PEER REVIEW REPORT ON **PENOXSULAM** 18.04.2007

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00	Cover page	00 penoxsulam cover
01	**All comments received on the DAR**	**01 penoxsulam all comments.**
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Comments on the Draft Assessment Report on penoxsulam

RMS: IT

End of commenting period: 22.05.2005 (NOT, MS)

Date	Supplier	File
13.04.2005	DAS	Penoxsulam comments NOT 2005 04 13 doc
22.04.2005	Austria	Penoxsulam comments AT 2005 04 22 doc.
22.04.2005	The Netherlands	Penoxsulam comments NL 2005 04.22 doc
09.05.2005	Germany	Penoxsulam comments DE 2005.05.20 doc
20.04.2005	France	Penoxsulam comments FR 2005 04.20 doc
22.06.2005	EFSA	Penoxsulam comments EFSA 2005.06.22 doc

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

* 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.

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
	B.2.1.11 Spectra for impurities (pg.11) **B.2.1.16** Direct phototransformation of purified a.i. in water using artificial light under sterile conditions (pg.14) **B.2.2.12** Viscosity (pg.17) **B.2.2.16** Stability after storage for 14 days at 54°C (pg.18) **B.2.2.18** Minimum content after heat stability testing (pg.19) **B.2.2.24** Spontaneity of dispersion (pg.19) **B.2.2.26** Dry sieve/Wet sieve test and wet sieve test (pg.19) **B.2.2.30** Emulsifiability, emulsion stability and re-emulsifiability (pg.20) **B.2.2.33** Pourability (including rinsed residue) (pg.21) **B.2.2.35** Physical compatibility of tank mixes (pg.21) **B.2.2.36** Chemical compatibility of tank mixes (pg.21)	All listed points have no evaluation or conclusion (acceptable,unacceptable, etc.).	

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	**B.2.2.14.** Relative density (pg.18)	The value should be 0.934 g/**mL**, not g/L	

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)	No Comments		

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)	No Comments		

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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)	No Comments		

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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)	**B.9.2.9.4/1** Microcosm study – Lemna minor (pg.66)	This not GLP study has been superceded and could be eliminated from the report with the data from the new study reported into 9.2.9.3 ref. The table is corrupted. It prints out in a single column over a couple of pages.	

6. 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, LOE, Classification and proposed labelling with regard to physical / chemical data	AT: Statement is missing	
2	Vol. 1, LOE analytical method for impurities	AT: Principle of the method and LOQ for the relevant impurity Bis-CHYMP is not reported	
3	Vol. 1, LOE analytical method for residues in soil and water	AT: A detailed specification of the individual metabolites determined with this method should be listed	
4	Vol. 1, LOE analytical method for residues in body fluids and tissues	AT: As penoxsulam is not classified as a toxic or highly toxic compound no method for the determination of residues is relevant and this shall be mentioned	
5	Vol. 3, B.1.2.9 Specification of Purity	AT: Minimum purity of the active substance is missing in Volume 3 and also in Volume 4	
6	Vol. 3, B.2.1.13 Solubility in organic solvents	AT: Purity of the active substance is not reported	
7	Vol. 3, B.2.2.5 Oxidizing Properties	AT: The non acceptability of the used method is claimed by RMS but not mentioned in volume 1 level 4 as a data requirement. Therefore it should be stated here that the test has to be performed according EEC A21	

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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.2.2.20 Shelf life	AT: The data gap is stated by RMS however not noted in volume 1 level 4 as a data requirement	
9	Vol. 3, B.2.2.22 Persistent foaming	AT: according Guideline 7109/VI/94-Rev. 6. GLP compliance is not necessary	
10	Vol. 3, B.2.2.23 Suspensibility	AT: Result (value) is not reported; according Guideline 7109/VI/94-Rev. 6. GLP compliance is not necessary	
11	Vol. 3, B.5.3.1 Analytical Method for soil	AT: Specification of soil used for residue analytical method is not reported	
12	Vol. 4, C.1.1, Detailed information on the manufacturing process	AT: Purity of starting material is not reported	
13	Vol. 4, C 1.2 Identity of isomers, impurities and additives	AT: Specification of relevant impurities is missing	
14	Vol. 4, C.1.3, Detailed specification of the preparation ➔active ingredient	AT: Content of the *pure* active substance is missing in the formulation compositions	
15	Vol. 4, C.1.3, detailed specification of the preparation ➔formulants	AT: CAS numbers of several formulants should be reported in volume 4 (confidential data)	
16	Vol. 4, C.1.4 Validation data for impurities	AT: Validation data for the relevant impurity Bis-CHYMP are not reported	

7. 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.6.12 Dermal absorption	AT: When setting the dermal absorption rate of penoxsulam, the content of a.i. located in the skin was not regarded by the RMS as "absorbed". However, considering the continuous decrease of this depot with time accompanied by a continuous increase of amount detected in urine, faeces, carcass and cage wash, in particular for the spray dilution, the amount deposited in the skin should be considered as bioavailable. Therefore dermal absorption rates (based on the values after 24 hours) should be corrected to approx. 12 % for the concentrate and approx. 18 % for the spray dilution	According to the Guidance Document on Dermal Absorption (Sanco/222/2000 rev.6) the amount detected in the application site after washing should be not be included in the amount absorbed if sampling is done over a sufficiently long period of time (e.g. until serial non-detects in excreta). However, this circumstance has not been demonstrated in this study. In addition, no attempt was made to distinguish if the substance is located in the stratum corneum (with a possible decrease by exfoliation) or in the epidermis itself (with a retarded dermal absorption). Therefore, the total amount of penoxsulam deposited in the skin should be considered as bioavailable.

section 3 - Residues (B.7)

8. 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. #, <<data point>>, <<description>>	<<MS>>: <<comment>>	

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9. 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. #, <<data point>>, <<description>>	<<MS>>: <<comment>>	

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10. 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, Appendix 3, List of end points: Photolytic degradation	AT: Four major photoproducts were found in photolysis study: TPSA, BSA, 2-amino-TP, 5-OH-2-amino-TP. These metabolites were not mentioned in endpoint list. Additionally the photolytic degradation (e.g. DT50) of major metabolites have to be stated.	
(2)	Vol. 1, Appendix 3, List of end points: Route and degradation in water	AT: For the distribution in water/sediment system no relevant metabolites were mentioned. However major metabolites (5-OH-DE-638 and BSTCA) were found in water and sediment phase of water/sediment study and should be stated in endpoint list.	

11. 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, 1.2.3,	NL: IUPAC name is 3-(2,2-difluoroethoxy)-*N*-(5,8-dimethoxy[1,2,4]triazolo[1,5-*c*]pyrimidin-2-yl)-α,α,α-trifluorotoluene-2-sulfonamide	See also list of endpoints See also 3.1 See also B.1.2.4
(2)	Vol. 1, 1.2.6, molecular and structural formula, molecular mass	NL: Data is missing	
(3)	Vol. 1, 1.2.7, manufacturer of the active substance	NL: Reference is made to Annex C. The manufacturer of the active substance is however not considered as confidential information	
(4)	Vol. 1, 1.2.9, specification of purity	NL: Reference is made to Annex C . The purity of the technical active substance should however be mentioned here.	See also B.1.2.9
(5)	Vol. 1, 1.3.3, type of preparation and code	NL: Oil dispersion (not dispersable)	See also 1.4 See also B.1.3.5
(6)	Vol.1, 2.2.3, Methods for residue analysis	NL: For surface water, ground water and drinking water	
(7)	Vol. 1, List of end points, minimum purity of the active substance as manufactured (g/kg)	NL: Minimum purity 980 g/kg (not 980 g/kg ± 3% relative)	
(8)	Vol. 1, List of end points, UV/VIS absorption (max.) (if absorption > 290 nm state ε at wavelength)	NL: $ë_{max}$ should be λ_{max}.	

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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
(9)	Vol. 1, List of end points, Methods of analysis, impurities in technical as (principle of method)	NL: The analytical method for relevant impurity, bis-chymp should also be mentioned in the LOEP.	
(10)	Vol. 1, List of end points, Methods of analysis, Food/feed of plant origin (…)	NL: Matrices should be mentioned.	Rice
(11)	Vol. 1, Level IV	NL: -Oxidizing properties of the ppp properties should be determined according to method EEG A17(B.2.2.5) -2 year stability test in commercial packaging at ambient temperature should be submitted (B.2.2.20) -packaging resitance (B3.5.1.3) -several other studies for the ppp are evaluated as not acceptable or it is concluded that a GLP study should be submitted (see B.2.2)	
(12)	Vol. 3, B.2.1.2, boiling point	NL: decomposes before melting should be decomposes after melting or decomposes before boiling	
(13)	Vol. 3, B.2.2.17, stability after storage for other periods and temperatures	NL:….wet sieve, syneresis, sedimentation and…. To which studies is being referred?	

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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
(14)	Vol. 3, B.5.3.1, analytical method for soil	NL: source and type of soil should be mentioned	
(15)	Vol. 3, B.5.3.2	NL: It is not clear for which type(s) of water the validation results are obtained. Sampling site and characteristics of the surface water should be mentioned.	
(16)	Vol. 4, C1.1	NL: Purity of the raw materials should be mentioned	
(17)	Vol. 4, C.1.4.2, analytical method	NL: UV detection at 360 nm for BIS-CHYMP, doesn't correspond with §5.1.1 where UV-detection at 260 is mentioned.	

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12. Mammalian toxicology (B.6)

Classification and labelling (B.4), part mammalian toxicology
No comments.

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. 1, List of End Points, ADME	NL: In the box 'toxicologically significant compounds' it is stated: 'none'. This probably should be 'parent compound' or 'parent compound and metabolites'	
(2)	Vol. 1, List of End Points, Reproductive toxicity	NL: Reproductive NOAEL is 30 mg/kg bw/day. But this is the parental NOAEL. The reproductive NOAEL > 300 mg/kg bw/day.	
(3)	Vol. 1, List of End Points, Summary	NL: The drinking water limit can be removed from the list of end points.	
(4)	Vol. 3, B.6.10, Summary of mammalian tox, ARfD	NL: No ARfD was derived and NL agrees. However, the argumentation in the DAR is very limited, since the acute oral LD50 is just one of the criteria for the ARfD. Some further argumentation why the ARfD is not applicable would be appreciated.	
(5)	B.6.12, dermal absorption	NL: The presentation of the results is limited. Based on the 2 tables, it is not clear whether there are serial non-detects or not. However, exposure was worst-case (24 hours) and the values of 2%/24 hours for the undiluted formulation and 0.4%/24 hours for the diluted formulation are supported.	

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13. 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 1, level 3, end points	NL: TMDI = 0,0039% of standard European diet. TMDI = 0,022% as depicted in the end point list refers to the worst case Portuguese diet.	

14. 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.8.3.2, PECsoil off-crop	NL: the mean DT_{50},lab was used for calculation whereas the most conservative, i.e. the highest, value should have been used.	
(2)	Vol. 3, B.8.3.3, PECsoil metabolites	NL: the mean DT_{50},lab was used for calculation of the PEC for BSTCA whereas the most conservative, i.e. the highest, value should have been used.	
(3)	Vol. 3, B.8.5.3, PECsediment	NL: the equations used for the calculation of PECsed are different from the ones mentioned in SANCO/1090/2000. Why? Why is the calculation not according to this GD?	
(4)	Vol. 3, B.8.8.3, residue definition for surface water	NL: the residue definition for sediment is missing.	
(5)	Vol.3, B.8.8.4, residue definition for air.	NL: the residue definition for air should be the parent by default.	
(6)	Vol.1, level 2, 2.5.1, definition of the residue	NL: the residue definition for air should be the parent by default and the residue definition for sediment is missing.	
(7)	Vol.1, Annex 3, list of endpoints	NL: In the route of degradation box no metabolites are reported whereas the major metabolites should have been reported here.	
(8)	Vol.1, Annex 3, list of endpoints	NL: Route of degradation-supplemental studies: Reported is ‘no relevant metabolites’, whereas major metabolites should have been reported.	

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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
(9)	Vol.1, Annex 3, list of endpoints	NL: Soil adsorption tests were performed for 17 soils. In Vol.3 it is stated that the sediment is not used and data from non European soils are treated as supplementary information. However, all values all values are included in the endpointslist without any extra information. Also the average value is based on all data and this is not correct. Non-European soils and sediment should not be used for the assessment (average value).	
(10)	Vol.1, Annex 3, list of endpoints	NL: A column leaching study was evaluated and should be included in the list of endpoints as it was an acceptable study. An aged residue study and a lysimeter study were not submitted and are not required.	
(11)	Vol.1, Annex 3, list of endpoints	NL: photolytic degradation: information about the major metabolites must be included in the list of endpoints.	
(12)	Vol.1, Annex 3, list of endpoints	NL: degradation in water/sediment: major metabolites must be reported in the list of endpoints both for the water phase and for the sediment (5-OH). Now in the box relevant metabolites it is reported none, this is not correct.	
(13)	Vol.1, Annex 3, list of endpoints	NL: PEC sediment: it is stated that the method of calculation is according to the GD 1090/2000. This is not the case, different equations are used.	

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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
(14)	Vol.1, Annex 3, list of endpoints	NL: residue definition: the residue definition for sediment is missing. The residue definition for air should be parent by default.	

15. Ecotoxicology (B.9)

Classifacation and Labelling (B.4)
No comments

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, List of End Points, Effects on other arthropod species	NL: In the heading please replace “Effect” by “Adverse effect”. It should be clearly stated (e.g. in a footnote) that the “–“ sign means a positive effect on fecundity.	
(2)	Vol. 3, B.9.2.11, Effects in aquatic organisms; exposure, hazard and risk assessment	NL: On page 83 (Refined risk assessment for aquatic plants) the endpoint for aquatic plants was taken as the ErC50 from the microcosm study. According to the Guidance document on Aquatic Toxicology the endpoint in microcosm studies is taken as the NOEC. It should be considered whether in this particular study the NOEC should be the endpoint. Also, it should be better underpinned why the growth rate was chosen as the endpoint instead of the number of fronds.	The toxicity to aquatic plants is a critical issue of the ecotox part of the DAR and should be carefully considered.

16. 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. 1, 2.3.5 and Vol. 3, B.6.10, Drinking water limit	DE: Remark: Since according to EU rules and practice the drinking water limit for active compounds is set at 0.1 µg/l, it is not appropriate to derive a substance-specific maximum level that is higher by 2290 times.	
(2)	Vol. 1, 3.1, AOEL	DE: Proposal: It was noted that in the section "Background to the proposed decision" a long-term AOEL is proposed that is not mentioned in other parts of the DAR and that is not necessary – generally and in particular when the conditions of application for this a.i. are taken into consideration. Thus, this suggestion should be deleted.	
(3)	Vol. 3, B.6.5, Long-term toxicity and carcinogenicity, Oral study in rats	DE: Data requirement: Historical control data of the performing laboratory on large granular lymphocytic leukaemia in Fisher rats as well as the cited publications should be made available to all MS	In the long-term rat study, the incidence of large granular lymphocytic leukaemia was clearly increased in all treated male groups. The historical control range of the performing laboratory was exceeded. Although the explanation of the RMS for disregarding these findings appears plausible, this issue should be discussed on an EPCO meeting. In preparation of this meeting, the historical control values mentioned in the DAR as well as the cited publications should be made available to the MS.

section 5 - Ecotoxicology (B.9)

17. 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, Point 9.2.1-1, Acute toxicity to fish-rainbow trout	DE: The mean body length of the rainbow trout used in the test (2.9 cm) was not in accordance with OECD guideline 203 (5.0 ± 1.0) and EEC method C.1 (6.0 ± 2.0 cm). Although this deviation is not believed to have an impact on the result or the validity of the study, it should be mentioned in the summary.	
(2)	Vol. 3, Point 9.2.11, Summary of effects in aquatic organisms – Exposure, hazard and risk assessment	DE: For refinement of the risk assessment on aquatic plants a higher tier meso-/microcosm study is needed. The chronic 28-day study with *Lemna* is a single species test under semi-natural condition that cannot be considered as a higher tier meso/microcosm study. This study can only provide an appropriate endpoint for a refined assessment on effects on the tested species *Lemna* but not on the whole aquatic plant community. Therefore the risk assessment on aquatic plants has not be completed yet, and no safe use has been demonstrated so far.	

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, Point B.9.6.2, Effects on earthworms	DE: In table B.9.6.2/2 (TER-calculation for the risk assessment for earthworms) the corresponding reference (formulation or active substance) is wrongly indicated. In addition, the toxicity value is an LC_{50} and not an EC_{50} as stated in table B.9.6.2/2. However, these shortcomings do not change the outcome of the ERA.	
(4)	Vol. 3, Point B.9.10, Effects on biological methods of sewage treatment	DE: A valid study is reported here, indicating no risk of the test substance. However, this result is not mentioned at all in the list of endpoints.	For reasons of completeness, the results of the sewage sludge study should also be presented in Vol. I (incl. list of endpoints).

18. 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 2.1.3: " When PENOXSULAM is used in a rice field, growers will be encouraged to use in this paddy additional herbicides (if required) with modes of action other than ALS inhibition (either in tank mix or in sequential programs). When resistance to an ALS inhibitor is suspected or confirmed in a field, it is recommended not to apply PENOXSULAM alone, but only in a program which includes an herbicide with another mode of action (eg. triclopyr, bentazone, propanil, etc.…) to control the suspected resistant weed."	FR: such recommendations seem not to be relevant in the frame of the DAR for a particular active substance. We suggest to delete it.	
(2)	Vol 1, listing of endpoints, long term risk assessment to mammals. This comment also refers to volume 3, point B.9.3.	FR: a justification for not taking into account of the NOAEL of 25 mg as/kg bw/d in the rabbit 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
(3)	Volume 3, annex B. General comment	FR: the risk assessment is based on tractor application technology only, it does not cover aerial applications mentioned as possible treatment technology under volume 1, point 1.4.3: " DE-638 can be applied …through adapted aeroplanes for aerial applications in the regions where this practice is allowed". It should be stated clearly that this practice is not covered by the EU assessment.	

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
(4)	Volume 3, annex B, point B.9.2.11 table B.9.2.11/4, vascular plants Standard ErC50: 0.587 mg product/L (0.0126 mg a.s./L) and conclusions from risk assessment page 81: "The growth rate was selected as the endpoint for use in the refined risk assessment because this parameter measures the effect on the population and indicates the long-term potential for recovery of the population."	FR: the study also mentions an EC50 based on frond number, of 0.00499 mg a.s./L. This value was disregarded also in the first tier risk assessment. It is suggested that recovery is taken into account if available data indicate that recovery is expected in general. To our opinion, a general recovery may not be expected from the information on Lemna only (which potential from recovery is high compared to other vascular species. This potential for recovery should be discussed prior to be used into the risk assessment.	

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

19. 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, p. 39, list of end points, minimum purity	EFSA: The given value needs to be clarified. Provided that the value should be read as the declared content, the "real" minimum purity shuld be given.	
(2)	Vol. 1, p. 46, list of end points, summary of intended uses	EFSA: For transparency and better comprehensibility, instead of the "summary of intended uses", the list of representative uses evaluated, as mentioned in EPCO Manual E4, should be used.	
(3)	Vol. 1, p. 47, list of end points, analytical methods for the active substance	EFSA: RMS should consider to remove from the table confidential information such as used columns or internal standards.	
(4)	Vol. 3, p. 19 , Physical, chemical and technical properties of the plant protection product	EFSA: The indicated requirements for GLP studies are at least arguable. It seems that according to Guidance document 7109/VI/94 rev. 6 ,there is no need to conduct for example the studies on persistent foaming and suspensibility in compliance with GLP.	
(5)	Vol. 3, p. 23ff, References	EFSA: RMS to clarify why the references are given twice and in addition why the references related to volume 4 is listed here.	

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
(6)	Vol. 3, p. 125 Analytical method for air in relation to Vol.1, p. 51, list of end points, definition of the residues	EFSA: It should be noted that as long as no residue definition for air is proposed an assessment of the respective analytical method is not possible. Furthermore, the given justification for no setting a residue definition should possibly be reconsidered. The exposure of operators, workers or bystanders during application has not been taken into account.	
(7)	Vol. 4, General	EFSA: For transparency and better comprehensibility, RMS should reconsider the use of abbreviations and codes (e.g. in the list on p. 24 only the chemical names are given, but only codes in the table of the batch analysis. Both are mentioned only in the tables starting on page 25; in table on page 39 the used analytical methods are mentioned, but it seems that the respective code is only mentioned in the references relied on in volume 3).	
(8)	Vol. 4, p. 24, C.1.2 identity of isomers, impurities and additives in relation to p. 39 of Vol. 4	EFSA: Clarification is needed regarding the specified limit of the impurities, where a limit higher than 1 g/kg is proposed, because none of them is reliable taken the submitted batches into account. At least, it must be confirmed that a specified limit above the maximum value found in the batch analyses is acceptable in respect to the toxicological and ecotoxicological assessment.	

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section 2 - Mammalian toxicology (B.6)

20. 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.6.12, dermal absorption	EFSA: the 24h value of absorption for the diluted formulation is 0.04%. However it is not the same in the list of end points (0.4%). Please clarify.	
(2)	Vol.1, App.3, List of end points	EFSA: please amend the following : - reproductive toxicity : indicate the NOAELs for the parents, for the offspring and for the reproductive effects - please move the results of acute and chronic neurotoxicity studies in the box Neurotoxicity - exposure scenarios : add numerical values (% of systemic AOEL)	
(3)	Vol.3, B.6.15, List of information, tests and studies	EFSA: please amend the list of references according to the guidance document (i.a. including open literature in the table)	

section 3 - Residues (B.7)

21. 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 Plant metabolism-Rice	EFSA: Comparability of the metabolism study with the cGAP should be clarified. The possible consequences of a later application in practice on the qualitative and quantitative findings in the metabolism study should be discussed.	The application on the plants in the metabolism study was made at the 5- to 6-leaf stage, whereas cGAP foresees an application on BBCH 31 (Panicle initiation/formation)
(2)	Vol. 3, B.7.1-1 Plant metabolism-Rice	EFSA: Total storage time of samples until finalisation of analysis is not very clear from the study. A repeated analysis was done" several weeks" after the initial analysis to prove storage stability. It should be clarified whether storage stability tests are available to cover the whole time of the experiment when samples were stored prior to analysis.	
(3)	Vol. 3, B.7.1-1 Plant metabolism-Rice	EFSA: The meaning of the straw samples numbering TP-1/TP-2 and Ph-1/Ph2, respectively, in table B.7.1-2 should be explained. Are these replicates or samples originated from different application mode (0.1 kg ai/ha vs 2x0.05 kg ai/ha)?	
(4)	Vol. 3, B.7.1-1 Plant metabolism-Rice	EFSA: The decline of parent in straw seems evenly over time and comparable for both labels with the exception of Ph-labelled straw harvested 30 DTA, where residues are significant higher. Is there any explanation for this observation?	

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.7.2.1-1 Metabolism in goat	EFSA: The recoveries of radioactivity from goat metabolism should be clarified. It is stated in the DAR that >99% of recovered radioactivity was found in urine and faeces. Ca 6-11% and 7-15% of the daily dose have been recovered in urine and faeces, respectively. Thus the total recovery rate in the study seems rather low (max 26% of administered dose). Is there any reasonable explanation for this observation? A low recovery may also affect the validity of the study.	
(6)	Vol.3, B.7.2.1-2 Metabolism in hen	EFSA: It is stated in the findings that with exception of day 6 no detectable residues in eggs were found. However, this is in contradiction with the results displayed in the respective table 7.2.2-1 (all egg samples < LOD) and should be clarified.	
(7)	Vol.3, B.7.3 Residue definition	EFSA: This paragraph elucidates the proposed residue definition for monitoring and it's appropriateness for enforcement purposes. Do these definitions also apply for risk assessment purposes or which are the proposed definitions for RA?	
(8)	Vol.3, B.7.6 Residue trials	EFSA: For the reported results from residue trials it was distinguished between non-detects and values < 0.01 (LOQ). For the sake of clarity the limit of detection should be reported for these trials.	

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
(9)	Vol.3, B.7.6 Residue trials	EFSA: The comment concerns the parameters applicable to the analytical method employed in reside trials. For the linearity over concentration range the unit was reported as □g/ml and should be clarified.	
(10)	Vol.3, B.7.6.1 Storage stability	EFSA: It was concluded that residues are stable up to 197 days; however, further analysis after 24 month was scheduled. Do the current storage stability studies cover the storage time spent for the residue trials samples or what is the need for further investigations?	
(11)	Vol.3, B.7.8 Livestock feeding study	EFSA: The view of RMS whether or not rice straw is used as a feeding stuff isn't consistent throughout the DAR. On one hand it is considered as a feeding stuff (metabolism studies), on the other hand it's not. Clarification is needed.	
(12)	Vol.3, B.7.9.1 Rotational crops	EFSA: The table (referred to as table B.7.9-1) with the TRR values found in the confined rotational crop study in the different RAC is lacking. For the sake of transparency this data should be presented.	

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.7.9.1 Rotational crops	EFSA: Apparently two new metabolites (BST and BSTCA) were identified in the crop rotation study, which were not found in the primary metabolism. The structure of these metabolites displayed in figure B.7.9-6 seems to be identical, clarification is needed on their real structure. Are these metabolites up-taken from the soil? If they are metabolised from 5-OH-DE-638 as stated by RMS, why weren't they found in the primary metabolism?	
(14)	Vol.3, B.7.9.1 Rotational crops	EFSA: It is noted that the shortest pre-planting interval investigated is 90 days. EFSA supports the RMS proposal of a 90 days crop rotation restriction.	
(15)	Vol.3, B.7.13 Import tolerances	EFSA: Was there already an import tolerance for penoxsulam/rice requested as one was proposed in the DAR?	
(16)	Vol.3, B.7.15 Intake assessment	EFSA: The intake figures for Europeans are rather old. The most current version of GEMS/food (FAO/WHO) consumption data should be used for the assessment. However, the data used in the calculation do not consider the intake by toddler/young children as the most vulnerable group. Even it will not alter the conclusion, the consumer risk assessment should be updated and reflect the current agreed standard.	

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
(17)	Vol.3, B.7.15 Intake assessment	EFSA: It is noted that an exposure assessment via air is usually not part of the residue section. Also exposure via drinking water is normally not considered due to the European drinking water limit of 0.1 µg/L. An estimate for drinking water containing 229 µg/L penoxsulam as presented in the DAR doesn't correspond with the European standard and is rather confusing.	

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

22. 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. 1, 2.5.1, groundwater Vol. 3, B.8.2.5. PECgw metabolites	EFSA: Vol.1 p. 11. The groundwater values written for BSTCA (and possibly 5-OH) should be updated in light of clarifications requested below, (vol. 3 comment) Vol. 3 p. 52. There is a need for the rapporteur to clarify, or get the notifier to clarify the basis for the metabolite PECgw calculations. In particular EFSA cannot agree the use of the formation % proposed (19%) for the metabolite BSTCA. It is also not clear what paddy water DT50 was used to calculate $TWA_{pw,t(close)}$ for both 5-OH and BSTCA.	BSTCA. 19% formation is assumed in the calculation, this originates from the anaerobic soil study (total system). The justification for using this study for the parent compound and 5-OH is considered acceptable as the behaviour in this anaerobic study gives comparable (parent compound) or more precautionary (5-OH) levels and endpoints, than the aerobic paddy field study that is also available. However this is not the case for BSTCA. In the field study (more appropriate aerobic conditions), water concentrations of BSTCA were 3.2-19.8µg/L. Adjusting for the fact that an exaggerated dose rate was used in this study for the intended application rate (40g/ha), concentrations of 1.3-7.9µg/L are estimated. 7.9µg/L is a higher concentration than the 3.01µg/L, calculated for $PEC_{pw,initial}$ that used the 19% formation assumption. The difference between 3.01µg/L and 7.9µg/L would be sufficient to make the PECgw for BSTCA currently calculated at 0.06µg/L above 0.1µg/L. Therefore it appears it is necessary for the notifier to produce more refined PECgw estimates at least for the BSTCA metabolite, that take account of the amount of BSTCA formed in the available field studies. The current calculation includes $TWA_{pw,t(close)}$ for BSTCA. How was this calculated as there is no DT50 for BSTCA available from any pertinent study currently in the DAR. For the calculation of the 5-OH $TWA_{pw,t(close)}$ DT50 are available, but please could it be clarified which value was used with a justification for the selection of the value used. See also 21 below

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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
(2)	Vol. 1, Endpoints, route of degradation (aerobic) in soil, mineralisation after 100 days	EFSA: Add for phenyl and triazolopyrimidine ring radiolabels	
(3)	Vol. 1, Endpoints, route of degradation (aerobic) in soil, Non extractable residues after 100 days	EFSA: Add for phenyl and triazolopyrimidine ring radiolabels	
(4)	Vol. 1, Endpoints, route of degradation (aerobic) in soil, Relevant metabolites	EFSA: Add 5-OH (max 15-40%AR at 14-58 days) and BSTCA (max 29-53%AR at 14-120 days)	Although the final conclusion of the DAR is that these metabolites are not relevant, in terms of the peer review and the endpoints sheet it is necessary to include all breakdown products considered major (see guidance document on preparing endpoints)
(5)	Vol. 1, Endpoints, route of degradation in soil, Supplemental studies, anaerobic degradation	EFSA: Add for phenyl and triazolopyrimidine ring radiolabels and list the major metabolites: 5-OH (max 33%AR at 14 days) and BSTCA (max 19%AR at 120 days)	
(6)	Vol. 1, Endpoints, route of degradation in soil, Supplemental studies, soil photolysis	EFSA: Add for phenyl and triazolopyrimidine ring radiolabels and list the major metabolites: 2 amino-TP (max 10.4%AR at 37 days) and BSTCA (max 11.1%AR at 30 days) also add: moist soil first order DT50 19 days at 25°C summer sunlight at 40°N (r^2=0.9)	
(7)	Vol. 1, Endpoints, rate of degradation in soil, method of calculation	EFSA: Add that linear first order kinetics was for the parent compound and that non linear Modelmaker compartment modelling was used for the metabolites 5-OH and BSTCA.	

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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
(8)	Vol. 1, Endpoints, rate of degradation in soil, laboratory studies	EFSA: For parent aerobic the range needs correcting to 2**2**-58 days. For parent anaerobic please add the soil DT50 of 8.8 days. The DT50 for the major metabolites need adding (5-OH and BSTCA for aerobic studies and 5-OH for anaerobic studies).	
(9)	Vol. 1, Endpoints, rate of degradation in soil, Degradation in the saturated zone	EFSA: Please amend to: data not submitted, not required.	
(10)	Vol. 1, Endpoints, rate of degradation in soil, Field studies	EFSA: please clarify that the DT50/90 currently quoted are for rice paddy water and that DT50 in the underlying paddy soil was < 1 day.	
(11)	Vol. 1, Endpoints, rate of degradation in soil, soil accumulation and plateau concentration	EFSA: Please amend to: data not submitted, not required	
(12)	Vol. 1, Endpoints, soil adsorption/desorption Vol. 3, B.8.2.1 Batch sorption	EFSA: For parent penoxsulam in the endpoints and on p 26 vol. 3, Table B.8.1.2-2, the kf value for the Amagon soil would appear to be incorrect, (is not consistent with the mean Kd and Koc quoted for this soil). Please check and amend as appropriate. In the endpoints please add the 1/n value associated with each Kf quoted.	

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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
(13)	Vol. 1, Endpoints, soil adsorption/desorption	EFSA: Please add the Kd and Koc values for the major soil metabolites 5-OH and BSTCA and provide a statement that the adsorption behaviour of these metabolites appears to be pH independent.	
(14)	Vol. 1, Endpoints, Mobility in soil, column leaching	EFSA: Please add the endpoints from this study that is available and noted as acceptable in Vol.3 p29-30 .	
(15)	Vol. 1, Endpoints, Mobility in soil, aged residues leaching and Lysimeter/field leaching studies	EFSA: Please amend to: data not submitted, not required	
(16)	Vol. 1, Endpoints, PEC soil, method of calculation PEC soil for metabolites is required	EFSA: For parent please add to this box the assumptions used i.e.: No crop interception, Koc 94 L/kg, DT50 8.8 days (soil phase of anaerobic study worst case compare to the field study where the DT50 was <1 day). PEC should also be added for the 2 major soil metabolites (global max values calculated should be sufficient) Of course in the method of calculation box the assumptions used (formation %, Koc,) should be identified.	

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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
(17)	Vol. 1, Endpoints, Route and rate of degradation in water, photolytic degradation.	EFSA: Please list the major metabolites produced and their max formation % (TPSA, 2-amino-TP, 5-OH-2-amino-TP, BSA) Please tabulate the available DT50 for these photolytic metabolites.	
(18)	Vol. 1, Endpoints, Route and rate of degradation in water, Degradation in water/sediment.	EFSA: Please list the DT50 that are available for the 5-OH metabolite and distribution between water and sediment of the major metabolites (5-OH and BSTCA)	
(19)	Vol. 1, Endpoints, PEC surface water, method of calculation. PESsurface water for metabolites is also required	EFSA: For parent please add to this box the assumptions used i.e.: based on paddy water concentrations from field studies that were comparable to step 1c calculations that assumed , no crop interception, Koc 94 L/kg and DT50 6.6 days (anaerobic whole system value). PEC should also be added for the major water metabolites (5-OH, BSTCA, BSA, TPSA, 2-amino-TP, 5-OH-2-amino-TP, global max values calculated for each would be sufficient). Of course in the method of calculation box the assumptions used (step 1b, formation %, DT50, Koc,) should be identified.	

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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
(20)	Vol. 1, Endpoints, PEC sediment, method of calculation. PECsediment for metabolites, 5-OH, BSTCA, PCA-5-OH, BSTCA –OH is required.	EFSA: For parent please add to this box the assumptions used i.e.: based on paddy water concentrations from step 1b calculations that assumed , no crop interception, Koc 94 L/kg and DT50 23 days (aerobic whole system value). PECsediment for metabolites need including in the endpoints. In the DAR these were only reported in the ecotoxicology section (Section B.9.2.11 p. 86). Please transfer these to the fate and behaviour endpoints sheet and note that the % formation in the sediment water study for BSTCA in this ecotox section is incorrect (0.3%AR) so for BSTCA the PEC calculated should be corrected to account for slightly higher 2.2%AR present in the sediment of the sediment water study.	

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
(21)	Vol. 1, Endpoints, PEC groundwater, method of calculation.	EFSA: Please add to this box the assumptions used i.e.: step1 no crop interception, parent: Koc 94 L/kg and DT50 5.3 days (anaerobic water phase value, comparable to that seen in the water phase of the field study). 5-OH: formation 33%, DT50 needs clarification, possibly whole system value 5.1 days (anaerobic water phase value?, worst case compared to field study where water concentrations were not detectable, <3µg/L) and Koc 59 L/kg BSTCA: formation 19%, DT50 unknown, needs clarification (anaerobic water phase value. Note there is an issue with this, see point 1 above.) and Koc 174 L/kg	For 5-OH and particularly BSTCA see point 1 above.
(22)	Vol. 3, B.8.1.1.1, Aerobic studies	EFSA: On p 6 Table B.8.1.1.1-8, first order DT50 are tabulated for 3 soil metabolites, calculated with Modelmaker. For completeness it would be helpful if the kinetic formation fractions calculated by Modelmaker and the metabolic pathway define for the Modelmaker kinetic fitting could be outlined.	

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
(23)	Vol. 3, B.8.1.1.12 Anaerobic studies	EFSA: On p 12 Table B.8.1.1.2-5, first order DT50 are tabulated for the metabolite, 5-OH calculated using sequential first order kinetics. For completeness it would be helpful if the kinetic formation fraction calculated using Excel could be outlined.	
(24)	Vol. 3, B.8.1.2 Field studies	EFSA: On p 17-18, there is some key information about the field study design missing. Information on soil characteristics (soil texture, oc content, pH etc) needs to be provided. Please could the soil depth of the soil samples that were extracted to produce the results in tables B.8.1,2-1 and B.8.1.2-3 be clarified (top 5cm, all the soil core i.e. 30cm or something else?). What was the extraction method used for the soil samples? Please confirm procedural recoveries for the analysis were in the acceptable range.	
(25)	Vol. 3, B.8.4.4 Natural aquatic soil or sediment studies	EFSA: On p 47 Table B.8.4.4-3, first order DT50 are tabulated for the metabolite, 5-OH calculated using Modelmaker and first order kinetics. For completeness it would be helpful if the kinetic formation fraction calculated by Modelmaker was outlined.	

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
(26)	Vol. 3, B.8.10 References relied on	EFSA: There are no references cited from the notifier relating to the calculation of predicted environmental concentrations. Are all the PEC values presented in the DAR produced by the rapporteur or were reports from the notifier used as the basis for what was in the DAR. If information from the notifier was relied on, please add these references to the list.	

section 5 - Ecotoxicology (B.9)

23. 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.9.11 References relied on	EFSA: For the reference IIA 8.1.2/02 a “b” is missing after 2000	
(2)	Vol. 3, page 79	EFSA: The table 10.2-4a seems to have a wrong number. Please amend to Table B.9.2.11/5	
(3)	Vol. 3, B.9.2.11, page 83 Refined risk assessment for aquatic plants	EFSA: A justification for why the endpoint based on frond number was disregarded for the risk assessment is needed.	
(4)	Vol. 3, B.9.5 Effects on other arthropod species	EFSA: A study on a foliage dwelling species is lacking. Two crop relevant species in addition to the standard species are required.	
(5)	Vol.1, list of endpoints	EFSA: Please add a proposal for classification and labelling with regard to ecotoxicological data	
(6)	Vol. 1, List of endpoints, TERs for birds	EFSA: Since off-crop scenarios are covered by the rice-paddy scenarios, which all have TERs above the trigger, it is not necessary to include the off-crop values for standard species in the list of endpoints. It would be fine with a footnote that explains that the TER values have been calculated based on the sum of dietary and drinking water ETE A box with a short explanation on how the risk assessment for the metabolites were conducted would be useful. Then it is not necessary to present TER values for all scenarios for the metabolites.	

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. 1. List of endpoints, Toxicity/exposure ratio for aquatic organisms	EFSA: Annex VI triggers of 10 and 1 are indicated with a reference to SANCO/1090/2000. In the final report of June 2003 these triggers are not mentioned. The in-field risk assessment should be performed at MS level taking into consideration specific local conditions, agricultural practices and particular aspects of environmental protection. Hence for the in crop assessment no specific triggers should be indicated, rather it should be stated that this is to be considered at member state level taking into account the above mentioned local conditions.	
(8)	Vol.3 B.9.2.11, p. 86 Tables B.9.11/12 and 13	EFSA: Maximum mass % applied radioactivity for BSTCA in these tables should be 2.2.	