PEER REVIEW REPORT ON **TRIFLURALIN** 04.04.2005

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Comments on the Draft Assessment Report (DAR) on trifluralin

End of commenting period: 30 October 2003

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

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.2.1.1, Melting point	UK: Agree with RMS, a new study using pure material is required.	
(2)	Vol. 3, B.2.1.2 & B.2.1.3, boiling point & decomposition	UK: New data generated with pure a.s. are required, together with temperature at which decomposition occurs. The decomposition is attributed only by colour change which may be an impurity rather than active substance. A temperature should be provided	
(3)	Vol. 3, B.2.1.4, density	UK: Agree with RMS new data would not yield additional information.	
(4)	Vol. 3, B.2.1.5, vapour pressure	UK: The DAR states the purity was 100%, is this correct?	
(5)	Vol. 3, B.2.1.11, spectra for impurities	UK: Are these data necessary i.e. is N-nitroso-di-n-propylamine a significant impurity? If it is then a new study is required because these data are published, very old and lack details e.g. purity of test substance	
(6)	Vol. 3, B.2.1.14, partition coefficient	UK: Substance was 100% pure – this appears to be high. Agree a.s. is lipophilic.	
(7)	Vol. 3, B.2.1.15, stability in water	UK: Agree with RMS new data would not yield additional information.	
(8)	Vol. 3, B.2.1.16, stability in water	UK: Suggest this section be summarised for tabular presentation or cross refer to appropriate section in DAR	
(9)	Vol. 3, B.2.1.19, stability in air	UK: Data suggest long range transport unlikely	

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(10)	Vol. 3, B.2.1.20, flammability	UK: Typographical error, statement should read "Trifluralin is a non-pyrophoric substance."	
(11)	Vol. 3, B.2.2.5, oxidising properties	UK: Is this a statement from the RMS or data submitter? Could the data submitter's statement be included together with the opinion of RMS.	
(12)	Vol. 3, B.2.2.7, flammability	UK: Would suggest to add '..for liquid' to indicate that this is not a data gap, but that the test is not appropriate for the formulation type.	
(13)	Vol. 3, B.2.11 & B.2.2.12, viscosity	UK: New GLP data needed at 40ºC Data suggest that R65 is appropriate but data do not satisfy study requirements/conditions.	
(14)	Vol. 3, B.2.2.13, surface tension	UK: Data at 25ºC appropriate and suggests that R65 is appropriate. Surface tension data alone are not sufficient to positively classify with respect to R65, therefore viscosity data at 40ºC still required.	
(15)	Vol. 3, B.2.2.16, storage stability – emulsion stability	UK: Emulsion stability test suggests agitation of product in the spray tank required during mixing and loading and until spraying complete.	
(16)	Vol. 3, B.2.2.16, low temperature stability	UK: Would suggest 'Protect from frost' to appear on the label. The study did not cycle the temperature.	
(17)	Vol. 3, B.2.2.17, shelf life	UK: Would agitation address concerns as per 2.2.16 (emulsion stability) above	
(18)	Vol. 3, B.2.2.28, emulsifiability	UK: Data suggest some separation of emulsion needing agitation on the label	
(19)	Vol. 3, B.2.2.28 – EAF-283	UK: What is 'Bloom', data submitter to define and qualify in terms of emulsion stability	

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

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(20)	Vol. 3, B.2.2.33	UK: Agree with data requirement for MS	
(21)	Vol. 3, B.5.1.2, Methods for impurities	UK: Conclusion states LOQ to be confirmed, does this mean that LOQ have not been supplied?	
(22)	Vol. 3, B.5.1.3, Methods for a.s. in PPP	UK: Conclusion states surfactants have changed and that this is minor, if all surfactants have changed then this suggests that the formulation change is major.	
(23)	Vol. 3, B.5.2, Methods for plants	UK: ILV for study GRM 96.12 is required if method needed for monitoring. However, it is noted that crops are not proposed/not subject to MRLs at this time.	

section 2 - Mammalian toxicology (B.6)

2. Mammalian toxicology (B.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.6.1 ADME studies. Bioaccumulation	UK: Only a limited number of tissues were evaluated following multiple oral administration of heptadeutero-labelled trifluralin (on propyl groups). Justification of the limited tissue sampling and the position of the radiolabel must be provided for the repeat dose studies. The yellow adipose tissue seen at necropsy in the toxicity studies suggests that bioaccumulation occurs.	
(2)	Vol 3, B.6.1/07 Metabolism in the rat and dog.	UK: The evidence that the metabolic pathways in the rat and dog are similar is not conclusive. Although similar metabolites have been identified in the rat and dog, the metabolites have not been adequately quantified in the dog.	
(3)	Vol 3, B.6.2.6 Skin sensitisation.	UK: We agree the commercial technical material must be classified as a skin sensitiser.	
(4)	Vol, 3, B.6.4 Genotoxicity	UK: The requirement for further *in vivo* genotoxicity data is justified.	

section 2 - Mammalian toxicology (B.6)

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.6.5.1 & 6.5.2 Rat chronic/carcinogenicity	UK: The quality of the long-term rat data does not meet modern requirements. A NOAEL has not been determined for the definitive chronic study. Consideration should be given to performing a 2-year chronic/carcinogenicity rat study to modern standards with commercial material of a known technical specification. An upper maximum limit for n-nitrosodipropylamine must be stipulated for the commercial technical material.	
(6)	Vol 3, B.6.5.3/01 Mouse carcinogenicity	UK: The dose-related decreases in the incidences of pituitary tumours in female mice and #Leydig cell tumours in male mice indicate that the test material may be an endocrine disruptor. # E Ebert, K H Leist, R Hack and G Ehling. Food Chem. Toxic. Vol 30, No12, pp 1031-1044, 1992.	
(7)	Vol 3, B.6.5.1, 6.5.2 & 6.5.3. Tumourgenicity in rats and mice and relevance to human risk assessment	UK: Various tumours have been found in rats (testes, kidney, thyroid and urinary bladder) and mice (liver, lung and stomach). The company have provided plausible mechanisms for the rat tumours but the supporting mechanistic data is equivocal or absent. No mechanisms or mechanistic data have been provided to explain the mouse tumours. Given the weak positive result in the mouse micronucleus study (Gebel *et al*, 1997), these rodent tumours must be regarded as relevant to humans until proven otherwise. CAT: 3 carcinogen (R40) is applicable at the present time	

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section 2 - Mammalian toxicology (B.6)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca. 10 lines)	Column 3 Further explanations
(8)	B.6.6.1.1/01 Two generation reproductive study	UK: The incidence of runts has been noted; historical control data are required.	
(9)	B.6.6.1.1/02 Two generation reproductive study	UK: The text refers to 'a few congenital defects were observed in the F1 litters'. These defects need to be listed/tabulated and historical data provided to allow an independent assessment. UK: Uterine atrophy may be related to endocrine disruption.	
(10)	B.6.6.1.2/03 Reproduction study in dogs.	UK: Although this study is unacceptable, it is noted that the reported pup deaths at 400 ppm and above include a runt.	
(11)	B.6.6.2.1./01 Rat developmental study	UK: The incidence of runts as been noted. Cleft palate is a rare event in rats; historical control data are required. UK: NOAEL for maternal toxicity is 100 mg/kg bw/day based on the dose-related alopecia at 225 and above.	
(12)	B.6.6.2.1./02 Rat developmental study	UK: Sparse pathological details for the high number of premature maternal deaths at 750 mg/kg bw/day. No deaths occurred in the previous study at 1000 mg/kg bw/day (Byrd, 1984a). A possible vehicle effect.	

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section 2 - Mammalian toxicology (B.6)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca. 10 lines)	Column 3 Further explanations
(13)	B.6.6.2.2./01 Rabbit developmental study	UK: Post-implantation loss/reduced placental weight may be related to endocrine disruption. The incidence of small foetuses has been noted (runts?) Discoloured urine has been dismissed as irrelevant toxicological findings without any explanation.	
(14)	B.6.6.2.2./02 Rabbit developmental study	UK: The incidence of runts is increased at all dose levels (zero in controls). Abortions at 500 mg/kg bw/day and above. Sex ratio affected at the top dose level.	
(15)	B.6.6.2.2./03 Rabbit developmental study	UK: Abortions at 225 mg/kg bw/day and above. High incidence of runts. Sex ratio affected at the top dose level.	
(16)	B.6.8.1 Toxicity studies on metabolites	UK: We agree with the data requirements for the plant metabolites TR-22 and TR-28.	
(17)	B.6.10.2.2 Establishment of an ARfD	UK: Several effects seen in the developmental studies occur at 120 mg/kg bw/day and above (e.g. deaths, abortions, post-implantation loss). Since these effects may occur after a single dose, an ARfD is essential. Based on the NOAEL of 50 mg/kg bw/day (Rubin, 1986) determined for post-implantation loss and applying a standard safety factor of 100, an ARfD of 0.5 mg/kg bw can be proposed.	
(18)	B.6.10.2.3 Establishment of an AOEL	UK: Based on the submitted data set, the NOAEL for the 1-year dog study should be used to set the AOEL (but current proposal acceptable).	

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section 2 - Mammalian toxicology (B.6)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca. 10 lines)	Column 3 Further explanations
(19)	B.6.3, 6.5 & 6.6 Persistent findings in the toxicity studies.	UK: Both the yellow adipose tissue and the discoloured urine have been dismissed as irrelevant toxicological findings. Please provide an explanation. The incidence of runts/small foetuses in the reproduction studies requires further consideration.	
(20)	B.6.12/01 Dermal absorption	UK: The dermal absorption data has not been generated with a representative formulation (ethanol vehicle used in the study). The xylene content (approximately 50%) of the commercial formulation could have a marked effect on dermal absorption. Default dermal absorption values must be used for the operator risk assessment until confirmatory data are provided.	
(21)	B.6.14.1 Estimation of operator exposure (Annex IIIA 7.2.1.1)	UK: Although only slightly volatile in its concentrated form, trifluralin is highly volatile on contact with water (H=10.2 Pa m^3 mol^{-1} @20^{O}C) therefore the risk of exposure arising from inhalation of the vapour during spraying should be quantified.	
(22)	B.6.14.3 Estimation of bystander exposure (Annex IIIA 7.2.2)	UK: Bystander exposure has not been quantified. Due to the volatility of trifluralin in water, exposure arising from inhalation of the vapour should be addressed along with dermal and inhalation exposure to the spray.	

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section 3 - Residues (B.7)

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
(1)	Vol. 3, B.7.1.1, Metabolism in cotton	UK: Has sufficient characterisation for cotton plants been undertaken, given the residues in various plant parts from N rate application, lipophilic nature of active and high persistent activity in soil?	
(2)	Vol. 3, B.7.1.2, Metabolism in Soybean	UK: Has sufficient characterisation for soybean plants been undertaken, given the residues in various plant parts from N rate application, lipophilic nature of active and high persistent activity in soil?	
(3)	Vol. 3, B.7.1.3, Metabolism in mustard	UK: Has sufficient characterisation been undertaken and was methanol a valid primary extraction solvent given that trifluralin solubility was lowest in this solvent?	
(4)	Vol. 3, B.7.1.4, Metabolism in maize	UK: Is this study, together with other studies sufficient to provide such a detailed metabolic pathway in plants? Maize is an 'unusual' cereal and the other studies only looked at TRR (mustard had some characterisation), but the pathway produced is quite complex.	
(5)	Vol. 3, B.7.2.2 & B.7.2.3, Metabolism in dairy cow and laying hens	UK: Reference made under several studies to Dow AgroSciences unpublished report no. 152. However, these seem to be dated 1965, 1989, 1966 and 1989 (laying hen)	

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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
(6)	Vol. 3, B.7.3.1, definition of the residue in plants	UK: Perhaps confirmation of the residue definition should only be made when the toxicological significance of metabolites not found in the rat has been addressed by toxicology data. The metabolism in oily crops was only limited in that no characterisation was made, residues in the oilseed were significant and the relative amounts of the metabolites may be different from those found in the maize crop.	
(7)	Vol. 3, B.7.6.1, residue trials in oilseed rape	UK: In the 1993 OSR trials, the LOQ was very high (0.2 mg/kg), which reduces the value of these trials for risk assessment purposes. Therefore, data from these trials should be discounted, especially as the case made for acceptability of a lack of trials for Southern MS is that residues will not be >0.01 mg/kg.	
(8)	Vol. 3, B.7.6.2, residue trials in sunflower	UK: Agree with RMS, exceptionally the data from USA can support EU use. This is because of the extremely exaggerated rate which still gave no detectable residues of parent.	
(9)	Vol. 3, B.7.6.4, residue trials in winter cereals (wheat)	UK: Only 4 trials from EU, use of USA/Canada data less robust as GAP not so exaggerated as for sunflower.	

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
(10)	Vol. 3, B.7.6.4, residue trials in winter cereals (barley)	UK: Only 2 trials from EU. Insufficient data. Use of 3 USA/Canada trials less robust and still insufficient in number for major cereal. Extrapolation of USA data not acceptable. Data from metabolism studies suggest residues much higher than in residue trials but have not been well characterised (except in maize)	
(11)	Vol. 3, B.7.6.4, oats, rye and triticale	UK: Only 4 trials for wheat and 2 trials for barley (all in Northern Member states). The case for extrapolation to oats, rye and triticale needs strengthening as extrapolation is usually acceptable with 8 trials on wheat and barley from Northern and Southern MS. Much of the residues trials package is supported by trials from USA and Canada. However, this is not an accepted standard extrapolation to the EU countries. The overall metabolism package may require further characterisation as this was only carried out in maize.	
(12)	Vol. 3, B.7.7, Effects of processing	UK: Although data not evaluated, these data would not allow any effects to be measured as incurred residues were already below the LOQ.	

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
(13)	Vol. 3, B.7.9, Residues in succeeding crops	UK: It might be useful to include additional information from the studies where characterisation and identification of TRR have been made in the succeeding crops. These data may help to support the primary metabolism studies where characterisation of residues has not been made for oilseed crops. These data may also aid in the case to preclude the requirement for further residues trials data. These succeeding crop metabolism studies are very important to the overall residue data package.	
(14)	Vol. 3, B.7.12, Proposed MRLs	UK: Assuming residues trials questions are addressed, we would suggest setting the MRLs at an LOQ of 0.05 mg/kg to allow for cost effective monitoring. (It is noted that the UK risk assessments for 0.05 are well within the 0.024 mg/kg bw/day ADI.)	

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

4. Environmental fate and behaviour (B.8)

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, page 537	UK: The major soil metabolite TR-4 formed under anaerobic conditions has a data requirement for degradation rate in soil under AEROBIC conditions. We agree with this but consider that the relative importance of anaerobic soil conditions depends on the crop and season of use etc – hence this data requirement should be at MS level.	
(2)	Vol 3, B.8, page 568	UK: For the anaerobic soil metabolite TR-4, soil sorption Koc value has been calculated giving a result of 13600 ml/g. This is very high and suggests that significant groundwater contamination is unlikely. Although, in general, Koc values should be determined experimentally, as TR-4 is formed under anaerobic conditions, we consider this to be sufficient information. Thus the data requirement on page 572 for column leaching on TR-4 is not needed.	
(3)	Vol 3, B.8, page 600	UK: The data requirement for another sediment/water study is not needed. There is sufficient information already available on the major sediment metabolite TR-4 in order to calculate a worst case PECsed (see page 605). This should provide enough information for a basic ecotoxicology risk assessment.	

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

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, B.8, page 609	UK: The PECgroundwater assessment for metabolite TR-4 uses calculated or assumed worst case values of soil degradation rate and sorption, which indicates that groundwater contamination is unlikely. We accept this but would prefer to see the complete PECgw results provided for all uses and all FOCUS scenarios.	

5. Ecotoxicology (B.9)

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-9.1.7 Summary and risk assessment (birds)	UK: In the first tier risk assessment for fish-eating birds, it is considered that a worst case residue estimate in fish should be used, derived by multiplying the fish bioconcentration factor by the surface water predicted environmental concentration (PECsw) from spray drift at 1 metre. Currently the PECsw value used in this calculation relates to that from spray drift contamination when risk mitigation in the form of a 5 metre no-spray buffer zone is included.	It is not considered appropriate to derive an estimate of active substance residue levels in fish in the first tier risk assessment by multiplying the 5 metre no-spray zone surface water initial PEC (i.e. 2.28 µg a.s./l) by the bioconcentration factor (5674). Instead the 1 metre PECsw value of 11.08 µg a.s./l should be used, this resulting in worst case fish residue levels of 63 mg a.s/kg fish, with TERs for fish-eating birds of approximately a fifth of those estimated in Tables B.9.1.7.08 to B.9.1.7.10. It is acknowledged however that these revised TERs will still be within Annex VI triggers.
(2)	Vol. 3 Annex B-9.2.5/01 Field monitoring pond mesocosm study	UK: It is considered that this study is not reported in sufficient detail in Vol. 3 to support the conclusions drawn. No justification is included as to how a field study conducted in central Indiana is representative of European conditions.	The results of the trifluralin field monitoring pond mesocosm study are briefly reported, with e.g. no details supplied for the range of species of fish collected at the treated site or for their individual numbers. The level of detail supplied is insufficient to support all of the conclusions drawn at the end of this section and is not adequate to support the statement included in the endpoint table that the 'tier 2' chronic risk assessment 'is substantiated by the findings of an extensive field monitoring study'. It is also doubtful whether the results of one field monitoring study conducted in central Indiana would be sufficiently representative in terms of climate and soil type to European conditions.

section 5 - Ecotoxicology (B.9)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca. 10 lines)	Column 3 Further explanations
(3)	Vol.3, Annex B.9.2.8 Summary and risk assessment	UK: The results of the aquatic chronic toxicity studies (summarised in Table B.9.2.8-03) suggest that the fathead minnow (*Pimephales promelas*) may be more sensitive to the effects of trifluralin than rainbow trout (*Oncorrhynchus mykiss)*. Therefore it is considered that the reported short-term exposure sub-lethal effect study with juvenile brown trout should have ideally been repeated using the fathead minnow. We consider that a strengthened argument for the chronic risk assessment is required.	The chronic risk assessment for fish is ultimately based on a short-term exposure study on juvenile brown trout (NOEC 25 µg/l based on an assessment of spinal column abnormalities). The initial chronic risk assessment was based on a more recent flow-through juvenile growth test on fathead minnow, which gave a NOEC of 0.3 µg a.s./l based on spinal abnormalities. The approximate 85-fold decrease in sensitivity might well have been influenced by the reduced exposure period in the trout study, but it is unfortunate that this study was not repeated using fathead minnow or that time-to-effect information is not available from the fathead minnow study. It is possible in this instance that brown trout are not such a sensitive species and that the usual 10-fold uncertainty factor is not sufficient.

section 1 – physical/chemical properties; details of uses and further information; methods of analysis (B.1-B.5)

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

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 1, 1.5.2 , Effects on harmful organisms	Finland: In Volume 1 point 1.5.2, it is stated that " trifluralin is incorporated in soil to be protected from degradation by sunlight". However, in Vol 1 in point 2.5.2 route of photolytic degradation in soil, it is stated that "irradiation of trifluralin on a soil surface under artificial sunlight…..after 30 days the majority of the applied radioactivity was present as trifluralin". These statements are contradictory, and we suppose that the incorporation of trifluralin to soil is due to the volatility of the trifluralin.	

section 4 – environmental fate and behaviour (B.8)

4. Environmental fate and behaviour (B.8)

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.8.4.2, photochemical degaradion	Finland: Based on the results presented in Vol 3, point B.8.4.2. the photodegradation of trifluralin in water is shown to be fast resulting to 2 major metabolites TR-6 and TR-15. The toxicity of these metabolites have been tested for fish, daphnia and algae. The toxicity of the metabolites and therefore also the risk from these metabolites was found to be smaller than from trifluralin. However, in Vol 1, in level 2 and 4 (data requirements) there is a suggestion that the ecotoxicological relevance of these metabolites should be assessed at Member State level. This should be defined more precisely, since if there is some doubt of the risk these metabolites pose, in our opinion this should addressed at EU-level.	
(2)	Vol 1, Point 2.5.2, Degradation in field	Finland: The mean degradation times in field studies in the point 2.5.2. (field dissipation studies) differ from the mean values given in list of end point sheet. Which values are the correct ones?	
(3)			

5. Ecotoxicology (B.9)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca. 10 lines)	Column 3 Further explanations
(1)	Vol. 1, point 2.6.1, Effects on birds and mammals	Finland: Risk assessment for birds are only carried out for birds that eat insects, earthworms and fish. However, application to winter cereals can be performed up to the three-leaf stage. Therefore there is possibility that birds eating young shoots could be exposed and therefore acute and short-term TER-values should be calculated for this exposure scenario also. The acute TER values for mammals should also be calculated. The long-term values for birds and mammals are not relevant, since the application is not during the breeding season.	

section 5 – ecotoxicology (B.9)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca. 10 lines)	Column 3 Further explanations
(2)	Vol. 1, point 2.6.2.1, Effects on fish……	Finland: We do not agree with the chosen chronic NOEC value (25 µg/l), based on the 24 hour exposure, for fish chronic risk assessment. Since the monitoring data show that trifluralin is found quite often from surface water (even in amounts of 0.6 µg/l), it cannot be assumed that the exposure of fish is only to brief exposure for high concentration, followed by rapid dissipation. The exposure can be continuous for low levels of trifluralin and therefore the lowest chronic NOEC value of 0.3 µg/l should be used in risk assessment.	The assumption that fish are only acutely exposed to trifluralin is not correct. The monitoring data show constant low levels of trifluralin in surface waters (other compartments not studied). Trifluralin is also present at sediment and suspended solids and as the study B.9.2.3/02 show, trifluralin is accumulated to fish even though it is bound to sediment (BCF 1087-1838). Most probably trifluralin will also be accumulated to fish by biomagnification through food web. Therefore the assumption that chronic risk assessment could be based on a one day acute exposure data as in draft assessment report has been done is not acceptable. We also do not agree with the explanation that the result of crooked ribs and vertebral lesions observed in the study with fathead minnows could be overlooked since same effects were not seen at the same concentrations in rainbow trout early-life toxicity test or sheephead minnow full life toxicity test. In our opinion the results only show that there is difference in the sensitivity of different fish species. The NOECs obtained with rainbow trout and sheephead minnow were at the same level than with fathead minnow, but the most sensitive end points were different.

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

4. Environmental fate and behaviour (B.8)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1a)	General	SE: We noted that this compound is persistent in combination with a high bioaccumulation potential and a high volatilisation. To our opinion, the PB properties alone make the substance unacceptable: -Long persistence and high bioaccumulation potential (in this case also volatilisation) increases the risk for widespread distribution to different environmental compartments, including biota. This implies a higher than normal uncertainty in the estimates of exposure. -Despite the large data package available, unpredictable effects following long-term exposure of biota cannot be excluded when substances are persistent in the environment. This implies a higher than normal uncertainty in the estimates of effects. A high potential for bioaccumulation implies a risk for bioconcentration in various organisms at lower levels of aquatic and terrestrial food chains, and for biomagnification at higher trophic levels. To address the risk for effects from such bioconcentration/ biomagnification would presumably necessitate an impracticable high number of studies. continued on next page..	

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

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1b	General, continued	... -The expected widespread distribution and the risk for unpredictable effects makes the applicability of point estimates of exposure and effects more uncertain in the risk assessment than for other compounds. Continued on next page... -If unforeseen effects eventually would appear, and *ad hoc* risk reduction measures then applied, it could still take a long time to bring down the environmental concentrations to levels at which affected biota can recover. -In this case, the available data package show effects on aquatic organsisms at low levels of exposure, including effects on reproduction, so the problem was not only related to "unpredictable" effects and increased uncertainty.	
(2)	Vol. 3, B.8.1, Degradation in soil	SE: The mean DT_{50} of 170 days in soil from field studies in DE, UK and USA was used. At least for some of the US studies, the relevance for the EU risk assessment is questionable due to different climatic conditions. Taking only the EU soils into account would give a mean DT50 of 227 days.	

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

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(3)	Vol. 3, B.8.1, Degradation in soil	SE: To be consistent, and to be used for modelling purposes, all DT50 values should be based on 1st order kinetics.	
(4)	Vol. 3, B.8. Definition of major residues in soil	SE: No major metabolites were observed in aerobic soil degradation studies, but in a soil photolysis and anaerobic soil degradation studies one metabolite occurred at >10% of applied. Generally, we feel that the assessment of major metabolites should be based on aerobic soil degradation studies. However, in cases where photolysis is considered as more important than microbial degradation, these metabolites could be treated equally. For trifluralin exposed to light (spray application to bare soil), photolysis is probably important under environmental conditions, while soil incorporated trifluralin will probably not be exposed to light to a significant extent. Therefor, we propose to include the photolytical product in the definition of the residue only when trifluralin is sprayed onto bare soil. Anaerobic metabolites may be relevant only in certain cases, for example for compounds that leach to deeper soil layers. This is not the case for trifluralin.	

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

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.8. Degradation in water	SE: The degradation rate in water/sediment systems was calculated by Timme-Frehse/'best fit'-models. Generally, in order to be used for the estimation of time weighted average concentrations, only first order kinetics should be used. In one of the systems, DT50 in the water phase was reported to be 13 days, while the whole system DT50 was 3 days. We propose re-calculation to check the reliability of these data. The re-calculation should be based on first order kinetics.	
(6)	Vol. 3, B.8. Volatilisation and degradation in air	SE: Trifluralin has a high potential for volatilisation, but is reported to be rapidly photolysed in air. However, the metabolites in air should be identified in order to address the risk for long range trransport.	

5. Ecotoxicology (B.9)

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.9.1.7, Risk assessment for birds	SE: We noted that the short term and the long term risk assessments for birds were based on the dietary concentrations. This should be corrected to daily dose, in accordance with the guidance document.	
(2)	Vol. 3, B.9.2.8, Risk assessment for aquatic organisms	SE: We do not agree with the selected NOEC for the refined risk assessment for fish; The long term NOEC of 25 µg/L was obtained from a study where juvenile brown trout were exposed for only 24 hours (acute exposure), and then observed for up to one year. From our point of view, these data cannot over-rule the results from studies with chronic exposure. Besides, the most sensitive species from those tested in standard chronic studies was not brown trout but fathead minnow (NOEC 0.3 µg/L).	

section 5 - Ecotoxicology (B.9)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(3)	Vol. 3, B.9.3.2, Risk assessment for mammals	SE: The study referred to for the selection of NOAEC for mammals seems to be wrong. In the study reported under B.6.5.1/01, did not include a test concentration of 200 ppm. The selection of reproduction endpoint should be clearly justified. SE: We noted that the short term and the long term toxicological endpoints for mammals were based on dietary concentrations. This should be recalculated to daily dose, in accordance with the guidance document.	
(4)	Vol. 3, B.9.9.3, Risk assessment for non-target plants	SE: Due to the high persistence of trifluralin in soil, the possible risk for effects on the succeeding crop should be addressed.	
(5)	Vol. 3, B.9.11, References relied on	SE: The list of references for this section seems to be incomplete.	

2. Mammalian toxicology (B.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.6.2.1, Acute oral toxicity	DE: The high vulnerability of newborn rats as compared to adult animals should be adressed and considered in the discussion on a possible need for ARfD setting.	PPP containing trifluralin are intended to be applied on crops (cereals, carrots *etc.*) that could be used for baby food preparation.
(2)	Vol. 3, B.6.2.5, Eye irritation	DE: By the EU (28th time council directive 67/548/EEC), trifluralin has been classified as "Irritant to the eyes" and labelled accordingly (R 36).	This apparent contradiction should be clarified by the RMS.
(3)	Vol. 3, B.6.3.2.1, Oral 90-day toxicity (rat)	DE: The NOEL for subchronic toxicity in the rat should be rather based on a study in male rats with special emphasis on urogenital tract findings that is reported under B.6.8.2 in the monograph. In this study, the NOEL was 2.6 mg/kg bw/d (50 ppm) corresponding well to that one obtained in dogs.	

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, B.6.3.2.2, Oral 90-day toxicity (dog) and B.6.3.2.3, Oral 1 yr toxicity (dog)	DE: The statement that a 90-day dog study was not conducted is not correct. At least three further subchronic studies in dogs are not mentioned in the monograph. Although they will not substantially change the assessment but rather support the NOEL and the overall conclusions, in particular the one-year feeding study might provide additional information on exposure via the diet. For other fields of toxicological testing, rather old studies are also referred to.	The following studies have been submitted by the companies *Hoechst* (later part of *Agrevo* and *Aventis*) and *Montedison* to the German authorities: Bathe, R. et al. : Trifluralin substance technical grade (code: Hoe 38474 O H AT210): 12-month oral toxicity (feeding) study in Beagle dogs (Project-Nr. RCC 008864; Study Nr. A29701); 1984, unpublished. Brunk et al.: Toxikologische Prüfung von Trifluralin (Hoe 38474 O H AT204) bei wiederholter oraler Applikation an Beagle-Hunden über 6 Monate (Report Nr. 626/81; Study Nr. A22284); 1981, unpublished. Sterner, W. et al.: 13-Wochen Toxizitätsprüfung von "Trifluralin techn. 95.6%" nach oraler Applikation an Beagle-Hunden (Report-Nr. 2-2-106-76); 1977, unpublished.
(5)	Vol. 3, B.6.4, Genotoxicity	DE: A clastogenic potential of trifluralin is not likely in particular when the in vivo studies are taken into account. In contrast, the possible induction of aneuploidy should be further examined as proposed by the RMS. However, if such an effect would be actually confirmed, the existence of a threshold can be assumed. In this case, special studies like with the benzimidazoles (carbendazim etc.) should be performed to identify the threshold level.	A certain likelihood of aneugenic effects is also provided by the fact that cyclization reactions leading to methyl or ethyl derivatives of benzimidazole compounds are part of the rat metabolism. This is a further trigger for requiring a special study.

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca. 10 lines)	Column 3 Further explanations
(6)	Vol. 3, B.6.5, Long term toxicity and carcinogenicity	DE: The proposal for classification (canc. cat. 3) and labelling (Xn, R 40) is strongly supported. It must be acknowledged that no NOAEL for cancerogenic effects could be established in Fischer 344 rats and that the available information is not sufficient to prove that the tumours are not relevant to humans. Therefore, we agree with the RMS that further mechanistic studies should be required to elucidate the mechanism(s) behind tumour formation.	
(7)	Vol. 3, B.6.5.1/B.6.5.1.2, Long term oral toxicity and carcinogenicity in the rat	DE: Apart from the not acceptable studies described in the DAR, there is a further valid study in Wistar rats that should be also taken into account. However, even though its results (NOAEL 200 ppm, corresponding to ca 10 mg/kg bw/day; no convincing evidence of cancerogenicity) might point to a different sensitivity of rat strains it would remain equivocal which one is the more appropriate model for humans.	The following study has been submitted by the company *Hoechst*: Donaubauer et al.: Trifluralin (Code: Hoe 38474 O H AT208): Kombinierte chronische Toxizitäts- und Kanzerogenitätsstudie an Ratten (24 bzw. 28 Monate Fütterungsversuch). Zusammenfassende Darstellung der Ergebnisse und Bewertung. Report-Nr. 86.0092; Projekt-Nr. 680; Studien-Nr. A33023; 1986, unpublished.
(8)	Vol. 3, B.6.5.3, Carcinogenicity study in the mouse	DE: In a further oncogenicity study in mice that is not mentioned in the monograph, a NOAEL of 50 ppm (ca. 7.5 mg/kg bw/day) was established. No evidence of cancerogenicity was obtained. The highest dose level tested was 800 ppm and, thus, well above the top dietary concentration in the only acceptable long-term mouse study used by the Rapporteur.	The following study has been submitted by the company *Hoechst*: Suter, P. et al.: Oncogenicity study with trifluralin active ingredient technical (Hoe 38474 O H AT210) in mice. Report No.. A32699, Project No. RCC 008853; 1986, unpublished.

section 2 - Mammalian toxicology (B.6)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca. 10 lines)	Column 3 Further explanations
(9)	Vol. 3, B.6.6, Reproductive toxicity	DE: The overall NOEL for reproductive toxicity should be based either on the impairment of reproductive performance or on adverse effects on offspring development but certainly not on parental toxicity. Accordingly, the overall reproductive NOEL for trifluralin should be about 40 mg/kg bw/day rather than 4.5-5.8 mg/kg bw/day.	
(10)	Vol. 3, B.6.6, Reproductive toxicity (Developmental toxicity/ teratogenicity)	DE: According to the toxicological data package submitted to the German authorities for national registration purposes, the lowest relevant NOAEL for developmental effects was 20 mg/kg bw/day and was obtained in rats. At the next higher dose level of 100 mg/kg bw/day, prenatal losses and developmental retardation were observed. However, this study has been apparently not provided to the RMS.	The following study has been submitted by the company *Hoechst*: Baeder et al.: Hoe 38474 - Wirkstoff (Code: Hoe 38474 O H AT210): Prüfung auf embryotoxische Wirkung an Wistar-Ratten bei oraler Verabreichung. Report no. 83.0557, Study no. A27217; 1983, unpublished.
(11)	Vol. 3, B.6.7, Neurotoxicity	DE: We agree with the Rapporteurs opinion that no neurotoxic properties have to be anticipated for this compound. However, we are aware of a study in chicken further supporting this assumption since it did not provide evidence of delayed neurotoxicity.	The following study has been submitted by the company *Hoechst*: Ebert, E. and Leist, K. H.: Trifluralin - Substanz technisch (Code: Hoe 038474 OH ZD 99 0002): Akute Neurotoxizität (acute delayed neurotoxicity) an weissen Leghornhennen. Report no. 85.0742, Study no. A32109; 1985, unpublished.

section 2 - Mammalian toxicology (B.6)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca. 10 lines)	Column 3 Further explanations
(12)	Vol. 3, B.6.8.1, Toxicity studies on metabolites	DE: In particular with regard to cancerogenic effects of the parent compound, the toxicological relevance of the plant metabolites TR 22 and TR 28 (both not occurring in the mammalian metabolism of trifluralin) must be adressed. To achieve this goal, the proposed genotoxicity tests are considered a first step but are certainly not sufficient. At least, an acute test and a 90-day feeding study should be additionally required to facilitate comparison of the toxicity to the parent.	For evaluating a possible cancerogenic potential, QSAR could be also taken into consideration.
(13)	Vol. 3, B.6.10.2.1, B.6.10.2.2, B.6.10.2.3, Reference doses	DE: The proposals for setting the ADI and AOEL are supported. The recommendation not to derive an ARfD is also followed although there are still doubts about acute effects in newborn rats [see comment (1)]. If evidence of aneuploidy induction would be confirmed in the required additional studies, this issue must be reconsidered.	

section 3 – Residues (B.7)

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
(1)	Vol. 3, B.7.16.11, Estimation of the Potential and Actual Exposure Through Diet and other Means	DE: The estimation of the acute risk is provisional due to the concerns raised in the toxicological section.	

Generell comments

During the commenting period of the DAR several essential studies have not been available for an extensive evaluation though they have been submitted to the RMS. Therefore a final comment is not possible at the moment. Furthermore, from the German point of view some essential studies for the toxicological evaluation of trifluralin have not been considered in the DAR, e.g. a long term study on rats and mice.

Classification and labelling (product)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 1, 2.1.4 (Classification and labelling), see also 2.1.2 (Physical and chemical properties)	DE: It is strongly recommended not to replace the safety phrase S 62 (in principle necessary because of R 65 labelling of the product) by S 46.	Justification: It should be clearly expressed not to induce vomiting before seeking medical advice. The term "immediately" (S 46) could be not sufficient in this context.

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

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

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.2.1.2/B.2.1.3, boiling point and temperature of decomposition or sublimation	NL: test should be carried out with purified a.s. The change of colour (indicating decomposition) of the technical material can be caused by the impurities.	
(2)	Vol. 3, B2.1.12, water solubility	NL: Is there an explanation for the difference of a factor 2 for the solubility between the two studies, as the purity difference is not that large.	
(3)	Vol. 3, B.5.1.2,analytical methods impurities, dow agroscience	NL: Method NAFST460 shows a not acceptable high recovery for impurity 1, and also the standard deviation is rather high. It looks very much so that there is another compound under impurity 1.	Is there sufficient evidence that the selectivity is sufficient, e.g. from the calibration curve offset?

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section 2 - Mammalian toxicology (B.6)

2. Mammalian toxicology (B.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.4.1, Proposals for the classification and labelling of the active substance	NL: Based on the results of the 28-day dermal toxicity study in rabbits trifluralin should be labeled with R66.	
(2)	Vol. 3, B.6	NL: In general: in majority of the studies, NOELs were derived instead of a NOAEL. Only NOAELs are considered relevant for risk assessment purposes.	
(3)	Vol. 3, B.6.1 Absorption, excretion and distribution studies	NL: A rather large amount of the administered radioactivity was excreted in bile. It is not clear whether the in bile excreted radioactivity had been systemically available. One should reconsider the overall oral absorption percentage of 80% and the fact that no correction for systemic availability was used.	
(4)	Vol. 3, B.6.3.2.1, oral 90-day toxicity (rat)	NL: It is not clear whether methaemoglobin was included in clinical chemistry investigations.	An increase in methaemoglobin was noted in a 1-year study in dogs at 40 mg/kg bw/day.
(5)	Vol. 3, B.6.3.3.3, percutaneous 28-day toxicity study	NL: Based on the observed moderate-to-severe skin irritation, trifluralin should be labelled with R66.	

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section 2 - Mammalian toxicology (B.6)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca. 10 lines)	Column 3 Further explanations
(6)	Vol. 3, B.6.8.2, Toxicity studies on metabolites	NL: *In* vitro genotoxicity studies with two plant metabolites TR-22 and TR-28 were requested. However, additional data to establish the toxicological properties of both metabolites should also be requested. Workers might be exposed to these metabolites.	
(7)	Vol. 3, B.6.10.2.1, Establishment of ADI	NL: The ADI was based on a 1-year oral study in dogs. A 1-year study in dogs is not considered a chronic study, while the ADI is derived for chronic exposure. This aspect should be addressed.	
(8)	Vol. 3, B.6.10.2.2, Establishment of ARfD	NL: One might consider the developmental NOAEL of 4.5 mg/kg bw/day for the establishment of the ArfD.	The NOAEL of 4.5 mg/kg bw/day was based on decreased offspring growth and survival and decreased ovarian weight at 40.7 mg/kg bw/day. At this latter dose level decreased maternal growth during gestation and lactation, and anemia were noted.

section 2 - Mammalian toxicology (B.6)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca. 10 lines)	Column 3 Further explanations
(9)	Vol. 3, B.6.10.2.3, Establishment of AOEL.	NL: No correction factor for systemic availability was required since oral absorption was established to be > 80%. However, a rather large amount of the administered radioactivity was excreted in bile. It is not clear whether the in bile excreted radioactivity had been systemically available. One should reconsider the overall oral absorption percentage of 80% and the fact that no correction for systemic availability was used.	

section 3 - Residues (B.7)

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
(1)	B7.6	NL: although no residue trials are provided performed in South Europe with oilseed rape, wheat and barley and for sunflower performed in North Europe, after evaluation of additional studies performed in USA/Canada and with over dosage the Netherlands feel that no residues are expected at this GAP for the crops mentioned.	
(2)	B7.10 (PHI)	NL: it is proposed that failure of crop growth of oilseed rape and cereals might result in feeding the remaining product, probably containing high levels of trifluralin, to livestock. Therefore, in our opinion an MRL should be set.	

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

4. Environmental fate and behaviour (B.8)

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., general	NL: no comments by RMS are included in the summaries.	Sometimes some comments are stated in the results but the consequences for the quality of the study are never mentioned.
(2)	Vol. 3, B.8.1.1, route of degradation	NL: There is no basis for the estimated values on CO_2 production for the non-covered soil experiment.	The values that were estimated for CO_2 production from the experiments with no mass balance have no basis. These cannot be used for further assessment. As a result the maximum %CO_2 formed is 18.5%. Adjustment of Volume 1 as well.
(3)	Vol. 3, B.8.1.2.2, field studies	NL:The 2nd study described hase a history of trifluralin use. Residues of trifluralin were measured in the control field.	The DT50 values is this study are clearly lower. Also because of the history of trifluralin use these should not be used for the assessment and not only because of the formulation
(4)	Vol 1, Level 2, 2.5.3, fate and behaviour in water	NL: An extra water/sediment study with application to the sediment is not considered necessary.	The pathway of environmental exposure will be spray drift or surface run-off. The requested study will not be according to general guidelines and will not represent the intended uses. It is therefore considered superfluous. TR-4 is not considered a major metabolite in sediment.

section 5 - Ecotoxicology (B.9)

5. Ecotoxicology (B.9)

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.9.1 Effects on birds	NL: - acute risk: For the acute risk assessment a small insectivorous bird (amongst others) has been chosen. But to estimate the ETE the RUD value for large insects has been taken. In the opinion of NL the RUD value for small insects (52) is the right value for the risk assessment for birds. This is also according to the Guidance Document on Risk Assessment for Birds and Mammals. However, it will not change the conclusion that there is a low risk for insectivorous birds. - short-term risk: Also here the RUD value for small insects (29) must be taken for the risk assessment for insectivorous birds. According to the Guidance Document the toxicity value and the exposure value have to be expressed in mg a.s./kg bw. - long-term risk: Also here the RUD value for small insects (29) must be taken for the risk assessment for insectivorous birds. According to the Guidance Document the toxicity value and the exposure value have to be expressed in mg a.s./kg bw.	

section 5 - Ecotoxicology (B.9)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca. 10 lines)	Column 3 Further explanations
(2)	Vol. 3, B.9.2 Effects on aquatic species	NL: Chronic risk assessment: There are two reproduction studies with two species of *Daphnia*. The 21-day NOECs from these two studies showed a large difference (NOEC-values of ≥ 50.7 μg as/L and 0.1 μg as/L). Is there an explanation for this difference? The chronic toxicity endpoint for fish has been changed from 0.3 to 25 μg/L in the refined chronic risk assessment. This is, according to the RMS, substantiated by the findings of an extensive field monitoring study. In this field study only run-off events occurred. Because trifluralin adsorbs fast to sediment there will not be much exposure of fish by the water phase. But when contamination of surface waters occurs through spray drift there will be exposure of fish by the water phase and effects can occur. NL agrees with the RMS that the exposure time will be short but sublethal effects can already be induced within a short period. Therefore NL has doubts if the endpoint should be changed from 0.3 to 25. To solve this point it is recommended to ask the notifier for a chronic water/sediment study with fish (static test) to mimic realistic conditions.	

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section 5 - Ecotoxicology (B.9)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca. 10 lines)	Column 3 Further explanations
(3)	Vol. 3, B.9.2 Effects on aquatic species	NL: Bioaccumulation It is stated that there is rapid elimination of trifluralin from fish tissues. This is not confirmed by the field monitoring study in which the half life of trifluralin in several fish species was determined to range from 15 – 30 days. However, from the risk assessment on birds and mammals it appeared that there is low risk to fish-eating birds and mammals using high BCF-values, so it can be concluded that the criteria for bioaccumulation are met.	
(4)	Vol. 3, B.9.3 Effects on other terrestrial vertebrates	NL: For assessing the short-term and long term risk the toxicity value and the exposure value have to be expressed in mg a.s./kg bw, according to the Guidance Document.	

section 5 - Ecotoxicology (B.9)

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.9.5 Effects on other arthropod species	NL: It is mentioned that the trigger for all the studies is 50%, according to ESCORT 2. But the 50% trigger is only valid for extended laboratory and (semi-)field tests. For first tier laboratory tests a trigger value of 30% is used. If there are LR50-values for *Aphidius rophalosiphi* and *Typhlodromus pyri* available a HQ-value can be calculated, but for trifluralin this is not the case. Using the trigger of 30% there is also a risk for *Phygadeuon trichops* (34.1%). However, this will not change the conclusions and NL can agree with the conclusion that there is a low risk for non-target arthropods, in-field as well as off-field.	
(6)	Vol. 3, B.9.6 Effects on earthworms	NL: Because the log Kow of trifluralin > 2, a correction factor of 2 for the organic matter content (from 10% to 5%) must be applied. The LD50 values will be divided by a factor of 2 and the TER-values will be two times lower. The conclusions of the acute risk assessment will not change, but regarding the chronic risk for earthworms it is not sure that the trigger of 5 will be exceeded (the TERlt $\geq$ 3), so a refined risk assessment or a new chronic study with a sufficient high concentration is necessary.	

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section 5 - Ecotoxicology (B.9)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca. 10 lines)	Column 3 Further explanations
(7)	Vol. 3, B.9.7.1 Organic matter breakdown	NL: it is concluded that in the litter bag test there was no evidence of any adverse effects on organic matter degradation arising from treatment with EF-1521, when applied at the maximum field rate of 2.5 L/ha (1200 g ai/ha). But also the toxic reference (methyl bromide) gave no adverse effects on the organic matter breakdown. Therefore the results of this study are questionable.	
(8)	Vol. 1, level 2	NL: The comments mentioned above regarding Volume 3, Annex B, are also relevant for volume 1, level 2.	
(9)	Endpoint list	NL: Effects on earthworms Toxicity values which are corrected for the organic matter content, must be mentioned in the list. The results of the litter bag test must be mentioned in the endpoint list.	

section 5 - Ecotoxicology (B.9)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca. 10 lines)	Column 3 Further explanations
(10)	Vol. 1, level 4: 4.9 Ecotoxicology	NL: - a refined risk assessment regarding the chronic risk to earthworms or a new sublethal toxicity study with earthworms with a sufficient high concentration is necessary.	

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

4. Environmental fate and behaviour (B.8)

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.8.1.1.1. Aerobic degradation.	DK. Vol. 3. B. 8.1.2.1b. Page 535. The DT_{50} values at 20^0C are estimated to be in the range from 95 – 418 days (Mean DT_{50} = 212 days.). B.8.1.2.1c. same page: the DT_{50} values at 10^0C are estimated to be in the range from 209 – 920 days (Mean DT_{50} = 466 days). According to Danish views such DT_{50} values are unacceptable.	DK. Vol. 3. B. 8.1.2.1b. Page 535. Overall conclusions:- Rate of aerobic degradation in soil at 20^0: The DT_{50} values at 20^0C are estimated to be in the range from 95 – 418 days (Mean DT_{50} = 212 days.). B.8.1.2.1c. same page: Overall conclusions – Rate of aerobic degradation at 10^0C. Based on the calculated DT_{50} values at 20^0C for trifluralin (DT_{50} = 95 – 418 days) and a Q_{10} factor of 2.2, the DT_{50} values at 10^0C are estimated to be in the range from 209 – 920 days (Mean DT_{50} = 466 days).
(2)	Vol. 3. B.8. 7. Fate and behaviour in air.	DK. Vol. 3. B. 8.1.7. Page 614. losses of trifluralin due to evaporation accounted for 41, 58 and 67 % AR after 24 hours. An evaporation of such a magnitude calls for further studies to determine the rate of wet/dry deposition down-wind in bordering zones to sprayed areas. The half-life of trifluralin in air is calculated to be 5.3 hours, which is quite sufficient to spread trifluralin to non-target areas at normal wind speed.	DK. Vol. 3. B. 8.1.7. Page 614. Overall conclusions:- Fate and behaviour in air. After spray application to soil surfaces, losses of trifluralin due to evaporation accounted for 41, 58 and 67 % AR after 24 hours in 3 replica tests with an application rate of 1200 g/ha. The resulting half-life of trifluralin in air was calculated to be 5.3 hours using AOP (version 1.90, Syracuse Research Corporation.)

5. Ecotoxicology (B.9)

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.9.2.1.acute toxicity to fish.	DK: The acute study-part of some of the chronic studies with the standard species of fish, done under static conditions, are not mentioned in the monograph under acute toxicity (B.9.2.1). **In these studies it is evident, that the lasting chronic damage, (spinal cord deformities,) besides mortality, takes place within 24 hours exposure or perhaps within four hours.** **So we suggest, that the acute $LC_{5024hours}$, besides mortality, also include spinal deformities, which in nature means certain death.** Therefore the $LC_{5024\ hours}$ for spinal deformities for *Salmo trutta* should be calculated.	DK: Volume 3. Page 696. In a study (from 1985) 15.4, % 59.3 % and 100 % of groups of around 75 brown trout (*Salmo trutta*) died after transfer to uncontaminated water for five months after a stay for 24 hours exposed to initial nominal concentrations of 25, 100 and 250 microgr. trifluralin/l, respectively. All fish exposed to 100 and 250 microgr. trifluralin/l "were prostrate or showed signs of swimming impairment after five hours of exposure. After 24 hours some fish exposed to these concentrations had dark dorso-ventral markings, which were suggested to be due to haemorrhage from spinal lesions" Percent trifluralin related column deformities were 3.2 %, 95,8 % and 100 %, respectively (see also below under chronic toxicity). **NOEC in this study for vertebral damage was 25 microgr./l, nominal.** **Half-life in the water was 6.5 – 8.7 hours in the test aquariums**. The acute $LC_{5024\ hours}$ is less than 100 microgr. Trifluralin/l for *Salmo trutta* in this study. This $LC_{5024\ hours}$ from a static test with *Salmo trutta* of less than 100 microgr./l compares well with the $LC_{5024\ hours}$ of 95,4 microgr. Trifluralin/l.from a 96 hour acute toxicity flow-though study with rainbow trout, *Oncorhynchus mykiss*. (Volume 3, B.9.2.1. page 667.) This demonstrates, that the effects from exposure to trifluralin take place within the half life of trifluralin in the water column.

section 5 – Ecotoxicology (B.9)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca. 10 lines)	Column 3 Further explanations
(2)	Vol. 3,B.9.2.2.Chronic toxicity to fish.	DK: The chronic end point of % spinal damage should be regarded as an acute end point in the risk assessment. (see above) and compared to the initial PEC	DK: On page 695 of volume 3 it is mentioned, that in *Pimephales promelas* **a concentration-dependant increase in spinal column compression was significant at a mean measured conc. of 0.7 microg. triflualin/l…** suggesting chronic damage under flow-though conditions in 35 days. The chronic NOEC was calculated to 0.3 microgr. trifluralin/l. It should also be mentioned here, that the max. value of trifluralin found in UK rivers in 1989 in the analysis of potentially dangerous substances was 0.226 microgr/l. **Max values of trifluralin in surface waters reported from Belgium, France, Greece and the UK are in the range of 0.2 – 0.7 microgr./l.**

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

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

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.2.1.1, melting point of pure as; Vol. 1, 4.2	DAS: A new study on melting point was completed 30 July 2003 using high purity (99.4%) analytical grade active substance (DAS Report FAPC033079).	This report is now available and will be submitted on request.
(2)	Vol. 3, B.2.2.17, shelf life of preparation Vol. 1, 4.2	DAS: The 2-year storage study will be completed in April 2004. DAR comments regarding "UK ambient temperature" and shelf-life specifications were forwarded to the study's Sponsor Monitor for incorporation into the final report.	
(3)	Vol. 3, B.2.2.17, shelf life of preparation Vol. 1, 4.2	DAS: Data on the content of impurity NDPA after 2 years of storage will be reported in a study which is separate from the ongoing 2-year storage study.	Retained samples that are two years old have been analyzed for NDPA. The levels of NDPA will be documented and a report will be submitted showing the levels. This report will be available in October 2003 and will be submitted on request.
(4)	Vol. 3, B.3.5.2, procedures for cleaning application equipment	DAS: A new justification that a study to demonstrate the effectiveness of cleaning procedures has been prepared and includes new text to replace the original text for this Annex Point in the Summary Dossier.	The main source of the information provided in the Summary Dossier was an internal Dow AgroSciences Manufacturing guideline on cleaning bulk tank and returnable mini-bulks. It is now recognised that the information required to fulfil this Annex Point needs to be directed at cleaning of sprayer equipment and not to those procedures which may be available to a manufacturing site. The new justification and text is provided electronically as "trifluralin cleaning effectiveness.doc" and accompanies the submission of this comments sheet.

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

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.3.5.4, recommended methods and precautions concerning handling, storage, transport or fire of preparation Vol. 1, 4.3	DAS: Information on transportation (Road & Rail, Sea, and Air) of EF-1521 was omitted from the Summary Dossier in error but is provided in Section 14 of the Safety Data Sheet for the preparation. Specific recommendation is given that sample shipment is not allowed by mail. A copy of the Safety Data Sheet was also omitted from the full Dossier in error.	A copy of the Safety Data Sheet is provided electronically as "safety data sheet.rtf" and accompanies the submission of this comments sheet.
(6)	Vol. 3, B.5.1.2, Analytical methods for the determination of isomers, impurities, and additives in the active substance as manufactured Vol. 1, 2.2.1 Vol. 1, 4.5	DAS: The report for determination of significant impurities in trifluralin technical stated the "limit of determination was 0.05% w/w", which was based on the lowest concentration used in the linearity test and is not equivalent to LOQ. LOQ has been determined based on peak area in linearity test to be 0.01% w/w for impurities A, B, C, and D, 0.02% for impurity E, and 0.03% for impurity F.	LOQ Calculation = [(SD/Mean)*10 (LOQ factor)] * [(1 µg/mL impurity standard)/(2000 µg/mL technical standard)]
(7)	Vol. 3, B.5.5.1, Evaluation and assessment of methods for formulation analysis Vol. 1, 2.2.2 Vol. 1, 4.5	DAS: A method for the representative preparation, EF-1521, has been validated and includes linearity as well as precision and accuracy data (Protocol No. DAS-AM-03-021).	This report will be available in October 2003 and will be submitted on request

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

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(8)	Vol. 3, B.5.5.1, Evaluation and assessment of methods for formulation analysis Vol. 1, 2.2.2 Vol. 1, 4.5	DAS: A method for determination of N-nitrosamines in the representative preparation, EF-1521, has been validated.	This report will be available in October 2003 and will be submitted on request.

section 2 - Mammalian toxicology (B.6)

2. Mammalian toxicology (B.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.6.4, Genotoxicity: Summary-Evaluation	DAS: p.230 An *in vivo* mouse bone marrow micronucleus assay with kinetochore staining is being conducted to a protocol agreed with the RMS.	This report is scheduled to be available by the end of October 2003 and will be submitted on request.
(2)	Vol. 3, B.6.5 Evaluation of the carcinogenic potential of trifluralin and possible relevance to human.	DAS: p277-284 Based on all of the points in our response to the RMS, we maintain that it would be inappropriate to consider trifluralin a possible human carcinogen and assign R40. This opinion is consistent with the decision taken the last time these same data were reviewed at Ispra, when no cancer classification was adopted.	For the benefit of other reviewers, the full text of our response to the RMS is provided electronically as "Trifluralin – Carcinogenicity comments to RMS.doc" and accompanies the submission of this comments sheet.
(3)	Vol. 3, B.6.8 Toxicity studies on metabolites	DAS: p.333-334 It is concluded that "The relevance of two plant metabolites, TR-22 and TR-28 which were identified in roots of mustard plants at <1% and 1.2% of the total radioactivity respectively and not in metabolism of mammals, should be addressed from a toxicological point of view." and that they "should be checked for their genotoxic potential, by performing at least three *in vitro* tests". We do not believe that this is justified.	For the benefit of other reviewers, the full text of our response to the RMS is provided electronically as "Trifluralin – Plant metabolites.doc" and accompanies the submission of this comments sheet.
(4)	Vol. 3, B.6	DAS: p.392 Table B.6.14.1-7: % of AOEL obtained with UK POEM model should be 'with the German model'	

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section 2 - Mammalian toxicology (B.6)

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.6.15 References relied on	DAS: p.406 The report IIA 5.2.1/03 was listed incorrectly in the Summary Dossier as 'N' for Data Protection Claimed. We now wish to claim data protection for this report.	
(6)	Vol. 3, B.6.15 References relied on	DAS: p.407 The report IIA 5.2.1/07 was listed incorrectly in the Summary Dossier as 'N' for Data Protection Claimed. We now wish to claim data protection for this report.	
(7)	Vol. 3, B.6.15 References relied on	DAS: p.407 The report IIA 5.2.1/08 was listed incorrectly in the Summary Dossier as 'N' for Data Protection Claimed. We now wish to claim data protection for this report.	
(8)	Vol. 3, B.6.15 References relied on	DAS: p.409 The report IIA 5.2.3/02 was listed incorrectly in the Summary Dossier as 'N' for Data Protection Claimed. We now wish to claim data protection for this report.	

section 3 - Residues (B.7)

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
(1)	Vol. 3, B.7.16.9, Proposed MRLs and Justification for the Acceptability of Those Residues	DAS: Page 497 under the section for treated plants it is stated that "no firm conclusion on residue definition for plants can be drawn." In all other sections in which the residue definition in plants is discussed (e.g., B.7.16.3.1), it is stated that "the residue definition for plants can be restricted to the parent compound trifluralin". Which is correct? We agree with the latter assessment.	Please see comments in section 2 on Mammalian toxicology (B.6.8) for a justification why these metabolites should be considered of no toxicological relevance. For the benefit of other reviewers, the full text of our response to the RMS is provided electronically as "Trifluralin – Plant metabolites.doc" and accompanies the submission of this comments sheet.
(2)	Vol. 3, B.7.16.9, Proposed MRLs and Justification for the Acceptability of Those Residues	DAS: Page 497 under the section for food of animal origin, the first sentence was incorrectly copied from a different document since it refers to acetamiprid instead of trifluralin. See section B.7.16.6 – Livestock Feeding Studies for an example of the proper phrasing for the first sentence.	

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

4. Environmental fate and behaviour (B.8)

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.8.1.2.1b, laboratory studies – aerobic degradation at 20ºC	DAS: By assuming a Q10 factor of 2.2, a DT_{50} of 212 days at 20ºC can be extrapolated from a mean DT_{50} of 181 days at 22ºC. However, the equation given by the RMS on p.535 appears incorrect as it does not give 212 days, but 207 days instead. Please check.	
(2)	Vol. 3, B.8.1.2.3, photolysis in soil	DAS: On p.538, the RMS concluded that the DT_{50} for soil photolysis was 44 days. However, this should be put into context by stating that the comparable DT_{50} for the dark control was 68 days. This then fits in with the conclusion that soil photolysis is not a significant route of degradation, as concluded under B.8.1.1.3 (p. 532).	
(3)	Vol. 3, B.8.2.2.3, lysimeter or field leaching studies	DAS: On p.572, the RMS should mention that an initial attempt has been made using modelling and estimated data to show that the PEC_{GW} for the anaerobic metabolite, TR-4, is <0.1 µg/L.	
(4)	Vol. 3, B.8.3, actual and time-weighted average PEC_S	DAS: On p.573, the RMS uses various field DT_{50} values to calculate the actual and time-weighted average PEC_S values. However, it is more usual to use laboratory data. In addition, a mean field DT_{50} of 170 days is used, when this should be 164 days according to the conclusions under B.8.1.2.2.1 on p.560. Please check.	

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

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.8.3, metabolites, initial PEC_S and actual and time-weighted average PEC_S	DAS: On p. 574, only initial PEC_S values have been provided for the anaerobic metabolite TR-4 because the initial value will provide the greatest soil exposure. This reasoning seems to have been accepted for the aquatic photoproducts TR-6 and TR-15 on p.604 (B.8.6.1), so why not for TR-4 ?	
(6)	Vol. 3, B.8.3, overall conclusions – predicted environmental concentrations in soil	DAS: The overall conclusions on p.575 should reflect the points mentioned under (4) and (5) above.	
(7)	Vol. 3, B.8.4.2, photochemical degradation	DAS: On p.588, the RMS concludes that the aquatic photoproducts TR-6 and TR-15 should be evaluated at MS level, presumably because the extent of aqueous photolysis varies under different MS conditions. Could this deference to MS assessment also not apply to the anaerobic soil metabolite TR-4, where anaerobic conditions will vary depending upon climate ?	
(8)	Vol. 3, B.8.4.2, quantum yield	DAS: On p.588, the RMS concludes that the assumptions made in the calculation of the quantum yield are reasonable. Therefore, it would be better to conclude, as under B.2.1.17, that the quantum yield is acceptable (rather than “not accurate”) but that it contains an uncertainty, although this does not affect the assessment that trifluralin is photolabile.	

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

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca. 10 lines)	Column 3 Further explanations
(9)	Vol. 3, B.8.5, impact on water treatment procedures	DAS: On p.600, the RMS states that no data are provided. However, this point has been addressed as described under Point IIIA, 9.2.2 of the Summary Dossier.	
(10)	Vol. 3, B.8.8, predicted environmental concentrations in air	DAS: On p.613, the RMS states that a PEC_{AIR} calculation is required. However, since no formal and agreed guidance at EU level is currently available on how to calculate this, and in the absence of a relevant risk assessment end-point, then a PEC_{AIR} value can not be provided at the present time.	
(11)	Vol. 3, B.8.10, definition of the residue	DAS: On p.623, the RMS should qualify the statement concerning the residue definition in soil so that TR-4 is mentioned only in case it cannot be excluded as relevant from the on-going ecotox studies ?	
(12)	Vol. 3, B.8.10, definition of the residue	DAS: On p.623, for surface water, since the PEC_{SW} for both the aquatic photoproducts TR-6 and TR-15 are <0.1 µg/L, then these should be excluded even at MS level ?	
(13)	Vol. 3, B.8.10, definition of the residue	DAS: On p.623, for sediment, TR-4 should also be qualified to say that it is included only until results of the on-going water/sediment study become available, when it will be reassessed ?	

section 5 - Ecotoxicology (B.9)

5. Ecotoxicology (B.9)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca. 10 lines)	Column 3 Further explanations
(1)	General	DAS: Inconsistent use of "µ" and "**microg**." throughout	
(2)	General	DAS: Suggest Tables are "linked" to avoid splitting across two pages	
(3)	Vol. 3, B.9.1.7, Risk to birds	DAS: More valid approach would be to use earthworm BCF to calculate residues in soil-dwelling insects as RUD values only really valid for direct overspray (e.g. foliar applications)	
(4)	Vol. 3, B.9.2.2/07, Chronic toxicity to Daphnia	DAS: NOEC is ≥ 50.7, since no effect was observed at the highest concentration tested. It is important to include the "≥" when the TER values are calculated as a TERlt of 5, for example at 1 m, indicates a defined risk. In fact the TERlt is **≥ 5**, i.e. an unacceptable risk has not been identified.	
(5)	Vol. 3, B.9.2.4/01-03, Effects on sediment-dwelling organisms	DAS: Suggest the Annex II references for these three studies given in parenthesis are changed to the Point for "sediment-dwelling organisms" (IIA.8.2.7) rather than "chronic toxicity to aquatic invertebrates" (IIA.8.2.5).	
(6)	Vol. 3, B.9.2.8, Refined aquatic risk assessment. Page 730	DAS: Suggest delete last sentence of second paragraph with reference to EQSs proposed by WRc to avoid possible confusion with EQSs agreed under Water Framework Directive	

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section 5 - Ecotoxicology (B.9)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca. 10 lines)	Column 3 Further explanations
(7)	Vol. 3, B.9.2.8, Effects on sediment-dwelling invertebrate species, Table B.9.2.8-07	DAS: NOEC is **m**g/kg and PEC is **µ**g/kg therefore TERs should be 1000-times higher i.e. 18,284 and 3,544	
(8)	Vol. 3, B.9.2.8, Effects on sediment-dwelling invertebrate species. Risk assessment	DAS: p.731 A study has now been conducted with the metabolite TR-4 according to OECD guideline 219. The data are currently being analysed but the indicated 28-day NOEC for *Chironomus riparius* is 0.831 mg TR-4/L, nominal (report in preparation). This demonstrates that the metabolite has lower toxicity than the parent. Therefore, there is no unacceptable risk from this metabolite.	This report will be available in October 2003 and can be submitted when requested.
(9)	Vol. 3, B.9.3.2, Risk to mammals	DAS: More valid approach would be to use earthworm BCF to calculate residues in soil-dwelling insects as RUD values only really valid for direct overspray (e.g. foliar applications)	
(10)	Vol. 3, B.9.3.2, Risk to mammals. Page 737, last paragraph	DAS: Delete part of sentence "…but it does not exceed…..…if NOAEC is 200 mg/kg". Contradicts first half of sentence.	
(11)	Vol. 3, B.9.6.4, Effects on earthworms. Risk assessment	DAS: A study has now been conducted with the metabolite TR-4 according to OECD guideline 207. The calculated 14-day LC50 for *Eisenia foetida* is 186 mg TR-4/kg dry soil (report in preparation). This produces a TER of 465 at a PEC_s of 0.192 mg/kg. Therefore, there is no unacceptable risk from this metabolite.	This report will be available in October 2003 and can be submitted when requested.

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section 5 - Ecotoxicology (B.9)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca. 10 lines)	Column 3 Further explanations
(12)	Vol. 3, B.9.8.2, Effects on soil micro-organisms. Risk assessment	DAS: A study has now been conducted with the metabolite TR-4 according to OECD guidelines 216 and 217. After 28 days exposure, no adverse effects were detected on nitrogen transformation (+4%) or respiration (-1.2%) at treatment rate of 2.0 mg TR-4/kg dry soil (report in preparation). Therefore, there is no unacceptable risk from this metabolite at ca. 10 times maximum PEC_s.	This report will be available in October 2003 and can be submitted when requested.