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

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00	Cover page	00 carbofuran cover
01	**All comments received on the DAR**	**01 carbofuran all comments**
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Comments on the Draft Assessment Report on carbofuran (Resubmission)

RMS BE

End of commenting period: 13 February 2009 (MS, NOT)

Date	Supplier	File
12.02.2009	France	01 Carbofuran comments FR 2009-02-12.doc
12.02.2009	FMC	02 Carbofuran comments FMC 2009-02-12.doc
13.02.2009	EFSA	03 Carbofuran comments EFSA 2009-02-13.doc
13.02.2009	Germany	04 Carbofuran comments DE 2009-02-13.doc
13.02.2009	The Netherlands	05 Carbofuran comments NL 2009-02-13.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)		No comment	

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)		No 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)		No comment	

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)		No comment	

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)		No comment	

2. Mammalian toxicology (B.6)

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 B6.12 b Dermal absorption	FR: we agree with the dermal absorption rate of 3 % retained by the RMS	

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.3 B6.15.1 Estimation of operator exposure	FR: the operator exposure estimate should be re-calculated with the new AOEL agreed for carbofuran of 0.00015 mg/kg bw/d during the focus peer review of benfuracarb (Jan 2009). However exposure will remain still acceptable with gloves when using UK POEM and with gloves and RPE when using the BBA model. But it will not be acceptable when using the PHED model.	

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. 3, B.7.14, Storage stability of residue samples	FR : Could you specified the owner of studies as in the other parts of the Vol.3, B.7 (before the studies of each owner)?	
(2)	Vol. 3, B.7.14, Storage stability of residue samples, FMC data	FR : How can you explain the different results from one study to another? Should one of these studies be invalidated?	In “Carbosulfan storage stability study in/on various crops – Burt J.E; 1982”, the carbosulfan in green alfalfa is stable up to 12 months, at 21 months the stability is not demonstrated (percent recovery 69,5%). In “Cold storage Stability of Carbofuran and Its Carbamate Metabloites on Various Loboratory Fortified Crop and Animal Matrices – Shreier T.C., 1989”, the carbosulfan in green alfalfa is stable up to 26 months. The both data are in contradiction. Same contradiction for corn forage.

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. 1, LOEP, p.74, Plant groups covered, FMC	FR : Foliar applications on sugar beet and on rice were not mentioned in the LOEP.	
(2)	Vol. 1, LOEP, p.74, Plant groups covered, ARYSTA	FR : The metabolism study on cabbage should not be mentioned on the LOEP because the level of radioactive residues remains low and no clarification on the lack of TRR (-25%) was proposed by the notifier. This plant group (leafy vegetable) is not covered by the submitted study. Could you please mentioned in the LOEP - The only valid metabolism study?	

Section 3 - Residues (B.7)

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
		- What active substance was radiolabelled? - What application method was used?	

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)		No 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)		No comment	

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)		No 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. 3, B.7.7.1, Effect on the nature of the residues, Table B.7.7.1-1	FR : All metabolites are quoted in a different order in pH 5.0 buffer, in pH 7.0 buffer and in pH 9.0 buffer. Is there a particular reason?	

Section 3 - Residues (B.7)

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
		For easier reading, could you please harmonized the order of the metabolites (name, percentage)?	
(2)	Vol. 3, B.7.7.1, Effect on the nature of the residues	FR : Could you mentioned that none of the submitted studies are in conformity with the guideline 7035/VI/95 rev.5 of 22/7/1997 – Appendix E – Processing studies?	

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)		No 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)		No comment	

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)		No comment	
(1)		No comment	

Other comments

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)		No 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. 3, B.8.1, Route and rate of degradation	FR: p.22; Willems 2005, Study might be in rate section instead of route section.	
(2)	Vol. 3, B.8.1, Route and rate of degradation	FR: p.23; for the carbufuran-3-hydroxy the geometric mean of 0.35 d might be inserted in an additional line in Table B.8.1.1.1-17 p8-26. same remark for geometric mean of 3.81 d calculated for carbufuran-3-keto in table Table B.8.1.1.1-19.	
(3)	Vol. 3, B.8.1, Route and rate of degradation	FR: p.37. Rate of degradation, aerobic. Table B.8.1.2.1-6. presented data are unnormalized.	
(4)	Vol. 3, B.8.1, Route and rate of degradation	FR: p.37. When comparing Table B.8.1.2.1-6 and table Table B.8.1.2.1-7, in the study from Markle (1981a) there is one site on the first table (Barney) and then 2 sites (Berney and Nebraska).	
(5)	Vol. 3, B.8.1, Route and rate of degradation	FR: p.38. General conclusion of the RMS on the degradation of an overall DT50 carbofuran. RMS considers that the overall mean values of 12.83 and 10.7 days are appropriate. Since this parameter is very sensitive for both PECgw and sw calculations then it should be clearly mentioned to use the worst case value.	

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	FR: p.53, Since K_{OC} value of 55 cm3/g as been selected as worst case, then 1/n value of 1 should be selected as worst case to (using K_D assume linearity	

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
	soil	). Units 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.54, In Table B.8.2.1-12 it's mentioned a Kfoc value of 48 cm3/g for the soil I. Then in conclusion it's mentioned that "FMC has chosen the an extreme worst case K_{OC} of 47.5cm3/g as input". K_{OC} in the text should be corrected to $K_{FOC.}$ In addition, It makes sense to round up 47.5 to 48; still for a clear understanding it would be better to harmonized data (table/text).	
(8)	Vol. 3, B.8.2, Adsorption, desorption and mobility in soil	FR: p.55, 1/n values calculated for carbofuran-phenol adsorption test for 3 soils range from 0.407 to 0.751 (the third value being 0.516). We wonder why there is such difference between soils and then if it's appropriate to calculate a mean value with such data distribution. Maybe it would be good to keep the worst case value.	
(9)	Vol. 3, B.8.2, Adsorption, desorption and mobility in soil	FR: p.62 (and 66). Lysimeter leachate sampling: It's mentioned that the leachate were collected every 14 days (as available). It should be empathized that this method might enhanced degradation in the leachate sample since time delay of 14 days (max. possible) might occur between leaching event and analysis.	
(10)	Vol. 3, B.8.2, Adsorption, desorption and mobility in soil	FR: p.62, Extraction of radioactivity: the soil was shaken twice with methanol and once with water. After soil extraction with methanol (supposed to be harsher that with water) ; how may an additional extraction with water be useful.	
(11)	Vol. 3, B.8.2, Adsorption, desorption and mobility in soil	FR: p.67, We agree with the RMS that both studies might be seen as additional information, and we would like to emphasized that extrapolation to these	In agreement with the conclusion of the RMS, we would like to mentioned that the low amounts of product leached through lysimeters may not necessarily be seen a low leaching potential for the active substance.

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
		data might be done only with respect to the apparent dry conditions.	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 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
(12)	Vol. 3, B.8.6.1, PECgw	FR: p.93, Regarding PECgw calculations performed for the metabolites 7-phenol-carbofuran, 3-hydroxy-carbofuran and 3-keto-carbufuran. It's mentioned that assuming worst case scenarios few exceedances of the 0.1 µg/L trigger might be observed. Even if the RMS mentioned that these last are not a concern; it might be good to indicated if these metabolites have toxicological	

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
		relevance or not (then no concern).	
(13)	Vol. 3, B.8.6.1, PECgw	FR:, p.96, Table B.8.6.2-1; 2-5; 2-9 and 2-12 In table B.8.6.2-1, plant uptake value has been set to 0 as “default value”. Since carbofuran is a systemic insecticide, 0 for plant uptake would be a worst case option (default value is 0.5 for systemic compounds).	
(14)	Vol. 3, B.8.6.1, PECgw	FR:, p.96, Table B.8.6.2-5 and 2-9. For the Freundlich coefficient 1/n the value 0.9 is used as “default Focus value”. The default worst case value to be used should be 1 (already discussed in previous PRAPeR meeting). In addition, since the Koc value is used, then no information on linearity or non-linearity of the isotherm might be done and the worst case value of 1 (for 1/n) may be used.	

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	FR: FR agrees with overall conclusion of RMS for birds. In addition, FR also highlights than the data from SAGIR and WIIS well underestimated the real mortality as it is assumed than only a limited percentage of the dead animals are found.	
(2)	Volume 3, B.9.1.10, Monitoring studies, reported cases	FR: even if the studies on uses of carbofuran on rice/broadcast application (indicated p.59) are not relevant for the supported uses, these studies should be kept as additional data to highlight that despite the application method, carbofuran is highly hazardous for birds.	
(3)	Volume 3, B.9.1.12 (point 6) and B.9.3.2 (point 5), Risk assessments for consumption of contaminated drinking water (birds and mammals)	FR: due to the high toxicity of the active substance to birds and mammals, a calculation could be done based on the new puddle calculation formulae proposed by EFSA (EFSA journal, July 2008).	
(4)	Vol. 3, B.9.3.2, Risk assessment presented by the RMS (points 4 and 9)	FR: it is unclear what are finally the conclusions about the risk from granule consumptions for mammals. Indeed a discussion of the results of the EPPO based assessment leads, for birds, to question its relevance to represent the level of risk (see page 110). So similarly, it remains difficult to understand why, considering that 0.24-6 granules correspond to the LD_{50} and NOAEL in a body weight of 15 to 50 g, in mammals, may be	

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
		deduced from the EPPO approach.	
(5)	Vol. 3, B.9.3.2, Risk assessment presented by the RMS (point 9)	FR: FR agrees with the conclusion of RMS for the risk via beet seedlings, earthworms and arthropods consumption for mammals.	

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
(6)	Vol. 3, B.9.2.6, Acute toxicity to aquatic invertebrates	FR: The study “acute toxicity of 3-Keto-Carbofuran” (Sayers, 2007b, p. 136) is acceptable but due to the actual concentration below the LOQ at the end of the test the data are of poor quality. The need for a new study, i.e. a flow-through study, should be driven by the margin of safety achieved by TER calculations.	
(7)	Vol. 3, B.9.2.16.1, Risk assessment for the active substance	FR: could you explain why the “risk is considered to be acceptable” since there is a TER value below the trigger value for *Ceriodaphnia dubia* (8.2) with the PECsw (Step 3) of the scenario D4 (Pond) in the Table B.9.2.16.1-3 (p. 152)? The figure should trigger the need for mitigation measures.	

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
(8)	Vol. 3, B.9.4.4, Effects on bees of residues on crops	FR: Even if the determination of residues of carbofuran in maize pollen and nectar is not	

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
		relevant for the evaluation since the intended use on maize is not supported anymore, it could be useful to have the opinion of the RMS on the acceptability and on the quality of the submitted data.	
(9)	Vol. 3, B.9.5.1, Effects of the active substance on non-target terrestrial arthropods	FR: FR considers that the studies on Rove Beetle (Schmuck R., 1993, p. 194-195 and Schmuck R., 1993, p. 201-203) and the study on Carabid Beetles (Schmuck, 1993, p 198-201) are not acceptable since no positive control was tested in these tests.	
(10)	Vol. 3, B.9.5.4, Summary of effects, exposure and risk assessment for non-target terrestrial arthropods	FR: FR agrees with overall conclusion of RMS for non-target terrestrial arthropods.	

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
(11)	Vol. 3, B.9.6.6, Summary and risk assessment for earthworms	FR: could we consider the field study performed with a capsule suspension preparation (Strömel C *et al.*, 2002) reliable for the risk assessment of a granule preparation?	
(12)	Vol. 3, B.9.7, Effects on other soil non-target macro-organisms	FR: The conclusion of the RMS that the risk for the other soil non-target macro-organisms is not fully acceptable at the application rate of 600 g a.s./ha	

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
		indicated in the Vol. 1 level 3 (3.1 Background of to the proposed decision, p. 132) should be also indicated in the Vol.3 B.9.7 (p. 246) for a better readability.	
(13)	Vol. 1, 2.6.4	FR: it is unclear why the risk posed by carbofuran to earthworms in sugar beet is acceptable in the part 2.6.4.1 and not fully addressed in the part 2.6.4.2. In addition no mention to the other soil non-target macro-organisms was found in this part. Could you please check this point?	

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

Other comments			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(14)	Volume 3, point B.9	FR: FR agrees with the RMS statement for the non inclusion of the reduced granular dose rate (60 g a.s./ha) in the risk assessment.	

6. 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
	Vol. #, <<data point>>, <<description>>	<<MS/notifier>>: <<comment>>	

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
	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
	Vol. #, <<data point>>, <<description>>	<<MS/notifier>>: <<comment>>	

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, B.3.2.3, Rate of application	**Notifier:** The DAR disagrees with the Risk assessment at reduced dose rate". However, the Article 15(1b) of	The RA conducted by the RMS shows that while the risk to granular intake at 600 g ai/ha is acceptable according to the EPPO scheme, the risk to secondary poisoning via ingestion of treated seedlings, earthworms and/or

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
		Regulation 33/2008/EC states that "*The supported uses are the same as those that were the subject of the non-inclusion Decision. They may only be changed insofar as this is necessary, in the light of the reasons which gave rise to the non-inclusion Decision, to permit inclusion of that substance in Annex I to Directive 91/414/EEC*". Whilst we appreciate the efforts to calculate the Risk assessment at 600 g ai/ha, we introduced risk assessments at 60 g ai/ha (and also 400 g ai/ha) in order to increase the chances to identify a safe use scenario. /	arthropods needs further refinement. This suggests that a lower application rate should be considered for the risk assessements, as wisely foreseen by Article 15b of the Regulation. Should the EC decide that registration of carbofuran is possible only with limitation on its maximum applied dose rate, this issue would be dealt by FMC at national level. Indeed, we are confident that certain technologies are efficient at dose rate equal or lower to 60 g carbofuran/ha. We would like to stress that diuron was re-submitted for Annex I inclusion defending an application rate of 0.5 kg/ha, which is lower than the dose rate originaly submitted (2 kg/ha). Diuron has recently been voted positively for inclusion to Annex I on the basis of the 0.5 kg/ha safe use.

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
	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

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

7. 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
	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
	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
	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
	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
	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
	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
	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
	Vol. #, <<data point>>, <<description>>	<<MS/notifier>>: <<comment>>	

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
(2)	Vol3, B.6.10, ADI, ARfD and AOEL	**Notifier** We refer to our position papers with regard to the setting of the ADI, ARfD and AOEL on the basis of the new AChE inhibition studies. We believe that the true NOEL is at 0.03 mg/kg bw/day since AChE inhibition does not overtake the 20% threshold at this concentration and no clinical sign is observed at that concentration. Lower safety factor should be applied to the NOEL since 1) it is established on pups and 2) it measures a purely toxicokinetic phenomena (the inhibition of AChE) before it can trigger measurable toxicodynamic effect.	We also refer to the recent WHO assessment of ADI and ARfD that took such consideration into account and concluded on an ADI and ARfD of 0.001 mg/kg bw/day.

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
	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
	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
	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
	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
	Vol. #, <<data point>>, <<description>>	<<MS/notifier>>: <<comment>>	

8. 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
	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
	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
	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
	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
	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
	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
	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
	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
(3)	Vol. 3, B.7.11, Estimates of the potential and actual exposure through diet and other means	**Notifier** The consumer risk assessment according to the PSD model demonstrates that carbofuran residue intake via refined sugar is at maximum 0.00008 mg/kg bw/day (53.3% ADI). Besides, we also agree with RMS that the model overestimates the risk to consumer since the residue database demonstrates a non residue situation and since any theoretical carbamate residue would hydrolyse to phenolic metabolites.	We agree that the use of the PSD model for assessing the acute and chronic exposure to consumer from the carbofuran use on sugar beet is relevant since refine sugar is the actual consumed commodity. However, the table on chronic dietary intake calculation by the PSD model sum up the intake from sugar beet root and refined sugar. The chronic intake of carbofuran residue via refined sugar only is at maximum 0.00008 mg/kg bw/day (53.3% ADI) for the toddlers and that of sugar beet is of 0.00056 mg/kg bw/day (373.3% ADI). Therefore, if the use on sugar beet is limited to roots intended for processing to refined sugar, then the risk to consumer is low.

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

9. 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
	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
	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
	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
	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
	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
	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
	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
	Vol. #, <<data point>>, <<description>>	<<MS/notifier>>: <<comment>>	

10. 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
(4)	Vol. 3, B9.1.1, AChE depression and recovery	**Notifier**: It should be noted that the aim of this study was to achieve an AChE response in order to measure the rapidity of AChE depression after ingestion of carbofuran, and the time to recovery in all dose levels. Therefore, the test doses were purposely selected to allow for an effect dose. Therefore, neither a NOAEL nor LC50 could be derived from the study. Clinical observations were also not recorded since it was not considered part of the study objectives.	The objective with this dose level selection was to achieve a relatively high level of cholinesterase depression and have the animals recover through the maximum time point of the study (6 hrs was selected as the maximum time point since was anticipated to cause a rapid onset of ChE depression and capture recovery at all dose levels). The low dose (0.75 mg a.i./kg body weight) was selected at approximately one-tenth of the oral LD50 and one-fourth the high dose to yield measurable differences in ChE inhibition and recovery time (a dose level that was practical for an accurate dosing). The relevant endpoints generated from this study are 1) that within15 min measurable AChE depression in birds occurs after carbofuran ingestion and 2) AChE recovery is observed after 1.1 to 4.4 hours. This information is helpful when running a tier 3 risk assessment and supports the fact that birds that are acutely exposed to carbofuran do not die due to several biological mechanism that cause them to seize from feeding or reduce the toxicity of the test item. While we appreciate the effort from the RMS in calculating a BMD10 / BMDL10, we disagree that such an endpoint would be relevant and should therefore not be included in the DAR for the following reason: 1) This method was adopted by US EPA in order to provide an additional level of safety in the evaluation of risk to humans. Ecotoxicological risk assessement aim to protect the wildlife population, as opposed to a Human Risk assessment that must protect the individual. Applying the similar level of safety in the ecotoxicological risk assessment would be an over-conservatism.

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
			2) A BMD10 / BMDL10 set at an arbitrary value of 5-10% AChE inhibition is already an over protection for human and not considered applicable to birds. Indeed, as mentioned by the RMS, AChE inhibition above 50 to 90% are needed to observe death of birds. (Ludke et al., (1975) proposed that brain ChE activity inhibition of 50% of avian control levels was a conservative predicator of death, while other research has shown that some avian species can tolerate more severe brain ChE inhibition than 50% (Hill 1988)).
(5)	Vol 3, B9.1.1, AChE depression and recovery	**Notifier**: We not believe that increasing the duration of the study - in regards to avian mortality – would be relevant. It is well documented that carbofuran is an acute toxin and birds that have survived passed the initial hours are highly unlikely to die later on. Since no significant mortalities were observed in the high dose group (3.0 mg/kg bw) at study termination (6 hrs), it is very unlikely that more death would occur beyond this time. In addition, as noted in above point, birds do survive with no observable adverse effects at ChE inhibition of up to 90%, due to the rapid reversibility of ChE inhibition. At termination birds were below 50% inhibition.	
(6)	B.9.1.3, Subchronic and reproductive toxicity Conclusions of the RMS	**Notifier**: The issue of reduced ovary size was most certainly not a detrimental symptom. Any time birds are	

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
	on the recalculation of the reproductive bird endpoints	forced into 12 weeks of productivity, many birds in the study will experience reproductive exhaustion and ovarian or testicular regression (withdrawal form reproductive physiology). In the wild, northern bobwhite lay a clutch of eggs within approximately 14-days. They may lay a second clutch after completing the first brooding effort or after a nest failure. This is a far cry from 12 weeks of continuous egg laying. The avian reproductive toxicity test places tremendous physiological stress on the birds, especially the females. It is entirely predictable that some birds will display regressed ovaries or testes toward the end of the egg laying period. Reviewing the number of eggs layed per mating pair would show that the birds were productive.	
(7)	B.9.1.10, Monitoring studies, reported cases *Examen spécial de l'insecticide carbofuran : Impact sur la faune avienne et valeur pour l'agriculture canadienne. (1993).*	**Notifier**: Whilst we value the weight of evidence approach, we would like to stress that carbofuran is used in North America in conditions significantly different compared to the EU, in particular, dose rate applied are much higher in North America. Therefore, the incidence reports from EU MSs would provide a better reflection of the potential impact of carbofuran on avian populations as it is applied in the EU.	
(8)	B.9.1.11 Evaluation of the risk assessment	**Notifier**: RMS wrote that "*the risk assessments at 400 or 60 g*	The RA conducted by the RMS shows that while the risk to granular intake at 600 g ai/ha is acceptable according to the EPPO scheme, the risk to

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
	submitted by the notifier	*a.s./ha do not comply with the GAP of 600 g a.s./ha that was proposed in the original DAR*". However, the Article 15(1b) of Regulation 33/2008/EC states that "*The supported uses are the same as those that were the subject of the non-inclusion Decision. They may only be changed insofar as this is necessary, in the light of the reasons which gave rise to the non-inclusion Decision, to permit inclusion of that substance in Annex I to Directive 91/414/EEC*". Whilst we appreciate the efforts to calculate the Risk assessment at 600 g ai/ha, FMC did submit valid risk assessments at 60 g ai/ha and 400 g ai/ha in order to demonstrate a safe use scenario that would be supported.	secondary poisoning via ingestion of treated seedlings, earthworms and/or arthropods needs further refinement. This suggests the value of the low dose rate risk assessements, as wisely foreseen by Article 15b of the Regulation. Should the EC decide that registration of carbofuran is possible only with limitation on its maximum applied dose rate, this issue would be dealt by FMC at a national level. We are confident that efficacy is achieved at a dose rate of 60 g carbofuran/ha. It should be noted that the 91/414/EEC revision introduced major changes in the way insecticides are used on the EU market. Therefore, a representative use of the late '90 will not necessarily be representative of the current market. In addition, we understand that the Regulators encourage the reduction in chemical use for agriculture. A supported reduction in the application rate of carbofuran contributes to this objective. We would also like to stress that diuron was re-submitted for Annex I inclusion defending an application rate of 0.5 kg/ha, which is lower than the dose rate originaly submitted (2 kg/ha). Diuron has recently been voted positively for inclusion to Annex I on the basis of the 0.5 kg/ha safe use.
(9)	B.9.1.11 Evaluation of the risk assessment submitted by the notifier, - Risk to granule intake	**Notifier**: As mentioned, the risk to birds *accidentally* or *intentionally* ingesting Furadan 5G granules is low when calculated following the EPPO scheme. However, the RMS has voiced doubts about this evaluation since '*a small bird reaches its LD50 with one granule'.* We believe that the conclusion of the	**Size of granules.** The size of Furadan 5G granules is determined in the Vol 3 B2 as ranging from 0.4 to 0.85 mm. A slightly different range of 0.6-0.85 mm would only propose a worst case figure since larger granules would obviously carry more carbofuran. **Weight of granules**

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
		EPPO scheme is validated by the incident data and PRA submitted. Please see further explanation for comments on the size and weight of granules.	The weight of evidence from EU incident data shows that bird 'incidents' are due to intentional poisoning and not from use in accordance with the GAP. This therefore provides further supporting information that is in agreement with the EPPO assessment for the potential risk posed from granular intake. In addition, the PRA approach also shows a low risk to birds. Therefore, the conclusion that the risk from granular uptake is low is supported by three pieces of evidence: 1) EPPO scheme, 2) Incident data and 3) PRA. This therefore demonstrates, as the risk assessment is intended to do, that the hazard, i.e. a small bird reaching an LD50 from the ingestion of one granule, is not observed in the field and the risk is therefore acceptable. The values of 0.37 mg granule weight and the amount of 0.0185 mg a.s./granule are used throughout the DAR and are mentioned in the EFSA conclusion on carbofuran as well. Thus these values were used in the probabilistic risk assessment. The RMS calculated the weight of 0.87 mg per granule from the study of Knäbe et al. (2008). In that study, granules that had been applied to the field and were found on the surface were weighed. The RMS calculated a mean weight from these numbers and also calculated the amount of active substance in a granule from this number: 1143 granules/g 1 granule = 1/1143 = 0.8748 mg 5% ratio of active substance => 0.87 * 0.05 = 0.0437 mg a.s./granule

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
			In contrast to: 0.37 mg / granule ; 0.0185 mg a.s. / granule (=> DAR) It is questionable whether the weight of granules that have already been applied to the field and then collected from the field surface can be used to accurately calculate the amount of a.s. from it. It could, e.g., be possible that the granules have already taken up water from the field and thus they can have become heavier. But this would not have an impact on the amount of active substance in the granule. It appears to be more appropriate to use the laboratory data on granule weight and amount of a.s. per granule that was provided in the DAR.
(10)	B.9.1.11 Evaluation of the risk assessments submitted by the notifier P 9-85 Risk to granule intake	**Notifier**: It is written that: “The TER that have been derived from this assessment were compared to the annual mortality rate of these birds. However, the annual mortality data should be recalculated for the relevant period of carbofuran application. Annual mortality for linnets is around 58.5 % anf for skylarks 44.75 %. It could be assumed that the granules are available for around 2 weeks after treatment. Recalculated mortality for linnets is then 2.25 % and for skylarks is 1.72 %. These results are almost in the range of the mortality figures obtained for scenario 1.” However, this only means that during the assumed time period of 2 weeks the mortality that might be	Scenario 1 is considered to be probably unrealistic as discussed in the report. However, using the 90th percentile effect probabilities from soil 3 (3.18%) and the random soil scenario (1.34%), see the following calculation: 58.5% + 3.18% = 61.68% 58.5% + 1.34% = 59.84% The "natural" annual mortality plus the effect possibly caused by carbofuran equal to 61.68% or 59.84%, respectively. These numbers represent the annual mortality of linnets including the possible effect of carbofuran. The annual mortality of linnets fluctuates between 53% and 64%. Thus the mortality is still within the normal range of the annual mortality (since 61.68% is smaller than 64%, and 59.84% < 64%, too). One has to keep in mind that these numbers hold for scenario 1, which is considered to be

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
		caused by carbofuran is at a level comparable to the natural mortality. The impact on the population, however, has to be compared to the annual mortality: Carbofuran is applied once per year and thus the described effects only occur once a year. Using the numbers stated by the RMS, a simple calculation shows that the possible impact is minor.	simplified but rather unrealistic since it overestimates the preference for the "end of row" zone (see discussion). This example show that the potential effects caused by carbofuran 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 carbofuran.
(11)	B.9.1.11 Evaluation of the risk assessment submitted by the notifier - Secondary poisoning – higher tier risk assessment (tier 2)	**Notifier**: We note that any PT factor was not considered in the tier 2 risk assessement, arguing that "*the PD determination is based on measurements of bird crop or faeces examination of birds commuting between treated fields and untreated areas. The PT factor is therefore already taken into account in the PD factor determination*". We disagree and believe that an additional PT value should be entered in the refined risk assessment. 1) Diet data based on crop contents or faecal samples provide useful information in determining an appropriate species-specific PD value for refining the risk calculation. PDs can be used in combination with a PT value, but not replace it. In the diet samples it is analyzed what the animals had ingested in a rather short time period before the sample had been taken (minutes to hours). Birds will take food in a rather limited area in this time.	FMC agrees that a conservative acute PT for a Tier II assessment can be set at 1. However, a PT of 1 does not accurately reflect a short or long-term exposure. The proposed PTs for the focal species is 0.3 (for woodpigeon, yellow wagtail and skylark). For a Tier II, conservative RA, blackbird PT feeding of earthworms was set at 1. However, we believe that the TER approach for earthworm eating birds is overly conservative since earthworm will continously produce slime and therfore eliminate residue from their surface. Dr. L. Brewer provides the following comment: *"While collecting earthworms during several pesticide field studies, conducted over a span of 20 years, it has been my observation that the body slime is constantly produced and soil or granules get sloughed off with the slime as the worms move forward. When earthworms have something sticking to them that is an irritant, they produce profuse amounts of slime to remove the irritant. I have conducted unofficial (undocumented) tests consisting of rolling worms in soil then putting them in a container to see how long it takes for them to slough the soil off. Generally, this took 1-2 minutes maximum, after which the*

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
		2) The purpose of including a PT factor value allows for the inclusion of the bird's behavior in the RA e.g. a change in feeding ground over the period of weeks to month. Over the period of weeks to month a field will change e.g. its growth stage. This would render the site into a less (e.g. woodpigeon and Yellow wagtail) preferred feeding area. 3) Furthermore, it is appropriate to use a PT value in the tier 2 risk assessment since the SANCO guidance accepts the use of a PT in a first tier assessment. Therefore we maintain our proposal of a PT values for the focal species.	*earthworms were perfectly clean again when I picked them back out of the container with forceps."* This behavior of earthworms is consistent with the very rapid decline of carbofuran residue observed in the residue studies.
(12)	B.9.1.11 Evaluation of the risk assessment submitted by the notifier, - Secondary poisoning – higher tier risk assessment (tier 3)	**Notifier**: 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	

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
		case of the granule distribution in the field, the data from Knäbe et al. (2008) is used. An overview of the granule distribution is shown in Fig. 5 in the report by Bastiansen & Wang (2008; FMC Study # PC-0404). The field size distribution that was used is shown in Fig. 6; the size of grit particles taken up by the focal species is taken from de Leeuw et al. (1995), the data which the distribution is based on is shown in figures 2&3. Distributions representing the body weight of the focal species are based on data from standard literature (Cramp et al., 1998, Dunning, 1993). Concluding, all of the distributions used to represent the respective parameters are based on experimental data and provided as part of the report (FMC Study # PC-0404).	
(13)	B.9.1.11 Evaluation of the risk assessment submitted by the notifier, - Secondary poisoning – higher tier risk assessment (tier 2)	**Notifier**: It is agreed that the residue in seedling should consist if the sum of carbofuran and 3-OH carbofuran (which is a major metabolite in plants). We also agree that the most valuable information comes from the decline curve residue trails (Waalkens and Baltussen, 2005 - France N&S). However, we disagree with the 6.13 extrapolation factor derived from the Zietz (2008) residue trails (see next column for further rationale). Instead the extrapolation factor of 2.5 set in the benfuracarb DAR is more robust since it is derived from a metabolism study. Besides,	The residue by Zietz (2008) analysed for carbofuran + 3-OH-carbofuran by a method (hydrolysis extraction) that enables the release of the conjugated residues. The total residues were measured at BBCH equivalent to the early time points of the decline curve (Waalkens and Baltussen, 2005) residue trails. The residues found remained lower to similar to those observed in the decline curve (DC) confirming that these DC present protective results. DALA in the residue study by Zietz (2008) are high compare to the BBCH because the dry weather conditions made the seedling emerge slowly. Therefore, more transformation of carbofuran to 3-OH-carbofuran

<table>
<tr><th colspan="4">Birds and mammals (B.9.1 and B.9.3)</th></tr>
<tr><th>No.</th><th>Column 1
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Comment * (restricted to 500 characters, ca.10 lines)</th><th>Column 3
Further explanations</th></tr>
<tr><td></td><td></td><td>using the same extrapolation factor will build up consistency across the dossiers.

We propose to use the following residue endpoints for a risk assessment at 600 g ai/ha:
Acute toxicity: use 10.4 mg/kg. At this time point, no significant 3-OH-carbofuran metabolisation has stared.
Short term toxicity: use 6.6 x 2.5 = 16.5 mg/kg (carbofuran + 3-OH-carbofuran)
Long term toxicity: use TWA of 2.4 x 2.5 = 6 mg/kg (carbofuran + 3-OH-carbofuran).

Residue values will be 10 times lower when conducting the risk assessment at 60 g ai/ha.</td><td>had time to happen in these trials which explain the abnormally high ratios of 3-OH-carbofuran compare to carbofuran.

Seedlings emerged quickly in the Decline Curve from France (Waalkens and Baltussen, 2005), therefore metabolisation of carbofuran to 3-OH-carbofuran should have been less extensive, which further support the use of the 2.5 transformation factor.</td></tr>
<tr><td>(14)</td><td>B.9.1.11 Evaluation of the risk assessment submitted by the notifier, - Secondary poisoning – higher tier risk assessment (tier 2)</td><td>Notifier:
Residue in earthworms and beetles should only consider carbofuran. Indeed, 3-OH-carbosuran is a minor metabolite in soil (<5%: see B.8.1.1.1 of original DAR) and will therefore not contaminate insect and soil dwelling arthropods in any significant concentrations. This is confirmed in the DAR of benfuracarb were the notifier Otsuka analysed both carbofuran and 3-OH-carbofuran in earthworm. These data confirms the modest contribution of 3-OH-carbofuran to the carbofuran residue.</td><td>Proposed Residue values (normalized from the measured residue obtained from Brown et al (2007) at an app rate of 375 g as/ha:

Earthworm:
<table>
<tr><th>App rate [g as/ha]</th><th>Acute [DAT 1]</th><th>Short-term [DAT 5]</th><th>Long-term [twa]</th></tr>
<tr><td>600</td><td>0.128</td><td>0.224</td><td>0.128</td></tr>
<tr><td>400</td><td>0.085</td><td>0.149</td><td>0.085</td></tr>
<tr><td>60</td><td>0.0128</td><td>0.0224</td><td>0.0128</td></tr>
</table>
Arthropods
<table>
<tr><th>App rate [g</th><th>Acute</th><th>Short-term</th><th>Long-term</th></tr>
</table></td></tr>
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<tr><th colspan="4">Birds and mammals (B.9.1 and B.9.3)</th></tr>
<tr><th>No.</th><th>Column 1
Reference to draft assessment report</th><th>Column 2
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Further explanations</th></tr>
<tr><td></td><td></td><td></td><td>
<table>
<tr><td>as/ha]</td><td>[DAT 1]</td><td>[DAT 5]</td><td>[twa]</td></tr>
<tr><td>600</td><td>5.84</td><td>0.512</td><td>2</td></tr>
<tr><td>400</td><td>3.89</td><td>0.34</td><td>1.33</td></tr>
<tr><td>60</td><td>0.584</td><td>0.05</td><td>0.2</td></tr>
</table>
</td></tr>
<tr><td>(15)</td><td>B.9.1.11 Evaluation of the risk assessment submitted by the notifier, - Secondary poisoning – higher tier risk assessment (tier 3)</td><td>Notifier:
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”.
We selected the PPPR panel approach for assessing pirimicarb since it is, in our knowledge, the only recognised reference in EU for conducting a tier 3 assessment of an insecticide risk against birds and mammals.
Since the tier 2 risk assessment concludes on the need for further refinements, then clarification are needed on the appropriate approach and acceptable input parameters into a tier 3 risk assessments.</td><td>Considering the large uncertainties in the factors two points should be noted.

First, parameters have all been conservatively estimated. E.g. the FPM has been taken from situations in which the food supply was rather optimal compared with the situation on a sugar beet field. On a sugar beet field the food intake rate will be probably be lower as assumed in the RA. The body weight is based on a considerable number of individuals. For the acute endpoint we calculated the HD5 which is an appropriate method to deal with uncertainties in the RA.

Second, to cover the uncertainties two calculations have been conducted. One assuming always the worst case number (highest food intake rate, lowest metabolism rate etc…) and one assuming an alternative more realistic situation. Even though it cannot be excluded completely that a single individual will behave according to the worst case assumption it is certainly unlikely that all individual of a population will always behave according to the worst case assumption in reality.</td></tr>
<tr><td>(16)</td><td>B.9.1.11 Evaluation of the risk assessment submitted by the notifier, - Secondary poisoning –</td><td>Notifier:
It is written that: “Moreover, in the conclusions of his own risk assessment for an application rate of 400 g a.s./ha, the notifier recognizes that in the</td><td></td></tr>
</table>

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
	higher tier risk assessment (tier 3)	*worst-case scenario, woodpigeons and wagtails may ingest a lethal carbofuran dose despite any ameliorative effects associated with ADME".* Birds may ingest a lethal dose only if all worst case assumptions fall together at the same time. It should be noted that this leads to a very unrealistic scenario. E.g., it appears that in the worst-case scenario for yellow wagtails, this bird may ingest slightly more than the lethal dose before they stop feeding. However, this seems unlikely because a yellow wagtail needs to feed at its maximum food intake rate only on contaminated insects without pause for more than half an hour. In reality a bird will feed with the maximum speed only for a couple of minutes. It will ingest contaminated and non contaminated arthropods (coming from adjacent fields and field margins). It appears that in the worst-case scenario, woodpigeons may ingest a lethal carbofuran dose. However, woodpigeons are known for their 'digestive bottleneck': a digestion rate of 0.5 g per min limits passage through the gut. The uptake of the active substance into the bird is therefore limited by digestion rate rather than by the food intake rate. Hence, the maximal food intake rate can realistically be assumed to b near 0.5 g/min. Therefore, the more	

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
		favourable assumptions seem to represent a more realistic case.	
(17)	B.9.1.11 Evaluation of the risk assessment submitted by the notifier, -Secondary poisoning – higher tier risk assessment (tier 3)	**Notifier**: It is written that: "*The brain AChE was meaningfully and dose-dependently decreased at all doses from 15' post-dosing time on, and was extensive until 90' (at 0.75 mg/kg b.w.), 4h (at 1.5 mg/kg b.w.) and until termination (at the top-dose). Based upon the extent of inhibition compared to the control group monitored at 5' post-dose, the maximum inhibition was attained at 30' post-dose for all dosing groups, and ranged from 64, 86, and 93% inhibition at the low- mid and top-dose, respectively. According to this study, the earliest symptoms of intoxication (AChE activity in the brains) could therefore occur at a later stage (15 min). Under those circumstances, birds could ingest a lethal dose before exhibiting symptoms of intoxication."* Even though the brain AChE was measurably decreased from 15' post-dosing time the animal could have a sensation of poisoning before carbofuran reaches the brain. The mode of action of carbamates is not restricted solely to the brain. Acetylcholine has functions both in the peripheral nervous system and in the central nervous system. In the peripheral nervous system acetylcholine activates muscles, and it is a major neurotransmitter in the	

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
		autonomic nervous system. The reaction to the toxin is almost immediately as shown by the studies in the RA.	
(18)	B9.3.1, Effects on other terrestrial vertebrates – Risk assessment presented by notifier	**Notifier**: We believe that the granule weight of 0.37 mg is correct.	**Size of granules.** The size of Furadan 5G granules is determined in the Vol 3 B2 as ranging from 0.4 to 0.85 mm. A slightly different range of 0.6-0.85 mm would only propose a worst case figure since larger granules would obviously carry more carbofuran. **Weight of granules** The values of 0.37 mg granule weight and the amount of 0.0185 mg a.s./granule are used throughout the DAR and are mentioned in the EFSA conclusion on carbofuran as well. Thus these values were used in the probabilistic risk assessment. The RMS calculated the weight of 0.87 mg per granule from the study of Knäbe et al. (2008). In that study, granules that had been applied to the field and were found on the surface were weighed. The RMS calculated a mean weight from these numbers and also calculated the amount of active substance in a granule from this number: 1143 granules/g 1 granule = 1/1143 = 0.8748 mg 5% ratio of active substance => 0.87 * 0.05 = 0.0437 mg a.s./granule In contrast to: 0.37 mg / granule ; 0.0185 mg a.s. / granule (=> DAR) It is questionable whether the weight of granules that have already been

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
			applied to the field and then collected from the field surface can be used to accurately calculate the amount of a.s. from it. It could, e.g., be possible that the granules have already taken up water from the field and thus they can have become heavier. But this would not have an impact on the amount of active substance in the granule. It appears to be more appropriate to use the laboratory data on granule weight and amount of a.s. per granule that was provided in the DAR.
(19)	B9.3.1, Effects on other terrestrial vertebrates – Risk assessment presented by notifier	**Notifier**: We note that RMS did not considered any PT factor in the tier 2 risk assessment, arguing that "*the PD determination is based on measurements of stomach contents or faeces examination of mammals commuting between treated fields and untreated areas. The PT factor is therefore already taken into account in the PD factor determination*". We disagree and believe that an additional PT value should be entered in the refined risk assessment. 1) Diet data based on stomach contents or faecal samples provide useful information in determining an appropriate species-specific PD value for refining the risk calculation. PDs can be used in combination with a PT value, but not replace it. In the diet samples it is analyzed what the animals had ingested in a rather short time period before the sample had been taken (minutes to hours). Mammals will take food in a rather limited area in this time.	

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
		2) The purpose of including a PT factor value allows for the inclusion of the focal species' behavior in the RA e.g. a change in feeding ground over the period of weeks to month. Over the period of weeks to month a field will change e.g. its growth stage. This would render the site into a less preferred feeding area. 3) Furthermore, it is appropriate to use a PT value in the tier 2 risk assessment since the SANCO guidance accepts the use of a PT in a first tier assessment. Therefore we maintain our proposal of a PT values for the focal species.	
(20)	B9.3.1, Effects on other terrestrial vertebrates – Risk assessment presented by notifier	**Notifier**: In its conclusion, the RMS states that "*Considering the large uncertainties on the numerous factors (FPM, Conc. in food, bw, half-life of ADME process, LD_{50}) that have to be estimated on the basis of scarce scientific evidence, the RMS does not take the responsibility to support this type of approach for carbofuran*". We selected the PPPR panel approach for assessing pirimicarb since it is, in our knowledge, the only recognised reference in EU for conducting a tier 3 assessment of an insecticide risk against birds and mammals.	Considering the large uncertainties in the factors two points should be noted. First, parameters have all been conservatively estimated, e.g. the FPM has been taken from situations in which the food supply was rather optimal compared with the situation on a sugar beet field. On a sugar beet field the food intake rate will be probably be lower as assumed in the RA. The body weight is based on a considerable number of individuals. Second, to cover the uncertainties two calculations have been conducted. One, assuming always the worst case number (highest food intake rate, lowest metabolism rate etc…) and one assuming an alternative more realistic situation. Even though it cannot be excluded completely that a

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
		Since the tier 2 risk assessment concludes on the need for further refinement for herbivore mammals, then clarification are needed on the appropriate approach and acceptable input parameters into a tier 3 risk assessments.	single individual will behave according to the worst case assumption it is certainly unlikely that all individual of a population will always behave according to the worst case assumption in reality.
(21)	B.9.3.2.1 Risk assessment presented by the RMS; Supported uses	**Notifier**: RMS wrote that "*the risk assessments at 400 or 60 g a.s./ha do not comply with the GAP of 600 g a.s./ha that was proposed in the original DAR*". However, the Article 15(1b) of Regulation 33/2008/EC states that "*The supported uses are the same as those that were the subject of the non-inclusion Decision. They may only be changed insofar as this is necessary, in the light of the reasons which gave rise to the non-inclusion Decision, to permit inclusion of that substance in Annex I to Directive 91/414/EEC*". Whilst we appreciate the efforts to calculate the Risk assessment at 600 g ai/ha, we submitted valid risk assessments at 60 g ai/ha and 400 g ai/ha in order to demonstrate a safe use scenario.	The RA conducted by the RMS shows that while the risk to granular intake at 600 g ai/ha is acceptable according to the EPPO scheme, the risk to secondary poisoning via ingestion of treated seedlings, earthworms and/or arthropods needs further refinement. This suggests the value of the low dose rate risk assessements, as wisely foreseen by Article 15b of the Regulation. Should the EC decide that registration of carbofuran is possible only with limitation on its maximum applied dose rate, this issue would be dealt by FMC at national level. Indeed, we are confident that certain technologies are efficient at dose rate equal or lower to 60 g carbofuran/ha. It should be noted that the 91/414/EEC revision induced major changes in the way insecticides are used on the EU market. Therefore, a use representative of the late '90 will not necessarily be representative of the current market. Besides, we understand that the Regulators encourage agriculture to reduce its chemical input. A reduced application rate of carbofuran contributes to this objective. We would also like to stress that diuron was re-submitted for Annex I

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
			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.
(22)	B.9.3.2.2 Risk assessment presented by the RMS; Source of uncertainty in the RA	**Notifier**: It is agreed that the residue in seedling should consist of the sum of carbofuran and 3-OH carbofuran (which is a major metabolite in plants). We also agree that the most valuable information comes from the decline curve residue trails (Waalkens and Baltussen, 2005 - France N&S). However, we disagree with the 6.13 extrapolation factor derived from the Zietz (2008) residue trails. Indeed, we believe that the extrapolation factor of 2.5 set in the benfuracarb DAR is more robust since it is derived from a metabolism study, and using the same extrapolation factor will build up consistency across the dossiers. We propose to use the following residue endpoints for a risk assessment at 600 g ai/ha: **Acute toxicity: use 10.4 mg/kg**. At this time point, no significant 3-OH-carbofuran metabolisation has stared. **Short term toxicity**: use 6.6 x 2.5 = **16.5 mg/kg** (carbofuran + 3-OH-carbofuran) **Long term toxicity**: use TWA of 2.4 x 2.5 = **6 mg/kg** (carbofuran + 3-OH-carbofuran). Residue values will be 10 times lower when	The residue by Zietz (2008) analysed for carbofuran + 3-OH-carbofuran by a method (hydrolysis extraction) that enables the release of the conjugated residues. The total residues were measured at BBCH equivalent to the early time points of the decline curve (Waalkens and Baltussen, 2005) residue trails. The residues found remained lower to similar to those observed in the decline curve (DC) confirming that these DC present protective results. DALA in the residue study by Zietz (2008) are high compare to the BBCH because the dry weather conditions made the seedling emerge slowly. Therefore, more transformation of carbofuran to 3-OH-carbofuran had time to happen in these trials which explain the abnormally high ratios of 3-OH-carbofuran compare to carbofuran. Seedlings emerged quickly in the Decline Curve from France (Waalkens and Baltussen, 2005), therefore metabolisation of carbofuran to 3-OH-carbofuran should have been less extensive, which further support the use of the 2.5 transformation factor. Furthermore, the Residue part of the dossier (B7) presents 2 carbofuran metabolism studies on sugar beet and maize seedlings (Mamouni ,2006) that confirms the extrapolation factor of 2.5 after 2 weeks or more. At the very earliest stage, these metabolism data confirm that the residue is essentially carbofuran.

<table>
<tr><th colspan="4">Birds and mammals (B.9.1 and B.9.3)</th></tr>
<tr><th>No.</th><th>Column 1
Reference to draft assessment report</th><th>Column 2
Comment * (restricted to 500 characters, ca.10 lines)</th><th>Column 3
Further explanations</th></tr>
<tr><td></td><td></td><td>conducting the risk assessment at 60 g ai/ha.</td><td></td></tr>
<tr><td>(23)</td><td>B.9.3.2.2 Risk assessment presented by the RMS; Source of uncertainty in the RA
p-9-170</td><td>Notifier:
Residue in earthworms and beetles should only consider carbofuran. Indeed, 3-OH-carbosuran is a minor metabolite in soil (<5%) and will therefore not contaminate insect and soil dwelling arthropods in a significant manner. This is confirmed in the DAR of benfuracarb were the notifier Otsuka analysed both carbofuran and 3-OH-carbofuran in earthworm. This data confirms the modest contribution of 3-OH-carbofuran to the carbofuran residue.</td><td>Proposed Residue values (normalized from the measured residue obtained from Brown et al (2007) at an app rate of 375 g as/ha:

Earthworm:
<table>
<tr><th>App rate [g as/ha]</th><th>Acute [DAT 1]</th><th>Short-term [DAT 5]</th><th>Long-term [twa]</th></tr>
<tr><td>600</td><td>0.128</td><td>0.224</td><td>0.128</td></tr>
<tr><td>400</td><td>0.085</td><td>0.149</td><td>0.085</td></tr>
<tr><td>60</td><td>0.0128</td><td>0.0224</td><td>0.0128</td></tr>
</table>
Arthropods
<table>
<tr><th>App rate [g as/ha]</th><th>Acute [DAT 1]</th><th>Short-term [DAT 5]</th><th>Long-term [twa]</th></tr>
<tr><td>600</td><td>5.84</td><td>0.512</td><td>2</td></tr>
<tr><td>400</td><td>3.89</td><td>0.34</td><td>1.33</td></tr>
<tr><td>60</td><td>0.584</td><td>0.05</td><td>0.2</td></tr>
</table></td></tr>
</table>

<table>
<tr><th colspan="4">Aquatic organisms (B.9.2)</th></tr>
<tr><th>No.</th><th>Column 1
Reference to draft assessment report</th><th>Column 2
Comment * (restricted to 500 characters, ca.10 lines)</th><th>Column 3
Further explanations</th></tr>
<tr><td>(1)</td><td>Vol. #, <<data point>>, <<description>></td><td><<MS/notifier>>: <<comment>></td><td></td></tr>
</table>

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			
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>>	

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

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, B.5.2.1, Method of analysis plant matrices, p.5-25	EFSA: The acceptability of the method developed and validated by Battelle (cf. report no. A-17-05-13 (Enriquez, 2006), sugar beet and maize) and of the ILV study by Zietz (2008) to be discussed in a meeting of experts in light of the modifications described in the ILV claimed to be necessary for robustness of the method	

12. 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>>	EFSA: <<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. 3, B.6.2.2, Acute percutaneous toxicity, p. 18-19: classification	EFSA: It is noted that the final decision of the European Chemical Bureau (ECB) was not to classify carbofuran relating to the acute dermal toxicity based on both studies summarised in the original DAR. See Commission Directive 2009/2/EC of 15 of January 2009.	

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>>	EFSA: <<comment>>	

Genotoxicity (B.6.4)

Section 2 - Mammalian toxicology (B.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>>	EFSA: <<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>>	EFSA: <<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>>	EFSA: <<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>>	EFSA: <<comment>>	

Other toxicological studies & Medical data (B.6.8-B.6.9)

Section 2 - Mammalian toxicology (B.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>>	EFSA: <<comment>>	

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.6.10.4, AOEL, p. 174	EFSA: A new AOEL of 0.00015 mg/kg bw/day was proposed for carbofuran during the PRAPeR teleconference TC04/09 on benfuracarb. As the RMS expressed a strong disagreement with this position after the teleconference, it is proposed to re-discuss this end-point.	

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>>	EFSA: <<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.6.12.1b, *in vitro* comparative dermal	EFSA: The validity of the study is in fact very limited due to discarding the 12 tape strips. It	

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 using rat and human skin, p. 187-188	should be discussed if it brings enough evidence to decrease the 10 % default value to the proposed 3 %.	

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>>	EFSA: <<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. 3, B.6.15.1, Operator exposure	EFSA: Pending on the discussion on the AOEL and dermal absorption values, operator exposure might have to be revised.	

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>>,	EFSA: <<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
	<<description>>		

13. Residues (B.7)

Storage Stability (B.7.0) B.7.14 in carbofuran DAR			
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: <<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.3, B.7.1.1 Metabolism in field corn (study by FMC)	EFSA: Page 7-3, 2nd paragraph: The statement that in grain 93.4% TRR remained as bound residues is in contradiction to what is reported in table B.7.1.1-1 (bound residue 31.1%). 93.4% were not solvent extractable, however succeeding acid hydrolysis released 61.1%. Was there any attempt made to identify compounds in this hydrolysed fraction?	
(2)	Vol.3, B.7 General: Metabolism studies with soil application (both FMC and Arysta studies)	EFSA: In a number of studies there was a significant portion of the TRR released by acid and/ or enzymatic hydrolysis. Based on these findings the presence of numerous glycoside conjugates was suggested, but there was no reporting on identification in the hydrolysed fractions. Was there any attempt made to identify the released compounds (aglycon) in these hydrolysed fractions?	

Section 3 - Residues (B.7)

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
(3)	Vol.3, B.7.1.3 Metabolism in maize and maize seedlings and Vol. 3, B. 7.1.4 Metabolism in sugar beet and sugar beet seedlings (studies by Arysta)	EFSA: In these studies identification was not attempted on residues below 10% TRR or less than 0.01 mg/kg, however it should be noted that according to current guidance an identification below the trigger is suggetsed for compounds with high toxicity (carbofuran is considered as such a compound). Moreover the number of reference standards used was very limited, and though these are new studies (2005/06) modern techniques such MS were not applied. In the sugar beet seedling study there were significant none-extractable fractions (70-92%) not further investigated. Altogether these new metabolism studies do not add any new information.	
(4)	Vol.3, B.7 General: Metabolism studies (Arysta)	EFSA: p.7-35 last paragraph on acceptance of plant metabolism studies. It is understood from this para that the studies conducted by Arysta are not considered acceptable to derive a metabolic pathway in the investigated crops. Can the RMS confirm this is correct?	

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. 3, B.7.2.1 Cow	EFSA: Even if in the metabolism study on cows	

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
	metabolism	there was only milk analysed for the TRR and for quantification of metbolites that could possibly be useful information as to whether residue levels in the milk are linear dose correlated. This can not be concluded on the basis of the feeding study, but may be necessary information.(see comment on expected residue levels in milk and RA)	

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 definition plant	EFSA: It was stated by the RMS in this chapter that 'metabolites formed were recovered as free and conjugated compounds'. In the light of the decision to include conjugates of carbofuran/3-OH- carbofuran in the RA residue definition for soil treated brassica vegetable (benfuracarb dossier), supported by the JMPR evaluation on soil treated crops, and considering the limitations in the submitted studies in the carbofuran dossier in terms of identification in the hydrolysed fractions (see comment above), the residue definition for root crops should be discussed by experts.	
(2)	Vol. B.7.3.2 Residue definition animal	EFSA: Since a ruminant study was triggered, and considering moreover the toxicological profile of	

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
	products	carbofuran and its carbamate metabolites a residue definition for risk assessment in animal commodities should be proposed and discussed by experts.	

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: p.1-51 analytical methods: Unless reported in chapter B.5.2, the detailed validation data for method Nr.A-17-00-15 and A-17-96-02 should be reported in this chapter B.7.6. These methods used acid refluxing and acidic hydrolysis respectively. Was the hydrolysis validated to quantitatively release conjugates?	
(2)	Vol. 3, B.7.6 Supervised residue trials- Analytical methods	EFSA: p.1-52 analytical methods: Unless also reported in chapter B.5.2, the detailed validation data for method Nr.A-17-05-13 should be reported in this chapter B.7.6. This method used acid refluxing. Would this step be considered sufficient to quantitatively release conjugates?	
(3)	Vol. 3, B.7.6.1 Supervised residue trials- Sugar beet (FMC trials)	EFSA: The conclusion is not clear with regard to the number of trials reported (N-EU 4, S-EU 14). Why were the trials with carbosulfan not considered, while the introduction to this chapter highlighted that they could be because of the rapid	

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
		degradation of carbosulfan to carbofuran.	
(4)	Vol. 3, B.7.6.1 Supervised residue trials-Sugar beet (FMC trials)	EFSA: In one of the trials a result of 0.112 mg/kg was found in the root. As agreed in previous EPCO and PRAPeR meetings, values should not be deleted if they may be true values and no obvious error has ocurred in a trial. The results in sugar beet (including Arysta data) correlate well with the findings in brassica crops (benfuracarb dossier), that were merely below the LOQ but showed occational low level residues are possible with this type of application and substance (see also indication by rotational crop data).	
(5)	Vol. 3, B.7.6.2 Supervised residue trials-Maize and Vol. 3, B.7.6.3 - Sunflower	EFSA: These data were not reviewed by EFSA as they are not relevant to the notifed use in sugar beet.	

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	EFSA: How relevant are the studies to reflect conditions of sugar beet processing, considering the tests were carried out at room temperature, the compound in one test was carbosulfan, and that alcaline pH was choosen in the test with	

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
		carbofuran? As agreed in previous EPCO and PRAPeR meetings the design in the phys-chem hydolysis study is less useful to describe the fate of an active substance and its metabolite under much different processing conditions. The case made should be discussed by experts.	
(2)	Vol. 3, B.7.7.2 Level of residue	EFSA: How relevant is this processing study when residues in the RAC were below the LOQ, as it was understood from the conclusion?	

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.3, B.7.8 Livestock feeding	EFSA: Considering an N rate of around 120 when the estimated dietary burden is compared with the dose rate in the FMC goat metabolism study and provided carbofuran and 3-OH carbofuran were defined as the relevant residues in animal matrices, residues of 0.3 µg/kg would be expected in milk and kidney (assuming linearity in dose and recovered level) , resp. It is noted that in the risk assessment for compounds with very low tox reference values the ‘usual’ trigger does not apply. A feeding study (carbosulfan) with LOQs of 0.025 and 0.05 mg/kg and only analysis in samples of too high dose groups is not considered	

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
		very useful to carry out an robust consumer risk assessment in terms of the notified use.	

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.3, B.7.9 Rotational crops	EFSA: The position paper summarised here does not address a situation of short plant back intervals. Moreover does the new confined study indicate signifcant residues could be expected. This is in line with the conclusion by PRAPeR TC05 regarding carbofuran residues in rotated crops (considering JMPR evaluation). It is again noted that in the light of the toxicological properties and low reference values for the carbofuran and 3-OH metabolite the trigger of 0.01 mg/kg is not applicable, as a consumer risk may be identified with even lower residue levels. Further data is expected.	

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

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	EFSA: The risk assessment does not consider potential residues in animal commodities (in particular milk) and in rotational crops (study ongoing). It should be noted that the estimated residue level of only 0.3 µg/kg in milk fills the ARfD to 25% and the ADI to 8%for children (EFSA PRIMo). This is a significant contribution and should thus be considered in a sound assessment, and so should be rotational crop residues when data will be available.	
(2)	Vol. 3, B.7.11 Consumer Risk Assessment	EFSA: It is not agreed that the data base showed a 'no residue situation' in sugar beet (leaves and root residues, see comment on trials). The acute riks assessment for sugar (beet) was carried out with 0.01 mg/kg while the highest residue was 0.112 mg/kg for carbofuran/3-OH carbofuran found in one trial with carbosulfan. However no refinement for sugar processing/raffination is possible due to lack of relevant data. The consumer risk assessment should be further discussed by experts.	
(3)	Vol. 3, B.7.12 MRLs	EFSA: It is noted that the proposed MRL will exceed the tox reference values in a consumer risk assessment.	

Other comments

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.7.15 Summary	EFSA: Consumer safety: EFSA does not agree with the RMS conclusion that there are no chronic and acute exposure concerns since 1) current assessment indicates an exceedance of both ADI and ARfD for one MS and data do not allow for further refinement and 2) the assessment is not finalised as it does not consider all means of consumer dietary exposure related to the notified use (animal products, rotated crop residues, drinking water)	

section 4 – Environmental fate and behaviour (B.8)

14. Environmental fate and behaviour (B.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.8.1.1 Route of degradation Conclusion of the study by Saxena) Page 8-8, Conclusion of the study by Schocken) Page 8-14	EFSA: It is stated for both studies that the study is not acceptable, but no detailed scientific argumentation is added for the exclusion. These studies were not regarded by the previous peer review as not acceptable; they are included in the EFSA conclusions on carbofuran, carbosulfan and benfuracarb. Moreover, the meeting of experts (PRAPeR 62, January 2009) of peer review on the resubmission of benfuracarb (2nd peer review) discussed and agreed to continue to accept this studies, and established a set of DT50 for carbofuran to be used further in the RA. For the set of DT50 see EFSA comment No (3).	
(2)	Vol. 3, B.8.1.1 Route of degradation 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). Comments (from UK and EFSA) on these studies and the evaluation of these comments by the RMS and the notifier can be found in the reporting table (rev 1-0, 1-12-2008) of benfuracarb. Therefore further clarification is probably not necessary.	

section 4 – Environmental fate and behaviour (B.8)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(3)	Vol. 3, B.8.1.2 Rate of degradation, B.8.1.2.1 Aerobic degradation Page 8-33 – 8-39	EFSA: The relevant pages for the DT50 derivation for carbofuran (page 8-33 – 8-39) were already discussed in the meeting of experts for the benfuracarb 2nd peer review in January 2009 (PRAPeR 62). The meeting agreed that all the refitted DT50 and the normalisation procedure indicated on these pages are acceptable and should be used further in the RA. It was also agreed that 3 other DT_{50} values from the studies by Saxena and Schocken (see EFSA comment (1)) should be added to the data set and that for Bretagne soil (study by Völkl) only the value from the experiment conducted at 20°C should be used. The resulting data set to be used is: 17.87, 14.01, 7.71, 13.56, 17.25, 6.92, 9.39, 11.46, 22.54, 22.19, 5.7, 20.39, 10.39, 11.69, 151, 54.6, 387 days. The median of these normalized SFO DT50 values is 14 days.	
(4)	Vol. 3, B.8.1.2 Rate of degradation, B.8.1.2.1 Aerobic degradation Page 8-39	EFSA: from the data set sorted in the General conclusions of the RMS on the derivation of an overall DT50 carbofuran it is not clear where the 6.1 days came from as in the individual reports there is no DT_{50} of 6.1 days. RMS please clarify it. 22.7 days should not be used as this is the average of the two DT_{50} values determined on the same soil at different temperatures. As input for PECgw and PECsw DT_{50} of 14d should be used. See also EFSA comment (3).	

* When mentioning page numbers of the DAR in your comments, **the page numbers should refer to the pdf-version** (not the WORD-version) of the DAR to ensure consistency among the Member States.

section 4 – Environmental fate and behaviour (B.8)

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.8.1.3 Field studies Page 8-41 – 8-44 & B.8.3 PECsoil	EFSA: In the previous peer review of carbofuran, carbosulfan and benfuracarb for calculation of PECsoil, DT_{50} of 71.9 days was used from the field study by Taylor and Houseman. The validity of this DT50 was already discussed in the meeting of experts for the benfuracarb 2nd peer review in January 2009 (PRAPeR 62) (the previous peer review was not able to make a conclusion on the reliability of this DT50). The meeting of experts (PRAPeR 62) agreed with the RMS that DT50 of 71.9 days is not relied on and for the PECsoil calculation, in line with this chapter, 27 days should be used (longest field dissipation data from the European sites from study by Mol, 2002). Therefore further clarification is probably not necessary.	
(6)	Vol. 3, B.8.2.1 **Adsorption and desorption of the active substance and relevant metabolites** Page 8-49	EFSA: In the EFSA conclusions for carbofuran and benfuracarb, the mean Koc (KFoc) of 22 ml/g (17 – 28 mL/g) for carbofuran is included (data gap was identified in this field in the carbosulfan EFSA conclusion). For PECgw and PECsw calculations for carbofuran, KFoc of 22 with 1/n of 0.96 was used in the EFSA conclusion for benfuracarb (2006). This value is supported in the carbofuran EFSA conclusion (2006) as well. Now, 23.3 mL/g as mean KFoc and 0.89 as mean 1/n value is calculated. Could RMS please clarify what is the reason for this change (see also EFSA comment (7)?	

* When mentioning page numbers of the DAR in your comments, **the page numbers should refer to the pdf-version** (not the WORD-version) of the DAR to ensure consistency among the Member States.

section 4 – Environmental fate and behaviour (B.8)

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.8.2.1 **Adsorption and desorption of the active substance and relevant metabolites** Study by Bradau E G, 1976b	EFSA: Results from the study by Bradau were ignored by the previous peer review, but it seems that now this study is considered as valid by the RMS. Maybe it is also true for the study by Daily D. Based on the EFSA conclusion; the only study considered valid by the previous peer review is Manouni A., 2002. Could the RMS please clarify on what bases he overruled the evaluation of the previous peer review (see also EFSA comment (6)? The results of this study (or studies) were not used regarding benfuracarb, the study (or studies) is not summarised in the benfuracarb documentation.	
(8)	Vol. 3, B.8.2.1 **Adsorption and desorption of the active substance and relevant metabolites** Studies of: Noorloos, B. van; Willems, H., 2005a, 2005b, 2005c	EFSA: Summaries of these studies were included in the additional report of benfuracarb (2008). Comments (from UK and EFSA) on these studies and the evaluation of these comments by the RMS and the notifier can be found in the reporting table (rev 1-0, 1-12-2008) of benfuracarb. The meeting of experts for benfuracarb (PRAPeR 62, January 2009) confirmed the values from these studies to use in the modelling. Therefore further clarification is probably not necessary.	
(9)	Vol. 3, B.8.4.4 Water/sediment study Page 8-73	EFSA: RMS should clearly state whether the RMS agree or disagree with the argumentation given in the position paper by Shaaban F. Elnaggar, 2005.	

* When mentioning page numbers of the DAR in your comments, **the page numbers should refer to the pdf-version** (not the WORD-version) of the DAR to ensure consistency among the Member States.

section 4 – Environmental fate and behaviour (B.8)

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.8.4.4 Water/sediment study Page 8-80	EFSA: It is noted that DT50 values for carbofuran are available from the benfuracarb dossier as well (see additional report for benfuracarb). However, these values were calculated from studies where carbofuran was formed as metabolite of benfuracarb and the values are shorter than the value, which is chosen for PEC calculation in this additional report for carbofuran. RMS please clarify moreover, what is the difference between the systems Millstream (A) and Millstream (D) in the table B.8.4.4-11? If these different values come from the same system and same study, both of them is valid and can be used?	
(11)	Vol. 3, B.8.6.1 PEC groundwater Table B.8.6.1-1	EFSA: The vapour pressure data of the metabolites used for the modelling seem to be higher than those were calculated by the QSAR methods (B.8.4.6). Carbofuran-7-phenol has a relatively high vapour pressure (calculated) and the used value is almost 5 times higher. The source of the used values is indicated as DAR, 2004 in the table B.8.6.1-1, but EFSA is not able to find these values in the original DAR. Please clarify this.	

section 4 – Environmental fate and behaviour (B.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. 3, B.8.6.1 PEC groundwater Vol. 3, B.8.6.2 PEC Surface water and sediment	EFSA: The proper input parameters to be used for the FOCUS modelling for carbofuran and its metabolites were discussed on the bases of the same data set during the peer review of the resubmission of benfuracarb (meeting of experts held in January 2009). For the agreed values please consider the Report of PRAPeR expert meeting 62 (15 January 2009), especially where the simulations presented here used input parameters that represent a 'better case'. Moreover please see EFSA comments No (3), No (6) No (10) and No (15).	
(13)	Vol. 3, B.8.6.2 PEC Surface water and sediment	EFSA: please indicate what the '*' mark means set for the Crop Wash-off Factor in the input data tables. Were any wash off from crop considered in the calculations where the application method is a soil incorporation? The simulations used should have resulted in all applied material reaching the soil. Please clarify.	
(14)	Vol. 3, B.8.10 Residue definition	EFSA: EFSA still agrees with the residue definition as it is stated in the carbofuran EFSA conclusion.	

section 4 – Environmental fate and behaviour (B.8)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(15)	Vol. 1, List of Endpoints	EFSA: please consider the following: - the 3 DT_{50} values from the studies by Saxena and Schocken should be added to the degradation box and the median of the whole dataset (14 days) should be presented (see EFSA comment (3)) - please check the normalization of the soil DT50 values of the metabolites of carbofuran (there are different values if they are compared with the values indicated in the benfuracarb LoEP - for Koc box please consider the EFSA comment No (7) - for the lysimeter studies some information about the results should be included - for input parameters for FOCUS calculations please consider EFSA comments No (11), No (12) and No (13) - for the definition of residue please consider the EFSA comment No (14)	

section 5 - Ecotoxicology (B.9)

15. 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. 1, Level 4 Data gaps in ecotoxicology	EFSA: The refined risk assessment for birds and mammals resulted in TERs below the triggers. The data gap identified in level 4 states that more information is needed on residue levels in feed items. However it is not clear if such a refinement would be sufficient to demonstrate a low risk. Further refinement may be necessary. Therefore it is suggested to broaden the wording of the data gap to "further refinement of the risk assessment to birds and mammals for the uptake of carbofuran residues in feed items is needed".	
(2)	Vol. 1, level 2, List of Endpoints	EFSA: The TERs for *Hypoaspis aculeifer* and *Folsomia candida* were mixed up.	
(3)	Vol. 3, B. 9. 1.12, 7.2 Higher tier risk assessment for birds from uptake of contaminated feed items.	EFSA: The PD values suggested for wood pigeon, yellow wagtail and skylark were not sufficiently supported by data. The RMS assessed the PD values as being of use in a qualitative way only. However the PD refinement was included in the TER calculation. It was referred to the dossier for benfuracarb where similar PD values were suggested. These PD values were rejected in the peer-review (see PRAPeR 63 in January 2009). Therefore it is suggested not to use the PD values in the TER calculation .	

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
(4)	Vol. 3, B.9.1, Risk assessment for birds for the uptake of contaminated drinking water.	EFSA: Carbofuran residues may be found in puddles formed after heavy rainfall. A risk assessment for the uptake of contaminated drinking water should be performed. Such a risk assessment was considered necessary in the peer-review for benfuracarb (PRAPeR 63 in January 2009).	
(5)	Vol. 3, B.9.1, Risk assessment for birds	EFSA: It should be discussed in an expert meeting whether the LC10 of 0.64 mg/kg bw/d from can be used in the risk assessment as a surrogate for the long-term NOEC from a reproduction study. (This discussion point was already identified in the peer-review for benfuracarb – see PRAPeR 63 in January 2009)	
(6)	Vol. 3, B. 9.3. Risk assessment for mammals	EFSA: It is not fully clear which studies were included in the calculation of the mean long-term NOAEL for mammals. Details on the effects observed in the different studies which were used to calculate the mean NOAEL should be provided. The endpoint for the long-term risk assessment should be discussed in an expert meeting. (This discussion point was already identified in the peer-review for benfuracarb – see PRAPeR 63 in January 2009).	

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
(7)	Vol. 3, B. 9.3. Risk assessment for mammals	EFSA: The PD values for the refined risk assessment for hares were derived on general considerations of the food compostion of hares. The relevance with regard to hares feeding in sugar beet fields is unclear. Particularly the refinement of the acute risk with a PD of 0.4 is highly uncertain. The information provided does not allow concluding that a hare would not feed solely on sugarbeet seedlings on the acute timescale.	
(8)	Vol. 3, B. 9.3. Risk assessment for mammals for the uptake of contaminated drinking water	EFSA: Carbofuran residues may be found in puddles formed after heavy rainfall. A risk assessment for the uptake of contaminated drinking water should be performed. Such a risk assessment was considered necessary in the peer-review for benfuracarb (PRAPeR 63 in January 2009).	
(9)	Vol. 3, B. 9.2. (p. 9-155) Risk assessment for aquatic organisms (sediment dwellers)	EFSA: The TER for *C. riparius* was below the trigger of 10 on the basis of FOCUS step1 PECsed values for carbofuran-phenol. It was concluded that the risk is acceptable. However the risk assessment should be conducted also with FOCUS step2 or step3 PECsed values in order to demonstrate that the trigger of 10 is exceeded.	

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
(10)	Vol. 3, B. 9.7. Risk assessment for non-target soil macro-organissms	EFSA: The conclusion on the risk to soil-dwelling non-target macro-organisms is unclear. The TER trigger is breached for *Folsomia candida*. In the text it is said that the risk is acceptable referring to the field study of Brown, K.C., Forster A., Davies N. A. (2007). However significant effects on collembola were observed in this study from May until September suggesting a high risk.	

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 Vol. 3, B.6.10.3, ARfD	DE: It is proposed to support both the ADI and the ARfD of 0.001 mg/kg bw as derived by the 2008 JMPR.	DE: The 2008 JMPR has evaluated the same toxicological data as the RMS in the updated DAR of November 2008. The RMS established an ADI and an ARfD of 0.00015 mg/kg bw based on a LOAEL of 0.03 mg/kg bw and a safety factor of 200. The JMPR established an ADI and ARfD of 0.001 mg/kg bw based on the overall NOAEL of 0.03 mg/kg bw per day identified on the basis of inhibition of brain acetylcholinesterase activity in rat pups aged 11 days (postnatal day 11) and a safety factor of 25. This NOAEL was supported by the $BMDL_{10}$ of 0.03 mg/kg bw extrapolated from data on inhibition of brain acetylcholinesterase activity in rat pups aged 11 days (postnatal day 11) from three studies. A safety factor of 25 was considered to be appropriate because the acute toxic effects of carbofuran are dependent on C_{max} rather than area under the curve of concentration–time (AUC) and data indicated that the sensitivity of humans and laboratory animals (rats, dogs) to inhibition of acetylcholinesterase activity by carbofuran was similar. A more detailed explanation is given in the JMPR Report 2008, pp.123-126 (carbofuran) and pp. 7-10 (Safety factors for acute C_{max}-dependent effects; specific considerations with respect to carbamates such as carbofuran).

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
(1)	Vol. 3, B.7.3.2, Definition of residue in animal products	DE: Given that Regulation (EC) No 396/2005 requires MRLs for each commodity listed in annex I thereto, a definition of residues is deemed necessary also for products of animal origin.	Even though no residues can reasonably be expected in products of animal origin it seems nevertheless desirable, as there are MRLs for carbofuran in the Community legislation, to be prepared for an answer to the question: "0.1* mg/kg of what ?". Livestock metabolism studies are available, so a residue definition for animal matrices should be provided.

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	DE: it appears misleading to insert the MRL of 0.01* mg/kg for sugar beet.	The UK model operates with an intake of 63,85 g sugar beet root per kg bw (calculated from the sugar intake and the amount of sugar beets needed to produce this amount of sugar); along with a body weight of 20.5 kg for an 4-6 y UK infant this means a consumption of 1.31 kg of sugar beet a day ! This approach appears flawed because even if one assumes (which is highly unlikely) that the level of residues in the raw sugar beet root equals that in the sugar and no reduction of residues occurs during processing, the consumed amount of refined sugar should be about one fifth corresponding to the sugar content of the root (1.3 kg x 0.2). In addition, when taking into account the results of the (recent) residue trials and the DT_{50}/DT_{90} values in soil, and keeping further in mind that any residue that may be left in the roots is substantially reduced during production of sugar, the outcome of the model is clearly overly conservative. As this conclusion is also shared by the RMS this should be stated more clearly because it might easily be overlooked when just swiftly scanning the report (at the moment just one sentence in the conclusion).

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. 1, 2.5.2, Fate and behaviour in soil, Aerobic metabolism	DE: see comment (4)	
(2)	Vol. 3, B.B.8.1.1.1, Aerobic degradation in soil	DE : Page 8-9 (revised in Nov. 2008) 'The incubation under aerobic/anaerobic conditions cannot be used to determine a valid DT_{50}.'Could you please give an explanation?	
(3)	Vol. 3, B.8.1.1.3, Soil photolysis	DE : Page 8-31 (revised in Nov. 2008) The temperature of the soil during radiation must be kept at about 20 °C. Furthermore the findings cannot be transferred to the North European conditions.	
(4)	Vol. 3, B.8.1.1.1, Aerobic degradation in soil	DE: RMS has excluded the aerobic soil metabolism study (Saxena A.M. et al., 1994) from the risk assessment although this study was considered of acceptable quality and taken into account in the original DAR. Please give a justification for the exclusion of the study.	

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. 3, B.8.2, Adsorption, desorption	DE : Page 8-45 ff :It is observed that Kf-values had been determined and given as Kd-values. Please	

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
	and mobility in soil	replace 'Kd' by 'Kf'.	

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. 3, B.8.4.2, Direct phototransformation	DE: RMS has excluded the aqueous photolysis study of FMC. Please give an explanation for the exclusion of the study.	

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.9.1.1, Acute oral toxicity	DE: Study on effects of Furadan 4F on the AChE activity. Due to the poor test design (too short observation period, lack of clinical examination) the ecotoxicological relevance of the findings can be regarded as questionable.	
(2)	Vol. 3, B.9.1.2, Acute dietary toxicity	DE: Regarding the sub-acute dietary toxicity study to the mallard duck only the 5-Day-LD_{50} was reported. Since mortality increased over time the 14-d median lethal value (LD_{50}) of 1.6 mg/kg /bw/d (corresponding to 21 ppm) should be mentioned.	
(3)	Vol. 3, B.9.1.12, Summary of effects on birds –exposure and risk assessment for birds	DE: According to the EPPO risk assessment scheme the risk is considered to be low, if ETR-values are below 1. This approach cannot be accepted since no safety factor were used and lethal effects might occur following ingestion of one single granule.	
(4)	Vol. 3, B.9.1.12, Summary of effects on birds –exposure and risk assessment for birds	DE: We fully agree with the conclusions by the RMS on the outcome of the risk assessment for birds. Due to the shortcomings in the reported studies and doubtful interpretation of data the risk of Furadan 5G granules to birds cannot be regarded acceptable.	

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
(5)	Vol. 3, B.9.3.1, Effects on other terrestrial vertebrates	DE: We agree with the RMS that the 3rd tier risk assessment of the notifier includes a lot of uncertainties on the numerous factors (FPM, concentration in food, body weight, half-life of ADME process) .	
(6)	Vol. 3, B.9.3.2 – 4.2, Effects on other terrestrial vertebrates	DE: see comment (3).	
(7)	Vol. 3, B.9.3.2, Effects on other terrestrial vertebrates	DE: The residue levels for carbofuran on earthworms and insects in the risk assessment for mammals are based on a field trial with a much lower application rate (0.375 kg as/ha) as the intended use (0.6 kg as/ha). Moreover the residue level does not include the contribution of 3-OH-carbufuran. Therefore they can not be used in the risk assessment.	
(8)	Vol. 3, B.9.3.2, Effects on other terrestrial vertebrates	DE: The residues of carbofuran in food (sugar beet seedlings) do not include the contribution of 3-OH-carbofuran.	
(9)	Vol. 3, B.9.3.2 – 7.2, Effects on other terrestrial vertebrates	DE: Refined risk assessment for the hare. As the PD is already set at 0,4 for non-grass herbs, the PT can not be set at 0,33. The PT factor is already taken into account in the PD factor determination.	
(10)	Vol. 3, B.9.3., Effects on other	DE: Due to the fact, that the refined acute TER for insectivorous mammals is 2.38 and the	

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
	terrestrial vertebrates	refined long-term TER is 0.97 as well as the refined acute TER for herbivorous mammals is 4.81 and the refined long-term TER is 3.53, the risk for mammals consuming sugar beet seedlings, earthworms and arthropods is not acceptable for the intended use.	

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, B.9.2.9, Effects on sediment dwelling organisms	DE: The analysis of the studies with sediment-dwelling organisms (effects of Carbofuran-7-phenol and effects on Carbofuran) are not correct. Although the amounts of the nominal concentrations after 28 days are just 23-46 (Carbofuran-7-phenol) and 44-53 (Carbofuran) %, the endpoints are based on the nominal concentrations. The endpoints must be based on mean measured concentrations.	

Bees and non-target arthropods (B.9.4 and B.9.5)

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. 3, B.9.5.2, Effects of the formulations on non-target terrestrial arthropods (laboratory, semi-field tests)	DE: In the study with the beetle *Poecilus cupreus* most animals were moribund directly after application, but 80 % recovered. Since in the field no moribund beetle would survive, the 20 % mortality value is considered to underestimate the effects of the test substance.	
(2)	Vol. 3, B.9.5.2, Effects of the formulations on non-target terrestrial arthropods (laboratory, semi-field tests)	DE: In the extended lab test (dose-response) with the beetle *Aleochara bilineata* no data on adult mortality are reported.	
(3)	Vol. 3, B.9.5.2, Effects of the formulations on non-target terrestrial arthropods (laboratory, semi-field tests)	DE: The extended laboratory toxicity test with *Poecilus cupreus* on Curaterr GR 5 Blau is not acceptable. The reference substance did not show toxic effects.	
(4)	Vol. 3, B.9.5.4, Effects of the formulations on non-target terrestrial arthropods (laboratory, semi-field tests).	DE: The field study on the effects of Furadan 5G (Brown, Forster, Davies, 2007) does not fully cover the application rate of 0,600 kg as/ha in sugar beet and can not be considered in the risk assessment for arthropods.	
(5)	Vol. 3, B.9.5.4, Effects of the	DE: The risk of carbofuran to non-target arthropods is not acceptable for the	

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
	formulations on non-target terrestrial arthropods (laboratory, semi-field tests)	intended use of 0,600 kg as/ha.	

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.9.7, Effects on other non target soil organisms	DE: The long-term risk of carbofuran to *Folsomia candida* is not acceptable. The field study of Brown, Forster and Davies (2007) does not fully address the proposed indication of 0,6 kg as/ha and can not be considered in the risk assessment.	

16. Physical/Chemical Properties; Details of Uses and Further Information; Methods of Analysis (B.1-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 1, LOEP, decomposition temperature	NL: August 2004 was quite some time ago, what is the status on the decomposition temperature study / information? (see also vol 3 of the DAR).	
2.	Vol 3, B.2.2.19a, Diafuran 5G Shelf-life	NL: Please state what type of packaging was used for the shelf-life study.	
3.	Addendum to Vol 3 B5, B.5.5.2	NL: It appears that the conclusion that a fully validated method for dry crops is not supported by the evaluation under B.5.2.1? The recoveries at 10xLOQ are not within acceptable range. Please also note that in the LOEP it is suggested that additional validation is required.	

section 2 - Mammalian toxicology (B.6)

17. Mammalian toxicology (B.6)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca. 10 lines)	Column 3 Further explanations
1.	B.6.10.4; AOEL	NL: In PRAPeR TC 3 the AOEL was discussed. As the development of the brain in rats at PNF 11 reflects the development of the human brain in late pregnancy and occupational exposure of pregnant woman cannot be excluded, the AOEL was set at the same value as the ADI and AOEL, i.e. 0.00015 mg/kg bw/day	
2.	B.6.12.2b; dermal absorption, conclusion.	NL: RMS proposes a dermal absorption value for the concentrate of 3%, based on the amount 6.19 % absorbed after 24h at a relevant area dose in an in vivo study in rats with carbofuran, and a correction factor of 2 based on an in vitro study with rat and human skin. NL can agree with the correction factor but has doubts by the value for the in vivo study. Urinary excretion shows significant further absorption after 24 h. Whether this is caused by a large available dermal depot or due to the fact that the skin was not washed after 6 or 24 hours is not clear. Therefore, NL proposes to use the more conservative value of 10% for in vivo rat as s originally used. After correction for the in vitro study this result in a dermal absorption for the concentrate in humans of 5%.	

section 3 - Residues (B.7)

18. 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	B7.1.4 (Arysta), metabolism in sugarbeet, page 7-26	NL: In the text it is concluded that 600 g/ha is the normal dose. However, under point B.7.4 it is reported that this was the dose proposed in the original submission by FMC but that at re-submission a dose of 60 g as/ha was proposed. Hence, the normal dose of 600 g as/ha, would be no longer the normal dose, but 10N. See also comment 2	
2	B.7.4	NL: There is no use pattern for Arysta reported, therefore, acceptability of the Arysta studies cannot be verified.	

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

19. Environmental fate and behaviour (B.8)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca. 10 lines)	Column 3 Further explanations
1	B.8.1.1	NL: In case of carbofuran-phenol a very low recovery was found. Because the metabolite has a Vp of 1.32 Pa, the volatility of this metabolite could be an important factor in the low mass balance. In the study summary the following is stated: 'Mean procedural recoveries were low (17-74%) at the LOQ and 20x LOQ level for all analytical series. However, even when a correction for this low recovery would be made, analytical results of the samples analysed within a few hours after spiking, would be <20% of applied. Hence, despite the low recoveries, the results do indicate rapid dissipation of carbofuran-phenol from soil with a half-life of <1 day. Carbofuran-phenol dissipated rapidly in soil with half-lives of <1 day in Speyer 2.2, Speyer 2.3 and Speyer 6S soils.' Nevertheless, the values are used as degradation parameters during the assessment. For modelling the consequence is that volatility is introduced in the models by the DisT50 and also by the vapour pressure. This is double counting of a loss process with impact on the predicted concentrations. No adequate DegT50 values of carbofuran-phenol are available in the dossier.	

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

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca. 10 lines)	Column 3 Further explanations
2	B.8.2.1 sorption metabolites 3-hydroxy-carbofuran	NL: In case of 3-hydroxy-carbofuran the soil used for risk assessment (lowest value) is not acceptable. Because only 2% has adsorbed after 6 hours according to OECD 106 no adequate Koc value can be derived. The Koc of 43 L/kg cannot be the result of 2% adsorption. Now it is assumed that the concentration decrease is due to adsorption (overestimation). The P criterion of 0.3 (OECD 106) is not met; p value of soil II is 0.2. Because the average recovery is 88% at least 12% loss can be due to degradation. Only 2 adequate values are available or the value of 43 L/kg should be corrected for degradation/recovery.	
3	B.8.2.1 sorption metabolites 3-keto-carbofuran	NL: In case of 3-keto-carbofuran in only 2 soils 1/n values are presented. Two values of 1.144 and 0.489 are available. The low value is not acceptable. Below a 1/n of < 0.7 no freundlich sorption is applicable.	
4	B.8.2.1 sorption metabolites carbofuran-phenol	NL: In case of carbofuran-phenol values of 0.4, 0.5 and 0.75 are available. The low values are not acceptable. Below a 1/n of < 0.7 no freundlich sorption is applicable. Moreover the metabolite has a Vp of 1.32 Pa, so the volatility of this metabolite could also be an explanation of the low mass balance.	

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

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca. 10 lines)	Column 3 Further explanations
5	B.8.6.1 PECgw	NL: Input values DT50 and Koc/Kom The input values used are not acceptable for 3-hydroxy-carbofuran and carbofuran-phenol	

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

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca. 10 lines)	Column 3 Further explanations
6	B.8.6.1 PECgw	NL: 1/n values For the metabolites no adequate 1/n values are available. According to the EFSA meetings if no adequate data is available a 1/n of 1 should be used. In PRAPeR 32 it was stated: The experts agreed that when soil adsorption was only measured at a single experimental concentration, so only a Kd value could be determined, subsequent FOCUS modelling simulations should be carried out using a 1/n value of 1 (as Kd estimations assume a linear isotherm). They agreed that in this situation a 1/n of 0.9 (FOCUS guidance default) should not be used. In case of 3-hydroxy-carbofuran only Kd values are available and no measured 1/n values. In case of 3-keto-carbofuran in only 2 soils 1/n values are presented. Two values of 1.144 and 0.489 are available. The low value is not acceptable. Below a 1/n of < 0.7 no freundlich sorption is applicable. In case of carbofuran-phenol values of 0.4, 0.5 and 0.75 are available. The low values are not acceptable. Below a 1/n of < 0.7 no freundlich sorption is applicable.	

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

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca. 10 lines)	Column 3 Further explanations
7	B.8.6.1 PECgw	NL: Q10 It is unclear if the new Q10 value has been used. According to the Scientific Opinion of the Panel on Plant Protection Products and their Residues on a request from EFSA related to the default Q10 value used to describe the temperature effect on transformation rates of pesticides in soil the median Ea value of 65.4 kJ mol-1 corresponding to a Q10 of 2.58 is the appropriate value.	
8	B.8.6.1 PECgw	NL: The incorporation depth is unclear. 7 cm is mentioned in B.8 and 5 cm in the LOEP.	

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

<table>
<tr><th>No.</th><th>Column 1
Reference to draft assessment report *</th><th>Column 2
Comment * (restricted to 500 characters, ca. 10 lines)</th><th>Column 3
Further explanations</th></tr>
<tr><td>9</td><td>B.8.6.1 PECgw</td><td>NL: Based on 1/n values for metabolites of 1, the Q10 of 65.4 higher concentrations are predicted (7 cm incorporation). Even with the non agreed input data (e.g. DT50 and Kom, Vp 7-phenol) a safe use in sugar beets is very limited.
An expert meeting on input data (e.g. DT50 and Kom, Vp 7-phenol) is recommended.
For Sevilla the results are based on spring application and not autumn.</td><td>Project summary report of project: carbofuran

Date: 26/01/2009

<table>
<tr><th>CARB</th><th>7-PHE</th><th>3OH</th><th>3-ket</th><th>LOCATIO</th></tr>
<tr><td>0.726951</td><td>0.001690</td><td>0.023188</td><td>0.3278</td><td>CHATEAUDU</td></tr>
<tr><td>0.758615</td><td>0.013239</td><td>0.023027</td><td>0.3430</td><td>HAMBUR</td></tr>
<tr><td>0.579800</td><td>0.000840</td><td>0.019479</td><td>0.2722</td><td>JOKIOINE</td></tr>
<tr><td>0.805551</td><td>0.002278</td><td>0.024848</td><td>0.3884</td><td>KREMSMUENSTE</td></tr>
<tr><td>0.774720</td><td>0.002935</td><td>0.024139</td><td>0.3507</td><td>OKEHAMPTO</td></tr>
<tr><td>1.882196</td><td>0.031035</td><td>0.055409</td><td>0.7222</td><td>PIACENZ</td></tr>
<tr><td>0.002158</td><td>0.000003</td><td>0.000128</td><td>0.0026</td><td>PORT</td></tr>
<tr><td>0.068046</td><td>0.000132</td><td>0.002560</td><td>0.0370</td><td>SEVILL</td></tr>
<tr><td>0.035446</td><td>0.000115</td><td>0.001230</td><td>0.0184</td><td>THIV</td></tr>
</table>
</td></tr>
<tr><td>10</td><td>B.8.6.1 PECsw/sed</td><td>NL: The comments on input data regarding degradation and sorption in soil for the metabolites are also relevant for PECsw/sed.</td><td></td></tr>
</table>

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

section 5 - Ecotoxicology (B.9)

20. 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.1, LoE, and Vol. 3, B.9.1: endpoint from bird reproduction study	NL: We agree with RMS that the long-term mallard study can be used to assess the effect on reproductive parameters. To avoid confusion, it would be good to indicate in the LoE that the long-term NOEC only includes reproductive parameters and not parental mortality. We do not understand why RMS indicates (e.g. in Table B.9.1.12-1 on page 9-91) that this NOEC of 10 ppm is based on adult mortality, as clear effects on adult mortality were seen at 2, 5 and 10 ppm.	
2	Vol. 3, B.9.1: long-term bird endpoint	NL: The endpoint used in the long-term risk assessment is the LC10 of 0.64 mg/kg bw/d. We wonder if this endpoint covers the effects seen in the reproduction study with the mallard. In that study, 16 out of 35 birds died at a concentration of 2 mg/kg feed. No information is available to recalculate this to daily dose, but it is probable that it would be lower than 0.64 mg/kg bw/d, as at 10 mg/kg feed the daily dose was 1.5 mg/kg bw/d.	
3	Vol. 3, B.9.1.12: Risk assessment birds, uptake of granules	NL: We agree with RMS that the risk to birds from uptake of granules is not acceptable considering the large likelyhood of effect from uptake of only one granule.	

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
4	Vol. 3, B.9.1.12: Risk assessment birds, uptake of other food items	NL: We agree with RMS that the risk to birds feeding on sugar beet seedlings, beetles and earthworms is not acceptable. Further insecurities in the calculations are: use of PT and PD refinements for acute exposure is generally not acceptable; the PD of 0.3 voor sugar beet seedlings for woodpigeon is not sufficiently supported (by radiotracking data) and can not be used quantitatively; the PD of 0.7 for yellow wagtail is more a PT, but is anyway not sufficiently supported for quantitative refinement; PD refinements for skylark were not accepted for benfuracarb in Praper 63.	
5	Vol.3, B9.3	NL: Considering the specific characteristics of carbofuran, the setting of the long term mammalian endpoint is a complicated issue. RMS has taken the mean of a range of very different studies, which is generally not acceptable. Furthermore, new neurotoxicity studies with carbofuran have recently become available in the mamtox section which lead to a long-term endpoint in the mamtox section ca. 10x as low as the one proposed here. We recommend a discussion on the ecologically relevant long-term mammalian endpoint in an expert meeting.	

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
6	Vol. 3, B.9.1.12: Risk assessment mammals, granules	NL: RMS has calculated ETR-values without considering a safety factor, which is not according to the EPPO-scheme (which states that either a 5th percentile of the toxicity distribution or a fixed extrapolation factor should be used).	
7	Vol. 3, B.9.1.12: Risk assessment mammals, granules	NL: For mammals the same conclusion can be drawn as for birds: there is a large likelyhood of effect from uptake of only one or a few granules. Therefore we wonder if the risk really is acceptable.	
8	Vol. 3, B.9.1.12: Risk assessment mammals, uptake of seedlings, earthworms and arthropods	NL: We agree with RMS that the risk to mammals feeding on sugar beet seedlings, arthropods and earthworms is not acceptable. A further insecurity in the calculations is that the use of PT and PD refinements for acute exposure is generally not acceptable.	