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Comments on the Draft Assessment Report on benfuracarb (EAS)

RMS BE

End of commenting period: 23 September 2008 (MS, NOT)

Date	Supplier	File
18.09.2008	UK	01 benfuracarb comments UK 2008-09-18.doc
18.09.2008	NOT	02 benfuracarb comments NOT 2008-09-18.doc
23.09.2008	DE	03 benfuracarb comments DE 2008-09-23.doc
23.09.2008	NL	04 benfuracarb comments NL 2008-09-23.doc
24.09.2008	FR	05 benfuracarb comments FR 2008-09-24.doc
26.09.2008	EFSA	06 benfuracarb comments EFSA 2008-09-26.doc

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

None.

section 2 - Mammalian toxicology (B.6)

None.

section 3 - Residues (B.7)

None.

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

1. 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
	Vol 3, B.8.1.1 additional data on aerobic degradation	UK: All 3 new study summaries in B.8.1.1 are quite brief (especially methods of analysis) but indicate fairly rapid degradation of the metabolites	
	Vol 3, B.8.1.1 additional study aerobic degradation benfuracarb at 10 and 20C in alkaline soils	UK: Brief study summary (especially methods of analysis) but indicates similar degradation rates to acidic/neutral soils.	
	Vol 3, B.8.1.1? Degradation of carbofuran in soil at low temps	UK: Please can the RMS clarify if/where these data have been evaluated to address this outstanding point as we were unable to identify any relevant studies here.	
	Vol 3, B.8.1.1.1, aerobic degradation in soil – determination of DT50s for modelling	UK: The DT50 values of 175 and 444 days for carbofuran are presented in the agreed list of end points for carbofuran so the UK considers they cannot be ignored (if the studies are generally considered invalid the DT50 values should not be listed in the endpoints). Unless the DT50 values are removed from the endpoints the risk assessment should take account of them.	
	Vol 3, B.8.2.1 additional data on adsorption	UK: Studies conducted to OECD guidelines, and are acceptable for risk assessment. Some kocs have a fairly wide range around the averages eg average 330 mL/g but range from 48 – 504 mL/g.	NB: SSLRC classifies koc of 55 mL/g as ‘mobile’, 330 mL/g as ‘moderately mobile’ and 1031 mL/g as ‘slightly mobile’.

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Comments of UK on the additional report on Benfuracarb

(18/9/08) 5/6

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

No.	<u>Column 1</u> Reference to draft assessment report *	<u>Column 2</u> Comment * (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
	Vol 3, B.8.6.1 new gw modelling	UK: Carbofuran exceeds 0.1µg/L in 4/7 spring scenarios and 3/5 summer scenarios using Pearl. Although carbofuran only exceeds 0.1µg/L in 1/12 scenarios using PELMO, we would normally take account of results using both models. There is also the strong possibility of carbofuran exceeding 0.1µg/L in more scenarios after taking account of the longer DT50s mentioned above.	This comment is also applicable to the modelling of the metabolites
	Vol 3, B.8.9, definition of residue	UK: Due to time and resource constraints we have focussed our attention to the key concern that prevented Annex I listing so have not reconsidered the residue definitions. We note there are additional data in the toxicology section that relate to the relevance of environmental metabolites.	

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section 5 - Ecotoxicology (B.9)

None.

Comments of Otsuka Chemical Co., Ltd on the additional report on benfuracarb

(18.09.2008) 1/10

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

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

No.	<u>Column 1</u> Reference to draft assessment report *	<u>Column 2</u> Comment * (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. 1, 1.1, purpose	Notifier:In general the notifier is pleased with the DAR and acknowledges the overall conclusions. The comments here given are limited and do not affect the overall conclusions. With respect to ecotox (birds) the notifier wishes to highlight differences between the submitted dossier and DAR, especially concerning the choice of ecotoxicological relevant toxicity endpoints and PD refinements used in the risk assessment.	

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section 2 - Mammalian toxicology (B.6)

3. Mammalian toxicology (B.6)

No.	<u>Column 1</u> Reference to draft assessment report *	<u>Column 2</u> Comment * (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
		Notifier: no comments	

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section 3 - Residues (B.7)

4. Residues (B.7)

No.	<u>Column 1</u> Reference to draft assessment report *	<u>Column 2</u> Comment * (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. 1, 2.3.6.4, consumer	Notifier: clarification: the reported % ARfD are based on IESTI 1 calculation of the EFSA model	
(2)	Vol. 1, 2.4.2, consumer	Notifier: clarification: the reported % ARfD are based on IESTI 1 calculation of the EFSA model	
(3)	Vol . 1, appendix I, LoEP	Notifier: footnote 1 under box on page 61 should be removed. Residue values at harvest were below LOQ for all components of the residue definition (report Feb 2008).	
(4)	Vol. 3, appendix C, residue data	Notifier: correction: on page 68 and 69, “in progress” is entered in the table for 42 day results. Actually, the report submitted by the notifier within the timelines of the Regulation did contain data for this timepoint. Trial AF/12036/OT-1: all residues in seedlings <LOQ at day 42 and for trial AF/10236/OT-2: residues in seedlings at 42 days <LOQ (BFC), 0.0242 (CF) and 0.0793 (3-OH-CF) mg/kg. This has no further effect on the risk assessment.	

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

5. Environmental fate and behaviour (B.8)

No.	<u>Column 1</u> Reference to draft assessment report *	<u>Column 2</u> Comment * (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. 1, 2.5.1, Definition of the residues	Notifier: correction second and last paragraph on page 34: carbofuran-phenol does <i>not</i> contain the active carbamate moiety	
(2)	Vol. 1, 2.5.1, Definition of the residues	Notifier: addition first paragraph on page 35: FOCUSgw calculations have indicated a number of safe scenarios (e.g. FOCUS-PELMO: 11 out of 12 safe scenarios, see Vol 3 B8.6.1 page 46)	
(3)	Vol. 1, 2.5.2, Fate and behaviour in soil	Notifier: correction 5 th paragraph under 2.5.2 on page 35: carbofuran-phenol does <i>not</i> contain the active carbamate moiety	

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section 5 - Ecotoxicology (B.9)

6. Ecotoxicology (B.9)

No.	<u>Column 1</u> Reference to draft assessment report *	<u>Column 2</u> Comment * (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. 1, 2.6.1.1, Effects on birds	Notifier: (page 84) the notifier disagrees with the choice of toxicological endpoint for the Tier I short-term risk assessment (carbofuran). The proposed endpoint comes from a non-standard 14 day duckling study. It is more appropriate to use the endpoint from the standard 5 day dietary study in mallard duck for short term exposure (LC ₅₀ 10 mg/kg bw/d), especially considering that maximum residue levels in food - which are used in the short term RA – are only present for a few days.	Notifier: (page 46) further justification of the proposed LC ₅₀ of 10 mg/kg bw/d. LC ₅₀ values have been determined in 6 studies for 2 bird species and were 1.6 (14d, ducklings), 10 (5d), 15.8 (14d), 17 (5d), 20.8 (7d) and 114 (5d) mg/kg bw/d. The proposed value of 10 mg/kg bw/day is the worst-case value of the more appropriate dietary studies (with more relevant exposure periods in relation to the representative use of benfuracarb).
(2)	Vol. 1, 2.6.1.1, Effects on birds	Notifier:(page 85) the RA performed by the RMS deviates from the submitted RA by the notifier. The RA performed by the RMS appears to be an extreme worst-case scenario (accumulation of worst-case residue values, worst-case toxicological endpoints and worst-case PD factors, no PT factor). See also comments (1) (8) (10) (11) (12) (13)	
(3)	Vol. 1, 2.6.1.2, Effects on other terrestrial vertebrates	Notifier: the RA performed by the RMS deviates from the submitted RA by the notifier. The RA performed by the RMS appears to be an extreme worst-case scenario (accumulation of worst-case residue values and worst-case PD factors, no PT factor). See also comments (14)(15)	

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section 5 - Ecotoxicology (B.9)

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(4)	Vol. 1, 2.6.4.1, Earthworms	Notifier: in relation to current guidance the data on earthworm fulfil all criteria of 91/414/EEC and demonstrate an acceptable risk to earthworms (TERacute > 10, DT50f <100 days and single application). It is considered that any sublethal effects will be reversible (typical for carbamate acetylcholinesterase inhibition) and so any effects will not persist and will not affect earthworm populations.	
(5)	Vol. 1, Appendix 1, LoEP	Notifier: page 84: see comment (1) above	
(6)	Vol. 1, Appendix 1, LoEP	Notifier: page 85-86: see comment (2) and (3) above	
(7)	Vol. 1, level 4, 4.9.6	Notifier: see comment (4) above	

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section 5 - Ecotoxicology (B.9)

No.	<u>Column 1</u> Reference to draft assessment report *	<u>Column 2</u> Comment * (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(8)	Vol. 3, 9.1.8, residue content in food items	<p>Notifier: In the table on page 17, The RMS has included two trials not used by the notifier. The notifier accepts the inclusion of the Montserrat 2005 trial by the RMS. The notifier disagrees with the inclusion of the Beaufort 2006 trial (see justification under further explanations). When omitting this trial the acute PECseedling becomes 3.3 mg/kg, the short-term PECseedling 2.01 mg/kg and the long-term PECseedling 0.79 mg/kg. Hence, the notifier is of the opinion that the RMS has overestimated the residue intake (birds and mammals) through seedlings by 20% (acute), 35% (short term) and 31% (long-term) (RMS values see page 18). The DAR (final sentence 1st paragraph page 19), makes reference to ruling out potential outliers but this does not appear to have been done (and in any case only applies to the acute exposure).</p>	<p>Notifier:</p> <ol style="list-style-type: none"> 1 The field growing period was too long. The crop variety Aviso has an average growing period of 72 days. The growing period in this trial was 130 days, which indicates the growth was retarded. 2 The crop was planted too late in the season. The planting date of this trial was 4th August. However, the variety Aviso is an early autumn cauliflower. Early autumn varieties are planted at the end of June/ beginning of July. 3 No duplicate samples on 7, 14, 21 and 28 days after application could be taken because of too little plant material. Outlier samples could therefore not be re-analyzed by means of the spare sample analysis. 4 According to the Dixons test, the value of 10.566 mg/kg carbofuran + 3-OH-carbofuran at day 14 after application should be considered as an outlier (in comparison with the observed maximum residue values in the other trials). [the Q-value is 0.649. The critical value at n=8 is 0.526 for Dixon's Q-test at 95% confidence level. The Q-value is higher than the critical value. Therefore the residue value of 10.566 should be considered as an outlier.
(9)	Vol. 3, 9.1.8, residue content in food items	<p>Notifier: correction table page 25. See B.7 residues comment (4). This has no impact on the risk assessment.</p>	

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section 5 - Ecotoxicology (B.9)

No.	<u>Column 1</u> Reference to draft assessment report *	<u>Column 2</u> Comment * (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(10)	Vol. 3, 9.1.9, feeding behaviour birds	Notifier: clarification: the RMS has selected a PD of 33% for the skylark (page 36). This is the maximum observed from three locations over a 2.5 year study period. This should be considered an extreme worst-case value and not “representative” as claimed (page 36 last paragraph). For the location with the highest % seedlings in the skylark diet from which the 33% value was taken, the 2.5 year mean value is ~8% and median only ~ 4%. The notifier has used a PD of 10% for the skylark in the submitted risk assessment. The same applies to the PD for earthworms in the black-headed gull diet (page 39)which is also extreme worst-case.	
(11)	Vol. 3, 9.1.9, feeding behaviour birds	Notifier: clarification: under conclusion of the RMS on page 40 the RMS states that the notifier has back calculated the PT factor to achieve an acceptable TER. This was in fact done to demonstrate the principle that a realistic PT refinement will lead to acceptable TERs. Such a refinement is MS specific and will be included at MS level.	

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section 5 - Ecotoxicology (B.9)

No.	<u>Column 1</u> Reference to draft assessment report *	<u>Column 2</u> Comment * (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(12)	Vol. 3, B.9.1.11, summary of effects on birds	<p>Notifier: (page 46-49)</p> <p>Acute toxicity endpoints for birds: the notifier is of the opinion that the LD₅₀ can be substituted with the LC₅₀ for acute risk assessment (in line with EFSA opinion on pirimicarb). Full argumentation is provided in the benfuracarb dossier (IIIA Section 6 page 6) and in the DAR B.9 page 47)</p> <p>Short-term LC₅₀: see comment (1).</p>	
(13)	Vol. 3, B.9.1.11, summary of effects on birds	<p>Notifier: (page 51-59)</p> <p>The presented risk assessment is extreme worst-case in terms of PECfood (see comments 8), toxicity endpoints (see comments 1 and 12) and PD factors (see comment 10) and does not include a PT refinement. Realistic worst-case inputs and realistic PT refinements will lead to acceptable TER values. A refined risk assessment is included in the dossier (IIIA, section 6, 10.1)</p>	
(14)	Vol. 3, B.9.3, effect on other terrestrial vertebrates	<p>Notifier: on page 91, second paragraph on long-term endpoint, the RMS disagrees with the proposed endpoint by the notifier because it “should be based on reproductive toxicity and teratogenicity studies”. However, the notifier proposed ecotoxicological long-term endpoint is based on a 3-generation rat study. It seems the argumentation of the RMS is not valid. Justification of the proposal of the notifier is given in the DAR on page 90.</p>	

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section 5 - Ecotoxicology (B.9)

No.	<u>Column 1</u> Reference to draft assessment report *	<u>Column 2</u> Comment * (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(15)	Vol. 3, B.9.3, effect on other terrestrial vertebrates	Notifier: clarification (page 94-95): the earthworm PD of 80% is the maximum observed in any month from a total of 5 studies (this value is based on the proportion of earthworms in the diet of the common shrew inhabiting a watercress bed in July, which seems of little relevance for the intended use of benfuracarb). A more realistic worst-case PD factor would be the 90 th percentile value (i.e. 28%) for the months February-August from the other three more relevant studies. On this basis, the selected PD by the RMS of 80% is clearly an extreme worst-case.	
(16)	Vol. 3, B.9.6.2, sublethal effects on earthworms	Notifier: see comment (4)	
(17)	Vol. 3, B.9.6.6, summary and risk assessment for earthworms	Notifier: see comment (4)	

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Comments of Germany on the additional Report on benfuracarb

(23.09.08) 1/3

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

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

No.	<u>Column 1</u> Reference to draft assessment report *	<u>Column 2</u> Comment * (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. 1, Level 2, Appendix 1 - List of endpoints	DE: For body fluids and tissues the residue definition for monitoring purposes is missing. We agree that the relevant residue for monitoring should be carbofuran.	Being aware that the harmonised template for the list of end points does not contain a residue definition for body fluids and tissues, it is important to add a respective line to facilitate the reading of the list of endpoints and to guarantee transparency and reliability.

Comments of Germany on the additional Report on benfuracarb

(23.09.08) 2/3

section 2 - Mammalian toxicology (B.6)

8. Mammalian toxicology (B.6)

No.	<u>Column 1</u> Reference to draft assessment report *	<u>Column 2</u> Comment * (restricted to 500 characters, ca. 10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. 1, List of endpoints, Impact on human and animal health, Vol. 3, B.6.12, Dermal absorption	DE: In the endpoint list in Vol. 1, a 100 % default value for dermal absorption is mentioned. In contrast, 10 % is given in Vol. 3 without any justification. Based on physico-chemical properties (as laid down in the EU Guidance document), we support 100 %. This assumption should be used for the exposure calculations.	
(2)	Vol. 1, 2.1.4, Classification and Labelling of Oncol 8.6 G	DE: Data on acute inhalation toxicity are not provided for Oncol 8.6 G. Therefore, according to Directive 1999/45/EC classification of the preparation with Xn, R20 is necessary based on the concentration of benfuracarb (> 3 %).	
(3)	Vol. 3, B.6.11.5, Eye irritation	DE: A tabular summary of individual scores of the eye irritation study should be given. Reversibility was not controlled later than 72 h. Nevertheless, the study is considered acceptable by the RMS. Iris scores are 1 for all animals at 24 and 48 h and 1 for 5/6 animals at 72 h which is just below the threshold for classification. Moreover, a clear tendency of reversibility was not shown. It should be discussed at the expert meeting, whether this study is acceptable.	
(4)	Vol. 3, B.6.14, Exposure data	DE: Operator exposure is calculated using 0.086 kg as/ha by the RMS. According to the summary of representative uses the application rate is 1.0 kg as/ha.	

Comments of Germany on the additional Report on benfuracarb

(23.09.08) 3/3

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

9. Environmental fate and behaviour (B.8)

No.	<u>Column 1</u> Reference to draft assessment report *	<u>Column 2</u> Comment * (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. 1, Level 4, 4.8 and 4.9	DE: DE suggests adding a note that the contamination of non-target areas and organism via dust drift during application needs to be considered on Member state level. This Exposure route depends on the application technology. The recent experience on exposure of non target areas by dust drift during sowing of treated seeds should Member states make aware of this possible exposure route also for application of a granular formulation.	
(2)	Vol. 3, B.8.6.1, PEC gw and Vol. 3, B.8.9, Definition of the residues	DE: As a result of the groundwater assessment carbofuran is most critical for leaching. PECgw simulations for carbofuran resulted in concentrations of > 0.1 µg/L in some scenarios. In case of a normal soil metabolite showing this behaviour an assessment of the relevance of this metabolite would be necessary to be documented in the DAR. Carbofuran is an active substance on itself that was not addressed in the DAR of benfuracarb. However, a note should be added that with respect to groundwater assessment carbofuran should be treated as an active substance.	

Comments of the Netherlands on the additional report on benfuracarb

(23.09.08) 1/7

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

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

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

Comments of the Netherlands on the additional report on benfuracarb

(23.09.08) 2/7

section 2 - Mammalian toxicology (B.6)

11. Mammalian toxicology (B.6)

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

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Comments of the Netherlands on the additional report on benfuracarb

(23.09.08) 3/7

section 3 - Residues (B.7)

12. Residues (B.7)

No.	<u>Column 1</u> Reference to draft assessment report *	<u>Column 2</u> Comment * (restricted to 500 characters, ca. 10 lines)	<u>Column 3</u> Further explanations
1.		NL: No comments.	

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Comments of the Netherlands on the additional report on benfuracarb

(23.09.08) 4/7

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

13. Environmental fate and behaviour (B.8)

No.	<u>Column 1</u> Reference to draft assessment report *	<u>Column 2</u> Comment * (restricted to 500 characters, ca. 10 lines)	<u>Column 3</u> Further explanations
1.		NL: No comments.	

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section 5 - Ecotoxicology (B.9)

14. Ecotoxicology (B.9)

No.	<u>Column 1</u> Reference to draft assessment report *	<u>Column 2</u> Comment * (restricted to 500 characters, ca. 10 lines)	<u>Column 3</u> Further explanations
1	Vol. 3, B.9.1.8, Residue content in food items table B.9.1.8-1	NL: Why starts the table with 7 days after planting and not earlier?	
2	Vol. 3, B.9.1.8, Residue content in food items	NL: It is stated that field studies indicate that the highest residues are found between day 4 and 14. This is not totally right because in several studies already at day 3 the highest residue was found (see table B.9.1.8-4). Further it is stated that the 14 day residue situation is considered representative for the risk assessment for birds/mammals as it also represents the situation when residue levels are highest. This is not right; in most field studies the highest residue was found at day 3 or 7 (see again table B.9.1.8-4).	
3	Vol. 3, B.9.1.8, Residue content in food items	NL: The 90 th percentile residue level is set to a level of 3.92 mg/kg. Because there are only 8 measurements the 90 th percentile should be the maximum residue from these measurements, in this case 10.566 mg/kg.	
4	Vol. 3, B.9.1.9 Habitation and feeding behaviour of birds in treated areas, 3.1 Crested lark	NL: 61% weeds as proposed by the notifier seems to be a very high percentage. It is concluded by the RMS that a PD of 33% for cabbage seedlings is acceptable. Where is this figure based on? Has not by mistake the PD-value for woodpigeon been taken here?	

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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
5	Vol. 3, B.9.1.9 Habitation and feeding behaviour of birds in treated areas, 3.2 Wood pigeon	NL: Why not taken 40% for cabbage seedlings as worst case, based on the figures in table B.9.1.9-11, and then 51% for weed seeds?	
6	Vol. 3, B.9.1.9 Habitation and feeding behaviour of birds in treated areas, 4. PT determination	NL: What is exactly the conclusion of the RMS with respect to the PT determination? This is not clear from the text.	
7	Vol. 3, B.9.1.11 Summary of effects on birds, 1.2 Long-term endpoint	NL: The LC10 of 0.64 mg carbofuran/kg bw/d has been taken as the relevant long-term endpoint. Why the LC0 of 0.12 mg carbofuran/kg bw/d has not been taken as the relevant endpoint?	
8	Vol. 3, B.9.1.11 Summary of effects on birds, 6.2 Higher tier risk assessment; PD refinement	NL: RMS has accepted PD-refinements for acute risk calculation. However, we doubt that the available data really show that at the acute feeding scale (1 feeding bout), an animal would still divide its food in different categories. Therefore, 100% feeding on the food item with the highest residues should be assumed for acute risk assessment.	
9	Vol. 3, B.9.1.11 Summary of effects on birds, 6.2 Higher tier risk assessment; PT refinement	NL: RMS mentions a 'weight of evidence' PT refinement which can be applied on MS level. We doubt that this would be applicable on the acute scale, as a bird can fulfill its entire food demand of one feeding bout on one field. Furthermore, there is not necessarily a connection between a low percentage of cabbage fields in an area and low feeding of birds on those fields.	

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Comments of the Netherlands on the additional report on benfuracarb

(23.09.08) 7/7

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.9.1.11 Summary of effects on birds, 6.2 Higher tier risk assessment	NL: Under Conclusions of the RMS a NOEC value of 0.74 mg carbofuran/kg bw/d is mentioned. According to subchapter 1.2. of this chapter this value should be 0.64 mg carbofuran/kg bw/d.	
11	Vol. 3, B.9.3 Effects on other terrestrial vertebrates	NL: Comments 1, 2, 3, 8 and 9 are also applicable to this chapter	
12	Vol. 3, B.9.3 Effects on other terrestrial vertebrates	NL: The mean value of former NOAEL values is used for the long-term risk assessment (mean NOAEL = 0.71 mg carbofuran/kg bw/d), but this is not in agreement with the LoEP of carbofuran, in which a NOEL of 0.1 mg/kg bw/d is mentioned.	
13	Vol. 3, B.9.3 Effects on other terrestrial vertebrates, 6.2.4 Higher tier TER calculations	NL: Table B.9.3-11: A PD value of 0.8 is used for risk assessment. But PD must always be summed up to 1. What is the remaining 20% and could this 20% be contaminated with carbofuran?	
14	Vol. 3, B.9.3 Effects on other terrestrial vertebrates, 7.2.2 Determination of the proportion of food type in the diet (PD value)	NL: The PD value of 0.25 for cabbage seedlings seems to be quite arbitrary. The height of this value is dependent on the availability of different food items. In our opinion a more conservative PD value is necessary to cover all situations (e.g. a PD value of 0.5).	

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Comments of France on the additional report on Benfuracarb

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section 3 - Residues (B.7)

15. Residues (B.7)

No.	<u>Column 1</u> Reference to draft assessment report *	<u>Column 2</u> Comment * (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. 3, B.7.3.1, Definition of the residue in plant products	FR: None of the metabolism studies provided in the first version of the DAR seems to be acceptable. Among the new studies of the revised DAR only two (sugar beet and apples) are acceptable. FR agrees with RMS conclusion about the study conducted on cabbage : “the validity of this study is borderline”. Thus as only two metabolisms are acceptable and as none of these two studies has been conducted on leafy crops (representative of the intended use on cabbage) no sufficient data are available to set a reliable residue definition. In practice, it seems that residue definition should be linked to the one of carbofuran.	

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Comments of France on the additional report on Benfuracarb

(24.09.2008) 2/4

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

16. Environmental fate and behaviour (B.8)

No.	<u>Column 1</u> Reference to draft assessment report *	<u>Column 2</u> Comment * (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Volume 3, point B.8.1.1 route of degradation	FR : does the formulation type has any influence on the dissipation time of the substance in soils, and further on the occurrence time of the degradation products ? this issue is linked with modelling hypothesis as well as with further exposure hypothesis used to discuss delayed effects in aged residue studies with soil organisms. It also conditions the relevance of study protocols in soil ecotoxicology studies that investigate effects of the formulated product on earthworms.	
(2)	Volume 3, point B.8.9 residue definition	FR: despite not expected at high concentration level in groundwater from the use of benfuracarb granules on cabbage, the degradation products 3-OH carbofuran, 3-keto carbofuran and carbofuran phenol are to be considered relevant as they bear the active moiety. They should be kept in the residue definition.	
(3)	Volume 3, point B.8.8 PEC in ground water	FR: from the results of both modelling and leaching studies, recommendation for MS to protect ground water from transfer of benfuracarb residues will have to be reported in the review report	

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Comments of France on the additional report on Benfuracarb

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section 5 - Ecotoxicology (B.9)

17. Ecotoxicology (B.9)

No.	<u>Column 1</u> Reference to draft assessment report *	<u>Column 2</u> Comment * (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Volume 3, point B.9.1.10 Monitoring data	FR: FR agrees with the RMS, any demonstration of a safe use for substances that have shown to be implicated in incidents should be discussed in light of monitoring feed back and relevant literature. This is as most important as a safe use is not identified from the refined risk assessment available for birds.	
(2)	Volume 3, point B.9.1.11 Risks from the consumption of drinking water (birds and mammals)	FR: due to the high toxicity of the active substance and its main metabolite to birds, a calculation could be done based on the new puddle calculation formulae proposed by EFSA (EFSA journal, July 2008).	
(3)	Volume 3, point B.9.4 Risk to bees	FR: a Spe8 phrase should be proposed in order to limit exposure of bees to flowering adventices growing on contaminated soils in the crop, in the case where flower removal would not be the rule.	
(4)	Volume 3, point B.9.5.2 aged residue study with <i>Aleochara bilineata</i>	FR: the acceptability of risks relies on acceptable effects on the soil staphylinid <i>Aleochara bilineata</i> in an aged residue study, where acceptable effects were observed even after 0 day aging at a rate of 1.0 kg a.s./ha. This result is not consistent with the effects observed in the extended laboratory study (no aging) at a rate of 1 kg a.s./ha. In addition, the increased toxicity at 119 days post-treatment is proposed to be not treatment-related, based on time-dependent release of benfuracarb from granules. This should be cross validated by information of efficacy (duration of protection and mode of protection) as well as with relevant fate data on the formulated product.	
(5)	Volume 3, point B.9.5.Risk to non target arthropods	FR: numerous studies are available in the scientific literature for side-effects of carbofuran on non target species (IOBC publications). This valuable information should be added in the risk assessment for benfuracarb as it fits with current guidelines for testing.	

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Comments of France on the additional report on Benfuracarb

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section 5 - Ecotoxicology (B.9)

No.	<u>Column 1</u> Reference to draft assessment report *	<u>Column 2</u> Comment * (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(6)	Volume 3, point B.9.6 Risk to earthworms	FR: we agree with the RMS that the risk to earthworms is not sufficiently assessed. The field study presents deficiencies among which the lack of effects of the reference substance. In addition, due to a possible delayed release of the active substance from granules, chronic studies are particularly of interest in this case.	

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section 2 – Mammalian toxicology (B.6)

18. 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.6.8.1.1 Toxicity studies on metabolites – carbofuran, p. 6-73 & Table p. 6-74, short term toxicity	EFSA: It is understood that the 60-day gavage study in rat and the 10-week dietary study also in rat are new studies, not referred in the carbofuran’s DAR or respective addendum; therefore a more detailed assessment should be made available.	
2)	B.6.8.1.1 Toxicity studies on metabolites – carbofuran, p. 6-79, maternal NOAEL from developmental studies in rat	EFSA: Another rat developmental study assessed in the DAR on carbofuran (Rao, 1978a FMC) presented a maternal LOAEL of 0.3 mg/kg bw/day and a NOAEL of 0.1 mg/kg bw/day that were considered relevant for risk assessment. Therefore, this overall maternal NOAEL for rat developmental toxicity studies of 0.1 mg/kg bw/day should be referred as well.	
3)	B.6.8.1.1 Toxicity studies on metabolites – carbofuran, p. 6-80, metabolites of carbofuran	EFSA: Depending on the fate assessment of ground water metabolites, it should be discussed further if data on genotoxicity of carbofuran (mainly <i>in vivo</i> tests) are applicable to 3-OH carbofuran metabolite.	
4)	B.6.8.1.1 Toxicity studies on metabolites – carbofuran, p. 6-82, ADI and ARfD	EFSA: At the time of finalization of the carbofuran conclusion, at the EFSA Evaluation Meeting in June 2006, it was noted that a new study on spermatogenesis in rat had been provided to the RMS and also to ECB for consideration as part of the classification process. The results of this study have not been considered or peer reviewed within the risk assessment process under Directive 91/414/EEC and would support a confirmation of the reference values i.e ADI and ARfD that were provisionally agreed at EPCO 33 (Mammalian toxicology experts’ meeting). Therefore it would be useful to assess this study to set an ADI and ARfD for carbofuran and to agree on the withdrawal of the provisional statement.	

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section 3 – Residues (B.7)

19. Residues (B.7)

No.	<u>Column 1</u> Reference to draft assessment report *	<u>Column 2</u> Comment * (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol.3 B.7.1.3 bis Metabolism in cabbage	EFSA: It is not clear what is meant by “ <i>high variability in the total recovered radioactive residues</i> ”. Does this statement refer to the observed increase of TRR with sampling time? Isn't an increase even expected to occur when seedlings/ young plants are growing due to a high availability of the substance in soil and an increasing capacity of the developing root system for uptake of compounds from soil?	

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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
(2)	Vol.3 B.7.1.3 bis Metabolism in cabbage	<p>EFSA: It is stated that in the sample preparation of the 4 week samples acidic hydrolysis was conducted to release conjugated residues from the aqueous soluble phase. It was noted by the RMS that carbofuran (17.2% TRR), carbofuran-3-keto (2.7%) and carbofuran-3-OH (6.1%) were released from conjugates, it however not clear how these findings were reflected in table B.7.1.3 bis-2.</p> <p>Considering the increase of radioactivity recovered in the aqueous soluble phase over the test period from 3 to 28 days a progressive formation of conjugated residues can be assumed until harvest of the mature crop. Has the RMS thought about of whether conjugates of carbofuran /carbofuran-3-OH/ carbofuran-3-keto might have to be included in the residue definition for risk assessment for the use in cabbage?</p>	

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Comments of EFSA on the additional report on benfuracarb

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section 3 – Residues (B.7)

No.	<u>Column 1</u> Reference to draft assessment report *	<u>Column 2</u> Comment * (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(3)	Vol.3 B.7.3.1 Residue definition	EFSA: We don't agree with the RMS statement <i>"None of the metabolite formed [...] was of particular toxicological concern as they were generally also produced by the rat"</i> . Separate toxicological studies with the benfuracarb metabolites carbofuran, carbofuran-3-OH and carbofuran-3-keto exist, and it has been shown that they are of higher toxicity than benfuracarb and therefore they are residues of particular concern. The statement is incorrect and misleading, and should hence be revised.	
(4)	Vol.3 B.7.3.1 Residue definition	EFSA: The provisionally established plant residue definition for risk assessment for the representative use (brassicas, soil treatment) has been pending clarification on the full picture of residues the consumer can be exposed to. The new metabolism study in cabbage indicates that conjugated metabolites might be of significance in brassica crops. Whether or not it is necessary to consider these compounds in the risk assessment should be further elaborated by the RMS and possibly discussed in a meeting of experts.	

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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
(5)	Vol.3. B.7.6 Residue trials - Methods	EFSA: The analytical methods include an extraction procedure with acetonitril/water In the light of the analysis steps carried out in the metabolism study in terms of the conjugated residues, are the methods used in the residue trials deemed to sufficiently extract all residues of carbofuran /carbofuran-3-OH/ carbofuran-3-keto present in the crops in both free and conjugated form?	
(6)	Vol.3. B.7.6 Residue trials - Methods	EFSA: It is noted that in some trials the LoQ of the validated method (0.005 mg/kg) for carbofuran 3-OH could not be reached, since even the detection limit (LoD) was higher when analysing the cauliflower samples. Is it really considered appropriate to define in these trials a new LOQ of 0.01 mg/kg while the LoD was already up to 0.009 mg/kg? Shouldn't the validation have been repeated at the same day and under the same conditions when the samples were analysed?	

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Comments of EFSA on the additional report on benfuracarb

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section 3 – Residues (B.7)

No.	<u>Column 1</u> Reference to draft assessment report *	<u>Column 2</u> Comment * (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(7)	Vol.3. B.7.6 Residue trials - Methods	EFSA: If reaching the LoQ for carbofuran 3-OH had already been a problem in supervised trials, isn't there good reason to believe that in routine monitoring it will become difficult to reach this LoQ of 0.005 mg/kg for carbofuran 3-OH and to be able to monitor the proposed MRL of 0.01 mg/kg for the sum of carbofuran and carbofuran-3-OH? Given the acute risk linked to carbofuran /carbofuran-3-OH (see comment 10 below), does the RMS agree that it is essential that laboratories are able to routinely reach the LoQ?	
(8)	Vol.3. B.7.6 Residue trials	EFSA: The meeting of experts EPCO 34 has required a complete set of residue trial data and concluded that due to the toxicological properties of benfuracarb and its metabolites it was not possible to flexible on the minimum number of trials. The decline studies and occasional positive findings at harvest in the available data set for brassica indicate that we cannot consider this a 'classical no-residue situation'. If the RMS has a differing view this should be (re-)discussed in a meeting of experts.	
(9)	Vol.3. B.7.9 Rotational crops	EFSA: RMS has argued that upon re-evaluation of the study by Taylor and Houseman (1982), considered valid and acceptable by the peer review in 2005, the DT50 for carbofuran from this study is no longer appropriate, and therefore a rotational crop study is not triggered.	

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Comments of EFSA on the additional report on benfuracarb

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section 3 – Residues (B.7)

No.	<u>Column 1</u> Reference to draft assessment report *	<u>Column 2</u> Comment * (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
		However, a transparent evaluation, giving the reasons why the study previously considered acceptable is revoked as inappropriate, is missing. Moreover, it is noted that the referred to inappropriate DT50 value is still included in the List of endpoints. As long as this hasn't been clarified the data gap for a rotational crop study previously identified should be maintained.	
(10)	Vol.3 B.7.11 Exposure assessment	EFSA: For the sake of transparency it had been helpful to clarify/ justify the input parameters used (MRL, HR, STMR, highest LoQ in new trials) before presenting the results of the calculation of the exposure and risk assessment.	
(11)	Vol.3 B7.13 Proposed MRLs	EFSA: Given the residue trial results for cauliflower for carbofuran /carbofuran-3-OH (HR 0.0101, LOQ in 2 trials 0.015 mg/kg) the proposed MRL should be at least 0.01 mg/kg (without asterisk) for flowering brassica if not even 0.015 mg/kg. It is acknowledged that the next "regular" MRL proposal would be 0.02 mg/kg, however with this MRL for carbofuran /carbofuran-3-OH in cauliflower/ broccoli the ARfD would be exceeded for both crops (132% and 116% ARfD for BE and NL child, resp).	

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Comments of EFSA on the additional report on benfuracarb

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section 3 – Residues (B.7)

No.	<u>Column 1</u> Reference to draft assessment report *	<u>Column 2</u> Comment * (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(12)	Vol.3 B.7.15 Summary and evaluation of residue behaviour	EFSA: RMS stated that from the available livestock data no animal residue definition could be concluded. At the end of the chapter it reads that “the contribution of animal products [to consumer exposure] was not considered since no residue definition was proposed. This could be misunderstood in the context of what has been concluded before and should be made clear. With regard to the available goat metabolism study (B.7.2.1) it would help to enhance understanding and increase transparency if the residue levels (TRR) in the analysed tissues (i.e. LoD/LoQ of the method) had been reported.	
(13)	Vol.3 B.7 Appendix C Residue trials	EFSA: From the table of critical residue data it appears from the RMS remarks that for some of the trials it might be unclear whether they are supported by storage stability data over the whole duration of storing the samples. Can the RMS please clarify the status of those data?	

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

20. Environmental fate and behaviour (B.8)

No.	<u>Column 1</u> Reference to draft assessment report *	<u>Column 2</u> Comment * (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. 3, B.8.1, Route and rate of degradation Willems, H., 2005a, Willems, H., 2005b, Willems, H., 2005c	EFSA: In the degradation studies of the carbofuran metabolites (carbofuran-3-hydroxy, carbofuran-3-keto and carbofuran-phenol) there were too few sampling points to derive reliable DT50 values (based on FOCUS kinetics), in addition some samples had been lost or <LOQ or <LOD increasing further the uncertainty. Recoveries of the studies were also below the acceptable range. However these compounds seem to be indeed inpersistent in aerobic soil.	
(2)	Vol. 3, B.8.1, Route and rate of degradation Willems, H., 2005c	EFSA: Further argumentation would need to justify the significant loss of carbofuran-phenol at the study initiation. No clear decay seems on the basis of the data after 1 d, however these data are below LOQ.	
(3)	Vol. 3, B.8.1, Route and rate of degradation	EFSA: RMS please clarify the normalisation of DT50 values came from the new study by Noorloos, B. van; Brands C.	In the Table B.8.1.1-1-22 two water holding capacity (are they MWHC?) values are reported for a single soil. Two (or a range) of water content at MWHC are reported (45-61%) as well, they may be refer to the experiments at different temperatures or different way of determination of MWHC (difference between the results is significant). Soil moisture is reported to be 26.3 % w/w in Table B.8.1.1.1-25 may be referring to the experiment at 20°C, only. In the LoEP 40% of MWHC is indicated.
(4)	Vol. 3, B.8.1, Route and rate of degradation	EFSA: RMS please indicate whether the DT ₅₀ values from Noorloos, B. van; Brands C study based on the HPLC or TLC analysis and which kinetic was used with an argument why this was chosen.	

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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)	Vol. 3, B.8.1, Route and rate of degradation Page 8-17	EFSA: Only four DT ₅₀ values (belonging to two studies) have already been peer reviewed. The 5 th value (0.13 d) comes from a newly submitted study on alkaline soil. Please clarify it this is correct as it is stated 5 values were all peer reviewed.	
(6)	Vol. 3, B.8.1, Route and rate of degradation Table B.8.1.1.1-25 & LoEP	EFSA: There are slight differences in case of some DT ₅₀ /DT ₉₀ values of carbofuran reported in this Table and LoEP of the additional report compared with the original DAR/EFSA conclusion of carbofuran.	Original DT ₅₀ /DT ₉₀ values (d) are: silt loam 15.1/50.1 (instead of 15/50), sandy loam 9.5/31.5 (instead of 9.5/32), clay loam 15.8/52.3 (instead of 15.8/52), loam 19.4/64.7 (instead of 19.3/65).
(7)	Vol. 3, B.8.1, Route and rate of degradation Page 8-17 last paragraph	EFSA: EFSA confirms that the lab. DT ₅₀ values that originate from the carbosulfan dossier should not be used, as the peer review of carbosulfan concluded these values were unreliable.	

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

No.	<u>Column 1</u> Reference to draft assessment report *	<u>Column 2</u> Comment * (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(8)	Vol. 3, B.8.1, Route and rate of degradation Page 8-18 – 8-20	EFSA: The data set included in the Table B.8.1.1.1-26 was peer reviewed during the carbofuran peer review. The three carbofuran DT ₅₀ values (norm. 175, 381, 444 d) originated by FMC, were considered reliable by the carbofuran peer review, while other data considered by this peer review disregarded as unreliable. The RMS conclusion on this studies deviates from the conclusion of the previous peer review. Until a detailed re-evaluation of these experiments by the RMS is made available, the existing conclusion of the peer review of MSs should not be changed/overruled and the accepted DT ₅₀ values should be used in the RA. The argument presented in the additional report of August 2008 is insufficient to conclude if changing the previous assessment is justified.	

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Comments of EFSA on the additional report on benfuracarb

(26.09.08) 12/17

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

No.	<u>Column 1</u> Reference to draft assessment report *	<u>Column 2</u> Comment * (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(9)	Vol. 3, B.8.1.3, Field studies	<p>EFSA: Field DT₅₀ of 71.9 d was used for PECsoil in the carbofuran DAR/EFSA conclusion for carbofuran. Whilst RMS stated he reassessed the study and concluded it was of limited quality. The reasons why the study is too deficient to be relied on are not explained adequately for others to tell if they would agree with the RMS position. As far as agreed lab. DT₅₀ values are > 60 d (see EFSA comment No 8), field dissipation experiments are required and field DT₅₀ should be used for PECsoil calculation.</p> <p>(Note: PECsoil of carbofuran in this additional Report is based on the worst case, not normalised lab DT₅₀ of 19.4 d. This seems to be inappropriate)</p>	
(10)	<p>Vol. 3, B.8.2.1, Adsorption, desorption and mobility</p> <p>Noorloos, B. van; Willems, H., 2005a, Noorloos, B. van; Willems, H., 2005b,</p>	<p>EFSA: It is agreed that worst case Koc (K_{foc} only for 2 solis) values should be taken into account for average calculation, but as 1/n 1 (or 1.144 for carbofuran-3-keto as worst case) should be used. In fact it seems that the equilibrium was not perfectly reached within the 6 hours and Freundlich isotherm could not be establish. For the two soils where K_{foc} were determined 1/n values are far from each other (1.144 and 0.489).</p>	

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Comments of EFSA on the additional report on benfuracarb

(26.09.08) 13/17

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
(11)	Vol. 3, B.8.2.1, Adsorption, desorption and mobility Noorloos, B. van; Willems, H., 2005c	EFSA: RMS please give more details which clarifies that if carbofuran-phenol was classified as “stable”, from where come from the significant difference in adsorption by 6 or 24 hrs. In the conclusion of this study 1031 cm ³ /g should be read as Kfoc instead of Koc.	
(12)	Vol. 3, B.8.6.1 PEC groundwater	EFSA: It is not clear how mean formation 0.86 relates to the maximum formation of 0.846 and how and why was ff establish for carbofuran from carbofuran DAR. This needs to be clarified.	
(13)	Vol. 3, B.8.6.1 PEC groundwater Page 8-46	EFSA: EFSA agrees that the formation fraction of carbofuran used in the modelling is too low, but contrary to the opinion of the RMS, a proper ground water modelling with an appropriately derived kinetic formation fraction is necessary.	
(14)	Vol. 3, B.8.6.1 PEC groundwater, Table B.8.6.1-1 PEC surface water, Table B.8.6.2-3	EFSA: for benfuracarb as 1/n of 1 should be used as HPLC method was used for the estimation of Koc.	
(15)	Vol. 3, B.8.6.1 PEC groundwater Table B.8.6.1-2 PEC surface water Table B.8.6.2-5 Page 8-56 regarding PECsw/sed for carbofuran-phenol	EFSA: For carbofuran, for derivation of soil degradation input parameter all the endpoints from accepted lab. experiments from the peer review of benfuracarb and carbofuran should be used, as no new data or re-evaluation of the existing data is available.	

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Comments of EFSA on the additional report on benfuracarb

(26.09.08) 14/17

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
(16)	Vol. 3, B.8.6.1 PEC groundwater Table B.8.6.1-7, Table B.8.6.1-8	EFSA: for 3-keto-carbofuran and 3-hydroxy-carbofuran as 1/n of 1 should be used. See EFSA comment No.10.	
(17)	Vol. 3, B.8.6.1 PEC groundwater	EFSA: RMS pls. clarify the application times used for the modelling. According to FOCUS GW cabbage can be planted in the Summer for areas represented by Thiva and Jokoinen scenarios, but not in Spring time. Moreover in the output tables some dates are not in the range as indicated in the text before (e.g. Thiva (spring appl., 22/08)).	
(18)	Vol. 3, B.8.6.2 PEC surface water Page 8-39	EFSA: It is still not perfectly clear how DT ₅₀ /DT ₉₀ values were derived for the different compartments of the compounds. Could RMS pls. give more details (e.g. the individual measurements involved, graphical presentation, if possible) about these calculations?	
(19)	Vol. 3, B.8.9 Residue definition	EFSA: EFSA still agrees with the residue definition as it is stated in the befuracarb EFSA conclusion.	
(20)	Vol. 3, B.8.10 References relied on	EFSA: RMS pls. include the studies of Yamasaki, 1999 and Hayashi, 1999 into the list of studies relied on.	
(21)	Vol. 3, B.8.10 References relied on	EFSA: In the References relied on studies under reference numbers of IIA, 7.2.1.2/01 and IIA, 7.2.1.2/02 are not summarised in the additional report. RMS pls. clarify it.	

* 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.

Comments of EFSA on the additional report on benfuracarb

(26.09.08) 15/17

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

No.	<u>Column 1</u> Reference to draft assessment report *	<u>Column 2</u> Comment * (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(22)	Dossier	EFSA: The CADDY-dossier submitted to EFSA does not contain PEC calculations, document KIIIA for Environmental fate and behaviour is completely missing.	

* 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 5 – Ecotoxicology (B.9)

21. Ecotoxicology (B.9)

No.	<u>Column 1</u> Reference to draft assessment report *	<u>Column 2</u> Comment * (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. 1, LoEP Risk assessment for birds and mammals	EFSA: Only the number of granules which are needed to reach the LC/LD 50 and NOEC are reported but no risk assessment for birds and mammals was included for the uptake of granules. The TERs for this exposure route should be included in the LoEP.	
(2)	Vol. 3, B. 9. 1.11. Risk assessment for birds	EFSA: It is noted that the risk assessment for birds from uptake of granules was conducted with extrapolated HC5 values (in appendix 1 to B.9). Such an approach would need further discussion in an expert meeting. It may be beneficial to present a more standard risk assessment with the observed endpoints and the trigger values of 10 and 5.	
(3)	Vol. 3, B. 9. 1.11. Risk assessment for birds	EFSA: The refined risk assessment for birds resulted in TERs below the triggers of 10 and 5. A data gap should be set for further refinement of the risk assessment for birds (e.g. by reliable estimates of the PT values).	
(4)	Vol. 3, B. 9.3. Risk assessment for mammals	EFSA: It is noted that the risk assessment for mammals from uptake of granules was conducted with extrapolated HC5 values (in the appendix 2 to B.9). Such an approach would need further discussion in an expert meeting. It may be beneficial to present a more standard risk assessment with the observed endpoints and the trigger values of 10 and 5.	

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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
(5)	Vol. 3, B. 9.3. Risk assessment for mammals	EFSA: The suggested refinement of PD for herbivorous and earthworm-eating mammals is based on general observations on the food composition of mammals. There is no specific investigation of the food uptake in the vicinity of treated fields where cabbage is grown. Benfuracarb acts predominantly as an acute toxin. The suggested PD may be sufficiently supported on the chronic time scale but the data do not provide evidence that herbivorous mammals or earthworm-eating mammals would not consume more than 26% and 80% of only one food type (cabbage or earthworms) on the acute time scale.	
(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. Were the same effects observed in the different studies which were used to calculate the mean NOAEL?	
(7)	Vol. 3, B.9.5.2 Effects of the formulation on non-target arthropods	EFSA: In the aged residue study with <i>Aleochara bilineata</i> (Geuijen I., 2005a) an increase of adverse effects were observed with the duration of ageing of residues (>50%). This was explained as not being related to the exposure situation in the test. However the observed increase in mortality was not fully explained and it is questionable if the study can be considered as valid.	

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