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REPORT OF PRAPeR EXPERT MEETING TC 18

HALOXYFOP-P

Rapporteur Member State: DK

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
2009-08-14	DK	Haloxyfop-P evaluation table rev1-0 (2009-08-14).doc
2009-07-17	DK	Haloxyfop-P reporting table rev1-1 (2009-07-17).doc
March 2009	DK	Haloxyfop-P_additional report_LoEP_(March 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: Gallant Winner, Gallant Super and Eloge.

5. Classification and labelling: not discussed

6. Recommended restrictions/conditions for use: not identified

7. Reference list: Not discussed

Areas of concern: assessment of ground water exposure for haloxyfop-P and its soil major metabolites not finalized.

Appendix 1: Discussion table: HALOXYFOP-P

Appendix 2: Evaluation table

Appendix 1: Discussion Table, Haloxyfop-P (Hb)

4. Fate and behaviour

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	Open point: 4.1 Pending on the outcome of the consultation of experts on the reliability of the degradation model with the "ghost" compartment used to re-evaluate the laboratory data, further details (i.e. the proposed chemical identification, the degradation rate and the assumed formation fraction) on this approach should be provided in the LoEP by RMS. See reporting table 4(1)	Since the degradation scheme has not been accepted (see O.P. 4(9)) there is no need to include the required information in the LoEP.	Open point closed.
	Open point: 4.2 RMS to include the goodness of fit and plots for the residuals of the degradation	The information has not been provided for discussion at the meeting of experts. (see also OP 4.9).	Open point still open.

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	model without “ghost compartment” (i.e. simple linear degradation route) in an addendum or revised Additional Report. See reporting table 4(2)		
	Open point: 4.3 RMS to recalculate the geomean FOMC DT50lab for the parent compound taking into consideration that the DT50 values derived from the same Marcham_SL soil with different radiolabelled positions should be consider as replicates, and to amend the LoEP accordingly. See reporting table 4(3)	The information has not been provided by the RMS in an addendum and the LoEP has not been amended. The experts agreed that it is unlikely that the revised geomean FOMC DT50lab for the parent compound can have an impact on the final risk assessment, but this end point is necessary for the correctness and completeness of the LoEP.	Open point open.
	Open point: 4.4 MS to discuss the re-calculation of field kinetics for haloxyfop-R and its soil metabolites (Havens, 2008) in a meeting of	This open point is a kind of replicate of open point 4.10 (see the discussion under this open point).	Open point closed

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	experts. See reporting table 4(4)		
	Open point: 4.5 MS to discuss in a meeting of experts the appropriate soil DT50 for metabolite DE-535 pyridinol to be used in FOCUS modeling. See reporting table 4(5)	As concluded in OP 4.10, the experts agreed that the field DT50 = 63 d (calculated fitting only the available field data of parent and pyridinol) could be used in FOCUS modelling for pyridinol in combination of a global formation fraction for this metabolite of 0.2466 (table B8.1.2.3/10 in Annex 1 of the additional report). In the available GW modelling the field geomean SFO DT50 (= 55d) obtained for pyridinol with the “ghost” compartment scheme was used in combination to a global formation fraction for pyridinol of 0.276 (0.298 x 0.927). The most consistent approach to use field data in PEC GW modelling would be to run a separate model for parent and pyridinol with the above input parameters. However, as a data gap was ser for a new groundwater modelling without the introduction of the ghost compartment in the degradation scheme, this could also be made part of an overall model.	Open point closed
	Open point:4.6 RMS to report the kinetic parameters (alpha and beta) for the DT50 calculated with a FOMC model (laboratory and field studies) in an addendum or revised Additional Report. See reporting table 4(6)	The information has not been provided by the RMS. This information is needed for completeness but the experts agreed that it is not crucial to finalise the risk assessment.	Open point still open.
	Open point: 4.7 MS to discuss in a meeting of experts the appropriate soilDT50	The applicant clarified that the worst case DT50 was only used to calculate the PEC GW of the parent but the appropriate geomean was used when the PEC GW of metabolites was calculated. EFSA noted an inconsistency in the value used for the “parent” in GW modelling, since a	Open point closed New open point proposed, see below.

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	for the “parent” compound to be used in FOCUS modeling. See reporting table 4(12)	FOMC DT50(field) of 30.9 d vas used instead of the correct value of 30.2 d (refer to Table B.8.1.2.3/09, p. 19 of Annex I). RMS is asked to amend the list of end points with an explanatory footnote.	
	New open point: 4.22 Identified at PRAPeR TC 18 meeting. RMS to amend the list of end points with an explanatory footnote in the GW modelling box on the correct value that should be used for soilDT50 for the “parent”.		Open point open.
	Open point: 4.8 MS to discuss in a meeting of experts the appropriate plant uptake factor used in FOCUS modelling for metabolites. See reporting table 4(16)	The FOCUS default value of 0.5 for the plant uptake factor was used in the modelling for parent and metabolites. Some experts are of the opinion that a value of 0 would be more appropriate for modelling the metabolites as there are no data if they’re systemic. EFSA mentioned that according to some studies on the sensitivity analysis made for FOCUS GW models input parameters this factor does not have a great impact on the modelling results. However, one of the experts considers that this is only true when concentrations in groundwater are estimated to be very low, but does not apply to situations where higher concentrations are predicted. An example where the PEC GW may change b y100 % when it is found in the range of 4 µg/L was mentioned by this expert. It is also indicated that the haloxyfop acid is systemic and mobile and therefore it would be justified to use a plant uptake factor of 0.5 and the same would apply for the pyridinone and the pyridinol metabolites (with Koc values lower than the value for the parent). For the phenol metabolite it may not be appropriate to use 0.5, but the experts agreed that impact on PEC GW in this particular case would not be affected since the concentrations are expected to be low.	Open point closed.

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
		The experts agreed that for future modelling a plant uptake factor of 0 should be used for the metabolites as recommended by FOCUS guidance.	
	Open point (a): 4.9 MS to discuss the kinetic modelling with the "ghost" compartment used to re-evaluate the laboratory data to derive the degradation rates of haloxyfop and its metabolite. See reporting table 4(19)	Data from the two original laboratory soil degradation studies were re-evaluated in the Additional Report (June 2008) using the latest FOCUS Degradation Kinetics methodology (p. 5-18). The linear degradation scheme was modified to include a "ghost" compartment. It was argued in the AR that the amount of the tentatively assigned DE 535 methoxypyridine formed in the soils would be very low and this could be the reason why the compound was not significant in any of the soil studies described. One of the experts states that the assumption of the "ghost" compartment is justifiable since a two step reaction may be expected from the mechanistic point of view. The experts discussed how the introduction of the "ghost" compartment affected the results of the kinetic fitting of the metabolites of concern. One of the open points proposed (see open point 4.2) was related to the submission of the visual fit of the linear degradation scheme in order to compare the quality of both approaches. In case both the approaches give results of the same quality, the simplest one should be used (this is the principle of the Ocham's razor). Unfortunately the details of the linear degradation scheme (simpler approach) are not available to the meeting and therefore a comparison could not be performed. The consensus of the experts was that from the experimental laboratory data available (soil Borstel and Marcham, from the study by Knowles, 2001) a reliable half life may not be obtained for the pyridinone metabolite, irrespective of the kinetic approach used as no decline is clearly observed (see Table B8.1.2.1/01 on p. 6 of the Additional Report). In the second study (Hale & Trigg, 1994) an unknown metabolite U2 was formed and the applicant suggested that it was likely to be the pyridinone metabolite. However, these additional data would confirm that no decline is observed in four more soils. In field studies pyridinone was not found and therefore no half lives for this metabolite may be calculated from the available field dissipation studies. In the absence of reliable data for the metabolite pyridinone a default value of DT50 = 1000d would be appropriate for environmental modelling, unless experimental data on the degradation of the metabolite in soil becomes available.	Open point closed New data gap proposed, see below.

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
		Experts acknowledged that in laboratory studies sometimes degradation of the last metabolites is not adequately addressed because experimental conditions are not good for degradation. The solution proposed for this is to have laboratory experiments performed directly with the metabolite in order to get a reliable half life for the metabolite. The 1000 d is regarded as a very conservative alternative in order to avoid additional experimentation. For pyridinol in only two of the six soils investigated, three or more data points showed a clear decline (which would allow to derive a reliable half life). However, for pyridinol field data are available and in effect the field DT50 was used in the available assessment. For the phenol metabolite the lab geometric mean SFO DT50 = 3.5 derived with the "ghost" compartment degradation scheme was used for FOCUS GW modelling. In this case it would be important to know what would be the result with the simpler kinetic fitting. If information on the results of the linear model fitting becomes available (see open point 4.2) and shows that the half life of the phenol is not substantially affected by the scheme assumed, then the half lives available could be considered valid.	
	New data gap: 4.1 Identified at PRAPeR TC 18 meeting. A reliable half life in soil for metabolite pyridinone is not available.		Data gap open.
	Open point (b): 4.10 MS to discuss the kinetic modelling with the "ghost" compartment used to re-evaluate the field dissipation data to derive the degradation	New dissipation field studies (2 sites in Germany, 1 in France and 1 in Poland) with spring application were provided in the AR (p. 18-23). Soil residues were analysed for DE 535 acid, and the metabolites pyridinol, phenol and pyridinone. No calculation of dissipation/degradation kinetics has been performed for this study for either the parent or the metabolites (generally formed at very low levels) A re-evaluation of the kinetic behaviour of the "parent" and the metabolite pyridinol from the	Open point close

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	rates of haloxyfop and its metabolite. See reporting table 4(19)	2 field studies (7 trials in Germany and France) was performed by Havens (2007) according to FOCUS kinetics and reported in the AR (p. 23). A further kinetic assessment was performed using the same "ghost scheme" used for the lab data. Because field results were only available for "parent" and DE 535 pyridinol, the decline rates for DE 535 phenol, DE 535 pyridinone and the "ghost" compartment were fixed within the model to the geometric mean SFO values determined in the laboratory data fitting, along with their formation fractions and the initial concentration of "parent". Visual fits are provided for parent alone (SFO and FOMC) and for pyridinol (two step model and "full pathway"), pp 22 –28. Here it may be seen that differences on the fitting curve of pyridinol and the half lives calculated in the two approaches are very minor. Some experts had concerns on the combination of field results and laboratory results at this level to derive reliable dissipation rates, in particular for the pyridinol metabolite. However, data with a linear scheme considering only the parent and the pyridinol metabolite is available. The half life obtained with the simplest model could be used for modelling (Ocham's razor) without need to deviate from FOCUS kinetic guidance. Experts agreed that the results obtained with the simplest model should be used for risk assessment unless a strong justification is provided to exclude it in favor of a more complicated one. The experts agreed that the arguments presented by the applicant in this case do not justify deviating form the simple model. Experts agreed that the field DT50 = 63 d might be used for pyridinol in combination of a global formation fraction for this metabolite of 0.2466 (table B8.1.2.3/10 in Annex 1 of the additional report).	
	Open point: 4.11 RMS to provide the p values for the fits of the kinetic modelling of laboratory degradation rates. See reporting table 4(20)	The information has not been provided by the RMS. Since this kinetic fitting is not considered appropriate by the meeting the open point is superseded.	Open point closed.
	Open point: 4.12 MS to discuss the need for $K_F$oc values	Experts agreed that in line with all list 3 and onward substances (including applications received for not included list 2 substances) the 1/n of 1 should be used where no attempt at	Open point closed

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	for modelling purposes or if it is appropriate to use $K_d$oc values associated with 1/n value of 1 in FOCUS GW. See reporting table 4(25)	a Freundlich determination has taken place as only a single concentration was investigated (just Kd determined, or when just a QSAR value was provided). This is in full agreement with current FOCUS groundwater guidance on sorption parameters used as input. The guidance states that when there is no data on the exponent of the Freundlich-isotherm, a default 1/n value of 0.9 should be used in combination with the measured Freundlich adsorption coefficients (Kf). No indication is given for the 1/n value associated to the linear partition coefficient (Kd). In fact there is no guidance on how to use Kd values. . In the LoEP it isnot clear which 1/n is used in the available modelling. RMS confirms that 1/n = 0.9 was used. Experts agreed that as it is known that this input parameter is sensitive and will impact the results a new GW modelling with the agreed 1/n= 1 value associated with the linear partition coefficients (Kd) would be needed.	New data gap proposed, see below.
	New data gap: 4.2 Identified at PRAPeR TC 18 meeting. FOCUS GW modelling with the agreed input parameters (including the agreed 1/n= 1 values associated with the linear partition coefficients (Kd)) is not available.		Data gap open.
	Open point: 4.13 RMS to include in the LoEP the values of the Freundlich parameter 1/n used in the FOCUS model. See reporting table	The LoEP has not been amended by the RMS. See the new data gap 4.2.	Open point superseded since a new data gap 4.2 has been identified

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	4(27)		
	Open point: 4.14 MS to discuss the appropriate Koc value to be used in FOCUS modelling for the metabolite DE-535 methoxypyridine, pending on the outcome of the discussion under comment 4(37) on the reliability of the approach used in FOCUS GW modelling. See reporting table 4(28)	Open point is superseded since the ghost metabolite is not considered to be justified for the modelling.	Open point superseded.
	Open point: 4.15 RMS to provide in an addendum or revised Additional Report further details on the adjustments used in PEARL and PELMO to allow the models to run 2 applications every three years. See reporting table 4(31)	The information has not been provided by the RMS in an addendum, but some clarifications were included in column 3 of the reporting table by the applicant. It is not clear how the adjustments needed in FOCUS models to run 2 applications every 3 years were implemented. However, since a new data gap has been identified for a new modelling (see open point 4.12) the submission of this information is not essential at this stage.	Open point still open.
	Open point (a): 4.16 RMS to provide specific data for the	The information has not been provided by the RMS in an addendum.	Open point still open.

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	precursor DE-535 acid used in the FOCUS Steps 1-2 calculations and to clarify for which crop the results presented in Table B.8.6.2.2 on p. 44 of Annex 1 to Addendum are referred to. See reporting table 4(32)		
	Open point (b): 4.17 MS to discuss in a meeting of experts the need for further assessment of DE-535-acid-furan, a metabolite with dibenzofuran “like” (not polychlorinated) structure which was measured in the irradiated samples of the photodegradation study in natural water. See reporting table 4(32)	In the EFSA conclusion report (EFSA Scientific Report (2006) 87, 1-96, Conclusion on the peer review of Haloxyfop-R) the following data requirement is mentioned in the List of studies to be generated: “Potential surface water contamination for the aqueous photolysis metabolite DE-535 furan to be addressed”. The PECsw were provided in Annex I on p. 40. This metabolite did not exceed 10 %. Experts in the meeting agreed that since the maximum amount was 8.4 % AR in the natural water experiment no further assessment is needed.	Open point closed.
	Open point: 4.18 RMS to include in the LoEP the new PECsw calculations for DE-535 furan provided in	The LoEP has not been amended by the RMS.	Open point still open.

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	Annex 1 to Addendum to Annex B8 Fate and Behaviour (March 2009). See reporting table 4(33)		
	Open point: 4.19 Pending on the outcome of the discussion on the reliability of the kinetic modelling of the degradation data (comment 4(19)) and the modelling scheme for groundwater (comment 4(37)), RMS to amend the LoEP with the results for the ghost compartment as indicated in Table B.8.6.1/02 on p. 33 of the Annex 1 to Addendum. See reporting table 4(35)	New data gap identified for PEC GW (see open point 4.12).	Open point superseded.
	Open point: 4.20 MS to discuss the conceptual model with the “ghost” compartment used in FOCUS groundwater	The “ghost” compartment was also included in the GW modelling scheme. The use of the “ghost” compartment scheme was not found appropriate for the kinetic evaluation (see OP 4.10 and OP 4.9). Therefore it would not be appropriate for the modelling either. For the pyridinone metabolite, a data gap has been identified since no reliable half life is	Open point closed.

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	modelling as reported in Annex I to Addendum of the Additional Report (March 2009). See reporting table 4(37)	available (OP 4.9).Therefore the available PEC GW for this metabolite cannot be considered acceptable. At this stage, it cannot be confirmed that the 0.75 limit would not be exceeded in the modelling. Additionally, following the discussion of OP 4.12 a new modelling calculation is needed.	
	Open point: 4.21 MS to discuss in a meeting of experts the environmental occurring metabolites requiring further assessment by other disciplines (tox and ecotox). See reporting table 4(38)	One MS commented that for the minor transient metabolite phenol would need to be included in the residue definition for assessment in GW. Experts agreed that the phenol metabolite need to be added as metabolite to be considered for modelling. For the rest the residue definition in the EFSA conclusion is confirmed.	Open point closed.

Appendix 2: Evaluation table

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
	Section 4 Open points: ***21*** Points for clarification: ***0*** Data gaps: ***0***			Section 4 Open points: ***7*** Points for clarification: ***0*** Data gaps: ***2***
	Open point: 4.1 Pending on the outcome of the consultation of experts on the reliability of the degradation model with the "ghost" compartment used to re-evaluate the laboratory data, further details (i.e. the proposed chemical identification, the degradation rate and the assumed formation fraction) on this approach should be provided in the LoEP by RMS. See reporting table 4(1)	DAS: Agree that further details of the ghost compartment could be included in the LoEP.	RMS agrees.	PRAPeR TC 18 (03 September 2009) Open point closed.
	Open point: 4.2 RMS to include the goodness of fit and plots for the residuals of the degradation model without "ghost compartment" (i.e. simple linear degradation route) in an addendum or revised Additional Report.	DAS: Agree that for reasons of transparency, the goodness of fit for the model without the "ghost" compartment could be included in an addendum.	RMS agrees.	PRAPeR TC 18 (03 September 2009) Open point still open.

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
	See reporting table 4(2)			
	Open point: 4.3 RMS to recalculate the geomean FOMC DT50lab for the parent compound taking into consideration that the DT50 values derived from the same Marcham_SL soil with different radiolabelled positions should be consider as replicates, and to amend the LoEP accordingly. See reporting table 4(3)	DAS: The recalculated DT50lab is 25.8 days from six measurements. Since the field "back calculated" DT50 field of 30.2 days was ultimately used in the groundwater assessment as a worst case for parent alone, the change will have no impact.	RMS: The explanation from Notifier sounds reasonable. In principle we agree that DT50 values derived from the same soil with different radiolabelled positions should be consider as replicates and will give a note or recalculate the value in LoEP.	PRAPeR TC 18 (03 September 2009) Open point open.
	Open point: 4.4 MS to discuss the re-calculation of field kinetics for haloxyfop-R and its soil metabolites (Havens, 2008) in a meeting of experts. See reporting table 4(4)	DAS: The ghost compartment was required **only** to model the formation of pyridinone metabolite when considering the laboratory data. At the time, DAS considered that for consistency, the field data should then be modelled in the same way. EFSA has commented that it may be unreliable to use field data for the acid and pyridinol and lab data for the other two metabolites, but DAS has provided new dissipation studies, at the request of EFSA, in this submission. Under comparable field conditions, the phenol and pyridinone metabolites	RMS: No further comments in the moment other than those giving in reporting table 4(4). We will work on more comments to the Experts Meeting.	PRAPeR TC 18 (03 September 2009) Open point closed

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
		were not detected at any meaningful level (always < LOQ and mostly < LOD). The field sampling times were selected to be the same as the lab studies and were the metabolite to be formed, it would have been seen during this period. If these data are taken into account, it could be argued that the "ghost" compartment is not required for modelling the field data, as the pyridinone is not formed in meaningful concentrations in the field. Further evidence is given by the results of the two lysimeter studies. The Guidance Document (SANCO/221/2000 rev 10, Feb 2003) for the assessment of the relevance of metabolites in groundwater states (Point 2: Context and general approach) that lysimeter studies are considered a worst case on a European scale, in compliance with Article 5 of the Directive. This is reinforced by a study of soil vulnerabilities across Europe, where only 0.5% of agricultural soils are more vulnerable to leaching than those used in the lysimeter studies (Jones and Truckell, 2007) Two guideline lysimeter studies (Yon & Schnöder, 2001a,b)		

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
		following autumn application to oilseed rape and spring application to sugar beet under typical worst case northern European conditions have been carried out These have previously been submitted. Here, haloxyfop-R and the DE-5353- pyridinol metabolite only were found in the leachate at a max annual concentration <0.1 ug/L. The DE-5350 pyridione metbaolite was not detected inany soil or leachate compartment.. DAS however retained the laboratory pyridinone data in the field modelling to provide a consistent approach; in retrospect, this may have detracted from the less complex case that the pyridinone and phenol metabolites are not present in the field. In this case, DAS would also argue that the pyridinone is not relevant in the environment under in-use field conditions.		
	Open point: 4.5 MS to discuss in a meeting of experts the appropriate soilDT50 for metabolite DE-535 pyridinol to be used in FOCUS modeling. See reporting table 4(5)	DAS: It can only be further re-iterated that the presence of a "ghost" compartment in the scheme above, which is considered to best represent the degradation of haloxyfop-R, only impacts the pyridinone by delaying its formation and improving the fit of the modelled	RMS agrees that the "ghost" compartment don't seem to influence on the soil DT50 value for the metabolite DE-535 pyridinol.	PRAPeR TC 18 (03 September 2009) Open point closed

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
		data to the measured values. The "ghost" compartment does not impact the pyridinol because it does not form from the "ghost" but from the phenol only; this is most likely in consideration of their structures. Also, the formation fraction of the pyridinol (0.927) is by far the dominant route from the phenol, the "ghost" only being 0.073. Furthermore, a two-step model with the exclusion of the phenol as the pre-cursor to pyridinol (as proposed by EFSA) would not be expected to give significantly different results when the phenol in itself is very short-lived in soil (DT_{50} 3.5 d) Therefore, DAS would propose that the data provided for the pyridinol provide an acceptable, accurate DT50.		
	Open point:4.6 RMS to report the kinetic parameters (alpha and beta) for the DT50 calculated with a FOMC model (laboratory and field studies) in an addendum or revised Additional Report. See reporting table 4(6)	See table at end of document	RMS: The requested parameters will reported in an addendum.	PRAPeR TC 18 (03 September 2009) Open point still open.
	Open point: 4.7	DAS: As a worst case for **parent**, the	RMS agrees.	PRAPeR TC 18 (03 September 2009)

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
	MS to discuss in a meeting of experts the appropriate soilDT50 for the "parent" compound to be used in FOCUS modeling. See reporting table 4(12)	geomean DT50(field) of 30.2 days should be used in the FOCUS modelling, "back calculated" from FOMC DT90/3.32. However, for the estimation of the PECgw for the **metabolites**, an SFO DT50 for parent is recommended (FOCUS kinetics guidance, Section 8.3.3.1, p.131) and in this case a geomean field value of 12.2 days should be used.		Open point closed New open point proposed, see below.
	New open point: 4.22 Identified at PRAPeR TC 18 meeting. RMS to amend the list of end points with an explanatory footnote in the GW modelling box on the correct value that should be used for soilDT50 for the "parent".			PRAPeR TC 18 (03 September 2009) Open point open.
	Open point: 4.8 MS to discuss in a meeting of experts the appropriate plant uptake factor used in FOCUS modelling for metabolites. See reporting table 4(16)	DAS: It is considered that changing the plant uptake factor for the metabolites from 0.5 to 0 will have no significant impact upon the overall assessment. However, should this not be accepted, an uptake factor of 0 for the metabolites has been included, along with other proposals to modify input parameters, in updated models	RMS cannot assess haw big impact a changing from 0.5 to 0 will have on the model results. If the metabolites are systemic as the parent, it is acceptable to use the FOCUS default of 0.5, unfortunately there is no information on this item. From a chemical point of view it seems that the metabolites would be relative soluble in water and the Kd are relative low so it seems reasonable to use a plant uptake factor bigger that 0, but	PRAPeR TC 18 (03 September 2009) Open point closed.

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
			we cannot give an exact value due to missing information.	
	Open point (a): 4.9 MS to discuss the kinetic modelling with the "ghost" compartment used to re-evaluate the laboratory data to derive the degradation rates of haloxyfop and its metabolite. See reporting table 4(19)	DAS: DAS provided the most reliable degradation pathway from the information and guidance available at the time for the original DAR. However, the methodology in the current kinetics guidance gave the opportunity to re-evaluate the pathway. In consideration of the metabolite structures, it would seem unlikely that the pyridinone would form directly from DE-535 acid because ring cleavage firstly has to occur followed by methylation, and the scheme subsequently derived by the notifier involving its formation from both the pyridinol and the "ghost" as intermediates and used in the kinetic and groundwater assessment would seem more realistic.	The explanation from Notifier sounds reasonable.	PRAPeR TC 18 (03 September 2009) Open point closed New data gap proposed, see below.
	New data gap: 4.1 Identified at PRAPeR TC 18 meeting. A reliable half life in soil for metabolite pyridinone is not available.			PRAPeR TC 18 (03 September 2009) Data gap open.
	Open point (b): 4.10 MS to discuss the kinetic	DAS: in the context of the point in the Reporting Table, please see the	RMS: Please see the response in Open Point 4.9 above.	PRAPeR TC 18 (03 September 2009)

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
	modelling with the "ghost" compartment used to re-evaluate the field dissipation data to derive the degradation rates of haloxyfop and its metabolite. See reporting table 4(19)	response in Open Point 4.9		Open point close
	Open point: 4.11 RMS to provide the p values for the fits of the kinetic modelling of laboratory degradation rates. See reporting table 4(20)		RMS: Can be done in an addendum.	PRAPeR TC 18 (03 September 2009) Open point closed.
	Open point: 4.12 MS to discuss the need for $K_F$oc values for modelling purposes or if it is appropriate to use $K_d$oc values associated with 1/n value of 1 in FOCUS GW. See reporting table 4(25)	DAS: This proposed change has not been formally reviewed or published, and the FOCUS guidance has not been updated. The only reference we have is to PRAPeR 32, Oct 2007, provided in the French comment below (4(26)). DAS' dossier was submitted in Jun 2007, before this date, so the current FOCUS guidance was used. It is very frustrating to be caught in this situation where positions have changed during the evaluation in a way which is not transparent.	RMS: The best solution is to use $K_F$oc values together with determined 1/n values, but as mentioned by the Notifier the positions have changed after the submission, so we understand the frustrating feeling of the Notifier.	PRAPeR TC 18 (03 September 2009) Open point closed New data gap proposed, see below.
	New data gap: 4.2 Identified at PRAPeR TC 18 meeting.			PRAPeR TC 18 (03 September 2009) Data gap open.

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
	FOCUS GW modelling with the agreed input parameters (including the agreed 1/n= 1 values associated with the linear partition coefficients (Kd)) is not available.			
	Open point: 4.13 RMS to include in the LoEP the values of the Freundlich parameter 1/n used in the FOCUS model. See reporting table 4(27)	DAS: See DAS comment to Open Point 4.12	RMS: Can be done in an addendum.	PRAPeR TC 18 (03 September 2009) Open point superseded since a new data gap has been identified
	Open point: 4.14 MS to discuss the appropriate Koc value to be used in FOCUS modelling for the metabolite DE-535 methoxypyridine, pending on the outcome of the discussion under comment 4(37) on the reliability of the approach used in FOCUS GW modelling. See reporting table 4(28)		RMS: No further comments.	PRAPeR TC 18 (03 September 2009) Open point superseded.
	Open point: 4.15 RMS to provide in an addendum or revised Additional Report further details on the adjustments used in PEARL and PELMO	DAS: The adjustments necessary in PELMO and PEARL to allow the models to run two applications in every 3 years (which is a "non-standard" scheme) is explained	RMS: Thanks to Notifier for the explanation. RMS can give the details in an addendum.	PRAPeR TC 18 (03 September 2009) Open point still open.

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
	to allow the models to run 2 applications every three years. See reporting table 4(31)	in GHE-P-11899 (Sections 2.8.1 (p.15) and 2.8.2 (p.16)). Further clarification is given as follows. For PELMO, a ".psm" file for a "standard" regime of one application every 3 years was created. The subsequent ".psm" file for each FOCUS scenario was then modified, with an application rate added for year 2 but with no treatment in year 3 which continued in sequence to year 36. Therefore, years 1-6 were for model equilibration, with years 7-36 providing 20 years of applications over a 30 year period. PELMO was run with the amended ".psm" file and data for years 7-36 were extracted into Excel, from which the 80th percentile annual average leachate concentrations for the modelled period were derived. Appendix II of GHE-P-11899 provides an example. For PEARL, the application dates for each crop/FOCUS scenario were entered as absolute applications (rather than relative timings), with one application in year 1 and one application in year 2 followed by no treatment in year 3. This continued in sequence through to year 36. As before, years 1-6 were for model		

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
		equilibration, with years 7-36 providing 20 years of application over a 30 year period. Individual schemes were necessary for each FOCUS scenario to cover the different (in some cases) application dates. The model wizard was then used to set up a run for each individual FOCUS scenario (since different application dates were set for each). The run was copied to allow the FOCUS run options to be modified, and the following edits were made to the copied run. In Output Control, the report was changed from "FOCUS report" to "No report" which allowed the run dates in Simulation Control to be changed from 1901-1926 to 1901-1936. Then in the Scenario tab, the repeat interval for application events was changed from "1" to "NoRepeat" which allowed 36 years worth of application cycles to be run individually for each FOCUS scenario. To process the data, the individual ".sum" file for each run was opened from within the PearlDB folder, and the "ConLeaFoc" data extracted into Excel, from which the 80th percentile annual average leachate concentrations were derived.		

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
		Appendix III of GHE-P-11899 provides an example.		
	Open point (a): 4.16 RMS to provide specific data for the precursor DE-535 acid used in the FOCUS Steps 1-2 calculations and to clarify for which crop the results presented in Table B.8.6.2.2 on p. 44 of Annex 1 to Addendum are referred to. See reporting table 4(32)	DAS: The worst case results for the PECsw of the furan metabolite are given by the autumn use in wOSR, and these are the results presented in Table 1 of the document. This is indicated by the crop type shown in the screen dump from FOCUS Steps 1-2.	RMS: The clarification can be brought in an addendum.	PRAPeR TC 18 (03 September 2009) Open point still open.
	Open point (b): 4.17 MS to discuss in a meeting of experts the need for further assessment of DE-535-acid-furan, a metabolite with dibenzofuran “like” (not polychlorinated) structure which was measured in the irradiated samples of the photodegradation study in natural water. See reporting table 4(32)	The DE-535-acid-furan does not exceed 10% AR in irradiated solution (and is only in natural water), unlike the DE-535-furan which reaches up to 18.6% AR in sterile buffer (lower in natural water). For this reason, no assessment is considered necessary for the minor DE-535-acid-furan degradate. Additionally, the need to assess the DE-535-acid furan was not raised as an outstanding point in the EFSA Scientific Report.	RMS agrees. If an assessment despite the comments is found to be needed it should be addressed to the ecotox section.	PRAPeR TC 18 (03 September 2009) Open point closed.
	Open point: 4.18 RMS to include in the LoEP the new PECsw calculations for DE-535 furan provided in Annex 1 to Addendum to		LoEP will be amended.	PRAPeR TC 18 (03 September 2009) Open point still open.

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
	Annex B8 Fate and Behaviour (March 2009). See reporting table 4(33)			
	Open point: 4.19 Pending on the outcome of the discussion on the reliability of the kinetic modelling of the degradation data (comment 4(19)) and the modelling scheme for groundwater (comment 4(37)), RMS to amend the LoEP with the results for the ghost compartment as indicated in Table B.8.6.1/02 on p. 33 of the Annex 1 to Addendum. See reporting table 4(35)		LoEP will be amended if needed.	PRAPeR TC 18 (03 September 2009) Open point superseded.
	Open point: 4.20 MS to discuss the conceptual model with the "ghost" compartment used in FOCUS groundwater modelling as reported in Annex I to Addendum of the Additional Report (March 2009). See reporting table 4(37)	DAS: The ghost compartment was required **only** to model the formation of pyridinone metabolite when considering the laboratory data. At the time, DAS considered that for consistency, the field data should then be modelled in the same way. EFSA has commented that it may be unreliable to use field data for the acid and pyridinol and lab data for the other two metabolites, but DAS has provided new dissipation studies	RMS: We accepted the modelling in Annex I to Addendum of the Additional Report (March 2009) and are now looking forward to the discussion on the Experts Meeting. RMS agrees with Notifier that metabolite exposure in field and lysimeter studies are quite different from the model results.	PRAPeR TC 18 (03 September 2009) Open point closed.

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
		in this submission. Under comparable field conditions, the phenol and pyridinone metabolites were not detected at any meaningful level (always < LOQ and mostly < LOD). The field sampling times were selected to be the same as the lab studies and were the metabolite to be formed, it would have been seen during this period. Further evidence showing this lack of metabolite exposure is shown in the extensive lysimeter data (see DAS comment in open point 4(4) If these data are taken into account, it could be argued that the "ghost" compartment is not required for modelling the field data, as the pyridinone is not formed in meaningful concentrations in the field. DAS however retained the laboratory pyridinone data in the field modelling to provide a consistent approach; in retrospect, this may have detracted from the less complex case that the pyridinone and phenol metabolites are not present in the field. In this case, DAS would also argue that the pyridinone is not relevant in the environment under in-use field conditions.		

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
	Open point: 4.21 MS to discuss in a meeting of experts the environmental occurring metabolites requiring further assessment by other disciplines (tox and ecotox). See reporting table 4(38)	DAS: In the gw modelling, DE-535-phenol never exceeded 0.1 µg/L so should not appear in the residue definition for groundwater. It is agreed that this metabolite should appear in the soil residue definition, as proposed by the RMS in the original DAR, and the relevant ecotox studies have been submitted and assessed by the RMS in the Additional Report.	RMS will follow up on this point before the Experts Meeting.	PRAPeR TC 18 (03 September 2009) Open point closed.

REPORT OF PRAPeR EXPERT MEETING TC 19

HALOXYFOP-P

Rapporteur Member State: DK

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
2009-08-14	DK	Haloxyfop-P evaluation table rev1-0 (2009-08-14).doc
2009-07-17	DK	Haloxyfop-P reporting table rev1-1 (2009-07-17).doc
March 2009	DK	Haloxyfop-P_additional report_LoEP_(March 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: Gallant Winner, Gallant Super, Gallant S

5. Classification and labelling: Proposed R51/R53

8. Recommended restrictions/conditions for use: None identified

9. Reference list: Not discussed

Areas of concern: Long term risk to mammels cannot be finalised. Mitigation measures are necessary for aquatic organism and terrestrial plants.

Appendix 1: Discussion table: HALOXYFOP-P

Appendix 2: Evaluation table

Appendix 1: Discussion Table, Haloxyfop-P (Hb)

5. Ecotoxicology

	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	Open point: 5.1 The experts should discus the proposal made by RMS in the Addendum that it is acceptable to change the chronic end point as described in Addendum Annex B.9 March 2009 for mammals outside of the reproducing season in order to refine the long-term risk for the herbivorous mammals. See reporting table 5(3)	The experts discussed the information in the additional report dated March 2009. The RMS considers that in Southern member states it cannot be excluded that the breeding season may correspond to the time of use and that this would not be the case in Northern Europe. This would mean that the NOAEL of the 16 weeks study could not be used to support use in oilseed rape in the southern EU. The refinement of the long-term risk for mammals based on the use of the 16 weeks study NOAEL of 2 mg /Kg bw/day would therefore only be appropriate for Northern member states or those member states that could be sure that breeding would not coincide with the time of application of the active substance. The dietary exposure is slightly higher in the Autumn than in the spring when estimating the proportion of contaminanted leafy crops (in the refined risk assessment). The experts agreed that for the EU level assessment the endpoint from the reproduction study should be retained for use in the risk assessment (NOAEL≥ 1 mg /kg bw/d). The experts suggested that member states could consider the coincidence of feed residues with the breeding season in their territories but that this was not appropriate for the EU level assessment. EFSA will indicate in the conclusion that the only situation where risk for reproduction could be concluded for the use on oilseed rape would be when residues in feed do not coincide with the breeding season. A data gap will be identified for a refinenment of the long term	Open point fulfilled New data gap proposed, see below. New open point proposed, see below.

	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
		risk for for the herbivorous mammals for the use in oilseed rape.	
	New data gap: 5.1 Identified at PRAPeR TC 19 meeting. New data gap identified for a refinenment of the long term risk to herbivorous mammels from the use assessed on oilseed rape.		Data gap open.
	New open point: 5.3 Identified at PRAPeR TC 19 meeting. RMS to update the TER values in the LoEP for long term risk to mammels in line with the discussion table at open point 5.1.		Open point open.
	Open point: 5.2 The experts should discus the long-term risk for the insectivorous mammals, and if further information are necessary to address the long-term risk for insectivorous mammals.	The experts considered that the refined risk assessment for herbivourous mammals does not cover the risk to insectivorous mammals (The risk assessment for insectivorous mammals available from the DAR gives TER values below annex VI triggers). Normally for a herbicide used on a leafy crop the risk to insectivorous animals would not be assessed as it is supposed to be covered by the tier 1 risk assessment for herbivourous mammels. In line with the discussion above the extrapolation from hebivourous mammals only demonstrates acceptable TER when the breeding season doesn't coincide with periods of dietary residues. Therefore whilst TER will be above the trigger in some territories for the EU level assessment further refinenment of the risk to insectivorous mammals is need.	Open point fulfilled

	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	See reporting table 5(7)	The EFSA conclusion will therefore include a data gap for this.	
	New data gap: 5.2 Identified at PRAPeR TC 19 meeting. New data gap identified for a refinenment of the long term risk to insectivorous mammals.		Data gap open.
	New open point: 5.4 Identified at PRAPeR TC 19 meeting. RMS to update the TER values in the LoEP for long term risk to mammals in line with the discussion table at open point 5.2.		Open point open.
5.1	Point for clarification RMS should clarify the units used to give the results of all the tests through the section. The units appear as mg a.i./L or µg a.i/L instead of mg metabolite /L or µg metabolite /L. This error that should be corrected in an addendum.	No discussion required	Point for clarification for the RMS remains. Please clarify the units used to give the results of all the tests through the section. The units appear as mg a.i./L or µg a.i/L instead of mg metabolite /L or µg metabolite /L. This error that should be corrected in an addendum. See reporting table 5(8)

	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	See reporting table 5(8)		
5.2	Point for clarification RMS should delete the risk assessment for field crops > 50 cm in the list of endpoints. See reporting table 5(14)	No discussion required	Point for clarification for the RMS remains. Please delete the risk assessment for field crops > 50 cm in the list of endpoints. See reporting table 5(14)
5.3	Point for clarification RMS should update the list of endpoint with the following TER be 6.9 (1 m) and 33 (5 m) for vegetative vigour and 8.5 (1 m) and 41 (5 m) for seedling emergence. See reporting table 5(15)	No discussion required	Point for clarification for the RMS remains. Please update the list of endpoint with the following TER be 6.9 (1 m) and 33 (5 m) for vegetative vigour and 8.5 (1 m) and 41 (5 m) for seedling emergence. See reporting table 5(15)

Appendix 2: Evaluation table

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
	Section 5 Open points: ***2*** Points for clarification: ***3*** Data gaps: ***0***			Section 5 Open points: ***2*** Points for clarification: ***3*** Data gaps: ***2***
	Open point: 5.1 The experts should discus the proposal made by RMS in the Addendum that it is acceptable to change the chronic end point as described in Addendum Annex B.9 March 2009 for mammals outside of the reproducing season in order to refine the long-term risk for the herbivorous mammals. See reporting table 5(3)	DAS: Insectivorous mammalian species are not considered to be at risk since arable fields with seedling leafy crops (BBCH 10-19) would provide neither adequate cover nor food resources for these species. Representative species (e.g. the shrew, *Sorex araneus*) would be found predominantly in the field margins, where vegetation provides sufficient cover from predation and where ground-dwelling invertebrates are more plentiful (evidence of this is widely available in the open literature). If a hypothetical tier 1 risk assessment were to be conducted, however, the TER_{LT} would be ≥3.7 for the spring	RMS agrees with Notifier and still find it acceptable to change the chronic end point outside of the reproducing season.	PRAPeR TC 19 (03 September 2009) Open point fulfilled New data gap proposed, see below. New open point proposed, see below.

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
		application relevant to the period of reproduction (AR 0.083 kg/ha, FIR 0.63, RUD 5.1). This tier 1 TER_{LT} value is based on the highly conservative NOAEL of ≥1 mg/kg bw/day, the highest concentration tested in the 3-generation reproduction study. Haloxyfop residues would never persist in an insect matrix for this length of time, however, and NOAEL values derived from shorter exposure periods are considerably greater than 1 mg/kg bw/day (see DAR for details). Furthermore, given the unsuitable nature of the habitat, PT is likely to be significantly less than 1. Since the TER_{LT} obtained under these highly conservative conditions is already close to the Annex VI trigger of 5, there is no need to generate a separate refined risk assessment for insectivorous species.		
	New data gap: 5.1			PRAPeR TC 19 (03 September

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
	Identified at PRAPeR TC 19 meeting. New data gap identified for a refinenment of the long term risk to herbivorous mammels from the use assessed on oilseed rape.			2009) Data gap open.
	New open point: 5.3 Identified at PRAPeR TC 19 meeting. RMS to update the TER values in the LoEP for long term risk to mammels in line with the discussion table at open point 5.1.			PRAPeR TC 19 (03 September 2009) Open point open.
	Open point: 5.2 The experts should discus the long-term risk for the insectivorous mammals, and if further information are necessary to address the long-term risk for insectivorous mammals.	DAS: Insectivorous mammalian species are not considered to be at risk since arable fields with seedling leafy crops (BBCH 10-19) would provide neither adequate cover nor food resources for these species. Representative species (e.g. the shrew, *Sorex araneus*) would be	RMS agrees with Notifier that it is possible to show safe use. Please note that the risk assessment presented in the original DAR was accepted in the EFSA Conclusion Report. The question raised was on herbivorous mammals.	PRAPeR TC 19 (03 September 2009) Open point fulfilled

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
	See reporting table 5(7)	found predominantly in the field margins, where vegetation provides sufficient cover from predation and where ground-dwelling invertebrates are more plentiful (evidence of this is widely available in the open literature). If a hypothetical tier 1 risk assessment were to be conducted, however, the TER_{LT} would be ≥3.7 for the spring application relevant to the period of reproduction (AR 0.083 kg/ha, FIR 0.63, RUD 5.1). This tier 1 TER_{LT} value is based on the highly conservative NOAEL of ≥1 mg/kg bw/day, the highest concentration tested in the 3-generation reproduction study. Haloxyfop residues would never persist in an insect matrix for this length of time, however, and NOAEL values derived from shorter exposure periods are considerably greater than 1 mg/kg bw/day (see DAR for details). Furthermore, given the		

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
		unsuitable nature of the habitat, PT is likely to be significantly less than 1. Since the TER_{LT} obtained under these highly conservative conditions is already close to the Annex VI trigger of 5, there is no need to generate a separate refined risk assessment for insectivorous species.		
	New data gap: 5.2 Identified at PRAPeR TC 19 meeting. New data gap identified for a refinenment of the long term risk to insectivorous mammals.			PRAPeR TC 19 (03 September 2009) Data gap open.
	New open point: 5.4 Identified at PRAPeR TC 19 meeting. RMS to update the TER values in the LoEP for long term risk to mammals in line with the discussion table at open			PRAPeR TC 19 (03 September 2009) Open point open.

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
	point 5.2.			
5.1	Point for clarification RMS should clarify the units used to give the results of all the tests through the section. The units appear as mg a.i./L or µg a.i/L instead of mg metabolite /L or µg metabolite /L. This error that should be corrected in an addendum. See reporting table 5(8)	Das: Agreed	RMS will clarify this in an addendum.	PRAPeR TC 19 (03 September 2009) Point for clarification for the RMS remains. Please clarify the units used to give the results of all the tests through the section. The units appear as mg a.i./L or µg a.i/L instead of mg metabolite /L or µg metabolite /L. This error that should be corrected in an addendum. See reporting table 5(8)
5.2	Point for clarification RMS should delete the risk assessment for field crops > 50 cm in the list of endpoints. See reporting table 5(14)	Das: Agreed	RMS will clarify this in an addendum.	PRAPeR TC 19 (03 September 2009) Point for clarification for the RMS remains. Please delete the risk assessment for field crops > 50 cm in the list of endpoints. See reporting table 5(14)
5.3	Point for clarification	Das: Agreed	RMS will clarify this in an	PRAPeR TC 19 (03 September

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
	RMS should update the list of endpoint with the following TER be 6.9 (1 m) and 33 (5 m) for vegetative vigour and 8.5 (1 m) and 41 (5 m) for seedling emergence. See reporting table 5(15)		addendum.	2009) Point for clarification for the RMS remains. Please update the list of endpoint with the following TER be 6.9 (1 m) and 33 (5 m) for vegetative vigour and 8.5 (1 m) and 41 (5 m) for seedling emergence. See reporting table 5(15)

Report of PRAPeR Expert MEETING TC 20

HALOXYFOP-P

Rapporteur Member State: DK

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
2009-08-14	DK	Haloxyfop-P evaluation table rev1-0 (2009-08-14).doc
2009-07-17	DK	Haloxyfop-P reporting table rev1-1 (2009-07-17).doc
Marhc 2009	DK	Haloxyfop-P_additional report_LoEP_(March 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:** EF-1400 EC

5. **Classification and labelling:** Not discussed

6. **Recommended restrictions/conditions for use:** Not discussed

7. **Reference List:** Not discussed

Areas of concern: None

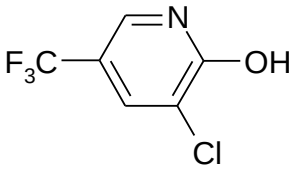
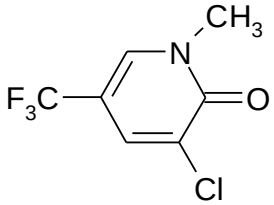
Appendix 1: Discussion table: HALOXYFOP-P

Appendix 2: Evaluation table

Appendix 1: Discussion Table, Haloxyfop-P (Hb)

2. Mammalian toxicology

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	Open point: 2.1 Providing that the groundwater metabolite DE-535 pyridinone passes step 1, step2 and stage 1 of step3 of the scheme of the Groundwater Metabolites Guidance Document SANCO/221/200 rev. 10, two points have to be discussed by the experts: 1st The completeness of the toxicological data package of DE-535 pyridinone (especially whether bridging data of DE-535 pyridinol is warranted) in order to conclude on its relevance. 2nd The toxicological relevance of the metabolite DE-535 pyridinone according to stage 2 and 3 of step 3. Further steps (Step 4 and 5) are considered not required	**DE-535 pyridinol:** The toxicological data package available: • QSAR modelling: alerts for genotoxicity and carcinogenicity (DEREK). • Acute oral toxicity study: LD50=1030 mg/kg bw/day (R22) • Ames test: Positive. • Gene mutation in CHO cells: Negative. • In vivo/in vitro UDS test: Negative. According to this data package: • Genotoxicity studies cover the stage 2 of step 3 of the Sanco Guidance Document: the metabolite is not relevant for groundwater • acute oral toxicity and QSAR modelling cover the stage 3 of step 3 (Haloxyfop-P has been proposed to be classified only as Xi R22 and R41) Therefore, during the written procedure it was concluded that the metabolite DE-535 pyridinol is not identified as being relevant according to the hazard screening outlined in the stage 2 and 3 of Step 3 of the scheme of the Groundwater Metabolites Guidance Document SANCO/221/200 rev. 10. Further steps (Step 4 and 5) are considered not required, provided that levels in groundwater remain below 0.75µg/l **DE-535 pyridinone** The toxicological data package for this GW metabolite is: • QSAR modelling: alerts for genotoxicity and carcinogenicity • Ames test: Negative The Applicant suggests that bridging data of DE-535 pyridinol is adequate (RMS agreed) as DE-535 pyridinone has a very similar structure to DE-535 pyridinol, which has already successfully completed stage 2 of step 3:	Open point closed. The data package on DE-535-pyridinone is not formally complete; however toxicological information can be bridged from the tox profile of DE-535-pyridinol. Based on this, the metabolite DE-535-pyridinone is not relevant according to step 3 of the Groundwater Metabolites Guidance Document SANCO/221/200 rev. 10. Further steps (Step 4 and 5) might be considered if levels in groundwater will exceed 0.75µg/l.

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	providing Groundwater levels remain below 0.75µg/l. See reporting table 2(5)	DE-535 Pyridinol:  DE-535 Pyridinone:  DE-535 pyridinone was tested in the assay identified by the pyridinol studies to be the most sensitive for determining its genotoxic potential, i.e., the Ames test. The DE-535 pyridinone Ames test was negative and hence no further testing was deemed necessary, a decision approved by the RMS. 1. Confirmation that DE-535 pyridinone passes stage 2 of step 3 comes from: (i) the pyridinone having no structural alerts for genotoxicity per se (Ashby & Tennant, 1991) (ii) knowledge that the pyridinone is intrinsically less DNA-reactive than the pyridinol due to the presence of a methyl group on the nitrogen atom of the pyridine ring preventing its oxidation and formation of a structural alert (N→O; Ashby & Tennant) (iii) data confirming that the pyridinone is less DNA-reactive than the pyridinol (i.e., its negative Ames test) (iv) data confirming that the more DNA-reactive pyridinol is negative in a gene mutation test with mammalian cells and a chromosome aberration test (v) a negative chromosome aberration test on parent DE-535 containing the	

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
		pyridinone at 0.88 g/kg, which is more than 1,000,000 times higher than a level of 0.75 μg/L. It is noted that the expert discussion for the Environmental Fate&Behaviour Group confirmed the GW metabolites DE-535 pyridinol and DE-535 pyridinone are likely to exceed the triggers (probably below 0.75 ug/L for pyridinol). However this was only based on a provisional discussion during the expert TC, and this is still an open point to be solved. The discussion in the MamTox TC focused on the possibility to bridge toxicological information from the pyridinol to the pyridinone. The MSs agrees with the proposed assessment provided that the trigger of 0.75 ug/L is not exceeded, as in this case only the genotoxicity has to be considered according to the GD.	

Appendix 2: Evaluation table

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
	Section 2 Open points: ***1*** Points for clarification: ***0*** Data gaps: ***0***			Section 2 Open points: ***0*** Points for clarification: ***0*** Data gaps: ***0***
	Open point: 2.1 Providing that the groundwater metabolite DE-535 pyridinone passes step 1, step2 and stage 1 of step3 of the scheme of the Groundwater Metabolites Guidance Document SANCO/221/200 rev. 10, two points have to be discussed by the experts: 1st The completeness of the toxicological data package of DE-535 pyridinone (especially whether bridging data of DE-535 pyridinol is warranted) in order to conclude on its relevance. 2nd The toxicological relevance of the metabolite DE-535 pyridinone according to stage 2 and 3 of step 3. Further steps (Step 4 and 5) are considered not required	DAS: If from the results of the field dissipation studies, it can be agreed that the pyridinone is not present at concentrations above the LOQ of the method, the need to establish its relevance is removed. Toxicological information for DE-535 pyridinone is available to show that it is not relevant according to stage 2 of step 3 of Sanco/221/2000 -rev.10- final, 25 February 2003. Points 1-3 below make this clear: 1. Evidence based on structure – DE-535 pyridinone has a very similar structure to a second metabolite, DE-535 pyridinol, which has already successfully completed stage 2 of step 3: DE-535 Pyridinol:	RMS agrees.	PRAPeR TC 20 (04 September 2009) Open point closed. The data package on DE-535-pyridinone is not formally complete; however toxicological information can be bridged from the tox profile of DE-535-pyridinol. Based on this, the metabolite DE-535-pyridinone is not relevant according to step 3 of the Groundwater Metabolites Guidance Document SANCO/221/200 rev. 10. Further steps (Step 4 and 5) might be considered if levels in groundwater will exceed 0.75µg/l.

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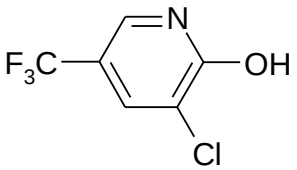
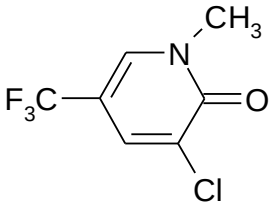
	providing Groundwater levels remain below 0.75µg/l. See reporting table 2(5)	 DE-535 Pyridinone:  2. DE-535 pyridinol was tested in a complete battery of genotoxicity tests comprising: • an Ames test • an HGPRT assay • a rat lymphocyte chromosomal aberration test • an *in vivo* UDS assay. All results, except for 2 of the 5 strains of bacteria used in the Ames test, were negative. Therefore, DE-535 pyridinone was tested in the assay identified by the pyridinol studies to be the most sensitive for determining its genotoxic potential, i.e., the Ames test. The DE-535 pyridinone Ames test was negative and hence no further testing was deemed necessary, a decision		

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		approved by the RMS. 3. Confirmation that DE-535 pyridinone passes stage 2 of step 3 comes from: (i) the pyridinone having no structural alerts for genotoxicity *per se* (Ashby & Tennant, 1991) (ii) knowledge that the pyridinone is intrinsically less DNA-reactive than the pyridinol due to the presence of a methyl group on the nitrogen atom of the pyridine ring preventing its oxidation and formation of a structural alert (N→O; Ashby & Tennant) (iii) data *confirming* that the pyridinone *is* less DNA-reactive than the pyridinol (i.e., its negative Ames test) (iv) data confirming that the more DNA-reactive pyridinol is negative in a gene mutation test with mammalian cells and a chromosome aberration test (v) a negative chromosome aberration test on parent DE-535 containing the pyridinone at 0.88 g/kg, which is more than 1,000,000 times higher than a level of 0.75 μg/L. In summary, the weight of evidence shows overwhelmingly that DE-535 passes stage 2 of step 3 and any science-based review by expert toxicologists will draw the same conclusion.		