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0. General

General				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
0(1)	List of End points, Appendix 1.4 and 1.5	DE: The residue definitions are changed as proposed below, because suitable analytical methods were provided for these analytes: **plants**: sum of haloxyfop, its conjugates and esters expressed as haloxyfop **animals**: sum of haloxyfop and its conjugates expressed as haloxyfop **soil**: haloxyfop, DE 535 pyridinol **ground/drinking water**: haloxyfop **surface water**: haloxyfop **air**: haloxyfop, haloxyfop-methylester Additional note for the residue definition for plants: According to the Pesticide Manual, 14th edition, haloxyfop, haloxyfop-etotyl, haloxyfop-P and haloxyfop-P-methyl are in use; Additional note for the residue definition for soil: haloxyfop-methylester should be deleted due to the fast degradation (DT_{90} < 3d) in soil.	DAS: The case has been put several times that the lack of a chiral method does not impact the residue definition. The amount of the –S enantiomer in any exposure compartment is extremely small. As the methods calculate total haloxyfop, the methods will only slightly over estimate the amount of –R enantiomer. However, the residue definition of racemic haloxyfop can be accepted. Since the 14th edition of the Pesticide Manual, DAS has ceased all production of haloxyfop etotyl, so is it no longer appropriate to include this moiety in the residue definition. RMS: We agree with NOT especially with the comments regarding the enantiomers/racemic haloxyfop. Concerning the residue definitions for soil we don't find that haloxyfop-methylester should be deleted as it is this compound that is applied on the vegetation and the soil. Please keep in mind that risk assessment of the effect of haloxyfop-methylester on soil organisms has been made despite the fast degradation.	See open point in comment 1(3).

General				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			Please also see the comments to 1(4) regarding the final residue definitions.	
0(2)	DAR, General	DE: It is unclear why the RMS is still refereeing to haloxyfop-R. It was agreed that the ISO common name of this substance is haloxyfop-P (see also List of End points, Section 1). Furthermore, the COM has confirmed more than once that the ISO common name should be used, if available.	DAS: To avoid confusion during the annex I process, the terminology haloxyfop-R was continued to be used. RMS: We agree that the correct name is haloxyfop-P, but has used the old name as it could be confusing to shift name late in the procedure. We will try to use the common ISO name when finalising the procedure. The problem has been addressed in the list of endpoints.	Addressed: The ISO name for this active substance is haloxyfop-P

1. Physical/Chemical Properties; Details of Uses and Further Information; Methods of Analysis

Identity (B.1, Annex C)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
	No comments			

Physical and chemical properties of the active substance (B.2.1)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
	No comments			

Physical, chemical and technical properties of the formulation (B.2.2)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
	No comments			

Further information (B.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
	No comments			

Classification and labelling (B.4)

For comments on classification and labelling see the relevant sections.

Methods of analysis (B.5)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
1(1)	Vol 4, C.1.4.3, impurity methods	EFSA: The new method validation uses a different column and perhaps there are other differences. How does the new method compare to the one used to analyse the batch data.	DAS: The method conditions in the 5-batch (DECO GL-AL MD-2000-004061) and the impurity method (DOWM 101332-ME92A) only differ in the column used. The 5-batch used an Ultra 1 column and the impurity method only states a cross-linked methylsilicone column to be used. As the Ultra 1 is a cross-linked methylsilicone column there are no differences. RMS: No comments.	Addressed: The columns are comparable.
1(2)	Vol. 4 Batch analysis	FR : Could RMS precise how identity of impurities was confirmed in the analysis of 5-batches	DAS: Batches of haloxyfop-R methyl ester technical were analysed using GC/MS. Confirmation of peak identifications for impurities above 0.1% were obtained by comparison to mass spectra of reference standards reported in DECO GL-AL MD-2000-004088. The peaks identified by GC/MS include: DMSO, Pyridinone, MAQME, DAQME, Haloxyfop-R ME, Isomer and ClF_2 Analog. One batch, TSN102229, was analyzed using ESI/LC/MS (Electrospray Interface/Liquid	Addressed: MS was used for impurity identity.

Methods of analysis (B.5)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			Chromatography/Mass Spectrometry) and ESI/LC/MS/MS. Confirmation of peak identifications for impurities above 0.1% were obtained by comparison to mass spectra of reference standards reported in DECO GL-AL MD-2000-004088. The peaks identified by LC/MS include: Pyridinone, DAQME, Haloxyfop, Isomer, Haloxyfop methyl ester and ClF_2-Analog. The mass spectrum for the haloxyfop peak, observed by LC/MS and not by GC/MS was due to low volatility by GC. Tentative peak identification was also assigned for several impurities that were present at less than 0.1%. RMS: We agree with the comments from NOT. We can mention that the information is resumed in the amendment to Annex C June 2006.	
1(3)	Vol. 3, B.5, methods, plant, animal, soil and water	EFSA: Depending on the final residue definitions further data may be required.	DAS: See response to 0(1). RMS: We agree that it depends on the final residue definition. Please see the comments to 0(1) too.	Open point: Depending on the residue definitions further data may be required. See also 0(1), 1(5), 1(6)

Methods of analysis (B.5)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
1(4)	List of End points, Appendix 1.5	DE: The following metabolites and an ester are included in the respective residue definitions for soil, ground/drinking water or surface water, but methods for the analysis of these metabolites and the ester are missing and should be provided: **soil**: DE 535 pyridinone and DE 535 phenol, **ground/drinking water**: haloxyfop (P) - methyl ester, DE 535 pyridinone and DE 535 pyridinol, **surface water**: haloxyfop (P) - methyl ester, DE 535 pyridinol and DE-535-furan	DAS: This element was not part of the EFSA data gaps that needed to be resolved before an Annex I decision can be made. However, DAS have developed methods as summarised below, and these were included in the updated dossier. Soil: A method to determine DE-535 acid and all metabolites in the residue definition was submitted in the updated dossier (method GRM07-02) Ground/drinking water: The ester has not been included in the proposed residue definition. A method to determine DE-535 acid and the three metabolites was submitted in the updated dossier (method GRM07-03) Surface water: A method has not been provided for the furan. Technical difficulties precluded synthesising a standard for this metabolite. See also comments in 0(1) RMS: We agree with NOT. The methods has not been evaluated as it was not part of the EFSA data gaps and as it was not directly included in the summary of points addressed from NOT. Please se the comments in 0(1) too.	Open point: 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.

Methods of analysis (B.5)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
1(5)	List of End points, Appendix 1.4 and 1.5	DE: The LoEP of the EFSA Scientific Report (2006) 87, 1-96, Conclusion on the peer review of haloxyfop-P – Updated by RMS March 2009 after resubmission contains enantioselective residue definitions for plants and animals (Appendix 1.4, p.15) as well as for the environment (Appendix 1.5, p.40). Assuming that the mentioned LoEP is valid, no suitable methods were provided, because all provided analytical methods measure the sum of haloxyfop-P and haloxyfop-M, i.e. haloxyfop is determined. Therefore, this issue needs to be clarified before a decision on a possible inclusion of haloxyfop-P into Annex I.	DAS: See comments in 0(1) RMS: Please see the comments in 0(1).	See open point in comment 1(3)

Methods of analysis (B.5)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
1(6)	List of End points, Appendix 1.2	DE: According to the summary of all analytical methods for residues (LoEP of the EFSA Scientific Report (2006) 87, 1-96, Conclusion on the peer review of haloxyfop-P – Updated by RMS March 2009 after resubmission, Appendix 1.2, table on p. 9/10) only methods for the sum of haloxyfop-P and haloxyfop-M (i.e. haloxyfop) and its metabolites were provided. These methods are not in compliance with the proposed enantioselective residue definitions and must be deleted from the table.	DAS: See 1(5) and 0(1) RMS: RMS: Please see the comments in 0(1).	See open point in comment 1(3)

2. Mammalian toxicology

Toxicokinetics (B.6.1)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
	No comments			

Acute toxicity (B.6.2)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
	No comments			

Short-term toxicity (B.6.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
	No comments			

Genotoxicity (B.6.4)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
	No comments			

Long-term toxicity and carcinogenicity (B.6.5)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
	No comments			

Reproductive toxicity (B.6.6)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
	No comments			

Neurotoxicity (B.6.7)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
	No comments			

Other toxicological studies & Medical data (B.6.8-B.6.9)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
2(1)	Vol. 3, B.6.8.1, Toxicity studies of metabolites	DE: The conclusion that the two metabolites DE535-pyridinol and DE-535-pyridinone are non relevant metabolites in groundwater is supported. The toxicity data for both metabolites are considered to be sufficient. A groundwater concentration of 0.75 ug/L should not be exceeded.	DAS: Agree and no further comment RMS: Concerning DE535-pyridinol, it can be concluded that it is not relevant, see point 2(2), 2(3) and 2(4). Concerning DE535-pyridinone we propose that this question forwarded to an expert meeting, see 2(5), 2(6), 2(7) and 2(8).	Addressed for DE-535 pyridinol. See open point on comment 2(5) for DE-535 pyridinone.
2(2)	Vol. 3, B.6.8 Further toxicological studies. (Non-)Relevance of Groundwater metabolite DE-535-Pyridinol	EFSA: Available toxicological information on DE-535-pyridinol is: • QSAR modelling (including comparison to the parent active substance). • Acute oral toxicity study • Ames test • Gene mutation in CHO cells • In vivo/in vitro UDS test Based on this data package, RMS concluded that the metabolite is non-relevant. It is noted that with regard to the tox relevance of this metabolite: • Genotoxicity studies could cover the stage 2 of step 3 of the Sanco Guidance Document *(if the final	DAS: A complete battery of test guideline and GLP-compliant reports for in vitro genotoxicity assays performed on the pyridinol metabolite in accordance with requirements of 91/414/EEC and Sanco/221/2000 - rev.10- final, 25 February 2003 was submitted and comprised: • an Ames test • an HGPRT assay • a rat lymphocyte chromosomal aberration test. In addition, a report of an in vivo UDS assay was also submitted. This study was triggered by the results for 2 of the 5 strains of bacteria used in the Ames test, as stated in 91/414/EEC (94/79/EC Annex I, 5.4.2.).	Addressed. Providing that the groundwater metabolite DE-535 pyridinol passes step 1, step2 and stage 1 of step3 of the scheme of the Groundwater Metabolites Guidance Document SANCO/221/200 rev. 10, 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. Further steps (Step 4 and 5) are considered not required, providing Groundwater levels remain below 0.75µg/l. .

Other toxicological studies & Medical data (B.6.8-B.6.9)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
		outcome is negative, see comment below) • Since the parent active substance, which has been proposed to be classified only as Xi R22 and R41, acute oral toxicity and QSAR modelling could cover the stage 3 of step 3 *(if the final outcome is that the metabolite has not certain properties, which qualify for considered as not relevant, see comment below) Based on the outcome of the discussion below the adequacy of the data package (enough number/type/quality of studies) in order to evaluate the relevance of this metabolite should be further discussed. Likewise the final outcome (relevance/non relevance) should be further discussed (see comments below in 2(4)). * Sanco Guidance Document: Guidance Document on the assessment of the relevance of metabolites in groundwater of substances regulated under Council Directive 91/414/EEC. Sanco/221/2000-rev.10. 25 February	Collectively, the results of these studies do not indicate a genotoxic risk for this metabolite, which is confirmed below in 2(4) RMS: Support the conclusion of the notifier.	

Other toxicological studies & Medical data (B.6.8-B.6.9)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
		2003		
2(3)	Vol. 3, B.6.8.1.1 QSAR modelling. DE-535-pyridinol	EFSA: the applicability of QSAR models to the risk assessment of metabolites is currently under discussion (An activity is ongoing between the EFSA PPR panel and JRC) The outcome of the QSAR modelling applied to DE535-Pyridinol should be further discussed.	DAS Response: QSAR models for use in *risk assessment* (i.e., Step 5 in Sanco/221/2000 - rev.10- final) are only relevant if levels of a metabolite are predicted to exceed 0.75 µg/l in groundwater. In the case of pyridinol, DAS generated the required data to establish relevance and although a QSAR was undertaken and reported, it was not used in risk assessment DAS is not aware of the ongoing discussions regarding the QSAR, so if this were needed as part of the risk assessment, it would not have been possible to take this into account. RMS: Support the conclusion of the notifier	Addressed.
2(4)	Vol. 3, B.6.8.1.5 In vivo/in vitro UDS test. DE-535-pyridinol	EFSA: A statistically significant increase in mean net nuclear grain counts (0.28) and in the percent of nuclei with five or more net grains (1%) at 300 mg/kg bw was observed (14-16 hour sampling time). Nevertheless, according to the evaluation criteria cited in the report this response was considered negative. In addition, according to the results, clinical signs of toxicity were observed at 300 mg/kg bw. EFSA has some concerns about the methods and results of this study:	DAS: **'Statistical significance'** - The mean net nuclear grain count (NNG) at 300 mg/kg, 14-16 h sampling group was 0.28 compared to the vehicle control value of -0.30. This is an increase of only 0.58 NNG over the vehicle control. The value in the treated group did not meet the *a priori* criteria for a positive UDS response, which is an absolute NNG of at least 5. In addition, the value observed in the treated group was within the historical vehicle control range (mean: -0.5, low:	Addressed. DE-535-pyridinol gave a negative response in the in vivo/in vitro UDS test.

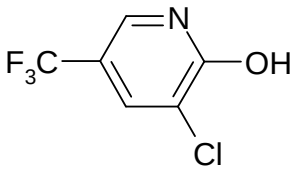
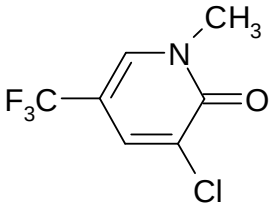
Other toxicological studies & Medical data (B.6.8-B.6.9)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
		The first one is the selection of the highest dose level tested: the highest dose level show clinical signs of toxicity. Could the RMS clarify the type/severity of the clinical signs? The second one is related to the evaluation criteria for a positive response. According to Kenelly et al, 1993*, the occurrence of a (N-C) value of zero or above in any treated animal should be taken as indicative of a UDS response. According to guidance OCDE 473 (1997) or B.39, within the examples of criteria for positive responses include: (i) NNG values above a pre-set threshold which is justified on the basis of laboratory historical data; or (ii) NNG values significantly greater than concurrent control. Could the RMS include the relevant laboratory historical data? In addition, and in order to evaluate in more detail the results it would be useful to have a summary table indicating the NNG, CG, NG for each treatment group and, the individual findings for each animal at the two dose levels tested.	-1.99, high: 0.44). Similarly, the mean % cells with 5 or more NNG of the 300 mg/kg 14-16 h sampling group was 1.00 compared to 0.00 in the control but this was also within the labs historical control range (mean: 4.11 with a range of 0.44 – 10.33). The OECD test guideline makes it clear that "…biological relevance of data should be considered… statistical significance should not be the only determining factor for a positive response." (OECD 486, para. 31). This is why the statistically identified difference in this study was interpreted to have no biological significance. **'Selection of the high dose level'** – comparison of dose levels used in the UDS with the acute oral toxicity study is not valid. The UDS study had its own specific dose-range finding study, which was conducted in the same laboratory and using the same treatment regimen to be used in the main UDS study, as required by the test guideline (OECD 486, para. 18). Cross-reference between two studies	

Other toxicological studies & Medical data (B.6.8-B.6.9)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
		According to the OCDE guideline 473 (1997) the highest dose is defined as the dose producing signs of toxicity such that higher dose levels, based on the same dosing regimen, would be expected to produce lethality. If the dose levels used in the UDS test are compared to the those used in the acute oral toxicity study (both performed in Fisher 344 rats), treated rats at dose level of 550 mg/kg bw (acute oral toxicity study, approximately 2 fold the highest dose level tested in the UDS test) did not show any mortality, sign of gross toxicity, adverse clinical signs, abnormal behavior or gross abnormalities during the 14-day observation period. *Kenelly et al, 1993. In vivo rat liver UDS assay (52-77) within the book Supplementary Mutagenicity Tests: UKEMS Recommended Procedures. David J. Kirkland and Margaret Fox. Cambridge University Press. 1993.	that simply are not comparable is not useful. In the UDS dose-range finding study all rats (3 males and 3 females) receiving 500, 1000 or 2000 mg/kg either died or were euthanized within a day of dosing. At 250 mg/kg all animals had reduced faecal output, five had ataxia and two were hypoactive after dosing; all survived until their scheduled sacrifice (2 days post-dose). Based on these results, a high dose level of 300 was selected for the main study. In the main study, all animals treated with 300 mg/kg survived until their scheduled sacrifice as required by the test guideline. Clinical signs noted among these animals included decreased activity, laboured breathing, squinted eyes, red crust around the nose, chromodacryorrhea, red stains around mouth, and hunched posture. 300 mg/kg is more than half the LD100 for the pyridinol metabolite. Based on this fact and the clinical effects seen in the main study, there is no doubt that it is a guideline compliant high dose level.	

Other toxicological studies & Medical data (B.6.8-B.6.9)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			'Evaluation criteria' - The criteria used to evaluate the results of the UDS assay are described on pages 16 and 17 of the report. These criteria were adapted from the report of a committee of internationally recognized experts in performing this assay and included such notable scientists as John Ashby, Gary Williams and Byron Butterworth (Butterworth et al., 1987). These criteria are also consistent with the recommendations of the OECD test guideline (486 not 473 as cited in the review which is a guideline for the conduct of in vitro chromosomal aberration tests). **'Historical control data'** - The historical control data are presented on the following pages in the report - vehicle control: pages 38 (2-4 h) and 40 (14-16 h); positive control: pages 39 (2-4 h) and 41 (14-16 h). In addition, Table 1 of the report has a summary of NNG, CG, and NG for each treatment group at each of the sacrifice times. The following tables in the report detail individual findings for each animal at the two levels tested. It is not clear what additional information is required by EFSA: • Table 6: individual data for the 2-4 h sacrifice time point • Table 9: individual data for the 14-14 h sacrifice time point.	

Other toxicological studies & Medical data (B.6.8-B.6.9)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			• RMS: We support the conclusion of the notifier. However, as it is proposed that the relevance of DE535-pyridinone is forwarded to an expert meeting, see 2(5), 2(6), 2(7) and 2(8), the RMS would not object to a discussion regarding the conclusions of present study if needed.	

Summary of mammalian toxicology and setting of ADI, AOEL and ARfD (B.6.10)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
2(5)	Vol. 3, B.6.8 Further toxicological studies. (Non-)Relevance of Groundwater metabolite DE-535-Pyridinone	EFSA: Available toxicological information on DE-535-pyridinol is: • QSAR modelling (including comparison to the parent active substance and metabolite DE-535-Pyridinol) • Ames test Based on this data package, RMS concluded that the metabolite is non-relevant. It is noted that with regard to the tox relevance of this metabolite:	DAS Response: EFSA's comment refers to the **pyridinone**, not the pyridinol. Screening for genotoxicity, as required by Sanco/221/2000 -rev.10- final, 25 February 2003, is effectively available for the pyridinone metabolite. The following points will hopefully make this point clear. 1. The pyridinol and pyridinone	Open point: 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.

Summary of mammalian toxicology and setting of ADI, AOEL and ARfD (B.6.10)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
		• An Ames test does not cover the stage 2 of step 3 of the Sanco Guidance Document *. • Since the parent active substance, which has been proposed to be classified only as Xi R22 and R41, QSAR modelling could cover the stage 3 of step 3 *(if the final outcome is that the metabolite has not certain properties, which qualify for considered as not relevant, see comment below) Based on the outcome of the discussion below the adequacy of the data package (enough number/type/quality of studies) in order to evaluate the relevance of this metabolite should be further discussed. Likewise the final outcome (relevance/non relevance) should be further discussed (see comments below = add point). * Sanco Guidance Document: Guidance Document on the assessment of the relevance of metabolites in groundwater of substances regulated under Council Directive 91/414/EEC.	metabolites have very similar structures: Pyridinol:  Pyridinone:  2. The pyridinol has been tested in a complete battery of genotoxicity tests: • an Ames test • an HGPRT assay • a rat lymphocyte chromosomal aberration test • an in vivo UDS assay.	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 providing Groundwater levels remain below 0.75µg/l.

Summary of mammalian toxicology and setting of ADI, AOEL and ARfD (B.6.10)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
		Sanco/221/2000-rev.10. 25 February 2003	All results, except for 2 of the 5 strains of bacteria used in the Ames test, were negative. Therefore, the pyridinone metabolite was tested in the assay identified by the pyridinol data to be the most sensitive assay for determining its genotoxicity potential, i.e., the Ames test. This assay was negative and hence no further testing was necessary. 3. Should further reassurance be required, a negative rat lymphocyte chromosomal aberration test on DE-535 containing the pyridinone metabolite at 0.88 g/kg is part of the submission (Linscombe, et al., 1999). While this level might appear low, it is in fact more than 1,000,000 times higher than a level of 0.75 μg/L. Collectively, the available data for the pyridinol and the pyridinone show beyond any reasonable doubt that neither molecule represents a genotoxic risk to humans from presence in groundwater and Stage 2	

Summary of mammalian toxicology and setting of ADI, AOEL and ARfD (B.6.10)				
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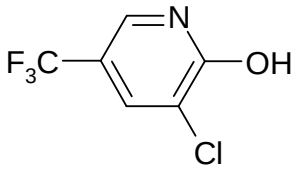
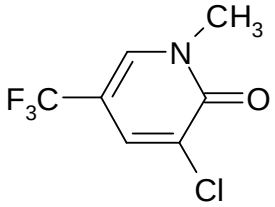
			of Step 3 of Sanco/221/2000 -rev.10-final is satisfied. RMS: The RMS recognizes that a principal discussion regarding the sufficiency of the data base is necessary (especially the question whether bridging to the data of DE535-pyridinolbased on the structural similarity) in order to conclude on the relevance of DE535-pyridinone is warranted.	
2(6)	Vol. 3, B.6.8.1.1 QSAR modelling. DE-535-pyridinone	EFSA: the applicability of QSAR models to the risk assessment of metabolites is currently under discussion (An activity is ongoing between the EFSA PPR panel and JRC). The outcome of the QSAR modelling applied to DE535-Pyridinone should be further discussed.	DAS Response: Although ,QSAR models for use in risk assessment (i.e., Step 5 in Sanco/221/2000 - rev.10- final) are only relevant if levels of a metabolite are predicted to exceed 0.75 µg/l in groundwater, in this case QSAR was used to compare with the pyridinol metabolite to decide which data to generate. DAS is not aware of the ongoing discussions regarding the QSAR, so if this were needed as part of the risk assessment, it would not have been possible to take this into account. RMS; To be discussed at an expert meeting, see 2(5)	See open point on comment 2(5).
2(7)	Vol. 6.8.1, Toxicology	FR : The table 6.8.1-1 “QSAR	DAS: Table 6.8.1-1 does show the	See open point on comment 2(5).

Summary of mammalian toxicology and setting of ADI, AOEL and ARfD (B.6.10)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
	studies of metabolites B.6.8.1.1 QSAR	comparison of the pyridinol and pyridinone metabolites with haloxyfop-R" doesn't show the TOPKAT or DEREK modelling of pyridinol. If pyridinol has the same structural alert as pyridinone, this should be specified. Besides, it would be useful to remind the chemical structure of the molecules.	TOPKAT and DEREK modelling of the pyridinol. However, the table is 'Landscape' while the DAR Addendum orientation is 'Portrait' and so the part containing the pyridinol data can not be seen. The structures are: Pyridinol:  Pyridinone:  RMS: to be discussed at taexpert meeting.	
2(8)	Vol. 3, B.6.8.1, toxicology studies of metabolites	UK: The assessment of relevance of metabolites that are predicted to exceed 0.1µg/l does not appear to be	**DAS: Biological Activity** was addressed in the updated dossier (IIA 5.8.1); the metabolites were tested at	Addressed for DE-535 pyridinol. See open point on comment 2(5) for DE-

Summary of mammalian toxicology and setting of ADI, AOEL and ARfD (B.6.10)				
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		complete. An overall summary and conclusion about this critical aspect of the evaluation would have been very helpful. By comparison with the scheme in the Groundwater Metabolites Guidance Document Sanco/221/2000 rev.10 (23rd Feb 2003):- For both metabolites biological activity (Stage 1 of Step 3) has not been fully addressed (eg only aquatic ecotox data on Chironomid larvae for the piridinol metabolite, and although there was reference to an earlier non-peer reviewed assessment of pesticidal activity, there was no assessment in this addendum). They are not likely to be active since they are much smaller than haloxyfop so one can probably assume they are inactive. Both metabolites would also pass Stage 3 of Step 3 for toxicity screening by comparison with the active (but this is not actually stated in the documents). Pyridinone metabolite – for Stage 2 of	elevated concentrations (x40 maximum application rate). These metabolites can be considered to be non-relevant as they clearly demonstrate <50% activity of that of the active moiety (haloxyfop-R). In addition, the metabolites are shown not to have any insecticidal or fungicidal properties at the predicted concentrations. **Toxicity of the pyridinone metabolite**: see 2(4) **RMS**: To be discussed at an expert meeting, see point 2(5).	535 pyridinone.

Summary of mammalian toxicology and setting of ADI, AOEL and ARfD (B.6.10)				
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		Step 3 at least 3 in vitro genotox studies are required (if all negative). Only 1 study is available. There could be arguments over whether the pyridinone metabolite was fully tested as an impurity in the technical active substance (this has been discussed to some extent in the 1st review but only in the context of the technical specification and impurity profile). There could (possibly) be arguments made about structural similarity to the active. However – the RMS has not presented any arguments for this metabolite – they seem to have simply declared it 'not relevant' on the basis of one Ames test only. Data gaps appear to remain – at the very least this should be discussed further. Pyridinol metabolite – a full genotoxicity package is available. There is a positive Ames test but a negative in vivo UDS assay so an overall negative conclusion for genotoxicity is reasonable. Concluding this metabolite as non-relevant (assuming it is not biologically active as a herbicide) seems reasonable, providing		

Summary of mammalian toxicology and setting of ADI, AOEL and ARfD (B.6.10)				
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		Groundwater levels remain below 0.75ug/l. These are toxicology issues which apply whatever GW levels the metabolites achieve above 0.1ug/l .		
2(9)	Vol. 3, B.6.10. Overall conclusion.	EFSA: pending on the ground water exposure assessment conclusion by the fate colleagues further assessment could be needed.	Agreed	Addressed. Further assessment could be needed depending on groundwater exposure assessment by the fate colleagues.
2(10)	B.6.8.1.2 to B.6.9	FR: The results of genotoxicity tests should be tabulated to be clearer.	DAS: The data have been tabulated and presented below	Addressed

Table of genotoxicity studies to address relevance of DE-535 pyridinol and pyridinone metabolites from an EU groundwater perspective

Test	Test Object	Test Material	Concentration	Result	Report Ref.
In vitro bacterial reverse mutation	*S. typhimurium*: TA 98, TA 100, TA 1535 & TA 1537; *E. coli*: WP2*uvr*A	DE-535 pyridinol	50.0, 100, 250, 500, 1000, 2000, 2500, 3000, 4000, and 5000 µg per plate, ±S9	**Positive** in TA1535 and WP2*uvr*A ±S9	Mecchi, M.S., 2005
In vitro mammalian forward mutation	Chinese hamster ovary cells (CHO/HGPRT)	DE-535 pyridinol	7.8, 15.6, 31.3, 62.5, 125, 250, 500, 1000, 1500 and 2000 µg/ml ±S9	Negative ±S9	Seidel, S.D. *et al*., 2005
In vitro mammalian cytogenetics	Rat lymphocytes	DE-535 pyridinol	250, 500, 750, 1000 and 1500 µg/ml (4 hours without S9); 0, 62.5, 125, and 250 µg/ml (24 hours without S9)	Negative ±S9	Charles, G.D. *et al*., 2005
In vivo mammalian UDS	Cultured primary rat hepatocytes	DE-535 pyridinol	Dose-ranging: 250, 500, 1000 and 2000 mg/kg; Main test: 150, 300 mg/kg at 2-4 and 14-16 hrs	Negative ±S9	Cifone, M.A., 2006
In vitro bacterial reverse mutation	*S. typhimurium*: TA 98, TA 100, TA 1535 & TA 1537; *E. coli*: WP2*uvr*A	DE-535 pyridinone	100, 333, 1000, 3300, and 5000 µg per plate, ±S9	Negative ±S9	Mecchi, M.S., 2007

In vitro chromosome aberration	Rat lymphocytes	DE-535 containing 0.88 g/kg pyridinone	10, 33.3 100, 333.3 µg/ml -S9 0, 100, 333.3 or 1000 µg/ml +S9	Negative ±S9	Linscombe, V.A. *et al*., 1999

Toxicity of the product(s) (B.6.11)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
	No comments			

Dermal absorption (B.6.12)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
	No comments			

Toxicity of non-active substances (B.6.13)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
	No comments			

Exposure data (B.6.14)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
	No comments			

Other comments				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
	No comments			

3. Residues

Storage Stability (B.7.0)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
	No comments			

Metabolism in plants (B.7.1)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
3(1)	Vol. 3, B.7.1	EFSA: Is there meanwhile any information available with regard to the potential for isomeric conversion of haloxyfop-isomer residues on plant commodities?	DAS: The assumption is that this point refers to the following comment in page 3 of the EFSA Scientific Report, even though this was not raised in the list of outstanding data points. 'Due to the lacking isomeric specificity of the pre-registration analytical methods any possible stereochemical inversion in either direction in food of plant and animal origin could not be detected, even though it is assumed based on available data in soil and in rats that if such inversion occurs it will be most likely from the S- to the R-isomer.' Data provided in the original dossier (Gerwick, *et al*, 1988) showed that application of samples enriched with the S-enantiomer were found to be less herbicidally active than the R-enantiomer in laboratory petri dish evaluations. The pure S-enantiomer was estimated by regression to be at least 10^3 less active than the R-enantiomer. These results were confirmed in field trials. These data lead to the conclusion that the S-enantiomer is	Addressed No new information has been made available.

Metabolism in plants (B.7.1)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			herbicidally inactive and also that plants are unable to stereoisomerise enantiomers. This has also been demonstrated for other aryloxyphenoxy propionate herbicides, eg diclofop (Nestler 1980), fluazifop (Bewick 1986) and quizalifop (Sakata 1985). RMS: No new information is available according to our knowledge	

Metabolism in livestock (B.7.2)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
	No comments			

Residue definition (B.7.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
	No comments			

Use pattern, critical GAP, residues trials (B.7.4 to B.7.6)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
	No comments			

Processing (B.7.7)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
	No comments			

Livestock feeding (B.7.8)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
	No comments			

Succeeding/Rotational crops (B.7.9)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
	No comments			

MRLs related issues and Consumer Risk Assessment (B.7.10 to B.7.15)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
3(2)	Vol. 3, B.7.15 Estimates of potential and actual dietary exposure through diet and other means	EFSA: Pending clarification of their toxicological relevance, for scenarios where groundwater metabolites >0.75 µg/L (threshold of concern) were found a consumer exposure and risk assessment should be carried out.	DAS: our aim is to maintain concentrations of metabolites to be under this threshold. However, an exposure assessment was submitted in the updated dossier and is reproduced below. **Refined risk assessments for non-relevant metabolites** As the pyridinone metabolite is considered a toxicologically non-relevant metabolite but could exceed the 0.75 µg/L limit in some situations, a further risk assessment is provided to address the potential toxicological significance of these exceedances for consumers. Based on the maximum predicted groundwater levels of 0.906 µg/L for the pyridinone, this equates to an exposure of 0.03 □g/kg bw/day for adults through drinking water (based on 2 L water consumed by a 60 kg person) which is equivalent to 4.65% of the **parent** ADI. For children, exposure would be 0.0906 µg/kg bw/day (based on 1L water consumed and 10 kg bw), equivalent to 13.9% of	Open point: Consumer risk assessment for groundwater metabolites pending the confirmation of the maximum predicted groundwater levels by the section of fate and behaviour

MRLs related issues and Consumer Risk Assessment (B.7.10 to B.7.15)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			the **parent** ADI. The dietary risk assessment indicates that under realistic conditions, the worst case intake of haloxyfop is 0.0000713 mg/kg bw/day for adults and 0.000107 mg/kg bw/day for infants (DAR Addendum B.7.15.1, Table 7.15.1-2, dated April 2006), which represent approximately 0.000000214 and 0.000000321 mg/kg bw/day, respectively, of impurity (based on 0.3% impurity in the manufacture specification). For this level to be of toxicological concern, the ADI would be ≤0.000000321 mg/kg bw/day (0.000321 µg/kg bw/day), and the toxicity of the compound ≥62-fold lower than the 'threshold of concern' for toxicity (0.02 µg/kg bw/day), as proposed in the Guidance Document on the Assessment of Relevance of Metabolites in Groundwater (SanCo/221/2000, Rev 10). If the substance is of equivalent toxicity to haloxyfop-R, the intake could represent 0.05% of the **parent** ADI. Therefore, although there are limited data on the pyridinone metabolite, based on data available for the toxicology	

MRLs related issues and Consumer Risk Assessment (B.7.10 to B.7.15)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			batches which contain this impurity, and the similarities between the results of the 90-day rat dietary studies with haloxyfop and haloxyfop-R, this would suggest that the impurity is not having a significant effect on the toxicology. In addition, when the levels of metabolites then occurring in groundwater are considered, if the toxicity of the metabolite is the same as the active substance, the maximum contribution to human exposure would be ≤ 13.95% of the **parent** ADI (considering both dietary and drinking water exposure). RMS: The data base, if the metabolites should exceed 0.75 µg/L (threshold of concern), should be discussed	

Other comments				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
	No comments			

4. Environmental fate and behaviour

Route and rate of degradation in soil (B.8.1)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier (DAS)	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(1)	Appendix 1, LoEP, Rate of degradation in soil, laboratory data	EFSA: More information on the "ghost" compartment should be provided (i.e. the proposed chemical identification, the degradation rate and the assumed formation fraction).	DAS: The conceptual "ghost" metabolite was included in the degradation scheme to provide an improved kinetic model fit to the measured pyridinone data. It is not entirely unrealistic, as described in Appendix 9 of report GHE-P-11491. This is because N and O methylation of substituted pyridine compounds can occur. In the case of haloxyfop, the resulting methylation products would be DE-535-pyridinone and DE-535-methoxypyridine. However, based upon the very low formation fraction of 0.073, the amount of DE-535-methoxypyridine (the "ghost" metabolite) formed in the soils would be very low, and this could be the reason why it was not seen in any of the soil studies. RMS: Agree with the comment from DAS. The data are summarised in "Annex I to Addendum Annex B8 Fate & behaviour, March 2009" table B8.6.1/01. RMS will amend the LoEP.	Open point: 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 comment 4(19).

Route and rate of degradation in soil (B.8.1)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier (DAS)	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(2)	Vol. 3 B.8.1.2.1 Rate of degradation in soil, laboratory data	EFSA: For reason of transparency, it would be better to have the goodness of fit and plots for the residuals of the degradation model without "ghost compartment" to justify the degradation kinetic analysis provided.	RMS: We will take this *ad notam*.	Open point: 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.
4(3)	Vol. 3 B.8.1.2.1 Rate of degradation in soil, laboratory data	EFSA: It should be considered that DT50 values derived from the same soil with a different radiolabelled position should be averaged before deriving the definitive endpoint for modelling (i.e. geomean FOMC DT50 for parent should be 25.8 days).	DAS: For the calculation of geomean, DAS considers that all individual values should be taken. In any case, since the field "back calculated" DT50 of 30.2 days was ultimately used in the groundwater assessment for parent alone, then this will have no impact. RMS: It is correct that using replicates in stead of average can have influence on the geomean. In the actual case where the resulting DT50 value is used for the parent alone it can be regarded as a conservative situation and thereby accepted.	Open point: 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.
4(4)	Vol. 3 B.8.1.2.3 Rate of degradation in soil, field data	EFSA: It is the opinion of EFSA that as the simpler two step model used to derive field DT50s for the parent compound and DE-535 pyridinol provided an acceptable visual fits (with chi2 % errors in the range 11.42-33.52), is unnecessary to perform a more complicated full kinetic scheme	DAS: The degradation of haloxyfop-R is complex and a definitive degradation scheme, particularly where low level metabolites are formed, sometimes late in the laboratory study, will be difficult to determine with absolute certainty. DAS followed all the recommendations of the FOUCS	Open point: MS to discuss the re-calculation of field kinetics for haloxyfop-R and its soil metabolites (Havens, 2008) in a meeting of experts.

Route and rate of degradation in soil (B.8.1)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier (DAS)	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
		with a "ghost" compartment, resulting in chi2 % errors in a very similar range (11.4-33.6). It is also questionable the use of the decline rates for the other two metabolites (which were not analysed in the field studies, DE 535 phenol and DE 535 pyridinone) were fixed within the model to the geometric mean SFO values determined in the laboratory data.	guidance to obtain the best fit for all the metabolites (see also DAS response to 4(5). DAS would also like to highlight that **field data have now been generated on the pyridinone and phenol metabolites,** which clearly demonstrate that the pyridinone is extremely unlikely to be seen in practical field conditions and the phenol metabolite is seen at or around the LOQ of the method. Under these conditions, there is a compelling argument that these metabolites should not be included in the FOCUS modelling. The occurrence and levels of the metabolite in the laboratory study lead to many challenges in traditional modelling, especially where the metabolites are seen sporadically and/or at very low levels. The new dissipation studies were undertaken specifically to address the challenges and concerns with using the laboratory-derived kinetics for the metabolites.	

Route and rate of degradation in soil (B.8.1)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier (DAS)	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			The Guidance on assessing relevance of metabolites in groundwater (SANCO 221/2000 rev 10 Feb 2003, Point 4) states that all metabolites expected to occur in soil under **normal use conditions** on the basis of soil degradation studies should be assessed. It is valid to consider the results of the field studies in this context, as it has previously been demonstrated that results from such studies adequately represent degradation. In addition, these results were given further strength 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	

Route and rate of degradation in soil (B.8.1)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier (DAS)	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			only 0.5% of agricultural soils are more vulnerable to leaching than those used in the lysimeter study (Jones and Truckell, 2007) The results of the new dissipation studies (Balluff, 2008) are summarised: Following a single spring application of EF-1400 on bare soil at four field sites in northern Europe, no pyridinone was detected (<LOD, i.e. <0.0005 mg/kg or <5% of applied)) in any of the treated soils analyzed except for only two 0-10 cm samples (121 and 193 d; Poland), but which had residues of only up to 0.001 mg/kg. The other metabolites (phenol and pyridinol) were generally at or around the LOQ (<0.002 mg/kg). The results of the lysimeter studies (Yon & Schnöder, 2001a,b). are summarised: Two guideline lysimeter studies 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	

Route and rate of degradation in soil (B.8.1)				
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			was only found in the leachate after autumn application (max. annual average 0.089 µg/L). DE-535-pyridinol never exceeded 0.015 µg/L, whilst other individual soil degradates were, at most, only 0.044 µg/L each. RMS: We find that the modelling has been made in good agreement with the recommendations from FOCUS. As there were no useful field data for DE 535 phenol and DE 535 pyridinone metabolites is seems reasonable to use the lab data. As the metabolism is complex and as lab and field data are contradicting with regard to degradation time one can always discus how to perform the modelling. I could be considered to discuss this point on an Experts Meeting. Moreover, as mentioned in Annex I to Addendum B.8 (March 2009) there is further information about degradation, metabolism and leaching that could be taken into account: Three duplicate lysimeter studies were evaluated in the original DAR. In these lysimeters annual average concentrations of DE-535, DE-535	

Route and rate of degradation in soil (B.8.1)				
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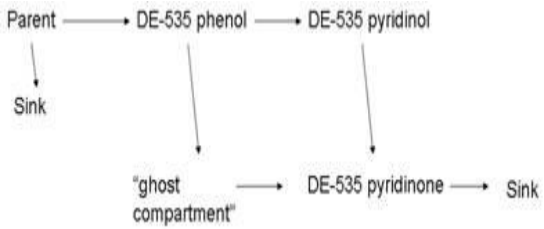
			phenol, DE-535 pyridinol and DE-535 acid did not exceed 0.1 µg as eq/L. Analysis for DE-535 pyridinone in the lysimeter leachates was not undertaken against an analytical standard, but no individual peaks of unknown radioactivity in the leachate were >0.1 µg eq/L. This indicates that DE-535 pyridinol and DE-535 pyridinone may not be found in concentrations exceeding 0.1 µg/L under practical conditions of use. A new field dissipation study evaluated in the Addendum to Annex B8 June 2008 was performed at four sites in Northern Europe in which DE-535 pyridinone was analysed for after spring application of DE-535. DE-535 pyridinone was very rarely detected and when it was, it was only detected at one of the four sites on two occasions below the LOQ. This indicates that this metabolite may only be formed at very low levels in the field.	
4(5)	Vol. 3 B.8.6.1 PECgw, input parameters, p. 32, DT50 DE-535 pyridinol	EFSA: The EFSA agrees with RMS that the use of normalised field DT50s for DE-535 acid and DE-535 pyridinol in GW modelling is appropriate.	DAS: The pyridinol field DT50 (55 d) was used in a way that encompasses the whole degradation scheme below; EFSA are proposing to just look at the degradation of parent to pyridinol scheme, where pyridinol degrades with a DT50 of 63 d.	Open point: MS to discuss in a meeting of experts the appropriate soilDT50 for metabolite DE-535 pyridinol to

Route and rate of degradation in soil (B.8.1)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier (DAS)	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
	Vol. 3 B.8.6.3 Summary of mobility in soil Appendix 1, revised LoEP, PECgw (March 2009)	However, for the metabolite DE-535 pyridinol the reliable field DT50 value (geometric mean normalised to temperature alone = 63 days) derived with the SFO model using the simple two-step model should be used in place of the value obtained with the full metabolic scheme where a "ghost" compartment has been introduced.	 However, pyridinol does not come directly from parent, but from the phenol and so EFSA's suggestion does not reflect the proposed degradation pathway. RMS: Please see our comments to point 4(4) above.	be used in FOCUS modeling.
4(6)	Vol.3, B8 (June 2008 & March 2009) Rate of degradation (lab & field)	FR: Globally, the kinetic analyses are very well explained. Could you just report the kinetic parameters (alpha and beta) for the DT50 calculated with a FOMC model (laboratory and field studies) both in the addenda of June 2008 and March 2009 please?	DAS: The kinetic parameters for the FOMC model for haloxyfop-R are shown in report GHE-P-11491 (Appendix 4) and in report 081098.02 (Results and Discussion section from p.18) for lab and field, respectively. RMS: If the addenda should be revised, we will insert the requested data.	Open point: 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.
4(7)	Vol.3, B8 (June 2008) Field studies p.23	FR: The Q10 value is not specified. It is expected it is 2.2, but could the RMS confirm this please?	DAS: The Q10 value used throughout was 2.2. RMS: We can confirm the use of a Q10 at 2.2.	Addressed.

Route and rate of degradation in soil (B.8.1)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier (DAS)	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(8)	Vol.3, B8 (June 2008 & March 2009) Field studies	FR: We wonder why the last field study (Balluff, 2008) summarized in the addendum of June 2008 is not used to derive DT50 values. Did the notifier give an explanation for this?	DAS: The primary aim of the field study (Balluff, 2008) was to investigate whether the metabolites (especially the pyridinone) were formed under realistic field conditions in a targeted approach. If any were found at an appreciable level (which is clearly not the case, indeed the pyridinone was only sporadically found in one trial and always <LOQ, i.e. <5% of applied), then kinetics would have been attempted. RMS: We can refer to the aim of the study as mentioned by the Notifier above. The very sparse detections/low concentrations of the phenol and pyridinone mean that the data is not sufficient to derive DT50 values. On the other hand, as mentioned in Addendum Annex B8 June 2008 page 22 (reviewer's assessment), the determination of degradation kinetics could provide further information, at least for DE-535-acid and DE-535-pyridinol. It is assessed that the levels of these two compounds are	Addressed.

Route and rate of degradation in soil (B.8.1)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier (DAS)	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			comparable with other field studies.	

Adsorption,desroptionand mobility in soil (B.8.2)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier (DAS)	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
	No comments			

PEC in soil (B.8.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier (DAS)	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(9)	Vol.3, B8 (June 2008 & March 2009) PECsoil	FR: As stated in the evaluation table rev 2-1 (19.06.2006), PECsoil and PECaccu have to be updated using the longest field DT50 and taking into account the type of kinetic in the calculation.	DAS: The EFSA Scientific report clearly stated in the text and in the list of endpoints (page 76, footnote 1) that no new calculations are required as no risk was identified for terrestrial organisms with the initial PEC soil. Therefore DAS did not provide revised calculations. RMS: No comments.	Addressed.

Fate and behaviour in water and impact on water treatment procedures (B.8.4-B.8.5)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
	No comments			

PEC in surface water and in ground water (B.8.6)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier (DAS)	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(10)	B.8.6 Predicted environmental concentrations in groundwater PECgw) (ANNEX IIIA 9.2.3)	NL: Why follow the route of complex FOCUS Degradation Kinetics modelling for PECgw metabolites when also non-relevance can be shown?	DAS: DAS agrees that the metabolites should be considered non-relevant due to their low level formation in field conditions, particularly for the pyridinone. In today's regulatory environment, much weight is placed upon theoretical groundwater modelling. It would be desirable to see a weight of evidence approach with as much consideration given to the more realistic, higher tier studies as to the modelling. RMS: No comments.	See open point (b) under comment 4(19).

PEC in surface water and in ground water (B.8.6)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier (DAS)	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(11)	Vol. 3 B.8.6.1 PECgw, input parameters, p. 32, DT50 DE-535 acid Appendix 1, revised LoEP, PECgw (March 2009)	EFSA: It is not clear the origin of the FOMC DT50(field) value of 30.9 days, as in Table B8.1.2.3/09 the reported geometric mean normalised to temperature alone is 30.2 days.	DAS: An FOMC DT50(field) of 30.9 days was used in the gw modelling for parent alone. However, it is accepted that this is an error, and that 30.2 days is the correct value. But this has little or no impact on the overall assessment as this is worst case. RMS: We will mention this with a note in the LoEP.	See open point in comment 4(12).

PEC in surface water and in ground water (B.8.6)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier (DAS)	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(12)	Vol.3, B8 (June 2008 & March 2009) PECgw	FR: We do not really understand why the DT90FOMC/3.32 values are not used for the parent when metabolites are included in the degradation scheme. As the FOMC kinetics give better fit for the parent, we would have used the SFO-back value.	DAS: In determining the degradation kinetics, formation fractions and appropriate metabolic profile, the kinetic assessment at both lab and field scales used SFO kinetics for parent as the starting point. Therefore, this approach for consistency should be adopted in the groundwater assessment as recommended by the FOCUS kinetics guidance (Section 8.3.3.1, p.131). However, it is considered that should the DT90FOMC/3.32 have been used for parent in the scheme that includes metabolites that it would actually not make any significant change. This is because the "back calculated" DT50 values are not too dissimilar to the SFO DT50 values (23.5 versus 9.2 d for lab, and 30.9 versus 12.2 d for field). RMS: We will refer to our general comments to the modelling: point 4(4).	Open point: MS to discuss in a meeting of experts the appropriate soilDT50 for the "parent" compound to be used in FOCUS modeling. See also comment 4(11)

PEC in surface water and in ground water (B.8.6)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier (DAS)	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(13)	Vol.3, B8 (June 2008 & march 2009) PECgw	FR: The scheme of application used in the simulation for sugar beets and oilseed rape is not very clear. It is reported “each use was investigated as two consecutive annual applications in every three year period”. Usually, this means that 2 applications are done on year 1, then there is no application on year 2 and 3. But this is not consistent with the GAP (1 application max). Please, could you give some more details on this point? Were the simulations performed with applications every three years in order to get lower PECgw? Does it correspond to the intended agronomic practice for all uses? (in the addendum of April 2005, the agronomic practice was reported to be 1 application every other year). Either the frequency of application really assessed should be mentioned in the GAP, or the scenario used to calculate PECgw should properly describe the intended uses.	DAS: The GAP in the simulations for both oilseed rape and sugar beet was one application in year 1, one application in year 2 and no application in year 3. This reflects agronomic practice since it is expected that cereals would be part of the crop rotation programme (at least once in every 3 years), and since haloxyfop is not used on cereals then no application in year 3 is considered realistic. RMS: We will ensure that the assessed application frequency is in accordance with the one mentioned in the GAP table including a specific restriction on use.	Addressed.

PEC in surface water and in ground water (B.8.6)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier (DAS)	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(14)	B.8.6 Predicted environmental concentrations in groundwater PECgw (ANNEX IIIA 9.2.3)	NL: Application in 2 out of 3 years is used in modelling. However this is not mentioned in the GAP-tabel, which should be the basis for the modelling. Moreover this is not common agricultural practice for oil seed rape. Is this restriction the result of the groundwater modelling? If so, a specific restriction on use should be included in the GAP table.	DAS: The regime of an application in years 1 and 2, but none in year 3 reflects agronomic practice. This is because it is expected that cereals would be part of the normal crop rotation programme (at least once in every 3 years), and haloxyfop is not used on cereals. Therefore, it cannot be used year on year. This could be reflected in the GAP table. RMS: Please see our comment to point 4(13) above.	Addressed.
4(15)	Vol.3, B8 (June 2008) PECgw p.48	FR: The RMS reports that no correction for moisture was done for the lab values, but as this correction would have shortened the DT50s, the un-normalised DT50s can be considered more conservative. We do not fully agree with this statement. We agree that it can be considered as more conservative for the parent. Nevertheless, when metabolites are also assessed, it is difficult to determine whether it will be more conservative or not. However in this case, it will not change the results of	DAS: The notifier agrees and further wishes to reiterate the conservative nature of the leaching assessment when taken in context with the field data (4(4)). RMS: We agree with the comment from France.	Addressed.

PEC in surface water and in ground water (B.8.6)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier (DAS)	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
		the risk assessment providing that the Tier 2 with the use of the field DT50 for the parent is accepted.		
4(16)	Vol.3, B8 (June 2008 & march 2009) PECgw	FR: It seems the FOCUS default value of 0.5 for the plant uptake factor was used for the parent and all its metabolites. The parent/DE-535 acid is known to be systemic. Nevertheless, it is assumed that no data is available for the other metabolites. Then, we would have used a plant uptake factor of 0 for these metabolites.	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 the modelling introduced at 4(25). Several succeeding crop studies have been undertaken, and reported in the DAR (Annex II, 6.6). Due to the low levels detected in the crops, and the techniques available when the studies were conducted, further characterisation was not successful. RMS: The proposal from France seems reasonable. Please see the comments on 4(25).	Open point: MS to discuss in a meeting of experts the appropriate plant uptake factor used in FOCUS modelling for metabolites.

PEC in surface water and in ground water (B.8.6)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier (DAS)	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(17)	Vol.3, B8 (June 2008 & March 2009) PECgw	FR: All field studies were conducted in Northern Europe, whereas some uses are sustained for Southern Europe. Then, we are not convinced that these field DT50 values should be used for the Southern uses. At least an argumentation explaining why the field DT50 are considered to be extrapolated to the Southern states should be provided by the notifier.	DAS: Since the day-lengths were subsequently normalised to reference temperature conditions for further use in kinetic and groundwater modelling, then any climatic differences are essentially removed. RMS: We will refer to the explanation from Notifier.	Addressed.

PEC in surface water and in ground water (B.8.6)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier (DAS)	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(18)	Vol.3, B8 (March 2009) PECgw	FR: In the addendum of March 2009, field DT50 used for the PECgw calculation were normalised for temperature only. Then, we think that the routine for moisture correction should be disabled in the models.	DAS: The field DT50 values for parent and the pyridinol used for the PECgw calculation were normalised for temperature only. The notifier subsequently ran the higher tier leaching assessment with a moisture exponent of 0.7 enabled in the models. However, for parent and the pyridinol metabolite, it could be considered more appropriate to switch this routine off (= 0). This has been included, along with other proposals to modify input parameters, in the modelling introduced at 4(25). RMS: The French proposal sounds reasonable. Please see comment on 4(25).	Addressed.
4(19)	B.8.1.2.1 Laboratory studies - FOCUS kinetic modelling of degradation rates B.8.1.2.2 Field studies	NL: The conceptual model is not in agreement with the degradation scheme presented in the original DAR and on page 4 of the additional raport. In the degradation scheme it can be seen that the degradation route is not linear as was assumed in the chosen conceptual model. DE-535 pyridinone is formed also directly from DE-535	DAS: The degradation of haloxyfop-R is complex and a definitive degradation scheme, particularly where low level metabolites are formed, will be difficult to determine with absolute certainty. However, in consideration of the metabolite structures, it would seem unlikely that the pyridinone would form directly from DE-535 acid, and the	Open point (a) 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 also comments 4(21), 4(22), 4(23). Open point (b)

PEC in surface water and in ground water (B.8.6)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier (DAS)	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
		acid. This last route is missing in the conceptual model. Further discussion amongst experts is considered required	scheme subsequently derived by the notifier and used in the kinetic and groundwater assessment would seem more realistic. See also the comments in 4(4). RMS: Please see the comment in point 4(4).	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 also comments 4(21), 4(22).
4(20)	B.8.1.2.1 Laboratory studies - FOCUS kinetic modelling of degradation rates Table B8.1.2.1/03 (SFO) and 8.1.2.1/04 (FOMC)	NL: p values for the fits are missing, could these please be included	RMS: If the addenda shall be revised we will insert the requested data.	Open point: RMS to provide the p values for the fits of the kinetic modelling of laboratory degradation rates.
4(21)	B.8.1.2.1 Laboratory studies - FOCUS kinetic modelling of degradation rates B.8.1.2.2 Field studies	NL: Regarding the disapproval of the conceptual model the derivation of the degradation parameters is questionable.	DAS: No specific comment, but see general comments in 4(4) RMS: Please see our general comments on point 4(4).	See open points in comment 4(19).
4(22)	B.8.1.2.1 Laboratory studies - FOCUS kinetic modelling of degradation rates B.8.1.2.2 Field studies	NL: a DT50 for a plateauing metabolite can not be used in modelling due to the fact that no decline is observed and as a consequence no reliable value can be derived..	DAS: No specific comment, but see general comments in 4(4) RMS: Please see our general comments on point 4(4).	See open points in comment 4(19).

PEC in surface water and in ground water (B.8.6)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier (DAS)	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(23)	B.8.1.2.1 Laboratory studies - FOCUS kinetic modelling of degradation rates	NL: it is stated on page 17 that 'As ca. 75% of the decline was well described in the Marcham sandy loam soil the determinations for the metabolite in this soil are considered acceptable for use in modelling.'. Overall the degradation is under-estimated by the predicted residues, resulting in a best-case situation for modelling.	DAS: This comment refers to the phenol metabolite, where the DT50 was very short, 3-4 days. The modelling results were all <0.001 µg/L, so even if the degradation is under-estimated in this case, it is very unlikely that a concentration of 0.1 µg/L will be exceeded. RMS: We agree with NOT if we have understood the question correct.	See open point a) in comment 4(19).
4(24)	LoEP; field-DT50 parent	NL: in the LoEP it is stated that normalisation was only undertaken for temperature. However, the time step normalisation includes a moisture correction (f moisture in Tables B8.1.2.3/01 to 07).	DAS: See 4(18) RMS: We will refer to our comments on 4(18).	Addressed.
4(25)	Vol. 3 B.8.6.1 PECgw, input parameters, Freundlich exponent Appendix 1, revised LoEP, PECgw (March 2009)	EFSA: As already agreed in previous experts' meetings in the environmental fate and behaviour where only $K_d$oc is available a Freundlich exponent 1/n of 1 should be used in simulations.	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	Open point: 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 also comment 4(26).

PEC in surface water and in ground water (B.8.6)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier (DAS)	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			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. However, although DAS strongly believe enough data has been provided to determine that metabolites are not present under practical use conditions, the consequences have been evaluated with additional modelling, which also takes into account the points raise by FR in 4(16) and 4(18) (Reeves, 2009, GHE-P-12088). The modelling used a measured Kfoc and 1/n values for parent but with a 1/n =1 for the metabolites (rather than 0.9). In addition, the plant uptake factor for the metabolites was set to 0 and the moisture correction was set at 0. Apart from the rate, the degradation pathway and other input parameters remained as in the modelling provided in the March 2009 Additional Report. DAS has generated data to demonstrate the relevance of the pyridinol and pyridinone metabolites up to a	

PEC in surface water and in ground water (B.8.6)				
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			concentration of 0.75 µg/L. In order to remain below this concentration, rates of 52g/ha in autumn and 38 g/ha in spring were modelled. The results for the autumn application are summarised below. Haloxyfop-R, the phenol and ghost metabolites are < 0.1 µg/L. Concentrations <0.75 µg/L are predicted for the pyridinol and pyridinone metabolites. Similar results were obtained for the spring application at 38 g/ha. 52 g/ha in the autumn is the commercial rate for annual weds and volunteer cereals, and is included in the GAP provided in Document D. 38 g/ha in spring is not a label rate. In this case, DAS can demonstrate a safe use for a commercial application. RMS: It is correct that PRAPeR 32 for reasons of safety decided to use a Freundlich exponent 1/n equal to 1.0. We understand the frustrated feeling of	

PEC in surface water and in ground water (B.8.6)				
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			the Notifier. It can be mentioned that the Freundlich constant K_f and the exponent 1/n has been determined for the active ingredient, but it is not peer reviewed. The new modelling take account for the comments 4(16) (setting the plant uptake factor equal to 0, 4(18) (disabling of moisture correction) and 4(25) (setting 1/n equal to 0). The new modelling has not been evaluated by RMS. RMS finds that this point should be discussed at an Expert Meeting.	

PEC_{GW}: Oilseed Rape (Winter), Higher Tier, 54 g/ha

Scenario	80th Percentile PEC_{GW} (µg/L) at 1 m Depth								
	Cha	Ham	Jok	Kre	Oke	Pia	Por	Sev	Thi
FOCUSPELMO									
Haloxyfop-R	<0.001	<0.001	-	<0.001	<0.001	<0.001	<0.001	-	-
Phenol	<0.001	<0.001	-	<0.001	<0.001	<0.001	<0.001	-	-
"Ghost"	0.012	0.020	-	0.015	0.021	0.012	0.006	-	-
Pyridinol	0.109	0.190	-	0.154	0.196	0.132	0.043	-	-
Pyridinone	0.690	0.713	-	0.576	0.450	0.508	0.263	-	-
FOCUSPEARL									
Haloxyfop-R	<0.001	<0.001	-	<0.001	<0.001	<0.001	<0.001	-	-
Phenol	<0.001	<0.001	-	<0.001	<0.001	<0.001	<0.001	-	-
"Ghost"	0.012	0.018	-	0.013	0.019	0.011	0.004	-	-
Pyridinol	0.139	0.188	-	0.149	0.197	0.147	0.050	-	-
Pyridinone	0.648	0.598	-	0.443	0.402	0.427	0.220	-	-

- *no FOCUS location for this crop*

PECGW: Sugar Beet, Higher Tier, 38 g/ha

Scenario	80th Percentile PEC_{GW} (µg/L) at 1 m Depth								
	Cha	Ham	Jok	Kre	Oke	Pia	Por	Sev	Thi
FOCUSPELMO									
Haloxyfop-R	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
Phenol	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001

"Ghost"	0.014	0.017	0.010	0.012	0.014	0.012	0.001	0.002	0.004
Pyridinol	0.153	0.143	0.074	0.122	0.121	0.143	0.005	0.012	0.040
Pyridinone	0.662	0.696	0.611	0.598	0.544	0.502	0.187	0.326	0.521
FOCUSPEARL									
Haloxyfop-R	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
Phenol	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
"Ghost"	0.017	0.017	0.014	0.012	0.013	0.012	0.002	0.006	0.007
Pyridinol	0.194	0.193	0.142	0.138	0.151	0.152	0.019	0.082	0.082
Pyridinone	0.539	0.642	0.584	0.447	0.435	0.361	0.191	0.425	0.375

4(26)	Vol.3, B8 (June 2008 & march 2009) PECgw	FR: In both addenda (June 2008 and March 2009), a default value of 0.9 for the Freundlich parameter 1/n is used. All the values of Koc are K**d**oc values. It was agreed in PRAPeR that when only a Kd is determined, FOCUS modelling simulations should be carried out using a 1/n value of 1 (see General Report from PRAPeR 32). As this parameter is known to have a strong influence on the results and there is no safety margin for PECgw of some metabolites, we think the simulations should be updated.	DAS: See 4(25) RMS: Please see our comments to 4(25).	See open point in comment 4(25).
4(27)	LoEP (March 2009) PECgw	FR: Please, could you add in the LoEP the values of the Freundlich parameter 1/n used in the models?	RMS: Off course.	Open point: RMS to include in the LoEP the values of the Freundlich parameter 1/n used in the FOCUS model.

4(28)	Vol.3, B8 (June 2008 & March 2009) PECgw	FR: For the "ghost compartment", a Koc value of 30.8 mL/g was used, as it was the worst-case value from all components modelled. It is reported as a worst-case compared to the QSAR value of 1390 mg/L obtained for DE-535 methoxypyridine, which is supposed to correspond to the ghost compartment. We are not convinced the use of a low Koc in the ghost compartment is a worst-case for DE-535 pyridinone. Indeed, according to the degradation scheme employed, we can think that with a high Koc, the substance will less leach, and so will be more available for its degradation in DE-535 pyridinone. Nevertheless, in this case, we think it can be acceptable as the formation fraction leading to the ghost compartment is only 0.073.	DAS: Agree with pragmatic approach, especially since the formation fraction for the ghost compartment is very low. RMS: We generally agree with the France comment - and it's correct that the formation percent is low.	Open point: 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.
4(29)	Vol.3, B8 (March 2009) PECgw	FR: We agree that the 1/n of 0.752 coming from the study of Woodburn & Richards (1988) cannot be used in the assessment as it was not submitted by the notifier and so could not be assessed by the RMS.	RMS: We agree that the assessment in principle have to be peer reviewed before use.	Addressed.

4(30)	Vol. 3 B.8.6.1 PECgw Appendix 1, revised LoEP, PECgw (March 2009)	EFSA: The EFSA noted that, generally, the simulations performed with FOCUS PEARL resulted in PECgw values higher than those obtained with FOCUS PELMO, with the unique exception of the results for metabolite DE-535 pyridinone in the scenario with OSR. Is there any possible explanation for this deviation?	DAS: No explanation can be given for these differences in the model. RMS: Interesting comment, but we have no explanation at the moment.	Addressed.
4(31)	Vol.3, B8 (June 2008 & March 2009) PECgw p.33	FR: On page 33 of the addendum of March 2009, it is reported that some adjustments were necessary in PEARL and PELMO to allow the models to run 2 applications every three years. These adjustments are not specified. If it is the case, could you also specify the ratio which was used?	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	Open point: 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.

			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 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. Appendix III of GHE-P-11899 provides an example. Please also refer to the comments in 4(13) and 4(14), RMS: Thanks for the explanation. If accepted by France (and all others) we recommend closing this point. Else it could be discussed on an Experts Meeting.	
4(32)	Vol. 3 B.8.6.2 PECsw for DE-535 furan	EFSA: Specific data for the precursor DE-535 acid used in the FOCUS Steps 1-2 calculations should be provided. In addition, it is not clear to which crop the results presented in Table B.8.6.2.2 on p. 44 of Annex 1 to Addendum are referred to. Finally, while commenting the additional report for the re-assessment for Annex 1 inclusion of haloxyfop-P (haloxyfop-R), the EFSA noted that another	DAS: The methodology used to derive a PECSW for the furan metabolite at FOCUS Steps 1 and 2 is given in the attached document which was provided to the RMS and should supersede the original calculation given in the DAR. It should be noted that this assessment was based on a parent rate of 104 g ae/ha, and that this metabolite PECSW will reduce by half in consideration of the lower rate	Open point (a): RMS to provide sSpecific 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. Open point (b): MS to discuss in a meeting of experts the need for further assessment of DE-535-acid-furan, a metabolite with

		metabolite with dibenzofuran “like” (not polychlorinated) structure was measured in the irradiated samples of the photodegradation study in natural water (i.e. DE-535-acid-furan at max. 8.4% AR at 4.8d, refer to table B.8.4.2/01-7, on p. 111 of the original DAR). An assessment of this metabolite should have been provided as well.	modelled for groundwater of 52 g ae/ha for oilseed rape (see 4(25)). *(The embedded document 'furan PECsw' has been removed by EFSA for procedural and confidentiality reasons)*. 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: The attached document regarding the DE-535-furan has been presented and evaluated on page 42-45 in Annex 1 to Addendum (March 2009) and the initial max concentration at 0.0627 µg/L has been accepted. It is correct that it is not clear to which crop the results presented in the table are referred to - RMS finds that it is the	dibenzofuran “like” (not polychlorinated) structure which was measured in the irradiated samples of the photodegradation study in natural water.

			worst case of the two modelled crops; wOSR and sugar beets. Regarding the DE-535-acid-furan we find that it is a very late time point to raise the question as this was not mentioned as an outstanding point in the EFSA Conclusion Report - Therefore, we have no comments in the moment. Please also refer to 5(9) and 5(10) in the ecotox section.	
4(33)	Appendix 1, LoEP, PECsw for DE-535 furan	EFSA: The new PECsw calculations provided in Annex 1 to Addendum to Annex B8 Fate and Behaviour (March 2009) should be reported in the LoEP.	RMS: Correct, we will do it.	Open point: 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).

4(34)	Vol.3, B8 (June 2008 & march 2009) PECgw	FR: Please, justify why some uses are not assessed (in particular carrots and fodder legumes).	DAS: Oilseed rape and sugar beet are supported in the Annex I resubmission and are considered to represent realistic worst case crops for autumn and spring applications, respectively, and so other crops were not specifically addressed by in the modelling. Fodder legumes and carrots earliest application will be at approximately the same seasonal timing as sugar beet (April). The growth stage at the earliest application will be BBCH 13-14 for fodder legumes and carrot, with similar crop coverage as sugar beet (25% as opposed to 20% for sugar beet). Therefore, it is considered that the sugar beet assessment is representative. Additionally, during a previous national approval (DE) this point was made when rejecting a late spring applied lysimeter study and the national agency considered the early spring application to represent a worst case. RMS: Agree with the explanation from NOT.	Addressed.

4(35)	Appendix 1, LoEP, PECgw	EFSA: For reason of transparency, also results for the ghost compartment as indicated in Table B.8.6.1/02 on p. 33 of the Annex 1 to Addendum, should be reported.	RMS: Correct, we will do it.	Open point: 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.
4(36)	Vol.3, B8 (June 2008 & march 2009) PECsw	FR: We think all PECsw should have been updated using the FOCUS steps usually used.	DAS: The resubmission focussed only on areas where issues were highlighted in the original Annex I submission, as specified in Commission Regulation 33/2008 Article 13 (2)(b). PECsw was not raised as on outstanding data requirement in the EFSA Scientific Report or the COMM Review Report. RMS: Agree with the comment from Notifier. It was the conclusion from PRAPeR 32.	Addressed.
4(37)	B.8.6 Predicted environmental concentrations in surface water and in groundwater (PECsw, PECgw) (Annex IIIA.9.2.1; Annex IIIA 9.2.3)	NL: Regarding the disapproval of the conceptual model and the fact that the ghost compartment is included in the simulation model, the derivation of the degradation parameters is questionable and therefore the modelling should be redone.	DAS: No additional comments, please see comments in 4(4). RMS: We will too refer to our comments in 4(4).	Open point: 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 also comments 4(5), 4(12), 4(19)

Fate and behaviour in air and PEC in air (B.8.7-8.8)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
	No comments			

Definition of the residues (B.8.9)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)

Definition of the residues (B.8.9)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(38)	Vol.3, B8 (June 2008 & March 2009) Residue definition Rapporteur: Denmark	FR: We thought that all major metabolites, minor non-transient metabolites, metabolites which do not achieve their maximum at the end of the soil degradation studies and metabolites found in lysimeter studies at annual average concentrations exceeding 0.1 µg/l in the leachate had to be reported in the residue definition for groundwater. If it is the case, metabolite DE-535 phenol should be added to this definition.	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 RMS: We agree with the comment from France and with the answer from NOT.	Open point: MS to discuss in a meeting of experts the environmental occurring metabolites requiring further assessment by other disciplines (tox and ecotox).

Other comments				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
	No comments			

5. Ecotoxicology

Birds and mammals (B.9.1 and B.9.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier (DAS)	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(1)	B.9.1.8.1 Risks to birds from exposure via drinking water	EFSA (April /09): EFSA noted that RMS proposed to assess the risk to birds form the consumption of contaminated water the Guidance Document SANCO/4145/2000. However, EFSA consider usually are not necessary that the short-term risk assessment was done.	DAS: Agreed. No objection to deleting the short-term assessment for drinking water. We included this as it was cited in the ESFA conclusion report as a data gap! RMS: We agreed to the comments from both EFSA and Notifier.	RMS proposes to close this point. Point closed. (Pendiente d la informacion q tengamos si se necesita una addendum entonces dejariamos el punto abierto).

Birds and mammals (B.9.1 and B.9.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier (DAS)	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(2)	Vol. 3, B.9.1.8.1, Risks to birds from exposure via drinking water	FR: Exposure estimates in drinking water were calculated by dividing the spray concentration by a dilution factor of 5, according to the Guidance Document SANCO/4145/2000, point 4.4. A more recent approach for estimation of exposure via drinking water was recently proposed by the PPR Panel in its opinion on the science behind the Guidance Document on risk assessment for birds and mammals. Considering the scenario of birds drinking in puddles would result in more realistic TER values, although not changing the outcome of the risk assessment. See the EFSA journal (2008) 734, 103-181	DAS: The Notifier is aware of the proposed revisions to the drinking water risk assessment, as presented in the EFSA Opinion, but does not believe that this document has formally replaced the SANCO/4145/2000 Guidance Document. Consequently, the Notifier sees no reason to deviate from this guidance, especially since the new proposals do not change the outcome of the assessment. RMS: We agreed with the comments from both France and Notifier – The fact that it will not change the outcome of the risk assessment means that there is no reason to change at this late time point.	Point closed
5(3)	B.9.3.2.1 Refined of the long-term risk for mammals.	EFSA agreed with the focal species selected (*Lepus europeans*) PD=0.2 for sugar beets, field peas and field beans in spring, and of 0.4 for oilseed proposed by the RMS for the refined of the long term risk for the small herbivorous mammals. However,	DAS: Unpalatable glucosinulates develop in rape seedlings about 1 month after germination, whereas Haloxyfop is applied at BBCH 10-19, i.e. typically 42 days after germination. Consequently, exposure for hares would be low in terms of both	Open point 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

Birds and mammals (B.9.1 and B.9.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier (DAS)	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
		taking into account the agreement of the experts at the EPCO 22 meeting on the use of NOAEL > 1 mg a.s. /Kg bw /day, as endpoint for the chronic risk assessment to mammals. EFSA has some concern to use a different value rather that than this.	contamination levels and duration at this time of year. Consequently, although a PD of 0.4 might be a reasonable estimate for early OSR seedlings, it is likely to be grossly exaggerated for Haloxyfop-treated mature seedlings in autumn. If it is accepted that the actual PD for treated seedlings is significantly lower (essentially zero), i.e. the animals are not likely to eat the treated seedlings, there would be no need to consider a different NOAEL to the one agreed at EPCO 22. RMS: We still find 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. The conclusion of the EPCO 22 meeting was to use the NOAEL > 1 mg as/kg bw/day as a reproduction end point. If there is no reproduction at the application time point another it seems meaningless to use that end point. Please see our comments to 5(4), too.	long-term risk for the herbivorous mammals.

Birds and mammals (B.9.1 and B.9.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier (DAS)	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(4)	B.9.3 Refined risk assessment herbivorous mammal, proposed refinement of NOAEL	NL: *'For autumn applications, however, reproductive endpoints are not particularly relevant, as this timing coincides with the end of the breeding season for hares (i.e. September/October, KEMI, 2006).'* Is this true for all MS, even in S-EU?	DAS: We agree that breeding in hares would likely continue (albeit to a lesser extent) throughout the year in southern MSs. However, the exposure at this time of year would be limited and highly transient due to the unpalatable nature of seedling OSR. Unpalatable glucosinulates develop in rape seedlings about 1 month after germination, whereas Haloxyfop is applied at BBCH 10-19, i.e. typically 42 days after germination. Consequently, exposure for hares would be low in terms of both contamination levels and duration. Under these circumstances, a long-term risk to hares is not envisaged. RMS: We agree with NOT. Many rodents are able to in a certain degree to continue the breeding season I the fall in Southern Europe. We still find that oil seed rape at the time point of fall application is very less attractive for the hare. It could be up to the member states to make the final assessment and decision.	See open point 5(3)

Birds and mammals (B.9.1 and B.9.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier (DAS)	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(5)	Vol. 3, B.9.3.2.2, Risk to mammals from exposure via drinking water	FR: See 5(2) regarding the risk to birds from exposure via drinking water	DAS: See 5(2) RMS: please refer to our comments on point 5(2).	Point closed
5(6)	Vol. 3, B.9.3.2. Refined chronic risk of haloxyfop-R to herbivorous mammals	FR: The crop-specific TERlt have been refined using published information on the diet and the crop use of a relevant focal species for the treated crops, the brown hare. The proposed PD values of 0.2 for sugar beets, field peas and field beans in spring, and of 0.4 for oilseed rape in autumn are consistent with other available published information on the brown hare. We agree with RMS that the long-term risk to herbivorous mammals is acceptable.	DAS: no further comment RMS: Thanks for this information.	Point closed
5(7)	Vol. 3, B.9.3.2 Risk assessment for mammals	FR: We wonder if the long term risk to insectivorous mammal has been sufficiently addressed. Indeed, in the table 9.3.2.1.2 of the DAR, a TER value of 5.7 was found in Tier 1, thought using the NOAEL of 2 mg a.s./kg bw/d. According to the EPCO expert meeting conclusions, the NOAEL of 1 mg a.s./kg bw/d should be used for risk assessment (with exception for	DAS: The EFSA Scientific Report concluded a safe use for such species. However, insectivorous 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	Open point 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.

Birds and mammals (B.9.1 and B.9.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier (DAS)	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
		autumnal applications on oilseed rape). This would lead to a TERlt < 5 for insectivorous mammals in Tier 1. Further refinement of the risk assessment for insectivorous mammals is needed. The insectivorous mammal scenario is not a standard scenario for leafy crop according to the Guidance Document SANCO/4145/2000, because it is considered to be covered by the herbivorous scenario in Tier 1. However, as the Tier 1 calculation resulted in TERlt values < 5 for herbivorous, the insectivorous mammals can no more considered covered by herbivorous and the risk to insectivorous has to be addressed. The refinement step proposed for herbivorous mammals in the additional report is based on the use of information on a focal species. This can not apply for refinement of long term risk for insectivorous mammals.	sufficient cover from predation and where ground-dwelling invertebrates are more plentiful. If a hypothetical tier 1 risk assessment were to be conducted, 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 for shorter exposure times 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 these species.	

Birds and mammals (B.9.1 and B.9.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier (DAS)	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			RMS: We understand the concern raised by France. On the other hand the risk assessment presented in the DAR was accepted in the EFSA Conclusion Report. Making a new risk assessment using the conservative NOAEL of 1 mg a.s./kg bw/d together with a refined PT would probably give a TERlt on the safe side of the trigger value.	

Aquatic organisms (B. 9.2)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier (DAS)	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(8)	B.9.2. Effects on aquatic organisms. Studies on toxicity of the phenol and pyrinone metabolite to aquatic organims (page 5-35)	EFSA: 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.	DAS: Agreed. No objection to this clarification RMS: This is obvious an error that should be corrected.	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.

Rapporteur: Denmark

Aquatic organisms (B. 9.2)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier (DAS)	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(9)	B.9.2.1.1 the ecotoxicological relevance of DE-535 Furan .	EFSA noted that not additional information was submitted to assess the ecotoxicological relevance of the DE-535 furan.	DAS: The Notifier agrees with the conclusion of the RMS, based on a recalculation of the PEC and the adoption of the Guidance Document recommended approach of assuming the metabolite is at most 10-times more toxic than the parent. According to this assessment, the TER for the furan metabolite exceeds the Annex VI trigger of 100, indicating low risk for aquatic organisms. RMS: It is correct that no additional information on the ecotoxicological relevance has been submitted, but a refined PECsw was done (please see the comment in 5(10), too.	Point closed
5(10)	Vol. 3, B.9.2.1.1, The ecotoxicological relevance of the aqueous photolysis metabolite DE-535 furan	FR: We agree with the conclusions of the RMS concerning the risk assessment for the metabolite DE-535 furan, which is based on more realistic PECsw obtained by FOCUS modelling.	DAS: No further comment RMS: Thanks, we take this *ad notam*.	Point closed

Aquatic organisms (B. 9.2)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier (DAS)	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(11)	Vol. 3, B.9.2.1.3, Risk assessment to aquatic organisms	FR: Referring to the French comment on PECsw in the e-fate section, the TER values for aquatic organisms should be re-calculated using PECsw obtained by Focus modelling.	DAS: See 4(36). The resubmission focussed only on areas where issues were highlighted in the original Annex I submission, as specified in Commission Regulation 33/2008 Article 13 (2)(b). PECsw was not raised as on outstanding data requirement in the EFSA Scientific Report or the COMM Review Report. Consequently, the risk assessment has not been repeated. Additionally, in the previous risk assessment, TER's of approx 70 for the most sensitive species were estimated, using a PEC of 0.4 µg/L and an additional safety factor of 10. With the new calculation of PECsw of 0.0627 µg/L, the TER will be in excess of 100, and further re-calculation for all species is not required. RMS: We agree that a new calculation of PECsw was not mentioned as a requirement in the EFSA Conclusion Report.	Point Closed

Bees and non-target arthropods (B. 9.4 and B.9.5)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
	No comments			

Earthworms and other soil non-target organisms (macro and micro) (B. 9.6, B.9.7 and B.9.8)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier (DAS)	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(12)	Vol. 3, B.9.6.5, Risk assessment for earthworms	FR: Referring to the French comment on PECsoil in the e-fate section, the TER should be re-calculated for the parent and the metabolites using updated PECsoil and PECaccu.	DAS: See 4(9): The EFSA Scientific report clearly stated in the text and in the list of endpoints (page 76, footnote 1) that no new calculations are required as no risk was identified for terrestrial organisms with the initial PEC soil. Therefore DAS did not provide revised calculations, and did not repeat the risk assessment RMS: Agree that a recalculation not was required in the EFSA Conclusion Report. Please se point 4(9).	Point Closed
5(13)	B.9.6.5	NL: What is the Log Pow for the metabolites? Is correction not required? Note that if correction is necessary, the long-term TER for pyridinol could be < 5.	DAS: The Log Pow for the pyridinol metabolite is <2 in a range of pHs, therefore no correction is required. These data were submitted in the original dossier (IIA Point 2)	Point closed.

Other non-target organisms (flora and fauna), sewage treatment (B.9.9 and B.9.10)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier (DAS)	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(14)	Vol. 3, B.9.9, Risk assessment for non-target organisms (flora and fauna)	DE: The results of the newly provided studies (see B.9) according to the presented risk assessment did not show a risk except for plants. However, it is not clear why the application in weed (grasses) over 0.5 m height was assessed. To our understanding only early applications shortly after emergence of weed are common practise. A differentiation of height of weeds is not indicated in the list of intended uses.	DAS: Agreed. The risk assessment for field crops >50 cm high is not relevant for this application RMS: Risk assessment for crops > 50 cm is not relevant and will be deleted in the List of End Points.	Point for clarification RMS should delete the risk assessment for field crops > 50 cm in the list of endpoints.

Other non-target organisms (flora and fauna), sewage treatment (B.9.9 and B.9.10)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier (DAS)	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(15)	B.9.9.2	NL: The risk assessment for non-target plants is confusing. Only data for vegetative vigour is available. At least a statement for seedling emergence should be expected. Furthermore, it is not clear if exposure assessment with spray drift was taken into account. The exposure would be 104 g a.s./ha * 2.77% drift (< 50 cm) or * 8.02% drift, resulting in PECs of 2.88 g a.s./ha and 8.34 g a.s./ha. TERs would be 6.9 and 2.37. This should be the initial assessment. Additional bufferzones for crops >50 cm could be proposed. Please include TERs.	DAS: An equivalent report on seedling emergence is available and has been supplied. Rockliff C. (2007): Evaluation of the Phytotoxicity of Gallant super (haloxyfop-methyl (R) 104 g ae/l EC) GLP Seedling Emergence and Seedling Growth Test Terrestrial Non Target Plant Study (Based on OECD Guideline 208). Europe 2006 Dow AgroSciences, unpublished report No. GHE-P-11555 Dow AgroSciences Study ID: 071010. Stockbridge Technology Centre study ID STC/07/E361 DAS: Agreed. TER values would be 6.9 (1 m) and 33 (5 m) for vegetative vigour and 8.5 (1 m) and 41 (5 m) for seedling emergence. RMS: The results should be included in the LoEP.	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.

Other comments				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier (DAS)	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
	No comments			