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List of all reports from EFSA Expert Meetings

Date		Section
13-15. 01 2009	PRAPeR expert meeting 62	Environmental Fate and Behaviour
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REPORT OF PRAPeR EXPERT MEETING 62

BENFURACARB

Rapporteur Member State: BE

Specific comments on the active substance in the section

4. Fate and behaviour in the environment

are already listed in the relevant reporting table. Comments submitted for this meeting are listed below.

1. Comments submitted for this meeting:

Date	Supplier	File Name
none		

2. Documents submitted for meeting:

Date	Supplier	File Name
2009-01-05	BE	Benfuracarb evaluation table rev 1-0 2009-01-05).doc
December 2008	BE	Benfuracarb List of endpoints (December 2008).doc
December 2008	BE	Benfuracarb reporting table rev 1-1 (December 2008).doc
January 2009	BE	benfuracarb_addendum Vol3_B8 (January 2009).doc

3. Documents tabled at the meeting:

Date	Supplier	File Name
13 January 2009	BE	Additional report of carbofuran (November 2008), page 33-39

The conclusions of the meeting were as follows:

- 4. Data on preparations: ONCOL 8.6G**
- 5. Classification and labelling:** not discussed
- 6. Recommended restrictions/conditions for use:** none identified
- 7. Reference list:** Not discussed

Areas of concern: None identified in the meeting

Appendix 1: Discussion table: BENFURACARB

Appendix 2: Evaluation table

Appendix 1: Discussion Table, Benfuracarb (In, Ne)

4. Fate and behaviour

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	<p>Open point: 4.1</p> <p>RMS to correct the List of End Points. 40% MWHC of the clay loam soil should be changed to 45% or 61%, the one which is more realistic/was measured in the same laboratory.</p> <p>See reporting table: 4(3)</p>	<p>The List of Endpoints has been corrected. The soil moisture in the experiment was 45% of MWHC. For MWHC, 58.1% was used (determined by Notox) for the normalisation of the relevant SFO DT50.</p>	<p>Open fulfilled.</p>
	<p>Open point: 4.2</p> <p>RMS to update the list of endpoints with the values listed in column 3 of the reporting table that are not in brackets.</p> <p>See reporting table: 4(6)</p>	<p>The List of Endpoints has been corrected. Rounding caused the differences.</p>	<p>Open point fulfilled.</p>
	<p>Open point: 4.3</p> <p>RMS to provide clear, independent</p>	<p><u>Carbofuran DT50</u></p> <p>EFSA presented to the meeting that a set of DT50 for carbofuran was agreed during the</p>	<p>Open point fulfilled. New open point proposed, see below.</p>

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	<p>summaries and assessments of the studies Saxena <i>et al.</i>, 1994 (laboratory degradation study in acid soil and alkali soil) and Schocken, 1989 in an addendum to support discussion of a meeting of experts. Information on soil pH, soil moisture content and microbial activity to be clearly presented.</p> <p>See reporting table: 4(8)</p>	<p>previous peer review of carbofuran, carbosulfan and benfuracarb (EFSA conclusions published in 2006). In the additional report of benfuracarb (August 2008) prepared for the 2nd peer review, 3 laboratory soil DT₅₀ values (from 2 studies, by Saxena, 1994 and Schocken, 1989) are missing. These were regarded as valid during the previous peer review and included in the EFSA conclusions. The studies were not summarised, but an argumentation for the exclusion of these three values can be found on page 8-18 of the additional report. This argumentation was commented as not appropriate for disregarding these studies. RMS has included the summaries of these studies in an addendum (Jan 2009) as requested, but no additional scientific argumentation was added which supports the exclusions to that in the additional report.</p> <p>Based on the original reports of these studies the followings can be stated:</p> <p>Study by Saxena:</p> <ul style="list-style-type: none"> - In this study two soils were used, called as acidic and alkaline soil. The alkaline soil was prepared by adding lime to the collected sandy loam soil (acidic), by this the pH was modified from 5.7 to 7.7. - The soil indeed seems to be dry if compared with e.g. the FOCUS default values for sandy loam, but the moisture holding capacity of the soil was determined in this GLP study and the actual moisture content was set for this (75% of 1/3 bar=4.05%) in accordance with EPA guidelines. - The microbial biomass was checked several times throughout the study and the results show that both soils were viable at the end of the study. <p>Study by Schocken:</p> <ul style="list-style-type: none"> - The pH of this sandy loam soil was also modified by lime from 5.8 to 7.1. - The microbial activity of the soil was checked by measuring the evolved ¹⁴C₂ from ¹⁴C labelled glucose up to 57 days in a parallel experiment. The evolved CO₂ was continuously increasing and reached 62.3% by the end of this term. <p>The meeting of experts discussed these studies and considered that there seemed to be no methodological reason to conclude that the studies were not valid for these soils.</p> <p>Moreover of these, some other DT₅₀ values for carbofuran have already been available for EFSA and MSs. These studies were regarded as valid during the previous peer review, but the fit of the data for DT₅₀/ DT₉₀ derivation was regarded as inappropriate. Now the re-fitting of these data according to the FOCUS Kinetics is available and is summarised by the RMS (BE) in the additional report of carbofuran (November 2008). Pages 33 to 39 of the</p>	

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
		<p>additional report for carbofuran were tabled at the meeting. In this report the following information is available: all the degradation endpoints for carbofuran from studies which were accepted by the previous peer review, the kinetic formation fractions for carbofuran, (from benfuracarb), degradation endpoints for benfuracarb (the individual values can be seen only in the original report, which is summarised on these pages).</p> <p>The experts agreed that the correct values for use in the EU risk assessment were as listed in the row of the discussion table below. For FOCUS modelling a median normalised value of 14 days was agreed as the most appropriate value.</p> <p>The experts discussed whether it was appropriate to use the data where the carbofuran DT50 were derived from studies dosed with carbosulfan, as these DT50s would be linked with the DT50 of precursor resulting in the formation fractions estimated in the fits. It was agreed that in this case, though not theoretically correct, the carbofuran DT50 values could be used from studies with both benfuracarb and carbosulfan dosing, as the formation fractions from carbosulfan and from benfuracarb should theoretically be close to 1. In this case it was agreed that in modelling a kinetic formation fraction of 1 from precursor should be used with this median DT50 of 14 days in the 3 carbamate evaluations (carbofuran, carbosulfan and benfuracarb).</p> <p><u>Benfuracarb DT50</u></p> <p>A conclusion on the Benfuracarb DT50 for use in modelling is required and was discussed. Experiments on 4 soils were available in the original DAR.</p> <p>In addition, one newly submitted study (Noorloos, B. van; Brands, C.) is evaluated in the benfuracarb additional report and the normalisation of these DT₅₀ values.</p> <p>In the carbofuran additional report, FOMC DT₅₀/DT₉₀ estimates with appropriate normalisations were available for the original 4 experiments in the DAR and the experts agreed that the DT50 from this FOMC fitting estimated by dividing the DT90 by 3.32 should be used (Note that the individual values can be seen only in the original report, on which the carbofuran additional report based). The same approach was also used for the Noorloos, B. van; Brands, C experiment in the meeting (resulting 0.24 days). The normalised values are then 1.17, 0.44, 0.23, 0.46 and 0.24. The geomean is then 0.42</p>	

No.	Subject	Discussion Expert Meeting					Conclusions Expert Meeting
		days.					
			Refitted value from the Carbofuran additional report Jan. 2009	Normalized value from the Carbofuran additional report	Kinetic (P→M)	ff	Comment
	Soil						
Matt (1986)	Attapulgus	sandy loam	13.72	17.87	SFO		
	Bretagne I	Silt loam	14.75	14.01	SFO		Taken only the value for 20°C
Völkl, S., 2002	Sp 2.3 (Vökl)	Sandy loam	8.97	7.71	SFO		
	Mussing	Clay loam	14.12	13.56	SFO		
	Wormingford	Loam	19.17	17.25	SFO		
	Sp. 2.2		6.92	6.92	SFO→SFO		
Baumann (2002)	St. Amand		11.61	9.39	FOMC→SFO		
	Manzanilla		13.04	11.46	FOMC→SFO		
	Liscate		25.99	22.54	FOMC→SFO		
Baumann and Ferreira (2001)	VS 236		Excluded				
Markle (1981a)	Barney Nebraska		Excluded	17.47	22.19	SFO→SFO	
Markle (1981b)	Barney Nebraska		No data for carbofuran No data for carbofuran				
Clay (1980)	Cosad (phenyl) Cosad (carbonyl)		Excluded Excluded				
Van Noorloos, B., Slangen, P.J., (2002a,b)	Sp. 2.3	sandy loam	6.7	5.7	FOMC→SFO	0.91	
	Sp. 2.2	sandy loam	20.39	20.39	FOMC→SFO	0.79	
	Sp. 3A	Loam	11.42	10.39	FOMC→SFO	0.83	
	Sp. 6S	Clay	23.38	11.69	FOMC→SFO	0.91	
Saxena, 1994	Acidic soil	sandy loam	307	151	SFO		These values are not included in the Carbofuran additional report.
	Alkaline soil	sandy loam	111	54.6	SFO		
Schocken, 1989	Forest city	sandy loam	362	387	SFO		
			median	14.01 days			

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	<p>New open point: 4.11 Identified at PRAPeR 62 meeting.</p> <p>RMS to update the list of endpoints lab DT50 values in line with the discussion table. Non linear fitting of the degradation of carbofuran from the studies by Saxena, 1994 and Schocken, 1989 and the appropriate normalization of the resulting DT50 values should be included in an addendum. FOMC fitting of the degradation of benfuracarb from the study by Noorloos, B. van; Brands, C. and the appropriate normalization of the resulting DT50 values should be included in an addendum.</p>		<p>Open point open.</p>
	<p>Open point: 4.4 MS to discuss in a meeting of experts if there is any need to require additional data on carbofuran</p>	<p>EFSA presented that during the previous peer review, a high temperature dependence of degradation of carbofuran was identified (only) in one soil (Bretagne I, silt loam) where the DT₅₀ at 10°C was 110d, while at 20°C 15.1d. The possible impact of this was discussed in a meeting of experts EPCO 31 (September 2005) where the rapporteur Member State informed the meeting that the notifier had submitted a position paper and a new study to address the degradation of carbofuran at low temperatures. The meeting of the experts</p>	<p>Open point fulfilled</p>

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	<p>degradation in soil at 10°C or whether the use of a standard Q10 is supported.</p> <p>See reporting table: 4(11)</p>	<p>(EPCO 31) agreed that this new study needs to be evaluated in an addendum. No such a study was submitted for carbofuran, but a summary of a new study conducted at 10 and 20°C with benfuracarb (Noorloos, B. van; Brands, C.) on a single soil is now available on page 14 to 16 of the additional report of benfuracarb (August 2008), and an argumentation from the Notifier in the Column 3 of the reporting table for the point 4(11). For benfuracarb the DT50 at 10°C was 11 hours, while at 20°C 3 hours.</p> <p>The experts did not support the argumentation from the applicant that evidence from the 1 benfuracarb investigation might give an indication of what would occur for carbofuran.</p> <p>The meeting of experts agreed that in line with the PPR panel opinion on Q10, evidence from more than a single soil at 2 different temperatures is required before it can be justified to go away from agreed default value for Q10 in modelling. Therefore the experts agreed that the default Q10 applicable to this submission (2.2) should be used in simulations of leaching of both benfuracarb and carbofuran.</p>	
	<p>Open point: 4.5</p> <p>a) RMS to provide a clear summary and assessment of the study by Taylor and Houseman, 1982 in an addendum to support discussion of a meeting of experts on the validity of this study and also report the Terry A. 2005 analysis if this is relevant.</p> <p>b) degradation endpoint used in the PECsoil calculation to be discussed in a meeting of experts</p>	<p>The RMS included a study summary of Taylor and Houseman, 1982 in an addendum (Jan 2009). The report of analysis by Terry A. 2005 was not included, but RMS is of the opinion that the study is not sufficient to derive an accurate DT₅₀.</p> <p>EFSA presented that for the previous peer review, field dissipation data for carbofuran were available from three sources:</p> <ul style="list-style-type: none"> -Half life in the EU trials (Taylor and Houseman, 1982, carbosulfan applied as parent) 71.9 d and (Mol, 2002) ranges between 1.3 to 27 days. -Half life in the USA sites assessed as relevant for the EU climatic conditions by the RMS, ranges between 5 and 121 d. <p>The meeting of the experts of the previous peer review of the carbofuran EPCO 31 (September 2005) was not able to determine the reliability of these studies and agreed that it is necessary to determine whether the studies from the USA sites are acceptable for the EU risk assessment. The used DT₅₀ for PECsoil concluded by EPCO 31 was 71.9 days.</p> <p>In the addendum to the additional report for benfuracarb the graphs for the study of Taylor and Houseman Nether Poppleton (UK) site were presented (carbosulfan was dosed). The experts agreed with the RMS assessment that from this study no reliable DT50 for carbofuran can be derived. Information on another 5 sites (where carbosulfan was dosed) (single first order DT50 were 1.3 to 27 days) are available from Mol 2002.</p>	<p>Open point fulfilled. New open point proposed, see below.</p>

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	See reporting table: 4(14)	The meeting agreed that for PECsoil single first order DT50 for carbofuran of 27 days should be used (DT90 91 days) in line with the proposal of the RMS. A message was sent to the residues teleconference that the field DT90 value considered reliable was 91 days.	
	<p>New open point: 4.12 Identified at PRAPeR 62 meeting.</p> <p>RMS to calculate new PEC soil for carbofuran using a single first order DT50 of 27 days and include in an addendum.</p>		Open point open.
	<p>Open point: 4.6 MSs to discuss in a meeting of experts the proper formation fraction to be used for the PECgw calculation for carbofuran. See also comment 4(19).</p> <p>See reporting table: 4(20)</p>	See discussion of Open point: 4.3. It was agreed that a formation fraction of 1 was appropriate.	Open point fulfilled.
	Open point: 4.7 MSs to discuss in a meeting of experts the proper degradation endpoint to be used for the PECgw and PECsw calculations for carbofuran. See also open point in comment	<p>See discussion of Open point 4.3 and 4.8.</p> <p>Benfuracarb DT50 Carbofuran DT50 formation fraction from benfuracarb Benfuracarb Kd 1/n of 1 Carbofuran DT50</p>	Open point fulfilled. New open point proposed, see below.

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	<p>4(8) and 4(18). See reporting table: 4(22)</p>		
	<p>New open point: 4.13 Identified at PRAPeR 62 meeting.</p> <p>New groundwater simulation required the input parameters of:</p> <p style="padding-left: 40px;">DT50 ff</p> <p>Koc 1/n</p> <p>Benfuracarb 0.42 - 9100 1</p> <p>Carbofuran 14 1 22 0.96</p> <p>3-OH carbofuran 0.41 0.1 55 1</p> <p>3-keto carbofuran 3.01 0.1 331 1</p> <p>should be used for these new groundwater simulations to be provided by the RMS in an addendum.</p> <p>New surface water simulation required the input parameters of:</p> <p style="padding-left: 40px;">Soil DT50 ff</p> <p>Koc 1/n</p> <p>Benfuracarb 0.42d - 9100 1</p>		<p>Open point open.</p>

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	<p>Carbofuran 14d 1 22 0.96 Carb phenol 1d 0.14 1031 0.9</p> <p>water DT50 sed DT50 Benfuracarb 1000d 15 hours Carbofuran 15.3d 1000d Carb phenol 1000d 9.9d</p> <p>should be used for these new surface water simulations to be provided by the RMS in an addendum.</p>		
	<p>Open point: 4.8 MSs to discuss in a meeting of experts the appropriate 1/n value to be used for benfuracarb and its metabolites. See also comments 4(16) and 4(21).</p> <p>See reporting table: 4(23)</p>	<p>The adsorption potential of benfuracarb was studied by HPLC method. For carbofuran 4 reliable Kf values are available For 3-hydroxy-carbofuran three Kd values are available. For 3-keto-carbofuran one Kd and two Kf values are available. No equilibrium time could be established from this experiment, 6 hours was selected for the adsorption isotherms as an approximate equilibrium time. The 1/n values for the two Kfoc are 1.144 and 0.489.</p> <p>The meeting agreed that for benfuracarb and 3-hydroxy-carbofuran a 1/n of 1 was appropriate. For carbofuran a 1/n of 0.96 was appropriate (arithmetic mean). For 3-keto-carbofuran a 1/n of 1 was agreed as the equilibrium was not reached within the 6 hour experiment.</p>	<p>Open point fulfilled. For new Open point for new simulations see Open point 4.7 above.</p>
	<p>Open point: 4.9 RMS to provide complete details (e.g</p>	<p>The used data for DT₅₀/DT₉₀ derivation (linear fit from the maximum observed concentration was used) for the total system of the W/S study for carbofuran and carbofuran-phenol and details of the statistics was included in the addendum (Jan 2009).</p>	<p>Open point fulfilled.</p>

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	<p>the individual measurements involved, graphical presentation) about the calculations used to derive the DT₅₀/DT₉₀ values for the different compartments of the compounds in the water sediment study.</p> <p>See reporting table: 4(26)</p>	<p>The experts were content that they now understood how the values were derived and accepted them for use in exposure assessment.</p>	
	<p>Open point: 4.10 MSs to discuss in a meeting of experts the residue definition for the environment.</p> <p>See reporting table: 4(29)</p>	<p>The meeting of experts agreed that there is no reason to change the definition of residue.</p> <p>Definition of the residue remains as: Soil: benfuracarb, carbofuran, 3-OH-carbofuran, 3-keto-carbofuran Ground water: benfuracarb, carbofuran, 3-OH-carbofuran, 3-keto-carbofuran Surface water: benfuracarb, carbofuran Sediment: carbofuran, carbofuran-7-phenol Air: benfuracarb, carbofuran.</p>	<p>Open point fulfilled.</p>
4.1	<p>Point of clarification to the applicant: The applicant to update the dossier provided to the MSs and EFSA with the models used for the PEC calculations and transparent model reports.</p> <p>See reporting table: 4(33)</p>	<p>The applicant indicated in Column B of the Evaluation table that the requested information was distributed in December 2008. EFSA and the member states confirmed that the information was available.</p>	<p>Point of clarification addressed.</p>

Appendix 2: Evaluation table

No.	<u>Column A</u> Conclusions of the EFSA Evaluation Meeting	<u>Column B</u> Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	<u>Column C</u> Rapporteur Member State comments on main data submitter / applicant comments	<u>Column D</u> Recommendations PRAPeR Expert Meeting / Conclusions of the evaluation group
	Section 4 Open points: 10 Points for clarification: 1 Data gaps: 0			Section 4 Open points: 3 Points for clarification: 0 Data gaps: 0
	Open point: 4.1 RMS to correct the List of End Points. 40% MWHC of the clay loam soil should be changed to 45% or 61%, the one which is more realistic/was measured in the same laboratory. See reporting table: 4(3)	Applicant: no comment. Action for RMS.	The listing of endpoints has been modified.	<u>PRAPeR 62 (13 – 15 January 2009)</u> Open point fulfilled.
	Open point: 4.2 RMS to update the list of endpoints with the values listed in column 3 of the reporting table that are not in brackets. See reporting table: 4(6)	Applicant: no comment. Action for RMS.	Differences because of rounding. The listing of endpoints 0has been modified.	<u>PRAPeR 62 (13 – 15 January 2009)</u> Open point fulfilled.
	Open point: 4.3 RMS to provide clear, independent summaries and assessments of the studies Saxena <i>et al.</i> , 1994	Applicant: no comment. Action for RMS.	In order to ease the work of the experts participating to the PRAPER meeting, the assessment of the 2 studies has been transferred from the DAR carbofuran in an Addendum	<u>PRAPeR 62 (13 – 15 January 2009)</u> Open point fulfilled. New open point proposed, see below.

No.	<u>Column A</u> Conclusions of the EFSA Evaluation Meeting	<u>Column B</u> Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	<u>Column C</u> Rapporteur Member State comments on main data submitter / applicant comments	<u>Column D</u> Recommendations PRAPeR Expert Meeting / Conclusions of the evaluation group
	<p>(laboratory degradation study in acid soil and alkali soil) and Schocken, 1989 in an addendum to support discussion of a meeting of experts. Information on soil pH, soil moisture content and microbial activity to be clearly presented.</p> <p>See reporting table: 4(8)</p>			
	<p>New open point: 4.11 Identified at PRAPeR 62 meeting.</p> <p>RMS to update the list of endpoints lab DT50 values in line with the discussion table. Non linear fitting of the degradation of carbofuran from the studies by Saxena, 1994 and Schocken, 1989 and the appropriate normalization of the resulting DT50 values should be included in an addendum. FOMC fitting of the degradation of benfuracarb from the study by Noorloos, B. van; Brands, C. and the appropriate normalization of the resulting DT50 values</p>			<p><u>PRAPeR 62 (13 – 15 January 2009)</u></p> <p>Open point open.</p>

No.	<u>Column A</u> Conclusions of the EFSA Evaluation Meeting	<u>Column B</u> Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	<u>Column C</u> Rapporteur Member State comments on main data submitter / applicant comments	<u>Column D</u> Recommendations PRAPeR Expert Meeting / Conclusions of the evaluation group
	should be included in an addendum.			
	<p>Open point: 4.4 MS to discuss in a meeting of experts if there is any need to require additional data on carbofuran degradation in soil at 10°C or whether the use of a standard Q10 is supported.</p> <p>See reporting table: 4(11)</p>	<p>Applicant: please refer to our argumentation in the reporting table</p>	<p>The following new study has been submitted and evaluated in the DAR: Determination of the aerobic degradation rate of benfuracarb in alkaline soil at 10°C and 20°C. (Noorloos, B. van; Brands, C.)</p>	<p><u>PRAPeR 62 (13 – 15 January 2009)</u> Open point fulfilled.</p>
	<p>Open point: 4.5 c) RMS to provide a clear summary and assessment of the study by Taylor and Houseman, 1982 in an addendum to support discussion of a meeting of experts on the validity of this study and also report the Terry A. 2005 analysis if this is relevant. d) degradation endpoint used in the PECsoil calculation to be discussed in a meeting of experts</p> <p>See reporting table: 4(14)</p>	<p>Applicant: please refer to our argumentation in the reporting table</p>	<p>In order to ease the work of the experts participating to the PRAPER meeting, the assessment of the Taylor and Houseman, 1982 has been transferred from the DAR carbofuran in an Addendum</p>	<p><u>PRAPeR 62 (13 – 15 January 2009)</u> Open point fulfilled. New open point proposed, see below.</p>
	<p>New open point: 4.12 Identified at PRAPeR 62 meeting.</p>			<p><u>PRAPeR 62 (13 – 15 January 2009)</u> Open point open.</p>

No.	<u>Column A</u> Conclusions of the EFSA Evaluation Meeting	<u>Column B</u> Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	<u>Column C</u> Rapporteur Member State comments on main data submitter / applicant comments	<u>Column D</u> Recommendations PRAPeR Expert Meeting / Conclusions of the evaluation group
	RMS to calculate new PEC soil for carbofuran using a single first order DT50 of 27 days and include in an addendum.			
	<p>Open point: 4.6 MSs to discuss in a meeting of experts the proper formation fraction to be used for the PECgw calculation for carbofuran. See also comment 4(19).</p> <p>See reporting table: 4(20)</p>	Applicant: please refer to our answer in the reporting table. See also “point of clarification” (last row of this section).	We consider that these minor changes (formation fraction, 1/n value,...) have no impact on the final outcome of the evaluation, namely that benfuracarb, 3-keto-carbofuran, 3-OH-carbofuran and carbofuran-phenol do not leach to groundwater. Carbofuran is the only metabolite that could leach to some extent, however, a sufficient number of safe scenarios has been identified, allowing annex I inclusion.	<u>PRAPeR 62 (13 – 15 January 2009)</u> Open point fulfilled.
	<p>Open point: 4.7 MSs to discuss in a meeting of experts the proper degradation endpoint to be used for the PECgw and PECsw calculations for carbofuran. See also open point in comment 4(8) and 4(18).</p> <p>See reporting table: 4(22)</p>	Applicant: please refer to our answer in the reporting table	See open point 4.6	<u>PRAPeR 62 (13 – 15 January 2009)</u> Open point fulfilled. New open point proposed, see below.
	New open point: 4.13 Identified at PRAPeR 62 meeting.			<u>PRAPeR 62 (13 – 15 January 2009)</u> Open point open.

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations PRAPeR Expert Meeting / Conclusions of the evaluation group																																																																																				
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	<p>hours Carbofuran 15.3d 1000d Carb phenol 1000d 9.9d should be used for these new surface water simulations to be provided by the RMS in an addendum.</p>			
	<p>Open point: 4.8 MSs to discuss in a meeting of experts the appropriate 1/n value to be used for benfuracarb and its metabolites. See also comments 4(16) and 4(21). See reporting table: 4(23)</p>	<p>Applicant: please refer to our answer in the reporting table. See also “point of clarification” (last row of this section).</p>	<p>See open point 4.6</p>	<p><u>PRAPeR 62 (13 – 15 January 2009)</u> Open point fulfilled. For new Open point for new simulations see Open point 4.7 above.</p>
	<p>Open point: 4.9 RMS to provide complete details (e.g the individual measurements involved, graphical presentation) about the calculations used to derive the DT₅₀/DT₉₀ values for the different compartments of the compounds in the surface water study. See reporting table: 4(26)</p>	<p>Applicant: no comments. Action for RMS.</p>	<p>In order to ease the work of the experts participating to the PRAPER meeting, the recalculation of the relevant endpoints has been put in an Addendum</p>	<p><u>PRAPeR 62 (13 – 15 January 2009)</u> Open point fulfilled.</p>
	<p>Open point: 4.10 MSs to discuss in a meeting</p>	<p>Applicant: no comments. The applicant supports the conclusions of the RMS.</p>	<p>No comment</p>	<p><u>PRAPeR 62 (13 – 15 January 2009)</u> Open point fulfilled.</p>

No.	<u>Column A</u> Conclusions of the EFSA Evaluation Meeting	<u>Column B</u> Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	<u>Column C</u> Rapporteur Member State comments on main data submitter / applicant comments	<u>Column D</u> Recommendations PRAPeR Expert Meeting / Conclusions of the evaluation group
	<p>of experts the residue definition for the environment.</p> <p>See reporting table: 4(29)</p>			
4.1	<p>Point of clarification to the applicant: The applicant to update the dossier provided to the MSs and EFSA with the models used for the PEC calculations and transparent model reports.</p> <p>See reporting table: 4(33)</p>	<p>Applicant: Several Appendices containing the FOCUS-PEARL and PELMO reports have been added to the PECgw calculations as submitted to the RMS with the resubmission dossier. The PECgw calculations and appendices have been distributed to RMS and all appropriate MS contact points by courier in the week of 15-19 December 2008.</p>	No comment	<p><u>PRAPeR 62 (13 – 15 January 2009)</u> Point of clarification addressed.</p>

REPORT OF PRAPeR EXPERT MEETING 63

BENFURACARB

Rapporteur Member State: BE

Specific comments on the active substance in the section

5. Ecotoxicology

are already listed in the relevant reporting table. Comments submitted for this meeting are listed below.

1. Comments submitted for this meeting:

Date	Supplier	File Name
none		

2. Documents submitted for meeting:

Date	Supplier	File Name
2009-01-05	BE	Benfuracarb evaluation table rev 1-0 2009-01-05).doc
December 2008	BE	Benfuracarb List of endpoints (December 2008).doc
December 2008	BE	Benfuracarb reporting table rev 1-1 (December 2008).doc
January 2009	BE	Benfuracarb_addendum Vol3_B9 (January 2009).doc

3. Documents tabled at the meeting:

Date	Supplier	File Name
none		

The conclusions of the meeting were as follows:

4. Data on preparations: ONCOL 8.6 G

5. Classification and labelling: R50/R53

6. Recommended restrictions/conditions for use: the use should be restricted to no flowering brassicae plants and granules should be incorporated into the soil.

7. Reference list: not discussed

Areas of concern: birds, mammals, bees, NTA, earthworms.

Appendix 1: Discussion table: BENFURACARB

Appendix 2: Evaluation table

Appendix 1: Discussion Table, Benfuracarb (In, Ne)

5. Ecotoxicology

	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	<p>Open point: 5.1 MSs to discuss in an expert meeting whether the maximum measured residue value should be used in the refined risk assessment for birds and mammals or the 90th percentile value from the 8 residue trials. Furthermore it should be discussed if the residue trial of Beaufort (2006) should not be included in the risk assessment.</p> <p>See reporting table: 5(3)</p>	<p>Based on 8 trials performed in EU, RMS suggested to use the 90th to refine the acute exposure (3.92 mg a.s/kg), considering that according to Dixons test the higher value of 10.566 mg a.s/kg could be an outlier. The meeting noted that this value derived from a trial not in line with the GAP. The majority agreed to the RMS assessment.</p>	<p>Open point fulfilled.</p> <p>The RMS's assessment was confirmed.</p>
	<p>Open point: 5.2 MSs to discuss in an expert meeting the PD values suggested in the refined risk assessment for crested lark.</p>	<p>The applicant presented data from literature on skylark to set PD for crested lark. The RMS considered this data only useful for a qualitative PD estimation and not sufficient to derive quantitative PD estimation. However to provide TERs the RMS proposed PD values based on this data as follow: 33% for cabbage seedlings, 6% for earthworms, 23% arthropods, 38% weed seeds.</p> <p>The meeting noted that there is some uncertainty to extrapolate data from skylark to crested lark. Moreover for quantitative PD values, data on diet of birds on the agricultural landscape related to the GAP should be provided.</p>	<p>Open point fulfilled.</p> <p>New data gap proposed, see below.</p>

	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	See reporting table: 5(6)	The meeting agreed not to use qualitative PD values in a quantitative TER calculations, even with those PD values the TERs are below the trigger. The meeting agreed that the risk was not addressed.	
	5.1 New data gap identified at PRAPeR 63: The risk to birds needs to be further addressed.		Data gap open.
	Open point: 5.3 MSs to discuss in an expert meeting the PD values suggested in the refined risk assessment for wood pigeon. See reporting table: 5(7)	The applicant presented data from literature on skylark to set PD for wood pigeon. The RMS considered this data only useful for a qualitative PD estimation and not sufficient to derive quantitative PD estimation. However to provide TERs the RMS proposed PD values based on this data as follow: 33% for cabbage seedlings, 58% for weed seeds, 3% arthropods, 6% cereal seeds. The meeting noted that for quantitative PD values, data on diet of birds on the agricultural landscape related to the GAP should be provided. The meeting agreed not to use qualitative PD values in a quantitative TER calculation, even with those PD values the TERs are below the trigger. The meeting agreed that the risk was not addressed.	Open point fulfilled.
	Open point: 5.4 The refined risk assessment (without a reduced PT) resulted in TERs below the trigger. Therefore it should be discussed in an expert meeting whether the	The RMS considered the PT estimation provided by the applicant not useful to refine the risk assessment at EU level. To derive reliable PT values robust data would be needed (i.e. radiotracking data). The meeting agreed with the RMS opinion: the provided PT values could not be use to refine the risk assessment.	Open point fulfilled. New data gap proposed, see data gap 5.1

	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	<p>information presented in the DAR allows a quantitative PT refinement or if a data gap remains.</p> <p>See reporting table: 5(8)</p>		
	<p>Open point: 5.5 MSs to discuss in an expert meeting the PD values suggested in the refined risk assessment for black headed gull.</p> <p>See reporting table: 5(9)</p>	<p>A PD value of 92% earthworm was proposed by the RMS for black-beaded gull, as the most reliable value. This is the max value observed (from Buxton et al 1998). The experts agreed not to use this PD for the refinement of acute risk assessment.</p>	<p>Open point fulfilled.</p> <p>New open point proposed, see below.</p>
	<p>New open point 5.19: RMS to calculate the acute TER with a PD of 1</p>		<p>Open point open.</p>
	<p>Open point: 5.6 RMS to include in an addendum an evaluation of the risk assessment for birds for the uptake of granules. MSs to discuss in an expert meeting the risk assessment for birds for the uptake of granules.</p>	<p>RMS provided in the addendum risk assessment for the uptake of granules according to the EPPO scheme 2003. One granule criterion was followed as first tier assessment. Then calculations by accidental and intentional ingestion were provided. The meeting accepted the EPPO scheme approach. A DT50 of 0.44 d in soil was use as surrogate of DT50 for granules to derive the twa-factor, used in the grit ingestion calculations. The meeting agreed that uncertainty is related to this assumption and data would be necessary to support this. A clarification on the GAP (i.e. method of application) is necessary: it is not clear if the granules are incorporated in the soil. The meeting agreed that if the granules are incorporated into the soil the risk could be considered low.</p>	<p>Open point fulfilled.</p> <p>New open point proposed, see below.</p>

	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	See reporting table: 5(12)		
	<p>New open point 5.20: RMS to provide new calculations without the DT50 value. RMS to clarify the GAP (are the granules covered by the soil?). RMS to update the LoE including the EPPO scheme calculations.</p>		Open point open.
	<p>Open point: 5.7 MSs to discuss in an expert meeting whether a risk assessment should be conducted for birds and mammals for the uptake of contaminated drinking water.</p> <p>See reporting table: 5(14)</p>	<p>RMs did not agree to provide drinking water risk assessment according to the new guidance (EFSA journal 2008). However the meeting considered necessary to address the risk from uptake of drinking water taking into account the exposure from puddles. This is relevant for carbofuran exposure.</p>	<p>Open point fulfilled.</p> <p>New open point proposed, see below.</p>
	<p>New open point 5.21: RMS to provide a risk assessment for the uptake of drinking water and to update the list of end points.</p>		Open point open.
	<p>Open point: 5.8 MSs to discuss in an</p>	<p>Due to the inconsistency between the NOEC reported in the benfuracarb dossier (<0.3 mg carbofuran /kg bw) and in the carbofuran dossier (1.5 mg carbofuran /kg bw), the RMS</p>	<p>Open point open pending on the outcome of the carbofuran</p>

	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	<p>expert meeting the long-term endpoint for carbofuran used in the risk assessment.</p> <p>See reporting table: 5(15)</p>	<p>assumed the NOEC = LC10 of 0.64 mg carbofuran /kg for both benfuracarb and carbofuran. One MS noted that the NOEC from a reproduction study in the benfuracarb dossier is lower (<0.3 mg/kg bw) and suggested to use the LC0 value of 0.12 mg carbofuran /kg as NOEC.</p> <p>EFSA noted that carbofuran resubmission will be discussed soon and therefore it was suggested to keep this point open until the peer review for carbofuran is finalised. The meeting agreed.</p>	<p>peer review.</p>
	<p>Open point: 5.9 MSs to discuss in an expert meeting the applicability of the suggested PD to refine the acute risk assessment for birds.</p> <p>See reporting table: 5(16)</p>	<p>The meeting considered the use of PD for the acute risk assessment in case of reliable data. Since no robust data were provided which allow a quantitative refinement of PD the experts agreed not to use the PD for the acute risk assessment.</p>	<p>Open point fulfilled.</p> <p>Refer to point 5.2, 5.3, 5.5.</p>
	<p>Open point: 5.10 RMS to include in an addendum an evaluation of the risk assessment for mammals for the uptake of granules. MSs to discuss the risk assessment for mammals for the uptake of granules.</p> <p>See reporting table: 5(21)</p>	<p>It has been done. The EPPO scheme was used with the same assumption as for birds. With regard the calculation of ftwa refer to point 5.6.</p>	<p>Open point fulfilled.</p> <p>see open point 5.20</p>
	<p>Open point: 5.11 MSs to discuss in an expert meeting the PD</p>	<p>The experts agreed to use the PD for the long term risk but not for the acute risk. Therefore, the meeting agreed that RMS has to update the acute risk assessment.</p>	<p>Open point fulfilled.</p> <p>New open point proposed, see</p>

	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	<p>values suggested to refine the acute and long-term risk to mammals.</p> <p>See reporting table: 5(22)</p>		<p>below.</p>
	<p>New open point 5.22: RMS to update the acute risk assessment for mammals. (without PD refinement).</p>		<p>Open point open.</p>
	<p>Open point: 5.12 RMS to provide in an addendum a comprehensive explanation on how the mean NOAEL (carbofuran) for the long-term mammal risk assessment was derived.</p> <p>See reporting table: 5(23)</p>	<p>The RMS derived the NOAEL as average of the available chronic studies on carbofuran. The meeting agreed to keep the point open until the peer review of carbofuran is finalised</p>	<p>Open point open pending on carbofuran peer review.</p>
	<p>Open point: 5.13 MSs to discuss in an expert meeting whether risk mitigation measures should be proposed for bees.</p> <p>See reporting table: 5(30)</p>	<p>A high risk to bees cannot be excluded for all the flowering brassicae (oilseed rape and mustard). The meeting agreed restrict the use to non flowering brassicae plants. Flowing plants/weeds should be removed or exposure should be avoid (Sp8).</p>	<p>Open point fulfilled.</p> <p>The meeting agreed restrict the use to non flowering brassicae plants. Flowing plants/weeds should be removed or exposure should be avoid (Sp8).</p>

	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	<p>Open point: 5.14 MSs to discuss in an expert meeting the validity of the aged residues study with <i>A. bilineata</i>.</p> <p>See reporting table: 5(32)</p>	<p>The RMS considered the effects observed with the duration of ageing of residues (>50%) not related to the exposure. The meeting noted that the effects on reproduction increase from the beginning until the end of the exposure (-57.8% 119 DAT), suggesting an exposure relationship. The meeting agreed that cannot be excluded that effects on <i>Aleochara</i> are treatment related, because the carbamate moiety is still present in the degradation products of carbofuran. The risk to <i>Aleochara</i> needs to be addressed further.</p>	<p>Open point fulfilled.</p> <p>New data gap proposed, see below.</p>
	<p>5.2 New data gap identified at PRAPeR 63:</p> <p>The risk to <i>Aleochara</i> needs to be further addressed.</p>		<p>Data gap open.</p>
	<p>Open point: 5.15 MSs to discuss in an expert meeting whether a data gap remains with regard to the risk to earthworms.</p> <p>See reporting table: 5(34)</p>	<p>The RMS considered the risk to earthworm not sufficiently addressed. The available field study has some deficiencies. The meeting agreed with the RMS that the risk needs to be further addressed.</p>	<p>Open point fulfilled.</p> <p>New data gap proposed, see below.</p>
	<p>5.3 New data gap identified at PRAPeR 63:</p> <p>The risk to earthworms need to be further addressed.</p>		<p>Data gap open.</p>
	<p>Open point: 5.16</p>	<p>See open point 5.6 and 5.10</p>	<p>See open point 5.6 and 5.10</p>

	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	<p>RMS to include details on the risk assessment for birds and mammals for the uptake of granules in the LoEP.</p> <p>See reporting table: 5(37)</p>		
	<p>Open point: 5.17 MSs to discuss in an expert meeting the long-term endpoint (carbofuran) used in the short-term risk assessment for birds.</p> <p>See reporting table: 5(38)</p>	<p>The meeting agreed to keep the point open until the peer review of carbofuran is finalised</p>	<p>Open point open pending on the carbofuran peer review.</p>
	<p>Open point: 5.18 RMS to present in an addendum the refined risk assessment for birds suggested by the applicant (including the justification for the proposed refinements) to be discussed in an expert meeting.</p> <p>See reporting table: 5(39)</p>	<p>It has been done</p>	<p>Open point fulfilled.</p>

Appendix 2: Evaluation table

No.	<u>Column A</u> Conclusions of the EFSA Evaluation Meeting	<u>Column B</u> Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	<u>Column C</u> Rapporteur Member State comments on main data submitter / applicant comments	<u>Column D</u> Recommendations PRAPeR Expert Meeting / Conclusions of the evaluation group
	Section 5 Open points: 18 Points for clarification: 0 Data gaps: 0			Section 5 Open points: 7 Points for clarification: 0 Data gaps: 3
	Open point: 5.1 MSs to discuss in an expert meeting whether the maximum measured residue value should be used in the refined risk assessment for birds and mammals or the 90 th percentile value from the 8 residue trials. Furthermore it should be discussed if the residue trial of Beaufort (2006) should not be included in the risk assessment. See reporting table: 5(3)	Applicant: we refer to the evaluation table points 5 (3) column 3 and 5(4) column 2. Please also see further justification included in the applicant's comments on the DAR (of 18 September 2008) and repeated below: 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	RMS (January 2009) : RMS agrees to discuss this point in an expert meeting.	<u>PRAPeR 63 (13 – 15 January 2009)</u> Open point fulfilled. The RMS's assessment was confirmed.

No.	<u>Column A</u> Conclusions of the EFSA Evaluation Meeting	<u>Column B</u> Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	<u>Column C</u> Rapporteur Member State comments on main data submitter / applicant comments	<u>Column D</u> Recommendations PRAPeR Expert Meeting / Conclusions of the evaluation group
		<p>of the spare sample analysis.</p> <p>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.</p>		
	<p>Open point: 5.2 MSs to discuss in an expert meeting the PD values suggested in the refined risk assessment for crested lark.</p> <p>See reporting table: 5(6)</p>	<p>Applicant: please refer to our answer in the reporting table.</p>	<p>RMS (January 2009) : RMS agrees to discuss this point in an expert meeting.</p>	<p><u>PRAPeR 63 (13 – 15 January 2009)</u></p> <p>Open point fulfilled.</p>
	<p>5.1. New data gap identified at PRAPeR 63:</p> <p>The risk to birds needs to be further addressed.</p>			<p><u>PRAPeR 63 (13 – 15 January 2009)</u></p> <p>Data gap open.</p>
	<p>Open point: 5.3 MSs to discuss in an expert meeting the PD values suggested in the refined risk assessment for wood pigeon.</p>	<p>Applicant: please refer to our answer in the reporting table.</p>	<p>RMS (January 2009) : RMS agrees to discuss this point in an expert meeting.</p>	<p><u>PRAPeR 63 (13 – 15 January 2009)</u></p> <p>Open point fulfilled.</p> <p>New data gap proposed, see data gap 5.1</p>

No.	<u>Column A</u> Conclusions of the EFSA Evaluation Meeting	<u>Column B</u> Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	<u>Column C</u> Rapporteur Member State comments on main data submitter / applicant comments	<u>Column D</u> Recommendations PRAPeR Expert Meeting / Conclusions of the evaluation group
	See reporting table: 5(7)			
	<p>Open point: 5.4 The refined risk assessment (without a reduced PT) resulted in TERs below the trigger. Therefore it should be discussed in an expert meeting whether the information presented in the DAR allows a quantitative PT refinement or if a data gap remains.</p> <p>See reporting table: 5(8)</p>	Applicant: please refer to our answer in the reporting table.	RMS (January 2009) : RMS agrees to discuss this point in an expert meeting. Please also refer to open point 5.18.	<u>PRAPeR 63 (13 – 15 January 2009)</u> Open point fulfilled.
	<p>Open point: 5.5 MSs to discuss in an expert meeting the PD values suggested in the refined risk assessment for black headed gull.</p> <p>See reporting table: 5(9)</p>	Applicant: please refer to our answer in the reporting table.	RMS (January 2009) : RMS agrees to discuss this point in an expert meeting.	<u>PRAPeR 63 (13 – 15 January 2009)</u> Open point fulfilled. New open point proposed, see below.
	New open point 5.19: RMS to calculate the acute TER with a PD of 1			<u>PRAPeR 63 (13 – 15 January 2009)</u> Open point open.
	Open point: 5.6 RMS to include in an addendum an evaluation of the risk assessment for birds	Applicant: please refer to our answer in the reporting table.	RMS (January 2009) : The evaluation is presented in an addendum. RMS agrees to discuss this point in an expert meeting.	<u>PRAPeR 63 (13 – 15 January 2009)</u> Open point fulfilled.

No.	<u>Column A</u> Conclusions of the EFSA Evaluation Meeting	<u>Column B</u> Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	<u>Column C</u> Rapporteur Member State comments on main data submitter / applicant comments	<u>Column D</u> Recommendations PRAPeR Expert Meeting / Conclusions of the evaluation group
	<p>for the uptake of granules. MSs to discuss in an expert meeting the risk assessment for birds for the uptake of granules.</p> <p>See reporting table: 5(12)</p>			<p>New open point proposed, see below.</p>
	<p>New open point 5.20: RMS to provide new calculations without the DT50 value. RMS to clarify the GAP (are the granules covered by the soil?). RMS to update the LoE including the EPPO scheme calculations.</p>			<p><u>PRAPeR 63 (13 – 15 January 2009)</u></p> <p>Open point open.</p>
	<p>Open point: 5.7 MSs to discuss in an expert meeting whether a risk assessment should be conducted for birds and mammals for the uptake of contaminated drinking water.</p> <p>See reporting table: 5(14)</p>	<p>Applicant: please refer to our answer in the reporting table. We support the position of the RMS.</p>	<p>RMS (January 2009) : RMS agrees to discuss this point in an expert meeting.</p>	<p><u>PRAPeR 63 (13 – 15 January 2009)</u></p> <p>Open point fulfilled.</p> <p>New open point proposed, see below.</p>
	<p>New open point 5.21: RMS to provide a risk assessment for the uptake of drinking water and to update the list of end points.</p>			<p><u>PRAPeR 63 (13 – 15 January 2009)</u></p> <p>Open point open.</p>

No.	<u>Column A</u> Conclusions of the EFSA Evaluation Meeting	<u>Column B</u> Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	<u>Column C</u> Rapporteur Member State comments on main data submitter / applicant comments	<u>Column D</u> Recommendations PRAPeR Expert Meeting / Conclusions of the evaluation group
	<p>Open point: 5.8 MSs to discuss in an expert meeting the long-term endpoint for carbofuran used in the risk assessment.</p> <p>See reporting table: 5(15)</p>	<p>Applicant: please refer to our answer in the reporting table. We support the position of the RMS.</p>	<p>RMS (January 2009) : RMS agrees to discuss this point in an expert meeting.</p>	<p><u>PRAPeR 63 (13 – 15 January 2009)</u></p> <p>Open point open pending on the outcome of the carbofuran peer review.</p>
	<p>Open point: 5.9 MSs to discuss in an expert meeting the applicability of the suggested PD to refine the acute risk assessment for birds.</p> <p>See reporting table: 5(16)</p>	<p>Applicant: please refer to our answer in the reporting table.</p>	<p>RMS (January 2009) : RMS agrees to discuss this point in an expert meeting.</p>	<p><u>PRAPeR 63 (13 – 15 January 2009)</u></p> <p>Open point fulfilled.</p> <p>Refer to point 5.2, 5.3, 5.5.</p>
	<p>Open point: 5.10 RMS to include in an addendum an evaluation of the risk assessment for mammals for the uptake of granules. MSs to discuss the risk assessment for mammals for the uptake of granules.</p> <p>See reporting table: 5(21)</p>	<p>Applicant: please refer to our answer in the reporting table.</p>	<p>RMS (January 2009) : The evaluation is presented in an addendum. RMS agrees to discuss this point in an expert meeting.</p>	<p><u>PRAPeR 63 (13 – 15 January 2009)</u></p> <p>Open point fulfilled.</p> <p>see open point 5.20</p>
	<p>Open point: 5.11 MSs to discuss in an expert meeting the PD values suggested to refine the acute and long-term risk to mammals.</p>	<p>Applicant: please refer to our answer in the reporting table.</p>	<p>RMS (January 2009) : RMS agrees to discuss this point in an expert meeting.</p>	<p><u>PRAPeR 63 (13 – 15 January 2009)</u></p> <p>Open point fulfilled.</p> <p>New open point proposed, see below.</p>

No.	<u>Column A</u> Conclusions of the EFSA Evaluation Meeting	<u>Column B</u> Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	<u>Column C</u> Rapporteur Member State comments on main data submitter / applicant comments	<u>Column D</u> Recommendations PRAPeR Expert Meeting / Conclusions of the evaluation group
	See reporting table: 5(22)			
	New open point 5.22: RMS to update the acute risk assessment for mammals. (without PD refinement).			<u>PRAPeR 63 (13 – 15 January 2009)</u> Open point open.
	Open point: 5.12 RMS to provide in an addendum a comprehensive explanation on how the mean NOAEL (carbofuran) for the long-term mammal risk assessment was derived. See reporting table: 5(23)	Applicant: no comments, action for RMS.	RMS (January 2009) : RMS agrees to discuss this point in an expert meeting.	<u>PRAPeR 63 (13 – 15 January 2009)</u> Open point open pending on carbofuran peer review.
	Open point: 5.13 MSs to discuss in an expert meeting whether risk mitigation measures should be proposed for bees. See reporting table: 5(30)	Applicant: no comments.	RMS (January 2009) : RMS agrees to discuss this point in an expert meeting.	<u>PRAPeR 63 (13 – 15 January 2009)</u> Open point fulfilled. The meeting agreed restrict the use to non flowering brassicae plants. Flowing plants/weeds should be removed or exposure should be avoid (Sp8).
	Open point: 5.14 MSs to discuss in an expert meeting the validity of the aged residues study with <i>A. bilineata</i> .	Applicant: please refer to our answer in the reporting table. We support the conclusion of the RMS.	RMS (January 2009) : RMS agrees to discuss this point in an expert meeting.	<u>PRAPeR 63 (13 – 15 January 2009)</u> Open point fulfilled. New data gap proposed, see below..

No.	<u>Column A</u> Conclusions of the EFSA Evaluation Meeting	<u>Column B</u> Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	<u>Column C</u> Rapporteur Member State comments on main data submitter / applicant comments	<u>Column D</u> Recommendations PRAPeR Expert Meeting / Conclusions of the evaluation group
	See reporting table: 5(32)			
	5.2 New data gap identified at PRAPeR 63: The risk to Aleochara needs to be further addressed.			<u>PRAPeR 63 (13 – 15 January 2009)</u> Data gap open.
	Open point: 5.15 MSs to discuss in an expert meeting whether a data gap remains with regard to the risk to earthworms. See reporting table: 5(34)	Applicant: 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. The applicant will confirm this by additional experiments (confirmatory data at MS level) if required.	RMS (January 2009) : RMS agrees to discuss this point in an expert meeting.	<u>PRAPeR 63 (13 – 15 January 2009)</u> Open point fulfilled. New data gap proposed, see below.
	5.3 New data gap identified at PRAPeR 63: The risk to earthworms need to be further addressed.			<u>PRAPeR 63 (13 – 15 January 2009)</u> Data gap open.
	Open point: 5.16 RMS to include details on the risk assessment for birds and mammals for the uptake of granules in the LoEP. See reporting table: 5(37)	Applicant: please refer to our answer in the reporting table. We support the conclusion of the RMS.	RMS (January 2009) : No changes since August 2008.	<u>PRAPeR 63 (13 – 15 January 2009)</u> See open point 5.6 and 5.10

No.	<u>Column A</u> Conclusions of the EFSA Evaluation Meeting	<u>Column B</u> Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	<u>Column C</u> Rapporteur Member State comments on main data submitter / applicant comments	<u>Column D</u> Recommendations PRAPeR Expert Meeting / Conclusions of the evaluation group
	<p>Open point: 5.17 MSs to discuss in an expert meeting the long-term endpoint (carbofuran) used in the short-term risk assessment for birds.</p> <p>See reporting table: 5(38)</p>	<p>Applicant: please refer to our answer in the reporting table. We welcome the discussion.</p>	<p>RMS (January 2009) : RMS agrees to discuss this point in an expert meeting.</p>	<p><u>PRAPeR 63 (13 – 15 January 2009)</u></p> <p>Open point open pending on the carbofuran peer review.</p>
	<p>Open point: 5.18 RMS to present in an addendum the refined risk assessment for birds suggested by the applicant (including the justification for the proposed refinements) to be discussed in an expert meeting.</p> <p>See reporting table: 5(39)</p>	<p>Applicant: please refer to our answer in the reporting table. We welcome the discussion.</p>	<p>RMS (January 2009) : The information is presented in an addendum. RMS agrees to discuss this point in an expert meeting.</p>	<p><u>PRAPeR 63 (13 – 15 January 2009)</u></p> <p>Open point fulfilled.</p>

Report of PRAPeR Expert MEETING TC 4

BENFURACARB

Rapporteur Member State: BE

Specific comments on the active substance in the section

2. Mammalian Toxicology

are already listed in the relevant reporting table. Comments submitted for this meeting are listed below.

1. Comments submitted for this meeting:

Date	Supplier	File Name
none		

2. Documents submitted for meeting:

Date	Supplier	File Name
2009-01-05	BE	Benfuracarb evaluation table rev 1-0 2009-01-05).doc
December 2008	BE	Benfuracarb List of endpoints (December 2008).doc
December 2008	BE	Benfuracarb reporting table rev 1-1 (December 2008).doc
January 2009	BE	Benfuracarb_ addendum Vol3_B6 (January 2009).doc

3. Documents tabled at the meeting:

Date	Supplier	File Name
none		

The conclusions of the meeting were as follows:

- Data on preparations:** ONCOL 8.6 G
- Classification and labelling:** T, "Toxic"; R22, "Harmful if swallowed"; R23, "Toxic by inhalation"; Repr. Tox. Cat. 3, R62, "Possible risk of impaired fertility"
- Recommended restrictions/conditions for use:** not discussed
- Reference List:** not discussed

Areas of concern: not discussed
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Appendix 1: Discussion table: BENFURACARB

Appendix 2: Evaluation table

Appendix 1: Discussion Table, Benfuracarb (In, Ne)

2. Mammalian toxicology

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	<p>Open point: 2.1 RMS to transfer the detailed evaluation of the new 60-day gavage study in rat and the new 10-week dietary study in rat from the carbofuran dossier to an addendum to the benfuracarb resubmission dossier to be discussed in an expert's meeting.</p> <p>See reporting table: 2(1)</p>	<p>The RMS presented the summary of the new study on carbofuran (also in the addendum of January 2009). Two NOAELs were proposed: one for the gavage part of the study (0.2 mg/kg bw/d) and one for the dietary part of the study (3 mg/kg bw/d). Some effects are observed on testicular endpoints at 180 ppm (high dose level in the dietary part of the study) but are not considered sufficient to trigger classification for reproductive toxicity.</p> <p>The experts agreed on these two NOAELs, and also not to propose classification related to this end-point (this is also in agreement with the ECB decision).</p> <p>Open point fulfilled.</p>	<p>In the 60-day, gavage part of the rat study with carbofuran, the agreed NOAEL is 0.2 mg/kg bw/day;</p> <p>In the 10-week dietary administration part of the study, the agreed NOAEL is 3 mg/kg bw/day.</p> <p>No classification is proposed for reproductive toxicity.</p> <p>Open point fulfilled.</p>
	<p>Open point: 2.2 As the new rat acute neurotoxicity studies on carbofuran appear to present more critical results, RMS to present its assessment in an addendum to the resubmission report of benfuracarb.</p> <p>See reporting table: 2(2)</p>	<p>The RMS presented the new acute neurotoxicity studies on carbofuran. Two sets of three studies were evaluated (one range-finding, one peak time identification and one main study). The Hoberman (2007,c) is considered the most relevant (a gavage study). The main results are presented in Table B.6.7.3-6 in the addendum of January 2009. A statistically significant inhibition of brain acetylcholinesterase of 20% compared to the controls is shown at the lowest dose of 0.03 mg/kg bw/day (in females). This is thus a LOAEL. Using a factor of 2, a NOAEL of 0.015 mg/kg bw/day is proposed.</p> <p>The experts agreed on the derivation of the LOAEL and NOAEL from this study. It was explained that benfuracarb is completely dissociated into carbofuran, and that the reference values that will be derived from this study are only related to the metabolite carbofuran. No change of the reference values of benfuracarb itself is proposed.</p> <p>The choice of an additional factor of 2 for the derivation of the NOAEL from the LOAEL was discussed. The real relevance of 20% decrease in brain cholinesterase</p>	<p>The new acute neurotoxicity study in rat with carbofuran resulted in a LOAEL of 0.03 mg/kg bw in pups (from which a NOAEL of 0.015 mg/kg bw is estimated);</p> <p>In adults the NOAEL is 0.03 mg/kg bw.</p> <p>Open point fulfilled.</p>

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
		<p>activity at the lowest dose level of 0.03 mg/kg bw/d was questionable but could not be neglected. Therefore the RMS used the BMD approach to extrapolate a dose inducing a 10% decrease in brain AChE activity as a NOAEL, leading to a global value of 0.015 (corresponding to the use of a factor of 2 from the LOAEL).</p> <p>On the other hand, there are no clinical signs (maybe subclinical signs but they were not monitored), but this is one of the few studies where brain acetylcholinesterase activity has been measured.</p> <p>The concern about a higher sensitivity of the pups (for brain AChE) was also raised, in relationship with a possible proposal for classification. In the DAR of carbofuran, one developmental neurotoxicity study (1980) did not raise a concern about a higher sensitivity of pups. It was proposed to flag these new results to EChA for further consideration.</p> <p>Open point fulfilled.</p>	
	<p>Open point: 2.3 Pending on the outcome of the environmental fate and behaviour section discussion, MSs to discuss genotoxicity of carbofuran's metabolite 3-OH in an expert's meeting.</p> <p>See reporting table: 2(3)</p>	<p>The Fate section concluded that the metabolite is not relevant (is not found in significant amounts in groundwater). This is not a major metabolite in groundwater.</p> <p>Open point fulfilled.</p>	<p>Open point fulfilled</p>
	<p>Open point: 2.4 MSs to discuss the reference values (ADI and ARfD) of carbofuran in an expert's meeting.</p> <p>See reporting table: 2(4)</p>	<p>The JMPR conclusion was that there was little interspecies variation and therefore they used a lower safety factor to extrapolate the ADI. The RMS reminded that for other carbamates, the usual factor of 100 was always used within the peer-review process (91/414/EC) and that human data were only used if more critical results were obtained (as was the case with aldicarb). Apparently the same studies were available during JMPR evaluation, but in 2008 JMPR was still supporting the use of a safety factor of 25 for the derivation of the ADI.</p> <p>The experts agreed with the usual safety factor of 100 for consistency, with an additional safety factor of 2 on the LOAEL of 0.03 mg/kg bw (in pups), resulting in an ADI of 0.00015 mg/kg bw/day; the same approach is relevant to derive the ARfD of</p>	<p>The ADI for carbofuran is 0.00015 mg/kg bw/day The ARfD for carbofuran is 0.00015 mg/kg bw</p> <p>Open point fulfilled</p>

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
		<p>0.00015 mg/kg bw.</p> <p>It was noted that this LOAEL was derived from a single administration study, but no cumulative effect is expected from the biokinetics of the carbofuran (carbamates in general).</p> <p>For completeness, it was also proposed to conclude on the AOEL for carbofuran (which should be reviewed within a short timeframe).</p> <p>The concern of exposure in utero during the use of carbofuran was discussed, because the RMS proposed to use the NOAEL for adults for the derivation of the AOEL (i.e. 0.03 mg/kg bw/day). Considering that the PND 11 in rats corresponds to the brain development phase in humans during the last quarter of pregnancy, the higher sensitivity of pups should be taken into account during the operator exposure (since pregnant women could be operators) and the NOAEL in rats at PND 11 was agreed to be the most relevant.</p> <p>Carbofuran is applied as a granule directly into the soil, therefore the exposure of the bystanders is expected to be negligible (but this should be considered independently of the setting of the AOEL).</p> <p>For consistency, it was proposed to use the same value for the AOEL as for the ADI, taking into account the most sensitive species and stage. Even though it is an extremely conservative approach, this was agreed by the majority of the experts; however the RMS disagreed with this position. The resulting AOEL would be 0.00015 mg/kg bw/day.</p> <p>As the RMS clearly expressed his disagreement with this value after the meeting, and proposes to review the data, EFSA proposes to re-discuss it with the carbofuran dossier.</p> <p>Open point fulfilled.</p>	

Appendix 2: Evaluation table

No.	<u>Column A</u> Conclusions of the EFSA Evaluation Meeting	<u>Column B</u> Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	<u>Column C</u> Rapporteur Member State comments on main data submitter / applicant comments	<u>Column D</u> Recommendations PRAPeR Expert Meeting / Conclusions of the Evaluation Meeting
	Section 2 Open points: 4 Points for clarification: 0 Data gaps: 0			Section 2 Open points: 0 Points for clarification: 0 Data gaps: 0
	Open point: 2.1 RMS to transfer the detailed evaluation of the new 60-day gavage study in rat and the new 10-week dietary study in rat from the carbofuran dossier to an addendum to the benfuracarb resubmission dossier to be discussed in an expert's meeting. See reporting table: 2(1)	Applicant: no comment. Action for RMS.	RMS 01.2009: The study was fully evaluated at the occasion of the resubmission of Carbofuran, and RMS refers to this DAR. In summary, it was concluded that in the new study, slight testicular effects were observed at the dietary top dose (180 mkd). In the gavage study, no histopathological effects were observed at 0.8 mg/kg b.w.. The effects were considered insufficient to support classification for reprotoxicity. The outcome of the study was without effect on the determination of the reference doses. See addendum.	<u>PRAPeR TC 4 (13 January 2009)</u> In the 60-day, gavage part of the rat study with carbofuran, the agreed NOAEL is 0.2 mg/kg bw/day; In the 10-week dietary administration part of the study, the agreed NOAEL is 3 mg/kg bw/day. No classification is proposed for reproductive toxicity. Open point fulfilled.
	Open point: 2.2 As the new rat acute neurotoxicity studies on carbofuran appear to present more critical results, RMS to present its assessment in an addendum to the resubmission report of benfuracarb.	Applicant: We were informed by the RMS that the safety factor used to derive the ADI/ARfD for carbofuran should still be discussed between experts. We refer to the discrepancy between the proposed safety factor by the JMPR (October 2008) and safety factor used by the RMS. The applicant supports the JMPR proposed ADI/ARfD of 0.001 mg/kg.	RMS 01.2009: RMS refers to Addendum. In short, the ARfD and the ADI were lowered to 0.00015 mg/kg b.w./d, and the AOEL to 0.0003 mg/kg b.w./d.. The relevant NOAEL's were based upon significant (≥ 20%) decreases of brain AChE after single administration. It is of note that the CF notifier disagreed with the proposed pup LOAEL and with the AF	<u>PRAPeR TC 4 (13 January 2009)</u> The new acute neurotoxicity study in rat with carbofuran resulted in a LOAEL of 0.03 mg/kg bw in pups (from which a NOAEL of 0.015 mg/kg bw is estimated); In adults the NOAEL is 0.03 mg/kg bw. Open point fulfilled.

No.	<u>Column A</u> Conclusions of the EFSA Evaluation Meeting	<u>Column B</u> Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	<u>Column C</u> Rapporteur Member State comments on main data submitter / applicant comments	<u>Column D</u> Recommendations PRAPeR Expert Meeting / Conclusions of the Evaluation Meeting
	See reporting table: 2(2)		of 200 to derive the ARfD.	
	Open point: 2.3 Pending on the outcome of the environmental fate and behaviour section discussion, MSs to discuss genotoxicity of carbofuran's metabolite 3-OH in an expert's meeting. See reporting table: 2(3)	Applicant: 3-OH-carbofuran dose not leach to groundwater (all FOCUS PECgw calculations <0.001 µg/L)	RMS 01.2009: The metabolite is of no environmental relevance.	<u>PRAPeR TC 4 (13 January 2009)</u> Open point fulfilled.
	Open point: 2.4 MSs to discuss the reference values (ADI and ARfD) of carbofuran in an expert's meeting. See reporting table: 2(4)	Applicant: see open point 2.2 above.	RMS 01.2009: Agreed to discuss the ADI and the ARfD.	<u>PRAPeR TC 4 (13 January 2009)</u> The ADI for carbofuran is 0.00015 mg/kg bw/day. The ARfD for carbofuran is 0.00015 mg/kg bw. Open point fulfilled

REPORT OF PRAPeR EXPERT MEETING TC 5

BENFURACARB

Rapporteur Member State: BE

Specific comments on the active substance in the section

3. Residues

are already listed in the relevant reporting table. Comments submitted for this meeting are listed below.

1. Comments submitted for this meeting:

Date	Supplier	File Name
none		

2. Documents submitted for meeting:

Date	Supplier	File Name
2009-01-05	BE	Benfuracarb evaluation table rev 1-0 2009-01-05).doc
December 2008	BE	Benfuracarb List of endpoints (December 2008).doc
December 2008	BE	Benfuracarb reporting table rev 1-1 (December 2008).doc
January 2009	BE	benfuracarb_addendum Vol3_B7 (January 2009).doc
November 2008	BE	Benfuracarb_additional report_addendum Vol3 B7 (November 2008).doc

3. Documents tabled at the meeting:

Date	Supplier	File Name
none		

The conclusions of the meeting were as follows:

4. **Data on preparations:** ONCOL 8.6G
5. **Classification and labelling:** not considered
6. **Recommended restrictions/conditions for use:** not considered
7. **Reference List:** not considered

Areas of concern:

- Consumer risk assessment can not be finalised due to a lack of data (definition of residue including conjugates and contribution of the rotational crops not taken into account).
- With the available data, there is an acute intake concern for all the brassica crops.

Appendix 1: Discussion table: BENFURACARB

Appendix 2: Evaluation table

Appendix 1: Discussion Table, Benfuracarb (In, Ne)

3. Residues

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	<p>Open point: 3.1 A new data requirement to address brassica metabolism was agreed in EPCO 34. Now, that new data in sugar beet and brassica is available, a re-discussion by experts is suggested to agree whether the data available is sufficient to establish a final residue definition in brassica crops.</p> <p>See reporting table: 3(2)</p>	<p>The new metabolism study on cabbage (2006) was considered not fully sufficient since the identification of metabolites was only performed on interim samples (up to 4 weeks after application at the latest) and not at harvest on the mature crop. However there was clear indication of the presence of metabolites in conjugated forms in significant amounts with an increase from the 1 week sample to the 4 week sample (conjugated 3-OH carbofuran 6.1% TRR, conj. 3-keto carbofuran 2.7%TRR, conj. carbofuran 17.2% TRR).</p> <p>In the sugar beet metabolism study identification was performed 8, 16 and 20 weeks after application, these delays seem more appropriate when compared to the PHI in the cabbage residues trials (between 80 and 130 days). Identification has been performed on sugar beet leaves of the mature crop. Significant polar fractions were recovered in sugar beet leaves (mainly T1 fraction, up to 36% TRR). Using TLC and gel permeation analyses, the water soluble T1 fraction was shown to be composed of macromolecules and did not contain any benfuracarb, carbofuran, 3-OH carbofuran, free or conjugated.</p> <p>It had been proposed by the applicant that during the initial phase of metabolism conjugates of carbofuran, 3-keto carbofuran and 3-OH carbofuran exist but they were further transformed to large MW compounds at harvest.</p> <p>However, the 1997 JMPR evaluation based on metabolism studies performed on corn, potato and soya plants using soil application, showed that carbofuran, 3-keto carbofuran, 3-OH carbofuran and the phenol metabolites and their conjugated forms were present at non negligible levels at longer sampling intervals and at harvest. It was highlighted by JMPR that in particular “conjugates of 3-OH carbofuran can constitute an appreciable proportion of the total residue.” Thus the free and conjugated 3-OH metabolite was included in the residue definition for risk assessment by JMPR. Other compounds, being less toxic than carbofuran and the 3-OH carbofuran, were not included in the residue definition.</p>	<p>Open point fulfilled.</p> <p>Taking into account the metabolism studies in the DAR and the 1997 JMPR evaluation the meeting agreed a new residue definition for risk assessment.</p>

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
		<p>The meeting was of the opinion that the JMPR evaluation based on corn, potato and soya where conjugates were observed in the plants at harvest cannot be ignored. Since also in the immature cabbage samples conjugates of carbamate metabolites were present in non-negligible increasing amounts and since it is not known whether these conjugates will indeed be absent at maturity of the cabbage, the meeting concluded that for precautionary reasons the carbofuran and 3-OH carbofuran conjugates should be included in the residue definition for risk assessment.</p> <p>In conclusion, the meeting agreed on the following residue definitions based on the bassica seedling study provided in the DAR and the JMPR evaluation: Monitoring: benfuracarb; and carbofuran + 3-OH carbofuran expressed as carbofuran Risk assessment: benfuracarb; and carbofuran + 3-OH carbofuran, both free and conjugated expressed as carbofuran</p> <p>It was noted that the validated method for the generation of the residue data presented in the DAR did not included a hydrolyse step to take into account possible conjugates.</p>	
	<p>Open point: 3.2 It should be agreed by experts whether the decision of EPCO 34 for requiring a full database should no longer be applicable, based on the case made by the applicant in column 3 of the reporting table</p> <p>See reporting table: 3(9)</p>	<p>The meeting was informed that the new value of 0.00015 mg/kg bw/d proposed for the ADI and the ARfD by the RMS, was confirmed this morning by the Tox teleconference meeting.</p> <p>A new risk assessment based on the highest residues observed in the residues trials for leafy and flowering brassica and the LOQ for head brassica was provided in the January 2009 addendum (see table B.7.6.1.). The ARfD is exceeded for each brassica crop (up to 396% ARfD for Broccoli, 286% for cauliflower, 157% for head cabbage...)</p> <p>New residue data was submitted where LOQs of 0.0015 and 0.0030 mg/kg were achieved for carbofuran and 3-OH carbofuran respectively (sum LOQ 0.0045 mg/kg). Because residue levels in all the analysed brassica crops were similar, the applicant was of the opinion that the residue database has to be considered complete and no further trials should be requested.</p> <p>However, since the residue definition has been changed and since conjugates are now included in the residue definition, a new data set has to be requested where the samples</p>	<p>Open point fulfilled.</p> <p>New data gap proposed, see below.</p>

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
		<p>should be analysed using a method that includes a hydrolyse step in order to take into account the possible conjugates (full data package for head brassica, flowering brassica and leafy brassica).</p> <p>However, due to the very low ARfD value, there is still an exceedance of the ARfD when the LOQ of 0.0045 mg/kg (in accordance with the residue definition for monitoring) is used in the EFSA acute consumption model. Therefore, it makes no sense to request new trials if it is not possible to achieve a lower LOQ for both carbofuran and 3-OH carbofuran. The current data show that the ARfD is already exceeded for flowering and leafy brassica and head brassica, potential conjugates not yet considered. However, for head cabbage, there is an exceedance for children when a variability factor of 5 is used (158% of the ARfD) but it is border line using a variability factor of 3 (95%), the evaluation being performed with the LOQ value of 0.0045 mg/kg.</p> <p>The meeting suggested two options (not exhaustive) to proceed further with head cabbage:</p> <ol style="list-style-type: none"> 1- Lowering once more the LOQ in the new residue trials to be conducted, 2- Conducting trials on the variability of residues in head cabbage that show a factor of 3 or below is justified to be used in acute RA 	
	<p>New data gap: 3.1 Identified at PRAPeR TC 5 meeting.</p> <p>Residue trials data in head brassica, flowering brassica and leafy brassica in compliance with the new residue definition for risk assessment have to be submitted.</p> <p>If, in the light of the acute risk assessment for flowering and leafy brassica, the applicant</p>		<p>Data gap open.</p>

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	<p>decided to only continue with the use on head brassica, a full data set for head cabbage in compliance with the new residue definition for risk assessment has to be submitted (8 northern and 4 southern trials).</p>		
	<p>Open point: 3.3 A new data requirement was agreed in EPCO34 to address carbofuran residues in succeeding crops. No new data is available but a case was made on a new DT50 (still to be confirmed by fate and behaviour) and on extrapolation to rotated cereal crops (not assessed in the additional report). A discussion by experts is suggested.</p> <p>See reporting table: 3(10)</p>	<p>The discussion of the fate and behaviour of the active substance benfuracrb took place simultaneously to the teleconference meeting on residues. According to information received by the fate PRAPeR meeting the DT₉₀ (lab) for carbofuran is greater than one year and the DT₉₀ (field) is 91 days (for carbofuran only; metabolites not included in this DT90 value). Therefore it is likely that 10% of the total pertinent residue (active substance and bio-available metabolites) can still be found in soil at 100 days.</p> <p>Thus rotational crop studies seem necessary.</p> <p>Even if uptake by rotational crops is probably at very low levels, an exceedance of the ARfD might still be expected depending on the contribution of the crop in the human diet.</p> <p>The meeting agreed that, if the new residue data as discussed under open point 3.2 demonstrated that the exposure of the consumer to head cabbage residues would be acceptable, additional rotational crop studies according to the OECD guidelines should be provided (intervals of 30, 120 days and 1 year on leafy crop, small grain crop and root crop).</p> <p>The meeting noted that rotational crop data is available in the JMPR evaluation, indicating that residues of carbofuran equivalents may occur above the current LOQ in all rotated crops. The applicant may consider this information in their further planning.</p>	<p>Open point fulfilled.</p> <p>New data gap proposed, see below.</p>
	<p>New data gap: 3.2 Identified at PRAPeR TC 5 meeting.</p> <p>If the new residue data</p>		<p>Data gap open.</p>

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	<p>as discussed under open point 3.2 demonstrated that the exposure of the consumer to head cabbage residues would be acceptable, additional rotational crop studies according to the OECD guidelines should be provided.</p>		
	<p>New open point LoEP to be amended in order to reflect the outcome of the discussion.</p>	<p>The meeting looked at the list of endpoints and suggested some changes. In this context the meeting considered whether processing data could be useful to refine the acute risk assessment, but did not conclude on this issue. The RMS is asked to incorporate the necessary changes in the LoEP in order to reflect the outcome of the discussion.</p>	<p>Open point open.</p>

Appendix 2: Evaluation table

No.	<u>Column A</u> Conclusions of the EFSA Evaluation Meeting	<u>Column B</u> Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	<u>Column C</u> Rapporteur Member State comments on main data submitter / applicant comments	<u>Column D</u> Recommendations PRAPeR Expert Meeting / Conclusions of the Evaluation Meeting
	Section 3 Open points: 3 Points for clarification: 0 Data gaps: 0			Section 3 Open points: 1 Points for clarification: 0 Data gaps: 2
	Open point: 3.1 A new data requirement to address brassica metabolism was agreed in EPCO 34. Now, that new data in sugar beet and brassica is available, a re-discussion by experts is suggested to agree whether the data available is sufficient to establish a final residue definition in brassica crops. See reporting table: 3(2)	Applicant: Indeed a new data requirement was identified by EPCO meeting 34. The new requirement was that additional information on metabolite fraction T1 was required. This information was submitted by the applicant as part of the resubmission dossier and evaluated by the RMS in the additional report. See also the comment of the RMS in the reporting table 3(5).	RMS 01.2009: RMS agrees to discuss the metabolism and the final residue definition in brassica crops (Head and flowering/leafy brassica) with reference to the open points 3(2), 3(3), 3(4), 3(5) and 3(6) in the reporting tables. Open points 3(2), 3(3) and 3(6) were also discussed in the Addendum to the DAR-B(7)-(January 2009).	<u>PRAPeR TC 5 (13 January 2009)</u> Open point fulfilled. Taking into account the metabolism studies in the DAR and the 1997 JMPR evaluation the meeting agreed a new residue definition for risk assessment.
	Open point: 3.2 It should be agreed by experts whether the decision of EPCO 34 for requiring a full database should no longer be applicable, based on the case made by the applicant in column 3 of the reporting table	Applicant: please refer to the reporting table for our position.	RMS 01.2009: RMS agrees to discuss this point. See also open points 3(7) and 3(8) of the reporting tables and discussed in the Addendum to the DAR-B(7)-(January 2009).	<u>PRAPeR TC 5 (13 January 2009)</u> Open point fulfilled. New data gap proposed, see below.

No.	<u>Column A</u> Conclusions of the EFSA Evaluation Meeting	<u>Column B</u> Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	<u>Column C</u> Rapporteur Member State comments on main data submitter / applicant comments	<u>Column D</u> Recommendations PRAPeR Expert Meeting / Conclusions of the Evaluation Meeting
	See reporting table: 3(9)			
	<p>New data gap: 3.1 Identified at PRAPeR TC 5 meeting.</p> <p>Residue trials data in head brassica, flowering brassica and leafy brassica in compliance with the new residue definition for risk assessment have to be submitted.</p> <p>If, in the light of the acute risk assessment for flowering and leafy brassica, the applicant decided to only continue with the use on head brassica, a full data set for head cabbage in compliance with the new residue definition for risk assessment has to be submitted (8 northern and 4 southern trials).</p>			<p><u>PRAPeR TC 5 (13 January 2009)</u> Data gap open.</p>
	<p>Open point: 3.3 A new data requirement was agreed in EPCO34 to address carbofuran residues in succeeding crops. No new</p>	<p>Applicant: please refer to the reporting table for our position.</p>	<p>RMS 01.2009:</p> <p>RMS agrees to discuss this point. At EPCO 34, the data requirement to address the residues of Carbofuran in</p>	<p><u>PRAPeR TC 5 (13 January 2009)</u> Open point fulfilled.</p>

No.	<u>Column A</u> Conclusions of the EFSA Evaluation Meeting	<u>Column B</u> Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	<u>Column C</u> Rapporteur Member State comments on main data submitter / applicant comments	<u>Column D</u> Recommendations PRAPeR Expert Meeting / Conclusions of the Evaluation Meeting
	<p>data is available but a case was made on a new DT50 (still to be confirmed by fate and behaviour) and on extrapolation to rotated cereal crops (not assessed in the additional report). A discussion by experts is suggested.</p> <p>See reporting table: 3(10)</p>		<p>succeeding crops referred to the inappropriate DT50 value of 71.9 days for Carbofuran.</p>	
	<p>New data gap: 3.2 Identified at PRAPeR TC 5 meeting.</p> <p>If the new residue data as discussed under open point 3.2 demonstrated that the exposure of the consumer to head cabbage residues would be acceptable, additional rotational crop studies according to the OECD guidelines should be provided.</p>			<p><u>PRAPeR TC 5 (13 January 2009)</u> Data gap open.</p>
	<p>New open point: 3.4 Identified at PRAPeR TC 5 meeting.</p> <p>LoEP to be amended in order</p>			<p><u>PRAPeR TC 5 (13 January 2009)</u> Open point open.</p>

No.	<u>Column A</u> Conclusions of the EFSA Evaluation Meeting	<u>Column B</u> Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	<u>Column C</u> Rapporteur Member State comments on main data submitter / applicant comments	<u>Column D</u> Recommendations PRAPeR Expert Meeting / Conclusions of the Evaluation Meeting
	to reflect the outcome of the discussion.			