0. General

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

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

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

Physical and chemical properties of the active substance (B.2.1)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
1(1)	Vol. 1, LoEP, Relative density, p. 69	EFSA: relative density is no longer mentioned in the new agreed template of the LoEP	DAS: No further comment RMS: Agreed. The relative density will be removed from the list of Endpoints.	Addressed: The relative density was removed from the list of endpoints.
1(2)	Vol. 1, LoEP, p. 69	EFSA: in the new agreed template of the LoEP hydrolytical stability photolytical stability and quantum yield of direct phototransformation have been removed because there are mentioned in the fate and behaviour section.	DAS: No further comment RMS: Agreed. The hydrolytical stability, the photolytical stability and the quantum yield of direct phototransformation will be removed from the list of Endpoints.	Addressed: The hydrolytical stability, the photolytical stability and the quantum yield of direct phototransformation were removed from the list of endpoints.

Physical and chemical properties of the active substance (B.2.1)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
1(3)	Vol. 1, LoEP, List of representative uses, GAP table, p. 71	EFSA: the reason of greying out should be given	DAS: No further comment RMS: The reasoning of greying out for oil crops is only due to the residue data missing. The cereals are not further supported by the notifier and this is why they are formatted both strikethrough and grey.	Open point: 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.

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

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

Classification and labelling (B.4)

For comments on classification and labelling see the relevant sections.

Methods of analysis (B.5)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)

3. Residues

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

Metabolism in plants (B.7.1)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
3(1)	Additional report to DAR, January 2009, B.7.1.5, Metabolism in oilseed rape	EFSA: It is stated in the conclusion that metabolite TSN 028333 accounts in seeds for 60.75% of the TRR (0.013 mg/kg), whereas this metabolite is only 32.83% of the TRR in table 7.1.5-3. It should be better to indicate that this assertion is only valid if it is supposed that the unknown fraction UnK 2/3 is exclusively composed of TSN 028333 conjugates that were not released after acid hydrolysis.	**DAS:** The notifier agrees that it was incorrect to add together the % TRR in the TSN028333 zone with the % TRR eluting in the region referred to as Unk 2/3 as found in Table 7.1.5-3 to arrive at a total value of 60.75% of the TRR in seed for TSN028333. This was not done either in the report or in any summaries prepared by the notifier since there was no evidence that the Unk 2/3 fraction following the acid hydrolysis step contained any additional conjugates of 028333. In fact, a strong argument could be made that it should not contain any additional residue related to 028333. Thus the maximum level of 028333 in seed from this study should not exceed 32.8% of the TRR or 0.0056 mg/kg. **RMS:** In the metabolism study it is stated that some of the metabolite TSN 028333 was priop to acidic hydrolysis and after that hydrolysis a percentage was identified as TSN 028333. A part of the polar conjugate remained as the unknown Unk 2/3 accounting up to 27.9% of the TRR. Assuming that Unk 2/3 is exclusively composed of TSN 028333 conjugate, the total amount is 60.75% (0.0103mg/kg correction due to calculation mistake of 0.13mg/kg). See also comment 3(6).	Addressed: The fraction Unk2/3 (obtained after acid hydrolysis and release of possible conjugates) should be considered as no containing additional TSN 028333 conjugates. To be clear: Fraction Unk 3 in table 7.1.5-2 was subjected to an acid hydrolysis which releases the following fractions (in table 7.1.5-3): Unk 2/3 27.92% TRR Unk 12 2.37% Unk 13 5.41% Unk 14 2.88% TSN 028333 32.83% (of which 6.15% free as observed in table 7.1.5-2) TSN 102442 6.43%

Metabolism in plants (B.7.1)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
3(2)	Additional report to DAR, January 2009, B.7.1.5, Metabolism in oilseed rape, Figure 2	EFSA: It is not easy to have a clear picture of the metabolism in plant since, depending on the DAR sections, on the studies within a section; different codes are allocated to a same metabolite. Moreover figure 7.1-4 page 454 in the DAR is confusing since one of the main metabolite (TR-14) is reported as being a nitro substituted compound whereas it seems to be an amine substituted metabolites. The RMS Should summarised in tabular form the metabolites identified in the different studies (rapeseed and maize), their respective % of TRR and using a common single reference for each individual metabolite.	**DAS**: A table such as that requested has been provided to the RMS. It is also confirmed that the metabolite referred to as TR-14 does contain an amine group at the 7-position of the benzimidazole ring and not a nitro group. The table is included in the attached document and provides additional information aimed at increasing the robustness of the assessment. ***(Attachment on additional information has been removed by EFSA for procedural and confidentiality reasons).*** **RMS**: RMS agrees with the comment. List of End Points has been amended accordingly.	Addressed: The updated list of end points (April 2009) gives effectively information on the different references used for each metabolite in the different studies.

Metabolism in plants (B.7.1)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
3(3)	Additional report to DAR, January 2009, B.7.1.5, Metabolism in oilseed rape, Figure 2	EFSA: The new metabolism study confirms effectively that trifluralin is not expected to be present in seeds at harvest. At the opposite the metabolite TSN 028333 (TR-14?), free and conjugated, represents a large part of the TRR (c.a. 50%, see comment 1) with an absolute level close or above 0.01 mg/kg. The RMS should address a statement on the toxicological relevance of this metabolite and why this metabolite has not to be included in the residue definitions (especially for risk assessment).	**DAS**: Following the correction noted in the response to item 3(1), the metabolite referred to as TSN 028333 is not present at levels exceeding 35% of the TRR. Thus even in the NOR study which was run at a 1.5X application rate, the absolute level of this metabolite barely exceeded 0.005 mg/kg, while at the cGAP rate it would not be expected to exceed 0.004 mg/kg. At these kinds of levels, this metabolite should not be considered significant and should not need to be included in the residue definition for purposes of risk assessment. **RMS**: The metabolism study in oilseed rape has been performed in an excess application rate (1.8 kg a.s./ha). Therefore, at the intended dose rate (1.2 kg a.s./ha), metabolite TSN 028333 is not expected to be higher than the trigger value of 0.01mg/kg. For that reason the RMS has not further addressed the metabolite's toxicological properties and has not proposed its inclusion in the residue definition.	Addressed. (should be considered under open point 3.8)

Metabolism in plants (B.7.1)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
3(4)	Vol. 3, B.7.1.5	NL: In the original DAR, other metabolite codes are used than in the DRAR/ This is very confusing and time consuming as metabolites need to be compared to verify whether they are the same.	**DAS**: See the response to item 3(2). **RMS**: see comment 3(2).	Addressed. (see comment 3.2)
3(5)	Vol. 3, B.7.1.5, findings, forage samples	NL: It is mentioned that "One, however, was very much the main component corresponding to TSN 028333" How is the component very much the same? Can it be considered as TSN 028333?	**DAS**: It is agreed that the description used for these residues in the DAR summary was not as clear as it could have been. The metabolite referred to as TSN 028333 did represent 43.1% of the TRR in rape forage. The identity of this component was confirmed by co-chromatography with the authentic reference standard using two different chromatographic techniques and by mass spectrometry. **RMS**: The mass spectrometric investigations confirm that TSN 028333 was present in forage samples in levels below 0.05mg/kg.	Addressed: TSN 028333 was effectively indentified in rape forage, 82 days after application, at a levels of 0.034 mg eq./kg (43.1% TRR), the application rate being 1.5N

Metabolism in plants (B.7.1)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
3(6)	Vol. 3, B.7.1.5, findings, seeds	NL: Some of metabolite TSN 028333 was in a polar form (possibly a conjugate) from which metabolite TSN 028333 can be released by hydrolysis. It appears, from adding the amounts of Unk 2/3 and TSN 028333 in table 7.1.5-3 that Unk 3 is the polar form of TSN 028333, but this is not clear enough in the text.	**DAS**: See the response to item 3(1) in this table. While some portion of the Unk 3 fraction before acid hydrolysis was a conjugate of TSN 028333 (this is the material referred to in Table 7.1.5-2), none of the residue in the Unk 3 fraction after acid hydrolysis (this is the material referred to in Table 7.1.5-3) should be considered as additional amounts of the TSN 028333 conjugate. As previously noted, the total levels of TSN 028333 (free and conjugated) in rape seed did not exceed 32.8% of the TRR. **RMS**: We agree with the comment. Although, according to the comment, it may not seem to be very clearly written in the text, from adding the amounts of Unk 2/3 and TSN 028333, Unk 2/3 is considered as the polar form of TSN 02833. See also comment 3(1).	Addressed: See comment 3.1: The fraction Unk2/3 (obtained after acid hydrolysis and release of possible conjugates) should be considered as no containing additional TSN 028333 conjugates.

Metabolism in plants (B.7.1)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
3(7)	Vol. 3, B.7.1.5, findings, seeds	NL: Metabolite Unk 3 is not mentioned in the findings, although this metabolite is most predominantly present in the seeds. It need to be proven that this metabolite is indeed a conjugate of TSN 028333 and not "possibly a conjugate"	**DAS**: In the initial HPLC analysis of the seed extract before acid hydrolysis, 71.7% of the TRR eluted in the region of the chromatogram referred to as Unk 3 (see Table 7.1.5-2). This was a highly polar fraction that was barely retained on the HPLC column (retention time of 3.5-4.5 min) and as such would be expected to be a mixture of polar components. Following an acid hydrolysis step, re-analysis of this extract (as reported in Table 7.1.5-3) showed only 27.9% of the TRR to now elute in the region of UnK 3, while a significant portion of the lost radioactivity (26.6%) now eluting as additional TSN 028333. Thus nearly 40% of the residue in the original UnK 3 fraction was shown to be a conjugate of 028333, while another 40% were other polar components that were not effected by the hydrolysis step. The remaining 20% of the radioactivity in the original fraction was divided among at least 4 other components that are shown in Table 7.1.5-3 as Unknowns 12, 13 and 14 and as metabolite TSN 102422. Based on these findings, it is clear that the material referred to as Unk 3 was a complex mixture of many components including some conjugates of 028333. **RMS**: Unk 2/3 is at very low levels (0.0047mg/kg), therefore RMS does not think that any further attempt to identify its composition would give any reliable result.	Addressed: See comment 3.1: Unk 3 (table 7.1.5-2) is not a metabolite but a fraction identified after acid hydrolysis to contain unknowns Unk 2/3, Unk 12, Unk 13, Unk 14 and metabolites TSN 028333 and TSN 102442

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

Residue definition (B.7.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
3(8)	Additional report to DAR, January 2009, B.7.3.1, Definition of the residue in plants.	EFSA: It should be considered if the metabolite TSN 028333 (TR-14 ?) has to be included in the residue definitions (see point 3 above)	**DAS**: As noted in the responses to item 3(3) above, the levels of TSN 028333 in rape seed would not be expected to exceed 0.004 mg/kg. Thus there is no need to include it in the residue definition for either risk assessment or monitoring purposes. **RMS**: see comment 3(3)	Open point: 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 study being performed at a 1.5N level.

Residue definition (B.7.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
3(9)	Vol 3, B.7.3.1, residue definition	UK: The proposed residue definition is acceptable as long as the plant metabolite TNS 028333 is not of toxicological concern (present in seed and forage at levels of 0.006 and 0.03 mg/kg respectively).	**DAS**: As noted in previous responses, residues of TSN 028333 in seed are not high enough to warrant inclusion in the residue definition. As for the levels in forage (approximately 0.034 mg/kg), once a correction is made for the 1.5X application rate that was used in the study, residues would only be about 0.020 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 residue of trifluralin 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 there is no need to include it in the plant residue definition simply due to the low levels at which it might be found in rape forage. **RMS**: See comment 3(3) for metabolite TSN 028333 in seeds. Additionally, in forage, the amount of the metabolite is below the trigger value of 0.05mg/kg for feeding staffs, so no further toxicological assessment or inclusion on the residue definition is required.	Addressed. (should be discussed under open point at comment 3.8)

Residue definition (B.7.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
3(10)	Vol. 3, B.7.3.1, residue defintion	NL: Parent trifluralin was not present in edible parts of oilseed rape at harvest. Predominant residue was TSN 028333 (free and conjugate). The toxcicological relevance of this metabolite was not assessed (see EFSA scientific report). As trifluralin is not present at harvest but TSN 028333 is at significant amounts (>10% TRR and >0.01 mg/kg), the residue definition should be TSN 028333 (free and conjugate).	**DAS**: As noted in previous responses (see items 3(1), 3(3), 3(6), 3(8) and 3(9)), no significant residues of TSN 028333 are present in either rape seed or rape forage. Thus the residue definition in plants does not need to be modified to include 028333 and should be maintained as trifluralin only. **RMS**: see comment 3(3)	Addressed. (should be discussed under open point at comment 3.8)

Residue definition (B.7.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
3(11)		NL: The toxicological relevance of TSN 028333 (free and conjugate) should be assessed, as this is the same as TR-22. Taken from ***EFSA Scientific Report* (2005) 28, 1-77, Conclusion on the peer review of trifluralin:** A data requirement was stated in the DAR regarding the plant metabolites TR-22 and TR-28 of the assessment of relevance of the metabolites in groundwater and that *in vitro* tests and acute test should be performed. However, at the expert meeting on Residues (11-12 May 2004) it was concluded that the proposed use in oilseed giving rise to this requirement was not supported by appropriate crop metabolism data. Thus, the toxicological significance of these metabolites was not needed to be considered. This message was forwarded to the expert meeting on Toxicology (May 2004) and it was agreed that the data requirement was no longer relevant.	**DAS**: As noted in previous responses, there is no reasonable expectation of human exposure to significant levels of TSN 028333 and thus no need to assess its toxicological relevance. **RMS**: see comment 3(3)	Addressed. (should be discussed under open point at comment 3.8)

Residue definition (B.7.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
3(12)		NL: As the amount of TSN 028333 (free and conjugate) greatly increased from 6.2% TRR to 32.8% after the acid hydrolysis, it should be considered whether the method(s) of analysis used in the supervised residue trials are adequate for analysing this metabolite and whether the method for monitoring is sufficiently adequate.	**DAS**: Due to the low levels of total residues in rape seed (barely in excess of 0.01 mg/kg), the total levels of TSN 028333 would not be expected to exceed 0.004 mg/kg. Thus there was no need to include this analyte in the method that was used in the supervised trials or in the method that will be used for monitoring purposes. **RMS**: see comment 3(3)	Open point: Depending on the final plant residue definitions (see open point at comment 3.8), it should be considered whether the method(s) of analysis have to include the metabolite TSN 028333 free and conjugated.

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

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

Livestock feeding (B.7.8)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
3(13)	Additional report to DAR, January 2009, table 7.1.5-1	EFSA: In rapeseed forage, the metabolite TSN 028333 (TR-14) accounts for a significant proportion (43% TRR). RMS has to reconsider the possible intake of the metabolite TSN028333 by livestock in case of crop failure and if rapeseed forage is used to feed animals.	**DAS**: As noted in previous responses 3(9), for the levels in forage (approximately 0.034 mg/kg), once a correction is made for the 1.5X application rate that was used in the study, residues would only be about 0.020 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 residue of trifluralin 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 there is no need to include it in the plant residue definition simply due to the low levels at which it might be found in rape forage. **RMS**: see comment 3(9)	Addressed: The intake by animal considering a possible residue level of 0.02 mg/kg is effectively below the trigger value of 0.1 mg/ kg DM.

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

MRLs related issues and Consumer Risk Assessment (B.7.10 to B.7.15)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
3(14)	Vol. 1, Appendix 1 – List of End Points and Vol. 3, Annex B-7, B.7.15.1	EUTTF: The notifier agrees with the RMS that the dietary risk is acceptable - up to only 0.7% of the ADI. This has been calculated by including both oil seed and cereal crop groupings. As the re-submission is for oil seed crops only, (See Doc D), the dietary risk assessment should be re-calculated for oil seed crops only.	**DAS**: No further comment **RMS**: RMS agrees with the comment and the results of the chronic dietary risk assessment for only oil seed crops are in the updated List of end points. The highest TMDI calculated and expressed as percentage of the estimated ADI accounts up to 0.1% of the ADI.	Addressed: The consumer risk assessment has been reconsidered in the LoEP taking into account the oil seed crops only.
3(15)	Vol 3, B,7.11, Community MRLs	UK: The EFSA conclusion sought 'Further information on conduct and comparability of North American residue trials in cereals is required to support Southern European uses. (relevant for the representative uses in cereals); This has not been provided so relevant uses must be restricted to NEU.	**DAS**: As noted in response to point 3(14) 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**: see comments 3(14) and 3(16)	Addressed: The cereal uses are no longer supported in the resubmission.

Other comments				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
3(16)	Vol. 1, Appendix 1 – List of End Points List of representative uses evaluated. Page 71, Winter Cereals in the Northern zone. Page 81, Metabolism in plants. Page 83, summary of critical residues data. Page 84 – Proposed MRL's	EUTTF: The cereal use, both in the Northern and Southern EU zones is not being supported by this re-submission action. An updated Doc D (submitted with dossier in July 2008) indicating the GAP's being supported in the re-submission are for oil seed crops only.	**DAS**: No further comment **RMS** agrees with the comment.	Addressed.
3(17)	EFSA conclusion	UK: Residues in forage were below the limit of determination, therefore no with-holding period is required. (point raised in EFSA conclusion)	**DAS**: No further comment	Addressed.
3(18)	Vol. 1, List of Endpoints, Summary of critical residues data	NL: In the second column next to sunflower it says: There are no residue trials for winter cereals in Southern Europe	DAS: As noted in response to point 3(14) 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: RMS agrees with the comment and the List of End Points has been amended appropriately.	Addressed: The cereal uses are no longer supported in the resubmission and the LoEP has been amended.

4. Environmental fate and behaviour

Adsorption,desroptionand mobility in soil (B.8.2)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(1)	Vol. 3, B.8.2, Adsorption and desorption and mobility in soil, p.568	FR : We note that new adsorption study was required for the anaerobic metabolite TR-4 if non-relevance can not be justified. Due to autumn use in the GAP this can be important. No new study/justification is given in the fate and behaviour section of the additional report.	DAS: 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) 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. Also see 4(9). RMS: According to the EFSA conclusion "relevance of metabolite TR-4 may be addressed by Member States where anaerobic conditions are envisaged to be relevant". Also, no mention is made to TR-4 in the section "LIST OF STUDIES TO BE GENERATED OR STILL ONGOING" of the EFSA conclusion.	Open point: 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.

PEC in soil (B.8.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)

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

PEC in surface water and in ground water (B.8.6)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(2)	Additional report, B.8.6.1, Table 8.6.1.1.	EFSA: The solubility in water and Koc of trifluralin are not estimated (as suggested by the foot note) but experimentally measured and reported in the list of end points.	DAS: No further comment, RMS to correct. RMS: Agree with EFSA and DAS. The LoEP will be corrected to address this inconsistency.	Addressed.
4(3)	Additional report, B.8.6.1	EFSA: Input parameters used for FOCUS Step 3 and Step 4 for the active substance are not in agreement with FOCUS kinetics recommendations. Since no kinetic degradation half lives in the separated phases (water and sediment) are available (only dissipation half lives), whole system half life should have been used for one phase and default worst case of 1000d should have been used for the other phase.	DAS: It is accepted that the latest FOCUS kinetics guidance has not been followed. However, 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 (8765 mL/g) such that even if a much longer water DT50 than 13 d was used (e.g. a default value of 1000 d), similar PECsw values would be obtained and this would not significantly change the risk assessment. RMS: Formally we agree with EFSA but due to the high Koc of trifluralin the PECsw values would not be significantly altered by the use of the appropriate DT50.	Open point: 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. Open point: Application window to be provided by the RMS in an addendum.

PEC in surface water and in ground water (B.8.6)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(4)	Additional report, B.8.6.1	EFSA: According the final version of the FOCUS Landscape and mitigation guidance a maximum cap of 90 % should be applied to the runoff that may be mitigated. For the 20 m vegetative strip it should be demonstrated that the 80 % reduction on the water loadings and 95 % reduction on the sediment loadings are not actually producing a run off mitigation higher than the 90 %. Effect of spray drift mitigation should always be presented isolated from the effect of run off mitigations in order to adequately asses the proposed mitigation measures.	DAS: No further comment, FOCUS Landscape and Mitigation group to address. RMS: The final report of FOCUS Landscape and mitigation was formally noted in March 2008, i.e., after the original notification of trifluralin. Thus, we consider that this guidance document should not apply to the evaluation of the re-submission dossier. From a technical point of view, for the runoff reduction into streams, it is necessary to account for the fact that only 20% of the upstream catchment is treated with pesticide (and therefore has runoff reduction applied to it). Therefore, for a 20 m buffer, the reduction in pesticide flux is 80% but the reduction in runoff water volume is 16% (i.e. 80% of 20%).	Open point: 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.
4(5)	Additional report, B.8.6.2	EFSA: 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.	DAS: No further comment, RMS to address. RMS: The following individual DT50's (22ºC, aerobic, moisture) were normalized to pF2 using the a Walker coefficient of 0.7 and subsequently averaged: - SL: 154 days, 75% MWHC - L: 81 days, 75% MWHC - CL: 179 days, 75% MWHC - Speyer 2.1: 136 days, 40% MWHC - Speyer 2.2: 356 days, 40% MWHC	Open point: 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.

PEC in surface water and in ground water (B.8.6)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(6)	Additional report, B.8.6.2	EFSA: additional to moisture DT 50 should be normalized for temperature to 20 ºC.	DAS: This is not necessary for model input if the series of DT50 values were all derived at the same temperature, and that this temperature is then entered into the model. RMS: Agree with DAS	See open point at comment 4(5)
4(7)	Vol. 3, B.8.6.1 Revised PEC sw and sed	UK: The input parameters for trifluralin have been checked against the agreed endpoints. There are some issues in that the DT50 in soil is incorrect (mean DT50 used if from studies at 22ºC, not 20ºC, thus mean DT50 should be 211 days) and we have reservations over the water and sediment half-lives. Water/sediment system half-lives appear, on the basis of the EFSA conclusion, to be strongly affected by volatilisation out of the systems, and thus it is unlikely that the DT50 values quoted represent true degradation. There is no justification at all for the sediment DT50 (from a check on the endpoints in the EFSA conclusion). It would have been useful to have seen the 'application window' used at Steps 3-4. However, that said, the input parameters listed above are unlikely to have a significant influence on the highest PECsw value as this appears to be dominated by spray drift input, as might be expected from the high Koc.	DAS: The impact of using a soil DT50 of 181 d versus 211 d in the aquatic risk assessment is not considered to have made a significant difference. DAS: As the notifier has already indicated in comments to point 4(5), it is accepted that the latest FOCUS kinetics guidance has not been followed. However, 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 (8765 mL/g) such that even if a much longer water DT50 than 13d was used (e.g. a default value of 1000 d), similar PECsw values would be obtained and this would not change the risk assessment. The notifier is pleased to see that the UK recognises this. RMS: Agree with DAS	See open points at comment 4(3) and 4(5)

PEC in surface water and in ground water (B.8.6)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(8)	Vol. 3, B.8.6.1 Revised PEC sw and sed	UK: PEC values for metabolites at Steps 1 and 2 are based on worse case assumption for formation and degradation, and software estimates for solubility and Koc. Thus peak PECsw is likely to be worst case and the PECsed will also be high due to the high Koc values used.	DAS: No further comment. RMS: No comment.	Addressed
4(9)	Vol 3, B.8.6.2 new PECgw using FOCUS pearl.	UK: The input parameters have been checked for both trifluralin and TR-4 metabolite. It would have been useful to have seen details of the moisture correction conducted on the trifluralin soil DT50 values, as we cannot tell whether this is appropriate from the information given. In addition, the formation fraction for TR-4 is a simple estimate of 0.5 and is not based on kinetic modelling. The TR-4 metabolite Koc is based on a software estimate, not an experimentally measured value, but this seems to have been accepted by EPCO. Overall we can accept the results as broadly indicating that risk to groundwater from both parent and TR-4 will be low, mainly driven by very high Koc.	DAS: No further comment. RMS: See comment to point 4(5)	See open points at comment 4(1) and 4(5).

PEC in surface water and in ground water (B.8.6)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(10)	Vol 3 B.8	NL: For PECsw/sed calculation the DT50 whole system should be used as input in the degrading compartment and a default of 1000 days for the non-degrading compartment, unless it is demonstrated that the separate compartment DT50 values really represent degradation values (level P-II approach as described in FOCUS Degradation Kinetics). Please explain the term SWAN (this is not SWASH?). Why was no incorporation applied for the D scenarios?	DAS: As the notifier has already indicated in comments to point 4(5), it is accepted that the latest FOCUS kinetics guidance has not been followed. However, 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 (8765 mL/g) such that even if a much longer water DT50 than 13d was used (e.g. a default value of 1000 d), similar PECsw values would be obtained and this would not change the risk assessment. SWAN = Surface Water Assessment eNabler. This is a tool developed by the FOCUS workgroup to more easily allow drift and run-off mitigation to be modelled at Step 4. No incorporation in the D scenarios (for a pesticide with a very high sorption Koc) should represent a worst case. RMS: Agree with DAS	See open points at comment 4(3) and 4(4).
4(11)	Vol 3 B.8	NL: For a 20m buffer, a reduction in the volume of runoff and pesticide loading into water of 80% for a 20 m buffer and a reduction into sediment of 95% was implemented that are derives from the FOCUS L&M report. For methomyl (discussed in teleconference_1) the same reduction % is used for both water and sediment (90 % drainage and run-off)). Please explain how a different run-off reduction percentage for water (80%) and sediment (95 %) could be implemented in this case.	DAS: The Notifier has followed the FOCUS L&M report and cannot comment on what was used for methomyl. RMS: See Table 7, p.33, FOCUS LANDSCAPE AND MITIGATION FACTORS IN AQUATIC ECOLOGICAL RISK ASSESSMENT, Volume 1, Extended Summary and Recommendations	See open points at comment 4(3) and 4(4).

PEC in surface water and in ground water (B.8.6)				
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4(12)	Vol 3 B.8, PECgw	NL: Please give justification to use the QSAR derived data (especially Koc, which may have large impact on the PEC) for TR4, since this is not accepted in case the metabolite is major or in case of a minor metabolite not represented well by the database in EPIWIN (see PRAPeR 32). The lack of experimental sorption data was mentioned as a data gap in the first peer review round. NL can agree with the other conservative assumptions regarding formation fraction and DT50. It is noted that the old Q10 (2.2) value is used. To our understanding the new Q10 value is to be used for resubmission dossiers.	DAS: Regarding the QSAR approach for the TR-4 Koc, see responses to point 4(1). DAS: Regarding the use of a Q10 of 2.2, this was the recommended value in place at the time of the modelling reports. With such high Koc values for trifluralin and TR-4, it is considered that re-modelling with the new Q10 of 2.58 would not change the PECgw. RMS: Re. QSAR, see comment to point 4(1). Re. the Q10 value, the old value should be used for resubmission dossiers (clarified at teleconference_7 cadusafos)	See open point at comment 4(1) (for Koc discussion) Open point: Formation fraction assumed for TR-4 needs to be justified in an addendum.
4(13)	Vol. 3, Annex B-8, Table B.8.6.1.1, Chemical Specific Input Parameters for Steps 1 and 2 for trifluralin	FR : The values, concerning Koc and the solubility in water, do not come from a calculation by EPI Suite. A solubility study in distilled water at 20°C has permitted to determine this value. Koc is a mean value, these data come from a study based on four soils. Please remove asterisk.	DAS: No further comment, RMS to correct. RMS will remove asterisks in an Addendum to the Additional report	Addressed.
4(14)	Vol. 3, Annex B-8, Table B.8.6.1.1, Chemical Specific Input Parameters for Steps 1 and 2 for trifluralin	FR : Concerning DT50 in soil for Trifluralin, it is mentioned that the value at 20°C is 181 days. According to the DAR and EFSA report, this data has been determined at 22°C and is a mean of five soils. DT50 at 20°C is 212 days according to the LoEP.	DAS: No further comment, RMS to clarify. RMS: DT50 in soil for Trifluralin is indeed 181 days at 22°C.	See open points at comment 4(3) and 4(5)
4(15)	Vol. 3, Annex B-8, Table B.8.6.1.3, Chemical Specific Input Parameters for Step 3 and 4	FR : As previous point, DT50 at 20°C should be 212 days.	DAS: No further comment, RMS to clarify. RMS: see comment to point 4(14)	See open points at comment 4(3) and 4(5)
4(16)	Vol. 3, Annex B-8, Table B.8.6.1.3, Chemical Specific Input Parameters for Step 3 and 4	FR : Concerning saturated vapour pressure, the value is correct but the study has been done at 25°C, not at 20°C.	DAS: No further comment, RMS to correct. RMS will correct this in an Addendum to the Additional report	Open point: RMS to remove asterisks in an Addendum to the Additional report

PEC in surface water and in ground water (B.8.6)				
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4(17)	Vol. 3, Annex B-8, B.8.6.1, Result of PECsw calculations at Step3 and 4	FR: The way the results of Step3 and 4 calculations are presented does not allow to estimate the exposure pattern in different scenarios. At least the actual concentrations should be presented for all the time points (as is done for twa concentrations) to be able to assess if exposure happened only at the day 0 or if exposure was more or less continuous (pulsed input). The exposure pattern should be checked also from the exposure figures in the model to be sure that the default days (1, 2, 4, 7, 14, 21 days etc.) follow the real pattern in the scenario. It is important for ecotoxicological risk assessment to know if exposure pattern including pulsed inputs can happen. It could induce a multiple exposure of aquatic organisms and possibly a more or less continuous exposure. If such a scenario is realistic, it should be considered by ecotox assessor, and the choice of the toxicological endpoint (obtained from flow-through / static test) for risk assessment may change. See FR ecotox comment N° 8; Vol. 3, Annex B-9, B.9.2., Chronic risk to aquatic organisms; Table B.9.2.8-16	DAS: In report GHE-P-11836, only the global max. and TWA concentrations are presented since these are required for the risk assessment. However, for the wOSR use where the maximum number of D and R scenarios are available (compared to sunflowers and cotton), the TOXSWA output files have been reviewed and the actual PECsw values extracted for the Step 4 analysis with a 20 m buffer zone. These are presented again below as appendix 1 to provide additional supplementary information aimed at increasing the robustness of the assessment. ***(Attachment on additional information has been removed by EFSA for procedural and confidentiality reasons).*** RMS: Agree with DAS	Data gap: Applicant to provide additional report with complete results of the FOCUS Step 3 Step 4 calculations. Open point: MSs to decide which missing information on the results of FOCUS SW simulations is considered essential to finalise the EU risk assessment. See also open point in comment 4(3) and 4(4). **For procedural reasons, new studies or additional information cannot be considered in the peer review.**

PEC in surface water and in ground water (B.8.6)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(18)	Vol. 3, Annex B-8, B.8.6.1, Result of PECsw calculations at Step 4	FR: It is not clear from the results of Step 4 calculations which route of entry is the main route (spray drift or run-off/drainage). Separate results for spray drift only and run-off/drainage should be presented. The choice of the more relevant DT50 in water (obtained from water-spiked or sediment-spiked test) for PECsw calculation will be induced by the main route of entry. The DT50 of 2 days might be more relevant if run-off is the main route of entry in water (active substance is adsorbed into soil particles when it enters the water body). Otherwise FR supports the use of the more conservative DT50 of 13 days. See FR ecotox comment N° 9; Vol. 3, Annex B-9, B.9.2., Chronic risk to aquatic organisms; Table B.9.2.8-16	DAS: Example graphs from TOXSWA at Step 4 providing additional supplementary information aimed at increasing the robustness of the assessment are shown in Appendix 2 at the end of this section for the drainage (D2) and run-off (R1) scenarios, with an application on 9 and 6 Oct, respectively. In general, spray drift is dominant for the D scenarios, whilst run-off gives rise to the maximum in the R scenarios. ***(Attachment on additional information has been removed by EFSA for procedural and confidentiality reasons).*** DAS: As the notifier has already indicated in comments to point 4(5), it is accepted that the latest FOCUS kinetics guidance has not been followed. However, 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 (8765 mL/g) such that even if a much longer water DT50 than 13d was used (e.g. a default value of 1000 d), similar PECsw values would be obtained and this would not change the risk assessment. RMS: Agree with DAS	See data gap and open point at comment 4(17). **For procedural reasons, new studies or additional information cannot be considered in the peer review.**
4(19)	Vol. 3, Annex B-8, B.8.6.2, Predicted Environmental Concentrations in Ground Water	FR : A new DT50 value (115 days) is used in Focus PEARL to estimate the PECgw, the reasoning is correct (geomean). However, DT50 should be normalised to 20°C, but t we don't expect this to affect the PECgw in this case, since all the concentrations are <0.001 µg/l.	DAS: Agree. RMS: This is not necessary for model input if the series of DT50 values were all derived at the same temperature, and that this temperature is then entered into the model.	See open point at comment 4(5).

PEC in surface water and in ground water (B.8.6)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(20)	Vol. 3, Annex B-8, B.8.6.2.2, Model Inputs to FOCUS PEARL	FR : For TR-4, the Freundlich sorption exponent used in Focus PEARL is 0.9. It is a default value for this model but for a conservative approach, a value of 1 can be suggested, since only one Koc is available from EPI Suite program.	DAS: This is AFSSA's opinion for national submission. The notifier believes that 0.9 is still appropriate at EU level unless further guidance is received. RMS: It is reasonable to use a 1/n value equal to the parent's. In view of the modelling outcome (TR4 conc. < 0.001 in all scenarios), using 1/n = 1 would not alter the assessment significantly.	See open point at comment 4(1)
4(21)	Vol. 3, Annex B-8, Table 8.6.2.3, Application Parameters	FR : The depth value is incorrect. Considering GAP, it should be 0.05 m. Is this just a typo error or has 0.005 m been used in modelling? Please correct the data.	DAS: The incorporation depth would at a minimum be 5 cm or 0.005m. RMS: It was just a typo.	Open point: 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.

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

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

Other comments				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(22)	Consideration of ´Recommended restriction/conditions for use´ decided at EPCO Expert Meeting 02 (27.04.2004) in update of conclusion on trifluralin	**DE:** The recommendation from the EPCO Expert Meeting 02 (fate & behaviour) regarding the restriction of uses to soil incorporated uses only was not included in the final conclusion of EFSA on trifluralin from 2005. Representing a relevant outcome of the expert discussion this recommended restriction should be considered in an updated conclusion on trifluralin. For uses without incorporation (post-sowing in cereals) unacceptable risk due to entries in non-target areas via volatilisation and deposition was identified by German authorities for a product evaluated within the national registration procedure, and therefore no authorisation is possible. Without incorporation the volatilisation of trifluralin from soil surface following spray application accounted for 41 to 67 % AR after 24 h whereas with incorporation it is reduced to 1.1- 1.4 % after 24 h. We think that the application of trifluralin without incorporation does not comply with GAP and common IPM principles. Under worst case conditions more than half of the active substance can be lost by volatilisation within 24 h and is therefore not available any more for its intended use as herbicide. Considering this fact and that the actual aquatic risk assessment (and for terrestrial ecosystems as well) does not even account for deposition after volatilisation as an entry path because of missing harmonised guidance we strongly support the conclusion of the EPCO 02-Meeting (27.04.2004) to restrict intended uses to uses with soil incorporation only.	DAS: As noted in response to point 3(14) and 3(16), the resubmission is for the support of oil seed crops only ie: incorporated uses only (See Doc D of the resubmission dossier) Cereal use ie:“non-incorporation” is not included or being supported in the resubmission action.	Open point: 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. Open point: 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.

Other comments				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(23)	Vol. 1, List of End points, PEC_{sw} point 9.2.3 and PEC_{gw} point 9.2.1	EUTTF: For the new PEC_{sw} and PEC_{gw} studies additional endpoints have been added to the List of Endpoints Section. However, as the original endpoints have been left included, there is not clarity for MS's as to which endpoints should be used.	DAS: No further comment. RMS: The LoEP will be amended accordingly	See open point at comment 4(3)
4(24)	General	NL: It seems no non relevance assessment was delivered for the metabolite. Correct?	DAS: Not required since the TR-4 PECgw was <0.001 µg/L. RMS: From ESFA conclusion: "Relevance of TR4 for the proposed representative uses and need for further assessment was discussed in the fate and behaviour in the environment expert meeting (EPCO 2, April 2004). Whereas it was not possible to exclude the relevance of anaerobic conditions for the representative uses it was judged, based on molecular structure, that this metabolite would be degraded under aerobic conditions. However, MS may need to address further the fate and behaviour and ecotoxicology of this metabolite for specific environmental conditions".	Addressed.
4(25)	Vol 1 LoEP	NL: No PECair was provided, based on the argument that there was no methodology available at the time the addendum was prepared. Methodology for calculating PECair is not included in FOCUS Air GD. However, the SRT and resulting deposition to soil and water could be addressed now. No further comments on LoEP (yellow/new parts).	DAS: No further comment. RMS: No comment	See open point at comment 4(26)

Other comments				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(26)	General comment	SE: We do not consider that the Additional Report to the DAR (January 2009) address the PBT-concerns that were raised during the review program. Trifluralin is a substance with properties that are clearly unwanted with regard to persistence in the environment, potential for bioaccumulation and toxicity. The substance has been assessed to fulfil the POP screening criteria by the TC NES sub group (DG Environment) in accordance with Regulation 850/2004. Trifluralin is a candidate for inclusion in the Annex I to the Protocol to the 1979 Convention on Long-Range Transboundary Air Pollution on Persistent Organic Pollutants (LRTAP Protocol on POPs). In the "TRIFLURALIN -Dossier prepared in support of a proposal of trifluralin to be considered as a candidate for inclusion in the Annex I to the Protocol to the 1979 Convention on Long-Range Transboundary Air Pollution on Persistent Organic Pollutants (LRTAP Protocol on POPs). European Commission, DG Environment, Brussels. July 2007" it is stated that	DAS: The notifiers' evaluation and mitigation statements addressing the pbt-concerns provided in the resubmission dossier have not been presented in the "Additional Report to the DAR (January 2009)". PBT criteria are not part of the evaluation according to Annex VI of the EU Directive 91/414. Additionally the notifier highlights: a) TC-NES sub-group The notifier is not aware that an assessment by this sub-group forms part of the 91/414 evaluation criteria. Furthermore, in the summary prepared for the Commission by the chairperson, Dr. Beatrice Schwarz-Schulz, not all Member States party to the sub-group agreed with the assessment as reflected in the statement below: "*This conclusion has been drawn having in mind that some of the comments indicate that a conclusion on the relevance of the persistence for the identification of a global concern may need more detailed investigation of the responsible boards"*	Open point: 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 of trifluralin are welcomed to present such data in a report to the RMS and EFSA for further consideration by the meeting of experts.**

Other comments				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
		"Based on the available data, trifluralin should be considered as a POP, warranting global action. All in all, safe levels of exposure cannot be set for substances such as trifluralin, which are not only highly persistent and highly bioaccumulative but also chronically toxic towards aquatic organisms, because of the difficulties in assessing long-term effects of life-long exposure to even low concentrations. Production and use of trifluralin continues and it is still extensively produced and used as a herbicide. When it is still used as pesticide, it will be directly released to the environment. Moreover, the high persistency of the substance has caused high contamination of soil and waters in the areas where it has been used and these contaminated sites can serve as a source of pollution for a long time.	b) LRTAP Trifluralin is not "*a candidate for inclusion in the Annex I to the Protocol to the 1979 Convention on Long-Range Transboundary Air Pollution on Persistent Organic Pollutants"* as claimed by the Member State. Trifluralin was nominated to the Executive Body of LRTAP in December 2008 for consideration and further evaluation under the LRTAP Protocol. However Canada raised concerns whether the nomination met the necessary criteria which have been documented in the minutes. Trifluralin will now be considered through Track A and B of the LRTAP protocol before being considered as a "candidate for inclusion in the Annex I of LRTAP". In summary, as presented in the notifiers' submitted evaluation and mitigation statements, the notifier believes trifluralin does not full fill the necessary screening criteria and therefore should not be considered as a POP. RMS: Issue to be discussed thoroughly in an expert's meeting.	See open point at comment 4(26).

Other comments				
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4(27)		It has been demonstrated that trifluralin is persistent in the environment. It has a high potential for bioaccumulation and biomagnification. There is monitoring data in arctic air that indicates long-range transport of the substance, but there are no monitoring data in biota from areas remote from sources. The physical and chemical properties as well as modelling of potential long range transport suggest that trifluralin can be transported over long distances bound to particles in air and water." Therefore, we consider that the appropriate measure to control the use of trifluralin is to withdraw the substance from the market.	DAS: See notifier's response to point 4(26). RMS: Issue to be discussed thoroughly in an expert's meeting.	See open point at comment 4(26).

5. Ecotoxicology

Aquatic organisms (B. 9.2)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(1)	Vol. 3, B.9.2.2, Chronic toxicity to fish	DE: We propose to discuss in the expert meeting whether for the chronic risk assessment the value of 10 µg/L from the study with *P. promelas* in the water/sediment-system (Hoberg, 2006) should rather be regarded as LOEC instead of being regarded as NOEC. For a product evaluation within the German registration procedure an applicant suggested a NOEAEC of 10 µg/L from Hoberg (2006), as the effects at this concentration level were only detected by radiographical analysis (changes in spinal column), but not by visual observation. This argumentation was not accepted. Instead of that the NOEC of 3.2 µg/L was used as relevant endpoint for the chronic risk assessment, because no conclusion should be drawn on the population ecological relevance of such specific effects under real conditions from test animals in a juvenile growth test. For setting of the assessment factor of 5, the available information from two juvenile growth tests mit *P. promelas*, one juvenile growth test with *S. trutta* and three ELS tests with *P. promelas, C. variegatus* and *O. mykiss* were taken into account regarding the uncertainty by interspecies variability.	DAS: We welcome the opportunity for this issue to be discussed at the expert meeting but would point out that the reduction in uncertainty afforded by setting an NOEC based on such a subtle parameter, compared to those gross effects considered in conventional tests, should lead to a substantial change in the uncertainty factor applied to this endpoint. A control mortality rate of 20% is allowable in chronic toxicity to fish tests. The premise that an incidence of "possible slight increases in bone density" in <20% of fish can somehow represent a greater threat to fish populations is overly conservative. A low incidence of such a slight and subtle change, even if real, should not be treated as a threat to fish populations, especially when such changes are known to occur naturally in response to many environmental factors (e.g. sediment loading). See also Note 5(14) by FR. The proposed reduction of the uncertainty factor to 5 is based purely on the reduction of uncertainty from interspecies variability. An additional reduction in this factor should be awarded on the basis of the extremely subtle parameters used to determine the NOEC in this study compared to those in conventional tests (survival, growth, gross abnormality etc.). RMS: We welcome a discussion on this issue. There is a large difference on the the selection of the end point from this study and the conventional testing. The uncertainty then is not the same.	Open point: 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 also open points at comment 5(8) and 5(12).

Aquatic organisms (B. 9.2)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(2)	Vol. 3, B.9.2.8, Summary and risk assessment	DE: Risk assessment should be updated regarding the relevant endpoint for chronic risk assessment for fish (see comment above).	DAS: A TERlt trigger of 10 is applied to the NOEC from conventional tests. If an NOEC of 3.2 ug/L is adopted, this has already reduced the uncertainty by a factor of 10, as the NOEC from this study, if based on conventional parameters, would normally be 32 ug/L (see report). The TER trigger applied to this NOEC should reflect to some extent this reduction in uncertainty. RMS: This is related to the previous comment.	Open point: 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 at comment 5(1)), the trigger to be applied (see open point at comment 5(12) and the outcome of the fate meeting discussion (see open point at comment 4(4)).
5(3)	Additional report, B.9.2.2/09, Fathead minnow study	EFSA: A NOEAC of 10 µg/L was set on the basis of slight to moderate increases in bone density and moderate abnormalities to the shape of occasional vertebrae. Those effects were observed on c.17% of fish. Slight effects on vertebral bone density were also observed in the control group on c.12% of fish. How can be explained the latter? Can the study be considered reliable in relation to skeletal system effects?	DAS: A background incidence of mild bone "abnormality" is to be expected in fish populations (see Note 5(14) for example). Studies should not be discounted on this basis. A background (i.e. control) mortality of 20% is allowed in this study, so a 12% incidence of very mild bone "abnormality" cannot be taken as evidence of an invalid study. RMS: Skeletal abnormalities can be reported in stressed environment (see DAR).	Addressed.

Aquatic organisms (B. 9.2)				
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5(4)	Additional report, B.9.2.4/04, effects on sediment dwelling organisms, conclusion	EFSA: the NOEC of 0.3324 mg TR-4/L is for development rate (female) and not for midge emergence.	DAS: Agree RMS: Agree.	Addressed. RMS to consider in a corrigendum that the NOEC of 0.3324 mg TR-4/L is for development rate (female) and not for midge emergence (B.9.2.4/04, effects on sediment dwelling organisms, conclusion).
5(5)	Additional report, B.9.2.8, summary and risk assessment to aquatic organisms,	EFSA: a clarification is necessary on the nature of mitigation measure applied to calculate Step 4 PECsw: the proposed 20 m of buffer zone is a no spray-drift buffer zone or it is a vegetated buffer strip?	DAS: The buffer zones introduced at FOCUS Step 4 is a simple “no-spray” zone with no assumptions on vegetation. RMS: no comment.	See open points at comment 4(3) and 4(4).

Aquatic organisms (B. 9.2)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(6)	Additional report, B.9.2.8, summary and risk assessment to aquatic organisms, refined chronic risk to fish	EFSA: it is noted that between flow-through and static studies the NOEC values differ of 1-2 order of magnitude. It is also noted that skeletal system effects were observed on only 6.9% of fish (against 3.8% in the control) within the field monitoring study. However, it is not clear if the field study took into account the species variation (i.e. how many species were analysed? Skeletal system effects were observed in all species analysed?). The selection of the final NOEC to be use for risk assessment should cover all the uncertainties. The NOAEC of 10 µg/L seems to be enough conservative to cover the chronic effects on fish but it should be expressed as mean measured concentration.	DAS: Agreed. This demonstrates that much higher concentrations of exposure are needed to cause equivalent effects on vertebral development when the exposure is transient, i.e. as under realistic environmental conditions. Data on individual species of fish are provided in the report (see Tables P3 & P4). The dominant species (almost exclusively) were Redear and Large-mouth bass in the control area and Redear, Large-mouth bass and Bluegill in the treatment area. Vertebral abnormalities were spread reasonably uniformly across the species present. Expressing the results from a sediment:water "simulation study" in terms of mean measured concentration would defeat the objective of the exercise i.e. to identify the effects caused by a single event exposure followed by dissipation. The measured concentrations achieved at the start of the exposure ranged from 110 to 120% of nominal across the test series. RMS: We agree that the NOAEC of 10 µg/L seems to be enough conservative.	Open point: 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.

Aquatic organisms (B. 9.2)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(7)	Vol. 3, B.9.2.2/09 Fathead minnow 36 day exposure in static system with sediment present.	UK: the NOEC from the study is considered to be 3.2 µg/L. This was on the basis of 9.1% thickening in fish vertebrae and an associated occurrence of 6.8% abnormalities in the shape of occasional vertebrae. It was noted that there was 12.2% thickening in the control and 6.5% in the 3.2 µg/L concentration. There was no reference to any abnormalities in the shape of vertebrae in either the control of 3.2 µg/L concentration. The RMS considered the effects seen at 10 µg/L to be minimal and of limited biological/ecological relevance and therefore discounted them. On this basis the RMS proposed that the endpoint should be a NOAEC of 10 µg/L. In selecting this endpoint, the RMS is assuming that the treatment related effects seen at 10 µg/L are not relevant. No justification has been given for this. It is proposed that, without justification, the endpoint for the risk assessment should be 3.2 µg/L.	DAS: In the control group, 6/90 (6.7%) showed signs of misshapen vertebrae compared to 0/46 (-) at 3.2 µg/L and 3/44 (6.8%) at 10 µg/L (see Table 1 in Hoberg, 2006). Although it is difficult to make precise comparisons on such subjective assessments, one cannot describe these differences as substantial. Although there is little likelihood of the anomalies seen at 10 µg/L causing adverse biological effects, this cannot be confirmed definitively. However, what is certain is that the TER of 10 that is applied to the NOEC from conventional tests, based on gross adverse effects that are clearly life threatening (e.g. mortality, reduction in body weight, gross abnormalities etc), is excessively conservative when applied to an NOEC based on almost imperceptible differences in high resolution radiographs. It is completely out of balance with conventional risk assessment criteria. Consequently, if 3.2 µg/L is adopted, a TER trigger of 3 would be far more appropriate. RMS: There are a lot of comments on this issue. We welcome a discussion in an expert meeting.	See open point at comment 5(1).

Aquatic organisms (B. 9.2)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(8)	Vol 3, B.9.2.8, aquatic risk assessment	UK: It is noted that the endpoint from the new fathead minnow study has been compared directly to the peak exposure concentrations from the FOCUS Step 3 and 4 output but there has been no consideration of the exposure profile. 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. The study conducted indicates that a short exposure to growing/developing fish can result in deformation of the spine. Therefore it is considered that the exposure in the study is similar to that predicted, hence it is considered appropriate for use in risk assessment. However the risk assessment should use the endpoint of 3.2 µg/L and not 10 µg/L as proposed. It is considered that the use of the peak PEC and comparing this to the nominal concentration is appropriate; hence safe scenarios use will be identified with >>20 m buffer zones.	DAS: See comment in response 5(7) above re. an appropriate TER trigger to be applied to an NOEC of 3.2 µg/L. RMS: There are a lot of comments on this issue. We welcome a discussion in an expert meeting.	Open point: 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 at comment 4(4)).

Aquatic organisms (B. 9.2)				
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5(9)	B.9.2.4	NL: For the water spiked test with trifluralin no explanation is given on why the NOEC can be based on nominal values, whilst initial measured concentrations are <80%.	DAS: Nominal values are considered to be relevant as they best represent the actual loading to the system, more so than measured values from the aqueous phase alone, especially when the substance is rapidly partitioning to the sediment. Since the species under investigation are sediment-dwellers, this is not considered to be a limitation. RMS: We agree with the notifier.	Addressed.
5(10)	B.9.2.4	NL: For the sediment spiked tests with the metabolites it is concluded that the NOEC can be based on nominal values, because on day –1 the nominal values were confirmed and the lower values result from binding to the sediment. This line of reasoning may be acceptable, since the PECsed values are also based on total content. Another approach could be to use initial measured values for the NOEC and use the PECsed after 1 day.	DAS: The notifier would still maintain that using (confirmed) nominal values is more representative as this is the total loading on the system. Partitioning between the aqueous and sediment systems is dynamic, but the test is to assess impact of an overspray event on sediment-dwellers, so it seems unnecessarily severe to disregard that proportion of the material which adsorbs to the sediment very rapidly. RMS: We agree with the notifier.	Addressed.

Aquatic organisms (B. 9.2)				
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5(11)	B.9.2.8 Refined chronic risk assessment fish	NL: The NOEC of 10 µg/L seems acceptable. However not agreed with the conclusion on the monitoring study: vertebral lesions do not seem to be correlated with trifluralin residues in fish but rather with the suspended sediment concentrations: this to our view does not show that the vertebral lesions cannot be related to trifluralin (as stated in the report). Fact remains that effects in the trifluralin site were twice as high as in the control.	DAS: We agree with NL that "10 µg/L seems acceptable". Regarding the supplemental field data, although the incidence of lesions was higher in the treatment group, it was less than 2-fold greater. Since the incidence was very low (6.9% v. 3.8%) this is not likely to be significant. The report author's conclusion that trifluralin was unlikely to be the cause of these observations was based principally on a weight of evidence approach e.g. the 3-fold increase in incidence in both control and treatment areas following high sediment run-off period plus the low residue levels measured in fish tissue (see Francis et al 1985). RMS: We agree that the NOAEC of 10 µg/L seems to be enough conservative. The incidence was very low. "Twice as high as in the control" does not have any biological or meaning at so low cases (6.9% and 3.8%)	See open point at comment 5(1) and open point at comment 5(6).

Aquatic organisms (B. 9.2)				
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5(12)	Vol. 3, Annex B-9, Table B.9.2.2/09, Chronic toxicity study with the fathead minnow (Hoberg, 2006)	FR : We agree with the proposal of RMS to use the toxicity endpoint from this study for assessment of chronic risks to fish. However, the use of the NOAEC of 10 µg trifluralin/L with a safety factor of only 10, generally used together with a NOEC value, is considered not appropriate. This option could have been retained if a wider range of toxicity data on fish (obtained in the same conditions) had been available, or if higher Tier study highlighting the low risk to fish in realistic conditions had been submitted.	DAS: As stated previously in response 5(7), if an NOEC of 3.2 µg/L is to be adopted as the critical endpoint, then we believe that a more appropriate TER trigger of 3 should be applied to reflect the considerably more sensitive indicators of toxicity under consideration. In this way a more even balance to the risk assessment will be achieved, which will bring this into closer alignment with the judgement criteria applied to other active substances. RMS: There are a lot of comments on this issue. We welcome a discussion in an expert meeting.	Open point: 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 also open point at comment 5(1).

Aquatic organisms (B. 9.2)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(13)	Vol. 3, Annex B-9, Table B.9.2.2/09, Chronic toxicity study with the fathead minnow (Hoberg, 2006)	FR : The RMS considers that the slight / moderate increase in bone density and moderate abnormalities in the shape of vertebrae observed in some fish exposed to trifluralin at 10 µg/L are not likely to have an impact on the health and survival of fish. It is our opinion that this assumption is not justified enough and that an expert judgement is needed. Moderate abnormalities have been observed in 6.8 % of the fish and the increase in bone density in 9.1 % of the fish is interpreted as a response of the organism to the fragility of the skeleton (likely to be related to vertebral lesions and loss of intervertebral material). In natural conditions, fish exhibiting such abnormalities are expected to be affected in their movements, which can as a consequence have a non-negligible influence on their survival and possibly on their fitness. As these impairments are expected to concern 10 – 15 % of a fish population, it should be considered as relevant effects at the population level. As a consequence, the real NOEC of 3.2 µg/L obtained in this study with *P. promelas* (Hoberg, 2006) should be used for chronic risk assessment.	DAS: The observations on differences in bone density are highly subjective and are based on a judgement of perceived differences in the brightness of the outline of the vertebrae on a high resolution radiograph. This is assumed to reflect a slight increase in bone density, but its biological and ecological relevance is not established. Even if this hypothesis were to be true, the effect is an increase in bone density and, consequently, concerns about the fragility of the vertebrae are not warranted. Regarding the incidence of misshapen vertebrae, this was observed in 6/90 fish (6.7%) in the control and 3/44 fish (6.8%) in the 10 µg/L treatment group. Although the abnormality was slightly more evident in the treated fish, only occasional vertebrae were affected and only 3 fish involved. This cannot be interpreted as a substantial adverse effect and attract the same level of precaution (i.e. the same uncertainty factor) as would be applied if the effects seen were significant reductions in survival or growth. RMS: We welcome a discussion in an expert meeting.	See open points at comments 5(1) and 5(6).

Aquatic organisms (B. 9.2)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(14)	*(Continue)*	In natural populations, vertebral abnormalities are expected to occur in around 10 % of the fish (Gill & Fisk, 1966; Poynton, 1987). It is confirmed in the study of Hoberg (2006) with 12.2 % of the fish in the control group exhibiting minimal to slight effects (increase in bone density / misshapen vertebrae). However, at the 10 µg/L dose, a similar proportion of fish exhibited effects of higher magnitude: moderate abnormalities (compressions and fusions of vertebrae) and slight to moderate increase in bone density. The effect classes (minimal / slight / moderate / severe) are not directly comparable to a percentage of change in the shape of the skeleton. However several authors have defined effects classes based on a gravity scale: asymmetry < synotosys < fusion (Witten *et al*., 2006; Deschamps *et al*., 2008). Fusions of vertebrae have been noticed in fish exposed at 10 µg/L and it would be interesting to compare more precisely the observed effects with this scale. In the studies of Hoberg (2006) and Meyerhoff & Gunnoe (1992), the most sensitive effect criteria were vertebral dysplasia, revealed at the end of the test by radiography for fish exposed at low concentrations. However, it does not imply that a 35-day exposure is needed to induce these effects. On the contrary, a short-term exposure to low levels of trifluralin is expected to induce an increase of mineral compounds concentration in the serum and hence an increase of bone density by mineralisation, as shown on *Cyprinodon variegatus* (Couch *et al*., 1979).	DAS: At 10 µg/L, only 3 fish were affected and, in these fish, the abnormality was limited to a slight change in the shape/bone density of occasional (typically 1) vertebrae – see Fig 3, as an example. The more severe abnormality of "fusion of the vertebrae" was only seen at 32 µg/L and above. No asymmetry or synostosis of the skeleton or any other obvious sign of abnormality was evident in the fish exposed to 10 µg/L. The objective of the study was to demonstrate that, although brief exposure can lead to vertebral abnormality, the concentrations causing an equivalent level of damage have to be considerably higher than those under continuous exposure. A comparison of the findings from the static and flow-through studies shows this increase in effective concentration to be approximately one order of magnitude. RMS: We welcome a discussion in an expert meeting.	See open points at comments 5(1) and 5(6).

Aquatic organisms (B. 9.2)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(15)	*(Continue)*	Based on the literature information, the observed effects of compression and fusion of vertebrae in fish exposed to sub-lethal doses of trifluralin could be explained by these successive steps: 1/ The disappearance of intervertebral space due to the alteration of the structural integrity of the notochord (dysfunctionning of notochord cells during the development) and/or lesions of intervertebral ligaments due to inflammation (Fjelldal *et al.*, 2007). 2/ Deposition of cartilage inducing the compression between two vertebrae (Witten *et al*., 2006). 3/ The mineralisation of this cartilage which increases the synotosis / union between vertebrae (Witten *et al*., 2006). In natural populations, fish exhibiting vertebral fusion and compression are expected to be affected in their movements, which have a direct and non-negligible influence on their survival and possibly on their fitness. Moreover, it has been shown on Carps exposed to trifluralin that the abnormal mineralisation of the skeleton could alter the calcium – phosphate balance of the individual (Poleksic & Karan, 1999). As a consequence, the stock of mineral compounds would not be available for the key stages of the fish life cycle such as growth and reproduction.	DAS: This is rather speculative and, in any case, relates primarily to the processes involved at higher concentrations, where noticeable damage occurs. At the proposed NOEC of 10µg/L, the effects observed were so minimal (both in the extent of the effect and in the numbers of fish affected) that an impact at the individual level, and especially at the population level, is highly unlikely. RMS: We welcome a discussion in an expert meeting.	See open points at comments 5(1) and 5(6).

Aquatic organisms (B. 9.2)				
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5(16)	*(Continue)*	For all these reasons, effects observed in fish exposed at the dose of 10 µg/L in the study of Hoberg (2006) are not considered negligible. This concentration should not be defined as a NOAEC but a LOEC. Therefore, the NOEC for vertebral dysplasia should be the 3.2 µg/L concentration, which should be used for risk assessment. Couch JA, Winstead JT, Hansen DJ, Goodman LR (1979) Vertabral dysplasia in young fish exposed to the herbicide trifluralin. Journal of fish Diseases 2: 35-42 Deschamps M-H, Kacem A, Ventura R, Courty G, Haffray P, Meunier FJ, Sire J-Y (2008) Assessment of "discreet" vertebral abnormalities, bone mineralization and bone compactness in farmed rainbow trout. Aquaculture 279: 11-17 Fjelldal PG, Hansen TJ, Berg AE (2007) A radiological study on the development of vertebral deformities in cultured Atlantic salmon (Salmo salar L.). Aquaculture Gill C.D. and Fisk D.M., Vertebral abnormalities in Sockeye, Pink, and Chum salmon, Trans. Am. Fish. Soc. 95 (1966), pp. 177–182. Poynton S.L. (1987) Vertebral column abnormalities in brown trout, Salmo trutta L. Journal of Fish Diseases 10, 53-57. Poleksic V, Karan V (1999) Effects of Trifluralin on Carp: Biochemical and Histological Evaluation. Ecotoxicology and Environmental Safety 43: 213-221 Witten EP, Obach A, Huysseune A, Baeverfjord G (2006) Vertebrae fusion in Atlantique salmon (Salmo salar): Development, aggravation and pathways of containment. Aquaculture 258: 164-172	DAS: 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. RMS: We welcome a discussion in an expert meeting.	See open points at comments 5(1) and 5(6).

Aquatic organisms (B. 9.2)				
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5(17)	Vol. 3, Annex B-9, B.9.2.4 Effects on sediment dwelling organisms; Report B.9.2.4/04	FR: According to OECD guideline N° 219, effect concentrations should have been expressed as concentrations in the overlaying water, based on measured concentrations at the beginning of the test (50.6 % recovery).	DAS: This is not a mandatory requirement in OECD Guideline 219. Unfortunately, measured values are not specifically available for the nominal NOEC of 0.3324 mg/L. However, values of 67.5% and 71.3% of nominal were measured for the exposure levels bounding the NOEC and a mean of these values (69.4%) could be applied as a correction factor if required, to give a corrected NOEC of 230.7 µg/L. RMS: See points 5.9 and 5.10.	Addressed.

Aquatic organisms (B. 9.2)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(18)	Vol. 3, Annex B-9, B.9.2.4 Effects on sediment dwelling organisms; Report B.9.2.4/04	FR: The peat content of the artificial sediment was 8 %, instead of 4-5 % (dry weight ratios), as recommended in the OECD guideline N° 219. As the metabolite TR-4 has a log Pow > 2, this two-fold higher content in peat could have modified the exposure pattern of organisms during the test. The effect concentration should be corrected.	DAS: As far as we are aware, there are no agreed correction factors that can be applied to Chironomus test endpoints, to correct for the carbon content of the sediment. If a "correction" factor of 0.5 were to be applied, however, this would further reduce the corrected NOEC to 115.3 µg/L, but still result in a TER >10 at FOCUS Step 1 (TER 11). Consequently, even with this highly conservative assessment, the conclusion of low risk to sediment-dwelling organisms from this metabolite would not be altered. RMS: The comment seams 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.	Open point: MSs to discuss the application of a correction factor to Chironomus test endpoints to correct the carbon content of the sediment.
5(19)	Vol. 3, Annex B-9, B.9.2.4 Effects on sediment dwelling organisms; Reports B.9.2.4/05 & B.9.2.4/06	FR: Despite the poor quality of the two sediment-spiked tests with the metabolites TR-7 and TR-14, we agree that they are sufficient to prove that no adverse effects are expected with these compounds on natural populations of sediment-dwelling organisms.	DAS: No further comment. RMS: No comment.	Addressed.

Aquatic organisms (B. 9.2)				
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5(20)	Vol. 3, Annex B-9, B.9.2., Chronic risk to aquatic organisms; Table B.9.2.8-15	FR: we agree with the refinement of the chronic risk to fish using a toxicity endpoint obtained in more realistic conditions than the endpoint from the study of Meyerhoff & Gunnoe (1992); however, as explained above, the NOEC of 3.2 µg/L should be used instead of the NOAEC of 10 µg/L obtained in the same study with *P. promelas* (Hoberg, 2006).	DAS: see notifiers response to Point 5(16). RMS: We welcome a discussion in an expert meeting.	See open points at comments 5(1) and 5(6).
5(21)	Vol. 3, Annex B-9, B.9.2., Chronic risk to aquatic organisms; Table B.9.2.8-16	FR: As proposed by RMS, the maximum PEC values should be used to calculate TER values. This is justified by the use of an endpoint from a study (Hoberg, 2006) which was conducted with the aim to simulate a relevant exposure profile, comparable with exposure conditions in field (transient exposure, static conditions, water column + sediment layer). However, the TER calculations using the NOEC of 3.2 µg trifluralin/L and the initial PEC values, considering a buffer zone of 20 m, would result to 7 TER values below the trigger of 10 for the scenario in oilseed rape. The chronic risk must be further refined (higher buffer zone).	DAS: see notifiers response to Point 5(16) i.e. the TER trigger should be reduced to 3 to reflect the reduction in uncertainty (range of species tested and highly sensitive indicator of sub-lethal exposure). The proposed buffer zones do not need to be amended. RMS: We welcome a discussion in an expert meeting.	See open points at comments 5(1), 5(2) and 5(6).

Aquatic organisms (B. 9.2)				
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5(22)	Vol. 3, Annex B-9, B.9.2., Chronic risk to aquatic organisms; Table B.9.2.8-16	FR: As noticed by e-fate assessor (see Section 4 fate and behaviour, point 5: Vol. 3, Annex B-8, B.8.6.1, Result of PECsw calculations at Step3 and 4), the maximum PEC should be presented for all the time points to be able to assess if exposure happened only at the day 0 or if exposure was more or less continuous (pulsed input). In case of a more or less continuous exposure of fish, it would be more relevant to use the chronic endpoint (NOEC = 0.3 µg/L) from the study of Meyerhoff & Gunnoe (1992) which was performed in flow-through conditions for risk assessment.	DAS: As stated previously by the notifier in 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. RMS: We welcome a discussion in an expert meeting.	See open point at comment 5(8).

Aquatic organisms (B. 9.2)				
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5(23)	Vol. 3, Annex B-9, B.9.2., Chronic risk to aquatic organisms; Table B.9.2.8-16	FR: An other option to refine the chronic risk to fish would be to use PEC_{TWA} together with the lowest endpoint of 0.3 µg trifluralin/L from the study of Meyerhoff & Gunnoe (1992). For PEC_{TWA} calculation, a time window of 7 days should be used with a DT_{50} of 13 days. The TER calculations using the NOEC of 0.3 µg trifluralin/L, the TWA PEC of 7 days, and considering a buffer zone of 20 m would result to TER values below the trigger of 10 for the scenario in oilseed rape. Higher buffer zone should also be considered for the refinement of the chronic risk assessment.	DAS: Due to rapid initial adsorption and the inability of the Timme-Frehse model to accommodate sampling times of less than 1 day, the DT50 estimate of 13 days relates only to the second phase of the dissipation curve i.e. to the background levels of trifluralin remaining in the water column after ca.95% adsorption to sediment had occurred. It is completely inappropriate to apply this DT50 of 13 days to initial theoretical PEC values in calculating time-weighted exposures. Since 74-97% dissipation occurred in this study by the time the first sample was taken at 6 hours, the true DT50 observed in this study must be <6 hours. If this study is to provide the DT50 critical endpoint for trifluralin, logical interpretation of the data is necessary. RMS: We welcome a discussion in an expert meeting.	Open point: 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.

Aquatic organisms (B. 9.2)				
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5(24)	*(Continue)*	In an addendum, the RMS proposed to compare the 48-day TWA concentration (TWA concentrations based on the DT_{50} of 2 days) with the 48-day NOEC derived from a constant exposure study on larval trout. However, it would not be appropriate to compare the 35-days NOEC of 0.3 µg trifluralin/L on *P. promelas* with a 7 TWA concentration based on a DT_{50} of 2 days. A DT_{50} of 13 days should be preferred for PEC_{TWA} calculation to be in accordance with the DT50 previously used to calculate the risk of secondary poisoning of fish-eating birds and vertebrates. The choice of the DT_{50} of 13 days is also supported by e-fate assessor (see Section 4 fate and behaviour, point 5 Vol. 3, Annex B-8, B.8.6.1, Result of PECsw calculations at Step 4). The time-window of 35 days is not considered appropriate because it is not clear if long-term exposure is necessary to induce effects at low dose. It was demonstrated in other studies in trout (Francis et al., 1985; Francis & Jordan, 1985) that effects may appear very rapidly with trifluralin at high levels (e.g. 20 min for hemorrhagic signs).	DAS: The DT50 of 2-days comes from a sediment de-sorption study and, consequently, is as erroneous as the DT50 of 13 days in describing the dissipation of trifluralin by adsorption to sediment. We agree with the proposal of a 7-day TWA as a default period, as promoted at the ELINK workshop. RMS: We welcome a discussion in an expert meeting.	See open point at comment 5(23)

Aquatic organisms (B. 9.2)				
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5(25)	*(Continue)*	However, in studies with long-term exposure at lowest levels, there is no indication on the time of appearance of the effects observed at the end of the experiments. As the exposure time-window necessary to induce effects measured on fish at the LOEC of 0.7 µg/L (study from Meyerhoff & Gunnoe, 1992) can not be precisely defined, a TWA PEC of 7 days should be used as a default, according to the E-link workshop recommendations (2007): "*when it is possible to use a TWA concentration approach it is proposed to use a TWA PEC of 7 days as a default if no specific information is available on the relation between exposure pattern and time-to-onset-of-effects for the (relevant life stages of the) organisms that triggered the chronic risk. It may be scientifically justified to lengthen or shorten the default 7-d TWA period when this time-to-onset-of-effect information is made available*".	RMS: We welcome a discussion in an expert meeting.	See open point at comment 5(23)

Aquatic organisms (B. 9.2)				
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5(26)	Vol. 3, Annex B-9, B.9.2., Chronic risk to aquatic organisms	FR: We disagree with the RMS that the field monitoring study (Francis *et al.*, 1985, B.9.2.5/01) is supporting the conclusion for no unacceptable effects on aquatic organisms. If it is noticed that exposure of fish at levels up to 0.3 µg/L seemed not to have led to significant level of skeletal lesions, it does not allow to conclude that low levels of trifluralin does not induce such effects. Indeed, no information are given on the fish species present in ponds, no details on the concentration analyses in water was given (did the measurements occur just after each run-off event (i.e. at peak concentration) ? What was the time interval between measurements (what is the exposure profile after a run-off event ?); furthermore, there is no proof that vertebral dysplasia did not affect fish, as injured fish would have been easy to catch by predators, and thus would not have been collected at the end of the trial.	DAS: This study provides supporting evidence that, under field conditions, exposure to trifluralin from various routes of input following heavy usage in an agricultural setting did not result in significant adverse effects (including vertebral abnormalities) on the fish population. Details on the fish species present are given in the report, with full details on the observations on individual fish collected. Similarly, full details are given on the dates of the run-off events. The timing of the sampling in relation to the occurrence of peak exposures, however, does not undermine the study as measured values not coinciding with peak values can only underestimate the actual exposure. If significant numbers had been affected, and then predated, then one would expect this to be reflected in a significant reduction in the numbers of fish collected from the treatment area. RMS: We welcome a discussion in an expert meeting.	See open point at comment 5(6)
5(27)	Vol. 1 LOEP	SE: In the list of endpoint table for the new fathead minnow study it is stated that the NOAEC is 10 mg/L it should be 10 µg/L.	DAS: The notifier agrees. RMS: We agree. The LoEP will be amended.	Open point: RMS to update the LoEP (the NOAEC for fish is 10 µg/L and not 10 mg/L).

Aquatic organisms (B. 9.2)				
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5(28)	Vol. 3, B.9.2.2./09 Chronic toxicity - fathead minnow study	Dk: The sediment/water ratio in the new study is not mentioned in the study description. A photoperiod of 16 h light has been used. It is therefore highly questionable whether this study provides for a realistic exposure regime.	DAS: The sediment depth was 3 cm and the water depth was 33 cm (see Points 2.5 & 2.6 of the report). Ambient lighting in the laboratory (210 to 1100 lux) was well below that typical of outdoor environmental conditions. Consequently, we agree these conditions are not exactly realistic but, instead are highly conservative, given the rapid photodegradation of trifluralin. RMS: We agree with the comments from the notifier.	Addressed. RMS to report the sediment/water ratio in a corrigendum.
5(29)	Vol. 3, B.9.2.8. Refined Chronic risk to fish	Dk: In our view the risk assessment should be based on the original endpoint of 0.3 ug/L (and a TER of 10) as the new study can not be considered to represent realistic exposure regime under different natural conditions. Furthermore the study does not address the ”time to event” issues which was raised during the expert meetings and the actual exposure concentrations have not been used in the risk assessment.	DAS: This static study was designed to simulate highly conservative environmental conditions, in terms of ambient lighting and therefore exposure regimes under “different natural conditions” are already covered. There was no need to model “dissipation rates” and “time to event” aspects as this was a “worst-case” simulation study based on measured peak exposures representing a spray-drift event. RMS: We welcome a discussion in an expert meeting.	See open point at comment 5(1).

Aquatic organisms (B. 9.2)				
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5(30)	Bioaccumulation BCF = 5674	Dk: In the EFSA conclusion it was highlighted that the expert meeting discussion on bioaccumulation assumed a CT50 of 6 h – this was not correct CT50 was 4.7 days and CT95 is not reached in 14 days. This issue has not been further addressed. We find that the risk to fish and the potential bioaccumulation are critical concerns.	DAS: Agreed. In the EFSA Scientific Report Appendix 1, critical endpoints are given as: CT50 4.7 days and CT90 15 days with 9.6% residues remaining after 14 days depuration. There are no Annex VI criteria based on these 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 has been reviewed. RMS: The FLC study has been reviewed.	Open point: MSs to reconsider the risk for bioaccumulation in fish, on the basis of the revised long-term risk assessment.

Earthworms and other soil non-target organisms (macro and micro) (B. 9.6, B.9.7 and B.9.8)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(31)	Additional report, Vol B.9	EFSA: why a new litter bag study requested with the previous peer review was not provided?	DAS: A new litter bag study was proposed by EFSA, but was never discussed in an EPCO Expert meeting. Consequently, this was not taken to be a data requirement at this stage for evaluation at Annex 1. RMS: We welcome a discussion in an expert meeting.	Open point: 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)

Earthworms and other soil non-target organisms (macro and micro) (B. 9.6, B.9.7 and B.9.8)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(32)	Vol. 3, A new litterbag study should be made available in which the tested dose rate reflects the concentration in the soil after a single application when the accumulation plateau has been reached. This data requirement is proposed by EFSA and has not been discussed in an EPCO expert meeting	UK: No study submitted. Strictly speaking, in the absence of any other data, one is still required; alternatively, data on the toxicity of trifluralin in soil macro-organisms could be used to address the concern.	DAS: See notifiers comment to point 5(31) RMS: We welcome a discussion in an expert meeting.	See open point at comment 5(31).
5(33)	Risk to soil organisms	Dk: Due to the high persistence (and high BCF) we do not consider that the risk to soil organisms has been adequately addressed. The EFSA conclusion also highlighted that the litterbag test did not cover the accumulation plateau PEC. This issue has not been addressed in the additional report.	DAS: See notifiers comment to point 5(31) RMS: We welcome a discussion in an expert meeting.	See open point at comment 5(31).

Other comments				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(34)	List of endpoints, aquatic organisms	EFSA: the toxicity /exposure ratios should be reported according to the format from EPCO manual rev 4 (September 20005).	DAS: No further comment. RMS: We agree. The LoEP will be amended.	Open point: RMS to amend the LoEP according to the format from EPCO manual rev 4 (September 20005).
5(35)	List of endpoints, classification and labelling	EFSA: classification and labelling should be reported for both the active substance and the formulation product.	DAS: No further comment. RMS: We agree. The LoEP will be amended.	Open point: RMS to amend the LoEP with the classification and labelling for both the active substance and the formulation product.
5(36)	Vol. 1, Appendix 1 – List of End Points Toxicity data for aquatic species. Page 119, last column of table.	EUTTF: Incorrect value entered for Fish (Fathead Minnow) 35-day NOEC with sediment chronic end point. Correct value is 0.01 mg/L (ie: 10 µg/L)	DAS: The notifier agrees. RMS: We agree. The LoEP will be amended.	See open point at comment 5(27).
5(37)	Vol. 1, List of endpoints GAP table, p. 4-5	Dk: In our view the GAP table should be gray for all uses evaluated (risk to fish, bioaccumulation and soil persistency). It is not clear while the table is gray for Winter cereals – southern zone and not for the other uses.	DAS: No further comment. RMS: We welcome a discussion in an expert meeting. According to the conclusion of the expert group the LoEP will be amended accordingly.	Open point: 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).
5(38)	Vol. 1, List of endpoints p. 52	New entry for fish (35 d NOEC) is 0.001 mg/L (the entry of 10 is in ug/L)	DAS: The notifier agrees, endpoint should be 10 µg/L or 0.010 mg/L (but not 0.001 mg/L). RMS: We agree. The LoEP will be amended.	See open point at comment 5(27).

Other comments				
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5(39)	Formulation studies	The EFSA conclusion highlighted (List of studies to be generated) that the formulations tested in the ecotox section differed from the lead formulation. This issue has not been addressed in the additional report.	DAS: An updated Doc J3 submitted in September 2003 included the composition details of several formulations referenced in the ecotox section of the original dossier (M3S6) along with that of the lead formulation. All formulations cited were 480 g/L EC based. The notifier agrees that confusion may have arisen as the formulation trade name and number have not always been cited in both documents. Therefore to clarify the correlation between formulation number and trade name: Treflan – EF-1521 Treflan EC – EAF-117 Elancolan – EAF-117 Triflurex - information previously supplied by Makhteshim –Agan EF-1492 – no trade name documented in the dossier. As composition data has already been submitted, the notifier therefore believes this point has been previously addressed. RMS: We welcome a discussion in an expert meeting.	Open point: MSs to discuss, on the basis of the available information, if the formulations tested in the ecotoxicological tests cover the lead formulation.