PEER REVIEW REPORT ON **TRIFLURALIN** 14 07 2009

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

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
	Section 1 Open points: ***1*** Points for clarification: ***0*** Data gaps: ***0***			Section 1 Open points: ***0*** Points for clarification: ***0*** Data gaps: ***0***
	Open point: 1.1 RMS to clarify the representative uses as under point B.7 of the Additional report to the DAR winter cereals are mentioned, while column 3 of the Evaluation table contains a contrary statement. See reporting table 1(3)	EUTTF: As previously highlighted in the Reporting Table in response to points 3(14), 3(15) and 3(16), the resubmission is for the support of oil seed crops only (See Doc D of the resubmission dossier) Cereals are not included in the resubmission action.	RMS: Indeed, as stated by EUTTF cereals are not included in the intended uses under this resubmission under Regulation 33/2008. The risk assessment initially performed in Section B.7 of the Additional Report to the DAR did indeed include these crops. However, in the updated LoEP recently submitted, the Risk Assessment as well as the MRL proposal does not include cereals any more.	Open point transferred to section 3.

2. Mammalian toxicology

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
	Section 2 Open points: ***0*** Points for clarification: ***0*** Data gaps: ***0***			

3. Residues

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
	Section 3 Open points: ***3*** Points for clarification: ***0*** Data gaps: ***0***			Section 3 Open points: ***0*** Points for clarification: ***0*** Data gaps: ***0***
	Open point: 1.1 (transferred from section 1): RMS to clarify the representative uses as under point B.7 of the Additional report to the DAR winter cereals are mentioned, while column 3 of the Evaluation table contains a contrary statement. See reporting table 1(3)	EUTTF: As previously highlighted in the Reporting Table in response to points 3(14), 3(15) and 3(16), the resubmission is for the support of oil seed crops only (See Doc D of the resubmission dossier) Cereals are not included in the resubmission action.	RMS: Indeed, as stated by EUTTF cereals are not included in the intended uses under this resubmission under Regulation 33/2008. The risk assessment initially performed in Section B.7 of the Additional Report to the DAR did indeed include these crops. However, in the updated LoEP recently submitted, the Risk Assessment as well as the MRL proposal does not include cereals any more.	PRAPeR 70 (5 – 8 May 2009): Open point transferred from section 1. Open point fulfilled.
	Open point: 3.1 It should be discussed in a meeting of experts if the metabolite TSN 028333 (TR-14) observed at a level of 0.0056 mg eq./kg (33% TRR) in rape seeds and 0.034 mg eq./kg (43% TRR) in rape forage has to be included in the plant residue definitions, the metabolism	EUTTF: When treated at the cGAP rate, residues of TSN 028333 in rape seed would be expected to be less than 0.004 mg/kg. Residues of TSN 028333 in rape seed at this level should not be considered significant and should not warrant inclusion in the plant residue definition. As for residues of TSN 028333 in rape forage (0.034 mg/kg in the NOR study), once a correction is made for	RMS: The metabolism study in oilseed rape has been performed in an excess application rate 1.5xN (1.8 kg a.s./ha). Therefore, at the intended dose rate (1.2 kg a.s./ha), metabolite TSN 028333 in seeds is not expected to be higher than the trigger value of 0.01 mg/kg. Additionally, in forage, the amount of the metabolite at 1.5XN is below 0.05 mg/kg (0.34 mg/kg) and further reduced to 0.023 mg/kg if the	PRAPeR 70 (5 – 8 May 2009): Open point fulfilled.

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
	study being performed at a 1.5N level. See reporting table 3(8)	the 1.5X application rate that was used in the NOR study, residues would be expected to be less than 0.023 mg/kg. Given the low levels at which rape forage is fed to livestock (a maximum of 10% in cattle diets, 20% in swine and 40% in sheep) along with the low transference rate of dietary residues of trifluralin-related residues into the meat and milk of ruminants, there is no reasonable expectation that residues of TSN 028333 would be observed in food products of animal origin. Thus as in the case for rape seed, there is no need to include TSN 028333 in the plant residue definition simply due to the low levels at which it might be found in forage, since these residues will not result in any significant human exposure to the metabolite.	adjustment to the expected at 1N residue level is made. Therefore, the RMS agrees with the applicant that no further toxicological assessment or inclusion of metabolite TSN028333 on the residue definition for either risk assessment or monitoring purposes is required.	
	Open point: 3.2 Depending on the final plant residue definitions (see open point 3.1), it should be considered whether the method(s) of analysis have to include the metabolite TSN 028333 free and conjugated.	EUTTF: As noted in the response to open point 3.1, residue levels of TSN 028333 in both rape seed and forage are not high enough to result in any significant exposure to humans. Thus, there should be no need to modify the method of analysis to include the free and conjugated forms of TSN 028333.	RMS: As noted in 3.1 there is no need for metabolite TSN028333 to be included in the residue definition. Therefore, the RMS agrees with the applicant that the method of analysis should not be modified to include the metabolite TSN 028333 free and conjugated.	PRAPeR 70 (5 – 8 May 2009): Open point closed.

section 3 – Residues

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
	See reporting table 3(12)			

4. Environmental fate and behaviour

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
	Section 4 Open points: ***12*** Points for clarification: ***0*** Data gaps: ***1***			Section 4 Open points: ***6*** Points for clarification: ***0*** Data gaps: ***2***
	Open point: 4.1 MSs to discuss in a meeting of experts if the estimation of the Koc with EPI Suite for metabolite TR-4 is acceptable, taking into account that it is an aniline, and therefore ionisable. In case the value is found acceptable, discuss which 1/n should be used for modelling when the Koc is not measured but estimated. In case a data gap is identified, this would not be considered essential to finalize the EU risk assessment, since the need to address the potential groundwater contamination by the anaerobic metabolite TR 4 has been considered not essential to finalize the EU assessment.	EUTTF: No additional comments to those presented in the reporting table, but as previously highlighted, the modelled estimation of parameters for TR-4 using EPI Suite is considered sufficiently conservative. The notifier supports the RMS opinion that this is not considered essential to finalise the EU risk assessment.	RMS: Modelled data for Koc (using EPI Suite) was derived in the absence of measured data. This was validated by reference to trifluralin (with a very similar structure - only difference is additional nitro group) where the modelled and measured Koc were compared. Good agreement was obtained for the parent and so the modelled Koc for TR-4 was considered valid. The Koc for both parent and metabolite (>5000) is sufficiently high not to raise any leaching concerns. The TR-4 metabolite Koc that is based on a software estimate and is not an experimentally measured value, seems to have been accepted by EPCO 03.	PRAPeR TC 10 (19 May 2009): Open point fulfilled. The experts agreed that it may be reasonable for the calculated Kdoc = 13 600 mL/g to be used to model fate and behaviour of the anaerobic trifluralin soil metabolite TR-4 together with a 1/n = 1 for the applied for representative uses. However, if an assessment at national level indicated that exposure was approaching a groundwater trigger or surface water tier 1 risk assessment trigger, then measured data on adsorption could be needed to assess uses where anaerobic soil conditions cannot be excluded.

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
	See reporting table 4(1)			
	Open point: 4.2 MSs to discuss the acceptability of the FOCUS Step 3 and Step 4 calculations paying attention to: - Dissipation half-life in water instead whole system half-life for one phase and default worst case of 1000d for the other phase has been used. -DT 50 used for sediment not justified. See reporting table 4(3)	EUTTF: The notifier re-iterates that for the critical water phase where the risk assessment is carried out, it is considered that the decline is strongly driven by the high Koc (mean 8765 mL/g). As such, the actual DT_{50} used for the water phase will have minimal impact on the resultant PECsw values, and any change would not significantly change the risk assessment. See open point 4.4, where this is clearly demonstrated.	RMS: See response to open point 4.4., below	PRAPeR TC 10 (19 May 2009): Open point fulfilled. New data gap proposed, see below.
	New data gap 4.2 identified at PRAPeR TC 10 meeting: FOCUS surface water step 3 and 4 calculations are required with PRZM simulations that evenly incorporate trifluralin over the top 5cm. The pesticide properties that should be used are as follows: Soil DT50 geometric mean normalised to FOCUS reference condition laboratory values (*ca.* 135			PRAPeR TC 10 (19 May 2009): Data gap open. Written procedure (June 2009) Data gap maintained.

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
	days see open point 4.5) Surface water DT50 1000 days Sediment DT50, a geomean of whole system values that represents actual degradation (includes volatile trap mass) KFoc 8765 mL / g; 1/n=0.972 Spray drift mitigation alone and spray drift + run-off mitigation at step 4 should be reported separately. For step 3 and 4 the patterns of exposure (eg. graphical outputs from TOXSWA) that the models produced should be reported. The application window used in simulations should be appropriate and clearly reported.			
	Open point: 4.3 Application window to be provided by the RMS in an addendum. See reporting table 4(3)	EUTTF: No further comment.		PRAPeR TC 10 (19 May 2009): Open point fulfilled. See new data gap 4.2.
	Open point: 4.4 RMS: Risk assessment based on a maximum	EUTTF: It is not possible to retrospectively separate drift mitigation in isolation from run-off mitigation.	RMS: The notifier's reports GHE-P-12080 and GHE-P-12083 have been provided in an Addendum	PRAPeR TC 10 (19 May 2009):

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	mitigation of 90 % for run-off needs to be provided. Effect of spray drift mitigation should be presented isolated from the effect of run-off mitigations in order to adequately assess the proposed mitigation measures. See reporting table 4(4)	This is because the two reductions were applied simultaneously at Step 4 in the SWAN analysis carried out in report GHE-P-11836. Therefore, in order to address this, and to deal with possible MS concerns regarding the DT_{50} to be used in the FOCUS Step 3 and 4 calculations (open point 4.2), the notifier has re-worked the kinetics to give a system $DegT_{50}$ of 106 d for the degrading compartment (sediment). This was derived from the existing water/sediment studies by following the FOCUS kinetics guidance, and this re-work is described in GHE-P-12080. ***Attachment has been removed by EFSA for procedural and confidentiality reasons***. The rework of the FOCUS Step 3 and 4 analysis is described in amended report GHE-P-12083 for the soil incorporated uses. Here, a default of 1000 d was used for the non-degrading compartment (water). ***Attachment has been removed by EFSA for procedural and***	1 to Additional Report and have been accepted by the RMS. The PECsw values do not change to any significant extent and therefore, the risk assessment for aquatic organisms will not change.	Open point fulfilled. See new data gap 4.2

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
		confidentiality reasons. In this work, the actual and TWA concentrations were derived for each time point, and graphs obtained to show the exposure profiles. Mitigation for spray drift only with a buffer zone (14 and 20 m) was first applied in one set of model runs, and then drift and run-off mitigations (the latter using the recommended values given in the FOCUS L&M report, and supported by Alterra report 1794) together in a second set of runs. A summary of the global max. PECsw from the existing analysis and that in the amended report is shown below. ***Attachment has been removed by EFSA for procedural and confidentiality reasons.*** It can clearly be seen that there is little or no difference between the two sets of analyses, and that following the latest guidance for kinetics and mitigation etc, that the PECsw values do not change to any significant extent. Therefore, the risk assessment for aquatic organisms will not change.		

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
	Open point: 4.5 Further details on the normalization procedure and factors employed to derive the soil normalized DT50 of 115 d at 22 ºC should be provided in an addendum (see please Appendix I in study report G. Reeves 2005 for further details). Additionally, RMS to provide normalization to 20 ^{o}C for the LoEP and to be used in further modelling by MSs. LoEP would need to be updated if normalization is found acceptable. See reporting table 4(5)	EUTTF: No further comment.	RMS: The details on the normalization procedure and the standard temperature-corrected DT50 have been provided in an Addendum 1 to the Additional Report. RMS (27/05/2009): An Addendum has been prepared with the calculated normalised DT50 for the temperature to 20°C as well as moisture to -10kPa. The LoEP has been updated to include the individual normalised values Open point fulfilled.	PRAPeR TC 10 (19 May 2009): Open point open. RMS to calculate the normalised DT50 for the temperature to 20°C as well as moisture to -10kPa and to update the LoEP to include the individual normalised values. Written procedure (June 2009) Open point fulfilled.
	Open point: 4.6 Formation fraction assumed for TR-4 needs to be justified in an addendum. See reporting table 4(12)	EUTTF: In the FOCUSPELMO gw modelling (GHE-P-10694), the degradation route used was trifluralin to TR-4 to sink. This quantitative conversion of parent to metabolite (formation fraction = 1) is worst-case. In the FOCUSPEARL gw modelling (GHE-P-11131) a formation fraction of 0.5 was used as a more realistic estimate, since appreciable amounts of NER were formed in the study which would give a formation fraction	RMS: agree with notifier's view.	PRAPeR TC 10 (19 May 2009): Open point fulfilled.

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		<1. However, this was not supported by data, since a full kinetic evaluation was not carried out for TR-4. But, in view of the FOCUSPELMO PECgw (<0.001 µg/L) and the PECgw from FOCUSPEARL with a formation fraction of 0.5 (<0.000001 µg/L) then this is considered to have minimal impact and so the PECgw would not rise above 0.1 µg/L. This is supported by supplementary information given under open point 4.9.		
	Open point: 4.7 RMS to remove asterisks in an Addendum to the Additional report. See reporting table 4(16)	EUTTF: No further comment.	RMS: The asterisks have been removed in a Corrigentum to the Additional Report	PRAPeR TC 10 (19 May 2009): Open point fulfilled. New open point proposed, see below.
	New open point: 4.13 RMS to update the list of endpoints FOCUSsw step 3 substance input parameters to indicate the temperature corresponding to the vapour pressure value.			PRAPeR TC 10 (19 May 2009): Open point open. Written procedure (June 2009) Open point fulfilled.
	Data gap: 4.1 Applicant to provide additional report with complete results of the	EUTTF: The output files from the FOCUS Step 3 and 4 analysis described in report GHE-11836 were reviewed, and supplementary	RMS: The notifier's reports GHE-P-12080 and GHE-P-12083 have been provided in an Addendum 1 to Additional Report and have been	PRAPeR TC 10 (19 May 2009): Data gap closed.

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
	FOCUS Step 3 Step 4 calculations. See reporting table 4(17)	information obtained on the actual concentrations (as well as the previously presented TWA concentrations) calculated at each time point. Graphs were also obtained to show the exposure profile and the dominant entry route. ***Attachment has been removed by EFSA for procedural and confidentiality reasons.*** Further information in the same format is provided to address this for the data given in the amended report (GHE-P-12083) from open point 4.4 as follows. ***Attachment has been removed by EFSA for procedural and confidentiality reasons.***	accepted by the RMS.	Replaced by the new data gap 4.2.
	Open point: 4.8 MSs to decide which missing information on the results of FOCUS SW simulations is considered essential to finalise the EU risk assessment. See reporting table 4(17)	EUTTF: No further comment.		PRAPeR TC 10 (19 May 2009): Open point fulfilled. See also open points 4.2, 4.4 and new data gap 4.2.

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
	Open point: 4.9 RMS to clarify which incorporation depth has been assumed in the PEC GW calculations (0.005 m is 0.5 cm as the French comment says and not 5 cm as stated in the applicant response). According to the original study report the incorporation depth was actually 0.005 m (as stated in the additional report). In case 0.005 had actually been used, the calculations may need to be repeated. Otherwise, a data gap for an amended report with the correct input parameters will be identified. See reporting table 4(21)	EUTTF: The notifier accepts there is an error in the incorporation depth used in the FOCUSPEARL gw modelling report (GHE-P-11131). The intention was to model to 5 cm depth but this was incorrectly entered into the model as 0.005 m (should be 0.05 m). To correct this, the original report has been amended as GHE-P-12082 with modelling carried out for an incorporation depth of 0.2 m (20 cm). This is worst case compared to 5 cm, and is the depth recommended in Commission Directive 95/36/EC, Point 9.1.3 for the risk assessment of soil-incorporated products. In addition, a formation fraction of 1 was used as a worst case for TR-4 which also addresses open point 4.6. Finally, a Freundlich constant (1/n) of 1 (rather than 0.9) was used as a default to add to the conservative nature of the assessment, which addresses open point 4.1. ***Attachment has been removed by EFSA for procedural and confidentiality reasons.*** To complement and be in alignment with this, the original FOCUSPELMO	RMS: The notifier's reports GHE-P-12081 and GHE-P-12082 generated to address this point have been provided in an Addendum 1 to Additional Report and have been accepted by the RMS. RMS (27/05/2009): An Addendum has been prepared with new groundwater simulations for the active substance trifluralin using an incorporation depth of 5cm and using the appropriate input values. Open point fulfilled.	PRAPeR TC 10 (19 May 2009): Open point open. RMS to carry out new groundwater simulations for the active substance trifluralin using an incorporation depth of 5cm to confirm the groundwater exposure assessment. Substance properties to be used: soil DT50 geometric mean of normalised to FOCUS reference condition laboratory values (*ca.* 135 days see open point 4.5) KFoc 8765 mL / g; 1/n=0.972 Written procedure (June 2009) Open point fulfilled. The new simulation has been carried out with PELMO and therefore supersedes the one available in the original dossier and already collected in the conclusion. Second model simulation is not available. No data gap is proposed at this stage.

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
		gw modelling report (GHE-10694) has also been amended (GHE-P-12081) to include soil incorporation to 20 cm depth, a formation fraction of 1, and a Freundlich constant (1/n) of 1. ***Attachment has been removed by EFSA for procedural and confidentiality reasons.*** In conclusion, the supplementary gw modelling (GHE-P-12082 and GHE-P-12081) showed that the PECgw for trifluralin and TR-4 was clearly <0.1 ug/L for all FOCUS scenarios. Consequently, this amended information closes the potential data gap.		
	Open point: 4.10 EFSA to emphasize in the conclusion, as part of the section on particular conditions of use, that only uses representative of incorporated applications have been considered in the risk assessment. See reporting table 4(22)	EUTTF: No further comment.		PRAPeR TC 10 (19 May 2009): Open point open. EFSA to emphasise in the conclusion, as part of the section on particular conditions of use, that only uses representative of incorporated applications have been considered in the risk assessment. Written procedure (June 2009)

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
				Open point fulfilled.
	Open point: 4.11 MSs to discuss in a meeting of experts if there is an indication that incorporation should be recommended as an effective risk management measure to mitigate surface water contamination through volatilization – deposition. See reporting table 4(22)	EUTTF: No further comment.		PRAPeR TC 10 (19 May 2009): Open point fulfilled. The experts agreed that recommendations regarding incorporation would potentially reduce volatilisation losses and increase the efficacy of the use of the product.
	Open point: 4.12 MSs to discuss in meeting of experts if there is any indication in the DAR or in the additional report that indicates potential for long-range transport of trifluralin through the atmosphere. Available information up to now do not suggest that trifluralin has potential to be a long-range contaminant, since the half-life in the atmosphere is predicted to be shorter than 2 d by Atkinson model calculation (actually 5.3 h has been	EUTTF: the notifier refers to the comments presented in the reporting table 4(26). The notifier re iterates the point that the "potential for long-range transport" does not form part of the evaluation according to Annex VI of the Directive 91/414. Therefore, the data being requested to be submitted to the RMS and EFSA should not be presented for consideration by the meeting of MS experts when evaluation trifluralin.		PRAPeR TC 10 (19 May 2009): Open point fulfilled. New data gap proposed, see below.

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
	calculated). Some monitoring data indicate potential contamination of SW, however there is no indication that this has been due to long-range transport. **MSs having data on potential long-range transport of trifluralin are welcomed to present such data in a report to the RMS and EFSA for further consideration by the meeting of experts.** See reporting table 4(26)			
	New data gap 4.3 identified at PRAPeR TC 10 meeting: Applicant to provide available monitoring data from the Arctic or other regions remote from agriculture to enable conclusions on the potential for long-range atmospheric transport to be drawn.			PRAPeR TC 10 (19 May 2009): Data gap open. Written procedure (June 2009) Data gap maintained.
	New open point 4.14 EFSA to include in the conclusion a comparison of the agreed study endpoints against the POP criteria in			PRAPeR TC 10 (19 May 2009): Open point open. Written procedure (June 2009)

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
	the Stockholm convention.			Open point fulfilled.
	New open point 4.15 RMS to update the LoEP in line with the conclusions of the teleconference discussion.		RMS (27/05/2009): The LoEP has been updated in line with the conclusions of the teleconference discussion. Open point fulfilled.	PRAPeR TC 10 (19 May 2009): Open point open. Written procedure (June 2009) Open point fulfilled.

5. Ecotoxicology

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
	Section 5 Open points: ***14*** Points for clarification: ***0*** Data gaps: ***0***			Section 5 Open points: ***6*** Points for clarification: ***0*** Data gaps: ***0***
	Open point: 5.1 MSs to discuss in an expert meeting the endpoint to be used for the chronic risk assessment to fish. RMS proposed the NOAEC of 10 µg a.s./L from the Hoberg, 2006 study. Some MSs were of the opinion that the NOEC of 3.2 µg a.s./L from the same study is more appropriate. Other MSs suggested to use the original NOEC of 0.3 µg a.s./L from Meyrhoff & Gunnoe, 1992. See reporting table 5(1)	EUTTF: This risk assessment has to be put into perspective within the conventional regulatory process applied to other active substances in order to reach an equitable conclusion. In the conventional risk assessment, a TER trigger of 10 is applied to an NOEC based on gross effects that are clearly damaging to individuals and populations alike. Some reduction in uncertainty has to be applied when the assessment is based on extremely slight and subtle effects - effects that are not even investigated for other actives. If it is decided that a highly conservative NOEC of 3.2 µg/L should be used in the risk assessment, then a reduction in the TER trigger to 3 is considered to be entirely appropriate. One MS has already proposed a reduction of the trigger to 5, based solely on the range of studies and species tested. A further reduction to 3, to reflect the additional reduction in certainty, is entirely appropriate given	RMS: We welcome a discussion on this issue. There is a large difference on the selection of the end point from this study and the conventional testing. The uncertainty then is not the same.	PRAPeR 68 (4 – 8 May 2009): Open point fulfilled. New open point proposed, see below.

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
		that the incidence and magnitude of this "effect" seen at 12.5 x PEC is in line with background levels of this anomaly seen in wild populations.		
	New open point: 5.15 RMS to check and confirm the selected endpoint (NOEC: 3.2 ug/L) to be used for the chronic risk assessment to fish and the PEC to be used with the endpoint based on the fate properties of the a.s.		27 May 2009 RMS: In the LoEP the TER values are based on the toxicity value NOEC: 3.2 ug/L and exposure values from FOCUS PECsw step 1 to step 3.	PRAPeR 68 (4 – 8 May 2009): Open point open. Written procedure (June 2009) Open point still open. No data on the exposure pattern was available allowing for a final decision on which chronic toxicity end point to fish should be used for risk assessment; in addition, only PECsw values calculated with step 3 of FOCUS were peer reviewed (see 4.2.1 in section on environmental fate and behaviour). Therefore, the chronic risk assessment to fish cannot be finalised.
	Open point: 5.2 RMS to update the LoEP, pending on the outcome of the discussion related to the chronic endpoint to be used for risk assessment to fish (see open point 5(1)), the trigger to be applied (see open point 5(5) and the outcome of the fate meeting discussion (see open point	EUTTF: No further comments	RMS: No comment. 27 May 2009 RMS: The LoEP was amended.	PRAPeR 68 (4 – 8 May 2009): Open point still open. Written procedure (June 2009) Open point fulfilled.

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	4(4)). See reporting table 5(2)			
	Open point: 5.3 MSs to discuss in an expert meeting if the field monitoring study designed to investigate the ecological effects of trifluralin, primarily on fish (Francis *et al* 1985, original DAR B9.2.5/01) can be considered appropriate to support the long-term risk assessment to fish. See reporting table 5(6)	EUTTF: The study reported by Francis *et al* 1985 represents an extensive and comprehensive examination of fish populations in a catchment area draining agricultural land extensively treated with trifluralin. The notifier finds it strange how this can be considered as "inappropriate"? The data are not presented to form the basis of the conclusion of low risk (this is provided by the higher tier laboratory data). The study is presented to show that there is no evidence from field monitoring that would undermine the conclusion of low risk derived from the higher tier risk assessment.	RMS: We agree with the notifier	PRAPeR 68 (4 – 8 May 2009): Open point fulfilled.
	Open point: 5.4 MSs to discuss if the exposure in the study from Hoberg, 2006 is appropriate in relation to the exposure profile of trifluralin (Pending on the outcome of the discussion of the fate expert meeting, see open point 4(4)).	EUTTF: As stated previously in the reporting table, Point 5(8), "*It is considered that due to the fate properties of trifluralin that the contamination of surface water by either drainflow or runoff will be minimal, i.e. the exposure will be spray drift driven.*" Consequently, the scenario of a single peak exposure followed by dissipation (as simulated in the static study) is considered to be the most representative model of	RMS: It can be discussed in an expert meeting.	PRAPeR 68 (4 – 8 May 2009): Open point closed. See open point 5.1.

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	See reporting table 5(8)	exposure. Although environmental conditions cannot be replicated entirely in the laboratory, the test conditions are considered to be "worst-case" due to the lower ambient lighting in the study (210-1100 lux). Given the rapid photodegradation of trifluralin, dissipation rates would be much faster outdoors. In addition, since the exposure is driven by the spray-drift route of entry, the chronic risk assessment will be dependent on the spray-drift management practices relevant for the individual MSs. Consequently, conclusions of acceptable risk with regard to this aspect should be taken at the MS level.		
	Open point: 5.5 MSs to discuss in an expert meeting the trigger to be applied to the chronic endpoint of fish (i.e. is the trigger of 10 appropriate with the NOAEC of 10 µg a.s./L? Should the trigger of 10 be lowered with the NOEC of 3.2 µg a.s./L?). See reporting table 5(12)	EUTTF: See notifiers comment to Open point: 5.1 above	RMS: It can be discussed in an expert meeting.	PRAPeR 68 (4 – 8 May 2009): Open point closed. See open point 5.1.

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
	Open point: 5.6 MSs to discuss the application of a correction factor to Chironomus test endpoints to correct the carbon content of the sediment. See reporting table 5(18)	EUTTF: There appears to be some confusion regarding the recommendations in this guideline. The carbon content of the sediment, at 2.3%, was within the guideline specification of 2 +/- 0.5%. The peat content was slightly higher, but this is allowed in the guideline in order to achieve the required carbon content. Consequently, the study is fully compliant with OECD 219 and no correction factor (even if there was an agreed one) is required.	RMS: The comment seems consistent with the risk assessment to soil organisms but there is no reference in the guidance. We should better keep consistent with the document. The risk is addressed anyway.	PRAPeR 68 (4 – 8 May 2009): Open point fulfilled.
	Open point: 5.7 MSs to discuss if the information available in the study from Hoberg 2006 with *P.promelas*, allows using a PEC_{TWA} approach as alternative option to refine the chronic risk assessment to fish. See reporting table 5(23)	EUTTF: A TWA approach, if applied, would only be applicable to the endpoint derived from the continuous flow study of Meyerhoff & Gunnoe, 1992. If this approach is looked at again, a more realistic estimate of the DT_{50} has to be applied. In the fate and behaviour sediment:water study, 74-97% dissipation occurred within the first 6 hours following application. Consequently a DT_{50} of, at most, 6 hours would be appropriate. However, we appreciate the concerns expressed previously that this approach might underestimate the impact of the initial exposure. This was the reason for conducting a second study under static conditions in the presence of sediment (Hoberg,	RMS: It can be discussed in an expert meeting.	PRAPeR 68 (4 – 8 May 2009): Open point closed. See open point 5.1.

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
		2006). Since the study simulated "worst-case" conditions, it was not necessary to make any assumptions on the kinetics of dissipation.		
	Open point: 5.8 RMS to update the LoEP (the NOAEC for fish is 10 µg/L and not 10 mg/L). See reporting table 5(27)	EUTTF: No further comments	RMS: It will be updated. 27 May 2009 RMS: The LoEP was amended.	PRAPeR 68 (4 – 8 May 2009): Open point still open. Written procedure (June 2009) Open point fulfilled.
	Open point: 5.9 MSs to reconsider the risk for bioaccumulation in fish, on the basis of the revised long-term risk assessment. See reporting table 5(30)	EUTTF: There are no Annex VI criteria based on BCF endpoints to indicate that this is an issue. In the EFSA Report it is stated that a full life cycle study would be triggered, but this is already available and had been included in the original 91/414 evaluation. It is not clear what additional information on the issue of bioaccumulation is provided by the chronic risk assessment since any chronic toxicity effects associated with accumulation of residues is inevitably covered in the chronic risk assessment itself.	RMS: As the BCF values are triggered an FLC is needed which is already available and has been reviewed. The risk assessment covers also this risk.	PRAPeR 68 (4 – 8 May 2009): Open point closed. See open point 5.1.
	Open point: 5.10 MSs to discuss the need of a new litter bag study (data gap identified by EFSA	EUTTF: A new litter bag study was proposed by EFSA, but was never discussed in an EPCO Expert meeting. Furthermore, it is our understanding that the litter bag study	RMS: It can be discussed in an expert meeting.	PRAPeR 68 (4 – 8 May 2009): Open point fulfilled. A new litter bag study is not required.

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	during the previous peer review of trifluralin, but not discussed in the EPCO meeting) See reporting table 5(31)	is not supported by most MSs. Consequently, this was not taken to be a data requirement at this stage for Annex 1 inclusion.		
	Open point: 5.11 RMS to amend the LoEP according to the format from EPCO manual rev 4 (September 20005). See reporting table 5(34)	EUTTF: No further comments	RMS: It will be updated. 27 May 2009 RMS: The LoEP was amended.	PRAPeR 68 (4 – 8 May 2009): Open point still open. Written procedure (June 2009) Open point fulfilled.
	Open point: 5.12 RMS to amend the LoEP with the classification and labelling for both the active substance and the formulation product. See reporting table 5(35)	EUTTF: No further comments	RMS: It will be updated. 27 May 2009 RMS: The LoEP was amended.	PRAPeR 68 (4 – 8 May 2009): Open point still open. Written procedure (June 2009) Open point fulfilled.
	Open point: 5.13 RMS to update the LoEP, pending on the outcome of the ecotox discussion (to highlight in grey the uses for which a potential high risk assessment will be identified).	EUTTF: No further comments	RMS: It will be updated. 27 May 2009 RMS: The LoEP was amended.	PRAPeR 68 (4 – 8 May 2009): Open point still open. Written procedure (June 2009) Open point fulfilled.

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
	See reporting table 5(37)			
	Open point: 5.14 MSs to discuss, on the basis of the available information, if the formulations tested in the ecotoxicological tests cover the lead formulation. See reporting table 5(39)	EUTTF: The majority of the ecotoxicity studies presented (and all of the "core" studies) were conducted on the lead formulation, EF-1521, a 480 g/L EC product. The earthworm sub-acute study (Elancolan) and the soil micro-organism study (EF-1492) were conducted on equivalent formulations, but these studies were conducted in order to fulfil Annex II data requirements (where only a representative formulation is required to administer the treatment). Specific studies on the lead formulation have not been triggered for these data points under the data requirements of Annex III. Additional studies were also performed on Treflan EC (chronic toxicity to Chironomus) and on Triflurex EC (4 additional NTA species). Both of these products are 480 g/L EC formulations similar to EF-1521. These studies were not triggered but were already available and therefore submitted in order to provide additional information on this type of formulation.	RMS: It can be discussed in an expert meeting.	PRAPeR 68 (4 – 8 May 2009): Open point fulfilled.