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1. Identity, Physical and chemical properties, Details of uses and further information, Methods of analysis

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 1 Open points: ***2*** Points for clarification: ***0*** Data gaps: ***0***			
	Open point: 1.1 Depending on the residue definitions further data may be required. See reporting table 1(3)			Written procedure: Open point fulfilled The need for additional methods is dealt with in the conclusion.
	Open point:1.2 The methods contained in the re-submission dossier for the metabolites in soil and water should be evaluated in an addendum. These are needed to support the residue definitions. See reporting table 1(4)	DAS: Soil and water methods for the metabolites have been provided to the RMS. However, as states by the RMS, these were not requirements in the EFSA conclusion report and it should not be necessary to assess these for this submission.	The methods contained in the re-submission dossier for the metabolites in soil and water will be evaluated in an addendum.	Written procedure: Open point fulfilled. The methods are evaluated in the addendum to the additional report September 2009. EFSA considers that the methods are acceptable.

2. Mammalian toxicology

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.	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:	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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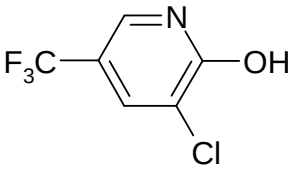
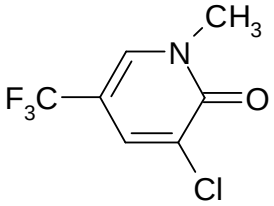
	Further steps (Step 4 and 5) are considered not required providing Groundwater levels remain below 0.75µg/l. See reporting table 2(5)	DE-535 Pyridinol:  DE-535 Pyridinone:  2. DE-535 pyridinol was tested in a complete battery of genotoxicity tests comprising: • an Ames test • an HGPRT assay • a rat lymphocyte 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.		

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		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 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		

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		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.		

3. Residues

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 3 Open points: ***1*** Points for clarification: ***0*** Data gaps: ***0***			
	Open point: 3.1 Consumer risk assessment for groundwater metabolites pending the confirmation of the maximum predicted groundwater levels by the section of fate and behaviour See reporting table 3(2)	DAS: Notifier believes from higher tier data no exposure of the metabolite is seen from field studies (ie: concentrations of the metabolite are <0.75 ug/L). Therefore consumer risk assessment not appropriate for the metabolite.	RMS agrees.	Open point open: A data gap (4.2) for a new ground water modelling was identified in the section of fate and behaviour

4. Environmental fate and behaviour

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. 14.09.2009: The requested data has been presented in an addendum (September 2009) to the Additional Report. Open point can be closed.	PRAPeR TC 18 (03 September 2009) Open point still open. Written procedure: 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. 14.09.2009: LoEP has been amended. Open point can be closed.	PRAPeR TC 18 (03 September 2009) Open point open. Written procedure: Open point fulfilled
	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.	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
		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. 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)		

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
		Two guideline lysimeter studies (Yon & Schnöder, 2001a,b) 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	DAS: It can only be further re-iterated that the presence of a “ghost” compartment in the scheme above,	RMS agrees that the “ghost” compartment don’t seem to influence on the soil DT50 value for the	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
	soilDT50 for metabolite DE-535 pyridinol to be used in FOCUS modeling. See reporting table 4(5)	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 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.	metabolite DE-535 pyridinol.	
	Open point:4.6 RMS to report the kinetic parameters (alpha and beta) for the DT50 calculated with a FOMC model (laboratory	See table at end of document	RMS: The requested parameters will reported in an addendum. 14.09.2009: The requested data has been presented in an addendum	PRAPeR TC 18 (03 September 2009) Open point still open. Written procedure:

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
	and field studies) in an addendum or revised Additional Report. See reporting table 4(6)		(September 2009) to the Additional Report. Open point can be closed.	Open point fulfilled.
	Open point: 4.7 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)	DAS: As a worst case for **parent**, the 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.	RMS agrees.	PRAPeR TC 18 (03 September 2009) 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".		14.09.2009: LoEP has been amended. Open point can be closed.	PRAPeR TC 18 (03 September 2009) Open point open. Written procedure: Open point fulfilled.
	Open point: 4.8 MS to discuss in a meeting of experts the appropriate plant uptake factor used in FOCUS	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	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	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
	modelling for metabolites. See reporting table 4(16)	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	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 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.

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
	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. Written procedure: 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 rates of haloxyfop and its metabolite. See reporting table 4(19)	DAS: in the context of the point in the Reporting Table, please see the response in Open Point 4.9	RMS: Please see the response in Open Point 4.9 above.	PRAPeR TC 18 (03 September 2009) Open point closed
	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.	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	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.

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(25)	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.		
	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.		14.09.2009: A new ground water modelling with the agreed input parameters has been submitted. The study has not been evaluated and peer reviewed.	PRAPeR TC 18 (03 September 2009) Data gap open. Written procedure: 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 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		RMS: No further comments.	PRAPeR TC 18 (03 September 2009) Open point superseded.

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
	4(37) on the reliability of the approach used in FOCUS GW modelling. See reporting table 4(28)			
	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)	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 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.	RMS: Thanks to Notifier for the explanation. RMS can give the details in an addendum. 14.09.2009: The requested data has been presented in an addendum (September 2009) to the Additional Report. Open point can be closed.	PRAPeR TC 18 (03 September 2009) Open point still open. Written procedure: 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
		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 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		

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		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. 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. 14.09.2009: The requested data has been presented in an addendum (September 2009) to the Additional Report. Open point can be closed.	PRAPeR TC 18 (03 September 2009) Open point still open. Written procedure: Open point fulfilled.
	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	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	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.

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
	polychlorinated) structure which was measured in the irradiated samples of the photodegradation study in natural water. See reporting table 4(32)	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.		
	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 Annex B8 Fate and Behaviour (March 2009). See reporting table 4(33)		LoEP will be amended. 14.09.2009: LoEP has been amended. Open point can be closed.	PRAPeR TC 18 (03 September 2009) Open point still open. Written procedure: Open point fulfilled.
	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		LoEP will be amended if needed.	PRAPeR TC 18 (03 September 2009) Open point superseded.

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
	Addendum. See reporting table 4(35)			
	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 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	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.

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		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.		
	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.

5. Ecotoxicology

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 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	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.

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		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 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.			PRAPeR TC 19 (03 September 2009) Data gap open. Written procedure Data gap still 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		14.09.2009: LoEP has been amended. Open point can be closed.	PRAPeR TC 19 (03 September 2009) Open point open. Written procedure 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
	with the discussion table at open point 5.1.			RMS has updated LoE
	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. See reporting table 5(7)	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 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	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
		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: 5.2 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. Written procedure Data gap still 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.		14.09.2009: LoEP has been amended. Open point can be closed.	PRAPeR TC 19 (03 September 2009) Open point open. Written procedure Open point closed. LoE has been updated. EFSA has included long-term TER values for insectivorous mammals for use in OSR
5.1	Point for clarification RMS should clarify the units	Das: Agreed	RMS will clarify this in an addendum.	PRAPeR TC 19 (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
	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)		14.09.2009: The requested corrections has been presented in an addendum (September 2009) to the Additional Report. Open point can be closed.	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) Written procedure Point for clarification fulfilled Units has been clarified in Addendum to the additional report (September 2009)
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. 14.09.2009: LoEP has been amended. Open point can be closed.	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) Written procedure Point for clarification fulfilled. LoE has been updated
5.3	Point for clarification	Das: Agreed	RMS will clarify this in an addendum.	PRAPeR TC 19 (03 September 2009)

section 5 - Ecotoxicology

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)		14.09.2009: LoEP has been amended. Open point can be closed.	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) Written procedure Point for clarification fulfilled. LoE has been updated

4.6 **Environmental fate and behaviour**

compound	lab or field?	report	soil	parameter	
haloxyfop	L	GHE-P-11491	Borstel, PY	2.4025	FOMC, a
				35.4061	FOMC, b
haloxyfop	L	GHE-P-11491	Marcham SL, PY	0.8319	FOMC, a
				3.0008	FOMC, b
haloxyfop	L	GHE-P-11491	Marcham SL, PH	0.7953	FOMC, a
				2.4995	FOMC, b
haloxyfop	L	GHE-P-11491	Highworth, PY	0.5214	FOMC, a
				2.3546	FOMC, b
haloxyfop	L	GHE-P-11491	Marcham LS, PY	0.8681	FOMC, a
				8.8541	FOMC, b
haloxyfop	L	GHE-P-11491	Marcham SCL, PY	0.7109	FOMC, a
				2.6659	FOMC, b
haloxyfop	L	GHE-P-11491	Speyer 2.2, PY	1.0743	FOMC, a
				14.4114	FOMC, b
haloxyfop	F	81098.02	Niedersachsen	0.9764	FOMC, a
				10.2604	FOMC, b
haloxyfop	F	81098.02	Bas-Rhin	0.8962	FOMC, a
				18.202	FOMC, b
haloxyfop	F	81098.02	Baden-Wurttemberg	4.3008	FOMC, a
				89.5059	FOMC, b
haloxyfop	F	81098.02	Champagne	1.161	FOMC, a
				14.4773	FOMC, b
haloxyfop	F	81098.02	Gross Shenkenberg	0.8449	FOMC, a
				10.4633	FOMC, b
haloxyfop	F	81098.02	Landsberg	0.629	FOMC, a
				1.654	FOMC, b
haloxyfop	F	81098.02	Ismanning	0.4729	FOMC, a
				0.6699	FOMC, b