PEER REVIEW REPORT ON **TRIFLURALIN** 03 07 2009

TABLE OF CONTENTS

	Document	**File Name**
00	Cover page	00 trifluralin cover
01	All comments received on the DAR	01 trifluralin all comments
02	Reporting table all sections	02 trifluralin rep table rev 1-1
03	**All reports from PRAPeR Expert Meetings**	**03 trifluralin all reports.**
04	Evaluation table	04 trifluralin eval table rev 2-1

List of all reports from PRAPeR Expert Meetings

Date		Section
04-08.05.2009	PRAPeR expert meeting 68	Ecotoxicology
05-08 05.2009	PRAPeR expert meeting 70	Residues
19.05.2009	PRAPeR expert meeting TC 10	Environmental Fate and Behaviour

REPORT OF PRAPeR EXPERT MEETING 68

TRIFLURALIN

Rapporteur Member State: GR

Specific comments on the active substance in the section

5. Ecotoxicology

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

1. Comments submitted for this meeting:

Date	Supplier	File Name
None		

2. Documents submitted for meeting:

Date	Supplier	File Name
2009-04-29	GR	Trifluralin_evaluation table rev 1-0 (2009-04-29)_phys-chem_residues_ecotox.doc
2009-04-08	GR	Trifluralin_reporting table rev 1-1 (2009-04-08).doc
April 2009	GR	Trifluralin_updated list of endpoints (April 2009).doc

3. Documents tabled at the meeting:

Date	Supplier	File Name
none		

The conclusions of the meeting were as follows:

4. Data on preparations: EF-1521 (Treflan), EAF-117, Triflurex 48EC

5. Classification and labelling: N, R50/53

6. Recommended restrictions/conditions for use: none

7. Reference list: Not discussed.

Areas of concern: aquatic organisms, terrestrial plants

Appendix 1: Discussion table: TRIFLURALIN

Appendix 2: Evaluation table

Appendix 1: Discussion Table, Trifluralin (Hb)

5. Ecotoxicology

	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	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)	In the control, some effects on bone were also seen (low occurrence). Control groups: 12.2% slight effect 3.2 ug/L: 6.5% slight effect 10 ug/L: 9.1% slight effect plus 6.8% moderate effect. This bone effect can be caused by a stressed environment (possibility for movement impaired). There is literature about this. According to the RMS it is possible to distinguish the bone effects from trifluralin from the bone effects from the stressed environment. The RMS set the NOEC of the study at 10 ug/L. The bone effects have to be high before effects on survival are seen in the test. The field environment can also be stressed. In the lab, other stressors are taken away (no food scarcity etc). The effect seen here is irreversible. In the dimoxystrobin PPR opinion, a small effect (5% on growth) was taken as the relevant endpoint and used with a safety factor of 10. Does the meeting feel that this effect on the spinal cord can be ignored, since it does not cause growth/survival effects? This is a more general point. A French expert considered that it is not possible to exclude that the bone effects at 10 ug/L will not have effects in the field. It was discussed whether the NOEC should be set at 3.2 µg/L. Some MSs felt that at 10 µg/L the effects seen are of a different class than in the control and at the lower dose. It is not possible to predict the effects in the field with the available information, and therefore to be precautionary, the NOEC should be 3.2 µg/L. The meeting agreed to set the NOEC at the treatment level of 3.2 µg/L. Whether the NOEC should be nominal or otherwise	Open point fulfilled. New open point proposed, see below.

	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
		depends on the outcome of the environmental fate and behaviour meeting. If the nominal is taken, it should be compared with PECmax. The question was raised which safety factor should be used with the NOEC of 3.2 µg/L? Normally a SF of 10 is used. The RMS highlighted that a 20% mortality level in the control is accepted according to the guideline (will be checked if this is true). Therefore they consider that a safety factor of 10 is highly protective. If the endpoint is based on a physiological effect, the safety factor should be reduced. Four species were tested in ELS tests. The effect was not seen for two other species. For cyprinodon the effects on bone were not looked at. The endpoint of the flow-through test was one order of magnitude lower than the endpoint of the water/sediment study which is now selected for risk assessment. This pattern is consistent in the chronic fish dossier. This has to be considered when determining the correct PEC and also for determining the safety factor. The endpoint is expressed in nominal concentrations while the a.s. disappeared from the water in the first 24 h during the test. Initially measured concentrations were >100% of nominal. The a.s. moves very quickly into the sediment. It might later move back into the water. It volatiles easily. Is run-off/drainage important? This still has to be clarified by the fate section. The question arose whether this study, which contained sediment, fully reflect the fate properties of trifluralin. A similar study was discussed in the PPR opinion on dimoxystrobin, in which suggestions were done for the relevant PEC to compare with the endpoint. The notifier considers that the nominal PECs are relevant because they best represent the loading to the system. Trifluralin will be discussed in a fate teleconference (19 May) after this PRAPeR ecotox meeting. The fate properties have to be explained further before it can be determined whether the study fully reflects the fate properties of the a.s. If so, the nominal NOEC of 3.2 should be compared with PECmax. If not, the dimoxystrobin opinion should be considered to determine the relevant PECs (both for effect and exposure). Depending on the fate discussions, either a flow-through or a static endpoint can be selected.	

	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
		The relevant endpoint from the flow-through studies is 0.3 ug/L for fathead minnow. Three species were tested in comparable flow-through studies and the results were consistent. Therefore the meeting would agree with a reduction in safety factor. The PPR opinion can be considered here. The three studies in which vertebrate effects were checked should be considered. The flow-through test gave for the physiological effect seen in the static test an endpoint 10x lower, after about 20 days. It is not known if this effect can already result from short-term exposure (24h) (this was discussed in the first round of trifluralin). Also, it is not known how fish in the field respond from an expected PEC pattern as for trifluralin (rather high initial and then still prolonged exposure). For these reasons, the use of an twa-PEC is not appropriate. The relevant endpoint from the static studies is 3.2 ug/L for fathead minnow. Which safety factor? Two species were tested (one species twice without sediment, one with sediment). Here it needs to be checked that the resulting TER is consistent with the TER from the static studies. Without knowledge of the fate of the a.s. in the test systems it is difficult to conclude on the safety factor. However, only the new study with sediment is considered relevant here, so there is no reduction of safety factor based on testing of several species. It should be confirmed that other effects are not overlooked when we focus on vertebrate effects. Open point fulfilled.	
	New open point: 5.15 RMS to check and confirm the selected endpoint (NOEC: 3.2 µg/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.		Open point open.

	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	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 4(4)). See reporting table 5(2)	The endpoint for chronic risk assessment to fish is not yet finalised, see discussion at open point.5.1. Open point still open.	Open point still open.
	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	Since the effects on bone were not classified in this study, it is not possible to use this study to support the selection of the NOEC. See open point 5.1. Open point fulfilled.	Open point fulfilled.

	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	5(6)		
	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)). See reporting table 5(8)	See open point 5.1. Open point closed.	Open point closed.
	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)	See open point 5.1. Open point closed.	Open point closed.
	Open point: 5.6 MSs to discuss the application of a correction factor to	The logPow of the a.s. is high. Should therefore the endpoint be corrected according to the procedure for soil organisms? The carbon content in the study was in accordance with the guideline (this was achieved by increasing the peat content). The correction for earthworms is done because earthworms feed on soil. This is not the	Open point fulfilled.

	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	Chironomus test endpoints to correct the carbon content of the sediment. See reporting table 5(18)	case for chironomids. No action is required at this stage. Open point fulfilled. It should be highlighted as a general point for the revision of the guidance documents.	
	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)	See open point 5.1. Open point closed.	Open point closed.
	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)	See open point 5.1. Open point still open.	Open point still open.
	Open point: 5.9 MSs to reconsider the risk for bioaccumulation in fish, on the basis of	The long-term risk assessment to fish has been discussed at open point 5.1. Open point closed.	Open point closed.

	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	the revised long-term risk assessment. See reporting table 5(30)		
	Open point: 5.10 MSs to discuss the need of a new litter bag study (data gap identified by EFSA during the previous peer review of trifluralin, but not discussed in the EPCO meeting) See reporting table 5(31)	The litterbag study was not performed based on PECplateau. Therefore EFSA identified a data gap after the EPCO meeting. The usefulness of the litter bag study is questionable. However, it is still included in the guidance. Should a new litter bag study be required? No. Open point fulfilled.	Open point fulfilled.
	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)	The updated format for the LoEP is available on CIRCA. Open point still open.	Open point still open.
	Open point: 5.12 RMS to amend the LoEP with the classification and labelling for both the active substance and the formulation	The list of endpoint regading classification and labelling will be updated. Open point still open.	Open point still open.

	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	product. See reporting table 5(35)		
	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). See reporting table 5(37)	The list of endpoint will be updated accordingly. Open point still open.	Open point still open.
	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)	The meeting agreed that the available studies are sufficient. Open point fulfilled.	Open point fulfilled.

Appendix 2: Evaluation table

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	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
		species tested. A further reduction to 3, to reflect the additional reduction in certainty, is entirely appropriate given 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.			PRAPeR 68 (4 – 8 May 2009): Open point open.
	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 4(4)). See reporting table 5(2)	EUTTF: No further comments	RMS: No comment.	PRAPeR 68 (4 – 8 May 2009): Open point still open.
	Open point: 5.3 MSs to discuss in an expert meeting if the field monitoring	EUTTF: The study reported by Francis *et al* 1985 represents an extensive and comprehensive examination of fish	RMS: We agree with the notifier	PRAPeR 68 (4 – 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 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)	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.		
	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)). See reporting table 5(8)	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 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	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
		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.
	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	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.

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
		correction factor (even if there was an agreed one) is required.		
	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, 2006). Since the study simulated "worst-case" conditions, it was not necessary to make any assumptions on the kinetics of dissipation.	RMS: It can be discussed in an expert meeting.	PRAPeR 68 (4 – 8 May 2009): Open point closed. See open point 5.1.
	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.	PRAPeR 68 (4 – 8 May 2009): Open point still open.
	Open point: 5.9 MSs to reconsider the risk for	EUTTF: There are no Annex VI criteria based on BCF endpoints to indicate	RMS: As the BCF values are triggered an FLC is needed which is already	PRAPeR 68 (4 – 8 May 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
	bioaccumulation in fish, on the basis of the revised long-term risk assessment. See reporting table 5(30)	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.	available and has been reviewed. The risk assessment covers also this risk.	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 during the previous peer review of trifluralin, but not discussed in the EPCO meeting) See reporting table 5(31)	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 is not supported by most MSs. Consequently, this was not taken to be a data requirement at this stage for Annex 1 inclusion.	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.
	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.	PRAPeR 68 (4 – 8 May 2009): Open point still open.
	Open point: 5.12 RMS to amend the LoEP with the classification and	EUTTF: No further comments	RMS: It will be updated.	PRAPeR 68 (4 – 8 May 2009): Open point still open.

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
	labelling for both the active substance and the formulation product. See reporting table 5(35)			
	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). See reporting table 5(37)	EUTTF: No further comments	RMS: It will be updated.	PRAPeR 68 (4 – 8 May 2009): Open point still open.
	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.	RMS: It can be discussed in an expert meeting.	PRAPeR 68 (4 – 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
		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.		

REPORT OF PRAPeR EXPERT MEETING 70

TRIFLURALIN

Rapporteur Member State: GR

Specific comments on the active substance in the section

3. Residues

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

1. Comments submitted for this meeting:

Date	Supplier	File Name
none		

2. Documents submitted for meeting:

Date	Supplier	File Name
2009-04-29	GR	Trifluralin_evaluation table rev 1-0 (2009-04-29)_phys-chem_residues_ecotox.doc
2009-04-08	GR	Trifluralin_reporting table rev 1-1 (2009-04-08).doc
April 2009	GR	Trifluralin_updated list of endpoints (April 2009).doc

3. Documents tabled at the meeting:

Date	Supplier	File Name
none		

The conclusions of the meeting were as follows:

4. **Data on preparations:** EF1521

5. **Classification and labelling:** none

6. **Recommended restrictions/conditions for use:** none

7. **Reference List:** not discussed

Areas of concern: none

Appendix 1: Discussion table: TRIFLURALIN

Appendix 2: Evaluation table

Appendix 1: Discussion Table, Trifluralin (Hb)

3. Residues

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	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)	The resubmission supports only sunflower, cotton and oilseed rape while the initial dossier supported also cereals. The use on cereals should be deleted from the GAP table in the list of endpoints. The list of endpoints have been upddated accordingly.	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	In the new oilseed metabolism study there was a major metabolite TSN 028333 (TR-14) in all crop parts that accounted for 33% in the seeds (free and conjugated) and more than 40% in the forage, however absolute levels were below 0.01 mg/kg in seeds and 0.05 mg/kg in forage in a 1.5 N study. Considering the application rate in the study and that there is no particular concern regarding its toxicological properties (TSN 028333 is a rat metabolite), it was agreed not to include TSN 028333 in the residue definition.	Open point fulfilled.

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	residue definitions, the metabolism study being performed at a 1.5N level. See reporting table 3(8)		
	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. See reporting table 3(12)	This open point became obsolete. Method(s) of analysis for the metabolite TSN 028333 free and conjugated not necessary as it was not included in the residue definitions.	Open point closed.

Appendix 2: Evaluation table

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 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	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	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	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
	the plant residue definitions, the metabolism study being performed at a 1.5N level. See reporting table 3(8)	forage (0.034 mg/kg in the NOR study), once a correction is made for 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.	below 0.05 mg/kg (0.34 mg/kg) and further reduced to 0.023 mg/kg if the 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.

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)			

REPORT OF PRAPeR EXPERT MEETING TC 10

TRIFLURALIN

Rapporteur Member State: GR

Specific comments on the active substance in the section

4. Fate and behaviour in the environment

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

1. Comments submitted for this meeting:

Date	Supplier	File Name
none		

2. Documents submitted for meeting:

Date	Supplier	File Name
May 2009	GR	Trifluralin_additional report_addendum_1 Vol3_B8 (May 2009).doc
May 2009	GR	Trifluralin_additional report_corrigendum_1 Vol3 B8 (May 2009).doc
2009-04-29	GR	Trifluralin_evaluation_table_rev 1-0 (2009-04-29)_phys-chem_residues_ecotox.doc
2009-05-07	GR	Trifluralin_evaluation_table_rev 1-0 (2009-05-07)_fate and behaviour.doc
2009-04-08	GR	Trifluralin_reporting table rev 1-1 (2009-04-08).doc
April 2009	GR	Trifluralin_updated list of endpoints (April 2009).doc

3. Documents tabled at the meeting:

Date	Supplier	File Name
None		

The conclusions of the meeting were as follows:

4. Data on preparations: EF-1521

5. Classification and labelling: candidate for R53

6. Recommended restrictions/conditions for use: Only soil incorporation by cultivation after spraying have been assessed in the resubmission.

7. Reference list: Not discussed

Areas of concern: Surface water exposure assessment not finalised. Potential for long range atmospheric transport cannot be concluded without the provision of the available monitoring data from areas remote from agriculture.

Appendix 1: Discussion table: TRIFLURALIN

Appendix 2: Evaluation table

Appendix 1: Discussion Table, Trifluralin (Hb)

4. Fate and behaviour

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	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	The applicant's reply to the FR comment in the Reporting Table was reproduced by the RMS in the evaluation table. In addendum 1, the leaching potential of metabolite TR-4 was addressed. The Koc of TR4 and trifluralin calculated with pckocwin v1.66 are compared and their molecular structure resemblance of these two substances is discussed. Trifluralin Measured K_{FOC} = 6414 – 13414 mL / g (mean 8764.7 mL / g). Calculated K_{dOC} = 9682 mL / g TR- 4 Calculated K_{dOC} = 13 600 mL / g The applicant proposes to use a default 1/n = 1 in the modelling. TR-4 is identical to trifluralin except for one of the nitro groups that has been reduced to amino. The resulting structure is an aniline. The calculated value is expected to represent the unprotonated aniline.Anilines may be protonated in neutral or acidic soils, but a measurement would be needed for confirmation.However, protonated compounds are expected to be more strongly adsorbed to soil than the neutral form that the QSAR has calculated. Protonation may increase water solubility as well as increase attraction to the overall negatively charged soil. In this case, the experts considered that the QSAR estimate could be regarded as a value that could be used as an input in soil mobility modelling. 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	Open point fulfilled.

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	TR 4 has been considered not essential to finalize the EU assessment. See reporting table 4(1)	with a 1/n = 1 for the applied for representative uses that have been assessed. 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.	
	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)	New PEC SW have been provided by the applicant in order to address this open point and open point 4.4. These new calculations have been reproduced by the RMS in addendum 1. According to Commission Regulation No. 33/2008, that regulates the accelerated procedure for $2^{nd}/3^{rd}/4^{th}$ stage substances (Art 13-22), new information after finalisation of the additional report is only allowed in case of stage 3 and 4 substances. The new modelling the applicant provided was not requested by the peer review. It was noted that the whole system sediment water decline rates that are available in this case (geomean 5.4 days) represent dissipation due to the measured volatility in the laboratory sediment water studies. Input values used in the Step 3 and Step 4 calculations were as presented in the additional report (on page 16). DissT50 water = 13 d (due to adsorption to sediment+volatilisation) was used as DT50 in water. DissT50 sediment = 17 d (whole system value from the Yon 1993 supplementary study where sediment alone was dosed that includes losses by volatilisation (volatile trap measured values not included)). The experts considered that the maximum PECsw and PECsed at step 3 would result from a loading to the water body driven by drift. If this maximum value is used for the risk assessment, as the maximum PEC will be driven by drift, then the existing step 3 PEC could be used. However if information on the pattern of exposure at step 3 or step 4 calculations are needed for the assessment, then the calculations in the additional report	Open point fulfilled. New data gap proposed, see below.

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
		(as amended by the corrigendum) provided for the teleconference could not be accepted. The exposure patterns from the modelling in the additional report were not reported by the applicant in their modelling report (see data gap 4.1). The experts discussed which soil incorporation depth was agronomically appropriate. As incorporation will be carried out using cultivation techniques that do not completely invert the soil (e.g. harrowing), a depth of 5 cm was considered most realistic. No discussion is possible on the new calculations presented in addendum1. The experts agreed the following data gap: 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 of FOCUS reference condition normalised laboratory values (*ca.* 135 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 that the models produced should be reported. The application window used in simulations should be appropriate and clearly reported. From the ecotoxicology meeting PRAPeR 68, it was clear that the ecotoxicology experts need to know the exposure profile and not only the max PEC SW in order to finalise the long-term assessment and to be able to set the long-term effects study end points. The necessary information was not available in the dossier evaluated by the RMS in the additional report and should be considered part of the data gap identified.	
	New data gap 4.2 identified at PRAPeR TC 10 meeting: FOCUS surface water		Data gap open.

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	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: Soil DT50 geometric mean normalised to FOCUS reference condition laboratory values (*ca.* 135 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 + runoff mitigation at step 4 should be reported separately. For step 3 and 4 the patterns of exposure (eg. graphical outputs from TOXSWA) that		

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	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)	The corrigendum to the additional report contains information of the application dates selected by the pesticide application timer (PAT), but the windows prescribed for the simulations in SWASH were not reported. The wording of the data gap at open point 4.2 makes it clear that this information is needed for the new simulations.	Open point fulfilled See new data gap 4.2.
	Open point: 4.4 RMS: Risk assessment based on a maximum 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)	The FOCUS Step 3 and FOCUS Step 4 calculation presented in the dossier evaluated for the additional report was performed with SWAN applying spray drift and run-off mitigation simultaneously (for run-off scenarios even incorporation over the top 5cm was appropriately parameterised). The applicant therefore stated that it was not possible to retrospectively separate the contribution of spray drift and run-off and drainage to the loads into surface water. New PEC SW have been provided by the applicant in order to address this open point and open point 4.2. The new calculations have been reproduced by the RMS in addendum 1. According to Commission Regulation No. 33/2008, that regulates the accelerated procedure for $2^{nd}/3^{rd}/4^{th}$ stage substances (Art 13-22), new information after finalisation of the additional report is only allowed in case of stage 3 and 4 substances. Therefore, no discussion on the new calculations presented is possible. Since Step 4 calculation cannot be confirmed, only Step 3 values presented in the additional report could in principle be taken into account for the risk EU risk assessment. However, as in this case consideration of mitigation and / or information on the exposure	Open point fulfilled. See new data gap 4.2

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
		pattern is proposed as being necessary to finalise the EU risk assessment, a new data gap is identified (see data gap and discussion at open point 4.2).	
	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 °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)	Further details have been presented in addendum 1 Appendix II (page 51). The applicant indicated that the table presented on page 51 corresponds to the table found in the Appendix I of G. Reeves 2005 study report. The values are normalised for moisture but not for temperature (GEOMEAN 115 d). They would need to be normalised for temperature (from 22 to 20 °C using the Q10 used for the submission (2.2)). EFSA did the normalisation. Norm moist Norm T 20°C T 22°C 20 91 105.8 57 66.3 139 161.6 116 134.9 240 279 114.95 133.66 29 3 Open point remains regarding temperature correction: 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.	Open point still 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.
	Open point: 4.6 Formation fraction assumed for TR-4 needs to be justified in an addendum. See reporting table	The applicant clarified that the formation fraction assumed in PEC SW calculations was 1. The formation fraction for PEC GW (PEARL simulations) was 0.5. This value is regarded by the applicant to be conservative, but was not supported by any kinetic analysis. The assessment of potential GW contamination by TR4 is not considered essential to finalise the EU risk assessment, since it appears as a major metabolite only under anaerobic conditions. However, the meeting discussed if the assumed formation fraction of 0.5 may be regarded as a worst case. It was noted that the maximum observed	Open point fulfilled.

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	4(12)	amount of TR4 was 13 % AR at the end of the anaerobic degradation study when only 23% AR remained as parent compound. Valid kinetic analysis was not possible, since there are only three data points available (0, 30 and 60 d after anaerobic conditions are established). The experts considered that generally a value for formation fraction of 1 should have been used for groundwater as well as surface water exposure simulations. In any future calculations this approach would be preferred. The experts did not see the need for new simulations in this case, as the results from the simulations would not be expected to change significantly here. More importantly, the simulations were not required to finalise the EU level exposure assessment.	
	Open point: 4.7 RMS to remove asterisks in an Addendum to the Additional report. See reporting table 4(16)	The requested amendment was included in the corrigendum to the additional report. However, the list of endpoints needs updating in a consequent way.	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.		Open point open.
	Data gap: 4.1 Applicant to provide additional report with complete results of the FOCUS Step 3 Step 4 calculations.	This data gap is replaced by the new data gap at open point 4.2	Data gap closed. Now incorporated in the new data gap 4.2.

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	See reporting table 4(17)		
	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)	See discussion under open points 4.2 and 4.4. The exposure patterns (eg. graphical outputs from TOXSWA), 'global maximum' concentrations and TWA values should be provided in the applicant's modelling report. In the RMS assessment the information necessary to complete the aquatic risk assessment would need reporting. Information from PRAPeR 68 indicates that the information on the exposure patterns (graphical outputs from TOXSWA) i.e. number of exposure peaks and interval between peaks at the different scenarios and season of exposures at different scenarios appear to be important for the long-term aquatic risk assessment.	Open point fulfilled. See also open points 4.2, 4.4 and new data gap 4.2.
	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.	The applicant confirmed that there was an error on the incorporation depth assumed in the PEC GW assessed in the additional report. Whilst new simulations have now been provided by the applicant , this new information cannot be considered according to Commission Regulation No. 33/2008. The experts therefore requested that the RMS does FOCUS simulations with one of the FOCUS groundwater models using an incorporation depth of 5cm for the active substance trifluralin.	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

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	Otherwise, a data gap for an amended report with the correct input parameters will be identified. See reporting table 4(21)		
	Open point: 4.10 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. See reporting table 4(22)	The experts agreed that this was important for this substance (mitigates potential volatilisation losses and is the basis for the exposure estimates from both the run-off scenarios that are available and that have been asked for in the data gaps).	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.
	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 –	The experts agreed that recommendations regarding incorporation would potentially reduce volatilisation losses and increase the efficacy of the use of the product. Therefore this would be important for volatilisation reduction, though the data needed for a quantitative assessment under field conditions across the EU are not available. A laboratory constant air velocity and humidity experiment (24 hour study) is available demonstrating reduced volatilisation when the active substance is incorporated (over the first 24 hours after application). Therefore the recommendation to incorporate seems sensible to reduce possible short range deposition and off crop exposure and these are the only uses sustained in the resubmission.	Open point fulfilled.

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	deposition. See reporting table 4(22)		
	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 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**	This issue was raised directly by the Commission. No data on monitoring from remote areas was received by the RMS or EFSA from the Member States before the teleconference meeting. No information on monitoring from remote areas was provided by applicant in the resubmission. However, DG environment have produced a report (of July 2007) that cites monitoring from the arctic (Canadian research) indicating that long-range atmospheric transport appears to be concern from uses of triflralin. Therefore the experts agreed that it would be appropriate to identify a data gap for the applicant to provide the available Canadian monitoring cited by DG environment. (This is potentially adverse information). Any other information available relating to this should also be provided.	Open point fulfilled. New data gap proposed, see below.

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	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.		Data gap open.
	New open point 4.14 EFSA to include in the conclusion a comparison of the agreed study endpoints against the POP criteria in the Stockholm convention.	EFSA was requested by the experts to compare the results from the pertinent studies against the POP criteria in the Stockholm convention in the EFSA conclusion.	Open point open.
	New open point 4.15 RMS to update the LoEP in line with the conclusions of the		Open point open.

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	teleconference discussion.		

Appendix 2: Evaluation table

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	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
	not essential to finalize the EU assessment. 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			PRAPeR TC 10 (19 May 2009): Data gap open.

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
	laboratory values (*ca.* 135 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 mitigation of 90 % for run-off needs to be provided. Effect	EUTTF: It is not possible to retrospectively separate drift mitigation in isolation from run-off mitigation. This is because the two reductions were applied simultaneously at Step 4 in the	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 accepted by the RMS. The PECsw	PRAPeR TC 10 (19 May 2009): 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
	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)	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 confidentiality reasons.*** In this work, the actual and TWA concentrations were derived for each timepoint, and graphs obtained to	values do not change to any significant extent and 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
		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.		
	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	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.	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

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 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)			values.
	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 <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.	RMS: agree with notifier's view.	PRAPeR TC 10 (19 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
		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.
	Data gap: 4.1 Applicant to provide additional report with complete results of the FOCUS Step 3 Step 4 calculations. See reporting table 4(17)	EUTTF: The output files from the FOCUS Step 3 and 4 analysis described in report GHE-11836 were reviewed, and supplementary information obtained on the actual concentrations (as well as the previously presented TWA concentrations) calculated at each timepoint. 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	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 accepted by the RMS.	PRAPeR TC 10 (19 May 2009): Data gap closed. Replaced by the 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
		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.***		
	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.
	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	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,	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.	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

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
	gap for an amended report with the correct input parameters will be identified. See reporting table 4(21)	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 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		

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
		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.
	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	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		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
	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 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)	should not be presented for consideration by the meeting of MS experts when evaluation trifluralin.		
	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.

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
	New open point 4.14 EFSA to include in the conclusion a comparison of the agreed study endpoints against the POP criteria in the Stockholm convention.			PRAPeR TC 10 (19 May 2009): Open point open.
	New open point 4.15 RMS to update the LoEP in line with the conclusions of the teleconference discussion.			PRAPeR TC 10 (19 May 2009): Open point open.