.	
(3)	Vol. 3, B.8.1, Route and rate of degradation	FR: p8.22. It's mentioned that data on anaerobic degradation in soil are not required based on the proposed uses. Then it's indicated "(granular application, foliar spraying)". That's the treatment timing and not the formulation which is important to expect (or not) for anaerobic conditions. By the way the formulation assessed is only Granular (foliar spraying should be taken away).	
(4)	Vol. 3, B.8.1, Route and rate of degradation	FR: p8-29. Field studies are performed with Granular and Capsule suspension formulated preparations. It is obvious that corresponding DT50 are correlated to the formulation type; DT50 of the granular form being >> DT50 from CS. Granular formulation might be seen as slow release formulation according to 95/36/CE. The worst case value for PECsoil calculations might be the geometric mean of the Granular formulation only.	

Section 4 - Environmental fate and behaviour (B.8)

Route and rate of degradation in soil (B.8.1)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(5)	Vol. 3, B.8.1, Route and rate of degradation	FR. P.8-29. If data from Nether Poppleton are not used for risk assessment purpose then they should be taken off table 8.1.3-1.	

Adsorption, desorption and mobility in soil (B.8.2)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(6)	Vol. 3, B.8.2, Adsorption, desorption and mobility in soil	FR: p.53, As already discussed in previous PRAPeR meeting, since K_{OC} values as been selected as worst case for 3-keto-carbofuran and 3-hydroxy-carbofuran, then 1/n value of 1 should be selected as worst case to (using K_D assumes isotherms linearity).. Rq. ; Unit from the metric system should be used (L instead of cm^3).	
(7)	Vol. 3, B.8.2, Adsorption, desorption and mobility in soil	FR: p.55, 1/n values calculated for carbofuran-phenol adsorption test for 3 soils range from 0.407 to 0.751 (the third value being 0.516). We wonder why there is such difference between soils. Taking the worst case value would have been conservative,	
(8)	Vol. 3, B.8.2, Adsorption, desorption and mobility in soil	FR: p.53 (and 66). Lysimeter leachate sampling (Sholtz, 1993 and 1992): It's mentioned that the leachate were collected every 14 days (as available). It should be empathized that this method might enhanced degradation in the leachate sample since time delay of 14 days (max. possible) might occur between leaching event and analysis.	
(9)	Vol. 3, B.8.2, Adsorption, desorption and mobility in soil	FR: p.54, RMS indicates that both studies (lysimeters) might be seen as additional information. It should be emphasized that extrapolation from	In agreement with the conclusion of the RMS, we would like to mentioned that the low amounts of product leached through lysimeters (Sholtz, 1993 and 1992) may not necessarily be seen a low leaching potential for the

Adsorption, desorption and mobility in soil (B.8.2)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
		these data might be done only with respect to the apparent dry conditions. Since these data are not useful for risk assessment because of the observed discrepancies, the acceptability of these studies is then questionable..	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.

PEC in soil (B.8.6)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(10)	Vol. 3, B.8.6.1, PECsoil	FR:, p.61. Since the representative use to be assessed at EU level is a granular application in the seed furrow then PECsoil should be calculated specifically for the furrow zone to account for exposure of soil macro-organisms (especially when dealing with nematicide). As performed in previous risk assessment (i.e. cadusafos), PECsoil in the	

PEC in soil (B.8.6)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
		furrow zone might be easily calculated by using a “concentration factor” (area represented by the furrow compared to the whole area) to accurately assess the exposure.	

PEC in surface water and ground water (B.8.6)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(11)	Vol. 3, B.8.6.1, PECgw	FR: p.83, Regarding PECgw calculations performed for the metabolites and more specifically 3-keto-carbufuran, few exceedances of the 0.1 µg/L trigger are observed when assessing the representative use. For other uses and other rates at MS level PECgw concentrations above 0.1µg/L might be observed and raise the question of the toxicological relevance of such metabolite (Sanco221/2000). More information on this specific point might be needed.	
(12)	Vol. 3, B.8.6.1, PECgw	FR:, see previous comment on Freundlich coefficient 1/n.	

8. Ecotoxicology (B.9)

Birds and mammals (B.9.1 and B.9.3)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol 9, point B.9.1.3: conclusions of the RM on the reclaculation of the reproductive bird endpoints, page 9-13	FR: we agree with the reasoning about the selection of endpoints for long term effects and risk assessment.	
(2)	Vol 9, point B.9.1.8: residue in earthworms and beetles, page 9-28 and page 9-33	FR: from the description of the study protocol, residues in earthworms have been quantified after a rinsing of earthworms. Residue quantification might then not be representative of residue to which birds may be exposed in the field. Was the soil content in gut extracted as well?	
(3)	Vol 9, point B.9.1.3.9.3 determination of the proportion of different food types in the diet of the focal species, page 9-9-43	FR: we agree with the reservations about the refinements, values retained by the RMS seem reasonable.	
(4)	Vol 9, point B.9.1.11, probabilistic risk assessment, pages 9-56 to 9-77	FR: the hypothesis behind the risk assessment proposed may miss some key issues somewhere, as it is strange that one could conclude to acceptable risks based on “% effects” close to 0% for a compound for which several granules may suffice to each a lethal dose or a dose affecting reproduction (from table B.9.1.12-7, page 9-85). In addition, ends of row may display the highest granule density so that birds living in vegetated area close to end row may in fact be very exposed. In general the same reservations as for	

Birds and mammals (B.9.1 and B.9.3)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
		the risk assessment that was proposed for carbofuran should be taken into account.	
(5)	Vol 9, point B.9.3.2, risk assessment for ingestion of granules, pages 9-157 to 9-165	FR: the same reservations as for birds apply (from 1.3 to 2.2 granules suffice to reach the NOEL for reproductive effects, which questions the EPPO approach and further refinement. See also comment (4).	
(6)	Vol 9, point B.9.3.2, refined risk assessment	FR: the risk assessment should be checked to be in line with expert agreements for carbofuran.	

Aquatic organisms (B.9.2)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(7)	Vol. 3, B.9.12, Microcosm and mesocosm study	FR: A reassessment of the results of the mesocosm study as been done. We agree with the conclusions of the recommendations, i.e. a NOEAEC of 0.4 µg/L, leading to an EAC of 0.1 µg/L with an AF of 4. We wonder why the RMS has set an EAC of 0.4 µg/L, which we disagree with. We therefore are in favour of a risk assessment conducted with the EAC of 0.1 µg/L and a LoEP amended with this EAC instead of 0.4 µg/L.	
(8)	Vol. 3, B.9.2.15, Summary of effects, Table B.9.2.15-1 Vol. 1, LoEP, endpoints	FR: In Vol. B.9, all acute toxicity studies to fish were considered of poor quality, essentially due to lack of analytical measurements. FR agrees with RMS. Nevertheless, these endpoints are included in the LoEP. We consider that these endpoints should	

Aquatic organisms (B.9.2)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
	on acute toxicity to fish	be removed from the LoEP and a gata gap should be set as no reliable data are available for the acute toxicity to fish.	
(9)	Vol. 3, B.9.2.15, Summary of effects, Table B.9.2.15-2 Vol. 1, LoEP, endpoints on acute toxicity to daphnids	FR: In Vol. B.9, all acute toxicity studies to daphnids were considered of poor quality, essentially due to lack of analytical measurements. FR agrees with RMS. Nevertheless, these endpoints are included in the LoEP. We consider that these endpoints should be removed from the LoEP and a gata gap should be set as no reliable data are available for the acute toxicity to daphnids.	
(10)	Vol. 3, B.9.2.15, Summary of effects, Table B.9.2.15-5 Vol. 1, LoEP, endpoints on the mesocosm study	FR: Considering our comment no (7), either replace the value of 0.4 µg/L by 0.1 µg/L, or replace the term EAC by NOEAEC.	
(11)	Vol. 3, B.9.2.16.1, Risk assessment for the active substance	FR: Considering our comments no (8) and (9), the endpoints for acute toxicity to fish and daphnids can not be used for the risk assessment , and values should be removed from Tables B.9.2.16.1-1, B.9.2.16.1-2 and B.9.2.16.1-3.	

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 draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(12)	Vol. 1, LoEP, Endpoints on soil macro-organisms	FR: Th NOEC values expressed as active substance for *Hypoaspis* and *Folsomia* are inverted.	

Section 5 - Ecotoxicology (B.9)

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 draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(13)	Vol. 3, B.9.6.6, Risk assessment for earthworms Vol. 1, LoEP, Field studies on earthworms	FR: The risk assessment is based on a PECsoil calculated for the whole surface. As mentioned in our comment no 4(10) in the e-fate section, as the representative use to be assessed at EU level is a in-furrow granular application, the PECsoil should be calculated specifically for the furrow zone to account for exposure of soil macro-organisms. New calculations should therefore be conducted in order to compare the application rate of the field study to this new PEC, and verify if the field study really covers the exposure of earthworms in the furrow. The conclusion has also to be revised in view of this assessment. The LoEP has to be amended also.	

9. Physical/Chemical Properties; Details of Uses and Further Information; Methods of Analysis (B.1-B.5)

Identity (B.1, Annex C)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol 4, general	EFSA: The applicant has proposed a new specification supported by new methods and batch analysis. According to Article 15 1a of Regulation 33/2008 this active substance is not eligible for submission under the accelerated procedure.	
(2)	Vol 4, C.1.2.2, new specification	EFSA: 5-chlorocarbofuran is a relevant impurity and it should have a numerical value in the specification.	
(3)	Vol 4, table C.1.2.3-4, tox batch	EFSA: This batch has N-Nitroso-dibutylamine at levels above 1 mg/kg. Is this batch a commercial batch manufactured by the current method of manufacture.	

Physical, chemical and technical properties of the formulation (B.2.2)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(4)	Vol 3, B.2.2.1.9b, shelf life	EFSA: This is still a data gap shelf life with analysis of 5-chlorocarbofuran and N-nitrosodibutylamine	

No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(5)	Vol. 3, B.5.5.2, new plant method	EFSA: These are the same studies as seen for carbofuran so the out come of the carbofuran peer review will have to be taken in to account.	

2. Mammalian toxicology (B.6)

Toxicokinetics (B.6.1)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/notifier>>: <<comment>>	

Acute toxicity (B.6.2)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/notifier>>: <<comment>>	

Short-term toxicity (B.6.3)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/notifier>>: <<comment>>	

Genotoxicity (B.6.4)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/notifier>>: <<comment>>	

Long-term toxicity and carcinogenicity (B.6.5)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/notifier>>: <<comment>>	

Reproductive toxicity (B.6.6)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/notifier>>: <<comment>>	

Neurotoxicity (B.6.7)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/notifier>>: <<comment>>	

Other toxicological studies & Medical data (B.6.8-B.6.9)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 3, B.6.8.1.1, toxicity of dibutylamine	EFSA: It is noted that the experts at EPCO 33 required a full *in vitro* data package on the metabolite dibutylamine, however only an Ames test was provided. It should be further discussed if	

Other toxicological studies & Medical data (B.6.8-B.6.9)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
		the data requirement is fulfilled.	

Summary of mammalian toxicology and setting ADI, AOEL, ARfD (B.6.10)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 3, B.6.10.2, ADI	EFSA: It is noted that the JMPR assessment is still using the 2-year rat study as a basis for the ADI setting, even when the acute neurotoxicity study was available. Therefore it might be useful to indicate that this was also considered to enhance transparency.	

Toxicity of the product(s) (B.6.11)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/notifier>>: <<comment>>	

Dermal absorption (B.6.12)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 3, B.6.12.2, comparative dermal	EFSA: According to the guidance document on dermal absorption, when only an *in vitro* study is	

Dermal absorption (B.6.12)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
	absorption *in vitro*	available, the results with human skin should be preferred, however in this case where a lower recovery was obtained with human skin, the use of the rat dermal absorption values is agreed. However it might be considered to use a rounding to 1 % when such low results are found (< 1 %). This approach would also account for a slightly lower total recovery than 100 %. Given the operator exposure assessment presented with the PHED model, even if this proposal is agreed, this is not expected not alter significantly the outcome of the overall risk assessment.	

Toxicity of non-active substances (B.6.13)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/notifier>>: <<comment>>	

Exposure data (B.6.14)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>,	<<MS/notifier>>: <<comment>>	

Section 2 - Mammalian toxicology (B.6)

Exposure data (B.6.14)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
	<<description>>		

Other comments			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<<MS/notifier>>: <<comment>>	

3. Residues (B.7)

Storage Stability (B.7.0) B.7.14 in carbosulfan DAR			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations

Metabolism in plants (B.7.1)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol.3, B.7.1 Plant metabolism -general	EFSA: It is noted that previous comments and decisions with regard to metabolism studies other than sugar beet (1st peer review 2005/2006) still apply. The EFSA comments on the resubmission will focus only on the notified use, i.e. sugar beet with soil application.	

Metabolism in livestock (B.7.2)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations

Residue definition (B.7.3)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. B.7.3.1 Residue	EFSA: Though there might be limitations in the	

Section 3 - Residues (B.7)

Residue definition (B.7.3)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
	definition plant	submitted soil applied metabolism studies, it is agreed that, given the similarity of the notified use compared to the assessed uses for benfuracarb (soil treated brassica vegetable) and carbofuran (soil treated sugar beet) the same residue definition with regard to the carbosulfan metabolite carbofuran should apply (carbofuran/3-OH- carbofuran and their conjugates).	
(2)	Vol. B.7.3.2 Residue definition animal products	EFSA: Given the data gaps identified in the meeting PRAPeR 70 with regard to conjugated residues in animal products, is there any more information to address the issue to be retrieved from the available animal studies with carbosulfan?	
(3)	Vol. B.7.3. Residue definition –tox relevance of metabolites in plants and livestock	EFSA: Nitrosamine structures may be generated from dibutylamine (DBA), one of the major metabolites of carbosulfan. In a previous meeting EPCO 34, it was agreed, that DBA should also be considered as a candidate component for both plant and animal residue definition for risk assessment purposes. There should be some more elaboration on the potential of the generation of nitrosamines from DBA.	
(4)	Vol. B.7.3. Residue definition –tox relevance of metabolites in plants and livestock	EFSA: It is mentioned that 3-keto-carbofuran is less toxic than carbofuran. This statement is contradictory to previous decisions of the toxicology meeting were it was agreed that, in analogy to 3-OH carbofuran, the reference values of carbofuran should apply for 3-keto-carbofuran.	

Section 3 - Residues (B.7)

Residue definition (B.7.3)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
		Clarification on this issue is needed.	

Use pattern, critical GAP, residues trials (B.7.4 to B.7.6)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 3, B.7.6 Supervised residue trials- Analytical methods	EFSA: Was the hydrolysis step used in the methods in residue trials with carbosulfan validated to quantitatively release / determine conjugates?	
(2)	Vol. 3, B.7.6.1 Supervised residue trials- Sugar beet	EFSA: Three results found in sugar beet residue trials were deleted as outliers, of them two in the same set of data . If at all, only one figure being significantly different from the rest of the data set may possibly be considered an outlier, but stepwise elimination of more than one result is not intended by this 'rule'. As agreed in previous EPCO and PRAPeR meetings, values should not be deleted if no obvious error has occurred in the trial because these results may be true values. If a trial is found not valid (as apparently the trial that comes to the result of 0.112 mg/kg in roots), the result should not be called an outlier. Any such explanation on the results from the other trials (0.248 and 0.063 mg/kg) is missing.	
(3)	Vol. 3, B.7.6.2 to Vol. 3, B.7.6.4 -Supervised residue trials- Maize,	EFSA: These data were not reviewed by EFSA as they are not relevant to the notified use in sugar beet. Previous comments and decisions with	

Use pattern, critical GAP, residues trials (B.7.4 to B.7.6)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
	cotton, citrus	regard to these trials (EPCO 34) still apply.	

Processing (B.7.7)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 3, B.7.7.1 Nature of residue and Vol. 3, B.7.7.2 Level of residue	EFSA: The relevance of the studies to reflect conditions of sugar beet processing is questionably, considering the tests were carried out at room temperature. The conclusions of PRAPeR 70 may apply with regard to the fate of the carbofuran part of the molecule, however the potential to generate degradation / conversion products of DBA that could be of concern (nitrosamine structure), is not considered as addressed by the available data.	

Livestock feeding (B.7.8)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations

Succeeding/Rotational crops (B.7.9)

Section 3 - Residues (B.7)

No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol.3, B.7.9 Rotational crops	EFSA: The position paper summarised here does not address a situation of short plant back intervals. Moreover does the new confined study indicate significant residues could be expected. This is in line with the conclusion by PRAPeR TC05 and PRAPeR 70 regarding carbofuran residues in rotated crops . It is again noted that in the light of the toxicological properties and low reference values for the carbofuran and 3-OH metabolite the trigger of 0.01 mg/kg is not applicable, as a consumer risk may be identified with even lower residue levels. Further data is expected.	

MRLs related issues and Consumer Risk Assessment (B.7.10 to B.7.15)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 3, B.7.11 Consumer Risk Assessment	EFSA: EFSA: Consumer safety: EFSA does not agree with the RMS conclusion that there are no chronic and acute exposure concerns since current assessment indicates an acute risk for consumers related to the notified use. Available data do not allow for further refinement. Further data are required, but for the time being the identified risk could only be mitigated by imposing restrictions to the notified use.	
(2)	Vol. 3, B.7.11 Consumer Risk Assessment	EFSA: New residue trial data clearly indicate the presence of carbosulfan, carbofuran and 3-OH	

MRLs related issues and Consumer Risk Assessment (B.7.10 to B.7.15)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
		carbofuran residues in sugar beet though at levels below the lowest validated level of quantification (see Table B.7.6.1-1) Given all 3 compounds have the same mode of action (cholinesterase inhibition) a combined exposure / risk assessment, should be conducted considering the different tox potency of carbofuran (plus 3-OH carbofuran) and carbosulfan.	
(3)	Vol. 3, B.7.12 MRLs	EFSA: It is noted that the proposed MRL for sugar beet will exceed the tox reference values in a consumer risk assessment (considering residue level equal to the MRL). Should the setting of MRLs for food of animal origin be considered (reference is made to PRAPeR 70 decision)?	

4. Environmental fate and behaviour (B.8)

Route and rate of degradation in soil (B.8.1)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	General for fate	EFSA: there are three different studies in the section of environmental fate and behaviour performed by Völkel 2007. These should have been distinguished	
(2)	Vol. 3, B.8.1.2. Rate of degradation, Table B.8.1.2.1-5 and B.8.1.1.1 Aerobic degradation in soil, Study by Baumann J., 2002	EFSA: The soil classification of the soil called St. Amand is different in the different chapters of the additional report (wrong in the study description). It is a silt loam soil under the USDA classification scheme (if data in the Table B.8.1.1.1-1 are correct). No clay-silt soil considered under FOCUS guidelines. Please check this and check the normalization of the DT50 value derived from this soil.	
(3)	Vol. 3, B.8.1.2. Rate of degradation, B.8.1.1.1 Aerobic degradation in soil, Study by Baumann J and Ferreira J., 2001	EFSA: The soil is called as St. Amand however it seems that under B.8.1.2 it has another name which appears not clarified in the study description. Please clarify this. The soil is classified under the German textural class as silt loam soil; however for the procedure of the DT50 normalization, the standard soil moisture value at pF2 for silt loam soil classified under the USDA classification scheme was used. Please clarify this, check the soil classification and check the normalization of the DT50 value derived from this soil.	

Section 4 - Environmental fate and behaviour (B.8)

Route and rate of degradation in soil (B.8.1)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(4)	Vol. 3, B.8.1.1.1 Aerobic degradation in soil, Study by Baumann J and Ferreira J., 2001	EFSA: Either the DT50 or the DT90 value or the used kinetic reported in the conclusions is wrong (or all of them). Please clarify. Moreover the new sentence in the conclusions is not clear.	
(5)	Vol. 3, B.8.1.1.1 Aerobic degradation in soil Studies of: Willems, H., 2005a, Willems, H., 2005b, Willems, H., 2005c	EFSA: Summaries of these studies were included in the additional report of benfuracarb (2008) and additional report of carbofuran (2008). Comments from several MSs and EFSA on these studies had already been evaluated by the RMS; the critical issues regarding these studies and the endpoints to be used had been discussed and agreed in the meetings of experts (see Report of PRAPeR expert meeting 62 and 67, 2009). Therefore further clarification is probably not necessary.	
(6)	Vol. 3, B.8.1.1.1 Aerobic degradation in soil, Study by Völkel, 2007, Table B.8.1.1.1-29	EFSA: The same value is reported for OC% and OM% content for the sand soil. Please clarify this. Check and confirm (or clarify) moreover please the CaCO3 content of the silt loam soil.	
(7)	Vol. 3, B.8.1.1.1 Aerobic degradation in soil, Study by Völkel, 2007	EFSA: It is stated in the 'Findings' that the low recoveries (reported values were normalized to time 0) of the experiments are due to the rapid and strong binding to soil, however from the study description of the adsorption/desorption study of dibutylamine the rapid and strong binding is not that evident. After clarification of that what is the proper vapour pressure and water solubility of this	

Route and rate of degradation in soil (B.8.1)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
		metabolite (see relevant EFSA comment on PECsw and PECsed) RMS please consider whether the results of this study can be regarded as DegT50s or DisT50 values.	
(8)	Vol. 3, B.8.1.1.1 Aerobic degradation in soil, Study by Völkel, 2007	EFSA: It seems that the determination of the degradation rate parameters of dibutylamin did not follow the recommendations of the FOCUS kinetic guidance. Based on FOCUS kinetics the degradation/dissipation of dibutylamin (DT50 / DT90) might be longer than indicated in the Table B.8.1.1.1-31 and kinetics might not be SFO. Please check this and calculate the DT50 values based on the recommendations of the FOCUS kinetic guidance and report the LOQ and LOD values of this study. The geomean of 0.06, 0.58 and 2.13 is not 0.46 as indicated. However it seems that dibutylamin is not persistent in aerobic soil. The LoEP might need to be corrected accordingly.	
(9)	Vol. 3, B.8.1.2 Rate of degradation, B.8.1.2.1 Aerobic degradation Table B.8.1.2.1-8, (determination of degradation endpoint for carbosulfan and formation fraction for carbofuran)	EFSA: The derivation of the values marked with two stars (**) is not clear like the 4th column (Average DT50) of the table. Please clearly clarify how these values were derived. If these values were the combination of two values from two studies why the formation fractions were not combined as well (St. Amand soil)? EFSA is of the opinion that the value from the study by Baumann J and Ferreira J., 2001 (10°C	The value of 8.14 is might be the geomean of the DT50s from the St.Amand soil (Baumann 2002) and the VS 236 soil (Baumann J and Ferreira J., 2001). Even if these two soils are the same (different MWHC is reported) these two values from different experiments might not be combined as there were differences like the batch of the test substances used (purity, labelling), extraction and analytical methods, temperatures, moreover the kinetics (SFO vs FOMC) and the DT50 derivation. Even if all of these are considered as insignificant (and the temperature differences is handled by normalization) and the values can be combined,

Route and rate of degradation in soil (B.8.1)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
		study) should not be used. RMS please provide the visual assessments of the fits from the Barney soils and reconsider the combination of the two values if necessary or use only the SFO DT50 from this data set (7.87 d). Please check whether the star (*) for the 7.87 d is correct. Please clarify moreover that fit from which study is acceptable for the Nebraska soil and the reason of the refuse of the fit for carbosulfan from the other study (data sets are similar, acceptable X2 values are reported in table B.8.1.2.1-4). Clarify moreover that which fit was used for the derivation of the formation fraction for carbofuran from the Nebraska soil. From the Table B.8.1.2.1-8 it seems that for this fit, the measured degradation for carbosulfan from the study by Markle 1981b was combined with the degradation of carbofuran observed in the study by Markle 1981a. Is it correct?	there is already an acceptable value determined at 20°C for this soil (Baumann 2002). It seems that the value of 6.0 d was derived, similarly to the previous case, by the combination of two values from the Barney soils (two studies with different positions of labelling of carbosulfan). If the conditions of the studies are regarded as the same (or well comparable), the combination of the values might be acceptable. However it seems that an SFO DT50 value is combined with an FOMC value and based on the reported X2 values the SFO kinetics could be accepted as well for this fit (instead of the FOMC one). If so the combination of the two SFO values might be used. Based on the presented, available information in the additional report, considering the issues mentioned above, the following data should be used for the exposure assessments: DT50 for carbosulfan: (days) 4.02, 8.72, 9.77, 11.43, 7.87, 0.53, geomean 5.0 d; ff for carbofuran: 1, 0.6, 0.59, 0,47, 1 (instead of 0.76 as realistic worst case), average 0.73.
(10)	Vol. 3, B.8.1.2 Rate of degradation, B.8.1.2.1 Aerobic degradation Page 8-22 – 8-27	EFSA: The relevant pages for the DT50 derivation for carbofuran (page 8-22 – 8-27) were already discussed in the meetings of experts (PRAPeR 62 and PRAPeR 67) for the benfuracarb and carbofuran 2nd peer review in January and April 2009. The meetings agreed that all the refitted	

Route and rate of degradation in soil (B.8.1)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
		DT50 and the normalisation procedure for carbofuran indicated on these pages are acceptable and should be used further in the exposure assessment. It was also agreed that 3 other DT50 values from the studies by Saxena and Schocken should be added to the data set and that for Bretagne soil (study by Völkl) only the value from the experiment conducted at 20°C should be used. The resulting data set to be used is: 17.87, 14.01, 7.71, 13.56, 17.25, 6.92, 9.39, 11.46, 22.54, 22.19, 5.7, 20.39, 10.39, 11.69, 151, 54.6, 387 days. The median of these normalized SFO DT50 values is 14 days. The LoEP needs to be corrected accordingly.	
(11)	Vol. 3, B.8.1.2 Rate of degradation, B.8.1.2.1 Aerobic degradation Page 8-28	EFSA: from the data set sorted in the General conclusions of the RMS on the derivation of an overall DT50 carbofuran it is not clear where the 6.1 days came from as in the individual reports there is no DT50 of 6.1 days. This should not be used as well as 22.7 days should not be used as this is the geomean of the two DT50 values determined on the same soil at different temperatures. As input for PECgw and PECsw DT50 of 14d should be used. See also EFSA comment (10).	
(12)	Vol. 3, B.8.1.2 Rate of degradation, B.8.1.2.1 Aerobic degradation	EFSA: The geomean of 3.81 d of 3-keto-carbofuran as reported in the General conclusions of the RMS on the derivation of DT50 for the metabolites is	

Route and rate of degradation in soil (B.8.1)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
	Page 8-28	might be the geomean of the non-normalized values. The geomean of the normalized values is 3.01 d. The endpoints for 3-keto-carbofuran, 3-OH-carbofuran and carbofuran phenol to be used in the exposure assessment had been discussed and agreed in the meetings of experts (see Report of PRAPeR expert meeting 62 and 67, 2009). For dibutylamin see EFSA comments (6), (7) and (8). The LoEP needs to be corrected accordingly.	
(13)	Vol. 3, B.8.1.3 Field studies & B.8.3 PECsoil	EFSA: Meetings of experts (PRAPeR 62, PRAPeR 67) already agreed with the RMS that DT50 of 71.9 days for carbofuran is not relied on and for the PECsoil calculation for carbofuran, 27 days should be used (longest field dissipation data from the European sites from study by Mol, 2002). Therefore further clarification on this is probably not necessary. However the statement in the last paragraph of the point B.8.1.3, as the DT50 values which were chosen for PECsoil are considered as extreme worst case, is disagreed.	

Adsorption, desorption and mobility in soil (B.8.2)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations

Section 4 - Environmental fate and behaviour (B.8)

Adsorption, desorption and mobility in soil (B.8.2)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(14)	Vol. 3, B.8.1.1.1, B.8.2.1.1, B.8.2.1.3, Studies by Völkel, 2007	EFSA: The three studies by Völkel 2007 used partly the same soils. The names and a part of the soil parameters are the same, but some other parameters are different among these studies conducted by the same author in the same year. Please make sure that the reported soil parameters are correct and the Koc values were calculated using the correct OC content of the relevant soils.	
(15)	Vol. 3, B.8.2.1.1, Table B.8.2.1.1-2	EFSA: It is noted that the 'Mean' in the last column means arithmetic mean.	
(16)	Vol. 3, B.8.2.1.2	EFSA: For carbofuran adsorption/desorption, the only study considered valid by the 1st and the 2nd peer reviews of carbofuran and benfuracarb is Manouni A., 2002. A data gap was identified in this field in the carbosulfan EFSA conclusion. The other studies were not accepted. No new study or re-evaluation of the existing studies is submitted. For PECgw and PECsw calculations for carbofuran, KFoc of 22 with 1/n of 0.96 have to be used, based on the Manouni study.	

Section 4 - Environmental fate and behaviour (B.8)

Adsorption, desorption and mobility in soil (B.8.2)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(17)	Vol. 3, B.8.2.1.3	EFSA: The advanced test was performed up to 48 hours, please provide argumentation what was the reason for this. This metabolite seems to be volatile (see EFSA comments (24) and (7)) and this could have affected the results of the study and the Koc and 1/n derivation from the results, especially with this prolonged equilibrium time. RMS please comment this issue. Note: neither the volatility nor the water solubility is clear from the additional report.	
(18)	Vol. 3, B.8.2.1.4, B.8.2.1.5, B.8.2.1.6	EFSA: Summaries of these studies were included in the additional report of benfuracarb (2008) and additional report of carbofuran (2008). Comments from several MSs and EFSA on these studies had already been evaluated by the RMS; the critical issues regarding these studies and the endpoints to be used had been discussed and agreed in the meetings of experts (see Report of PRAPeR expert meeting 62 and 67, 2009). Therefore further clarification is probably not necessary.	

Section 4 - Environmental fate and behaviour (B.8)

Adsorption, desorption and mobility in soil (B.8.2)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(19)	Vol. 3, B.8.2.4	EFSA: A data gap was set by the previous peer review for the determination of the levels of dibutylamine in the available lysimeter study. This data gap is still not fulfilled in the additional report. However the data gap might be regarded as obsolete as new information is available for the mobility (adsorption to soil) of this metabolite. The two lysimeter studies for carbofuran (Scholz, 1993, 1992) were already discussed at the meeting of experts from Member States for carbofuran (PRAPeR 67) and it was agreed that these studies do not provide valuable information regarding the mobility of carbofuran or its metabolites. It was agreed moreover that the relevant box of the LoEP should contain 'Non reliable information available'.	

PEC in soil (B.8.3)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations

PEC in soil (B.8.3)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(20)	Vol. 3, B.8.3, PECsoil	EFSA: The 'kinetic' PECsoil calculation for the metabolites which is performed in the additional report is a novel kind of calculation. Please provide all the relevant details regarding how these calculations were performed. EFSA notes that following the usual calculation method the max. PECsoil for the metabolites would be higher. Further PEC calculations (by the 'usual' way) therefore appear to be necessary.	

Fate and behaviour in water and impact on water treatment procedures (B.8.4 – B.8.5)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(21)	Vol. 3, B.8.4.2, Photolysis	EFSA: It is noted that major fraction(s) of degradation products were not identified. However this is not an essential issue at EU level regarding the applied for representative use of the PPP.	
(22)	Vol. 3, B.8.4.4, Water/sediment study	EFSA: It is noted that a major unidentified metabolite (unknown metabolite 3) was found in the sediment phase (max 16.53%AR, 20°C). This should be included in the residue definition for sediment. It would appear that an exposure and risk assessment for this metabolite is necessary.	

Fate and behaviour in water and impact on water treatment procedures (B.8.4 – B.8.5)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(23)	Vol. 3, B.8.4.4 Modelling endpoints derived from the water/sediment studies Page 8-71	EFSA: It is noted that DT50 values for carbofuran and 7-phenol carbofuran are available from the benfuracarb dossier as well (see additional report for benfuracarb). However, these values were calculated from studies where 7-phenol carbofuran and carbofuran was originated from benfuracarb and the values are shorter than the value, which is chosen for PEC calculation in this additional report for carbosulfan (the use of the DT50 of 70.07 for carbofuran in the PEC calculations is agreed and regarded as worst case). For completeness please amend the LoEP with the values from the experiments dosed with benfuracarb.	

PEC in surface water and ground water (B.8.6)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(24)	Vol. 3, B.8.6.1 PEC Surface water and sediment and B.8.6.2 PEC groundwater Input parameters	EFSA: Many parameters used in the Focus modelling (for both GW and SW/sed) are disagreed. Please note that most of the parameters had already been agreed (on the bases of the same data set) during the peer reviews of the resubmission of benfuracarb and cabofuran (please consider the Report of PRAPeR expert	- 3-OH-carbofuran • Koc (55 mL/g) • Kom (31.9 mL/g) • Freundlich exponent (1.0) (would be appropriate if Step 3 or 4 calculated) - carbofuran phenol • PEC SW/Sed: meeting of PRAPeR 67 recommended to use the

PEC in surface water and ground water (B.8.6)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
		meeting 62 and 67). Please note moreover that some other parameters depend on the outcome of the comments in this table. The following parameters need to be changed (or reconsider) (proposed values in brackets; some represents 'better case', some 'worst case' comparing with the value used in the additional report): - carbosulfan • DT_{50} in water (1000 d) • DT_{50} in sediment (5.57 d) • DT_{50} in W/S (5.57 d) • soil DT_{50} (5 d), see EFSA comment (9) • temperature for the solubility (25°C) - carbofuran • soil DT_{50} (14 d) • Koc (22 mL/g) • Kom (12.76 mL/g) • Freundlich exponent (0.96) • Formation fraction in soil (0.73) - 3-keto-carbofuran • soil DT_{50} (3.01 d) • Koc (331 mL/g) • Kom (192 mL/g) • Freundlich exponent (1.0) See column 3 for continuation.	STEP 3 PEC for carbofuran as a conservative estimate for carbofuran-phenol after a potential correction for molar weight and maximum occurrence (for details see the Report of PRAPeR expert meeting 67). This might be appropriate here as well. • PEC GW: not needed (this metabolite was not in the residue definition for soil or ground water, this metabolite do not contain the carbamate moiety) - dibutylamin • soil DT_{50} (0.42 d), see EFSA comment (8) • for Koc/Kom and 1/n please see EFSA comment (17) • significantly different data were used for vapour pressure and water solubility in PEC SW/Sed and PECgw calculations. The wash-off factor depends on the water solubility. Please clearly clarify the sources of these data, the quality and acceptability of these data and indicate which should be used and why. The other parameters included in the relevant tables of the input parameters (page 8-73 – 8-76 and 8-81) are agreed, but please consider the EFSA comment No (25) below beside the other relevant comments of this table. The FOCUS calculations should be repeated based on information/comments above (and below). The LoEP needs to be updated.
(25)	Vol. 3, B.8.6.1 PEC	EFSA: Regarding FOCUS PEC calculations, RMS	

PEC in surface water and ground water (B.8.6)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
	Surface water and sediment and B.8.6.2 PEC groundwater	please consider and comment these: • It is noted that for carbofuran metabolites different data set for vapour pressure is available and used. Please comment which Vp data set are more realistic. • It is not clear what is indicated for the formation fraction in sediment in the tables for input parameters (value: 0, reference: Not major metabolite in water sediment) especially in case of carbofuran and carbofuran phenol • Please check the temperature used in the calculations for the water solubility, somewhere 20°C somewhere else 25°C is indicated for the same value • It is noted that the agreed soil DT50 for 3-OH-carbofuran is 0.41 d, however 0.35 d can be accepted as well (for details see LoEP for carbofuran) • If PECgw are calculated for carbofuran phenol (not necessary) for 1/n 0.9 should be used. The agreed value for soil DT50 is 1 d, however 0.3 d can be accepted as well (for details see LoEP for carbofuran) • A formation fraction (in soil) of hydroxy-carbofuran of 0.5 (from carbofuran) was estimated during the meeting of PRAPeR 67	

PEC in surface water and ground water (B.8.6)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
		(on carbofuran resubmission), followed by a formation fraction of 1 for 3-keto-carbofuran from hydroxyl-carbofuran. It was noted also that if a refinement were ever needed for future exposure assessments, a kinetic fit of the formation fractions would be desirable.	
(26)	Vol. 3, B.8.6.1 PEC Surface water and sediment and B.8.6.2 PEC groundwater	EFSA: Please amend the soil incorporation depth for PECgw and PECsw to 7 cm in the LoEP.	

Fate and behaviour in air and PEC in air (B.8.7 – B.8.8)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(27)	Vol. 3, B.8.7, Fate and behaviour in the air	EFSA: The Atkinson calculation is missing from the additional report, please provide this in an addendum and include the concentration of atmospheric hydroxyl radicals used in the calculation in the LoEP.	

Definition of the residues (B.8.9)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations

Section 4 - Environmental fate and behaviour (B.8)

Definition of the residues (B.8.9)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(28)	Vol. 3, B.8.9 The definition of the residue	EFSA: It is several times indicated in this chapter that carbofuran phenol contains the carbamate moiety, please confirm that not this is the case. Considering all the information available (1st and 2nd peer-review of carbosulfan, carbofuran and benfuracarb) the proposal for the definition of residue for risk assessment is: - soil: carbosulfan, carbofuran, 3-keto-carbofuran, 3-OH-carbofuran, dibutylamine Notes: 3-OH-carbofuran and 3-keto-carbofuran are minor in soil studies dosed with carbosulfan and 3-OH-carbofuran might be regarded as transient in nature, but both contain the carbamate moiety; no PECsoil are available for this metabolites - GW: carbosulfan, carbofuran, 3-keto-carbofuran, 3-OH-carbofuran, dibutylamine - SW&Sed: carbosulfan, carbofuran, 3-keto-carbofuran, 3-OH-carbofuran, carbofuran phenol, dibutylamine, Unknown metabolite 3 - air: carbosulfan	

Other comments			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations

Section 4 - Environmental fate and behaviour (B.8)

Other comments			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(29)	Vol. 1, List of Endpoint	EFSA: Essential data are missing from the LoEP. Please amend the LoEP and for this please consider all the comments of the reporting table.	
(30)		EFSA: Please see EFSA comments (1) and (14) as general comments as well.	

5. Ecotoxicology (B.9)

Birds and mammals (B.9.1 and B.9.3)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 3, B.9.1.3 Subchronic and reproductive effects on birds	EFSA: The long-term endpoint for the metabolite carbofuran should be amended in accordance to the outcome of the expert discussion on carbofuran (PRAPeR 68 in May 2009). (The LC10 (14d) = 0.64 was suggested to be used in the risk assessment together with an increased safety factor of 10).	
(2)	Vol. 3, B.9.1.7 Higher tier risk assessment for birds	EFSA: The PD/PT values suggested in the refined risk assessment are based on general considerations of diet compostion. This was not agreed to be used in a quantitative risk assessment for benfuracarb and carbofuran. It is proposed to indicate this in the LoEP (as was done for benfuracarb and carbofuran).	
	Vol. 3, B.9.1.8 Residue levels in food items	EFSA: The residue trial with insects and earthworms was discussed in the context of the refined risk assessment for carbofuran. The measured residues potentially underestimate the real exposure under field situations. The risk assessment/evaluation of the residue trials should be updated in accordance to the outcome of the expert discussion on carbofuran.	
	Vol. 3, B.9.1.8 Residue levels in food items	EFSA: The earthworms were rinsed and stored overnight before analysis. This treatment has most likely reduced the residue levels in earthworms.	

Section 5 - Ecotoxicology (B.9)

Birds and mammals (B.9.1 and B.9.3)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
	Vol. 3, B.9.3.2 Risk assessment for mammals	EFSA: The NOAEL of 0.1 mg carbofuran/kg bw/d was agreed in the meeting on carbofuran. The risk assessment for mammals needs to be updated accordingly.	
	Vol. 3, B.9.3.2 Risk assessment for mammals	EFSA: The suggested refinement of PD for hare and shrew are uncertain since they were not derived from targeted studies in sugarbeet fields. This should also be highlighted in the LoEP.	
	Vol. 3, B.9.3.2 Risk assessment for mammals	EFSA: If the new (agreed endpoint) long-term endpoint of 0.1 mg carbofuran/kg bw/d is used in the mammal risk assessment then the TER trigger would not be met (TER = 2, including the PD refinement). Therefore the long-term risk to herbivorous mammals would need to be addressed further. It should also be considered that shortcomings of the residue trials with sugarbeet-seedlings were identified by the RMS and that there are uncertainties with regard to the suggested PD refinements.	

Aquatic organisms (B.9.2)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>,	EFSA: No comment	

Section 5 - Ecotoxicology (B.9)

Aquatic organisms (B.9.2)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
	<<description>>		

Bees and non-target arthropods (B.9.4 and B.9.5)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	EFSA: No comment	

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 draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 3, B 9.6.5 Field test with earthworms	EFSA: The study of Broadbent and Tomlin (1982) was considered as key information to address uncertainties with regard to differences in effects on earthworm populations from different exposure patterns (local exposure from in-furrow treatment versus even distribution of the active substance). The study should have been submitted and summarized in the DAR. A data gap for submission of this study was identified in the meeting of experts in the discussion on carbofuran.	

Other non-target organisms (flora and fauna), sewage treatment (B.9.9 and B.9.10)

Section 5 - Ecotoxicology (B.9)

No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	EFSA: No comments	

Other comments			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	EFSA: No comments	

10. Physical/Chemical Properties; Details of Uses and Further Information; Methods of Analysis (B.1-B.5)

Identity (B.1, Annex C)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	General	DE: Could the RMS please explain why a new specification is proposed? It seems that this approach is not in compliance with the substantive and procedural requirements of Article 15 of Regulation 33/2008 where it is clearly stated that "…the specification of the active substance is the same as was the subject of the non-inclusion Decision. It may only be changed insofar as this is necessary, in the light of the reasons which gave rise to the non-inclusion Decision, to permit inclusion of that substance in Annex I to Directive 91/414/EEC;…" It should be clarified whether the explanation/justification given in Volume 4 (pages 22/23) is generally acceptable to amend the specification even if the specification was not an issue with respect to the non-inclusion of the substance.	
(2)	Vol. 1, 1.3.10	DE: Relevant impurities should not be regarded as confidential.	

Other comments			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 1, List of end points	DE: The RMS should consider to use the current harmonised version of the list of end points.	Data on hydrolysis, photostability and quantum yield are still given.
(2)	Vol. 3, 3.2.3	DE: A rate of 100 g as/ha for granules can be effective on some pest insects of sugar beet, if row treatment is used. Test with LD_{90} values of carbosulfan applied in soil (not topical application as mentioned under 3.2.3) showed clear activity to Diabrotica larvae. More than 1 ppm in soil will be present if row application of 100 g is used.	

4. Environmental fate and behaviour (B.8)

Route and rate of degradation in soil (B.8.1)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 3, general comment, active substance	DE: Carbosulfan was rapidly degraded to carbofuran under aerobic conditions (DT_{50soil} < 1 day). Carbofuran is intended to none inclusion in Annex I (91/414/EWG) by RMS Belgium.	

PEC in surface water and ground water (B.8.6)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 3, point B.8.6.1, PECs surface water	DE: PECs in surface water/sediment were calculated for granular application and soil incorporation at -7 cm. In FOCUS PRZM the chemical application method No. 8 (CAM 8) was chosen. This virtually excludes entry from run-off and consequently all PECs for the run-off scenarios at FOCUS Step 3 are zero. However, a single run-off event can contribute significantly to the PEC_{sw}. Therefore, FOCUS Step 3 calculations should be repeated with CAM 4 or CAM 5.	CAM 8: "incorporation in soil with total application located at user-specified depth"; CAM 4: "incorporation in soil with uniform profile and user-specified depth"; CAM 5: "incorporation in soil with profile linearly increasing to user-specified depth";

5. Ecotoxicology (B.9)

Birds and mammals (B.9.1 and B.9.3)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 3, B.9.1, Effects on birds	DE: In order to reduce the risk to birds, application in plant hole at lower dosage is proposed by the RMS to reduce the amount of active substance used per hectare. However, the notifier has not yet demonstrated the feasibility of this technique. For that reason, as well as due to the high toxicity to terrestrial vertebrates and due to insufficient data on residue levels in feed items, the refinement of the risk assessment should not be transferred to national level.	
(2)	Vol. 3, B.9.3, Effects on mammals	DE: In order to reduce the risk to mammals, application in plant hole at lower dosage is proposed by the RMS to reduce the amount of active substance used per hectare. However, the notifier has not yet demonstrated the feasibility of this technique. For that reason, as well as due to the high toxicity to terrestrial vertebrates and due to insufficient data on residue levels in feed items, the refinement of the risk assessment should not be transferred to national level.	

Aquatic organisms (B.9.2)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 3, point B.9.2.16, Exposure and risk assessment for aquatic organisms	DE: In case that surface water PECs need to be revised (in order to take into account entry via run-off), the aquatic risk assessment requires revision too. Current aquatic TERs are near to the trigger values in some cases (e.g. for *Ceriodaphnia dubia*) and increased PECs would indicate risk.	
(2)	Vol. 3, point B.9.2.16, Exposure and risk assessment for aquatic organisms	DE: The mesocosm with a low value for the EAC (0.1 µg/L; not 0.4 µg/L) is not considered in the aquatic risk assessment, because a need was denied for formal reasons. However, since the validity of the EAC from the mesocosm was confirmed after the request by the EFSA SR (2006), this endpoint can not be ignored. Carbofuran could not be quantified in the mesocosm study. Nevertheless, the EAC should be related to the (revised) carbofuran PEC_{sw}.	