PEER REVIEW REPORT ON **CADUSAFOS** 16 04 2009

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1. Identity, Physical and chemical properties, Details of uses and further information, Methods of analysis

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
	Section 1 Open points: ***4*** Points for clarification: ***0*** Data gaps: ***1***			Section 1 Open points: ***1*** Points for clarification: ***0*** Data gaps: ***3***
	Open point: 1.1 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 [redacted] as starting material is redundant. See reporting table 1(2)	**FMC February 2009**: We agree. [redacted] is an intermediate produced by step 1 of the manufacturing process.	**RMS,** 25 February 2009**:** In the original Annex C of the DAR (May 2004) it was clearly stated that, originally, the toxicology registration sample was prepared from carefully distilled [redacted] but some years later, the notifier was able to purchase [redacted] Therefore step 1 of the manufacturing process was considered obsolete by the RMS and that is why data on the identity of [redacted] were required as it was considered as a starting material.	PRAPeR TC 06 (4 March 2009): Open point fulfilled. The meeting agreed that step one of the manufacturing process appears to be obsolete New data gap proposed, see below.
	New data gap 1.2 identified at PRAPeR TC 06 meeting: Notifier to provide information about the purity of the new starting material [redacted]			PRAPeR TC 06 (4 March 2009): New data gap: Notifier to provide information about the purity of one of the starting materials
	Open point: 1.2 The acceptability of the technical specification to be discussed in a meeting of experts.	**FMC- February 2009**: We agree with RMS: impurities [redacted] can be removed from the specification.	**RMS,** 25 February 2009**:** The revised proposed specifications of cadusafos technical as presented in table 2 of the second addendum to Annex C are considered acceptable by	PRAPeR TC 06 (4 March 2009): Open point fulfilled. The revised proposed specifications of cadusafos technical was discussed.

Rapporteur: GR

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	See reporting table 1(3)		the RMS. Impurity [redacted] (new code "impurity 6") should be deleted from table 2, as it was included there due to typing error.	New data gap proposed, see below. Message sent to the tox and ecotox sections.
	New data gap 1.3 identified at PRAPeR TC 06 meeting: Notifier to submit further justification (e.g QC data) for specifying impurities [redacted] or they should be removed from the specification.			PRAPeR TC 06 (4 March 2009): New data gap. Notifier to submit further justification (e.g QC data) for specifying some impurities, or to remove them from the specification.
	Open point: 1.3 The acceptability of presenting 5-batch data for impurities based on calculations should be discussed in a meeting of experts. See reporting table 1(10)	**FMC February 2009**: It should be noted that [redacted] analysis is technically not feasible when mixed in cadusafos technical, in the sense that such analysis suffers to many interferences. Besides, [redacted] is an [redacted] as opposed to an impurity.	**RMS,** 25 February 2009: Since the determination of the [redacted] impurities in the presence of [redacted] is not feasible, RMS accepts the notifier's approach via calculation.	PRAPeR TC 06 (4 March 2009): Open point fulfilled. It was noted that the formula for the conversion given in the DAR was not correct, but the calculated values are accepted.The formula was corrected in a Corrigendum to vol. 4 (March 2009)
	Data gap: 1.1 Applicant to clarify if an overage is used in the formulation due to the fact that addition of [redacted] seems to consistently cause lower values in the a.s.	**FMC February 2009**: This is correct. [redacted] s used [redacted]	**RMS,** 25 February 2009: Clarification is acceptable by the RMS.	PRAPeR TC 06 (4 March 2009): Data gap closed. The original question was a misunderstanding.

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	content determination. However, it should be noted that additional information cannot be taken into account in the peer-review. See reporting table 1(11)	[redacted]		
	Open point: 1.4 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. See reporting table 1(16)		**RMS,** 25 February 2009: No comment. To be discussed in a meeting of experts.	PRAPeR TC 06 (4 March 2009): Open point fulfilled. New data gap proposed, see below.
	New data gap 1.4 identified at PRAPeR TC 06 meeting: Notifier to provide information about the shear rate for the viscosity measurement.			PRAPeR TC 06 (4 March 2009): New data gap: Notifier to provide information about the shear rate for the viscosity measurement.
	New open point 1.5 RMS to amend the list of end points according to the discussion table.		RMS, 17 March 2009: The LoEP has been amended accordingly.	PRAPeR TC 06 (4 March 2009): Open point fulfilled. The LoEP has been amended
	Message from section 1 to the meeting on mammalian toxicology (PRAPeR TC 08):			Answer from PRAPeR TC 08 (4 March 2009):

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	Can you accept the specification as given on page 4 of addendum 2 to Vol. 4. (January, 2009)			The Tox meeting accepted the specification as given on page 4 of addendum 2. Additionally, further deletions in the TS during the phys-chem meeting were proposed and an opinion of the tox meeting was required. Considering the high toxicity of cadusafos and the available information including the level tested in tox batches the experts agreed with this proposal.
	Message from section 1 to the meeting on ecotoxicology (PRAPeR TC 09): Can you accept the specification as given on page 4 of addendum 2 to Vol. 4. (January, 2009)			Answer from PRAPeR TC 09 (5-6 March 2009): New data gap 5.8 has been identified at PRAPeR TC 09 meeting: Applicant to provide information whether the batches used in the ecotox studies cover the specification given on page 4 of addendum 2 to Vol. 4.

2. Mammalian toxicology

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
	Section 2 Open points: ***3*** Points for clarification: ***0*** Data gaps: ***0***			Section 2 Open points: ***1*** Points for clarification: ***0*** Data gaps: ***2***
	Open point: 2.1 The equivalence of the toxicological batches with the new technical specification (see Addendum 2 to Volume 4 of January 2009) has to be confirmed. See reporting table 2(9)	**FMC February 2009**: We agree with the RMS analysis described on page 9-10 of the additional report to Annex C.	**RMS,** 25 February 2009**:** On pages 9-10 of the additional report to Annex C the equivalence of batch E2876:8 with the new technical specification has been demonstrated. The batch E2876:8 was used in all the subchronic toxicity studies, the *in vitro* genotoxicity studies, the chronic – carcinogenicity studies and in the 2-generation reproductive toxicity study. This batch was also used in the majority of the acute toxicity studies. Therefore, from a toxicological point of view, the available data demonstrating the equivalence of E2876:8 to the new technical specification are considered sufficient. No data are available on the impurity profile of the batches used in the rest of the toxicity studies.	PRAPeR TC 08 (4 March 2009): Open point still open. The toxicological equivalence of the batches used in the mammalian toxicity studies and the proposed technical specification cannot be concluded, as well as the relevance of the impurities 8 and 17. New data gaps 2.1 and 2.2 proposed, see below.
	New data gap 2.1 identified at PRAPeR TC 08 meeting: The potential for genotoxicity of the impurity [redacted] has to be			PRAPeR TC 08 (4 March 2009): Data gap open. Written procedure: Data gap still open.

Rapporteur: GR

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
	addressed by the applicant.			
	New data gap 2.2 identified at PRAPeR TC 08 meeting: The potential for genotoxicity of the impurity [redacted] has to be addressed by the applicant.			PRAPeR TC 08 (4 March 2009): Data gap open. Written procedure Data gap still open.
	Message from section 1 (Phys-Chem) to the meeting on mammalian toxicology: Can you accept the specification as given on page 4 of addendum 2 to Vol. 4?			PRAPeR TC 08 (4 March 2009): Answer: The mammalian toxicology meeting accepted the specification as given on page 4 of addendum 2. Additionally, further deletions in the technical specification during the phys-chem meeting were proposed and an opinion of the mammalian toxicology meeting was required. Considering the high toxicity of cadusafos and the available information including the level tested in the tox batches the experts agreed with this proposal. See also open point 2.1. After written procedure: Except for the 2 impurities [redacted] the levels proposed for the impurities were considered acceptable.

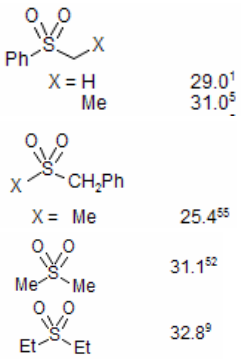
No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
	Open point: 2.2 Further consideration 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 reporting table 2(10)	**FMC February 2009:** -the parameters were gathered from the field and therefore represent the field conditions of use of the product - the release in time study is a GLP one and gives an indication of the behaviour of the active when use by drip irrigation. - we agree with the conclusions of the RMS in the Addendum of Vol 3 (June 2005).	**RMS,** 25 February 2009**:** A safe scenario has been identified under specific conditions (formulation of encapsulated cadusafos, drip irrigation, application rate of 1ha/day). Thus, at this stage there is no need for further data.	PRAPeR TC 08 (4 March 2009): Open point fulfilled. New open points 2.5 and 2.6 identified see below.
	New open point 2.5: RMS to provide an addendum with revised operator exposure estimates for a lower application rate of 4 kg as/ha (instead of 6 kg as/ha).			PRAPeR TC 08 (4 March 2009): Open point open. RMS: The operator exposure estimates for the application rate of 4 kg as/ha are presented in Addendum 3, June 2005. Written procedure: Open point fulfilled.
	New open point 2.6: RMS to update the LOEP with the amount of cadusafos released from the microcapsules and the final exposure estimates.			PRAPeR TC 08 (4 March 2009): Open point open. RMS: The LoEP has been updated.

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
				Written procedure: Open point fulfilled.
	New open point: 2.3 The results of the discussions in ECB about classification and labelling of cadusafos have to be reflected by the RMS. See reporting table 2(13)	**FMC February 2009:** From the summary record dated August 2007, of the TCC&L meeting (March 2006), "the TC C&L agreed to classify cadusafos with T=, R26/27-T; R25. The labelling would then be the symbol: T+ and the R-phrases: 25-26/27 and the S-phrases: (1/2)13-36/37-45-63. RMS had added already the R – phrases in the additional report. Applicant agrees that **RMS should add now the S-phrases as per ECB conclusions.**	**RMS,** 25 February 2009**:** Concerning the C&L of cadusafos the results of the discussions held at ECB meetings on 2006 are available at the ECB site (http://ecb.jrc.ec.europa.eu/classification-labelling/search-classlab/) and include the following classification with regard to health effects: T+; R26/27 T; R25 and the safety phrases: S1/2-13-36/37-45-63	PRAPeR TC 08 (4 March 2009): Open point still open. RMS to send to EFSA the confirmation of the agreed classification on the ECB in order to update the EFSA Conclusion. RMS: All the required information has been sent to EFSA. Written procedure: Open point fulfilled.
	New open point 2.4 The toxicological relevance of the ground water metabolite methyl-2-butyl sulfone to be discussed.			PRAPeR TC 08 (4 March 2009): Open point still open. Pending on the confirmation of the level of the metabolite methyl-2-butyl sulfone in the groundwater, further information on its toxicological relevance should be provided by the applicant. Written procedure: Open point turned into a pending data gap.

3. Residues

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
	Section 3 Open points: ***0*** Points for clarification: ***0*** Data gaps: ***0***			

4. Environmental fate and behaviour

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
	Section 4 Open points: ***10*** Points for clarification: ***0*** Data gaps: ***0***			Section 4 Open points: ***0*** Points for clarification: ***0*** Data gaps: ***3***
	Open point: 4.1 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 4(2)	**FMC-February 2009:** There is no expectation of pH dependence on the adsorption/desorption characteristics of methyl-2-butyl sulfone. A strong base is required to dissociate the molecule. Strong bases (e.g. sodium amide or potassium hydroxide) are not anticipated to be present within environmentally relevant pH ranges for EU soils. Unlike many other pesticide sulfones, methyl-2-butyl sulfone, with only limited small chain alkyl substutients, is a weak nucleophile and will only release its slightly acidic hydrogen upon addition of a strong base. The pKa is estimated to lie within the region of pH >10.	**RMS,** 25 February 2009**:** From open literature: pKa (in DMSO) of various sulfones around 30, e.g.,  http://www.chem.wisc.edu/areas/reich/pkatable/, therefore very weak acids	PRAPeR TC 07 (4 March 2009): Open point fulfilled. New data gap proposed, see below.
	New data gap 4.1 identified at PRAPeR TC 07 meeting: A guideline batch adsorption study on 3 soils is necessary			PRAPeR TC 07 (4 March 2009): Data gap open. Written Procedure

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
	for methyl-2-butyl-sulfone.			Data gap open The data gap is included in the updated EFSA conclusion
	Open point: 4.2 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. See reporting table 4(3)	**FMC-February 2009:** The FOCUS PEARL and PELMO citrus scenarios for Southern Europe can be considered reasonable surrogates for the Canary Islands given the assumptions of no crop interception, comparable to higher precipitation/applied irrigation patterns, similar volumetric field capacity, and wilting points. The predictions of both widely accepted EU models consisting of PEARL and PELMO indicate a safe use (values below the 0.1 g/L trigger) within standard scenarios in which the Jarvis paper identifies as an acceptable surrogate (citrus). The main difference noted in the Jarvis paper is related to the hydrologic group soil series classification where the Canary Islands soil is considered potentially more vulnerable to leaching. The comparison is performed to an only single point soil of Tenerife. It is difficult to ascertain whether this is representative or not of the Canary Islands as a whole and has not been through the rigorous reviews for representativeness that has occurred for the FOCUS scenarios.	**RMS,** 25 February 2009**:** 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.**	PRAPeR TC 07 (4 March 2009): Open point fulfilled. New data gap proposed, see below.
	New data gap 4.2 identified at PRAPeR TC 07 meeting: Groundwater simulations using PEARL and PELMO or PRZM and the FOCUS climate scenario definition for			PRAPeR TC 07 (4 March 2009): Data gap open. Written Procedure

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
	Sevilla in combination with the soil hydrological parameterisation described in the scenario that was outlined in the modelling report 'Jarvis T (2005) Predicted Environmental Concentrations of Cadusafos in Surface Water Following Use on Bananas in the Canary Islands FMC Chemical sprl, Brussels Belgium, Study No : FM22305-1'. Simulations to include application dates that cover all the possible application times for bananas. For cadusafos if just the available data are utilised a geomean single first order laboratory soil DT50 (at FOCUS reference conditions normalised using an appropriate Q10 and Walker coefficient of 0.7) and KFoc of 227mL/g and 1/n= 0.988 should be used as input. Inputs for methyl-2-butyl-sulfone to be consequent to the results of the data gaps identified for additional soil adsorption investigations and soil degradation rate data for this metabolite. An			Data gap open The data gap is included in the updated EFSA conclusion

<table>
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<tr><td></td><td>appropriate kinetic formation fraction for methyl-2-butyl-sulfone from cadusafos should be used (derived in accordance with FOCUS kinetics guidance). In the currently available acceptable study this value is 0.315.</td><td></td><td></td><td></td></tr>
<tr><td></td><td>Open point: 4.3
RMS to provide groundwater simulations with the PEARL model that covers all the possible application timings for banana.

See reporting table 4(5)</td><td>FMC-February 2009:

PEARL Modelling Parameters:

<table>
<tr><th>Parameter</th><th>Cadusafos</th><th>Methyl-2-Butyl Sulfone</th></tr>
<tr><td>Molar Mass (g/mol)</td><td>270.4</td><td>136.21</td></tr>
<tr><td>Vapour pressure (Pa, 25°C)</td><td>0.1196</td><td>60.53</td></tr>
<tr><td>Formation fraction</td><td>NA</td><td>0.315</td></tr>
<tr><td>Water solubility (mg/L, 20°C)</td><td>245</td><td>48680</td></tr>
<tr><td>Plant uptake factor</td><td>0</td><td>0</td></tr>
<tr><td>Soil DT_{50} (days, 20°C, pF2.0)</td><td>52.57</td><td>4.5</td></tr>
<tr><td>K_{OC} (mL/g)</td><td>227</td><td>30.2</td></tr>
</table></td><td>RMS, 25 February 2009:
Pending on expert’s discussions on points 4(2), 4(3), 4(7), 4(8), 4(9) and 4(11) of the reporting table.

e.g., The 1/n value of the metabolite that was originally assumed same as the parent’s (i.e., 0.99) could be replaced by
a 1/n value of 1.</td><td>PRAPeR TC 07 (4 March 2009):

Open point closed.
Open point superseded by data gap 4.2 for further groundwater modelling.</td></tr>
</table>

<table>
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Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure</th></tr>
<tr><td></td><td></td><td>
<table>
<tr><td>K_{OM} (mL/g)</td><td>131.67</td><td>17.52</td></tr>
<tr><td>Freundlich exponent</td><td>0.99</td><td>0.99</td></tr>
<tr><td>Crop</td><td colspan="2">Citrus</td></tr>
</table>
NA not applicable

These parameters are as used in the modelling reported in Jones, RJ (2008) FOCUS PELMO Modeling for Cadusafos on Bananas, P-3967, except as follows:

• Parent soil DT_{50} was the geometric mean of the laboratory studies, as reported (adjusted to 20°C) by the RMS:
•
<table>
<tr><th colspan="2">Lab soil DT50</th></tr>
<tr><td></td><td>77.9</td></tr>
<tr><td></td><td>70.3</td></tr>
<tr><td></td><td>18.4</td></tr>
<tr><td></td><td>62.3</td></tr>
<tr><td></td><td>62.1</td></tr>
<tr><td></td><td>50.9</td></tr>
<tr><td></td><td>58.2</td></tr>
<tr><td></td><td>50.5</td></tr>
<tr><td></td><td></td></tr>
<tr><td>geomean:</td><td>52.57</td></tr>
</table>
• The formation fraction for Methyl-2-Butyl
</td><td></td><td></td></tr>
</table>

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Sulfone (MBS) was taken as 0.315, as derived by the RMS.

The GAP for use of cadusafos on bananas is one application at 4 kg a.s./ha in either autumn or spring. In Spain, this corresponds to the end of February/beginning of March (for Spring) and in September/October for autumn. Therefore, for the modelling three application dates were run separately, with no crop interception:

- 1 March
- 15 September
- 15 October

FOCUS PEARL: cadusafos use on bananas (FOCUS citrus), at 4 kg a.s./ha

Scenario	**Application Date**	**80th percentile PEC_{GW} (µg/L)**	
		Cadusafos	**MBS**
Piacenza	1 Mar	16.715	0.811
Porto		**0.038**	**0.013**
Sevilla		5.411	0.390
Thiva		5.375	0.263
Piacenza	15 Sep	25.827	1.594
Porto		0.120	0.047

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
		Sevilla 5.991 0.442 **Thiva** 9.148 0.445 **Piacenza** 24.930 1.476 15 Oct **Porto** 0.124 0.038 **Sevilla** 7.761 0.625 **Thiva** 11.141 0.547		
	Open point: 4.4 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 4(7)		**RMS,** 25 February 2009**:** The 1/n value of the metabolite was originally assumed same as the parent's. A 1/n value of 1 could be used as input.	PRAPeR TC 07 (4 March 2009): Open point closed. Open point superseded by the data gap 4.1 for guideline batch adsorption studies for methyl-2-butyl-sulfone.
	Open point: 4.5 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		**RMS,** 25 February 2009**:** We welcome the discussion.	PRAPeR TC 07 (4 March 2009): Open point fulfilled. New open point proposed, see below.

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	soil are retained). See reporting table 4(8)			
	New open point: 4.12 RMS to add the single first order DT50 for methyl-2-butyl-sulfone of 4.5 days and its kinetic formation fraction of 0.315 to soil laboratory degradation rate box to the LoEP, indicating that this value is at 25°C and 75%field capacity soil moisture. In addition, a value normalised to FOCUS reference conditions should also be added (normalised using a Q10 of 2.2 and Walker coefficient of 0.7).		RMS (17 March 2009): LoEP has been amended accordingly	PRAPeR TC 07 (4 March 2009): Open point open. Written Procedure Open point fulfilled The list of endpoints was appropriately updated by the RMS.
	Open point: 4.6 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 reporting table 4(9)	**FMC-February 2009:** EFSA concluded (Scientific report, 2006) that methyl-2-butyl sulfone exhibits low persistence and from the laboratory study available, the DT50 (4.5 d) was appropriate for a groundwater risk assessment. However, further information can be provided at MS level, looking for different type of soils.	**RMS,** 25 February 2009**:** RMS agrees with Notifier.	PRAPeR TC 07 (4 March 2009): Open point fulfilled. New data gap proposed, see below. New open point proposed, see below.
	New data gap 4.3 identified at			PRAPeR TC 07 (4 March 2009):

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	PRAPeR TC 07 meeting: Aerobic soil DT50 are required for methyl-2-butyl-sulfone in at least 2 additional soils.			Data gap open. Written Procedure Data gap open The data gap is included in the updated EFSA conclusion
	New open point: 4.13 RMS to indicate in the LoEP soil aerobic laboratory rate of degradation box that a data gap is identified for aerobic soil DT50 for methyl-2-butyl-sulfone in at least 2 additional soils.		RMS (17 March 2009): LoEP has been amended accordingly	PRAPeR TC 07 (4 March 2009): Open point open. Written procedure Open point fulfilled The LoEP was updated as requested by the RMS
	Open point: 4.7 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. See reporting table 4(10)	**FMC-February 2009:** PEARL and PELMO modelling inputs described in open point 4.3 and 4.8.	**RMS,** 25 February 2009**:** A Q10 value of 2.2 was used. See attached output PELMO files (sections highlighted in yellow) and Notifier comments to open points 4.3 and 4.8.	PRAPeR TC 07 (4 March 2009): Open point fulfilled.
	Open point: 4.8 RMS to provide Pelmo	**FMC-February 2009:**	**RMS,** 25 February 2009**:**	PRAPeR TC 07 (4 March 2009):

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<tr><td></td><td>simulations to cover the range of possible application dates.

See reporting table 4(11)</td><td>PELMO Modelling Parameters:

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</table>
NA not applicable

These parameters are as used in the modelling reported in Jones, RJ (2008) FOCUS PELMO Modeling for Cadusafos on Bananas, P-3967, except as follows:</td><td>Pending on expert’s discussions on points 4(2), 4(3), 4(7), 4(8), 4(9) and 4(11) of the reporting table.</td><td>Open point closed.
Open point superseded by data gap 4.2 for further groundwater modelling.</td></tr>
</table>

<table>
<tr><th>No.</th><th>Column A
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Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure</th></tr>
<tr><td></td><td></td><td>
• Parent soil DT_{50} was the geometric mean of the laboratory studies, as reported (adjusted to 20°C) by the RMS:
<table>
<tr><th colspan="2">Lab soil DT50</th></tr>
<tr><td></td><td>77.9</td></tr>
<tr><td></td><td>70.3</td></tr>
<tr><td></td><td>18.4</td></tr>
<tr><td></td><td>62.3</td></tr>
<tr><td></td><td>62.1</td></tr>
<tr><td></td><td>50.9</td></tr>
<tr><td></td><td>58.2</td></tr>
<tr><td></td><td>50.5</td></tr>
<tr><td></td><td></td></tr>
<tr><td>geomean:</td><td>52.57</td></tr>
</table>
• The formation fraction for Methyl-2-Butyl Sulfone (MBS) was taken as 0.315, as derived by the RMS.

The GAP for use of cadusafos on bananas is one application at 4 kg a.s./ha in either autumn of spring. In Spain, this corresponds to the end of February/beginning of March (for Spring) and in September/October for autumn. Therefore, for the modelling three application dates were run separately, with no crop interception:
• 1 March
• 15 September
</td><td></td><td></td></tr>
</table>

<table>
<tr><th>No.</th><th>Column A
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Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure</th></tr>
<tr><td></td><td></td><td>• 15 October

<table>
<tr><th rowspan="2">Scenario</th><th rowspan="2">Application Date</th><th colspan="2">80th percentile PECGW (µg/L)</th></tr>
<tr><th>Cadusafos</th><th>MBS</th></tr>
<tr><td>Piacenza</td><td rowspan="4">1 Mar</td><td>2.105</td><td>0.099</td></tr>
<tr><td>Porto</td><td>0.004</td><td>0.002</td></tr>
<tr><td>Sevilla</td><td>0.102</td><td>0.014</td></tr>
<tr><td>Thiva</td><td>0.328</td><td>0.021</td></tr>
<tr><td>Piacenza</td><td rowspan="4">15 Sep</td><td>4.056</td><td>0.254</td></tr>
<tr><td>Porto</td><td>0.013</td><td>0.009</td></tr>
<tr><td>Sevilla</td><td>0.297</td><td>0.036</td></tr>
<tr><td>Thiva</td><td>0.973</td><td>0.073</td></tr>
<tr><td>Piacenza</td><td rowspan="4">15 Oct</td><td>3.914</td><td>0.231</td></tr>
<tr><td>Porto</td><td>0.017</td><td>0.012</td></tr>
<tr><td>Sevilla</td><td>0.067</td><td>0.012</td></tr>
<tr><td>Thiva</td><td>0.564</td><td>0.042</td></tr>
</table>
</td><td></td><td></td></tr>
<tr><td></td><td>Open point: 4.9
Member State experts to discuss and agree the residue definition for groundwater exposure assessment and consideration by other disciplines.</td><td>The calculations with Focus PELMO show several passing scenarios where the predicted concentrations in groundwater remain below the trigger value of 0.1 µg/l for both cadusafos and methyl-2-butylsulfone. In addition, the toxicological and metabolism studies did not highlight the toxicological relevance of this metabolite. The residue definition in groundwater should remain the parent cadusafos only.</td><td>RMS, 25 February 2009:

Pending on the outcome of the expert’s meeting.</td><td>PRAPeR TC 07 (4 March 2009):

Open point fulfilled.
New open point proposed, see below.</td></tr>
</table>

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
	See reporting table 4(18)			
	New open point: 4.14 RMS to update the LoEP residue definition for which groundwater exposure assessment was triggered or consideration would be required by other disciplines to indicate: Soil: cadusafos Groundwater: cadusafos and methyl-2-butyl-sulfone Surface water: cadusafos Sediment: cadusafos Air: cadusafos		RMS (17 March 2009): LoEP has been updated accordingly	PRAPeR TC 07 (4 March 2009): Open point open. Written Procedure Open point fulfilled The LoEP was appropriately updated as requested by the RMS.
	Open point: 4.10 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 reporting table 4(20)	**FMC February 2009:** see comment of open point 5.16 below	**RMS,** 25 February 2009**:** We welcome the discussion.	PRAPeR TC 07 (4 March 2009): Open point fulfilled. New open points 4.15 and 4.16 proposed, see below.
	New open point: 4.15 RMS to add a footnote in the list of end points that concentration in soil next to the drip irrigation system will		RMS (17 March 2009): LoEP has been amended accordingly	PRAPeR TC 07 (4 March 2009): Open point open. Written Procedure

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
	be six times higher than the ones presented in the table.			Open point fulfilled The LoEP was appropriately updated as requested by the RMS.
	New open point: 4.16 EFSA to indicate in the conclusion the particular conditions of use assumed in the soil assessment that resulted in the estimate that only 16 % of the area is actually treated.			PRAPeR TC 07 (4 March 2009): Open point open. Written Procedure Open point fulfilled The information was included in the updated EFSA conclusion.
	New open point : 4.11 RMS to update the LoEP in accordance with the discussion table: The original entry for PEC surface water and sediment for bananas should be reinstated, so it is in line with the EFSA conclusion LoEP finalised April 2006. The original entry for PEC groundwater for bananas should be reinstated, in line with the EFSA conclusion LoEP finalised April 2006, as the groundwater exposure is still not appropriately assessed.		RMS (17 March 2009): LoEP has been amended accordingly	PRAPeR TC 07 (4 March 2009): Open point open. Written Procedure Open point fulfilled The LoEP was appropriately updated as requested by the RMS.

5. Ecotoxicology

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
	Section 5 Open points: ***17*** Points for clarification: ***0*** Data gaps: ***0***			Section 5 Open points: ***6*** Points for clarification: ***0*** Data gaps: ***8***
	Open point: 5.1 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 reporting table 5(1)	**FMC-February 2009**: The risk assessment to birds provided in the additional report is a refinement of the one in the Addendum of May 2005. In the additional report, more details and information are provided regarding the data source and the occurrence of birds and mammals in the banana plantation in the Canary Islands. However this risk assessment took into account conservative standard assumptions such as a depth of 0.05 m for the initial PEC calculations, knowing that during the drip irrigation, the product spreads in the first 15-20 cm around the roots of the banana plants guaranteeing its nematicide/insecticide effect. It would therefore be interesting and more accurate to refine the risk assessment in that sense.	**RMS,** 25 February 2009**:** A more pragmatic risk assessment is provided in addition following the current GD for birds and mammals (SANCO/4145/2000) taking into consideration RUD values according to Fletcher et al. (1994) and Fischer and Bowers (1997) (Appendix II, table 10) rather than using RUD of endogaeic arthropods (living in the soil) to be equal to initial PECsoil. **RMS,** 17 March 2009**:** A new risk assessment has been provided and the LoEP has been amended accordingly.	PRAPeR TC 09 (5-6 March 2009): Open point open. RMS to update the risk assessment for birds according to the recommendations in the expert meeting. (refer to Discussion table). Written procedure Open point fulfilled. LoEP was updated.
	Open point: 5.2 MSs to discuss the relevance of measured residues on	**FMC-February 2009**: Since cadusafos will spread to a greater depth (15-20 cm) than the standard assumption (5 cm) used in the calculation of soil	**RMS,** 25 February 2009**:** We welcome a discussion on this topic.	PRAPeR TC 09 (5-6 March 2009):

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
	earthworms to refine the risk for earthworm-eating birds and mammals. See reporting table 5(2)	concentration, the laboratory derived residues are 3-4 times greater than the highest expected field residues. Drip irrigation close to the tree trunk confines the cadusafos to proximity of the trees. Calculation that 84% of the area of the plantation will be uncontaminated resulting in markedly lower mean earthworm residues.		Open point fulfilled. New open point proposed, see below.
	New open point: 5.18 RMS to recalculate the first-tier TERs for earthworm-eating birds and mammals based on the standard approach (PECsoil, Kow, Koc). It should be checked whether a reliable BCF can be derived from the earthworm reproduction study. If so, then this BCF can be used in the refined risk assessment for earthworm-eating birds and mammals.		**RMS,** 17 March 2009**:** A new risk assessment has been provided and the LoEP has been amended accordingly.	PRAPeR TC 09 (5-6 March 2009): Open point open. Written procedure Open point fulfilled. LoEP was updated.
	Open point: 5.3 MSs to discuss the relevance of blackbird as focal species for risk assessment of cadusafos in banana plantations. See reporting table 5(3)	**FMC-February 2009:** According to the two main sources of information about the distribution of birds in banana plantations on the Canary Islands (**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, and **Martín, A., Lorenzo, J.A. (2001)**. Aves del Archipiélago Canario. Francisco Lemus Editor. La Laguna.), blackbirds are the most abundant species in banana plantations foraging on ground dwelling invertebrates. Hence,	**RMS,** 25 February 2009**:** 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.	PRAPeR TC 09 (5-6 March 2009): Open point fulfilled. Data gap proposed, see below.

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
		this species should be considered as the focal species.		
	New data gap 5.1 identified at PRAPeR TC 09 meeting: The risk to ground feeding small insectivorous birds needs to be addressed (e.g. grey wagtail was abundant in banana plantations).			PRAPeR TC 09 (5-6 March 2009): Data gap open. Written procedure Data gap remains open.
	Open point: 5.4 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 reporting table 5(4)	**FMC-February 2009:** No new data has to be taken account. The report 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) is mentioned on the reference list on page 70 in the "additional report". The data presented in the "additional report" (section B. 9.1.4) is taken from this report. Hence, both documents provide the same data.	**RMS,** 25 February 2009**:** No new data was taken into account. 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.	PRAPeR TC 09 (5-6 March 2009): Open point fulfilled. New data gap proposed, see below.

<table>
<tr><th>No.</th><th>Column A
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Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure</th></tr>
<tr><td></td><td>New data gap 5.2 identified at PRAPeR TC 09 meeting:
Applicant to submit the articles on which the literature review was based on. On the basis of the information included in the dossier it was not possible to judge the reliability of the literature review of Giessing, B. 2005.</td><td></td><td></td><td><u>PRAPeR TC 09 (5-6 March 2009):</u>

Data gap open.

<u>Written procedure</u>
Data gap remains open.</td></tr>
<tr><td></td><td>Open point: 5.5
MSs to discuss the use of initial PECsoil as RUD. Since the logPow of cadusafos is greater than 3, residues can accumulate in insects.

See reporting table 5(5)</td><td>FMC-February 2009:
The soil PECs were calculated (Table below; Crop: Banana, Application dose: 4000 g a.i./ha, Inc. depth: 0.05 m, DT_{50}=61 d, single application, fraction intercepted by the plant=0% m).

Initial PECs are the worst-case values that were generated, considering that in reality, the product spreads under 15-20 cm and not as assumed, on the first 5 cm of soil from, depth at which it wouldn’t reach the targeted nematodes and some soil insects and therefore wouldn’t be efficient. This initial PECs should be 3 to 4 time lower.

Worst-case was assessed according to these PECs from the 3 May 2005 Addendum and in the additional report.

$PEC_{(s)}$ (mg/kg)
<table><tr><td>Single application Actual</td><td>Single application Time weighted average (DT_{50}: 61 d)</td></tr></table></td><td>RMS, 25 February 2009:
A new risk assessment is provided in an Addendum 1 to Additional Report (B.9).
A more pragmatic risk assessment is provided in addition following the current GD for birds and mammals (SANCO/4145/2000) taking into consideration RUD values according to Fletcher et al. (1994) and Fischer and Bowers (1997) (Appendix II, table 10) rather than using RUD of endogaeic arthropods (living in the soil) to be equal to initial PECsoil.</td><td><u>PRAPeR TC 09 (5-6 March 2009):</u>

Open point fulfilled.

New open point proposed, see below.</td></tr>
</table>

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
		(DT_{50}: 61 d) Initial 5.333 5.333 Short term 5.273 5.303 5.213 5.273 24h 5.096 5.214 2d 4d Long term 4.926 5.127 7d 3.880 4.568 3.022 4.069 28d 1.712 3.187 50d 100d		
	New open point: 5.19 RMS to recalculate the TER values for insectivorous birds based on new PECsoil (PECsoil as a surrogate for the residues on insects).		**RMS,** 17 March 2009**:** A new risk assessment has been provided and the LoEP has been amended accordingly.	PRAPeR TC 09 (5-6 March 2009): Open point open. Written procedure Open point fulfilled. LoEP was updated.
	Open point: 5.6 MSs to discuss if the risk assessment for birds and	**FMC-February 2009:** According to common practices in Spain spring application is conducted around Feb until Mid March and autumn application	**RMS,** 25 February 2009**:** We welcome a discussion on this topic.	PRAPeR TC 09 (5-6 March 2009):

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
	mammals can be considered addressed for both spring and autumn application. Furthermore, the PD refinements should be agreed. See reporting table 5(6)	in Sept – Oct. The diet data presented in the refinement for blackbirds describes the situation in spring. Hence this scenario is covered. In autumn – due to seasonal highest food availability in general - there are even more alternative food sources available. It is highly unlikely that the blackbirds diet will consist solely (or a higher percentage) of animal feed items; rather, the majority of its diet is likely to consist of fall berries and fruits from the islands. Therefore the expected utilisation of highly exposed food items should be even lower than considered in the risk assessment, and will be therefore covered by the spring scenario data, too. For the Algerian Hedgehog worst case assumptions were considered in terms of diet consumption. Hence for birds and mammals actual consumption of contaminated food should even be lower than presented in the refined risk assessment.		Open point fulfilled. New data gap proposed, see below.
	New data gap 5.3 identified at PRAPeR TC 09 meeting: Studies to support the suggested PD values are missing. The information should also address potential differences in the seasonal composition of the diet (autumn and spring application).			PRAPeR TC 09 (5-6 March 2009): Data gap open. Written procedure Data gap remains open.
	Open point: 5.7 MSs to discuss and agree the PT refinements used for risk assessment for birds. See reporting table 5(10)	**FMC-February 2009**: The focal species chosen represent resident rather than migratory species. Consequently, they are considered representation of fauna of the Canary Islands (as clearly stated in the references used in the Rifcon report by B. Giessing). The	**RMS,** 25 February 2009**:** We welcome a discussion on this topic.	PRAPeR TC 09 (5-6 March 2009): Open point fulfilled. New data gap proposed, see

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
		original and preferred habitat of blackbirds is forests and scrubland. Banana plantations differ notably from this prime habitat and can therefore be considered as similar to orchards (man-made environment, homogeneous landscape). Therefore results from the UK radio-tracking study in orchards (Crocker et al., 1998) where 43 blackbirds were monitored, can be considered as surrogate data in the absence of information from banana plantations because of the similarities in the landscape structure. As the bananas plantations is not prime habitat then it can be expected that PT for the banana plantations in the Canary islands is lower.		below. New open point proposed, see below.
	New data gap 5.4 identified at PRAPeR TC 09 meeting: Justification is needed for the extrapolation of PT values from UK orchard studies to banana plantations.			PRAPeR TC 09 (5-6 March 2009): Data gap open. Written procedure Data gap remains open.
	New open point: 5.20 RMS to recalculate the TERs without PT refinement(acute) and the 95th percentile PT for the chronic risk assessment. A footnote should be included in the LoEP explaining that the PT refinement was based on UK data.		**RMS,** 17 March 2009**:** A new risk assessment has been provided and the LoEP has been amended accordingly.	PRAPeR TC 09 (5-6 March 2009): Open point open. Written procedure Open point fulfilled. LoEP was updated.
	Open point: 5.8 MSs to agree that the mode of application of cadusafos (drip-	**FMC-February 2009**: Drip irrigation system loses practically no water to runoff, deep percolation, evaporation, and reduces water contact with the	**RMS,** 25 February 2009**:** It is considered conservative for estimating the potential	PRAPeR TC 09 (5-6 March 2009):

<table>
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<tr><td></td><td>irrigation) does not cause exposure of ground dwelling arthropods and therefore the residue on epigaeic arthropods can be considered negligible.

See reporting table 5(11)</td><td>crop. In terms of "subsurface drip irrigation" a drip tape or tube is buried below the soil surface. The product can be applied more efficiently with drip irrigation, since only the crop root zone is irrigated; this zone of irrigation goes into 15-20 cm depth and remains localised to the surface around the roots.
In addition, assuming that epigaeic arthropods have same concentration as earthworms, we pass the TERS as below.

<table>
<tr><th>Diet items</th><th>Epigaeic arthropods</th><th>Endogaeic arthropods</th><th>Earthworms</th></tr>
<tr><td>Application rate (kg a.i/ha)</td><td>4.0</td><td>4.0</td><td>4.0</td></tr>
<tr><td>C (mg a.i/kg)</td><td>0.5</td><td>5.33</td><td>0.50</td></tr>
<tr><td>FIR</td><td>0.50</td><td>0.50</td><td>1.06</td></tr>
<tr><td>AV</td><td>1</td><td>1</td><td>1</td></tr>
<tr><td>PT</td><td>0.82* / 0.218^</td><td>0.82* / 0.218^</td><td>0.82* / 0.218^</td></tr>
<tr><td>PD</td><td>0.66</td><td>0.06</td><td>0.22</td></tr>
<tr><td>ETE</td><td>0.54* / 0.14^</td><td>0.13* / 0.03^</td><td>0.10* / 0.03^</td></tr>
<tr><td>ETE total</td><td colspan="3">0.77* / 0.2^</td></tr>
</table>

<table>
<tr><th>Scenario</th><th>ETE</th><th>Toxicity Daily dose</th><th>TER</th></tr>
<tr><td>Acute</td><td>0.77</td><td>16.1</td><td>21</td></tr>
</table></td><td>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.</td><td>Open point fulfilled.
Residues on epigaeic insects were considered negligible.</td></tr>
</table>

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
		<table><tr><td>Short-term</td><td>0.77</td><td>10.8</td><td>14</td></tr><tr><td>Long-term</td><td>0.2</td><td>1.1</td><td>55</td></tr></table> Furthermore, because drip irrigation confines the cadusafos to the proximity of the tree 84% of the area of a plantation will be uncontaminated. The majority of arthropods will have no exposure. Where exposure and adverse effect do occur, recolonisation of soil areas close to the trees will occur within a short time frame. Recovery can occur after 14 days from the drip irrigation event.		
	Open point: 5.9 MSs to discuss and agree the refined risk assessment to mammals provided in the additional report and the addendum. See reporting table 5(17)		**RMS,** 25 February 2009**:** We welcome a discussion on this topic. **RMS,** 17 March 2009**:** A new risk assessment has been provided and the LoEP has been amended accordingly.	PRAPeR TC 09 (5-6 March 2009): Open point open. RMS to update the risk assessment for mammals according to the recommendations in the expert meeting. (refer to Discussion table) Written procedure Open point fulfilled. LoEP was updated.
	Open point: 5.10 MSs to discuss the relevance of Algerian hedgehog (*Atelerix algirus*) as focal species for	According to 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) the Algerian hedgehog can be expected to occur in banana plantations. Because of the food	A report prepared by Rifcon proposes focal species according to recommendations provided in the SANCO/4145/2000	PRAPeR TC 09 (5-6 March 2009): Open point fulfilled.

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
	risk assessment of cadusafos in banana plantations. See reporting table 5(18)	preferences of its congener, the Western hedgehog (Erinaceus europaeus), the Algerian hedgehog is supposed to be the most likely candidate for the focal species in banana plantation.	guidelines. It can be discussed in an expert meeting.	New data gap proposed, see below.
	New data gap 5.5 identified at PRAPeR TC 09 meeting: The key studies which should support the choice of the focal species for risk assessment of cadusafos in banana plantations should be provided.			PRAPeR TC 09 (5-6 March 2009): Data gap open. Written procedure Data gap remains open
	Open point: 5.11 MSs to discuss and agree the PT refinements used for the risk assessment for mammals. See reporting table 5(22)	The habitat preferences of the Algerian hedgehog differ from the structure in banana plantations. The hedgehog mainly occurs in shrub-like habitats (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). Hence, the low PT of 0.1 is considered to be adequate.	**RMS,** 25 February 2009**:** We welcome a discussion on this topic.	PRAPeR TC 09 (5-6 March 2009): Open point fulfilled. New data gap proposed, see below.
	New data gap 5.6 identified at PRAPeR TC 09 meeting: Information needs to be provided to support the suggested PT refinement for the focal species suggested in the refined mammalian risk assessment.			PRAPeR TC 09 (5-6 March 2009): Data gap open. Written procedure Data gap remains open
	Open point: 5.12		**RMS,** 25 February 2009**:**	PRAPeR TC 09 (5-6 March

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
	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) See reporting table 5(23)		A new risk assessment is provided in an Addendum 1 to Additional Report (B.9). No comment.	2009): Open point fulfilled. See open point 5.6 and data gap 5.3.
	Open point: 5.13 MSs to discuss if cadusafos could be considered of low concern for the reproductive effects of mammals. See reporting table 5(25)	Cadusafos is applied once the year and breaks down quickly; therefore it is unlikely that long term effects due to frequent exposures occur. In addition, from the review of mammalian toxicity studies and ECB classification, no effects on the reproduction on mammals were identified. Furthermore, endpoints chosen are protective of maternal and reproductive effects.	**RMS,** 25 February 2009**:** 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).	PRAPeR TC 09 (5-6 March 2009): Open point fulfilled.
	Open point: 5.14 MSs to discuss if PD values based on studies with Western hedgehog	Since both species are close related (and were even the same species in the past, and split in two species by modern analytical methods) the food preferences of the Algerian hedgehog (*Atelerix algirus*) is not expected to differ notably	**RMS,** 25 February 2009**:** We welcome a discussion on this topic.	PRAPeR TC 09 (5-6 March 2009): Open point fulfilled.

No.	Column A Conclusions from the Reporting Table	Column B Comments from the notifier / applicant	Column C Rapporteur Member State comments on the notifier / applicant comments	Column D Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
	(*Erinaceus europaeus*) can be used for Algerian hedgehog (*Atelerix algirus*). See reporting table 5(31)	from the Algerian hedgehog (*Atelerix algirus*) and should reflect their similar nutritional requirements.		See open point 5.6 and data gap 5.3.
	Open point: 5.15 MS to discuss the relevance of the application time of cadusafos with respect to breading season of mammals in the canary islands. See reporting table 5(33)	There is no information that the reproductive periods of Algerian hedghogs (*Atelerix algirus*) on the Canary island differ from the population on the Spanish mainland (see e.g. http://en.wikipedia.org/wiki/Algerian_Hedgehog or Spanish Mammal Atlas).	**RMS,** 25 February 2009**:** We welcome a discussion on this topic.	PRAPeR TC 09 (5-6 March 2009): Open point fulfilled. See open point 5.10.
	Open point: 5.16 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 reporting table 5(34)	**FMC-February 2009:** The cadusafos from each dripper spreads in soil to a depth of 15-20 cm. If the horizontal spread through the soil was assumed to equal 20 cm per dripper then each dripper would treat an area of 0.13m^2. With six drippers per tree the treated area per tree would be 0.78 m^2. Normal spacing between banana trees in the Canary islands is 2.0 m within rows and either 2.5 m or 3.0 m between rows. Taking 2.5 m as worst case this gives an area occupied by each tree of 5 m^2. The treated soil area per tree (0.78m) therefore represents 16% of the total area per tree. Expanding this to the whole plantation it can be said that 16% of the surface area of soil of a banana plantation would be treated.	**RMS,** 25 February 2009**:** We welcome a discussion on this topic.	PRAPeR TC 09 (5-6 March 2009): Open point fulfilled.
	Open point: 5.17	**FMC-February 2009**:	**RMS,** 25 February 2009**:**	PRAPeR TC 09 (5-6 March

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	MSs to discuss the reliability of the earthworm field study to address the risk to earthworm population in banana plantation. See reporting table 5(43)	The UK field study is considered a representation, but in a way conservative one, of the potential chronic adverse effects to earthworm populations exposed to Rugby 200 CS for the following reasons: (i) the field study had similar earthworm species to bananas plantations in the Canary Islands and representatives of both epilobous and tanylobous worms (ii) the application rate proposed in bananas (4000 g as ha^{-1}) is lower than the rate used in the earthworm study (4500 g as ha^{-1}), (iii) the study involves irrigation after treatment, simulating a drip scenario but across the whole plot area, (iv) bananas are a crop that is highly irrigated and fertilized, increasing the rate of cadusafos degradation and thus reducing potential exposure. Therefore the results from the UK field study (i.e., recoverable effects to earthworm abundance and biomass) translate directly as a relevant “worst-case” in banana plantations.	We welcome a discussion on this topic.	2009): Open point fulfilled. New data gap proposed, see below. New open point proposed, see below.
	New data gap 5.7 identified at PRAPeR TC 09 meeting: Applicant to provide information on the potential of recolonisation of earthworms in the treated area in banana plantations or alternatively effects on earthworm populations in banana plantations			PRAPeR TC 09 (5-6 March 2009): Data gap open. Written procedure Data gap remains open
	New open point: 5.21 RMS to update the LoEP according to the suggestions of the experts: The LoEP needs to be		**RMS,** 17 March 2009**:** The LoEP has been amended accordingly.	PRAPeR TC 09 (5-6 March 2009): Open point open. Written procedure

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	updated with new application rates and PECsoil for the treated area. An explanatory footnote should be included (explaining the exposure situation – 16% of the area is treated).			Open point fulfilled. LoEP was updated.
	Message from section 1 (Phys-chem meeting): Can you accept the specification as given on page 4 of addendum 2 to Vol. 4?			PRAPeR TC 09 (5-6 March 2009): New data gap proposed, see below.
	New data gap 5.8 identified at PRAPeR TC 09 meeting: Applicant to provide information whether the batches used in the ecotox studies cover the specification given on page 4 of addendum 2 to Vol. 4.			PRAPeR TC 09 (5-6 March 2009): Data gap open. Written procedure Data gap remains open.