PEER REVIEW REPORT ON **CADUSAFOS** 15 04 2009

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0. General

General				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
0(1)	Vol 3, B1-B5	**UK:** The additional report to the DAR confirms additional data have been submitted in respect of the data gaps identified for Physical/Chemical properties	**RMS:** Agreed.	Addressed.
0(2)	**Vol. 1**, **List of endpoints** *–Summary of representative uses evaluated*	**Applicant:** Table page 5: As the only representative use defended is bananas, 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.	**RMS:** We agree that the use of potatoes is not supported any more under Resubmission in accordance to Reg 33/2008, However, it is more appropriate if it remains on the List of endpoints but formatted as strikethrough, in order to be consistent with the conclusions initially drawn**.**	Addressed.
0(3)	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.	**RMS:** An updated level 4 of volume 1 can be prepared if agreed by the meeting of experts.	Addressed: RMS to consider the identified data gaps in an updated level 4 of volume 1.

1. Physical/Chemical Properties; Details of Uses and Further Information; Methods of Analysis

Identity (B.1, Annex C)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
1(1)	**Vol. 4, C.1.1.1** *Manufacturer or manufacturers of the active substance* *b. Location of Plant(s):*	**Applicant:** The actual address of the [redacted] plant is: [redacted] The address of the [redacted] is: [redacted]	**RMS:** A clarification has been given about the location of plant by the applicant and is accepted. The full address of the manufacturing plant is mentioned in a second addendum to Annex C.	Addressed.
1(2)	**Vol. 4, C.1.1.2** *Method or methods of manufacture*	**Applicant** : RMS asks for CAS Number, structural formula, purity and supplier of the starting materials. This information is provided under the further explanations of this commenting table.	**RMS:** Data on the identity of the starting materials have been submitted and are presented in a second addendum to Annex C. Only data for ethyl dichlorophosphate are missing.	Open point: RMS to clarify whether step 1 of the manufacturing process described in the DAR is valid, as in this case the need for additional information concerning ethyl dichlorophosphate as starting material is redundant. See also comment 1(6), 1(7)
1(3)	**Vol 4, C.1.2.3** *Analytical profile of batches*	**Applicant:** We agree with RMS to remove the impurities [redacted] from the specification	**RMS:** The RMS proposed that impurities [redacted] should be removed from the technical specification and the Applicant agreed. However the acceptability of the technical specification should be discussed in a meeting of experts.	Open point: The acceptability of the technical specification to be discussed in a meeting of experts. See also comments 1(4), 1(7), 1(8)

Identity (B.1, Annex C)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
1(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.	**RMS:** The acceptability of the technical specification should be discussed in a meeting of experts.	See open point in comment 1(3) See also comments 1(7), 1(8)
1(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?	**RMS:** This understanding is correct.	Addressed.
1(6)	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	**RMS:** The missing data on the identity of the starting materials have been provided and are presented in a second addendum to Annex C. Only data for [redacted] are still missing.	See open point in comment 1(2)

Identity (B.1, Annex C)				
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1(7)	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]	**RMS:** The applicant has agreed to remove impurity [redacted] from the technical specification. However the acceptability of the technical specification should be discussed in a meeting of experts.	See open point in comment 1(3) See also comments 1(4), 1(8)
1(8)	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.	**RMS:** The RMS proposed that impurities [redacted] should be removed from the technical specification and the applicant agreed. For impurities [redacted] as they were detected in the five batch analysis [redacted] has been accepted. However the acceptability of the technical specification should be discussed in a meeting of experts.	See open point in comment 1(3) See also comments 1(4), 1(7)
1(9)	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	**RMS:** Agreed.	Addressed: RMS to correct the names of the substances In a corrigendum

Identity (B.1, Annex C)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
1(10)	Vol. 4, Table 3. Analytical profile of batches after addition of copper naphthenate 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 additive 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?	**RMS:** The content of each impurity in the cadusafos batches was calculated using the following equation: [redacted] If more clarifications are required this can be discussed in a meeting of experts.	Open point: The acceptability of presenting 5 batch data for impurities based on calculations should be discussed in a meeting of experts.
1(11)	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	**RMS:** Clarification on this matter will be requested from the applicant as, on the re-submission dossier, no data were provided about the formulation.	Data gap: Applicant to clarify if an overage is used in the formulation due to the fact that [redacted] seems to consistently cause lower values in the a.s. content determination. However it should be noted that additional information cannot be taken into account in the peer-review.
1(12)	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	**RMS:** Agreed. However the acceptability of the technical specification should be discussed in a meeting of experts.	See open point in comment 1(3) See also comments 1(4), 1(7), 1(8)

Identity (B.1, Annex C)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
1(13)	Vol. 4, B.5.1.2 Analytical methods for the impurities, additives p.12	**EFSA:** it is not clear how the additive was measured in the 5 batch	**RMS:** The [redacted] content in the cadusafos batches was calculated using the following equation: [redacted]	Addressed. See also comment 1(10)

Physical and chemical properties of the active substance (B.2.1)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
1(14)	**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 '*EFSA Scientific Report* (2006) 68, 1-70, Conclusion on the peer review of cadusafos Appendix 1 – list of endpoints.	**RMS:** In the latest format of "List of Endpoints"(see EPCO Manual E4-rev4) the hydrolytical stability, the photolytical stability and quandum yield of direct phototransformation have been removed by the Phys/chem Section of "List of Endpoints" because they are mentioned in the Fate and Behaviour section.	Addressed.
1(15)	Vol. 1, LoEP, Flammability	**EFSA:** not highly flammable	**RMS:** Agreed. In the "List of endpoints"(October 2008), only the points affected by the additional data submitted after the re-submission of Cadusafos were altered. The flammability point has been corrected in the updated "List of endpoints"(January 2009).	Addressed.

Physical, chemical and technical properties of the formulation (B.2.2)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
1(16)	**Vol. 3, B2.2.12** *Dynamic viscosity*	**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.	**RMS:** In the study assessed in DAR, the information of the rotational speed (6 rpm) had been provided but still the data gap regarding the shear rate (at that the measurement of the viscosity has been conducted) was identified (see Reporting Table of Cadusafos rev.1-1, 9.3.2007 No 1(7) and also EFSA Scientific Report (2006) 68, p. 30 of 70). This should be discussed in a meeting of experts.	Open point: Whether information on the shear rate at which the viscosity measurement has been conducted is still required (provided that the rotational speed was 6rpm) should be discussed in a meeting of experts.

Further information (B.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)

Classification and labelling (B.4)

For comments on classification and labelling see the relevant sections.

Methods of analysis (B.5)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
1(17)	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.	**RMS:** The format of the "List of Endpoints" was based on the latest version of the EPCO Manual E4 (rev.4 - September 2005). The residue definition for body fluids and tissues is: Cadusafos (see Addendum to DAR - October 2008)	Addressed.
1(18)	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.	**RMS:** In the "List of endpoints"(October 2008), only the points affected by the additional data submitted after the resubmission of Cadusafos were altered. For the sampling condition and sampling time of the analytical method for cadusafos in air please see Annex B of DAR.	Addressed.

2. Mammalian toxicology

Toxicokinetics (B.6.1)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)

02. Mammalian toxicology

Acute toxicity (B.6.2)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)

Short-term toxicity (B.6.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
2(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 8 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'.	RMS: See RMS position on this topic in the Cadusafos Additional Report (October 2008), page 21. See also RMS response at point 2(8).	Addressed. See also open point in comment 2(10).
2(2)	Vol.3.B6.3.3 short term toxicity, Other routes	FR : 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.	RMS: Accepted.	Addressed.

Short-term toxicity (B.6.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
2(3)	Additional Report to DAR Vol.3, B.6.3.3, Short term toxicity by inhalation, p.21	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). 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. 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.	RMS agrees to the need for stressing that the estimation of operator exposure has been performed for the specific use conditions proposed and that any alteration of these conditions should lead to reconsideration of the assumptions made. Nevertheless, it should be noted that the available study on the release profile of cadusafos from Rugby 200CS after dilution in water (Dexter, 2005) and the conclusion that the "free" cadusafos in the aqueous solution is 1.12% after 2 minutes was accepted by the physical-chemical properties EPCO Meeting (EPCO 30). No further data was required at that time. See also RMS response at point 2(1).	See open point in comment 2(10).

Genotoxicity (B.6.4)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)

Long-term toxicity and carcinogenicity (B.6.5)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)

Reproductive toxicity (B.6.6)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)

Neurotoxicity (B.6.7)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)

Other toxicological studies & Medical data (B.6.8-B.6.9)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
2(4)	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.	RMS: As addressed in the Cadusafos Additional Report (October 2008), page 22, hydroxy-2-butanesulfonic acid is structurally similar to cadusafos metabolites identified in rats. More specifically, it is the hydroxylation product of the rat metabolite sec-butyl-sulfonic acid, the toxicological assessment of which is covered by the data for the parent compound, cadusafos. Furthermore, the OP moiety is not present in hydroxy-2-butanesulfonic acid, thus no cholinergic activity is possible. Overall, it may be concluded that hydroxy-2-butanesulfonic acid is of low toxicological concern.	Addressed.
2(5)	Vol.3B.6.8.1 Toxicity studies with metabolites	FR : 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.	RMS: Accepted	Addressed.

Other toxicological studies & Medical data (B.6.8-B.6.9)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
2(6)	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.	RMS: See RMS position on this topic in the Cadusafos Additional Report (October 2008), page 22. The need for conduction of genotoxicity studies with hydroxy 2-butanesulfonic acid should be discussed in a meeting of experts.	Addressed. The residual amount of this metabolite being less than 0.01 ppm (in both pulp and peel), its toxicological relevance doesn't need to be addressed by further genotoxicity test.
2(7)	Vol.3.B6.8.2 Supplementary study	FR : 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.	RMS: Accepted	Addressed.
2(8)	Vol.3.B.6.9.1 report on medical surveillance on manufacturing plant personnel	FR : the information provided is sufficient.	RMS: Accepted	Addressed.

Other toxicological studies & Medical data (B.6.8-B.6.9)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
2(9)	Additional Report to DAR Vol.3, B.6.8.2 Supplementary studies, p.23 and Additional Report to Vol.4, p.9	EFSA: Based on the information mentioned in column 3, the following questions are raised: - 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. 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.	RMS: It should be noted that due to a typing error E3628-129-1 was mentioned in the DAR (p.153). However, E3638-129-1 actually contained the new impurity [redacted] In the additional report to Vol.4, all the available information on the impurity profile of cadusafos is presented. In case additional data are considered necessary, these should be requested by the applicant.	Open point The equivalence of the toxicological batches with the new technical specification (see Addendum 2 to Volume 4 of January 2009) has to be confirmed.

Summary of mammalian toxicology and setting of ADI, AOEL and ARfD (B.6.10)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)

Toxicity of the product(s) (B.6.11)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)

Dermal absorption (B.6.12)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)

Toxicity of non-active substances (B.6.13)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)

Exposure data (B.6.14)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
2(10)	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.	RMS: After dilution of Rugby 200CS (encapsulated cadusafos) in water, the a.s. cadusafos is gradually released, with the rate and extent of release being limited by the permeability of the shell wall and the low solubility of cadusafos in water. This greatly reduces the potential operator exposure to cadusafos, particularly by the dermal route. Concerning the possible operator exposure by inhalation this is considered to be negligible during application by drip irrigation. Concerning the used work rate of 1ha/day, this has been proposed by the notifier as the representative size of a banana plantation in the Canary Islands. The RMS considers that this is an issue that could be resolved at Member State level. Concerning the mixing/loading calculations and the use of the existing exposure models, although not really appropriate for the examined scenario, the RMS still considers that the estimation approach followed in the DAR and the respective Addenda is conservative. There are no pouring operations and possible exposure during the removal of the tubes is expected to be low considering also the use of gloves. The accidental ingestion of small amounts of cadusafos is not of relevance for the estimation of operator/worker/bystander exposure to cadusafos used as a plant protection product. Only the exposure by the dermal and inhalation routes is considered relevant.	Open point Further consideration should be given to the exposure estimates with regard to - the appropriate parameters of the scenario - the amount of cadusafos released from the capsules - the potential exposure to volatilised pesticide with respect to bystander and worker exposure See also comments 2(1) and 2(3).

Other comments				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
2(11)	Vol. 1, Appendix I to Level 2, List of endpoints (October 2008 version), Fate and behaviour in the environment section	DE: It seems that 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.	RMS: Groundwater concentrations of cadusafos (no metabolites exist) have been calculated according to FOCUS PELMO model. See Fate and Behaviour Section of the LoEP (January 2009).	See in section 4 (Fate and Behaviour): open points in comments 4(3), 4(5), 4(10), 4(11) and 4(18).
2(12)	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 LoEP. This error should be corrected.	RMS: The LoEP has been amended accordingly.	Addressed
2(13)				New open point The results of the discussions in ECB about classification and labelling of cadusafos have to be reflected by the RMS.

3. Residues

Storage Stability (B.7.0)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)

Metabolism in plants (B.7.1)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
3(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.	RMS: Accepted. No comment	Addressed. The agreed residue definition is cadusafos only.

Metabolism in livestock (B.7.2)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)

Residue definition (B.7.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
3(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.	RMS: Agreed. No comment.	Addressed: The agreed residue definition is cadusafos only.

Use pattern, critical GAP, residues trials (B.7.4 to B.7.6)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
3(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.	RMS: Accepted. No comment.	Addressed: The residues data are sufficient.

Processing (B.7.7)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)

Livestock feeding (B.7.8)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)

Succeeding/Rotational crops (B.7.9)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)

MRLs related issues and Consumer Risk Assessment (B.7.10 to B.7.15)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
3(4)	**Vol. 1, List of endpoints-** *Summary of critical residues data*	**Applicant**: Table page 19: As the only representative use defended is bananas, 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*.	**RMS:** We agree that the use of potatoes is not supported any more under Resubmission in accordance to Reg 33/2008, However, it is more appropriate if the data relevant to this use remains on the List of endpoints but formatted as strikethrough, in order to be consistent with the conclusions initially drawn**.**	Addressed.
3(5)	**Vol. 1**, **List of endpoints**- *Consumer risk assessment*	**Applicant**: Page 20: TMDI (European and national diets) & Acute Exposure: suggests either the parts related to potatoes to be deleted or at least strikethrough.	**RMS:** See comment 3(4) above.	Addressed.
3(6)	**Vol. 1, List of endpoints**- *Consumer risk assessment*	**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.	**RMS:** See comment 3(4) above.	Addressed.

Other comments				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)

4. Environmental fate and behaviour

Route and rate of degradation in soil (B.8.1)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)

Adsorption, desorption and mobility in soil (B.8.2)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)

PEC in soil (B.8.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)

Fate and behaviour in water and impact on water treatment procedures (B.8.4-B.8.5)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)

PEC in surface water and in ground water (B.8.6)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(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.	RMS: RMS agree with UK comment	Addressed. Note there is an inaccuracy in the original UK comment. The DT50 of 38 days is the geomean normalised laboratory value. The not normalised geomean field DT50 value is 50 days. The field value of 59 days that was used in the modelling presented in the additional report is the longest DT50 from a southern European field dissipation trial site.

PEC in surface water and in ground water (B.8.6)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(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).	RMS: RMS agree in principle with the approach proposed by the UK. However, the RMS's original position was that methyl-2-butyl sulfone should not be at all considered as a major soil metabolite based on the fact its concentration profile marginally fulfills the "above 5%AR at 2 consecutive time points" criterion; indeed, in one of the three soils tested, methyl-2-butyl sulfone was present at 5.4%AR at 7 days and 7.5%AR at 14 days before declining to 2.75%AR by day 30, while in the other 2 soils investigated it was present concentrations below 1.7%AR at all sampling times.	Open point Member state experts to discuss if they can accept the presented QSAR estimated Koc value for methyl-2-butyl-sulfone or whether they would require a guideline batch adsorption study on three soils. Discussion to include a consideration of the potential for dissociation and therefore pH dependence of adsorption at environmentally relevant pH. See reporting table comments 4(2), 4(6), 4(13) and 4(16).

PEC in surface water and in ground water (B.8.6)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(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.	RMS: The adapted scenario that was originally developed utilised the climatic and citrus growing (surrogate for banana) data from the FOCUS Seville scenario but included soil data specific to Tenerife. The predicted PECgw concentrations for cadusafos were determined to be 0.042 µg/l following use in autumn and 0.011 µg/l following use in spring. The potential for the soil metabolite methyl-2-butyl sulfone to contaminate groundwater was not assessed in this study.	Open point Member state experts to discuss whether they can accept the standard FOCUS groundwater scenarios for Citrus or whether the soil parameterisation for the canary Islands as used in Jarvis, T (2005) should have been used.
4(4)	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 little risk of groundwater contamination...” by “there is a low 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).	RMS: The RMS consider that the clarity of the sentence is not compromised by the word “little”.	Addressed.

PEC in surface water and in ground water (B.8.6)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(5)	Vol. 3, B.8.6 PECgw	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.	RMS: RMS agrees with NL comment	Open point RMS to provide groundwater simulations with the PEARL model that cover all the possible application timings for banana. Note this can only be sensibly done after any discussion of experts using the agreed outcomes of open points 4(2), 4(3), 4(7), 4(8), 4(9) and 4(11).
4(6)	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.	RMS: See point 4(2)	See open point at comment 4(2).
4(7)	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.	RMS: The 1/n value of the metabolite was assumed same as the parent's.	Open point Member state experts to discuss and agree the appropriate 1/n value to use in leaching modelling for methyl-2-butyl sulfone. See reporting table comments 4(7) and 4(13).

PEC in surface water and in ground water (B.8.6)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(8)	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.	RMS: The formation fraction of methyl-2-butyl sulfone used as modelling input was considered as a worst case value.	Open point Member state experts to discuss and agree the appropriate kinetic formation fraction to use in leaching modelling for methyl-2-butyl sulfone from cadusafos. (EFSA estimated a value of 0.315 is appropriate if the DT50 for cadusafos (12.3 days) and methyl-2-butyl sulfone (4.5 days) as estimated by the RMS in the DAR for the pertinent silt loam soil are retained). See reporting table comments 4(8) and 4(13).
4(9)	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.	RMS: This metabolite was only observed at concentrations above 5% in just one of the three soils tested. The only DT50 value available is therefore the one noted in the EFSA conclusion as an indicative value.	Open point Member state experts to discuss and agree what further information is required regarding the soil half life of methyl-2-butyl sulfone and agree a DT50 endpoint from the available laboratory study where cadusafos was dosed. See also open point 4(8).

PEC in surface water and in ground water (B.8.6)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(10)	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?	RMS: See point 4(1) The primary modeling was the one using a DT50 of 38 days (geometric mean and median DT50lab, normalisation to pF2, 20oC, aerobic, first order kinetics); a secondary analysis was performed using a DT50 of 59 days as the longest value from the available southern European studies as a clearly worst case value.	Open point RMS to clarify how the model was set up for the PELMO simulations that used the DT50 of 59 days (not normalised longest southern European field value). I.e. which values were used for Q10 and the Walker equation exponent.
4(11)	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).	RMS: The simulated application period was autumn (September)	Open point RMS to provide Pelmo FOCUS groundwater simulations to cover the range of possible application dates. Note this can only be sensibly done after any discussion of experts using the agreed outcomes of open points 4(2), 4(3), 4(7), 4(8) and 4(9).

PEC in surface water and in ground water (B.8.6)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(12)	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 risk assessment 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)	RMS: See point 4(5)	See open point at comment 4(5).
4(13)	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 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).	RMS: See previous points	See open points at comments 4(2), 4(7) and 4(8)

Fate and behaviour in air and PEC in air (B.8.7-8.8)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)

Definition of the residues (B.8.9)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)

Other comments				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(14)	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.	RMS: The parts related to potatoes have been deleted	Addressed.
4(15)	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.	RMS: The parts related to potatoes have been deleted	Addressed.
4(16)	Vol. 1, List of endpoints	NL: The QSAR Koc derived for the metabolite should be included in the LoEP.	RMS: LoEP has been amended to include the Koc values for methyl-2-butyl sulfone	Addressed.
4(17)	Vol. 1, List of endpoints	NL: PECsw for potatoes should be removed from the LoEP.	RMS: The parts related to potatoes have been deleted	Addressed.
4(18)	Vol. 1, List of endpoints	NL: the residue definition should be updated with regard to metabolite methyl-2-butyl	RMS: Pending on the outcome of the expert's meeting	Open point Member state experts to discuss and agree the residue definition for groundwater exposure assessment and consideration by other disciplines.

Other comments				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(19)	Vol. 1Appendix 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.	RMS: LoEP has been corrected	Addressed.
4(20)	Vol. 1Appendix 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.	RMS: New PECs values have been calculated using longest sEurope DT50 of 59 days. The LoEP has been amended accordingly.	Open point Member state experts to discuss the appropriateness of the case made regarding localised soil exposure around each banana plant as presented in Vol.3 B.9.5 of the additional report page 83. See open point at comment 5(34) and comment 5(36).
4(21)	Vol. 1Appendix 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?	RMS: The new FOCUS PELMO 3.3.2 GW modelling results have been now included in the revised version of the LoEP.	Addressed.

Other comments				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(22)	Vol. 1Appendix 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.	RMS: This information has been included in the revised LoEP.	Addressed.
4(23)	Vol. 1Appendix 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.	RMS: The LoEP has been updated accordingly.	Addressed.
4(24)	Vol. 1Appendix 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?	RMS: The FOCUS GW modelling results re. methyl-2-butyl sulfone have been accepted by the RMS. Consequently, the phrase 'For groundwater further data on methyl-2-butyl sulfone is required before the residue definition can be concluded' has been removed from the Definition of the Residue box.	See open point at comment 4(18)

5. Ecotoxicology

Birds and mammals (B.9.1 and B.9.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(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	Clarification of GAP: There are references from the notifier for application in autumn every three years. No revised GAP was provided by the notifier. According the re-submission dossier the representative use supported (Appendix 1) by the applicant is one application per year (Spring or Autumn) via drip irrigation at the max application rate of 4 kg as/ha. The RMS consider the latter as the relevant GAP. A new risk assessment is provided in an Addendum. It can be discussed in an expert meeting.	Open point MSs to discuss and agree the refined risk assessment to birds provided in the additional report and the addendum (it seems that both documents report the same risk assessment. Could the RMS clarify?). See also comment on open points 5(2), 5(3), 5(4), 5(5), 5(6), 5(10), 5(11).

Birds and mammals (B.9.1 and B.9.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(2)	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?	Please see DAR point B.9.6.2 Other studies. The reproduction test with cadusafos and the earthworm *Eisenia fetida* including data on the bioaccumulation of cadusafos indicates that «The bioconcentration test revealed that cadusafos residues were below the level of quantification until day 7, thereafter the residue level was found to be 0.28 (day 7), 0.44 (day 28) and 0.53 (day 56) mg/kg bw.» The value were used for the risk assessment. The soil DT50 of cadusafos is 59 days. Earthworms are continues exposed to cadusafos reaching higher residues after a period of time.	Open point: MSs to discuss the relevance of measured residues on earthworms to refine the risk for earthworm eating birds and mammals.
5(3)	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.	A new risk assessment is provided in an Addendum. A report prepared by Rifcon proposes focal species according to recommendations provided in the SANCO/4145/2000 guidelines. It can be discussed in an expert meeting.	Open point: MSs to discuss the relevance of blackbird as focal species for risk assessment of cadusafos in banana plantations.

Birds and mammals (B.9.1 and B.9.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(4)	Vol. 3, B.9.1.4 Additional data birds(and mammals0	NL: Martin&Lorenzo (2001) and Ludwigs & Wuebbenhorst (2000a/b) are not included in the reference list.	The notifier provided a report prepared by RIFCON (Giessing, B. (2005). Birds and mammals inhabiting banana plantations on the Canary Islands - Literature survey and re-analysis of monitoring data. RIFCON GmbH Report RC 05-015.). Within this document the results of the survey of current literature on the distribution of birds and mammals on the Canary Islands are summarised. Various references are reported in this document among these also the one requested.	Open point No new data can be taken into account. RMS to clarify if the RIFCON (Giessing, B. (2005) report (*Birds and mammals inhabiting banana plantations on the Canary Islands - Literature survey and re-analysis of monitoring data.* RIFCON GmbH Report RC 05-015.) provides the same data considered in the additional report. The report was only mentioned in the reporting table and it was not mentioned on the reference list of the additional report and of the addendum). See comment 5(4)of the reporting table
5(5)	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.	A new risk assessment is provided in an Addendum.	Open point MSs to discuss the use of initial PECsoil as RUD. Since the logPow of cadusafos is greater than 3, residues can accumulate in insects.
5(6)	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).	A new risk assessment is provided in an Addendum. It can be discussed in an expert meeting. See also point 5(1) for clarification regarding the GAP.	Open point MSs to discuss if the risk assessment for birds and mammals can be considered addressed for both spring and autumn application. Furthermore the PD refinements should be agreed.

Birds and mammals (B.9.1 and B.9.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(7)	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.	A new risk assessment is provided in an Addendum. It can be discussed in an expert meeting.	See comment on open point 5(6)
5(8)	Vol. 3, B.9.1.7, Refinement of PD	NL: For PD, it should be distinguished between spring an autumn values.	A new risk assessment is provided in an Addendum. It can be discussed in an expert meeting.	See comment on open point 5(6)
5(9)	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.	A new risk assessment is provided in an Addendum. It can be discussed in an expert meeting.	See comment on open point 5(3)

Birds and mammals (B.9.1 and B.9.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(10)	Vol. 3, B.9.1.7, Refinement of PT	NL: The use of the 50th percentile of the PT should be substantiated with more arguments, based on data from the radiotracking study (e.g. number of catched 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.	A new risk assessment is provided in an Addendum. It can be discussed in an expert meeting. In addition according to the GD for bird and mammals there are various proposals in order to reduce the PT of 1 to a more realistic figure. "In order to do this data from radiotracking studies may, if they are available, help, however it is appreciated that these will be rarely available. Therefore, an alternative option would be to carry out an appropriate literature search to try and determine the proportion of the diet that may be obtained from the treated area. However, before doing this, key species that may be exposed should be identified."	Open point MSs to discuss and agree the PT refinements used for risk assessment for birds (pending on the discussion to open point at comments 5(3) and 5(9)).

Birds and mammals (B.9.1 and B.9.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(11)	Vol. 3, B.9.1.7, Refined exposure assessment	NL: It should be substantiated why the residue on epigaeic arthropods is zero, since these arthropods can also come in contact with the a.s.	A new risk assessment is provided in an Addendum. It can be discussed in an expert meeting. It is considered conservative for estimating the potential exposure to cadusafos since the single drip-irrigation application is targeted to reach 15 to 20 cm below the surface and the product does not remain in the soil surface where dwelling arthropods are often found, hence limiting the amount of available contaminated feed. Finally, cadusafos has a Henry's Law Constant of 1.32 x 10-1 Pa.m3.mol-1 (at 25°C) and can be considered as volatile, therefore the potential for contamination of insects on the soil or plant surface is also negligible.	Open point MSs to agree that the mode of application of cadusafofos (drip-irrigation) does not cause exposure of ground dwelling arthropods and therefore the residue on epigaeic arthropods can be considered negligible. See also comment on open point 5(34).
5(12)	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.	The notifier brovided a report prepared by RIFCON (Giessing, B. (2005). Birds and mammals inhabiting banana plantations on the Canary Islands - Literature survey and re-analysis of monitoring data. RIFCON GmbH Report RC 05-015.). Within this document the results of the survey of current literature on the distribution of birds and mammals on the Canary Islands are summarised. Various references are reported in this document. .	See comment on open point 5(3) and 5(4).

Birds and mammals (B.9.1 and B.9.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(13)	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).	See point 5(2).	See comment on open point 5(2)

Birds and mammals (B.9.1 and B.9.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(14)	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.	A new risk assessment is provided in an Addendum. It can be discussed in an expert meeting.	See comment on open point 5(6)
5(15)	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.	A new risk assessment is provided in an Addendum. It can be discussed in an expert meeting. However, this is an assumption. For more information see also 5(11).	See comment on open point 5(5)
5(16)	Vol. 3, B. 9.1 Effects on birds	EFSA: It was assumed that the epigaeic 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.	A new risk assessment is provided in an Addendum. It can be discussed in an expert meeting. See also 5(11).	See comment on open point 5(11)

Birds and mammals (B.9.1 and B.9.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(17)	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	A new risk assessment is provided in an Addendum. It can be discussed in an expert meeting. See point 5(1)	Open point MSs to discuss and agree the refined risk assessment to mammals provided in the additional report and the addendum. See also comment on open points 5 (4), 5(18), 5(20), 5(22), 5(23), 5(25), 5(31), 5(33).
5(18)	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.	A new risk assessment is provided in an Addendum. A report prepared by Rifcon proposes focal species according to recommendations provided in the SANCO/4145/2000 guidelines. It can be discussed in an expert meeting.	Open point: MSs to discuss the relevance of Algerian hedgehog (*Atelerix algirus*) as focal species for risk assessment of cadusafos in banana plantations.

Birds and mammals (B.9.1 and B.9.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(19)	B.9.3, Effects on other terrestrial vertebrates (Annex III 10.1 and 10.3)	DE: 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. 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.	It can be discussed in an expert meeting. According to the common agricultural practice leaching of water into the soil occurs at a faster rate than the water flow from the irrigation line. No standard risk through drinking water is expected only accidentally.	Addressed

Birds and mammals (B.9.1 and B.9.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(20)		DE: 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 *Gallotia spp*., which are endemic on the Canary Islands.	We welcome any thoughts that improve the risk assessments but this is a generic issue outside the technical groups and even more individual active substances. Reptiles and amphibians are everywhere in Europe and we hope in the future to have a guidance with some thoughts or even better procedures proposed in order to identify potential risk.	Addressed. Risk assessment for other terrestrial vertebrates (reptiles and amphibians) is outside of the current procedure. The general issue was already pointed out within the oncoming revision of the terrestrial guidance document. Therefore in the next future some indications could be available.
5(21)	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..	A new risk assessment is provided in an Addendum. No comment.	See comment on open point 5(17)
5(22)	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.	We disagree with this general statement. Quantitive and qualitive risk assessment is of the same importance in the risk assessment. For this case it can be discussed in an expert meeting.	Open point MSs to discuss and agree the PT refinements used for the risk assessment for mammals.
5(23)	Vol. 3, B.9.3.4.3 Refined exposure assessment	NL: It seems a bit strange to assume a PD total of >1.	A new risk assessment is provided in an Addendum. No comment.	Open point RMS to provide a clarification on the PD values used for the risk assessment for mammals (the PD values reported in the additional report and addendum are >1)
5(24)	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.	A new risk assessment is provided in an Addendum. No comment.	See comment on open point 5(17)

Birds and mammals (B.9.1 and B.9.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(25)	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.	This is a general statement which we agree. The main issue for organophospahates is the acute risk. Literature support that for organophospahates reproductive effects are of low concern. For this group of substances the excretion rate is high and the potential for long term risk due to short application is low. For cadusafos excretion is rapid and higher than 90% at 168 hrs, mainly via urine, secondary via the expired air ($^{14}CO_2$), regardless of sex or route or mode of administration (see toxicological end points).	Open point MSs to discuss if cadusafos could be considered of low concern for the reproductive effects of mammals.

Birds and mammals (B.9.1 and B.9.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(26)	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 occurance/feeding in banana plantations. The Algerian hedgehog (*Ateleris algrius*) was proposed as a focal species. However it was stated in the text that the Osorio shrew (*Crocidura Osorio*) 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.	According the Rifcon's report the Osorio shrew (*Crocidura osorio*) inhabits the humid evergreen forest and degraded habitats in the northern part of Gran Canaria. For the diet selection of the Osorio shrew data for the closely related Greater white-toothed shrew (*Crocidura russula*) have been used. Thereafter the main components of their diet are Myriapods, Isopods, larvae of Lepidoptera, Gastropods and Aranea. It can not be excluded that the Osorio shrew (*Crocidura osorio*) also inhabits banana plantations on Gran Canaria. As a conclusion they report that with regard to pesticides applied to the ground underneath the banana plants only the Blackbird and potentially the Algerian hedgehog can be regarded as a relevant species for refined exposure assessments. For sprayed products also insectivorous canopy dwelling birds like the Canary island chaffinch and regarding the mammals the bats should be taken into consideration for a refined exposure assessment.	See comment on open point 5(18) and 5(4).
5(27)	Vol. 3, B.9.4.2 Risk assessment for mammals	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.	A new risk assessment is provided in an Addendum. It can be discussed in an expert meeting. However, this is an assumption. For more information see also 5(11).	See comment on open point 5(5)

Birds and mammals (B.9.1 and B.9.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(28)	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).	See point 5(2).	See comment on open point 5(2)
5(29)	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.	The notifier provided a report prepared by RIFCON (Giessing, B. (2005). Birds and mammals inhabiting banana plantations on the Canary Islands - Literature survey and re-analysis of monitoring data. RIFCON GmbH Report RC 05-015.). Within this document the results of the survey of current literature on the distribution of birds and mammals on the Canary Islands are summarised.	See comment on open point 5(4)
5(30)	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.	A new risk assessment is provided in an Addendum. It can be discussed in an expert meeting.	See comment on open point 5(22)

Birds and mammals (B.9.1 and B.9.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(31)	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 endogaeic arthropods was used to derive PD values. The suggested PD values are based on studies with Western hedgehog (*Erinaceus europaeus*). 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.	It is not the mean value but the highest one between two references. It can be discussed in an expert meeting.	Open point MSs to discuss if PD values based on studies with Western hedgehog (*Erinaceus europaeus*) can be used for Algerian hedgehog (*Atelerix algirus*).
5(32)	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.	A new risk assessment is provided in an Addendum.	See comment on open point 5(23)

Birds and mammals (B.9.1 and B.9.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(33)	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.	A new risk assessment is provided in an Addendum. It can be discussed in an expert meeting.	Open point MS to discuss the relevance of the application time of cadusafos with respect to breading season of mammals in the canary islands.

Bees and non-target arthropods (B. 9.4 and B.9.5)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(34)	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	It can be discussed in an expert meeting.	Open point MSs to discuss if the risk to ground dwelling insects can be considered of low concern. The argumentation that only a small part of the treated area is exposed to cadusafos (due to the mode of application) could be considered acceptable. However a more clear explanation would be appreciated (i.e. how the 16% was derived?) as well as data to support this. See also comment on open point 5(36).

Bees and non-target arthropods (B. 9.4 and B.9.5)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(35)	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 *Poecilus cupreus* (see B.9.5.1.2), which is not a sensitive species.	We cannot understand the comment. The product is applied through drip irrigation.	Addressed
5(36)	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.	It can be discussed by the fate experts.	See open point at comment 4(20).
5(37)	Vol. 3, B.9.5.1.2 Toxicity data non-target arthropods	NL: For the study with *P. cupreus* in the list of endpoints it is not clear that it concerns aged residues.	Actually it is a semi field trial.	Addressed

Bees and non-target arthropods (B. 9.4 and B.9.5)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(38)	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.	The product is not against all the soil organisms but only these that are settled (like nematodes) or feed from the roots (like Agriotes). Actually it is a common application when you want to protect the rhizosphere.	See comment on open point 5(34)

Earthworms and other soil non-target organisms (macro and micro) (B. 9.6, B.9.7 and B.9.8)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(39)	Vol. 3 B.9.6.1.1 earthworm field study	NL: Preferably the results are presented numerically in tables.	More information are presented in an Addendum.	Addressed

Earthworms and other soil non-target organisms (macro and micro) (B. 9.6, B.9.7 and B.9.8)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(40)	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.	No comment.	Addressed
5(41)	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)?	This information has been presented by the notifier.	Addressed RMS to consider in a corrigendum to make the table 19 "comparison of earthworm species in UK and Tenerife "from additional report more clear.
5(42)	Vol. 3 B.9.6.1.1	NL: In the text it is stated that the species Ocnerodrillus occidentalis and Amynthas morris 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.	Please see the 3rd column also.	See comment on point 5(41)
5(43)	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).	No comment.	Open point MSs to discuss the reliability of the earthworm field study to address the risk to earthworm population in banana plantation.

Earthworms and other soil non-target organisms (macro and micro) (B. 9.6, B.9.7 and B.9.8)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(44)	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 (*Allolobophora chlorotica*) 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.	More information has been presented in an Addendum.	See comment on open point 5(43)

Other comments				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(45)	**Vol. 1, List of endpoints-** *Toxicity/exposure ratios for the most sensitive aquatic organisms (Annex IIIA, point 10.2)*	**Applicant**: page 37: suggests that a note is inserted below the table indicating that the use on potatoes is not supported...	We agree.	Addressed
5(46)	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.	We agree.	Addressed

Other comments				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(47)	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.	We agree.	Addressed