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Comments on the Draft Assessment Report on haloxyfop-p (EAS - Resubmission)

RMS DK

End of commenting period: 08.05.2009 (NOT, MS)

| Date | Supplier | File |
|------------|----------|---|
| 30.04.2009 | FR | 01 Haloxyfop-P comments FR 2009-04-29.doc |
| 05.05.2009 | UK | 02 Haloxyfop-P comments UK 2009-05-05.doc |
| 11.05.2009 | DE | 03 Haloxyfop-P comments DE 2009-05-08.doc |
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| 11.05.2009 | EFSA | 05 Haloxyfop-P comments EFSA 2009-05-11.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)

| Identity (B.1, Annex C) | | | |
|--------------------------------|---|--|---|
| No. | <u>Column 1</u> Reference to draft assessment report | <u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines) | <u>Column 3</u> Further explanations |
| 1(1) | Vol. 4 Batch analysis | FR : Could RMS precise how identity of impurities was confirmed in the analysis of 5-batches | |

Comments of France on the additional report on Haloxyfop-P

(29/04/09) 2/12

Section 2 - Mammalian toxicology (B.6)

2. Mammalian toxicology (B.6)

| Other toxicological studies & Medical data (B.6.8-B.6.9) | | | |
|---|---|--|---|
| No. | <u>Column 1</u> Reference to draft assessment report | <u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines) | <u>Column 3</u> Further explanations |
| 2(1) | Vol. 6.8.1, Toxicology studies of metabolites B.6.8.1.1 QSAR | FR : The table 6.8.1-1 “QSAR comparison of the pyridinol and pyridinone metabolites with haloxyfop-R” doesn’t show the TOPKAT or DEREK modelling of pyridinol. If pyridinol has the same structural alert as pyridinone, this should be specified. Besides, it would be useful to remind the chemical structure of the molecules. | |
| 2(2) | B.6.8.1.2 to B.6.9 | FR: The results of genotoxicity tests should be tabulated to be clearer. | |

Section 3 - Residues (B.7)

3. Residues (B.7)

No B7 section is presented in the additional report.

Comments of France on the additional report on Haloxyfop-P

(29/04/09) 4/12

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

4. Environmental fate and behaviour (B.8)

| Route and rate of degradation in soil (B.8.1) | | | |
|--|---|--|---|
| No. | <u>Column 1</u> Reference to draft assessment report | <u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines) | <u>Column 3</u> Further explanations |
| 4(1) | Vol.3, B8 (June 2008 & March 2009) Rate of degradation (lab & field) | FR: Globally, the kinetic analyses are very well explained. Could you just report the kinetic parameters (alpha and beta) for the DT50 calculated with a FOMC model (laboratory and field studies) both in the addenda of June 2008 and March 2009 please? | |
| 4(2) | Vol.3, B8 (June 2008) Field studies p.23 | FR: The Q10 value is not specified. It is expected it is 2.2, but could the RMS confirm this please? | |
| 4(3) | Vol.3, B8 (June 2008 & March 2009) Field studies | FR: We wonder why the last field study (Balluff, 2008) summarized in the addendum of June 2008 is not used to derive DT50 values. Did the notifier give an explanation for this? | |

| PEC in soil (B.8.3) | | | |
|----------------------------|---|---|---|
| No. | <u>Column 1</u> Reference to draft assessment report | <u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines) | <u>Column 3</u> Further explanations |
| 4(4) | Vol.3, B8 (June 2008 & March 2009) PECsoil | FR: As stated in the evaluation table rev 2-1 (19.06.2006), PECsoil and PECaccu have to be updated using the longest field DT50 and taking into account the type of kinetic in the calculation. | |

Comments of France on the additional report on Haloxyfop-P

(29/04/09) 5/12

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

| PEC in surface water and ground water (B.8.6) | | | |
|--|---|---|---|
| No. | <u>Column 1</u> Reference to draft assessment report | <u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines) | <u>Column 3</u> Further explanations |
| 4(5) | Vol.3, B8 (June 2008 & march 2009) PECgw | FR: Please, justify why some uses are not assessed (in particular carrots and fodder legumes). | |
| 4(6) | Vol.3, B8 (June 2008 & march 2009) PECgw | FR: The scheme of application used in the simulation for sugar beets and oilseed rape is not very clear. It is reported "each use was investigated as two consecutive annual applications in every three year period". Usually, this means that 2 applications are done on year 1, then there is no application on year 2 and 3. But this is not consistent with the GAP (1 application max). Please, could you give some more details on this point? Were the simulations performed with applications every three years in order to get lower PECgw? Does it correspond to the intended agronomic practice for all uses? (in the addendum of April 2005, the agronomic practice was reported to be 1 application every other year). Either the frequency of application really assessed should be mentioned in the GAP, or the scenario used to calculate PECgw should properly describe the intended uses. | |
| 4(7) | Vol.3, B8 (June 2008 & March 2009) PECgw p.33 | FR: On page 33 of the addendum of March 2009, it is reported that some adjustments were necessary in PEARL and PELMO to allow the models to run 2 applications every three years. These adjustments are not specified. Does it refer to the | |

Comments of France on the additional report on Haloxyfop-P

(29/04/09) 6/12

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

| PEC in surface water and ground water (B.8.6) | | | |
|--|---|--|---|
| No. | <u>Column 1</u> Reference to draft assessment report | <u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines) | <u>Column 3</u> Further explanations |
| | | <p>adjustments explained on p.44 of the addendum of June 2008?</p> <p>If it is the case, could you also specify the ratio which was used?</p> | |
| 4(8) | Vol.3, B8 (June 2008) PECgw p.48 | <p>FR: The RMS reports that no correction for moisture was done for the lab values, but as this correction would have shortened the DT50s, the un-normalised DT50s can be considered more conservative.</p> <p>We do not fully agree with this statement. We agree that it can be considered as more conservative for the parent. Nevertheless, when metabolites are also assessed, it is difficult to determine whether it will be more conservative or not. However in this case, it will not change the results of the risk assessment providing that the Tier 2 with the use of the field DT50 for the parent is accepted.</p> | |
| 4(9) | Vol.3, B8 (June 2008 & March 2009) PECgw | FR: We do not really understand why the DT90 _{FOMC} /3.32 values are not used for the parent when metabolites are included in the degradation scheme. As the FOMC kinetics give better fit for the parent, we would have used the SFO-back value. | |
| 4(10) | Vol.3, B8 (June 2008 & March 2009) PECgw | FR: All field studies were conducted in Northern Europe, whereas some uses are sustained for Southern Europe. Then, we are not convinced that these field DT50 values should be used for the Southern uses. At least an argumentation | |

Comments of France on the additional report on Haloxyfop-P

(29/04/09) 7/12

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

| PEC in surface water and ground water (B.8.6) | | | |
|--|---|--|---|
| No. | <u>Column 1</u> Reference to draft assessment report | <u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines) | <u>Column 3</u> Further explanations |
| | | explaining why the field DT50 are considered to be extrapolated to the Southern states should be provided by the notifier. | |
| 4(11) | Vol.3, B8 (March 2009) PECgw | FR: In the addendum of March 2009, field DT50 used for the PECgw calculation were normalised for temperature only. Then, we think that the routine for moisture correction should be disabled in the models. | |
| 4(12) | Vol.3, B8 (June 2008 & march 2009) PECgw | FR: In both addenda (June 2008 and March 2009), a default value of 0.9 for the Freundlich parameter $1/n$ is used. All the values of K_{oc} are K_{doc} values. It was agreed in PRAPeR that when only a K_d is determined, FOCUS modelling simulations should be carried out using a $1/n$ value of 1 (see General Report from PRAPeR 32). As this parameter is known to have a strong influence on the results and there is no safety margin for PECgw of some metabolites, we think the simulations should be updated. | |
| 4(13) | Vol.3, B8 (March 2009) PECgw | FR: We agree that the $1/n$ of 0.752 coming from the study of Woodburn & Richards (1988) cannot be used in the assessment as it was not submitted by the notifier and so could not be assessed by the RMS. | |
| 4(14) | Vol.3, B8 (June 2008 & March 2009) PECgw | FR: For the “ghost compartment”, a K_{oc} value of 30.8 mL/g was used, as it was the worst-case value from all components modelled. It is reported as a worst-case compared to the QSAR | |

Comments of France on the additional report on Haloxyfop-P

(29/04/09) 8/12

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

| PEC in surface water and ground water (B.8.6) | | | |
|--|---|--|---|
| No. | <u>Column 1</u> Reference to draft assessment report | <u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines) | <u>Column 3</u> Further explanations |
| | | <p>value of 1390 mg/L obtained for DE-535 methoxy pyridine, which is supposed to correspond to the ghost compartment.</p> <p>We are not convinced the use of a low Koc in the ghost compartment is a worst-case for DE-535 pyridinone. Indeed, according to the degradation scheme employed, we can think that with a high Koc, the substance will less leach, and so will be more available for its degradation in DE-535 pyridinone. Nevertheless, in this case, we think it can be acceptable as the formation fraction leading to the ghost compartment is only 0.073.</p> | |
| 4(15) | Vol.3, B8 (June 2008 & march 2009) PECgw | FR: It seems the FOCUS default value of 0.5 for the plant uptake factor was used for the parent and all its metabolites. The parent/DE-535 acid is known to be systemic. Nevertheless, it is assumed that no data is available for the other metabolites. Then, we would have used a plant uptake factor of 0 for these metabolites. | |
| 4(16) | LoEP (March 2009) PECgw | FR: Please, could you add in the LoEP the values of the Freundlich parameter 1/n used in the models? | |
| 4(17) | Vol.3, B8 (June 2008 & march 2009) PECsw | FR: We think all PECsw should have been updated using the FOCUS steps usually used. | |

Definition of the residues (B.8.9)

Comments of France on the additional report on Haloxyfop-P

(29/04/09) 9/12

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

| No. | <u>Column 1</u> Reference to draft assessment report | <u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines) | <u>Column 3</u> Further explanations |
|-------|--|--|---|
| 4(18) | Vol.3, B8 (June 2008 & March 2009) Residue definition | FR: We thought that all major metabolites, minor non-transient metabolites, metabolites which do not achieve their maximum at the end of the soil degradation studies and metabolites found in lysimeter studies at annual average concentrations exceeding 0.1 µg/l in the leachate had to be reported in the residue definition for groundwater. If it is the case, metabolite DE-535 phenol should be added to this definition. | |

Comments of France on the additional report on Haloxyfop-P

(29/04/09) 10/12

Section 5 - Ecotoxicology (B.9)

5. Ecotoxicology (B.9)

| Birds and mammals (B.9.1 and B.9.3) | | | |
|--|---|---|--|
| No. | <u>Column 1</u> Reference to draft assessment report | <u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines) | <u>Column 3</u> Further explanations |
| (5.1) | Vol. 3, B.9.1.8.1, Risks to birds from exposure via drinking water | FR: Exposure estimates in drinking water were calculated by dividing the spray concentration by a dilution factor of 5, according to the Guidance Document SANCO/4145/2000, point 4.4. A more recent approach for estimation of exposure via drinking water was recently proposed by the PPR Panel in its opinion on the science behind the Guidance Document on risk assessment for birds and mammals. Considering the scenario of birds drinking in puddles would result in more realistic TER values, although not changing the outcome of the risk assessment. | See the EFSA journal (2008) 734, 103-181 |
| (5.2) | Vol. 3, B.9.3.2.2, Risk to mammals from exposure via drinking water | FR: See point (5.1) regarding the risk to birds from exposure via drinking water | |
| (5.3) | Vol. 3, B.9.3.2. Refined chronic risk of haloxyfop-R to herbivorous mammals | FR: The crop-specific TERIt have been refined using published information on the diet and the crop use of a relevant focal species for the treated crops, the brown hare. The proposed PD values of 0.2 for sugar beets, field peas and field beans in spring, and of 0.4 for oilseed rape in autumn are consistent with other available published information on the brown hare. We agree with RMS that the long-term risk to herbivorous mammals is acceptable. | |
| (5.4) | Vol. 3, B.9.3.2 Risk | FR: We wonder if the long term risk to | The insectivorous mammal scenario is not a standard scenario for leafy |

Comments of France on the additional report on Haloxyfop-P

(29/04/09) 11/12

Section 5 - Ecotoxicology (B.9)

| Birds and mammals (B.9.1 and B.9.3) | | | |
|--|---|---|--|
| No. | <u>Column 1</u> Reference to draft assessment report | <u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines) | <u>Column 3</u> Further explanations |
| | assessment for mammals | insectivorous mammal has been sufficiently addressed. Indeed, in the table 9.3.2.1.2 of the DAR, a TER value of 5.7 was found in Tier 1, thought using the NOAEL of 2 mg a.s./kg bw/d. According to the EPCO expert meeting conclusions, the NOAEL of 1 mg a.s./kg bw/d should be used for risk assessment (with exception for autumnal applications on oilseed rape). This would lead to a TERlt < 5 for insectivorous mammals in Tier 1. Further refinement of the risk assessment for insectivorous mammals is needed. | crop according to the Guidance Document SANCO/4145/2000, because it is considered to be covered by the herbivorous scenario in Tier 1. However, as the Tier 1 calculation resulted in TERlt values < 5 for herbivorous, the insectivorous mammals can no more considered covered by herbivorous and the risk to insectivorous has to be addressed. The refinement step proposed for herbivorous mammals in the additional report is based on the use of information on a focal species. This can not apply for refinement of long term risk for insectivorous mammals. |

| Aquatic organisms (B.9.2) | | | |
|----------------------------------|--|--|---|
| No. | <u>Column 1</u> Reference to draft assessment report | <u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines) | <u>Column 3</u> Further explanations |
| (5.5) | Vol. 3, B.9.2.1.1, The ecotoxicological relevance of the aqueous photolysis metabolite DE-535 furan Vol. 3, B.9.2.1.3, Risk assessment to aquatic | FR: We agree with the conclusions of the RMS concerning the risk assessment for the metabolite DE-535 furan, which is based on more realistic PECsw obtained by FOCUS modelling. Referring to the French comment on PECsw in the e-fate section, the TER values for aquatic | |

Comments of France on the additional report on Haloxyfop-P

(29/04/09) 12/12

Section 5 - Ecotoxicology (B.9)

| Aquatic organisms (B.9.2) | | | |
|----------------------------------|---|--|---|
| No. | <u>Column 1</u> Reference to draft assessment report | <u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines) | <u>Column 3</u> Further explanations |
| | organisms | organisms should be re-calculated using PECsw obtained by Focus modelling. | |

| Earthworms and other soil non-target organisms (macro and micro) (B.9.6, B.9.7 and B.9.8) | | | |
|--|---|---|---|
| No. | <u>Column 1</u> Reference to draft assessment report | <u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines) | <u>Column 3</u> Further explanations |
| (5.6) | Vol. 3, B.9.6.5, Risk assessment for earthworms | FR: Referring to the French comment on PECsoil in the e-fate section, the TER should be re-calculated for the parent and the metabolites using updated PECsoil and PECaccu. | |

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

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

Section 2 - Mammalian toxicology (B.6)

7. Mammalian toxicology (B.6)

| Other toxicological studies & Medical data (B.6.8-B.6.9) | | | |
|---|---|--|--|
| No. | <u>Column 1</u> Reference to draft assessment report | <u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines) | <u>Column 3</u> Further explanations |
| (1) | Vol. 3, B.6.8.1, toxicology studies of metabolites | UK: The assessment of relevance of metabolites that are predicted to exceed 0.1µg/l does not appear to be complete. An overall summary and conclusion about this critical aspect of the evaluation would have been very helpful. | <p>By comparison with the scheme in the Groundwater Metabolites Guidance Document Sanco/221/2000 rev.10 (23rd Feb 2003):-</p> <p>For both metabolites biological activity (Stage 1 of Step 3) has not been fully addressed (eg only aquatic ecotox data on Chironomid larvae for the pyridinol metabolite, and although there was reference to an earlier non-peer reviewed assessment of pesticidal activity, there was no assessment in this addendum). They are not likely to be active since they are much smaller than haloxyfop so one can probably assume they are inactive. Both metabolites would also pass Stage 3 of Step 3 for toxicity screening by comparison with the active (but this is not actually stated in the documents).</p> <p>Pyridinone metabolite – for Stage 2 of Step 3 at least 3 in vitro genotox studies are required (if all negative). Only 1 study is available. There could be arguments over whether the pyridinone metabolite was fully tested as an impurity in the technical active substance (this has been discussed to some extent in the 1st review but only in the context of the technical specification and impurity profile). There could (possibly) be arguments made about structural similarity to the active. However – the RMS has not presented any arguments for this metabolite – they seem to have simply declared it ‘not relevant’ on the basis of one Ames test only. Data gaps appear to remain – at the very least this should be discussed further.</p> |

Comments of UK on the additional report on Haloxyfop P

(5/5/09) 3/6

Section 2 - Mammalian toxicology (B.6)

| Other toxicological studies & Medical data (B.6.8-B.6.9) | | | |
|---|---|--|---|
| No. | <u>Column 1</u> Reference to draft assessment report | <u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines) | <u>Column 3</u> Further explanations |
| | | | <p>Pyridinol metabolite – a full genotoxicity package is available. There is a positive Ames test but a negative in vivo UDS assay so an overall negative conclusion for genotoxicity is reasonable. Concluding this metabolite as non-relevant (assuming it is not biologically active as a herbicide) seems reasonable, providing Groundwater levels remain below 0.75ug/l.</p> <p>These are toxicology issues which apply whatever GW levels the metabolites achieve above 0.1ug/l .</p> |

Section 3 - Residues (B.7)

8. Residues (B.7)

No comments

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

9. Environmental fate and behaviour (B.8)

No comments

Section 5 - Ecotoxicology (B.9)

10. Ecotoxicology (B.9)

No comments

Comments of Germany on the additional report on haloxyfop-P

(08.05.2009) 1/5

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

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

| Methods of analysis (B.5) | | | |
|----------------------------------|---|---|---|
| No. | <u>Column 1</u> Reference to draft assessment report | <u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines) | <u>Column 3</u> Further explanations |
| (1) | List of End points, Appendix 1.4 and 1.5 | <p>DE: The LoEP of the EFSA Scientific Report (2006) 87, 1-96, Conclusion on the peer review of haloxyfop-P – Updated by RMS March 2009 after resubmission contains enantioselective residue definitions for plants and animals (Appendix 1.4, p.15) as well as for the environment (Appendix 1.5, p.40). Assuming that the mentioned LoEP is valid, no suitable methods were provided, because all provided analytical methods measure the sum of haloxyfop-P and haloxyfop-M, i.e. haloxyfop is determined.</p> <p>Therefore, this issue needs to be clarified before a decision on a possible inclusion of haloxyfop-P into Annex I.</p> | |
| (2) | List of End points, Appendix 1.2 | <p>DE: According to the summary of all analytical methods for residues (LoEP of the EFSA Scientific Report (2006) 87, 1-96, Conclusion on the peer review of haloxyfop-P – Updated by RMS March 2009 after resubmission, Appendix 1.2, table on p. 9/10) only methods for the sum of haloxyfop-P and haloxyfop-M (i.e. haloxyfop) and its metabolites were provided. These methods are not in compliance with the proposed enantioselective residue definitions and must be deleted from the table.</p> | |

Comments of Germany on the additional report on haloxyfop-P

(08.05.2009) 2/5

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

| Methods of analysis (B.5) | | | |
|----------------------------------|---|--|---|
| No. | <u>Column 1</u> Reference to draft assessment report | <u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines) | <u>Column 3</u> Further explanations |
| (3) | List of End points, Appendix 1.5 | <p>DE: The following metabolites and an ester are included in the respective residue definitions for soil, ground/drinking water or surface water, but methods for the analysis of these metabolites and the ester are missing and should be provided:</p> <p>soil: DE 535 pyridinone and DE 535 phenol, ground/drinking water: haloxyfop (P) - methyl ester, DE 535 pyridinone and DE 535 pyridinol, surface water: haloxyfop (P) - methyl ester, DE 535 pyridinol and DE-535-furan</p> | |
| (4) | List of End points, Appendix 1.4 and 1.5 | <p>DE: The residue definitions are changed as proposed below, because suitable analytical methods were provided for these analytes:</p> <p>plants: sum of haloxyfop, its conjugates and esters expressed as haloxyfop animals: sum of haloxyfop and its conjugates expressed as haloxyfop soil: haloxyfop, DE 535 pyridinol ground/drinking water: haloxyfop surface water: haloxyfop air: haloxyfop, haloxyfop-methylester</p> <p>Additional note for the residue definition for plants: According to the Pesticide Manual, 14th edition, haloxyfop, haloxyfop-etotyl, haloxyfop-</p> | |

Comments of Germany on the additional report on haloxyfop-P

(08.05.2009) 3/5

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

| Methods of analysis (B.5) | | | |
|----------------------------------|---|--|---|
| No. | <u>Column 1</u> Reference to draft assessment report | <u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines) | <u>Column 3</u> Further explanations |
| | | P and haloxyfop-P-methyl are in use; Additional note for the residue definition for soil: haloxyfop-methylester should be deleted due to the fast degradation ($DT_{90} < 3d$) in soil. | |

| Other comments | | | |
|-----------------------|---|---|---|
| No. | <u>Column 1</u> Reference to draft assessment report | <u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines) | <u>Column 3</u> Further explanations |
| (1) | DAR, General | DE: It is unclear why the RMS is still refereeing to haloxyfop-R. It was agreed that the ISO common name of this substance is haloxyfop-P (see also List of End points, Section 1). Furthermore, the COM has confirmed more than once that the ISO common name should be used, if available. | |

Comments of Germany on the additional report on haloxyfop-P

(08.05.2009) 4/5

Section 2 – Mammalian toxicology (B.6)

12. Mammalian toxicology (B.6)

| Other toxicological studies & Medical data (B.6.8-B.6.9) | | | |
|---|---|--|---|
| No. | <u>Column 1</u> Reference to draft assessment report | <u>Column 2</u> Comment * (restricted to 500 characters, ca.10 lines) | <u>Column 3</u> Further explanations |
| (1) | Vol. 3, B.6.8.1, Toxicity studies of metabolites | DE: The conclusion that the two metabolites DE535-pyridinol and DE-535-pyridinone are non relevant metabolites in groundwater is supported. The toxicity data for both metabolites are considered to be sufficient. A groundwater concentration of 0.75 ug/L should not be exceeded. | |

Section 5 – Ecotoxicology (B.9)

13. Ecotoxicology (B.9)

| Other non-target organisms (flora and fauna), sewage treatment (B.9.9 and B.9.10) | | | |
|--|--|--|---|
| No. | <u>Column 1</u> Reference to draft assessment report | <u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines) | <u>Column 3</u> Further explanations |
| (1) | Vol. 3, B.9.9, Risk assessment for non-target organisms (flora and fauna) | DE: The results of the newly provided studies (see B.9) according to the presented risk assessment did not show a risk except for plants. However, it is not clear why the application in weed (grasses) over 0.5 m height was assessed. To our understanding only early applications shortly after emergence of weed are common practise. A differentiation of height of weeds is not indicated in the list of intended uses. | |

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

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

NL did not consider this section.

Section 2 - Mammalian toxicology (B.6)

15. Mammalian toxicology (B.6)

NL did not consider this section.

Section 3 - Residues (B.7)

16. Residues (B.7)

No additional report on residues.

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

17. 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 | B.8.1.2.1 Laboratory studies - FOCUS kinetic modelling of degradation rates B.8.1.2.2 Field studies | NL: The conceptual model is not in agreement with the degradation scheme presented in the original DAR and on page 4 of the additional report. In the degradation scheme it can be seen that the degradation route is not linear as was assumed in the chosen conceptual model. DE-535 pyridinone is formed also directly from DE-535 acid. This last route is missing in the conceptual model. Further discussion amongst experts is considered required | |
| 2 | B.8.1.2.1 Laboratory studies - FOCUS kinetic modelling of degradation rates Table B8.1.2.1/03 (SFO) and 8.1.2.1/04 (FOMC) | NL: p values for the fits are missing, could these please be included | |
| 3 | B.8.1.2.1 Laboratory studies - FOCUS kinetic modelling of degradation rates B.8.1.2.2 Field studies | NL: Regarding the disapproval of the conceptual model the derivation of the degradation parameters is questionable. | |
| 4 | | NL: a DT50 for a plateauing metabolite can not be used in modelling due to the fact that no decline is observed and as a consequence no reliable value can be derived.. | |

Comments of the Netherlands on the additional report on haloxyfop-P

(08.05.09) 5/7

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 | B.8.1.2.1 Laboratory studies - FOCUS kinetic modelling of degradation rates | NL: it is stated on page 17 that ‘As ca. 75% of the decline was well described in the Marcham sandy loam soil the determinations for the metabolite in this soil are considered acceptable for use in modelling.’ Overall the degradation is underestimated by the predicted residues, resulting in a best-case situation for modelling. | |
| 6 | LoEP; field-DT50 parent | NL: in the LoEP it is stated that normalisation was only undertaken for temperature. However, the time step normalisation includes a moisture correction (f moisture in Tables B8.1.2.3/01 to 07). | |
| 7 | B.8.6 PREDICTED ENVIRONMENTAL CONCENTRATIONS IN SURFACE WATER AND IN GROUNDWATER (PECSW, PECGW) (ANNEX IIIA.9.2.1; ANNEX IIIA 9.2.3) | NL: Regarding the disapproval of the conceptual model and the fact that the ghost compartment is included in the simulation model, the derivation of the degradation parameters is questionable and therefore the modelling should be redone. | |

Comments of the Netherlands on the additional report on haloxyfop-P

(08.05.09) 6/7

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 | B.8.6 PREDICTED ENVIRONMENTAL CONCENTRATIONS IN GROUNDWATER PECCW) (ANNEX IIIA 9.2.3) | NL: Application in 2 out of 3 years is used in modelling. However this is not mentioned in the GAP-tabel, which should be the basis for the modelling. Moreover this is not common agricultural practice for oil seed rape. Is this restriction the result of the groundwater modelling? If so, a specific restriction on use should be included in the GAP table. | |
| 9 | B.8.6 PREDICTED ENVIRONMENTAL CONCENTRATIONS IN GROUNDWATER PECCW) (ANNEX IIIA 9.2.3) | NL: Why follow the route of complex FOCUS Degradation Kinetics modelling for PECgw metabolites when also non-relevance can be shown? | |
| 10 | LoEP; field-DT50 parent | NL: in the LoEP it is stated that normalisation was only undertaken for temperature. However, the time step normalisation includes a moisture correction (f moisture in Tables B8.1.2.3/01 to 07). | |
| 11 | LoEP | NL: The LoEP should be amended regarding the remarks mentioned above. | |

Section 5 - Ecotoxicology (B.9)

18. Ecotoxicology (B.9)

| No. | <u>Column 1</u> Reference to draft assessment report * | <u>Column 2</u> Comment * (restricted to 500 characters, ca. 10 lines) | <u>Column 3</u> Further explanations |
|-----|--|--|---|
| 1 | B.9.3 Refined risk assessment herbivorous mammal, proposed refinement of NOAEL | NL: <i>'For autumn applications, however, reproductive endpoints are not particularly relevant, as this timing coincides with the end of the breeding season for hares (i.e. September/October, KEMI, 2006).'</i> Is this true for all MS, even in S-EU? | |
| 2 | B.9.6.5 | NL: What is the Log Pow for the metabolites? Is correction not required? Note that if correction is necessary, the long-term TER for pyridinol could be < 5. | |
| 3 | B.9.9.2 | NL: The risk assessment for non-target plants is confusing. Only data for vegetative vigour is available. At least a statement for seedling emergence should be expected. Furthermore, it is not clear if exposure assessment with spray drift was taken into account. The exposure would be 104 g a.s./ha * 2.77% drift (< 50 cm) or * 8.02% drift, resulting in PECs of 2.88 g a.s./ha and 8.34 g a.s./ha. TERs would be 6.9 and 2.37. This should be the initial assessment. Additional bufferzones for crops >50 cm could be proposed. Please include TERs. | |

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)

| Identity (B.1, Annex C) | | | |
|--------------------------------|---|---|---|
| No. | <u>Column 1</u> Reference to draft assessment report | <u>Column 2</u> Comment * (restricted to 500 characters, ca.10 lines) | <u>Column 3</u> Further explanations |
| (1) | Vol 4, C.1.4.3, impurity methods | EFSA: The new method validation uses a different column and perhaps there are other differences. How does the new method compare to the one used to analyse the batch data. | |

| Methods of analysis (B.5) | | | |
|----------------------------------|---|--|---|
| No. | <u>Column 1</u> Reference to draft assessment report | <u>Column 2</u> Comment * (restricted to 500 characters, ca.10 lines) | <u>Column 3</u> Further explanations |
| (1) | Vol. 3, B.5, methods, plant, animal, soil and water | EFSA: Depending on the final residue definitions further data may be required. | |

Section 2 - Mammalian toxicology (B.6)

20. Mammalian toxicology (B.6)

| Other toxicological studies & Medical data (B.6.8-B.6.9) | | | |
|--|---|--|--|
| No. | Column 1 Reference to draft assessment report | Column 2 Comment * (restricted to 500 characters, ca.10 lines) | Column 3 Further explanations |
| | Vol. 3, B.6.8 Further toxicological studies. (Non-)Relevance of Groundwater metabolite DE-535-Pyridinol | <p>EFSA: Available toxicological information on DE-535-pyridinol is:</p> <ul style="list-style-type: none"> • QSAR modelling (including comparison to the parent active substance). • Acute oral toxicity study • Ames test • Gene mutation in CHO cells • In vivo/in vitro UDS test <p>Based on this data package, RMS concluded that the metabolite is non-relevant.</p> <p>It is noted that with regard to the tox relevance of this metabolite:</p> <ul style="list-style-type: none"> • Genotoxicity studies could cover the stage 2 of step 3 of the Sanco Guidance Document *(if the final outcome is negative, see comment below) • Since the parent active substance, which has been proposed to be classified only as Xi R22 and R41, acute oral toxicity and QSAR modelling could cover the stage 3 of step 3 *(if the final outcome is that the metabolite has not certain properties, which qualify for considered as not relevant, see comment below) | <p>* Sanco Guidance Document: Guidance Document on the assessment of the relevance of metabolites in groundwater of substances regulated under Council Directive 91/414/EEC. Sanco/221/2000-rev.10. 25 February 2003</p> |

Section 2 - Mammalian toxicology (B.6)

| Other toxicological studies & Medical data (B.6.8-B.6.9) | | | |
|---|---|--|--|
| No. | <u>Column 1</u> Reference to draft assessment report | <u>Column 2</u> Comment * (restricted to 500 characters, ca.10 lines) | <u>Column 3</u> Further explanations |
| | | <p>Based on the outcome of the discussion below the adequacy of the data package (enough number/type/quality of studies) in order to evaluate the relevance of this metabolite should be further discussed.</p> <p>Likewise the final outcome (relevance/non relevance) should be further discussed (see comments below).</p> | |
| | Vol. 3, B.6.8.1.1 QSAR modelling. DE-535-pyridinol | <p>EFSA: the applicability of QSAR models to the risk assessment of metabolites is currently under discussion (An activity is ongoing between the EFSA PPR panel and JRC)</p> <p>The outcome of the QSAR modelling applied to DE535-Pyridinol should be further discussed.</p> | |
| | Vol. 3, B.6.8.1.5 In vivo/in vitro UDS test. DE-535-pyridinol | <p>EFSA: A statistically significant increase in mean net nuclear grain counts (0.28) and in the percent of nuclei with five or more net grains (1%) at 300 mg/kg bw was observed (14-16 hour sampling time). Nevertheless, according to the evaluation criteria cited in the report this response was considered negative.</p> <p>In addition, according to the results, clinical signs of toxicity were observed at 300 mg/kg bw.</p> <p>EFSA has some concerns about the methods and results of this study:</p> <p>The first one is the selection of the highest dose level</p> | <p>According to the OCDE guideline 473 (1997) the highest dose is defined as the dose producing signs of toxicity such that higher dose levels, based on the same dosing regimen, would be expected to produce lethality.</p> <p>If the dose levels used in the UDS test are compared to the those used in the acute oral toxicity study (both performed in Fisher 344 rats), treated rats at dose level of 550 mg/kg bw (acute oral toxicity study, approximately 2 fold the highest dose level tested in the UDS test) did not show any mortality, sign of gross toxicity, adverse clinical signs, abnormal behavior or gross abnormalities during the 14-day observation period.</p> <p>*Kenelly et al, 1993. In vivo rat liver UDS assay (52-77) within the book Supplementary Mutagenicity Tests: UKEMS Recommended Procedures.</p> |

Section 2 - Mammalian toxicology (B.6)

| Other toxicological studies & Medical data (B.6.8-B.6.9) | | | |
|---|--|--|---|
| No. | <u>Column 1</u> Reference to draft assessment report | <u>Column 2</u> Comment * (restricted to 500 characters, ca.10 lines) | <u>Column 3</u> Further explanations |
| | | <p>tested: the highest dose level show clinical signs of toxicity. Could the RMS clarify the type/severity of the clinical signs?</p> <p>The second one is related to the evaluation criteria for a positive response. According to Kenelly et al, 1993*, the occurrence of a (N-C) value of zero or above in any treated animal should be taken as indicative of a UDS response. According to guidance OCDE 473 (1997) or B.39, within the examples of criteria for positive responses include: (i) NNG values above a pre-set threshold which is justified on the basis of laboratory historical data; or (ii) NNG values significantly greater than concurrent control.</p> <p>Could the RMS include the relevant laboratory historical data? In addition, and in order to evaluate in more detail the results it would be useful to have a summary table indicating the NNG, CG, NG for each treatment group and, the individual findings for each animal at the two dose levels tested.</p> | David J. Kirkland and Margaret Fox. Cambridge University Press. 1993. |
| | Vol. 3, B.6.8 Further toxicological studies. (Non-)Relevance of Groundwater metabolite DE-535-Pyridinone | <p>EFSA: Available toxicological information on DE-535-pyridinol is:</p> <ul style="list-style-type: none"> • QSAR modelling (including comparison to the parent active substance and metabolite DE-535-Pyridinol) | * Sanco Guidance Document: Guidance Document on the assessment of the relevance of metabolites in groundwater of substances regulated under Council Directive 91/414/EEC. Sanco/221/2000-rev.10. 25 February 2003 |

Section 2 - Mammalian toxicology (B.6)

| Other toxicological studies & Medical data (B.6.8-B.6.9) | | | |
|---|---|---|---|
| No. | <u>Column 1</u> Reference to draft assessment report | <u>Column 2</u> Comment * (restricted to 500 characters, ca.10 lines) | <u>Column 3</u> Further explanations |
| | | <ul style="list-style-type: none"> Ames test <p>Based on this data package, RMS concluded that the metabolite is non-relevant.</p> <p>It is noted that with regard to the tox relevance of this metabolite:</p> <ul style="list-style-type: none"> An Ames test does not cover the stage 2 of step 3 of the Sanco Guidance Document *. Since the parent active substance, which has been proposed to be classified only as Xi R22 and R41, QSAR modelling could cover the stage 3 of step 3 *(if the final outcome is that the metabolite has not certain properties, which qualify for considered as not relevant, see comment below) <p>Based on the outcome of the discussion below the adequacy of the data package (enough number/type/quality of studies) in order to evaluate the relevance of this metabolite should be further discussed.</p> <p>Likewise the final outcome (relevance/non relevance) should be further discussed (see comments below).</p> | |
| | Vol. 3, B.6.8.1.1 QSAR modelling. DE-535-pyridinone | EFSA: the applicability of QSAR models to the risk assessment of metabolites is currently under discussion (An activity is ongoing between the | |

Section 2 - Mammalian toxicology (B.6)

| Other toxicological studies & Medical data (B.6.8-B.6.9) | | | |
|---|---|---|---|
| No. | <u>Column 1</u> Reference to draft assessment report | <u>Column 2</u> Comment * (restricted to 500 characters, ca.10 lines) | <u>Column 3</u> Further explanations |
| | | EFSA PPR panel and JRC). The outcome of the QSAR modelling applied to DE535-Pyridinone should be further discussed. | |
| | Vol. 3, B.6.10. Overall conclusion. | EFSA: pending on the ground water exposure assessment conclusion by the fate colleagues further assessment could be needed. | |

Section 3 - Residues (B.7)

21. Residues (B.7)

| Storage Stability (B.7.0) | | | |
|----------------------------------|---|--|---|
| No. | <u>Column 1</u> Reference to draft assessment report | <u>Column 2</u> Comment * (restricted to 500 characters, ca.10 lines) | <u>Column 3</u> Further explanations |
| (1) | Vol. #, <<data point>>, <<description>> | <<MS/notifier>>: <<comment>> | |

| Metabolism in plants (B.7.1) | | | |
|-------------------------------------|---|--|---|
| No. | <u>Column 1</u> Reference to draft assessment report | <u>Column 2</u> Comment * (restricted to 500 characters, ca.10 lines) | <u>Column 3</u> Further explanations |
| (1) | Vol. 3, B.7.1 | EFSA: Is there meanwhile any information available with regard to the potential for isomeric conversion of haloxyfop-isomer residues on plant commodities? | |

| Metabolism in livestock (B.7.2) | | | |
|--|---|--|---|
| No. | <u>Column 1</u> Reference to draft assessment report | <u>Column 2</u> Comment * (restricted to 500 characters, ca.10 lines) | <u>Column 3</u> Further explanations |
| (1) | Vol. #, <<data point>>, <<description>> | <<MS/notifier>>: <<comment>> | |

| Residue definition (B.7.3) | | | |
|-----------------------------------|---|--|---|
| No. | <u>Column 1</u> Reference to draft assessment report | <u>Column 2</u> Comment * (restricted to 500 characters, ca.10 lines) | <u>Column 3</u> Further explanations |
| (1) | Vol. #, <<data point>>, <<description>> | <<MS/notifier>>: <<comment>> | |

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Section 3 - Residues (B.7)

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

| Use pattern, critical GAP, residues trials (B.7.4 to B.7.6) | | | |
|--|---|--|---|
| No. | <u>Column 1</u> Reference to draft assessment report | <u>Column 2</u> Comment * (restricted to 500 characters, ca.10 lines) | <u>Column 3</u> Further explanations |
| (1) | Vol. #, <<data point>>, <<description>> | <<MS/notifier>>: <<comment>> | |

| Processing (B.7.7) | | | |
|---------------------------|---|--|---|
| No. | <u>Column 1</u> Reference to draft assessment report | <u>Column 2</u> Comment * (restricted to 500 characters, ca.10 lines) | <u>Column 3</u> Further explanations |
| (1) | Vol. #, <<data point>>, <<description>> | <<MS/notifier>>: <<comment>> | |

| Livestock feeding (B.7.8) | | | |
|----------------------------------|---|--|---|
| No. | <u>Column 1</u> Reference to draft assessment report | <u>Column 2</u> Comment * (restricted to 500 characters, ca.10 lines) | <u>Column 3</u> Further explanations |
| (1) | Vol. #, <<data point>>, <<description>> | <<MS/notifier>>: <<comment>> | |

| Succeeding/Rotational crops (B.7.9) | | |
|--|--|--|
|--|--|--|

Comments of EFSA on the additional report on Haloxyfop-P

(11.05.2009) 9/18

Section 3 - Residues (B.7)

| No. | <u>Column 1</u> Reference to draft assessment report | <u>Column 2</u> Comment * (restricted to 500 characters, ca.10 lines) | <u>Column 3</u> Further explanations |
|-----|---|--|---|
| (1) | Vol. #, <<data point>>, <<description>> | <<MS/notifier>>: <<comment>> | |

MRLs related issues and Consumer Risk Assessment (B.7.10 to B.7.15)

| No. | <u>Column 1</u> Reference to draft assessment report | <u>Column 2</u> Comment * (restricted to 500 characters, ca.10 lines) | <u>Column 3</u> Further explanations |
|-----|--|---|---|
| (1) | Vol. 3, B.7.15 Estimates of potential and actual dietary exposure through diet and other means | EFSA: Pending clarification of their toxicological relevance, for scenarios where groundwater metabolites >0.75 µg/L (threshold of concern) were found a consumer exposure and risk assessment should be carried out. | |

Other comments

| No. | <u>Column 1</u> Reference to draft assessment report | <u>Column 2</u> Comment * (restricted to 500 characters, ca.10 lines) | <u>Column 3</u> Further explanations |
|-----|---|--|---|
| (1) | Vol. #, <<data point>>, <<description>> | <<MS/notifier>>: <<comment>> | |

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

22. Environmental fate and behaviour (B.8)

The comments are referred to the Additional Report, Annex I to Addendum (March 2009)

| Route and rate of degradation in soil (B.8.1) | | | |
|--|--|---|---|
| No. | <u>Column 1</u> Reference to draft assessment report | <u>Column 2</u> Comment * (restricted to 500 characters, ca.10 lines) | <u>Column 3</u> Further explanations |
| (1) | Appendix 1, LoEP, Rate of degradation in soil, laboratory data | EFSA: More information on the “ghost” compartment should be provided (i.e. the proposed chemical identification, the degradation rate and the assumed formation fraction). | |
| (2) | Vol. 3 B.8.1.2.1 Rate of degradation in soil, laboratory data | EFSA: For reason of transparency, it would be better to have the goodness of fit and plots for the residuals of the degradation model without “ghost compartment” to justify the degradation kinetic analysis provided. | |
| (3) | Vol. 3 B.8.1.2.1 Rate of degradation in soil, laboratory data | EFSA: It should be considered that DT50 values derived from the same soil with a different radiolabelled position should be averaged before deriving the definitive endpoint for modelling (i.e. geomean FOMC DT50 for parent should be 25.8 days). | |

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

| Route and rate of degradation in soil (B.8.1) | | | |
|--|--|--|---|
| No. | <u>Column 1</u> Reference to draft assessment report | <u>Column 2</u> Comment * (restricted to 500 characters, ca.10 lines) | <u>Column 3</u> Further explanations |
| (4) | Vol. 3 B.8.1.2.3 Rate of degradation in soil, field data | EFSA: It is the opinion of EFSA that as the simpler two step model used to derive field DT50s for the parent compound and DE-535 pyridinol provided an acceptable visual fits (with χ^2 % errors in the range 11.42-33.52), is unnecessary to perform a more complicated full kinetic scheme with a “ghost” compartment, resulting in χ^2 % errors in a very similar range (11.4-33.6). It is also questionable the use of the decline rates for the other two metabolites (which were not analysed in the field studies, DE 535 phenol and DE 535 pyridinone) were fixed within the model to the geometric mean SFO values determined in the laboratory data. | |

| Adsorption, desorption and mobility in soil (B.8.2) | | | |
|--|---|--|---|
| No. | <u>Column 1</u> Reference to draft assessment report | <u>Column 2</u> Comment * (restricted to 500 characters, ca.10 lines) | <u>Column 3</u> Further explanations |
| (1) | Vol. #, <<data point>>, <<description>> | <<MS/notifier>>: <<comment>> | |

| PEC in soil (B.8.3) | | | |
|----------------------------|---|--|---|
| No. | <u>Column 1</u> Reference to draft assessment report | <u>Column 2</u> Comment * (restricted to 500 characters, ca.10 lines) | <u>Column 3</u> Further explanations |
| (1) | Vol. #, <<data point>>, <<description>> | <<MS/notifier>>: <<comment>> | |

Comments of EFSA on the additional report on Haloxyfop-P

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

| PEC in soil (B.8.3) | | | |
|----------------------------|---|--|---|
| No. | <u>Column 1</u> Reference to draft assessment report | <u>Column 2</u> Comment * (restricted to 500 characters, ca.10 lines) | <u>Column 3</u> Further explanations |
| | <<description>> | | |

| Fate and behaviour in water and impact on water treatment procedures (B.8.4 – B.8.5) | | | |
|---|---|--|---|
| No. | <u>Column 1</u> Reference to draft assessment report | <u>Column 2</u> Comment * (restricted to 500 characters, ca.10 lines) | <u>Column 3</u> Further explanations |
| (1) | Vol. #, <<data point>>, <<description>> | <<MS/notifier>>: <<comment>> | |

| PEC in surface water and ground water (B.8.6) | | | |
|--|--|--|---|
| No. | <u>Column 1</u> Reference to draft assessment report | <u>Column 2</u> Comment * (restricted to 500 characters, ca.10 lines) | <u>Column 3</u> Further explanations |
| (5) | Vol. 3 B.8.6.1 PEC _{gw} , input parameters, p. 32, DT50 DE-535 acid Appendix 1, revised LoEP, PEC _{gw} (March 2009) | EFSA: It is not clear the origin of the FOMC DT _{50(field)} value of 30.9 days, as in Table B8.1.2.3/09 the reported geometric mean normalised to temperature alone is 30.2 days. | |

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

| PEC in surface water and ground water (B.8.6) | | | |
|--|--|---|---|
| No. | <u>Column 1</u> Reference to draft assessment report | <u>Column 2</u> Comment * (restricted to 500 characters, ca.10 lines) | <u>Column 3</u> Further explanations |
| (6) | Vol. 3 B.8.6.1 PECgw, input parameters, p. 32, DT50 DE-535 pyridinol Vol. 3 B.8.6.3 Summary of mobility in soil Appendix 1, revised LoEP, PECgw (March 2009) | EFSA: The EFSA agrees with RMS that the use of normalised field DT50s for DE-535 acid and DE-535 pyridinol in GW modelling is appropriate. However, for the metabolite DE-535 pyridinol the reliable field DT50 value (geometric mean normalised to temperature alone = 63 days) derived with the SFO model using the simple two-step model should be used in place of the value obtained with the full metabolic scheme where a “ghost” compartment has been introduced. | |
| (7) | Vol. 3 B.8.6.1 PECgw, input parameters, Freundlich exponent Appendix 1, revised LoEP, PECgw (March 2009) | EFSA: As already agreed in previous experts’ meetings in the environmental fate and behaviour where only K_{doc} is available a Freundlich exponent $1/n$ of 1 should be used in simulations. | |
| (8) | Vol. 3 B.8.6.1 PECgw Appendix 1, revised LoEP, PECgw (March 2009) | EFSA: The EFSA noted that, generally, the simulations performed with FOCUS PEARL resulted in PECgw values higher than those obtained with FOCUS PELMO, with the unique exception of the results for metabolite DE-535 pyridinone in the scenario with OSR. Is there any possible explanation for this deviation? | |

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

| PEC in surface water and ground water (B.8.6) | | | |
|--|---|---|---|
| No. | <u>Column 1</u> Reference to draft assessment report | <u>Column 2</u> Comment * (restricted to 500 characters, ca.10 lines) | <u>Column 3</u> Further explanations |
| (9) | Vol. 3 B.8.6.2 PEC _{sw} for DE-535 furan | EFSA: Specific data for the precursor DE-535 acid used in the FOCUS Steps 1-2 calculations should be provided. In addition, it is not clear to which crop the results presented in Table B.8.6.2.2 on p. 44 of Annex 1 to Addendum are referred to. Finally, while commenting the additional report for the re-assessment for Annex 1 inclusion of haloxyfop-P (haloxyfop-R), the EFSA noted that another metabolite with dibenzofuran “like” (not polychlorinated) structure was measured in the irradiated samples of the photodegradation study in natural water (i.e. DE-535-acid-furan at max. 8.4% AR at 4.8d, refer to table B.8.4.2/01-7, on p. 111 of the original DAR). An assessment of this metabolite should have been provided as well. | |
| (10) | Appendix 1, LoEP, PEC _{sw} for DE-535 furan | EFSA: The new PEC _{sw} calculations provided in Annex 1 to Addendum to Annex B8 Fate and Behaviour (March 2009) should be reported in the LoEP. | |
| (11) | Appendix 1, LoEP, PEC _{gw} | EFSA: For reason of transparency, also results for the ghost compartment as indicated in Table B.8.6.1/02 on p. 33 of the Annex 1 to Addendum, should be reported. | |

Fate and behaviour in air and PEC in air (B.8.7 – B.8.8)

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

| No. | <u>Column 1</u> Reference to draft assessment report | <u>Column 2</u> Comment * (restricted to 500 characters, ca.10 lines) | <u>Column 3</u> Further explanations |
|-----|---|--|---|
| (1) | Vol. #, <<data point>>, <<description>> | <<MS/notifier>>: <<comment>> | |

| Definition of the residues (B.8.9) | | | |
|---|---|--|---|
| No. | <u>Column 1</u> Reference to draft assessment report | <u>Column 2</u> Comment * (restricted to 500 characters, ca.10 lines) | <u>Column 3</u> Further explanations |
| (1) | Vol. #, <<data point>>, <<description>> | <<MS/notifier>>: <<comment>> | |

| Other comments | | | |
|-----------------------|---|--|---|
| No. | <u>Column 1</u> Reference to draft assessment report | <u>Column 2</u> Comment * (restricted to 500 characters, ca.10 lines) | <u>Column 3</u> Further explanations |
| (12) | | | |
| (1) | Vol. #, <<data point>>, <<description>> | <<MS/notifier>>: <<comment>> | |

Section 5 - Ecotoxicology (B.9)

23. Ecotoxicology (B.9)

| Birds and mammals (B.9.1 and B.9.3) | | | |
|--|---|--|---|
| No. | <u>Column 1</u> Reference to draft assessment report | <u>Column 2</u> Comment * (restricted to 500 characters, ca.10 lines) | <u>Column 3</u> Further explanations |
| (1) | B.9.1.8.1 Risks to birds from exposure via drinking water | EFSA (April /09): EFSA noted that RMS proposed to assess the risk to birds from the consumption of contaminated water the Guidance Document SANCO/4145/2000. However, EFSA consider usually are not necessary that the short-term risk assessment was done. | |
| (2) | B.9.3.2.1 Refined of the long-term risk for mammals. | EFSA agreed with the focal species selected (<i>Lepus europeans</i>) PD=0.2 for sugar beets, field peas and field beans in spring, and of 0.4 for oilseed proposed by the RMS for the refined of the long term risk for the small herbivorous mammals. However, taking into account the agreement of the experts at the EPCO 22 meeting on the use of NOAEL > 1 mg a.s. /Kg bw /day, as endpoint for the chronic risk assessment to mammals. EFSA has some concern to use a different value rather than this. | |

| Aquatic organisms (B.9.2) | | | |
|----------------------------------|---|---|---|
| No. | <u>Column 1</u> Reference to draft assessment report | <u>Column 2</u> Comment * (restricted to 500 characters, ca.10 lines) | <u>Column 3</u> Further explanations |
| (1) | B.9.2. Effects on aquatic organisms. Studies on | EFSA: RMS should clarify the units used to give the results of all the tests through the section. The | |

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Section 5 - Ecotoxicology (B.9)

| Aquatic organisms (B.9.2) | | | |
|----------------------------------|--|--|---|
| No. | <u>Column 1</u> Reference to draft assessment report | <u>Column 2</u> Comment * (restricted to 500 characters, ca.10 lines) | <u>Column 3</u> Further explanations |
| | toxicity of the phenol and pyrinone metabolite to aquatic organisms (page 5-35) | units appear as mg a.i./L or µg a.i/L instead of mg metabolite /L or µg metabolite /L. | |
| (1) | B.9.2.1.1 the ecotoxicological relevance of DE-535 Furan . | EFSA noted that not additional information was submitted to assess the ecotoxicological relevance of the DE-535 furan. | |

| Bees and non-target arthropods (B.9.4 and B.9.5) | | | |
|---|---|--|---|
| No. | <u>Column 1</u> Reference to draft assessment report | <u>Column 2</u> Comment * (restricted to 500 characters, ca.10 lines) | <u>Column 3</u> Further explanations |
| (1) | Vol. #, <<data point>>, <<description>> | <<MS/notifier>>: <<comment>> | |

| Earthworms and other soil non-target organisms (macro and micro) (B.9.6, B.9.7 and B.9.8) | | | |
|--|---|--|---|
| No. | <u>Column 1</u> Reference to draft assessment report | <u>Column 2</u> Comment * (restricted to 500 characters, ca.10 lines) | <u>Column 3</u> Further explanations |
| (1) | Vol. #, <<data point>>, <<description>> | <<MS/notifier>>: <<comment>> | |

| Other non-target organisms (flora and fauna), sewage treatment (B.9.9 and B.9.10) | | | |
|--|--|--|--|
|--|--|--|--|

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| No. | <u>Column 1</u> Reference to draft assessment report | <u>Column 2</u> Comment * (restricted to 500 characters, ca.10 lines) | <u>Column 3</u> Further explanations |
|-----|---|--|---|
| (1) | Vol. #, <<data point>>, <<description>> | <<MS/notifier>>: <<comment>> | |

| Other comments | | | |
|-----------------------|---|--|---|
| No. | <u>Column 1</u> Reference to draft assessment report | <u>Column 2</u> Comment * (restricted to 500 characters, ca.10 lines) | <u>Column 3</u> Further explanations |
| (1) | Vol. #, <<data point>>, <<description>> | <<MS/notifier>>: <<comment>> | |