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Comments on the Draft Assessment Report on cadusafos (EAS)

RMS EL

End of commenting period: 21 November 2009 (MS, NOT)

Date	Supplier	File
18.11.2008	UK	01 cadusafos comments UK 2008-11-18.doc
20.11.2008	NOT	02 cadusafos comments NOT 2008-11-20.doc
21.11.2008	NL	03 cadusafos comments NL 2008-11-21.doc
21.11.2008	DE	04 cadusafos comments DE 2008-11-21.doc
18.11.2008	EFSA	05 cadusafos comments EFSA 2008-11-18.doc
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25.11.2008	DE	07 cadusafos comments DE (ecotox) 2008-11-25.doc

section 2 - Mammalian toxicology (B.6)

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

No.	<u>Column 1</u> Reference to draft assessment report *	<u>Column 2</u> Comment * (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol 3, B1-B5	UK : The additional report to the DAR confirms additional data have ben submitted in respect of the data gaps identified for Physical/Chemical properties	

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section 2 - Mammalian toxicology (B.6)

2. Mammalian toxicology (B.6)

No.	<u>Column 1</u> Reference to draft assessment report *	<u>Column 2</u> Comment * (restricted to 500 characters, ca. 10 lines)	<u>Column 3</u> Further explanations
(1)	Vol 3, B6.3.3, Short term inhalational toxicity	UK : The case seems to rely on low acute inhalation toxicity of formulation and no risk identified for user, bystander or re-entry worker. UK had some concerns about how robust those estimates were. (see comment 3 below). In particular, exposure to volatilised pesticide has still not been accounted for. This may be important with respect to bystander and residential exposure, especially in light of the fact the cadusafos is 'moderately volatile'.	
(2)	Vol 3, B.6.8.1, Toxicity of metabolite hydroxy-2-butane sulfonic acid	UK : The hydroxybutane sulphonate should not have any cholinesterase activity so is unlikely to be of any toxicological significance. The reaction that produces it is simple hydrolysis consistent with the way parent reacts at the cholinesterase active site so it should be a significant metabolite in rat. There is therefore no obvious reason why it can't be excluded from the residue definition.	

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section 2 - Mammalian toxicology (B.6)

No.	<u>Column 1</u> Reference to draft assessment report *	<u>Column 2</u> Comment * (restricted to 500 characters, ca. 10 lines)	<u>Column 3</u> Further explanations
(3)	Vol 3, B.6.14, exposure data	UK : We remain concerned about the adequacy of the exposure estimates. Our specific concerns are listed in column 3.	<p>1. There has been no justification of the workrate of 1ha/day, which is critical in determining the amount of product required and, therefore, the number of mixing and loading operations.</p> <p>2. Existing exposure models are not really appropriate for the scenario presented and, although it is stated in the DAR that their use is conservative, as there are no pouring operations, there are genuine contamination concerns inherent with the use of dip legs etc. The tubes need to be removed from containers and it is possible that residues will be transferred from one container to another.</p> <p>3. The argument that only 1.12% of cadusaphos is free after 2 minutes in aqueous solution does not account for inhaled, or accidentally ingested active, where the capsules are likely to be in solution for much longer than 2 minutes!</p> <p>4. Accidental ingestion of small amounts of a compound with such a low AOEL was an issue which raised concerns. In the resubmission, a report of cholinesterase monitoring in a manufacturing plant was reported, which suggested that accidental ingestion might be unlikely. However, are the conditions of exposure the same. How do PPE and engineering controls compare?</p> <p>5. Exposure to volatilised pesticide has still not been accounted for. This may be important with respect to bystander and residential exposure, especially in light of the fact the cadusafos is 'moderately volatile'.</p>

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section 3 - Residues (B.7)

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 3, B.7.1.5, metabolism in tomatoes.	UK : Cadusaphos is an oxon OP so any changes to the structure are likely to reduce toxicity rather than increase it (i.e. it is like omethoate to start with rather than dimethoate) – therefore as time increases tox is likely to decrease. Thus in this case using a short PHI would be protective for toxicity versus a longer PHI. The study is therefore acceptable.	
(2)	Vol 3, B.7.3, residue definition	UK : based on assessment of lack of toxicological relevance of metabolite hydroxy-2-butane sulfonic acid, we agree the residue definition in plants should be parent only.	
(3)	Vol 3, B.7.6.2, residues from supervised trials	UK : Given that the intermediate harvest intervals also indicate residues < LOQ and application was at 2x GAP then we agree there are enough residues data to support an LOQ residues situation for parent.	

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

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. 3, B.8.6, Predicted environmental concentrations in groundwater, parent	UK : the approach taken for cadusafos appears acceptable and in line with the agreed EFSA endpoints. We would suggest that results based on the DT50 of 38 d are most appropriate (although this is a non-normalised field value which wouldn't normally be used, it is entirely consistent with the mean value from the normalised lab data set and therefore acceptable). See also comment 3 in environmental fate section.	

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

No.	<u>Column 1</u> Reference to draft assessment report *	<u>Column 2</u> Comment * (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(2)	Vol 3, B.8.6, Predicted environmental concentrations in groundwater, PCKOCWIN estimate for metabolite	UK : In general the view of the PRAPeR meetings has been that where it is technically feasible to perform a full batch sorption study (in accordance with OECD 106) this study should be performed. Only when such tests cannot be performed (e.g. due to rapid hydrolysis of the test compound) should alternative tests be employed. The Notifier has used the PCKOCWIN software to estimate sorption (i.e. Koc) of the methyl-2-butyl-sulfone metabolite only. For consistency with other substances that have passed through the system recently, we would suggest that a formal study would be needed and the impact of the results on the groundwater assessment will need to be reassessed when results are available. In addition, in the modelling the Notifier has used the peak amount of metabolite in place of a kinetically derived formation fraction. This will lead to some underestimation of the leaching risk and would need to be corrected when re-modelling is performed along side the measured Koc value.	The risk posed by the metabolite remains unresolved due to the absence of an acceptable Koc value. We would suggest that this requirement could be fulfilled within 2 years by running an OECD 106 study and re-running the groundwater modelling (if the study indicates greater mobility than the current PCKOCWIN estimate).

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

No.	<u>Column 1</u> Reference to draft assessment report *	<u>Column 2</u> Comment * (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(3)	Vol. 3, B.8.6, Predicted environmental concentrations in groundwater,	UK: When originally considered, a specific groundwater scenario was developed to represent Canary Islands soils and climates. Since the standard FOCUS scenarios were developed to be representative of large areas of the EU, they wouldn't necessarily be representative of the specific conditions on the Canary Islands. We would suggest that modelling with the specific Canary Islands scenario would be more appropriate than the current simulation in the re-submission based on standard scenarios. However we would also suggest that the experts from Spain would be better placed to comment on the acceptability of the groundwater assessment than UK.	

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section 5 - Ecotoxicology (B.9)

5. 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)	Vol 3, B.9.1.7, refined risk assessment for birds	UK : The assumptions made in refining the risk assessment should be discussed by the experts. The text suggests the TERs are not acceptable for long term exposure without yet further refinement. If concluded to be acceptable the conditions of use should be restricted to reflect the conditions assumed by the risk assessment eg use only in autumn and once every 3 years	
(2)	Vol 3, B.9.3.4.2, refined risk assessment for mammals	UK : The assumptions made in refining the risk assessment should be discussed by the experts. The text suggests the TERs are not acceptable for long term exposure without yet further refinement. If concluded to be acceptable the conditions of use should be restricted to reflect the conditions assumed by the risk assessment eg use only in autumn and once every 3 years	
(3)	Vol 3, B.9.5, non-target arthropods	UK : We note the requested Aleochara study was not submitted and a case made that concludes the in crop risk is acceptable. We also note that the requested data on collembola and mites have not been submitted. Expert discussion is required to confirm the current risk assessment	

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Comments of the applicant FMC on the additional report on Cadusafos

(20.11.08) 1/8

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)

No.	Column 1 Reference to additional report *	Column 2 Comment * (restricted to 500 characters, ca. 10 lines)	Column 3 Further explanations
(1)	Vol. 1, List of endpoints- Photostability	Applicant: Page 3: Photostability (DT ₅₀) ‡ (aqueous, sunlight, state pH): this part is missing in the List of endpoints. The values should be reported as they are in 'EFS4 Scientific Report (2006) 68, 1-70, Conclusion on the peer review of cadusafos Appendix 1 – list of endpoints'.	
(2)	Vol. 1, List of endpoints – <i>Summary of representative uses evaluated</i>	Applicant: Table page 5 : As the only representative use defended is <u>bananas</u> , the use on potatoes and any other reference to this use has to be deleted from this table. Note (1) Page 7: To be deleted according to our comment above.	
(3)	Vol. 3, B2.2.12 <i>Dynamic viscosity</i>	Applicant: The shear rate is proportional to the rotational speed when the same spindle is used. Therefore, the information that a spindle#2 was used at a rotation of 6 rpm replaces the shear rate information.	
(4)	Vol. 4, C1.1.1 <i>Manufacturer or active substance</i> <i>b. Location of Plant(s):</i>	Applicant: The actual address of the [REDACTED] plant is: [REDACTED] The address of the [REDACTED] is: [REDACTED]	

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

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Comments of the applicant FMC on the additional report on Cadusafos

(20.11.08) 5/8

Section 2 - Mammalian toxicology (B.6)

7. Mammalian toxicology (B.6)

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

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Section 3 - Residues (B.7)

8. 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. 1, List of endpoints- <i>Summary of critical residues data</i>	Applicant: Table page 19: As the only representative use defended is <u>bananas</u> , the residues information on potatoes has to be deleted from this table. Note (a): should be deleted because all residue levels < 0.01 mg/kg*.	
(2)	Vol. 1, List of endpoints- <i>Consumer risk assessment</i>	Applicant: Page 20: <u>TMDI</u> (European and national diets) & Acute Exposure: suggests either the parts related to potatoes to be deleted or at least strikethrough.	
(3)	Vol. 1, List of endpoints- <i>Consumer risk assessment</i>	Applicant: Page 20: Proposed MRLs: suggests either the potatoes MRL to be deleted or at least strikethrough, as this use was already withdrawn during the peer review (not supported by the applicant), additionally this use is still not defended in this re-submission.	

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Comments of the applicant FMC on the additional report on Cadusafos

(20.11.08) 7/8

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

9. 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. 1, List of endpoints- PEC soil-(Annex IIIA, point 9.3-Parent	Applicant: Page 24: Application rate: suggests either the parts related to potatoes to be deleted or at least strikethrough.	
(2)	Vol. 3, B8.6.2. Predicted Environmental Concentrations in Ground water	Applicant: Page 50: suggest to RMS to re-word the sentence “there is a <u>little</u> risk of groundwater contamination...” by “there is a <u>low</u> risk “ because the word “little” is confusing as the results show that the PECs for cadusafos and the metabolite methyl-2-butyl- sulfone do not exceed the trigger value in groundwater (0.1 *g/l) for 3 out of 4 PELMO scenarios one meter below the surface , at the recommended dose in bananas (4 kg ai/ha).	

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Comments of applicant FMC on the additional report on Cadusafos

(20.11.08) 8/8

Section 5 - Ecotoxicology (B.9)

10. 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)	Vol. 1, List of endpoints- <i>Toxicity/exposure ratios for the most sensitive aquatic organisms (Annex IIIA, point 10.2)</i>	Applicant: page 37: suggests that a note is inserted below the table indicating that the use on potatoes is not supported...	

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Comments of the Netherlands on the additional report on cadusafos

(21.11.08) 1/8

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)

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

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section 2 - Mammalian toxicology (B.6)

12. Mammalian toxicology (B.6)

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

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section 3 - Residues (B.7)

13. 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

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

14. 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. 1, List of endpoints	NL: Since bananas is the only intended use, risk assessment for potatoes should be removed from the list of endpoints.	
2	Vol. 1, List of endpoints	NL: The QSAR Koc derived for the metabolite should be included in the LoEP.	
3	Vol. 1, List of endpoints	NL: PEC _{sw} for potatoes should be removed from the LoEP.	
4	Vol. 1, List of endpoints	NL: the residue definition should be updated with regard to metabolite methyl-2-butyl	
5	Vol. 3, B.8.6 PEC _{gw}	NL: Calculations are performed with the PELMO model only. From the results it can be seen that there is a possibility for some leaching in vulnerable scenarios, though mostly below 0.1 µg/L. Because of this the calculations should have been done with a second model, preferably PEARL, as well.	

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

15. 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 endpoints	NL: Since bananas is the only intended use, risk assessment for potatoes should be removed from the list of endpoints.	
2.	Vol. 3, B.9.1.4 Additional data birds(and mammals)	NL: Martin&Lorenzo (2001) and Ludwigs & Wuebbenhorst (2000a/b) are not included in the reference list.	
3.	Vol. 3, B.9.1.7, Risk assessment insectivorous birds	NL: We think more arguments should be provided in the text on why the use of the PECsoil as insect RUD is justified and/or worst case.	
4.	Vol. 3, B.9.1.7, Refined risk assessment birds	NL: According to the table of intended use, application in bananas takes place in both spring and autumn, whilst in this section it is suggested that application is only in autumn. This should be clarified, and if spring application is also included, several lines of reasoning in the text have to be revised (e.g. on PD data).	
5.	Vol. 3, B.9.1.7, Focal species (Blackbird)	NL: The species field survey took place in april; it should be clearly substantiated whether this is also representative for autumn application.	
6.	Vol. 3, B.9.1.7, Refinement of PD	NL: For PD, it should be distinguished between spring an autumn values.	

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section 5 - Ecotoxicology (B.9)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca. 10 lines)	Column 3 Further explanations
7.	Vol. 3, B.9.1.7, Refinement of PT	NL: We find it questionable to assume a UK orchard radiotracking study representative for banana plantations on the Canary islands. Apart from the landscape structure, which we think will also be of influence contrary to what is stated by RMS, we think it very likely that (black)birds on these specific islands and in such a different climate will have different behaviour from (black)birds in the UK.	
8.	Vol. 3, B.9.1.7, Refinement of PT	NL: The use of the 50 th percentile of the PT should be substantiated with more arguments, based on data from the radiotracking study (e.g. number of caught animals, finding place, range etc.). However, if it is concluded that the UK study is not acceptable for this risk assessment, this point is redundant.	
9.	Vol. 3, B.9.1.7, Refined exposure assessment	NL: It should be substantiated why the residue on epigeaic arthropods is zero, since these arthropods can also come in contact with the a.s..	
10.	Vol. 3, B.9.3.4.3 refined risk assessment mammals	NL: Several of our remarks on the bird risk assessment also apply for the mammal r.a..	
11.	Vol. 3, B.9.3.4.3 Refinement of PT	NL: PT refinement should be based on experimental data and not on general assumptions. This was already stated by RMS in the addendum.	
12.	Vol. 3, B.9.3.4.3 Refined exposure assessment	NL: It seems a bit strange to assume a PD total of >1.	
13.	Vol. 3, B.9.3.4.3, Conclusion	NL: We don't understand the argument below table 15 on why a TER below 5 is acceptable.	('..not a concern since cadusafos is highly unlikely to remain at the surface for a significant period of time..').

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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
14	Vol. 3, B.9.3.4.3, Conclusion	NL: We don't agree that long term risk is based on repeated exposure only, a single exposure can cause reproductive effects as well.	
15	Vol. 3, B.9.5.1.1 Risk to non-target arthropods	NL: The information supplied here on the details of application and resulting exposure to the soil do not seem to have been considered for the PECsoil calculation.	PECsoil calculation simply assumes homogeneous distribution over top 5 cm.
16	Vol. 3, B.9.5.1.2 Toxicity data non-target arthropods	NL: For the study with <i>P. cupreus</i> in the list of endpoints it is not clear that it concerns aged residues.	
17	Vol. 1, List of endpoints earthworm field study	NL: The location (UK) and type of agrosystem (bare soil) should also be reported in the list of endpoints.	
18	Vol. 3 B.9.6.1.1 earthworm field study	NL: Preferably the results are presented numerically in tables.	
19	Vol. 3 B.9.6.1.1 earthworm field study, Relevance of UK study	NL: In the paragraph 'Arable plot comparison' we see no arguments that the UK plot should be comparable with a banana plantation on the Canary islands.	
20	Vol. 3 B.9.6.1.1 earthworm field study, Relevance of UK study	NL: Table 19: How can the Lumbricus species be 'typical in banana plantations' when there appear to be no data specific for banana plantations for these species (footnotes under the table)?	

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section 5 - 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
21	Vol. 3 B.9.6.1.1	NL: In the text it is stated that the species <i>Ocnerodrillus occidentalis</i> and <i>Amyntas morris</i> are found in abundance in both banana plantations and the UK field study. However, this does not appear in table 19. We see only 4 species that are found both in the UK site and in banana plantations. To us, Table 19 does not demonstrate clearly that the UK/Tenerife species composition are comparable.	

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Comments of Germany on the additional report on cadusafos

(21.11.2008) 1/3

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

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

No.	<u>Column 1</u> Reference to draft assessment report *	<u>Column 2</u> Comment * (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	General	DE: A couple of data gaps were identified by the RMS. Consequently, something like an updated level 4 of Volume 1 would be helpful for transparency reason and to facilitate the follow up of the next steps.	
(2)	Vol. 1, List of endpoints, Residue definitions	DE: A box for the residue definition in body fluids and tissues should be added.	Being aware that this would be a change of the harmonised template, EFSA agreed on the PRAPeR 56 meeting that this amendment can be accepted.
(3)	Vol. 1, List of endpoints, Analytical methods for residues	DE: Sampling condition and sampling time for the analytical method for cadusafos in air is missing and should be added.	
(4)	Vol. 4, C.1.2.3, Analytical profile of batches, Discussion on the new proposed specification	DE: Independent on the fact that it looks like that the proposed specification can be accepted as it is covered by the tox-tests, it should be noted that the quoted rule of thumb cannot be used as a strict criteria to accept a specification or not ("The upper certified limits have been altered in order to be in line with the recently produced five representative batches and to fit with the statistical "rule of thumb"). This rule is just a support for the assessment of the specification and nothing more. Furthermore, it seems to be questionable to argue with an existing EU specification as the substance was not included in Annex I.	

Comments of Germany on the additional report on cadusafos

(21.11.2008) 2/3

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

No.	<u>Column 1</u> Reference to draft assessment report *	<u>Column 2</u> Comment * (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(5)	Vol. 4, B.5.1.1, Table B.5.1.1-1	DE: Just to clarify the understanding of the given validation data, 5 samples of the TC were analysed and the results of one sample were identified as outlier. Is this understanding correct?	

section 2 – Mammalian toxicology (B.6)

17. Mammalian toxicology (B.6)

No.	<u>Column 1</u> Reference to draft assessment report *	<u>Column 2</u> Comment * (restricted to 500 characters, ca. 10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. 3, B.6.8.1, Toxicity studies of metabolites	DE: The plant metabolite hydroxyl-2-butane sulfonic acid that occurs in banana peel was found only at a low amount in rats. Toxicological data is not available but the RMS is believed to be right to assume that its toxicity will be lower than that of the parent compound because the organophosphate moiety is lacking. However, genotoxicity of this metabolite remains to be addressed.	
(2)	Vol. 1, Appendix I to Level 2, List of endpoints (October 2008 version), Fate and behaviour in the environment section	DE: It seems that groundwater concentrations of cadusafos or its metabolites have not been calculated. With regard to Annex IIIA, point 9.2.1, it is stated in the LEP that this data was required. For a compound of such a high acute toxicity, relatively low concentrations might be of toxicological concern and some knowledge is necessary before a decision can be taken.	It is stated in the LEP that no leaching was observed in Southern Europe and that surface water will not be contaminated but this latter statement is explicitly confined to the island Tenerife conditions. Is that sufficient to waive any groundwater considerations?
(3)	Vol. 1, Appendix I to Level 2, List of endpoints (October 2008 version), Impact on human and animal health section	DE: Acute dermal toxicity of cadusafos was tested in rabbits and not in rats as erroneously mentioned in the LEP. This error should be corrected.	

Comments of EFSA on the draft assessment report on cadusafos

(18.11.2008) 1/17

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

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

No.	Column 1	Column 2	Column 3
	Reference to draft assessment report *	Comment * (restricted to 500 characters, ca.10 lines)	Further explanations
(1)	Vol. 4, C.1.1.2. Method of manufacture p.1	EFSA agrees with the RMS on the necessity to provide the missing data on the starting materials	
(2)	Vol. 4, C.1.1.2. Method of manufacture p.1, Table 1, p.2	EFSA: taking into account the reference to the statement in the original Vol.4, p.11 about the purity of starting material [REDACTED] it is not clear why a specification still exists for impurity [REDACTED]	
(3)	Vol. 4, Table 1. New proposed technical specification p.2 and Table 2. Analytical profile of batches p.6	EFSA: if none of the impurities of the technical material are of toxicological relevance, it should be explained why there is a need to specify impurities [REDACTED] For impurities [REDACTED] supporting QC data would be necessary to justify their specification.	
(4)	Vol. 4, Table 1. New proposed technical specification p.2 and p.12-13	EFSA: there are some "typos" in the names of the substances, mainly s used instead of S	
(5)	Vol. 4, Table 3. Analytical profile of batches after addition of [REDACTED] p.7	EFSA has reservations on presenting 5 batch data for impurities based on calculations: even if the results for the a.s. content in the batches with [REDACTED] were within the repeatability value (r) of method ACG 120 based on the modified Horwitz eq. Were the data for the impurities derived assuming this r for the impurity determinations, too and on each individual batch or from the repeatability of each individual impurity from the method ACG 135?	

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Comments of EFSA on the draft assessment report on cadusafos

(18.11.2008) 2/17

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. 4, Batch data Table 2 p.6 and Table 3, p.7	EFSA: it seems that adding [REDACTED] to the technical material consistently causes lower values in the a.s. content determination. Is this addressed in the case of the formulation? Is the formulation overdosed to meet the specification? Clarification is needed	
(7)	Vol. 4, C.1.2.3 Analytical profile of batches p.5	EFSA agrees with the RMS in their conclusion about the specification of the impurities	
(8)	Vol. 4, B.5.1.2 Analytical methods for the impurities, additives p.12	EFSA: it is not clear how the [REDACTED] was measured in the 5 batch	
(9)	Vol. 1, LoEP, Flammability	EFSA: not highly flammable	

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section 2 – Mammalian toxicology (B.6)

19. Mammalian toxicology (B.6)

No.	<u>Column 1</u> Reference to draft assessment report *	<u>Column 2</u> Comment * (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Additional Report to DAR Vol.3, B.6.3.3, Short term toxicity by inhalation, p.21	<p>EFSA: The reasoning for waiving the short term inhalation study is rather convincing given the current restricted use (automatic drip irrigation, no hand held application, use of gloves during mixing/loading, work rate of only 1 ha/day).</p> <p>However further reassurance should be given with regard to the operator exposure to cadusafos released from the microcapsules. No information is available on the stability of the microcapsules during storage.</p> <p>It is noted that any change of the use of this product would lead to reconsideration of this data requirement for short term toxicity by inhalation.</p>	<p>It is also noted that</p> <ul style="list-style-type: none"> - even if the formulation is of low acute inhalation toxicity (LC₅₀ >3.87 mg/L air), no NOAEL could be derived and clinical signs of toxicity (including deaths) were observed during the first days post-exposure - cadusafos is very toxic by inhalation whereas it is toxic if swallowed (and ADI/AOEL are based on oral toxicity studies)

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section 2 – Mammalian toxicology (B.6)

No.	<u>Column 1</u> Reference to draft assessment report *	<u>Column 2</u> Comment * (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(2)	Additional Report to DAR Vol.3, B.6.8.2 Supplementary studies, p.23 and Additional Report to Vol.4, p.9	<p>EFSA: Based on the information mentioned in column 3, the following questions are raised:</p> <ul style="list-style-type: none"> - Has the toxicological relevance of the impurities been assessed (independently of their levels but in comparison with the active substance)? - Is there a difference between E3638-129-1 and E3628-129-1 or is it a typo error ? - Do you have any information on the levels of impurities in the batches E2445-148 and PL 03-0412 ? This would help to conclude on the equivalence of the technical specifications from the tox point of view. <p>A comparative table mentioning the purity and the levels of impurities in the proposed technical specification and the toxicological batches (as well as the studies related to) would be very helpful to conclude.</p>	<p>In the toxicological studies provided to demonstrate the toxicological equivalence of the old and new technical specifications, the batches used were E3638-129-1 (acute oral test and invalid Ames test) and E2445-148 (13-wk dog).</p> <p>In addendum 1, the batch E4549:117-2 is used in acute and 13-wk neurotox studies (these studies are used to justify a safety factor of 100 for the derivation of the reference values).</p> <p>In addendum 3, a supplementary Ames test with batch PL 03-0412 was evaluated, and a batch analysis was required by the RMS.</p> <p>In the original DAR (p.153), only the batch E3628-129-1 is mentioned as containing the new impurity 8 up to 3%.</p> <p>In the additional report to Vol.4, only the batch E2876:8 is referred to with regard to the levels of impurities.</p>

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section 3 – Residues (B.7)

20. Residues (B.7)

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

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

21. 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)	Annex B.8.6.2.1 predicted environmental concentrations in groundwater.	EFSA: A QSAR estimate for the adsorption of methyl-2-butyl sulfone has been provided, as the basis for groundwater modelling input. The use of a QSAR and not measured batch adsorption data adds additional uncertainty to the leaching estimate. With the low adsorption predicted for this compound measured batch adsorption values from 3 soils should have been provided for this minor but non transient metabolite.	
(2)	Annex B.8.6.2.1 predicted environmental concentrations in groundwater.	EFSA: In the available modelling what justification was given for using a 1/n value of 0.99 for methyl-2-butyl sulfone when only a QSAR estimation of adsorption was available. A 1/n value of 1 should probably have been used as input.	
(3)	Annex B.8.6.2.1 predicted environmental concentrations in groundwater.	EFSA: The formation fraction of methyl-2-butyl sulfone used as modelling input is a maximum observed value from a study. A kinetic formation fraction should have been estimated for this metabolite.	

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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
(4)	Annex B.8.6.2.1 predicted environmental concentrations in groundwater.	EFSA: The DT50 for methyl-2-butyl sulfone of 4.5 days used as modelling input is not an agreed EU endpoint. (It was not listed in the LoEP in the EFSA conclusion of April 2006). This is just an estimated value from a single soil noted in section 4.1.2 of the EFSA conclusion as an indicative value. It is unclear how this first order value was estimated. Is it a decline from the maximum observed or is it a true degradation value? For a minor non transient metabolite degradation DT50 values for 3 soils should be made available to derive the necessary value for input into groundwater modelling.	

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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
(5)	Annex B.8.6.2.1 predicted environmental concentrations in groundwater.	EFSA: Why for the simulations using the results from field trials was a value of 59 days selected when the agreed EU endpoint (as listed in the LoEP in the EFSA conclusion of April 2006) was a geomean (not normalised) DT50 from 4 trials of 50 days? Is the 59 days a normalised value to reference conditions (no normalisation presented in the additional report) or just the longest value from the available southern European trials (as only 3 DT50 are available if the result of the dutch trial is excluded). The additional report provides no justification for the selection of 59 days and does not explain how the simulations were carried out with regard to whether temperature and moisture routines were switched on or not for the simulation of the degradation of cadusafos?	
(6)	Annex B.8.6.2.1 predicted environmental concentrations in groundwater.	EFSA: What application date or range of application dates were simulated in the groundwater modelling? Did the dates selected cover the possible application period that is possible according the GAP table (i.e. spring and autumn).	

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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
(7)	Annex B.8.6.2.1 predicted environmental concentrations in groundwater.	EFSA: Groundwater simulations using PEARL in addition to PELMO are required and have not been presented (See EFSA PPR panel opinion on the FOCUS groundwater models comparability and the consistency of this riskassessment of ground water contamination(Question N° EFSA-Q-2004-58) The EFSA journal 2004 93 , 1-20 http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178620774670.htm)	
(8)	Vol. 1 Appendix 1 to Level 2 List of endpoints October 2008	EFSA: Why has the Lysimeter /field leaching study box entry been amended from the entry as listed in the LoEP in the EFSA conclusion of April 2006. This should not have been changed as no new information regarding this endpoint has been provided in the additional report.	
(9)	Vol. 1 Appendix 1 to Level 2 List of endpoints October 2008	EFSA: Why has an SFO DT50 of 61 days for parent cadusafos been used to calculate the updated PEC soil when the longest S European field dissipation study DT50 is 59 days and this was what was agreed for use in this calculation in the LoEP in the EFSA conclusion of April 2006. From where does this value originate. What is the explanation for this difference.	

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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
(10)	Vol. 1 Appendix 1 to Level 2 List of endpoints October 2008	EFSA: The list of endpoints under PEC groundwater still states ‘acceptable calculations not available. Data required’. Whilst EFSA has a number of questions about the new groundwater modelling and is unsure if the new simulations satisfy the outstanding issues regarding groundwater exposure that were identified in the original conclusion, information on new simulations has been included in the List of endpoints? Is the RMS conclusion ‘acceptable calculations not available. Data required’ or did you accept the new calculations?	
(11)	Vol. 1 Appendix 1 to Level 2 List of endpoints October 2008	EFSA: The list of endpoints under PEC groundwater does not indicate that the FOCUS simulations use the crop Citrus as a surrogate for the requested use on the crop bananas. This important information should be added.	
(12)	Vol. 1 Appendix 1 to Level 2 List of endpoints October 2008	EFSA: The list of endpoints under PEC groundwater and adsorption should be updated to include any clarification provided against EFSA comments 1 to 7 above.	

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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
(13)	Vol. 1 Appendix 1 to Level 2 List of endpoints October 2008	EFSA: The list of endpoints under definition of the residue relevant for the environment still states ‘For groundwater further data on methyl-2-butyl sulfone is required before the residue definition can be concluded’. Whilst EFSA has a number of questions about the new groundwater modelling and is unsure if the new simulations satisfy the outstanding issues regarding groundwater exposure for methyl-2-butyl sulfone that were identified in the original conclusion, new information was provided? Is the RMS conclusion ‘For groundwater further data on methyl-2-butyl sulfone is required before the residue definition can be concluded’ or did you accept the new information addressed the original concerns?	

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section 5 – Ecotoxicology (B.9)

22. Ecotoxicology (B.9)

No.	<u>Column 1</u> Reference to draft assessment report *	<u>Column 2</u> Comment * (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. 3, B. 9.1 Effects on birds	EFSA: The choice of focal species in the refined risk assessment was based on a literature review. However the key studies on which the literature review was based on were not submitted. On the basis of the provided information it is not possible to judge whether the choice of focal species is sufficiently supported by the studies cited in the literature review.	
(2)	Vol. 3, B. 9.1 Effects on birds	EFSA: The residue data in earthworms were refined using measured residues in earthworms. It is unclear how these residue data were obtained. No summary of the residue study was provided and no study report on the earthworm residue study was submitted. Therefore the suggested residue value of 0.5 mg/kg worm cannot be accepted. It is suggested to calculate the residues in earthworms according to the formula in SANCO 4145 (risk assessment for secondary poisoning of earthworm eating birds).	

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section 5 – 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
(3)	Vol. 3, B. 9.1 Effects on birds	EFSA: A mean value of the percentage of earthworms and epigaic, and endogaeic arthropods was used to derive PD values. The relevance of the observed food composition in the different studies in relation to banana plantation is uncertain. In table 7 it is stated that in one of the studies the habitat is unknown and in another one it is stated that various habitats were investigated. Further it needs to be clarified if the percentage of food is in terms of weight or in terms of numbers of food items. The studies on the food composition of blackbirds were not provided and not summarized in the additional report.	
(4)	Vol. 3, B. 9.1 Effects on birds	EFSA: It was assumed that the residues in (endogaeic) soil dwelling arthropods would be equal to the soil concentration. However it may happen that the residues accumulate in insects since the logPow is >3.	
(5)	Vol. 3, B. 9.1 Effects on birds	EFSA: It was assumed that the epigaic arthropods carry no residues. However soil surface dwelling insects are in contact with contaminated soil and hence it is likely that they also carry residues.	

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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
(6)	Vol. 3, B.9.3 Effects on other terrestrial vertebrates	EFSA: The choice of focal species to refine the mammal risk assessment is based on general considerations but not on data of occurrence/feeding in banana plantations. The Algerian hedgehog (<i>Ateleris algrius</i>) was proposed as a focal species. However it was stated in the text that the Osorio shrew (<i>Crocidura Osorio</i>) also inhabits banana plantations. The risk to Osorio shrew would probably not be covered by the risk assessment for Algerian hedgehog since the shrew is a much smaller insectivorous species.	
(7)	Vol. 3, B.9.4.2 Risk assessment for mammals	EFSA: It was assumed that the residues in (endogaecic) soil dwelling arthropods would be equal to the soil concentration. However it may happen that the residues accumulate in insects since the logPow is >3.	
(8)	Vol. 3, B.9.4.2 Risk assessment for mammals	EFSA: The TERs calculated in the first tier were already based on refined residue data in earthworms. It is unclear how these residue data were obtained. No summary of the residue study was provided and no study report on the earthworm residue study was submitted. Therefore the suggested residue value of 0.5 mg/kg worm cannot be accepted. It is suggested to calculate the residues in earthworms according to the formula in SANCO 4145 (risk assessment for secondary poisoning of earthworm eating birds).	

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section 5 – 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
(9)	Vol. 3, B.9.3.4.3 Refined risk assessment using focal species	EFSA: The text in the additional report on pages 77-78 gives the impression that a study was conducted on the canary island to identify the focal species. However the cited study of Giessing (2005) is a brief literature survey and the studies on which it relies on were not summarized and not submitted in the dossier.	
(10)	Vol. 3, B.9.3.4.3 Refined risk assessment using focal species	EFSA: The PT values of 0.1 and 0.3 seem to be based on considerations of exposure of soil dwelling arthropods. This approach is considered not correct. The PT should reflect the proportion of diet taken from the treated area.	
(11)	Vol. 3, B.9.3.4.3 Refined risk assessment using focal species	EFSA: A mean value of the percentage of earthworms and epigaic, and endogaic arthropods was used to derive PD values. The suggested PD values are based on studies with Western hedgehog (<i>Erinaceus europaeus</i>). The studies on the food composition of Western hedgehog were not provided and not summarized in the additional report. It is unclear if it is possible to extrapolate from the diet composition of Western hedgehog to Algerian hedgehog. The relevance of the observed food composition in the two studies with Western hedgehog in relation to Algerian hedgehog feeding in banana plantation is uncertain.	

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section 5 – 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
(12)	Vol. 3, B.9.3.4.3 Refined risk assessment using focal species	EFSA: It seems that there is a mistake in the suggested PD values. The PD values do not sum up to 1 (100%). Correction/clarification is needed.	
(13)	Vol. 3, B.9.3.4.3 Refined risk assessment using focal species	EFSA: It is stated in the report that the long-term (reproductive) risk to mammals is low because cadusafos is applied outside of the breeding season. This weight of evidence approach is not agreed. Due to the climate in the canary islands it is likely that small mammals can reproduce all year round. No information was provided which confirms that mammals do not reproduce during autumn/winter in the canary islands.	
(14)	Vol. 3, B.9.5.1.1 Risk to non-target arthropods	EFSA: A potential high risk was indicated in the first-tier risk assessment for non-target arthropods. Due to the mode of application (via drip irrigation) only soil dwelling arthropods are considered to be exposed. The RMS concludes on an acceptable risk based on the assumption that only 10% of the area of the banana plantation would be treated and thus leaving enough untreated refuges for arthropods. It is surprising that the product can be used efficiently against soil dwelling insects/nematodes if 90% of the in-field area is left untreated. The assumption that only 10% of the area is treated needs some further justification including considerations on the effectiveness of the suggested application method.	

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section 5 – 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
(15)	Vol. 3, B.9.6 Effects on earthworms	EFSA: No analytical verification of the concentrations of cadusafos in soil is reported in the study summary of the earthworm field study (Sprosen & Pease 2005).	
(16)	Vol. 3, B.9.6 Effects on earthworms	EFSA: From the study report on the earthworm field study (Sprosen & Pease 2005) it is apparent that on almost all sampling occasions the number of individuals of different earthworm species was too low to allow a statistical analysis. Only for one species (<i>Allolobophora chlorotica</i>) the number of individuals was sufficient on one sampling date to allow a statistical analysis. It is questionable if a conclusion on the impact on individual earthworm species can be drawn from this study.	

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Comments of France on the additional report on Cadusafos

(25/11/08) 1/3

section 2 - Mammalian toxicology (B.6)

23. 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.B6.3.3 short term toxicity, Other routes	<u>FR</u> : since the intended use has been restricted to drip irrigation only and since the formulation Rugby 200 CS is of lower acute inhalation toxicity than the a.s. with agree with the RMS that further short term inhalation testing is no longer warranted.	
(2)	Vol.3B6.8.1 Toxicity studies with metabolites	<u>FR</u> : as hydroxy 2-butanesulfonic acid is devoid of the OP moiety and can be considered structurally close to a metabolite identified in the rat we agree with the justification submitted by the applicant and the conclusion of the RMS.	
(3)	Vol.3.B6.8.2 Supplementary study	<u>FR</u> : we can consider that the potential for genotoxicity of cadusafos has been sufficiently investigated and we agree with the overall conclusion of the RMS that cadusafos is unlikely to be genotoxic.	
(4)	Vol.3.B.6.9.1 report on medical surveillance on manufacturing plant personnel	<u>FR</u> : the information provided is sufficient.	

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Comments of France on the additional report on Cadusafos

(25/11/08) 2/3

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

24. 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)	Additional report, point B.8.6.2.1, PECgw calculations for methyl-2-butyl sulfone	FR : it is noted that the Koc of methyl-2-butyl sulfone molecular structure was assessed based on SMILES and PCKOCWIN model. This generates uncertainty as no similarity analysis nor cross validation is reported, so that these calculations may only be considered as informative. Models should be favoured to avoid animal testing, for chemical and physical parameters, dedicated studies should be envisaged by the notifier in order to support the acceptability of uses. Otherwise a the non relevance of the metabolite should be addressed. In addition, the value used as a formation fraction of "7.5" is in fact the max occurrence percentage for this compound and should not be used as a formation fraction value. For 1/n, in principle a default 1 value should be used (not different of 0.99 in this case).	

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Comments of France on the additional report on Cadusafos

(25/11/08) 3/3

section 5 - Ecotoxicology (B.9)

25. 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)	Additional report, point B.9.1.7, risk assessment to birds	FR: for earthworm eating birds, it is proposed to use the concentrations measured during the reproduction study, and to use concentrations in earthworms from day 14 to day 56. Is this proposal checked and discussed with regard to soil DT50 for cadusafos?	
(2)	Additional report, point B.9.1.7, risk assessment to birds	FR: the risk assessment is refined for the most abundant species registered in Banana plantations, the blackbird. The history for use of cadusafos should be addressed in the area used for bird sampling, as in fact this bird may in a way be the most abundant in relation to the repeated use of cadusafos, i.e. the risk assessment is performed for the species being "favoured" compared to other species. This is critical for such a toxic substance. A way to limit this possible bias would be to also address the risks to other species reported on this crop.	
(3)	Additional report, point B.9.3.4.3, risk assessment to mammals	FR: the risk assessment is refined for the most abundant species expected in Banana plantations, the Algerian hedgehog. As for birds, there could be a risk to in fact assess the risks for the species that was the less impacted by uses of cadusafos. A way to limit this possible bias would be to also address the risks to other species reported on this crop.	
(4)	Additional report, point B.9.5.1.1, risk assessment to non target arthropods	FR: it is proposed to consider the low expected exposure of soil organisms, based on a high interception from banana leaves, to support acceptable risks. This proposal could be accepted if supported by measured concentrations in soils, as the product displayed some toxicity towards <i>Poecilus cupreus</i> (see B.9.5.1.2), which is not a sensitive species.	

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Comments of Germany on the additional report on cadusafos

(25.11.2008) 1/2

section 6 - 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, Effects on other terrestrial vertebrates (Annex III 10.1 and 10.3)	<p>Potential exposure of terrestrial vertebrates (and consequently risk) from uptake of irrigation water as drinking water is not discussed in the Additional Report. The issue was raised in the EPCO 27 meeting and resulted in a data requirement (New data requirement 5.11: Notifier to carry out a risk assessment for birds and mammals to indicate which species occur in banana plantations and their associated diets. (.) Assessment should also cover risk (.) from contaminated drinking water.) It was thereafter stated in Appendix I to Addendum 2 - Volume 3, B.9: Ecotoxicology (January 2006) that "since water is quickly absorbed by soil there is no exposure, and therefore the risk of birds or wild mammals of drinking water containing residues of cadusafos is acceptable." In line with that, the EFSA Conclusion, finalized 2006-04-24 stated that "since application to bananas is by drip irrigation to the soil, the risk due to exposure to contaminated drinking water is also considered low." However, these statements were not supported further by data or background information.</p> <p>Typically, irrigation lines consist of perforated tubing lying on the soil surface. Can it be ensured under all circumstances that leaching of water into the soil occurs at a faster rate than the water flow from the irrigation line? Otherwise, temporary formation of puddles and thus exposure of vertebrates to the irrigation solution containing cadusafos cannot be safely excluded.</p>	

Comments of Germany on the additional report on cadusafos

(25.11.2008) 2/2

section 6 - 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
(2)		Detailed assessments on potential exposure of birds and mammals in banana plantations are documented. In principle, the risk assessment for mammals is intended to cover the risk to all "terrestrial vertebrates other than birds", which would include also reptiles and amphibians. It should be considered (based on available data and general knowledge) whether the refined assessments for birds and mammals are still likely to cover the risk for other vertebrates, e.g. reptiles like <i>Gallotia spp.</i> , which are endemic on the Canary Islands.	