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REPORT OF PRAPeR EXPERT MEETING TC 06

CADUSAFOS

Rapporteur Member State: GR

Specific comments on the active substance in the section

1. Physical and Chemical Properties

are already listed in the relevant reporting table. Comments submitted for this meeting are listed below.

1. Comments submitted for this meeting:

Date	Supplier	File Name
none		

2. Documents submitted for meeting:

Date	Supplier	File Name
2009-02-25	GR	Cadusafos evaluation table rev 1-0 (2009-02-25).doc
January 2009	GR	Cadusafos_additional_report_addendum 2 to Vol 4 (January 2009).doc
2009-01-28	GR	Cadusafos_reporting table rev 1-1 (2009-01-28).doc
January 2009	GR	Cadusafos_updated list of endpoints (January 2009).doc

3. Documents tabled at the meeting:

Date	Supplier	File Name
none		

The conclusions of the meeting were as follows:

4. **Data on preparations:** Rugby 200 CS
5. **Classification and labelling:** not discussed
6. **Recommended restrictions/conditions for use:** none
7. **Reference list:** Not discussed

Areas of concern: None

Appendix 1: Discussion table: CADUSAFOS

Appendix 2: Evaluation table

Appendix 1: Discussion Table, Cadusafos (In, Ne)

1. Physical and Chemical Properties

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	<p>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 ethyl dichlorophosphate as starting material is redundant.</p> <p>See reporting table 1(2)</p>	<p>The meeting agreed that step one of the manufacturing process appears to be obsolete and they now purchase [REDACTED]. Open point fulfilled.</p> <p>New data gap: The purity of this new starting material has been identified as a data gap.</p>	<p>Open point fulfilled. New data gap proposed, see below.</p> <p>Data gap open.</p>
	<p>New data gap 1.2 identified at PRAPeR TC 06 meeting: Notifier to provide information about the purity of this new starting material (ethyl dichlorophosphate).</p>	<p>The meeting agreed that water content should be 0.7% and impurity [REDACTED] is removed.</p>	<p>Open point fulfilled. New data gap proposed, see below. Message sent to the tox and ecotox sections.</p>
	<p>Open point: 1.2 The acceptability of the technical specification to be discussed in a meeting of experts.</p>	<p>There are still impurities listed in the specification even when they are not found at significant levels in the batch analysis. The levels are well below 1 g/kg. It was agreed that the specification was not acceptable for impurities [REDACTED] (2nd Addendum to vol. 4) and further justification is required or the specification should be amended. The RMS is of the opinion that the current specification is acceptable.</p>	<p>Open point fulfilled. New data gap proposed, see below. Message sent to the tox and ecotox sections.</p>

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	See reporting table 1(3)	<p>Open point fulfilled.</p> <p>New data gap: Further justification is required for impurities [REDACTED] e.g QC data, or they should be removed from the specification.</p> <p>Message to Tox and Ecotox: Can you accept the specification as given on page 4 of addendum 2 to Vol. 4.</p>	Data gap open.
	<p>New data gap 1.3 identified at PRAPeR TC 06 meeting: Notifier to submit further justification (e.g QC data) for specifying impurities 1, 7, 8 and 10, or they should be removed from the specification.</p>	<p>The meeting agreed that the impurities in the batch analysis were measured and then the additive was added and the new values calculated. It was not clear why it was necessary to calculate the content of the additive and would this make a difference to the values in the specification. The meeting agreed that the difference with or without the additive will not be significant and it will not influence the specification.</p> <p>It was noted that the formula for the conversion given in the DAR was not correct, but the calculated values are accepted.</p>	<p>Open point fulfilled.</p> <p>It was noted that the formula for the conversion given in the DAR was not correct but the calculated values are accepted.</p>
	<p>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)</p>	<p>Open point fulfilled.</p> <p>It was discussed that there was no method for the copper additive, but it was agreed that a specific method is not required as there are standard methods (eg AAS) that can quantify the copper content and it was agreed that this is sufficient.</p>	Data gap closed.
	Data gap: 1.1	<p>The addition of the additive is just diluting the a.s. cadusafos and then the correct nominal value is added to the formulation. The original question was a misunderstanding.</p>	

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	<p>Applicant to clarify if an overage is used in the formulation due to the fact that addition of the additive 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.</p> <p>See reporting table 1(11)</p>	<p>Data gap obsolete.</p>	<p>The original question was a misunderstanding.</p>
	<p>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.</p> <p>See reporting table 1(16)</p>	<p>The issue was clarified: the rotational speed was 6 rpm and a spindle 2 was used but the real shear rate has not been provided. Without further information on the apparatus used, it is not possible to calculate the shear rate.</p> <p>Open point fulfilled.</p> <p>New data gap: The shear rate for the viscosity measurement has been identified as a data gap.</p>	<p>Open point fulfilled.</p> <p>New data gap proposed, see below.</p>
	<p>New data gap 1.4 identified at PRAPeR TC 06 meeting: Notifier to provide</p>		<p>Data gap open.</p>

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	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.	The entry new batch analysis can be deleted. Temperature of decomposition should be changed to not determined. For the residue definition for body fluid and tissues Cadusafos should be added.	Open point open.
	Message from section 1 to the meeting on mammalian toxicology (PRAPeR TC 08): Can you accept the specification as given on page 4 of addendum 2 to Vol. 4. (January, 2009)		Message sent to tox.
	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)		Message sent to ecotox.

Appendix 2: Evaluation table

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

No.	Column A	Column B	Column C	Column D
<p>Conclusions from the Reporting Table</p> <p>Section 1</p> <p>Open points: 4</p> <p>Points for clarification: 0</p> <p>Data gaps: 1</p>	<p>Comments from the notifier / applicant</p>	<p>Rapporteur Member State comments on the notifier / applicant comments</p>	<p>Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure</p> <p>Section 1</p> <p>Open points: 1</p> <p>Points for clarification: 0</p> <p>Data gaps: 3</p>	<p>PRAPeR TC 06 (4 March 2009):</p> <p>Open point fulfilled.</p> <p>New data gap proposed, see below.</p>
<p>Open point: 1.1</p> <p>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.</p> <p>See reporting table 1(2)</p>	<p>FMC February 2009:</p> <p>We agree. [redacted] is an intermediate produced by step 1 of the manufacturing process.</p>	<p>RMS, 25 February 2009:</p> <p>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 ethyl dichlorophosphate... 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.</p>	<p>PRAPeR TC 06 (4 March 2009):</p> <p>Data gap open.</p>	<p>PRAPeR TC 06 (4 March 2009):</p> <p>The acceptability of the</p>
<p>Open point: 1.2</p> <p>The acceptability of the</p>	<p>FMC- February 2009:</p> <p>We agree with RMS: impurities [redacted]</p>	<p>RMS, 25 February 2009:</p> <p>The revised proposed specifications of</p>	<p>PRAPeR TC 06 (4 March 2009):</p> <p>Data gap open.</p>	<p>PRAPeR TC 06 (4 March 2009):</p> <p>New data gap 1.2 identified at PRAPeR TC 06 meeting: Notifier to provide information about the purity of the new starting material (ethyl dichlorophosphate).</p>

No.	Column A	Column B	Column C	Column D
<p>Conclusions from the Reporting Table</p> <p>technical specification to be discussed in a meeting of experts.</p> <p>See reporting table 1(3)</p>	<p>Comments from the notifier / applicant</p> <p>██████████ can be removed from the specification.</p>	<p>cadusafos technical as presented in table 2 of the second addendum to Annex C are considered acceptable by the RMS. Impurity ██████████ (new code "impurity 6") should be deleted from table 2, as it was included there due to typing error.</p>	<p>Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure</p> <p>Open point fulfilled.</p> <p>New data gap proposed, see below.</p> <p>Message sent to the tox and ecotox sections.</p> <p>PRAPeR TC 06 (4 March 2009):</p> <p>Data gap open.</p>	
<p>New data gap 1.3 identified at PRAPeR TC 06 meeting: Notifier to submit further justification (e.g QC data) for specifying impurities 1, 7, 8 and 10, or they should be removed from the specification.</p> <p>Open point: 1.3</p> <p>The acceptability of presenting 5-batch data for impurities based on calculations should be discussed in a meeting of experts.</p> <p>See reporting table 1(10)</p>	<p>FMC February 2009:</p> <p>It should be noted that Copper naphthenate analysis is technically not feasible when mixed in cadusafos technical, in the sense that such analysis suffers to many interferences. Besides, ██████████ is ██████████ – as opposed to an impurity.</p>	<p>RMS, 25 February 2009:</p> <p>Since the determination of the organic impurities in the presence of copper naphthenate is not feasible, RMS accepts the notifier's approach via calculation.</p>	<p>PRAPeR TC 06 (4 March 2009):</p> <p>Open point fulfilled.</p> <p>It was noted that the formula for the conversion given in the DAR was not correct, but the calculated values are accepted.</p>	
<p>Data gap: 1.1</p> <p>Applicant to clarify if an overage is used in the formulation due to the fact that addition of the additive seems to consistently cause lower values in the a.s.</p>	<p>FMC February 2009:</p> <p>This is correct. An overage of technical material is used in order to meet the active ingredient content in terms of pure cadusafos. When formulating the product, the plant will consider the purity of the batch (impurities and additive taken into account) in order to</p>	<p>RMS, 25 February 2009:</p> <p>Clarification is acceptable by the RMS.</p>	<p>PRAPeR TC 06 (4 March 2009):</p> <p>Data gap closed.</p> <p>The original question was a misunderstanding.</p>	

No.	<u>Column A</u> Conclusions from the Reporting Table	<u>Column B</u> Comments from the notifier / applicant	<u>Column C</u> Rapporteur Member State comments on the notifier / applicant comments	<u>Column D</u> Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
	<p>content determination. However, it should be noted that additional information cannot be taken into account in the peer-review.</p> <p>See reporting table 1(11)</p>	<p>determine the quantity of technical material exactly equivalent to the targeted amount of pure cadusafos.</p>		
	<p>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.</p> <p>See reporting table 1(16)</p>		<p>RMS, 25 February 2009: No comment. To be discussed in a meeting of experts.</p>	<p><u>PRAPeR TC 06 (4 March 2009):</u> Open point fulfilled. New data gap proposed, see below.</p>
	<p>New data gap 1.4 identified at PRAPeR TC 06 meeting: Notifier to provide information about the shear rate for the viscosity measurement.</p>			<p><u>PRAPeR TC 06 (4 March 2009):</u> Data gap open.</p>
	<p>New open point 1.5 RMS to amend the list of end points according to the discussion table.</p>			<p><u>PRAPeR TC 06 (4 March 2009):</u> Open point open.</p>
	<p>Message from section 1 to the meeting on mammalian toxicology (PRAPeR TC 08): Can you accept the specification as given on</p>			<p><u>Answer from PRAPeR TC 08 (4 March 2009):</u> The Tox meeting accepted the specification as given on page 4 of</p>

No.	<u>Column A</u> Conclusions from the Reporting Table	<u>Column B</u> Comments from the notifier / applicant	<u>Column C</u> Rapporteur Member State comments on the notifier / applicant comments	<u>Column D</u> Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
	page 4 of addendum 2 to Vol. 4. (January, 2009)			<p>addendum 2.</p> <p>Additionally, further deletions in the TS during the phys-chem meeting were proposed and an opinion of the tox meeting was required.</p> <p>Considering the high toxicity of cadusafos and the available information including the level tested in tox batches the experts agreed with this proposal.</p>
	<p>Message from section 1 to the meeting on ecotoxicology (PRAPeR TC 09):</p> <p>Can you accept the specification as given on page 4 of addendum 2 to Vol. 4. (January, 2009)</p>			<p><u>Answer from PRAPeR TC 09 (5-6 March 2009):</u></p> <p>New data gap 5.8 has been identified at PRAPeR TC 09 meeting:</p> <p>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.</p>

REPORT OF PRAPeR EXPERT MEETING TC 07

CADUSAFOS

Rapporteur Member State: GR

Specific comments on the active substance in the section

4. Fate and behaviour in the environment

are already listed in the relevant reporting table. Comments submitted for this meeting are listed below.

1. Comments submitted for this meeting:

Date	Supplier	File Name
none		

2. Documents submitted for meeting:

Date	Supplier	File Name
2009-02-25	GR	Cadusafos evaluation table rev 1-0 (2009-02-25).doc
January 2009	GR	Cadusafos_additional_report_addendum 2 to Vol 4 (January 2009)_cover page.doc
2009-01-28	GR	Cadusafos_reporting table rev 1-1 (2009-01-28).doc
January 2009	GR	Cadusafos_updated list of endpoints (January 2009).doc
February 2009	GR	PELMO output file containing clarifications on the input parameters used in the model_Autumn_15_Oct (February 2009).doc
February 2009	GR	PELMO output file containing clarifications on the input parameters used in the model_Autumn_15_Sep (February 2009).doc
February 2009	GR	PELMO output file containing clarifications on the input parameters used in the model_Spring (February 2009).doc

3. Documents tabled at the meeting:

Date	Supplier	File Name
None		

The conclusions of the meeting were as follows:

4. **Data on preparations:** Rugby 200 CS
5. **Classification and labelling:** Not discussed
8. **Recommended restrictions/conditions for use:** Not discussed
9. **Reference list:** Not discussed

Areas of concern: The groundwater exposure assessment for cadusafos and methyl-2-butyl-sulfone could not be finalised.

Appendix 1: Discussion table: CADUSAFOS

Appendix 2: Evaluation table

Appendix 1: Discussion Table, Cadusafos (In, Ne)

4. Environmental fate and behaviour

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	<p>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.</p> <p>See reporting table 4(2)</p>	<p>The applicant provided a quantitative structure activity relationship (QSAR) estimation instead of a guideline adsorption/desorption study.</p> <p>The experts in the meeting agreed that a study would be required for this metabolite, since there is no technical reason or other justification provided not to perform a study. The need of a study was considered justified by the experts, because the available estimated ground water concentrations for methyl-2-butyl-sulfone are border line with respect to the 0.1µg/L trigger and the QSAR are expected to have up to one order of magnitude uncertainty. Even though the molecule is not expected to dissociate at environmentally relevant pH, the meeting considered that the adsorption /desorption study was necessary due to the reasons as outlined above. The meeting noted that the molecule is very soluble in water.</p> <p>The experts in the meeting identified a data gap for a guideline adsorption / desorption study for methyl-2-butyl-sulfone.</p>	<p>Open point fulfilled.</p> <p>New data gap proposed, see below.</p>
	<p>New data gap 4.1 identified at PRAPeR TC 07 meeting: A guideline batch</p>		<p>Data gap open.</p>

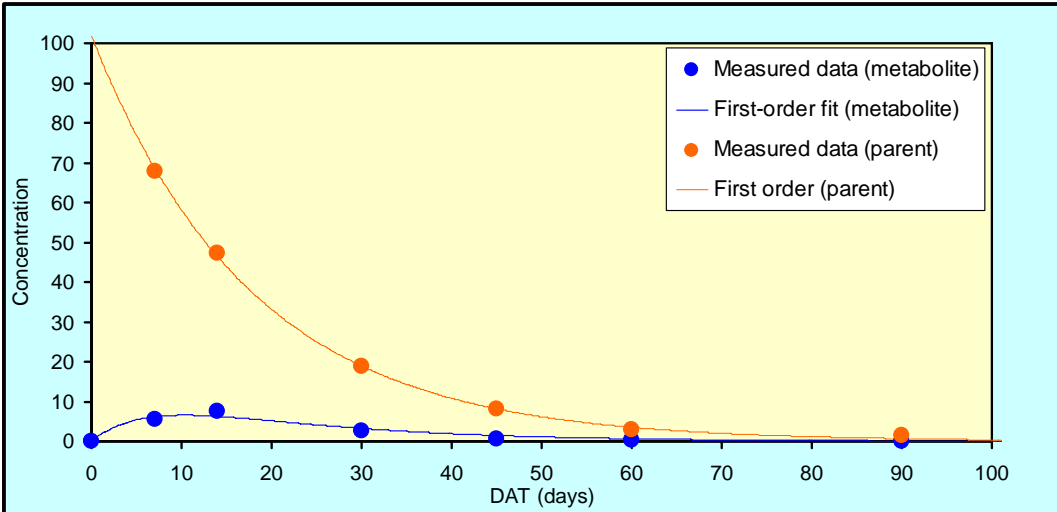
No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	adsorption study on 3 soils is necessary for methyl-2-butyl-sulfone.		
	<p>Open point: 4.2 Member State experts to discuss whether they can accept the standard FOCUS groundwater scenarios for Citrus or whether the soil parameterisation for the canary Islands as used in Jarvis, T (2005) should have been used.</p> <p>See reporting table 4(3)</p>	<p>In the original submission a specific scenario for banana in Tenerife (with respect to soil hydrology) was parameterised and used in the risk assessment. In the resubmission the assessment provided by the applicant was based on standard FOCUS GW scenarios for citrus.</p> <p>In the opinion of the RMS the Canary island soils are a very specific situation. However, in the original submission (as summarised in the EFSA conclusion of 2006) the applicant considered that the Canary island soils are more vulnerable for leaching than those in the Sevilla scenario. The experts agreed at that time with the use of the hybrid scenario for banana /citrus that reflected the situation (with respect to soil hydrology) in the Canary Islands. It was noted that the surface water assessment is still based on a Canary island scenario and it was agreed that it would not be consistent if the new ground water assessment was accepted that used soil hydrological descriptions that were not pertinent for Canary Island bananas. For surface water the available assessment assumed and accepted the case that in Tenerife there would not be run off because of the high infiltration capacity of the soil there. The use in banana in the EU is also very specific and the Canary island is one of the principle banana growing regions within the EU. All the other EU growing banana regions (for example Martinique or Guadalupe) are not expected to be represented by either standard FOCUS SW scenarios parameterised for citrus or by the Tenerife / Canary island scenario that was presented in the applicant's earlier submission (as summarised in the EFSA conclusion of 2006).</p> <p>One of the experts questioned whether the climatic data in Sevilla were relevant. The RMS indicated that some climatic data provided by the applicant indicated that the Sevilla scenario was the more similar to the Tenerife climatic data available. It was agreed that for pragmatic reasons the previous peer review exercise found that it was acceptable to use the Sevilla daily weather data for this assessment for a Tenerife banana scenario.</p> <p>The majority of the experts in the teleconference found more appropriate to have an assessment of a specific scenario for bananas such as the one presented in the original submission for Tenerife.</p> <p>The experts agreed that to be consistent with the available satisfactory surface water exposure assessment (that uses specific soil hydrological conditions for Tenerife), that the groundwater exposure assessment should also retain the Tenerife specific soil</p>	<p>Open point fulfilled.</p> <p>New data gap proposed, see below.</p>

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
		<p>hydrological parameterisation such as that, which was provided previously by the applicant as described in the modelling report Jarvis, T (2005). This was necessary as this Jarvis report indicated that the soil hydrology conditions in Tenerife in the banana growing areas were more vulnerable to leaching than the standard FOCUS Sevilla scenario.</p> <p>The experts therefore agreed a data gap for new PEARL and PELMO or PRZM simulations using the FOCUS climate scenario definition for 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 and using for cadusafos a geometric mean single first order laboratory soil DT50 (at FOCUS reference conditions normalised using an appropriate Q10 and Walker coefficient of 0.7) and K_{Foc} of 227mL/g and 1/n= 0.988. Inputs for methyl-2-butyl-sulfone to be consequent to the data gaps indicated at open points 4.1 and open point 4.6</p>	
	<p>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 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</p>		<p>Data gap open.</p>

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	<p>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</p>		

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	<p>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.</p>		
	<p>Open point: 4.3 RMS to provide groundwater simulations with the PEARL model that cover all the possible application timings for banana.</p> <p>See reporting table 4(5)</p>	<p>Whilst information on additional simulations with PEARL were provided by the applicant (just in the evaluation table), the experts did not make use of this new information as its reporting was very brief, and initially they did not understand how the soil DT50 used for cadusafos of 52.57 days had been derived. It was noted that the values agreed as appropriate for use in simulation modelling in the EFSA conclusion of April 2006 were a geomean / median laboratory value of ca. 38 days (following normalisation to FOCUS reference conditions using a Q10 of 2.2 and Walker equation coefficient of 0.7) or a field not normalised to reference condition geomean value of 50 days.</p> <p>The RMS clarified that the DT50 used by the applicant in the modelling presented in the evaluation table was normalised only for the temperature, but had not been normalised for soil moisture. This would be a worst case in terms of consequently estimated cadusafos concentrations, but would be favourable for the estimated concentrations of the metabolite methyl-2-butyl-sulfone.</p> <p>One of the experts inquired about the possible effect of the capsule formulation on the persistence of the active substance.</p> <p>The effect of the formulation had been previously discussed in the framework of the no longer requested potato use. It was noted that one of the laboratory incubations available had been carried out using the granular formulation and the capsule suspension in the same soil and no significant differences were observed in the degradation rates. The previous peer review accepted that the formulation type was not impacting the degradation rate.</p> <p>The experts concluded that the open point was redundant as it had been superseded by the data gap identified under open point 4.2 above.</p>	<p>Open point closed as it has been superseded by data gap 4.2 for further groundwater modelling.</p>

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	<p>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.</p> <p>See reporting table 4(7)</p>	<p>This will be dependent on the results of the data gap identified at open point 4.1 above.</p>	<p>Open point closed as it has been superseded by the data gap 4.1 for guideline batch adsorption studies for methyl-2-butyl-sulfone.</p>
	<p>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.</p> <p>(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).</p>	<p>In the original DAR the RMS estimated a single first order DT50 for methyl-2-butyl-sulfone of 4.5 days in the single soil incubation where it was formed above 5% AR. In this study the associated cadusafos single first order DT50 was 12.3 days. The visual fit using these parameters and non-linear regression was good resulting in an associated kinetic formation fraction of 0.315 (see below). It was noted that the experimental conditions of this study were 25°C and 75% field capacity soil moisture. Before use in modelling, this value should be normalised to FOCUS reference conditions.</p> <p>The RMS noted that there is only data for one soil, because this was the only soil where this metabolite was found.</p> <p>Formation fraction and half-life for metabolites are correlated and the pair proposed from the data available were accepted partly for pragmatic reasons, since the half-life of 4.5 days was already agreed in the previous peer review and the formation fraction calculated (0.315) is the one corresponding to this DT₅₀, but also because this combination gives a reasonable visual fit (see below).</p> <p>The following end points were agreed from this study. Cadusafos DT50 12.3 days $r^2=1$ (chi sq = 1.4) methyl-2-butyl-sulfone DT50 4.5 days $r^2=0.942$ (chi sq = 20.6) formation fraction from cadusafos 0.315.</p>	<p>Open point fulfilled.</p> <p>New open point proposed, see below.</p>

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	See reporting table 4(8)		
	<p>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</p>		Open point open.

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	be added (normalised using a Q10 of 2.2 and Walker coefficient of 0.7).		
	<p>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.</p> <p>See reporting table 4(9)</p>	<p>In principle, for a metabolite that needs to be assessed for potential ground water contamination, data on degradation in at least three soils are required. These data would probably need to be obtained in soils dosed with the metabolite, since in soils dosed with the parent, the metabolite may not always be present in significant amounts that enable DT50 to be reliably estimated.</p> <p>The experts agreed that DT50 for methyl-2-butyl-sulfone were necessary from experiments on a further 2 soils. Therefore a data gap was confirmed.</p>	<p>Open point fulfilled.</p> <p>New data gap proposed, see below.</p> <p>New open point proposed, see below.</p>
	<p>New data gap 4.3 identified at PRAPeR TC 07 meeting: Aerobic soil DT50 are required for methyl-2-butyl-sulfone in at least 2 additional soils.</p>		<p>Data gap open.</p>
	<p>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-</p>		<p>Open point open.</p>

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	sulfone in at least 2 additional soils.		
	<p>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.</p> <p>See reporting table 4(10)</p>	<p>It was clarified by the RMS and confirmed by EFSA (by reference to the original study report, Jones 2008) that in the groundwater simulations that used a field DT50 of 59 days a Q10 of 2.2 and Walker equation exponent of 0.7 had been used in the simulations.</p> <p>This is usually inappropriate when the field value has not been normalised to reference conditions as in this case. The Q10 should have been set at 1 and the Walker equation exponent at 0, to disable soil temperature and soil moisture corrections for modifying degradation rates.</p>	Open point fulfilled.
	<p>Open point: 4.8 RMS to provide Pelmo FOCUS groundwater simulations to cover the range of possible application dates.</p> <p>See reporting table 4(11)</p>	<p>Whilst information on additional simulations with PELMO were provided by the applicant (a summary just in the evaluation table supplemented by some PELMO input and output files provided to experts), the experts did not make use of this new information. It was noted that the values agreed as appropriate for use in simulation modelling in the EFSA conclusion of April 2006 were a geomean / median laboratory value of ca. 38 days (following normalisation to FOCUS reference conditions using a Q10 of 2.2 and Walker equation coefficient of 0.7) or a field not normalised to reference condition geomean value of 50 days.</p> <p>The experts concluded that the open point was redundant as it had been superseded by the data gap identified under open point 4.2 above.</p>	Open point closed as it has been superseded by data gap 4.2 for further groundwater modelling.
	Open point: 4.9 Member State experts to discuss and agree the residue definition for groundwater	The experts agreed that the appropriate residue definition for which groundwater exposure assessment was triggered or consideration would be required by other disciplines were: Soil: cadusafos Groundwater: cadusafos and methyl-2-butyl-sulfone	Open point fulfilled. New open point proposed, see below.

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	<p>exposure assessment and consideration by other disciplines.</p> <p>See reporting table 4(18)</p>	<p>Surface water: cadusafos Sediment: cadusafos Air: cadusafos</p>	
	<p>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</p>		<p>Open point open.</p>
	<p>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</p>	<p>The experts discussed the information presented in Vol.3 B.9.5 of the additional report page 83, and the additional information provided in column 2 of the evaluation table that clarified the calculation that had been made that supported the assertion that only 16% of the surface area of the soil of a banana plantation would have cadusafos present.</p> <p>The application rate is given on average per surface area without consideration of the un-homogeneity derived by the application technique employed. The meeting noted that the area with substantial input of cadusafos will depend on the soil properties and also on the fact that some diffusion may occur from the time of application and migration of the compound between rows to some extent. There are no agreed tools to calculate the effect</p>	<p>Open point fulfilled.</p> <p>New open points 4.15 and 4.16 proposed, see below.</p>

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	<p>83.</p> <p>See reporting table 4(20)</p>	<p>of this non uniform distribution. PEC soils were calculated assuming uniform application.</p> <p>The experts agreed that the assumptions used in the calculation of the exposed surface area are reasonable but may depend on the particular conditions of use in Tenerife. EFSA will indicate in the conclusion what the assumptions are that were taken into account for this 16% surface area estimate. In deeper soil layers the spread of the active substance may be greater than at the surface. Even at the soil surface, exposure may exceed the 16% estimate, but the experts agreed that there would be some proportion of the surface area with negligible exposure. In the exposed area the PEC soil would be about six times higher than the ones provided in the LoEP that assume uniform application and mixed over 5 cm.</p>	
	<p>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 be six times higher than the ones presented in the table.</p>		<p>Open point open.</p>
	<p>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.</p>		<p>Open point open.</p>
	<p>New open point : 4.11 RMS to update the LoEP in accordance with the discussion table.</p>	<p>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.</p> <p>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.</p>	<p>Open point open.</p>

Appendix 2: Evaluation table

2. 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: 6 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 substituents, 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	<u>PRAPeR TC 07 (4 March 2009):</u> Open point fulfilled. New data gap proposed, see below.
	New data gap 4.1 identified			<u>PRAPeR TC 07 (4 March 2009):</u>

No.	<u>Column A</u> Conclusions from the Reporting Table	<u>Column B</u> Comments from the notifier / applicant	<u>Column C</u> Rapporteur Member State comments on the notifier / applicant comments	<u>Column D</u> Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
	at PRAPeR TC 07 meeting: A guideline batch adsorption study on 3 soils is necessary for methyl-2-butyl-sulfone.			Data gap open.
	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 µg/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 .	<u>PRAPeR TC 07 (4 March 2009):</u> 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			<u>PRAPeR TC 07 (4 March 2009):</u> Data gap open.

No.	<u>Column A</u> Conclusions from the Reporting Table	<u>Column B</u> Comments from the notifier / applicant	<u>Column C</u> Rapporteur Member State comments on the notifier / applicant comments	<u>Column D</u> Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
	<p>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</p>			

No.	<u>Column A</u> Conclusions from the Reporting Table	<u>Column B</u> Comments from the notifier / applicant	<u>Column C</u> Rapporteur Member State comments on the notifier / applicant comments	<u>Column D</u> Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure																											
	this metabolite. An 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.																														
	<p>Open point: 4.3 RMS to provide groundwater simulations with the PEARL model that covers all the possible application timings for banana.</p> <p>See reporting table 4(5)</p>	<p>FMC-February 2009:</p> <p>PEARL Modelling Parameters:</p> <table border="1" data-bbox="640 778 1240 1380"> <thead> <tr> <th>Parameter</th> <th>Cadusafos</th> <th>Methyl-2-Butyl Sulfone</th> </tr> </thead> <tbody> <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 DT₅₀ (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> <tr> <td>K_{OM} (mL/g)</td> <td>131.67</td> <td>17.52</td> </tr> </tbody> </table>	Parameter	Cadusafos	Methyl-2-Butyl Sulfone	Molar Mass (g/mol)	270.4	136.21	Vapour pressure (Pa, 25°C)	0.1196	60.53	Formation fraction	NA	0.315	Water solubility (mg/L, 20°C)	245	48680	Plant uptake factor	0	0	Soil DT ₅₀ (days, 20°C, pF2.0)	52.57	4.5	K _{OC} (mL/g)	227	30.2	K _{OM} (mL/g)	131.67	17.52	<p>RMS, 25 February 2009:</p> <p>Pending on expert's discussions on points 4(2), 4(3), 4(7), 4(8), 4(9) and 4(11) of the reporting table.</p> <p>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.</p>	<p><u>PRAPeR TC 07 (4 March 2009):</u></p> <p>Open point closed. Open point superseded by data gap 4.2 for further groundwater modelling.</p>
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		<table border="1" data-bbox="645 360 1243 456"> <tr> <td data-bbox="645 360 835 419">Freundlich exponent</td> <td data-bbox="835 360 1003 419">0.99</td> <td data-bbox="1003 360 1243 419">0.99</td> </tr> <tr> <td data-bbox="645 419 835 456">Crop</td> <td colspan="2" data-bbox="835 419 1243 456">Citrus</td> </tr> </table> <p data-bbox="645 459 819 488"><i>NA not applicable</i></p> <p data-bbox="645 528 1205 651">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:</p> <ul data-bbox="645 695 1256 786" style="list-style-type: none"> • Parent soil DT₅₀ was the geometric mean of the laboratory studies, as reported (adjusted to 20°C) by the RMS: • <table border="1" data-bbox="792 823 1099 1238"> <thead> <tr> <th colspan="2" data-bbox="792 823 1099 863">Lab soil DT50</th> </tr> </thead> <tbody> <tr><td data-bbox="792 863 954 903"></td><td data-bbox="954 863 1099 903">77.9</td></tr> <tr><td data-bbox="792 903 954 943"></td><td data-bbox="954 903 1099 943">70.3</td></tr> <tr><td data-bbox="792 943 954 983"></td><td data-bbox="954 943 1099 983">18.4</td></tr> <tr><td data-bbox="792 983 954 1023"></td><td data-bbox="954 983 1099 1023">62.3</td></tr> <tr><td data-bbox="792 1023 954 1062"></td><td data-bbox="954 1023 1099 1062">62.1</td></tr> <tr><td data-bbox="792 1062 954 1102"></td><td data-bbox="954 1062 1099 1102">50.9</td></tr> <tr><td data-bbox="792 1102 954 1142"></td><td data-bbox="954 1102 1099 1142">58.2</td></tr> <tr><td data-bbox="792 1142 954 1182"></td><td data-bbox="954 1142 1099 1182">50.5</td></tr> <tr><td data-bbox="792 1182 954 1222"></td><td data-bbox="954 1182 1099 1222"></td></tr> <tr> <td data-bbox="792 1222 954 1238">geomean:</td> <td data-bbox="954 1222 1099 1238">52.57</td> </tr> </tbody> </table> <ul data-bbox="645 1286 1234 1372" style="list-style-type: none"> • The formation fraction for Methyl-2-Butyl Sulfone (MBS) was taken as 0.315, as derived by the RMS. 	Freundlich exponent	0.99	0.99	Crop	Citrus		Lab soil DT50			77.9		70.3		18.4		62.3		62.1		50.9		58.2		50.5			geomean:	52.57		
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		<p>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:</p> <ul style="list-style-type: none"> • 1 March • 15 September • 15 October <p>FOCUS PEARL: cadusafos use on bananas (FOCUS citrus), at 4 kg a.s./ha</p> <table border="1" data-bbox="640 868 1146 1374"> <thead> <tr> <th rowspan="2">Scenario</th> <th rowspan="2">Application Date</th> <th colspan="2">80th percentile PEC_{GW} (µg/L)</th> </tr> <tr> <th>Cadusafos</th> <th>MBS</th> </tr> </thead> <tbody> <tr> <td>Piacenza</td> <td rowspan="4">1 Mar</td> <td>16.715</td> <td>0.811</td> </tr> <tr> <td>Porto</td> <td>0.038</td> <td>0.013</td> </tr> <tr> <td>Sevilla</td> <td>5.411</td> <td>0.390</td> </tr> <tr> <td>Thiva</td> <td>5.375</td> <td>0.263</td> </tr> <tr> <td>Piacenza</td> <td rowspan="4">15 Sep</td> <td>25.827</td> <td>1.594</td> </tr> <tr> <td>Porto</td> <td>0.120</td> <td>0.047</td> </tr> <tr> <td>Sevilla</td> <td>5.991</td> <td>0.442</td> </tr> <tr> <td>Thiva</td> <td>9.148</td> <td>0.445</td> </tr> <tr> <td>Piacenza</td> <td rowspan="2">15 Oct</td> <td>24.930</td> <td>1.476</td> </tr> <tr> <td>Porto</td> <td>0.124</td> <td>0.038</td> </tr> </tbody> </table>	Scenario	Application Date	80 th 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	Sevilla	5.991	0.442	Thiva	9.148	0.445	Piacenza	15 Oct	24.930	1.476	Porto	0.124	0.038		
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	<p>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.</p> <p>See reporting table 4(7)</p>		<p>RMS, 25 February 2009:</p> <p>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.</p>	<p><u>PRAPeR TC 07 (4 March 2009):</u></p> <p>Open point closed. Open point superseded by the data gap 4.1 for guideline batch adsorption studies for methyl-2-butyl-sulfone.</p>								
	<p>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.</p> <p>(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).</p> <p>See reporting table 4(8)</p>		<p>RMS, 25 February 2009: We welcome the discussion.</p>	<p><u>PRAPeR TC 07 (4 March 2009):</u></p> <p>Open point fulfilled.</p> <p>New open point proposed, see below.</p>								
	New open point: 4.12			<u>PRAPeR TC 07 (4 March 2009):</u>								

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	<p>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).</p>			<p>Open point open.</p>
	<p>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.</p> <p>See reporting table 4(9)</p>	<p>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.</p>	<p>RMS, 25 February 2009: RMS agrees with Notifier.</p>	<p><u>PRAPeR TC 07 (4 March 2009):</u> Open point fulfilled. New data gap proposed, see below. New open point proposed, see below.</p>
	<p>New data gap 4.3 identified at PRAPeR TC 07 meeting: Aerobic soil DT50 are required for methyl-2-butyl-sulfone in at least 2 additional</p>			<p><u>PRAPeR TC 07 (4 March 2009):</u> Data gap open.</p>

No.	<u>Column A</u> Conclusions from the Reporting Table	<u>Column B</u> Comments from the notifier / applicant	<u>Column C</u> Rapporteur Member State comments on the notifier / applicant comments	<u>Column D</u> Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure									
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	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.			<u>PRAPeR TC 07 (4 March 2009):</u> Open point open.									
	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.	<u>PRAPeR TC 07 (4 March 2009):</u> Open point fulfilled.									
	Open point: 4.8 RMS to provide Pelmo FOCUS groundwater simulations to cover the range of possible application dates. See reporting table 4(11)	FMC-February 2009: PELMO Modelling Parameters: <table border="1" data-bbox="640 1187 1216 1385"> <thead> <tr> <th>Parameter</th> <th>Cadusafos</th> <th>Methyl-2-Butyl Sulfone</th> </tr> </thead> <tbody> <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> </tbody> </table>	Parameter	Cadusafos	Methyl-2-Butyl Sulfone	Molar Mass (g/mol)	270.4	136.21	Vapour pressure (Pa, 25°C)	0.1196	60.53	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.	<u>PRAPeR TC 07 (4 March 2009):</u> Open point closed. Open point superseded by data gap 4.2 for further groundwater modelling.
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		<table border="1" data-bbox="792 1066 1099 1364"> <thead> <tr> <th colspan="2">Lab soil DT50</th> </tr> </thead> <tbody> <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> </tbody> </table>			Lab soil DT50			77.9		70.3		18.4		62.3		62.1		50.9		58.2		
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	58.2																					

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		<table border="1" data-bbox="792 360 1099 475"> <tr> <td></td> <td>50.5</td> </tr> <tr> <td>geomean:</td> <td>52.57</td> </tr> </table> <ul style="list-style-type: none"> • The formation fraction for Methyl-2-Butyl Sulfone (MBS) was taken as 0.315, as derived by the RMS. <p>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:</p> <ul style="list-style-type: none"> • 1 March • 15 September • 15 October <table border="1" data-bbox="640 1018 1144 1385"> <thead> <tr> <th rowspan="2">Scenario</th> <th rowspan="2">Application Date</th> <th colspan="2">80th percentile PEC_{GW} (µg/L)</th> </tr> <tr> <th>Cadusafos</th> <th>MBS</th> </tr> </thead> <tbody> <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> </tbody> </table>		50.5	geomean:	52.57	Scenario	Application Date	80 th percentile PEC _{GW} (µg/L)		Cadusafos	MBS	Piacenza	1 Mar	2.105	0.099	Porto	0.004	0.002	Sevilla	0.102	0.014	Thiva	0.328	0.021	Piacenza	15 Sep	4.056	0.254	Porto	0.013	0.009	Sevilla	0.297	0.036	Thiva	0.973	0.073		
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		<table border="1"> <tr> <td data-bbox="640 363 786 395">Piacenza</td> <td data-bbox="786 363 882 395"></td> <td data-bbox="882 363 1039 395">3.914</td> <td data-bbox="1039 363 1144 395">0.231</td> </tr> <tr> <td data-bbox="640 395 786 427">Porto</td> <td data-bbox="786 395 882 427">15</td> <td data-bbox="882 395 1039 427">0.017</td> <td data-bbox="1039 395 1144 427">0.012</td> </tr> <tr> <td data-bbox="640 427 786 459">Sevilla</td> <td data-bbox="786 427 882 459">Oct</td> <td data-bbox="882 427 1039 459">0.067</td> <td data-bbox="1039 427 1144 459">0.012</td> </tr> <tr> <td data-bbox="640 459 786 491">Thiva</td> <td data-bbox="786 459 882 491"></td> <td data-bbox="882 459 1039 491">0.564</td> <td data-bbox="1039 459 1144 491">0.042</td> </tr> </table>	Piacenza		3.914	0.231	Porto	15	0.017	0.012	Sevilla	Oct	0.067	0.012	Thiva		0.564	0.042		
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	<p>Open point: 4.9 Member State experts to discuss and agree the residue definition for groundwater exposure assessment and consideration by other disciplines.</p> <p>See reporting table 4(18)</p>	<p>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.</p>	<p>RMS, 25 February 2009: Pending on the outcome of the expert's meeting.</p>	<p><u>PRAPeR TC 07 (4 March 2009):</u> Open point fulfilled. New open point proposed, see below.</p>																
	<p>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</p>			<p><u>PRAPeR TC 07 (4 March 2009):</u> Open point open.</p>																

No.	<u>Column A</u> Conclusions from the Reporting Table	<u>Column B</u> Comments from the notifier / applicant	<u>Column C</u> Rapporteur Member State comments on the notifier / applicant comments	<u>Column D</u> Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
	<p>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.</p> <p>See reporting table 4(20)</p>	<p>FMC February 2009: see comment of open point 5.16 below</p>	<p>RMS, 25 February 2009: We welcome the discussion.</p>	<p><u>PRAPeR TC 07 (4 March 2009):</u></p> <p>Open point fulfilled.</p> <p>New open points 4.15 and 4.16 proposed, see below.</p>
	<p>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 be six times higher than the ones presented in the table.</p>			<p><u>PRAPeR TC 07 (4 March 2009):</u></p> <p>Open point open.</p>
	<p>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.</p>			<p><u>PRAPeR TC 07 (4 March 2009):</u></p> <p>Open point open.</p>
	<p>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</p>			<p><u>PRAPeR TC 07 (4 March 2009):</u></p> <p>Open point open.</p>

No.	<u>Column A</u> Conclusions from the Reporting Table	<u>Column B</u> Comments from the notifier / applicant	<u>Column C</u> Rapporteur Member State comments on the notifier / applicant comments	<u>Column D</u> Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
	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.			

Report of PRAPeR Expert MEETING TC 08

CADUSAFOS

Rapporteur Member State: EL

Specific comments on the active substance in the section

2. Mammalian Toxicology

are already listed in the relevant reporting table. Comments submitted for this meeting are listed below.

1. Comments submitted for this meeting:

Date	Supplier	File Name
none		

2. Documents submitted for meeting:

Date	Supplier	File Name
2009-02-25	RMS	Cadusafos evaluation table rev 1-0 (2009-02-25).doc
January 2009	RMS	Cadusafos_additional_report_addendum 2 to Vol 4 (January 2009)_cover page.doc
2009-01-28	RMS	Cadusafos_reporting table rev 1-1 (2009-01-28).doc
January 2009	RMS	Cadusafos_updated list of endpoints (January 2009).doc
February 2009	EFSA	EFSA Background_TC08_cadusafos_ResubOct08_rev1.doc
February 2009	RMS	Batches of technical cadusafos_TOX_RMSFeb09.doc
March 2008	Applicant	pdf 4.1-Tox evaluation met-but-sulf-P3964.pdf

3. Documents tabled at the meeting:

Date	Supplier	File Name
March 2009	EFSA	Vol4_compToxBatch_TSs

The conclusions of the meeting were as follows:

- Data on preparations:** Rugby 200 CS
- Classification and labelling:** See open point 2.3.
- Recommended restrictions/conditions for use:** None
- Reference List:** Not discussed.

Areas of concern: Restricted and specific use conditions.

Appendix 1: Discussion table: CADUSAFOS

Appendix 2: Evaluation table

Appendix 1: Discussion Table, Cadusafos (In,Ne)

2. Mammalian toxicology

No.	Subject	Discussion Expert Meeting			Conclusions Expert Meeting
	<p>Open point: 2.1</p> <p>The equivalence of the toxicological batches with the new technical specification (See Addendum 2 to Volume 4 of January 2009) has to be confirmed.</p> <p>See reporting table 2(9)</p>	<p>The RMS presented briefly the information provided in the additional report to Volume 4 (October 2008) and in the addendum 2 to the Volume 4 of January 2009. The reference of the impurities is the number mentioned in the additional report to Volume 4 of October 2008 (p.7 and 8).</p> <p>A comparison of the composition of the batch used in the mammalian toxicology studies and the proposed technical specification (January 2009) was made during the teleconference. It was noted that 6 impurities had been removed from the technical specification (TS) [REDACTED].</p> <p>The attention of the experts focused on two impurities [REDACTED] which were present in unknown or lower amounts in the toxicological batch. Therefore, the contribution of these impurities to the toxicological profile of the new TS was checked. Due to the toxicological profile of cadusafos (high acute toxicity), the potential for acute toxicity of these impurities was not considered, but the experts agreed to focus on the potential for genotoxicity.</p> <p>It was reminded that the impurity [REDACTED] was a new impurity, mentioned in the Volume 4 (October 2008) as not present in the batch used for the toxicological studies. A new batch with 3% of impurity [REDACTED] showed a similar acute toxicity as the batch used in the main toxicological studies, but another new batch used in an Ames test (with negative results) had not been analyzed for the impurity [REDACTED] and EPCCO 28 (June 2005) set a data gap for further batch analysis. During the resubmission, no further data were provided about this batch.</p> <p>Considering that further batch analysis was not available, the experts agreed to modify this data gap. Therefore, the applicant is required to provide an assessment of the genotoxic potential of the impurity [REDACTED] in order to demonstrate its non relevance and the acceptability of the proposed level.</p>			<p>Open point still open.</p> <p>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 [REDACTED].</p> <p>New data gaps 2.1 and 2.2 proposed, see below.</p>

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	<p>New data gap 2.1 identified at PRAPeR TC 08 meeting:</p> <p>The potential for genotoxicity of the impurity 8 has to be addressed by the applicant.</p>	<p>For the impurity [REDACTED] the applicant had not addressed its toxicological relevance. Taking into account the high acute toxicity of cadusafos, the experts considered that only the potential for genotoxicity should be addressed by the applicant to demonstrate the non relevance of this impurity.</p> <p>With regard to the acceptability of the proposed level in the TS, higher than the one tested within the batch used for mammalian toxicity tests, the RMS proposed to set the limit at 0.1%.</p> <p>In conclusion, 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 [REDACTED]</p>	<p>Data gap open.</p>
	<p>New data gap 2.2 identified at PRAPeR TC 08 meeting:</p> <p>The potential for genotoxicity of the impurity 17 has to be addressed by the applicant.</p>	<p>For the discussion, the experts considered the numbering of the impurities as presented in the Volume 4 of October 2008 (before removal of any impurity).</p> <p>In comparison with the addendum 2 to Volume 4 of January 2009, it was proposed during the teleconference of the section physical-chemical properties to remove four additional impurities from the TS (i.e. the impurities [REDACTED] as referred to in</p>	<p>Data gap open.</p>
	<p>Message from section 1 (Phys-Chem) to the meeting on mammalian toxicology:</p> <p>Can you accept the specification as given on page 4 of addendum 2 to</p>	<p>Message answered:</p> <p>The mammalian toxicology meeting accepted the specification as given on page 4 of addendum 2.</p>	

No.	Subject	Discussion Expert Meeting			Conclusions Expert Meeting
Vol. 4?	<p>Open point: 2.2</p> <p>Further consideration should be given to the exposure estimates with regard to</p> <ul style="list-style-type: none"> - 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 <p>See reporting table 2(10)</p>	<p>the Volume 4 of October 2008). This was considered acceptable by the experts in mammalian toxicology.</p> <p>Except for the two impurities, the levels proposed for the other impurities were considered as acceptable (see discussion in open point 2.1).</p>			<p>Additionally, further deletions in the TS during the phys-chem meeting were proposed and an opinion of the tox meeting was required.</p> <p>Considering the high toxicity of cadusafos and the available information including the level tested in the tox batches the experts agreed with this proposal.</p>
	<p>Open point: 2.2</p> <p>Further consideration should be given to the exposure estimates with regard to</p> <ul style="list-style-type: none"> - 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 <p>See reporting table 2(10)</p>	<p>No new information has been received during the re-submission procedure with regard to exposure assessment. During the second stage review process (see EFSA conclusion, 2006), a safe use was identified for operator, worker and bystander, although with some uncertainties. During the commenting phase of the resubmission, some comments were provided about these uncertainties and were summarized in the EFSA background document for the discussion by the experts.</p> <p>The first point discussed was the size of banana plantation of 1 ha/day to be treated. In some countries like Costa Rica (out of EU), one expert mentioned that the area is much higher than 1 ha. According to the applicant, the area to be treated in the Canary Islands is 1 ha/day. Some experts expressed their concern in relation to this parameter. Nevertheless, during the discussion, it was confirmed that the banana plantations in the Canary Islands and the French Antilles (EU) have a size which doesn't exceed 1ha in most of the cases.</p> <p>The second point discussed was related to the proposed scenario. It was explained that the main task of the operator was to connect the pump to the container with the formulation, and then a direct injection system would ensure the dilution in the tank and an automatic drip irrigation would be used in the plantation (at the soil level). Therefore there is no pouring operation as usually considered for the operator, and the experts agreed that the estimations according to the UK and BBA model (for mixing and loading only) were an extreme worst case for the operator.</p> <p>On the other hand, this would counterbalance the restrictions of the scenario (1</p>			<p>Open point fulfilled.</p> <p>New open points 2.5 and 2.6 identified, see below.</p>

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
		<p>ha/day, automatic drip irrigation).</p> <p>The third point discussed was related to the amount of cadusafos released from the microcapsules. The value of 1.12% (released after 2 minutes) was taken into account in the first evaluation (see EFSA conclusion, 2006). The experts considered that due to the direct injection system used to perform "mixing/loading", a contact with the formulation longer than 2 minutes was not expected. Therefore the value of 1.12% was kept as suggested.</p> <p>Besides, it was considered that this information should be mentioned in the List of End Points (new open point for the RMS).</p> <p>With regard to the new application rate for the resubmission (4 kg a.s./ha instead of 6 kg a.s./ha), the RMS has been requested to provide recalculations of the operator exposure assessment in an addendum (since this had not been performed in the additional report).</p> <p>Concerning the bystanders and the workers, the concern for potential exposure to volatilized pesticide was discussed. It was reminded that cadusafos is a volatile pesticide. However, considering the available information (i.e. lower application rate, increased PHI, drip irrigation directly into the soil), the experts concluded that there was no concern.</p> <p>For the restricted representative use as supported by the applicant and evaluated by the RMS, it was possible to conclude on an estimated exposure level below the AOEL. However, some uncertainties raised already during the EFSA conclusion (2006) have not been solved and will be mentioned in the revised conclusion. Further information would be useful for consideration at MS level to better refine the risk assessment</p>	
	<p>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</p>		<p>Open point open.</p>

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	kg as/ha).		
	New open point 2.6: RMS to update the LOEP with the amount of cadusafos released from the microcapsules and the final exposure estimates.		Open point open.
	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)	In the EPCO meeting 28 (June 2005), some concerns were raised concerning the possible classification and labelling according to reproductive properties (i.e. teratogenicity). In the ECB webpage some documents are available, but it is not clear if the potential for teratogenicity was discussed. The RMS has to send to EFSA the confirmation of the agreed classification on the ECB in order to update the EFSA Conclusion.	Open point still open.
	New open point 2.4 The toxicological relevance of the ground water metabolite methyl-2-butyl sulfone to be discussed.	A position paper was submitted by the applicant in the dossier (in the section Fate and Behaviour) and discussed during the meeting. No toxicological studies are available for the metabolite methyl-2-butyl sulfone. It is a minor rat metabolite (less than 1%). According to the structure it is proposed to be of lower toxicity and similar to DMSO ₂ (dimethyl sulfone). This was not considered sufficient by the experts to exclude its toxicological relevance. According to the Guidance Document on the assessment of the relevance of metabolites in groundwater, Sanco/221/2000 – rev.10 – 25 February 2003, the absence of severe toxicological properties, at least in comparison to the parent, should be demonstrated. Pending on the confirmation of the level of the metabolite in the groundwater, further information will have to be provided by the applicant in order to define its toxicological relevance.	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.

Appendix 2: Evaluation table

3. Mammalian toxicology

No.	<u>Column A</u> Conclusions from the Reporting Table	<u>Column B</u> Comments from the notifier / applicant	<u>Column C</u> Rapporteur Member State comments on the notifier / applicant comments	<u>Column D</u> Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
Section 2 Open points: 3 Points for clarification: 0 Data gaps: 0	Open point: 2.1	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 <i>in vitro</i> 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.	Section 2 Open points: 5 Points for clarification: 0 Data gaps: 2 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 [REDACTED] New data gaps 2.1 and 2.2 proposed, see below.
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)	New data gap 2.1 identified at PRAPeR TC 08 meeting:		PRAPeR TC 08 (4 March 2009): Data gap open.	

No.	<u>Column A</u> Conclusions from the Reporting Table	<u>Column B</u> Comments from the notifier / applicant	<u>Column C</u> Rapporteur Member State comments on the notifier / applicant comments	<u>Column D</u> Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
	The potential for genotoxicity of the impurity 8 has to be addressed by the applicant.			
	New data gap 2.2 identified at PRAPeR TC 08 meeting: The potential for genotoxicity of the impurity 17 has to be addressed by the applicant.			<u>PRAPeR TC 08 (4 March 2009):</u> Data gap 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?			<u>PRAPeR TC 08 (4 March 2009):</u> 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.
	Open point: 2.2	FMC February 2009:	RMS, 25 February 2009:	<u>PRAPeR TC 08 (4 March 2009):</u>

No.	<u>Column A</u> Conclusions from the Reporting Table	<u>Column B</u> Comments from the notifier / applicant	<u>Column C</u> Rapporteur Member State comments on the notifier / applicant comments	<u>Column D</u> Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
	<p>Further consideration should be given to the exposure estimates with regard to</p> <ul style="list-style-type: none"> - 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 <p>See reporting table 2(10)</p>	<p>-the parameters were gathered from the field and therefore represent the field conditions of use of the product</p> <ul style="list-style-type: none"> - 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). 	<p>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.</p>	<p>Open point fulfilled.</p> <p>New open points 2.5 and 2.6 identified, see below.</p>
	<p>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).</p>			<p><u>PRAPeR TC 08 (4 March 2009):</u></p> <p>Open point open.</p>
	<p>New open point 2.6: RMS to update the LOEP with the amount of cadusafos released from the microcapsules and the final exposure estimates.</p>			<p><u>PRAPeR TC 08 (4 March 2009):</u></p> <p>Open point open.</p>
	<p>New open point: 2.3 The results of the discussions in ECB about classification and labelling of cadusafos have to be reflected by the</p>	<p>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;</p>	<p>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 site</p>	<p><u>PRAPeR TC 08 (4 March 2009):</u></p> <p>Open point still open. RMS to send to EFSA the confirmation of the agreed classification on the ECB in</p>

No.	<u>Column A</u> Conclusions from the Reporting Table	<u>Column B</u> Comments from the notifier / applicant	<u>Column C</u> Rapporteur Member State comments on the notifier / applicant comments	<u>Column D</u> Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
	<p>RMS.</p> <p>See reporting table 2(13)</p>	<p>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.</p> <p>RMS had added already the R – phrases in the additional report.</p> <p>Applicant agrees that RMS should add now the S-phrases as per ECB conclusions.</p>	<p>(http://ecb.jrc.ec.europa.eu/classification-labelling/search-classlab/) and include the following classification with regard to health effects:</p> <p>T+; R26/27 T; R25 and the safety phrases: S1/2-13-36/37-45-63</p>	<p>order to update the EFSA Conclusion.</p>
	<p>New open point 2.4</p> <p>The toxicological relevance of the ground water metabolite methyl-2-butyl sulfone to be discussed.</p>			<p><u>PRAPeR TC 08 (4 March 2009):</u></p> <p>Open point still open.</p> <p>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.</p>

REPORT OF PRAPeR EXPERT MEETING TC 09

CADUSAFOS

Rapporteur Member State: GR

Specific comments on the active substance in the section

5. Ecotoxicology

are already listed in the relevant reporting table. Comments submitted for this meeting are listed below.

1. Comments submitted for this meeting:

Date	Supplier	File Name
none		

2. Documents submitted for meeting:

Date	Supplier	File Name
2009-02-25	GR	Cadusafos evaluation table rev 1-0 (2009-02-25).doc
January 2009	GR	Cadusafos_additional_report_addendum 1 to Vol3_B9 (January 2009).doc
January 2009	GR	Cadusafos_additional_report_addendum 2 to Vol 4 (January 2009)_cover page.doc
2009-01-28	GR	Cadusafos_reporting table rev 1-1 (2009-01-28).doc
January 2009	GR	Cadusafos_updated list of endpoints (January 2009).doc

3. Documents tabled at the meeting:

Date	Supplier	File Name
none		

The conclusions of the meeting were as follows:

The applied use is very particular only Canary islands and drip irrigation. No conclusion can be drawn on the risk to other forms of banana planting.

4. Data on preparations: Rugby 200 CS

5. Classification and labelling: N, R50/53

10. Recommended restrictions/conditions for use: Not more than 16% of the in-field area should be treated.

11. Reference list: Not discussed.

Areas of concern: Birds, mammals, earthworms

Appendix 1: Discussion table: CADUSAFOS

Appendix 2: Evaluation table

Appendix 1: Discussion Table, Cadusafos (In, Ne)

5. Ecotoxicology

	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	<p>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?).</p> <p>See reporting table 5(1)</p>	<p>It was agreed to use blackbird as a focal species for predominantly vermivorous birds. It was noted that also small insectivorous birds (grey wagtail) occur in banana plantations. Therefore the risk for small insectivorous birds needs to be addressed. The suggested PT and PD values were not agreed since they were not justified by data which would allow a quantitative refinement of PD and PT. However, it should be taken into account that only 16% of the in-field area is treated due to the drip irrigation, which would leave the majority of feed items uncontaminated. This information can be used in a weight of evidence approach (qualitative assessment).</p> <p>A rough estimate of the PECsoil can be done by multiplying the current PECsoil by 6 according to the fate discussion in order to calculate the TERs for secondary poisoning of earthworm-eating birds.</p>	<p>Open point open. RMS to update the risk assessment for birds according to the recommendations in the expert meeting.</p>
	<p>Open point: 5.2 MSs to discuss the relevance of measured residues on earthworms to refine the risk for earthworm-eating birds and mammals.</p> <p>See reporting table 5(2)</p>	<p>It was noted in the fate meeting that the PECsoil is about 6 times higher than the PECsoil currently used, which assumed a uniform distribution of the a.s. over the whole growing area (standard PECsoil for 5cm soil depth). The high PECsoil values will occur only locally (at the irrigation points, about 16% of the total surface). A rough estimate of the PECsoil can be done by multiplying the current PECsoil by 6 according to the fate discussion.</p> <p>It was agreed that the concentration in earthworms should be based on the PECsoil in 5cm depth in the treated area (16% of the total area). This leaves a large area untreated where earthworms would not be contaminated (negligible concentrations of cadusafos according to the fate discussion). This could be taken into account in a “weight of evidence” approach in the risk assessment.</p> <p>The suggested residue values in the refined risk assessment for earthworm-eating birds</p>	<p>Open point fulfilled.</p> <p>New open point proposed, see below.</p>

	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
		<p>and mammals in addendum 1 was not agreed, since the plateau concentration in earthworms was not reached. Furthermore, it was noted that the new soil concentrations would be higher than the concentrations in the test system. The residues measured in the earthworm reproduction study may be used to calculate a BCF. It was unclear from the study summary if the information is sufficient to derive a reliable BCF (the plateau concentration in earthworms was not reached in the study). The BCF could be used to calculate the concentration in earthworms in the refined risk assessment for earthworm-eating birds and mammals.</p>	
	<p>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.</p>		<p>Open point open.</p>
	<p>Open point: 5.3 MSs to discuss the relevance of blackbird as focal species for risk assessment of cadusafos in banana plantations.</p> <p>See reporting table 5(3)</p>	<p>Blackbird was chosen as the focal species in the refined risk assessment. It was noted that the literature review provided by the applicant lists also Grey wagtail as one of the 3 most abundant/dominant species of ground feeding birds. Grey wagtail is smaller than Blackbird and hence would not be covered by the risk assessment. It was noted that Grey wagtail would be more insectivorous and less vermivorous.</p> <p>The experts agreed to use blackbird as a focal species representing vermivorous/omnivorous birds, but the risk to smaller insectivorous birds also needs to be addressed (e.g. grey wagtail).</p>	<p>Open point fulfilled.</p> <p>Data gap proposed, see below.</p>

	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	<p>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).</p>		<p>Data gap open.</p>
	<p>Open point: 5.4 No new data can be taken into account. RMS to clarify if the RIFCON (Giessing, B. (2005) report (<i>Birds and mammals inhabiting banana plantations on the Canary Islands - Literature survey and re-analysis of monitoring data.</i> 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).</p>	<p>The articles which were cited in the literature review were not included in the dossier, also no summaries of the studies were provided. Therefore, it was not possible in the teleconference to judge whether the information was reliable and robust.</p>	<p>Open point fulfilled. New data gap proposed, see below.</p>

	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	See reporting table 5(4)		
	<p>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.</p>		Data gap open.
	<p>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.</p> <p>See reporting table 5(5)</p>	<p>No information was provided on accumulation in insects. It was considered likely that the insects would be killed before cadusafos could accumulate in insects. It was agreed that the PECsoil can be used for the risk assessment as a surrogate for residues on insects. The RMS pointed out that the PECsoil cannot be calculated exactly, but it will be assumed to be about 6 times higher than the current PECsoil. A rough estimate of the PECsoil can be done by multiplying the current PECsoil by 6 according to the fate discussion</p>	<p>Open point fulfilled.</p> <p>New open point proposed, see below.</p>
	<p>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).</p>		Open point open.

	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	<p>Open point: 5.6 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.</p> <p>See reporting table 5(6)</p>	<p>The studies supporting the suggested PD refinement for blackbird were not submitted and not summarised. It was not possible for the RMS or the experts in the meeting to verify the PD values suggested by the applicant. The habitats where the food composition was investigated was unclear (it seems that one study was conducted in oak forest but the other study just states various habitats).</p> <p>Also for the Algerian hedgehog no studies were submitted which would support the suggested PD values (only literature references were given).</p> <p>The suggested PD values were not sufficiently justified and therefore not accepted for the refined risk assessment.</p> <p>A data gap was identified to submit the information supporting the suggested PD values.</p>	<p>Open point fulfilled.</p> <p>New data gap proposed, see below.</p>
	<p>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).</p>		<p>Data gap open.</p>
	<p>Open point: 5.7 MSs to discuss and agree the PT refinements used for risk assessment for birds.</p> <p>See reporting table</p>	<p>The PT values were from orchards in the UK. There is a high uncertainty if the values can be extrapolated to banana plantations. The experts commended that a scientifically sound argumentation should be provided to justify the extrapolation of PT data from UK orchards to banana plantations. The experts agreed to use the 95th percentile PT for the long-term risk assessment instead of the 50th percentile to account for the uncertainty with regard to the extrapolation to banana plantations. For the acute risk assessment no PT refinement should be applied.</p>	<p>Open point fulfilled.</p> <p>New data gap proposed, see below.</p> <p>New open point proposed, see below.</p>

	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	5(10)	A footnote should be included in the LoEP explaining that the PT refinement was based on UK data.	
	<p>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.</p>		Data gap open.
	<p>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.</p>		Open point open.
	<p>Open point: 5.8 MSs to agree that the mode of application of cadusafos (drip-irrigation) does not cause exposure of ground dwelling arthropods and therefore the residue on epigaeic arthropods can be considered negligible.</p>	<p>The residues on epigaeic arthropods were considered negligible by the experts due to the mode of application. There would be only 16% of the surface area treated and the epigaeic arthropods are quite mobile (movement from the untreated area to the treated area and vice-versa).</p>	<p>Open point fulfilled. Residues on epigaeic insects were considered negligible.</p>

	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	See reporting table 5(11)		
	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)	The refined risk assessment was not agreed. The RMS needs to update the risk assessment for mammals. See following discussion points.	Open point open. RMS to update the risk assessment for mammals according to the recommendations in the expert meeting.
	Open point: 5.10 MSs to discuss the relevance of Algerian hedgehog (<i>Atelerix algirus</i>) as focal species for risk assessment of cadusafos in banana plantations. See reporting table 5(18)	It was noted that the <i>Osorio shrew</i> was listed in the RIFCON literature review as one of the species potentially occurring in banana plantations. The risk assessment for the Algerian hedgehog would not cover the risk to shrew since it is a much smaller species. The key studies (literature) on which the literature review was based on were not included in the dossier and no study summaries were provided. Therefore it was not possible for the RMS and the experts in the meeting to verify the suggested focal species.	Open point fulfilled. 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.		Data gap open.
	Open point: 5.11	No information on the food taken from the treated area of hedgehog in banana plantation	Open point fulfilled.

	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	<p>MSs to discuss and agree the PT refinements used for the risk assessment for mammals.</p> <p>See reporting table 5(22)</p>	<p>was provided. It was suggested by the applicant that a hedgehog would only take 10% of the food from the treated area. As a conservative approach it was proposed by the applicant to use a PT of 0.3. This PT refinement suggested by the applicant was based on a qualitative assessment considering that a hedgehog would not use the banana plantation to 100% for foraging. Without supporting data this quantification of a qualitative consideration was not accepted by the experts.</p>	<p>New data gap proposed, see below.</p>
	<p>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.</p>		<p>Data gap open.</p>
	<p>Open point: 5.12 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)</p> <p>See reporting table 5(23)</p>	<p>See discussion in open point 5.6.</p>	<p>Open point fulfilled. See open point 5.6 and data gap 5.3.</p>
	<p>Open point: 5.13 MSs to discuss if cadusafos could be considered of low</p>	<p>The long-term NOEL for mammals was discussed. The value of 0.045 mg/kg bw/d based on behavioural effects (reduced locomotion in females) was considered as a conservative value. Some refinement of the long-term endpoint based on maternal toxicity may be possible. The RMS proposed a long-term endpoint of 6 mg/kg bw/d. A NOEL of 0.026</p>	<p>Open point fulfilled.</p>

	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	<p>concern for the reproductive effects of mammals.</p> <p>See reporting table 5(25)</p>	<p>mg/kg bw/d was based on reduced body weight gain in female rats in the rat reproduction study. However, no dose-response relationship was observed and the effect was only about 10%. Without information on the reversibility of the behavioural effects the experts did not agree to use the endpoint of 6 mg/kg bw/d for the long-term risk assessment.</p>	
	<p>Open point: 5.14 MSs to discuss if PD values based on studies with Western hedgehog (<i>Erinaceus europaeus</i>) can be used for Algerian hedgehog (<i>Atelerix algirus</i>).</p> <p>See reporting table 5(31)</p>	<p>See discussion in open point 5.6.</p>	<p>Open point fulfilled. See open point 5.6 and data gap 5.3.</p>
	<p>Open point: 5.15 MS to discuss the relevance of the application time of cadusafos with respect to breeding season of mammals in the canary islands.</p> <p>See reporting table 5(33)</p>	<p>See discussion in open point 5.10.</p>	<p>Open point fulfilled. See open point 5.10.</p>
	<p>Open point: 5.16 MSs to discuss if the risk to ground-dwelling insects can be considered of low</p>	<p>The experts agreed to the argumentation that only 16% of the surface is treated leaving enough uncontaminated refuges, from where recolonisation of the treated area could take place. Therefore the data gap to address the risk to Aleochara and Colembola identified in the EPCO meeting in 2005 were considered not relevant any more.</p>	<p>Open point fulfilled.</p>

	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	<p>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.</p> <p>See reporting table 5(34)</p>		
	<p>Open point: 5.17 MSs to discuss the reliability of the earthworm field study to address the risk to earthworm population in banana plantation.</p> <p>See reporting table 5(43)</p>	<p>The RMS pointed out that the PECsoil cannot be calculated exactly but it will be assumed to be about 6 times higher than the current PECsoil.</p> <p>No significant effects were observed in the field study with the positive control (carbendazim). This questions the validity of the earthworm field study. The soil conditions in the study site in the UK and the exposure conditions (uniform distribution of the a.s. in soil instead of points with high concentrations and untreated areas in between) were not comparable to the use in bananas. On the other hand the degradation of cadusafos under cooler UK weather conditions may be slower leading to a longer exposure period compared to the canary islands. The study was considered of not being of use in the risk assessment. Further clarification should be provided by the applicant on why no effects were observed in the positive control before the study can be accepted for risk assessment.</p> <p>The exposure of earthworms will be significantly higher in the treated area (about 6 times higher than the current PECsoil). The acute toxicity to earthworms is high and hence would lead to high mortality in the treated areas. Cadusafos is not persistent in soil ($DT_{50} =$</p>	<p>Open point fulfilled.</p> <p>New data gap proposed, see below.</p> <p>New open point proposed, see below.</p>

	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
		<p>12 – 60 d). Since there is a large area left untreated (84%) and cadusafos is applied only once per year, there is potential of recolonisation of the treated part of the field from the untreated parts. However, no data were provided to show that recolonisation is possible and the TERs for the acute risk are far below the trigger of 10 suggesting high mortality in the treated parts of the field.</p> <p>The LoEP needs to be 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).</p>	
	<p>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.</p>		<p>Data gap open.</p>
	<p>New open point: 5.21 RMS to update the LoEP according to the suggestions of the experts: The LoEP needs to be updated with new application rates and PECsoil for the treated area. An explanatory footnote should be</p>		<p>Open point open.</p>

	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	included (explaining the exposure situation – 16% of the area is treated).		
	<p>Message from section 1 (Phys-chem meeting):</p> <p>Can you accept the specification as given on page 4 of addendum 2 to Vol. 4?</p>	<p>No comparison of the batches tested and the impurities in the batches was provided by the applicant. No conclusion could be drawn in the meeting. A data gap was set for the 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.</p>	<p>New data gap proposed, see below.</p>
	<p>New data gap 5.8 identified at PRAPeR TC 09 meeting:</p> <p>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.</p>		<p>Data gap open.</p>

Appendix 2: Evaluation table

4. Ecotoxicology

No.	<u>Column A</u> Conclusions from the Reporting Table	<u>Column B</u> Comments from the notifier / applicant	<u>Column C</u> Rapporteur Member State comments on the notifier / applicant comments	<u>Column D</u> 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 endogaic arthropods (living in the soil) to be equal to initial PECsoil.	<u>PRAPeR TC 09 (5-6 March 2009):</u> Open point open. RMS to update the risk assessment for birds according to the recommendations in the expert meeting. (refer to Discussion table).
	Open point: 5.2 MSs to discuss the relevance of measured residues on earthworms to refine the risk for earthworm-eating birds and mammals.	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 concentration, the laboratory derived residues are 3-4 times greater than the highest expected field residues.	RMS, 25 February 2009: We welcome a discussion on this topic.	<u>PRAPeR TC 09 (5-6 March 2009):</u> Open point fulfilled. New open point proposed,

No.	<u>Column A</u> Conclusions from the Reporting Table	<u>Column B</u> Comments from the notifier / applicant	<u>Column C</u> Rapporteur Member State comments on the notifier / applicant comments	<u>Column D</u> Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
	See reporting table 5(2)	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.		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.			<u>PRAPeR TC 09 (5-6 March 2009):</u> Open point open.
	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, this species should be considered as the focal species.	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.	<u>PRAPeR TC 09 (5-6 March 2009):</u> Open point fulfilled. Data gap proposed, see below.
	New data gap 5.1 identified			<u>PRAPeR TC 09 (5-6 March</u>

No.	<u>Column A</u> Conclusions from the Reporting Table	<u>Column B</u> Comments from the notifier / applicant	<u>Column C</u> Rapporteur Member State comments on the notifier / applicant comments	<u>Column D</u> Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
	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).			<u>2009</u>): Data gap open.
	Open point: 5.4 No new data can be taken into account. RMS to clarify if the RIFCON (Giessing, B. (2005) report (<i>Birds and mammals inhabiting banana plantations on the Canary Islands - Literature survey and re-analysis of monitoring data</i> . 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 (<i>Birds and mammals inhabiting banana plantations on the Canary Islands - Literature survey and re-analysis of monitoring data</i> . 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). <i>Birds and mammals inhabiting banana plantations on the Canary Islands - Literature survey and re-analysis of monitoring data</i> . 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.	<u>PRAPeR TC 09 (5-6 March 2009)</u>): Open point fulfilled. New data gap proposed, see below.
	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			<u>PRAPeR TC 09 (5-6 March 2009)</u>): Data gap open.

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															
	information included in the dossier it was not possible to judge the reliability of the literature review of Giessing, B. 2005.																		
	<p>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.</p> <p>See reporting table 5(5)</p>	<p>FMC-February 2009: The soil PECs were calculated (Table below; Crop: Banana, Application dose: 4000 g a.i./ha, Inc. depth: 0.05 m, DT₅₀=61 d, single application, fraction intercepted by the plant=0% m).</p> <p>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.</p> <p>Worst-case was assessed according to these PECs from the 3 May 2005 Addendum and in the additional report.</p> <table border="1" data-bbox="831 1015 1229 1370"> <thead> <tr> <th data-bbox="831 1015 1014 1198">PEC_(s) (mg/kg)</th> <th data-bbox="1014 1015 1055 1198">Single application Actual (DT₅₀: 61 d)</th> <th data-bbox="1055 1015 1229 1198">Single application Time weighted average (DT₅₀: 61 d)</th> </tr> </thead> <tbody> <tr> <td data-bbox="831 1198 1014 1238">Initial</td> <td data-bbox="1014 1198 1055 1238">5.333</td> <td data-bbox="1055 1198 1229 1238">5.333</td> </tr> <tr> <td data-bbox="831 1238 1014 1278">Short term</td> <td data-bbox="1014 1238 1055 1278">5.273</td> <td data-bbox="1055 1238 1229 1278">5.303</td> </tr> <tr> <td data-bbox="831 1278 1014 1318"></td> <td data-bbox="1014 1278 1055 1318">5.213</td> <td data-bbox="1055 1278 1229 1318">5.273</td> </tr> <tr> <td data-bbox="831 1318 1014 1370">24h</td> <td data-bbox="1014 1318 1055 1370">5.096</td> <td data-bbox="1055 1318 1229 1370">5.214</td> </tr> </tbody> </table>	PEC _(s) (mg/kg)	Single application Actual (DT ₅₀ : 61 d)	Single application Time weighted average (DT ₅₀ : 61 d)	Initial	5.333	5.333	Short term	5.273	5.303		5.213	5.273	24h	5.096	5.214	<p>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 endogaic arthropods (living in the soil) to be equal to initial PECsoil.</p>	<p><u>PRAPeR TC 09 (5-6 March 2009):</u></p> <p>Open point fulfilled.</p> <p>New open point proposed, see below.</p>
PEC _(s) (mg/kg)	Single application Actual (DT ₅₀ : 61 d)	Single application Time weighted average (DT ₅₀ : 61 d)																	
Initial	5.333	5.333																	
Short term	5.273	5.303																	
	5.213	5.273																	
24h	5.096	5.214																	

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
		2d 4d Long term 7d 28d 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).					PRAPeR TC 09 (5-6 March 2009): Open point open.
	Open point: 5.6 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. See reporting table 5(6)	FMC-February 2009: According to common practices in Spain spring application is conducted around Feb until Mid March and autumn application 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			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.

No.	<u>Column A</u> Conclusions from the Reporting Table	<u>Column B</u> Comments from the notifier / applicant	<u>Column C</u> Rapporteur Member State comments on the notifier / applicant comments	<u>Column D</u> Recommendations of the PRAPeR Expert Meeting / Conclusions from the written procedure
		<p>than considered in the risk assessment, and will be therefore covered by the spring scenario data, too.</p> <p>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.</p>		
	<p>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).</p>			<p><u>PRAPeR TC 09 (5-6 March 2009):</u></p> <p>Data gap open.</p>
	<p>Open point: 5.7 MSs to discuss and agree the PT refinements used for risk assessment for birds.</p> <p>See reporting table 5(10)</p>	<p>FMC-February 2009:</p> <p>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 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).</p> <p>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</p>	<p>RMS, 25 February 2009: We welcome a discussion on this topic.</p>	<p><u>PRAPeR TC 09 (5-6 March 2009):</u></p> <p>Open point fulfilled.</p> <p>New data gap proposed, see below. New open point proposed, see below.</p>

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		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.						
	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.			<u>PRAPeR TC 09 (5-6 March 2009):</u> Data gap open.				
	New open point: 5.20 RMS to recalculate the TERs without PT refinement(acute) and the 95 th 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.			<u>PRAPeR TC 09 (5-6 March 2009):</u> Open point open.				
	Open point: 5.8 MSs to agree that the mode of application of cadusafos (drip-irrigation) does not cause exposure of ground dwelling arthropods and therefore the residue on epigeaic arthropods can be considered negligible. See reporting table 5(11)	FMC-February 2009: Drip irrigation system loses practically no water to runoff, deep percolation, evaporation, and reduces water contact with the 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 epigeaic arthropods have same concentration as earthworms, we pass the TERS as below. <table border="1" data-bbox="640 1342 1386 1396"> <tr> <td data-bbox="640 1342 792 1396"><i>Diet</i></td> <td data-bbox="792 1342 969 1396"><i>Epigeaic</i></td> <td data-bbox="969 1342 1155 1396"><i>Endogaenic</i></td> <td data-bbox="1155 1342 1386 1396"><i>Earthworms</i></td> </tr> </table>	<i>Diet</i>	<i>Epigeaic</i>	<i>Endogaenic</i>	<i>Earthworms</i>	RMS, 25 February 2009: 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.	<u>PRAPeR TC 09 (5-6 March 2009):</u> Open point fulfilled. Residues on epigeaic insects were considered negligible.
<i>Diet</i>	<i>Epigeaic</i>	<i>Endogaenic</i>	<i>Earthworms</i>					

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		<table border="1" data-bbox="640 360 1384 916"> <thead> <tr> <th><i>items</i></th> <th><i>arthropods</i></th> <th><i>arthropods</i></th> <th><i>arthropods</i></th> </tr> </thead> <tbody> <tr> <td><i>Application rate (kg a.i./ha)</i></td> <td>4.0</td> <td>4.0</td> <td>4.0</td> </tr> <tr> <td><i>C (mg a.i./kg)</i></td> <td>0.5</td> <td>5.33</td> <td>0.50</td> </tr> <tr> <td><i>FIR</i></td> <td>0.50</td> <td>0.50</td> <td>1.06</td> </tr> <tr> <td><i>AV</i></td> <td>1</td> <td>1</td> <td>1</td> </tr> <tr> <td><i>PT</i></td> <td>0.82* / 0.218^</td> <td>0.82* / 0.218^</td> <td>0.82* / 0.218^</td> </tr> <tr> <td><i>PD</i></td> <td>0.66</td> <td>0.06</td> <td>0.22</td> </tr> <tr> <td><i>ETE</i></td> <td>0.54* / 0.14^</td> <td>0.13* / 0.03^</td> <td>0.10* / 0.03^</td> </tr> <tr> <td><i>ETE total</i></td> <td colspan="3">0.77* / 0.2^</td> </tr> </tbody> </table> <table border="1" data-bbox="640 954 1178 1232"> <thead> <tr> <th>Scenario</th> <th>ETE</th> <th>Toxicity Daily dose</th> <th>TER</th> </tr> </thead> <tbody> <tr> <td>Acute</td> <td>0.77</td> <td>16.1</td> <td>21</td> </tr> <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> </tbody> </table> <p data-bbox="640 1241 1384 1396">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</p>				<i>items</i>	<i>arthropods</i>	<i>arthropods</i>	<i>arthropods</i>	<i>Application rate (kg a.i./ha)</i>	4.0	4.0	4.0	<i>C (mg a.i./kg)</i>	0.5	5.33	0.50	<i>FIR</i>	0.50	0.50	1.06	<i>AV</i>	1	1	1	<i>PT</i>	0.82* / 0.218^	0.82* / 0.218^	0.82* / 0.218^	<i>PD</i>	0.66	0.06	0.22	<i>ETE</i>	0.54* / 0.14^	0.13* / 0.03^	0.10* / 0.03^	<i>ETE total</i>	0.77* / 0.2^			Scenario	ETE	Toxicity Daily dose	TER	Acute	0.77	16.1	21	Short-term	0.77	10.8	14	Long-term	0.2	1.1	55	<p>Finally, cadusafos has a Henry's Law Constant of $1.32 \times 10^{-1} \text{ Pa.m}^3.\text{mol}^{-1}$ (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.</p>	
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		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.	<u>PRAPeR TC 09 (5-6 March 2009):</u> Open point open. RMS to update the risk assessment for mammals according to the recommendations in the expert meeting. (refer to Discussion table)
	Open point: 5.10 MSs to discuss the relevance of Algerian hedgehog (<i>Atelerix algirus</i>) as focal species for risk assessment of cadusafos in banana plantations. See reporting table 5(18)	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 preferences of its congener, the Western hedgehog (<i>Erinaceus europaeus</i>), the Algerian hedgehog is supposed to be the most likely candidate for the focal species in banana plantation.	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.	<u>PRAPeR TC 09 (5-6 March 2009):</u> Open point fulfilled. 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.			<u>PRAPeR TC 09 (5-6 March 2009):</u> Data gap open.
	Open point: 5.11	The habitat preferences of the Algerian hedgehog differ from	RMS, 25 February 2009:	<u>PRAPeR TC 09 (5-6 March</u>

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	<p>MSs to discuss and agree the PT refinements used for the risk assessment for mammals.</p> <p>See reporting table 5(22)</p>	<p>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.</p>	<p>We welcome a discussion on this topic.</p>	<p><u>2009</u>):</p> <p>Open point fulfilled.</p> <p>New data gap proposed, see below.</p>
	<p>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.</p>			<p><u>PRAPeR TC 09 (5-6 March 2009)</u>:</p> <p>Data gap open.</p>
	<p>Open point: 5.12 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)</p> <p>See reporting table 5(23)</p>		<p>RMS, 25 February 2009: A new risk assessment is provided in an Addendum 1 to Additional Report (B.9). No comment.</p>	<p><u>PRAPeR TC 09 (5-6 March 2009)</u>:</p> <p>Open point fulfilled. See open point 5.6 and data gap 5.3.</p>
	<p>Open point: 5.13 MSs to discuss if cadusafos could be considered of low concern for the reproductive effects of mammals.</p> <p>See reporting table 5(25)</p>	<p>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</p>	<p>RMS, 25 February 2009: The main issue for organophosphates is the acute risk. Literature support that for organophosphates reproductive effects are of low concern. For this group</p>	<p><u>PRAPeR TC 09 (5-6 March 2009)</u>:</p> <p>Open point fulfilled.</p>

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		effects.	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: 5.14 MSs to discuss if PD values based on studies with Western hedgehog (<i>Erinaceus europaeus</i>) can be used for Algerian hedgehog (<i>Atelerix algirus</i>). See reporting table 5(31)	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 (<i>Atelerix algirus</i>) is not expected to differ notably from the Algerian hedgehog (<i>Atelerix algirus</i>) and should reflect their similar nutritional requirements.	RMS, 25 February 2009: We welcome a discussion on this topic.	<u>PRAPeR TC 09 (5-6 March 2009):</u> Open point fulfilled. 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 breeding season of mammals in the canary islands. See reporting table 5(33)	There is no information that the reproductive periods of Algerian hedghogs (<i>Atelerix algirus</i>) 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.	<u>PRAPeR TC 09 (5-6 March 2009):</u> Open point fulfilled. See open point 5.10.
	Open point: 5.16 MSs to discuss if the risk to	FMC-February 2009: The cadusafos from each dripper spreads in soil to a depth of	RMS, 25 February 2009: We welcome a discussion on	<u>PRAPeR TC 09 (5-6 March 2009):</u>

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	<p>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.</p> <p>See reporting table 5(34)</p>	<p>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 0.13m². With six drippers per tree the treated area per tree would be 0.78 m². 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 m². 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.</p>	<p>this topic.</p>	<p>Open point fulfilled.</p>
	<p>Open point: 5.17 MSs to discuss the reliability of the earthworm field study to address the risk to earthworm population in banana plantation.</p> <p>See reporting table 5(43)</p>	<p>FMC-February 2009: 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.</p>	<p>RMS, 25 February 2009: We welcome a discussion on this topic.</p>	<p><u>PRAPeR TC 09 (5-6 March 2009):</u></p> <p>Open point fulfilled.</p> <p>New data gap proposed, see below.</p> <p>New open point proposed, see below.</p>

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	<p>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</p>			<p><u>PRAPeR TC 09 (5-6 March 2009):</u> Data gap open.</p>
	<p>New open point: 5.21 RMS to update the LoEP according to the suggestions of the experts: The LoEP needs to be 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).</p>			<p><u>PRAPeR TC 09 (5-6 March 2009):</u> Open point open.</p>
	<p>Message from section 1 (Phys-chem meeting): Can you accept the specification as given on page 4 of addendum 2 to Vol. 4?</p>			<p><u>PRAPeR TC 09 (5-6 March 2009):</u> New data gap proposed, see below.</p>
	<p>New data gap 5.8 identified at PRAPeR TC 09 meeting:</p>			<p><u>PRAPeR TC 09 (5-6 March 2009):</u></p>

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	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.			Data gap open.