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Comments on the Draft Assessment Report on trifluralin (EAS)

RMS EL

End of commenting period: 24 February 2009 (MS, NOT)

Date	Supplier	File
23.02.2009	DE	01 trifluralin comments DE 2009-02-23.doc
24.02.2009	EFSA	02 trifluralin comments EFSA 2009-02-24.doc
24.02.2009	Notifier	03 trifluralin comments NOT 2009-02-24.doc
24.02.2009	UK	04 trifluralin comments UK 2009-02-24.doc
24.02.2009	NL	05 trifluralin comments NL 2009-02-24.doc
24.02.2009	FR	06 trifluralin comments FR 2009-02-24.doc
24.02.2009	SE	07 trifluralin comments SE 2009-02-24.doc
24.02.2009	DK	08 trifluralin comments DK 2009-02-24.doc

Section 4 - Environmental fate and behaviour (B.8)

1. Environmental fate and behaviour (B.8)

Other comments			
No.	<u>Column 1</u> Reference to draft assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	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.

Section 5 - Ecotoxicology (B.9)

2. Ecotoxicology (B.9)

Aquatic organisms (B.9.2)			
No.	<u>Column 1</u> Reference to draft assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(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 <i>P. promelas</i> 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 <i>P. promelas</i> , one juvenile growth test with <i>S. trutta</i> and three ELS tests with <i>P. promelas</i> , <i>C. variegatus</i> and <i>O. mykiss</i> were taken into account regarding the uncertainty by interspecies variability.
(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).	

3. Physical/Chemical Properties; Details of Uses and Further Information; Methods of Analysis (B.1-B.5)

Physical and chemical properties of the active substance (B.2.1)			
No.	<u>Column 1</u> Reference to draft assessment report	<u>Column 2</u> Comment * (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. 1, LoEP, Relative density, p. 69	EFSA: relative density is no longer mentioned in the new agreed template of the LoEP	
(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.	
(3)	Vol. 1, LoEP, List of representative uses, GAP table, p. 71	EFSA: the reason of graying out should be given	

Section 2 - Mammalian toxicology (B.6)

4. Mammalian toxicology (B.6)

Not applicable.

Section 3 - Residues (B.7)

5. Residues (B.7)

Metabolism in plants (B.7.1)			
No.	<u>Column 1</u> Reference to draft assessment report	<u>Column 2</u> Comment * (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(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.	
(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.	

Section 3 - Residues (B.7)

Metabolism in plants (B.7.1)			
No.	<u>Column 1</u> Reference to draft assessment report	<u>Column 2</u> Comment * (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(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).	

Residue definition (B.7.3)			
No.	<u>Column 1</u> Reference to draft assessment report	<u>Column 2</u> Comment * (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(4)	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)	

Livestock feeding (B.7.8)			
No.	<u>Column 1</u> Reference to draft assessment report	<u>Column 2</u> Comment * (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(5)	Additional report to	EFSA: In rapeseed forage, the metabolite TSN	

Section 3 - Residues (B.7)

Livestock feeding (B.7.8)			
No.	<u>Column 1</u> Reference to draft assessment report	<u>Column 2</u> Comment * (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
	DAR, January 2009, table 7.1.5-1	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.	

Section 4 - Environmental fate and behaviour (B.8)

6. Environmental fate and behaviour (B.8)

PEC in surface water and ground water (B.8.6)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	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.	
(2)	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.	
(3)	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	

Section 4 - Environmental fate and behaviour (B.8)

PEC in surface water and ground water (B.8.6)			
No.	<u>Column 1</u> Reference to draft assessment report	<u>Column 2</u> Comment * (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
		in order to adequately asses the proposed mitigation measures.	
(4)	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 °C should be provided in an addendum.	
(5)	Additional report, B.8.6.2	EFSA: additional to moisture DT 50 should be normalized for temperature to 20 °C.	

Section 5 - Ecotoxicology (B.9)

7. Ecotoxicology (B.9)

Aquatic organisms (B.9.2)			
No.	<u>Column 1</u> Reference to draft assessment report	<u>Column 2</u> Comment * (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	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?	
(2)	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.	
(3)	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 PEC _{sw} : the proposed 20 m of buffer zone is a no spray-drift buffer zone or it is a vegetated buffer strip?	
(4)	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	

Section 5 - Ecotoxicology (B.9)

Aquatic organisms (B.9.2)			
No.	<u>Column 1</u> Reference to draft assessment report	<u>Column 2</u> Comment * (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
		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.	

Earthworms and other soil non-target organisms (macro and micro) (B.9.6, B.9.7 and B.9.8)			
No.	<u>Column 1</u> Reference to draft assessment report	<u>Column 2</u> Comment * (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(5)	Additional report, vol B.9	EFSA: why a new litter bag study requested with the previous peer review was not provided?	

Other comments			
No.	<u>Column 1</u> Reference to draft assessment report	<u>Column 2</u> Comment * (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(6)	List of endpoints, aquatic organisms	EFSA: the toxicity /exposure ratios should be reported according to the format from EPCO manual rev 4 (September 20005).	
(7)	List of endpoints, classification and labelling	EFSA: classification and labelling should be reported for both the active substance and the formulation product.	

Section 1 – Physical/Chemical Properties; Details of Uses and Further Information; Methods of analysis (B.1 – B.5)

8. Physical/Chemical Properties; Details of Uses and Further Information; Methods of Analysis (B.1-B.5)

The notifier has no comments in Section 1.

Section 2 - Mammalian toxicology (B.6)

9. Mammalian toxicology (B.6)

The notifier has no comments in Section 2

Comments of EUTTF on the additional report on Trifluralin

(23.02.09) 3/5

Section 3 - Residues (B.7)

10. Residues (B.7)

MRLs related issues and Consumer Risk Assessment (B.7.10 to B.7.15)			
No.	<u>Column 1</u> Reference to draft assessment report	<u>Column 2</u> Comment * (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	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 <u>oil seed crops only</u> , (See Doc D), the dietary risk assessment should be re-calculated for oil seed crops only.	

Other comments			
No.	<u>Column 1</u> Reference to draft assessment report	<u>Column 2</u> Comment * (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	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 <u>oil seed crops only</u> .	

Section 4 - Environmental fate and behaviour (B.8)

11. Environmental fate and behaviour (B.8)

Other comments			
No.	<u>Column 1</u> Reference to draft assessment report	<u>Column 2</u> Comment * (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	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.	

Section 5 - Ecotoxicology (B.9)

12. Ecotoxicology (B.9)

Other comments			
No.	<u>Column 1</u> Reference to draft assessment report	<u>Column 2</u> Comment * (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	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)	

Section 1 – Physical/Chemical Properties; Details of Uses and Further Information; Methods of analysis (B.1 – B.5)

13. Physical/Chemical Properties; Details of Uses and Further Information; Methods of Analysis (B.1-B.5)

No comments

Section 2 - Mammalian toxicology (B.6)

14. Mammalian toxicology (B.6)

No comments

Comments of UK on the additional report on trifluralin

(24/2/09) 3/9

Section 3 - Residues (B.7)

15. Residues (B.7)

Residue definition (B.7.3)			
No.	<u>Column 1</u> Reference to draft assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol 3, B.7.3.1, residue definition	UK: The proposed residue definition is acceptable as long as the plant metabolite TNS028333 is not of toxicological concern (present in seed and forage at levels of 0.006 and 0.03 mg/kg respectively)	

MRLs related issues and Consumer Risk Assessment (B.7.10 to B.7.15)			
No.	<u>Column 1</u> Reference to draft assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	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.	
(2)	Vol 3 B.7.15.1, estimated dietary exposure	UK: No risk assessment concerns	

Other comments

Comments of UK on the additional report on trifluralin

(24/2/09) 4/9

Section 3 - Residues (B.7)

No.	<u>Column 1</u> Reference to draft assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	EFSA conclusion	UK: Residues in forage were below the limit of determination, therefore no with-holding period is required. (point raised in EFSA conclusion)	

Section 4 - Environmental fate and behaviour (B.8)

16. Environmental fate and behaviour (B.8)

PEC in surface water and ground water (B.8.6)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	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 22°C, not 20°C, 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 PEC _{sw} value as this appears to be dominated by spray drift input, as might be expected from the high K _{oc} .	
(2)	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 K _{oc} . Thus peak PEC _{sw} is likely to be worst case and the PEC _{sed} will also be high due to the high K _{oc} values used.	

Comments of UK on the additional report on trifluralin

(24/2/09) 6/9

Section 4 - Environmental fate and behaviour (B.8)

PEC in surface water and ground water (B.8.6)			
No.	<u>Column 1</u> Reference to draft assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(3)	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.	

Section 5 - Ecotoxicology (B.9)

17. Ecotoxicology (B.9)

Aquatic organisms (B.9.2)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	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.	
(2)	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	

Section 5 - Ecotoxicology (B.9)

Aquatic organisms (B.9.2)			
No.	<u>Column 1</u> Reference to draft assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
		<p>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.</p>	

Earthworms and other soil non-target organisms (macro and micro) (B.9.6, B.9.7 and B.9.8)			
No.	<u>Column 1</u> Reference to draft assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	<p>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</p>	<p>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.</p>	

Section 5 - Ecotoxicology (B.9)

Earthworms and other soil non-target organisms (macro and micro) (B.9.6, B.9.7 and B.9.8)			
No.	<u>Column 1</u> Reference to draft assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
	has not been discussed in an EPCO expert meeting		

section 1 - Physical/Chemical Properties; Details of Uses and Further Information; Methods of Analysis (B.1-B.5)

18. Physical/Chemical Properties; Details of Uses and Further Information; Methods of Analysis (B.1-B.5)

No.	<u>Column 1</u> Reference to draft assessment report *	<u>Column 2</u> Comment * (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations

Comments of the Netherlands on the additional report on trifluralin

(24.02.09) 2/8

section 2 - Mammalian toxicology (B.6)

19. Mammalian toxicology (B.6)

No.	<u>Column 1</u> Reference to draft assessment report *	<u>Column 2</u> Comment * (restricted to 500 characters, ca. 10 lines)	<u>Column 3</u> Further explanations

* When mentioning page numbers of the DAR in your comments, **the page numbers should refer to the pdf-version** (not the WORD-version) of the DAR to ensure consistency among the Member States.

section 3 - Residues (B.7)

20. Residues (B.7)

No.	<u>Column 1</u> Reference to draft assessment report *	<u>Column 2</u> Comment * (restricted to 500 characters, ca. 10 lines)	<u>Column 3</u> Further explanations
1	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.	
2	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?	
3	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 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.	
4	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”	

* When mentioning page numbers of the DAR in your comments, **the page numbers should refer to the pdf-version** (not the WORD-version) of the DAR to ensure consistency among the Member States.

Comments of the Netherlands on the additional report on trifluralin

(24.02.09) 4/8

section 3 - Residues (B.7)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca. 10 lines)	Column 3 Further explanations
5	Vol. 3, B.7.3.1, residue definition	<p>NL: Parent trifluralin was not present in edible parts of oilseed rape at harvest. Predominant residue was TSN 028333 (free and conjugate). The toxicological relevance of this metabolite was not assessed (see EFSA scientific report).</p> <p>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).</p>	
6		<p>NL: The toxicological relevance of TSN 028333 (free and conjugate) should be assessed, as this is the same as TR-22.</p>	<p>Taken from EFSA Scientific Report (2005) 28, 1-77, Conclusion on the peer review of trifluralin:</p> <p>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 <i>in vitro</i> 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.</p>

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Comments of the Netherlands on the additional report on trifluralin

(24.02.09) 5/8

section 3 - Residues (B.7)

No.	<u>Column 1</u> Reference to draft assessment report *	<u>Column 2</u> Comment * (restricted to 500 characters, ca. 10 lines)	<u>Column 3</u> Further explanations
7		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.	
8	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	

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section 4 - Environmental fate and behaviour (B.8)

21. Environmental fate and behaviour (B.8)

No.	<u>Column 1</u> Reference to draft assessment report *	<u>Column 2</u> Comment * (restricted to 500 characters, ca. 10 lines)	<u>Column 3</u> Further explanations
1	General	NL: It seems no non relevance assessment was delivered for the metabolite. Correct?	
2	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).	
3	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?	

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Comments of the Netherlands on the additional report on trifluralin

(24.02.09) 7/8

section 4 - Environmental fate and behaviour (B.8)

No.	<u>Column 1</u> Reference to draft assessment report *	<u>Column 2</u> Comment * (restricted to 500 characters, ca. 10 lines)	<u>Column 3</u> Further explanations
4	Vol 3 B.8	<p>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.</p>	
5	Vol 3 B.8, PECgw	<p>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.</p> <p>NL can agree with the other conservative assumptions regarding formation fraction and DT50.</p> <p>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.</p>	

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section 5 - Ecotoxicology (B.9)

22. Ecotoxicology (B.9)

No.	<u>Column 1</u> Reference to draft assessment report *	<u>Column 2</u> Comment * (restricted to 500 characters, ca. 10 lines)	<u>Column 3</u> Further explanations
1	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%.	
2	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.	
3	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.	

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Section 4 - Fate and behaviour (B.8)

23. Environmental fate and behaviour (B.8)

Adsorption, desorption and mobility in soil (B.8.2)			
No.	<u>Column 1</u> Reference to draft assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(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.	

PEC in surface water and ground water (B.8.6)			
No.	<u>Column 1</u> Reference to draft assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	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.	
(2)	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.	
(3)	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.	

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Section 4 - Fate and behaviour (B.8)

PEC in surface water and ground water (B.8.6)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(4)	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.	
(5)	Vol. 3, Annex B-8, B.8.6.1, Result of PEC _{sw} 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 two 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
(6)	Vol. 3, Annex B-8, B.8.6.1, Result of PEC _{sw} 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 PEC _{sw} 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
(7)	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 PEC _{gw} , the reasoning is correct (geomean). However, DT50 should be normalised to 20°C, but t we don't expect this to affect the PEC _{gw} in this case, since all the concentrations are <0.001 µg/l.	

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Section 4 - Fate and behaviour (B.8)

PEC in surface water and ground water (B.8.6)			
No.	<u>Column 1</u> Reference to draft assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(8)	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.	
(9)	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.	

Fate and behaviour in air and PEC in air (B.8.7 – B.8.8)			
No.	<u>Column 1</u> Reference to draft assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. 1, LoEP, Fate and behaviour in air	FR : The vapour pressure of trifluralin (9.5 x 10 ⁻³ Pa) triggers short-range transport assessment according to the FOCUS air report. We note that this vapour pressure is determined at 25°C, while the trigger value is determined at 20°C. Also Step4 calculations are needed to mitigate aquatic risks. Following FOCUS air guidance modelling would be needed to determine the amount of trifluralin deposition after volatilisation. We think that incorporation into soil after application should be included for every use of trifluralin to reduce losses due to evaporation. We believe that long-range transport is not very likely, since the DT50 in air is 5.3 hours (trigger of 2 days suggested in FOCUS air report).	

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Section 5 – Ecotoxicology (B.9)

24. Ecotoxicology (B.9)

Aquatic organisms (B.9.2)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	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.	
(2)	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	<p>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 < synotosis < fusion (Witten <i>et al.</i>, 2006; Deschamps <i>et al.</i>, 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.</p> <p>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.</p>

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Section 5 – Ecotoxicology (B.9)

Aquatic organisms (B.9.2)			
No.	<u>Column 1</u> Reference to draft assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
		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 <i>P. promelas</i> (Hoberg, 2006) should be used for chronic risk assessment.	<p>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 <i>Cyprinodon variegatus</i> (Couch <i>et al.</i>, 1979). 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:</p> <p>1/ The disappearance of intervertebral space due to the alteration of the structural integrity of the notochord (dysfonctionning of notochord cells during the development) and/or lesions of intervertebral ligaments due to inflammation (Fjelldal <i>et al.</i>, 2007).</p> <p>2/ Deposition of cartilage inducing the compression between two vertebrae (Witten <i>et al.</i>, 2006).</p> <p>3/ The mineralisation of this cartilage which increases the synostosis / union between vertebrae (Witten <i>et al.</i>, 2006).</p> <p>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.</p> <p>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.</p>

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Section 5 – Ecotoxicology (B.9)

Aquatic organisms (B.9.2)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
			<p>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</p> <p>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</p> <p>Fjellidal PG, Hansen TJ, Berg AE (2007) A radiological study on the development of vertebral deformities in cultured Atlantic salmon (Salmo salar L.). Aquaculture</p> <p>Gill C.D. and Fisk D.M., Vertebral abnormalities in Sockeye, Pink, and Chum salmon, Trans. Am. Fish. Soc. 95 (1966), pp. 177–182.</p> <p>Poynton S.L. (1987) Vertebral column abnormalities in brown trout, Salmo trutta L. Journal of Fish Diseases 10, 53-57.</p> <p>Poleksic V, Karan V (1999) Effects of Trifluralin on Carp: Biochemical and Histological Evaluation. Ecotoxicology and Environmental Safety 43: 213-221</p> <p>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</p>
(3)	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).	
(4)	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.	

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Section 5 – Ecotoxicology (B.9)

Aquatic organisms (B.9.2)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
		The effect concentration should be corrected.	
(5)	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.	
(6)	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 <i>P. promelas</i> (Hoberg, 2006).	
(7)	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).	
(8)	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	

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Section 5 – Ecotoxicology (B.9)

Aquatic organisms (B.9.2)			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
		<p>happened only at the day 0 or if exposure was more or less continuous (pulsed input).</p> <p>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.</p>	
(9)	<p>Vol. 3, Annex B-9, B.9.2., Chronic risk to aquatic organisms; Table B.9.2.8-16</p>	<p>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).</p> <p>For PEC_{TWA} calculation, a time window of 7 days should be used with a DT₅₀ of 13 days.</p> <p>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.</p>	<p>In an addendum, the RMS proposed to compare the 48-day TWA concentration (TWA concentrations based on the DT₅₀ 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 <i>P. promelas</i> with a 7 TWA concentration based on a DT₅₀ of 2 days. A DT₅₀ 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 DT₅₀ 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 PEC_{sw} calculations at Step 4).</p> <p>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). 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):</p> <p><i>“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-</i></p>

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Section 5 – Ecotoxicology (B.9)

Aquatic organisms (B.9.2)			
No.	<u>Column 1</u> Reference to draft assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
			<i>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”.</i>
(10)	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 <i>et al.</i> , 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.	

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Section 4 - Environmental fate and behaviour (B.8)

25. Environmental fate and behaviour (B.8)

Other comments			
No.	<u>Column 1</u> Reference to draft assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	General comment	<p>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.</p> <p>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.</p> <p>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</p> <p>"Based on the available data, trifluralin should be considered as a POP, warranting</p>	

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Section 4 - Environmental fate and behaviour (B.8)

Other comments			
No.	Column 1 Reference to draft assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
		<p>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.</p> <p>.....</p> <p>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</p>	

* When mentioning page numbers of the DAR in your comments, **the page numbers should refer to the pdf-version** (not the WORD-version) of the DAR to ensure consistency among the Member States.

Section 4 - Environmental fate and behaviour (B.8)

Other comments			
No.	<u>Column 1</u> Reference to draft assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
		<p>long range transport suggest that trifluralin can be transported over long distances bound to particles in air and water.”</p> <p>Therefore, we consider that the appropriate measure to control the use of trifluralin is to withdraw the substance from the market.</p>	

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Section 5 - Ecotoxicology (B.9)

26. Ecotoxicology (B.9)

Aquatic organisms (B.9.2)			
No.	<u>Column 1</u> Reference to draft assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	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.	

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Section 5 - Ecotoxicology (B.9)

27. Ecotoxicology (B.9)

Aquatic organisms (B.9.2)			
No.	<u>Column 1</u> Reference to draft assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	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.	
(2)	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.	
(3)	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.	

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Section 5 - Ecotoxicology (B.9)

Earthworms and other soil non-target organisms (macro and micro) (B.9.6, B.9.7 and B.9.8)			
No.	<u>Column 1</u> Reference to draft assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	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.	

Other comments			
No.	<u>Column 1</u> Reference to draft assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	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.	
(2)	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)	
(3)	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.	

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