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REPORT OF PRAPeR EXPERT MEETING 66

LENACIL

Rapporteur Member State: BE

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
2009-04-14	BE	Lenacil evaluation table rev1-0 (2009-04-14).doc
April 2009	BE	Lenacil List of endpoints (April 2009).doc
2009-03-02	BE	Lenacil reporting table rev1-1 (2009-03-02).doc
March 2009	BE	Lenacil VOL4(C1-C2)_update March 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:** Venzar 80 WP

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: LENACIL

Appendix 2: Evaluation table

Appendix 1: Discussion Table, Lenacil (Hb)

1. Physical and Chemical Properties

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
1.1	Point of clarification for the applicant: Applicant to provide information on the level of [redacted] of [redacted] See reporting table 1(2)	Information was included in updated Vol 4	Point of clarification addressed
	Open point: 1.1 The expression of the content of impurity 9 in the five batch to be discussed in a meeting of experts See reporting table 1(11)	Explanation accepted by the meeting	Open point fulfilled
	Open point: 1.2 To be discussed in a meeting of experts whether the 5-batch analysis study (Wittig, 2000) sufficiently covers the analytical profile of lenacil technical.	Information accepted by the meeting, taking into account the closure in the 5 batches being near 100 %	Open point fulfilled

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	See reporting table 1(12)		
	Open point: 1.3 The acceptability of the water measurement by „loss on drying' to be discussed in a meeting of experts. See reporting table 1(14)	The meeting did not accept the "loss on drying" being a good measure of water content	Open point fulfilled. New data gap proposed, see below.
	New data gap identified at PRAPeR 66 meeting: The material quantified under "loss on drying" should be quantified by specific methods		Data gap open.
	Open point: 1.4 The necessity to request the „accelerated' storage stability testing of the preparation if a shelf life study is available to be (re-)discussed in a meeting of experts. See reporting table 1(21)	The meeting discussed the requirement of both studies and concluded that an accelerated storage test is needed because it is required in the Directive and it also models exposure of the PPP to higher temperatures that occur in certain MS.	Open point fulfilled New data gap proposed, see below.
	New data gap		Data gap open.

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	identified at PRAPeR 66 meeting: Accelerated storage stability test of the preparation is required.		
	Open point: 1.5 The acceptability of the suspensibility study to be discussed in a meeting of experts See reporting table 1(22)	The suspensibility issue was discussed and found borderline to unsatisfactory before and after storage.	Open point fulfilled. New data gap proposed, see below.
	New data gap identified at PRAPeR 66 meeting: A sprayability test is required.		Data gap open.
1.2	Point of clarification for the applicant: Applicant to provide information demonstrating acceptable performance of the preparation under field conditions See reporting table 1(25)	See open point 1.5 and the new data gap for sprayability	Point of clarification addressed

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
1.3	Point of clarification for the applicant: Applicant to clarify the unit used in table B.3.5.1.1-1 No. 3 under material/bag See reporting table 1(28)	Applicant provided information on the units used in table B.3.5.1.1-1 No. 3	Point of clarification addressed
	Open point: 1.6 The acceptability of the linearity determination of method (Hansen, 1998 – Report No. AMR 3747-96) to be discussed in a meeting of experts See reporting table 1(29)	Open point redundant because method and 5 batch study was not relied on	Open point fulfilled
	Open point: 1.7 The acceptability of the ICP-OES method (Wittig, 2000 – Report No. PR00/015) to be discussed in a meeting of experts See reporting table 1(30)	The acceptability of the ICP-OES Method was discussed and the meeting agreed that additional validation data was not needed taking into consideration the nature of the impurity and the corresponding analytical technique	Open point fulfilled
	Open point: 1.8 The necessity to provide further data to	The applicability of the multi-residue method was discussed and the meeting concluded that the validation of the S 19 method did not comply with SANCO 825 (only one sample per fortification level), was not fully validated. However sufficient data were presented to	Open point fulfilled

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	demonstrate the applicability of the multi-residue method to be discussed in a meeting of experts. See reporting table 1(35)	demonstrate the applicability of the multi-method in the light that another fully validated method is available.	
	Open point: 1.9 The acceptability of method Brodsky and Zietz as primary method should be discussed in a meeting of experts See reporting table 1(38)	The acceptability of method Brodsky and Zietz as primary method was discussed and found acceptable.	Open point fulfilled
	Open point: 1.10 The necessity to require a confirmatory method for determination of residues in water to be discussed in a meeting of experts See reporting table 1(39)	The necessity for a confirmatory method was discussed and the meeting concluded that a confirmatory technique is now required because of the lack of specificity with DAD.	Open point fulfilled New data gap proposed, see below.
	New data gap identified at PRAPeR 66 meeting: A confirmatory method		

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	for determination of residues in water.		
	Open point: 1.11 The acceptability of the air method with the validated LOQ to be discussed in a meeting of experts See reporting table 1(42)	The acceptability of the air method and the validated LOQ was discussed and the meeting concluded that a new method was required with a LOQ of at least 48 □g/m^3.	Open point fulfilled New data gap proposed, see below.
	New data gap identified at PRAPeR 66 meeting: An air method with a LOQ of at least 48 □g/m^3.is required.		Data gap open.
	New open point 1.12: RMS to amend the list of end points according to the discussions during the PRAPeR 66 meeting	Monitoring methods: method for air is open Method for water: confirmatory method is open Method for soil: delete “primary method” Use correct name for PPP “Venzar 80 WP”	

Appendix 2: Evaluation table

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations PRAPeR Expert Meeting / Conclusions of the Evaluation Meeting
	Section 1 Open points: ***11*** Points for clarification: ***3*** Data gaps: ***0***			Section 1 Open points: ***1*** Data gaps: ***5***
1.1	Point of clarification for the applicant: Applicant to provide information on the level of [redacted] of [redacted] See reporting table 1(2)	The trade name of the additive [redacted] is [redacted] According to published information by the producer (See enclosed << [redacted] product info.pdf>>, the degree of [redacted] is indicated by the first two digits in the trade name. In conclusion [redacted] contains [redacted] moles of [redacted] mole.	RMS considers the provided clarification to be sufficient. The information on degree of [redacted] of the additive has been included in the updated Vol.4 (C) (dated March 2009).	PRAPeR 66 (21 – 24 April 2009): Point of clarification addressed.
	Open point: 1.1 The expression of the content of impurity 9 in the five batch to be discussed in a meeting of experts See reporting table 1(11)	Impurity 9 was determined as total [redacted] n the study report the corresponding [redacted] content has been calculated (The calculation factor is 4.29) and this value has been used in the calculation based on the information from the synthesis process and the earlier 5-batch analysis where [redacted] has been analysed for instead of [redacted]	The mentioned results for [redacted] content from an earlier 5-batch analysis were not provided to the RMS, but this is considered irrelevant.	PRAPeR 66 (21 – 24 April 2009): Open point fulfilled.

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations PRAPeR Expert Meeting / Conclusions of the Evaluation Meeting
		8.3. results  UCL GmbH, Köln page 27/99		
	Open point: 1.2 To be discussed in a meeting of experts whether the 5-batch analysis study (Wittig, 2000) sufficiently covers the analytical profile of lenacil technical. See reporting table 1(12)	The notifier is of the opinion that the 5-batch analysis study does cover the analytical profile of lenacil technical sufficiently. A full screening was done by UCL and each peak has been identified at the time. As the manufacturing process was not changed at [redacted], UCL was able to use previous experience on possible impurities and information from former 5 batch analysis.	Indeed, a limited number of impurities was sought for in the 5-batch analysis study by Wittig (2000). Looking back to the study report, it is noted that two peaks observed in the provided sample chromatogram were not identified. As the identity is unknown, estimating the concentration level is hard; However, comparing their response at wavelengths 200 nm, 270 nm and 285 nm with that of the impurities sought for, it is considered unlikely that these unknown compounds were present at significant levels in the technical material analysed.	PRAPeR 66 (21 – 24 April 2009): Open point fulfilled.
	Open point: 1.3 The acceptability of the water measurement by „loss on drying' to be discussed in a meeting of experts. See reporting table 1(14)	Water content is measured constantly during quality control at Schirm via Karl Fisher Titration. Results from 1999 – 2009 can be provided upon request. The water content for lenacil technical ranges between [redacted] The mean water content measured by "loss on drying" in the five batch analysis study is [redacted] should	The quality control data referred to by the applicant were not provided to the RMS.	PRAPeR 66 (21 – 24 April 2009): Open point fulfilled. New data gap proposed, see below.

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations PRAPeR Expert Meeting / Conclusions of the Evaluation Meeting
		therefore be acceptable.		
	New data gap identified at PRAPeR 66 meeting: The material quantified under "loss on drying" should be quantified by specific methods			PRAPeR 66 (21 – 24 April 2009): Data gap open.
	Open point: 1.4 The necessity to request the „accelerated' storage stability testing of the preparation if a shelf life study is available to be (re-)discussed in a meeting of experts. See reporting table 1(21)	It should be noted that both Croplife Monograph 17 (GIFAP) and CIPAC MT46 clearly indicate that the 54°C stability test is an accelerated test which may be used as a temporary indicator of shelf life stability. If a full 2 year shelf life study has been presented, then accelerated data is redundant and therefore not necessary.	RMS: no additional comment	PRAPeR 66 (21 – 24 April 2009): Open point fulfilled. New data gap proposed, see below.
	New data gap identified at PRAPeR 66 meeting: Accelerated storage stability test of the preparation is required.			PRAPeR 66 (21 – 24 April 2009): Data gap open.
	Open point: 1.5 The acceptability of the suspensibility study to be discussed in a meeting of experts See reporting table 1(22)	The notifier requests that this issue is addressed at member state level during the re-registration of Venzar 80 WP. Evidence of satisfactory importance and homogeneity of the diluted spray solution in the form of efficacy data will be submitted in the biological assessment dossier to	RMS: The overall results for suspensibility (before and after storage) were considered to be unsatisfying, based on the laboratory tests. Further information is to be requested at Member State level.	PRAPeR 66 (21 – 24 April 2009): Open point fulfilled.

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations PRAPeR Expert Meeting / Conclusions of the Evaluation Meeting
		member state authorities.		
	New data gap identified at PRAPeR 66 meeting: A sprayability test is required.			PRAPeR 66 (21 – 24 April 2009): Data gap open.
1.2	Point of clarification for the applicant: Applicant to provide information demonstrating acceptable performance of the preparation under field conditions See reporting table 1(25)	The notifier requests that this issue is addressed at member state level during the re-registration of Venzar 80 WP. Evidence of satisfactory importance and homogeneity of the diluted spray solution in the form of efficacy data will be submitted in the biological assessment dossier to member state authorities.	See open point 1.5	PRAPeR 66 (21 – 24 April 2009): Point of clarification addressed.
1.3	Point of clarification for the applicant: Applicant to clarify the unit used in table B.3.5.1.1-1 No. 3 under material/bag See reporting table 1(28)	“my” was used for the unit “micrometers”: 3. HDPE film, 20 micrometers, needled.	RMS: The point has been sufficiently clarified by the applicant.	PRAPeR 66 (21 – 24 April 2009): Point of clarification addressed.
	Open point: 1.6 The acceptability of the linearity determination of method (Hansen, 1998 – Report No. AMR 3747-96) to be discussed in a meeting of experts See reporting table 1(29)	This method was used in the previous 5-batch analysis report that is provided for reference only and there should be no need to further discuss its acceptability. The HPLC-UV method used in the batch analysis study Wittig (2000) is suitable for the determination of lenacil content in the technical material.	RMS agrees with applicant.	PRAPeR 66 (21 – 24 April 2009): Open point fulfilled.
	Open point: 1.7		Linearity and accuracy data were not	PRAPeR 66 (21 – 24 April 2009):

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations PRAPeR Expert Meeting / Conclusions of the Evaluation Meeting
	The acceptability of the ICP-OES method (Wittig, 2000 – Report No. PR00/015) to be discussed in a meeting of experts See reporting table 1(30)		provided for the ICP-OES method. Following waiver was received from the applicant: *"ICP-OES is a well established technique for inorganic analysis and is generally accepted as being linear and acceptably accurate for all purposes."* RMS can agree that full validation data should have been provided for this method.	Open point fulfilled.
	Open point: 1.8 The necessity to provide further data to demonstrate the applicability of the multi-residue method to be discussed in a meeting of experts. See reporting table 1(35)		The validation data provided in the study by Tillkes (1998) do not fully comply with the requirements of SANCO/825/00. RMS therefore considered the study as being not acceptable, whereas EFSA is of the opinion that it does sufficiently address the demonstration of the applicability of DFG S19, even with the poor validation data set.	PRAPeR 66 (21 – 24 April 2009): Open point fulfilled.
	Open point: 1.9 The acceptability of method Brodsky and Zietz as primary method should be discussed in a meeting of experts See reporting table 1(38)	The notifier agrees with the RMS comments in the reporting table.	RMS considers the method to be acceptable as primary method in the range 0.05 to 0.5 mg/kg. Sufficient replicates were done at each of the fortification levels.	PRAPeR 66 (21 – 24 April 2009): Open point fulfilled.
	Open point: 1.10 The necessity to require a confirmatory method for determination of residues in water to be discussed in a meeting of experts		Before the DAR was finalised, the RMS asked this question to the applicant, who provided the following answer:	PRAPeR 66 (21 – 24 April 2009): Open point fulfilled. New data gap proposed, see below. d.

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations PRAPeR Expert Meeting / Conclusions of the Evaluation Meeting
	See reporting table 1(39)		*"[…] Identity is primarily confirmed by comparison of retention times against standard solutions of lenacil. This is supported by the comparison of UV spectra, which has been reported in a GLP study so presentation of the raw data should not be required. HPLC/DAD is an inherently self-confirmatory technique."*	
	New data gap identified at PRAPeR 66 meeting: A confirmatory method for determination of residues in water.			PRAPeR 66 (21 – 24 April 2009): Data gap open.
	Open point: 1.11 The acceptability of the air method with the validated LOQ to be discussed in a meeting of experts See reporting table 1(42)		Indeed, the validated LOQ of the method is below the relevant concentration C, which was estimated following the guidelines described in SANCO/825/00 rev.7. However, it should be noted that the difference between validated LOQ and concentration C is quite small. In addition, lenacil is a very slightly volatile compound (see B.2.1.5) and furthermore, it should be kept in mind that there is already a safety factor of 100 included in the AOEL and an additional safety factor of 10 for the calculation of concentration C. Therefore, the request for further data may not be necessary in this case.	PRAPeR 66 (21 – 24 April 2009): Open point fulfilled. New data gap proposed, see below.
	New data gap identified at			PRAPeR 66 (21 – 24 April 2009):

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations PRAPeR Expert Meeting / Conclusions of the Evaluation Meeting
	PRAPeR 66 meeting: An air method with a LOQ of at least 48 □g/m^3.is required.			Data gap open.
	New open point 1.12: RMS to amend the list of end points according to the discussions during the PRAPeR 66 meeting			PRAPeR 66 (21 – 24 April 2009): Open point open.

REPORT OF PRAPeR EXPERT MEETING 67

LENACIL

Rapporteur Member State: BE

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
March 2009	BE	Lenacil Addendum to Vol3_B8 (March 2009).doc
2009-04-14	BE	Lenacil evaluation table rev1-0 (2009-04-14).doc
April 2009	BE	Lenacil List of endpoints (April 2009).doc
2009-03-02	BE	Lenacil reporting table rev1-1 (2009-03-02).doc

3. Documents tabled at the meeting:

Date	Supplier	File Name
None		

The conclusions of the meeting were as follows:

4. Data on preparations: Venzar

5. Classification and labelling: candidate for R53

6. Recommended restrictions/conditions for use: none identified

7. Reference list: Not discussed

Areas of concern: groundwater exposure assessment have not been finalised because of non-identified metabolites.

Appendix 1: Discussion table: LENACIL

Appendix 2: Evaluation table

Appendix 1: Discussion Table, Lenacil (Hb)

4. Fate and behaviour

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	Open point: 4.1 RMS to clarify which DT_{50} values for IN-KE121 are the proper values for Sheringham and Wick soils and if necessary, to normalize these values to FOCUS reference conditions in an addendum. Note: the „k' values of these DT_{50} values are reported in Table B.8.1.2.1-13 originating from the report of Shaw (2004). See reporting table 4(5)	The exact DT50 value for the Wick soil was 10.48 days which was rounded to 11 by RMS, notifier states it should be 10 days. 12.3 is the exact value for the Sheringham soil. This was also rounded. The correct actual (without normalisation) DT50 values are: Speyer 2.2: 4.0 days Wolston: 6.2 days Wick: 10.5 days Whimple: 4.7 days Sheringham: 12.3 days Only Sheringham needs moisture correction. This would lead to a normalised DT50 value of 8.9 days instead of 9.0 days. The new geomean is 6.4 days instead of 6.5 days. This has no impact on the exposure assessment. Values as indicated here should be included in the LoEP. Open point fulfilled.	Open point fulfilled.
4.1	Point of clarification for the applicant: Regarding the studies by Theis (2003), Girkin (2003), Berg (1994a) and Berg (1994b): a) correctly	The requested information was provided by the applicant and included in the revised B.8 (March 2009). The experts are content with the classification of the soils and normalisation of the DT50 values. The DT50 values to be selected are discussed in Open point 4.2.	Point of clarification fulfilled.

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	classify the soils b) appropriately normalize the soils to soil moisture (e.g without normalization, where the soils were wet enough) and to temperature where necessary c) calculate the geometric mean values of the normalized DT_{50} values from the studies by Theis (2003) and Girkin (2003) d) calculate the geometric mean values of the normalized DT_{50} values considering all studies e) calculate the mean values of the kinetic formation fractions of the metabolites Before the normalization procedure and derivation of the mean values it should be considered that f) DT_{50} values for IN-KE121 for Sheringham and Wick	Point of clarification fulfilled.	

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	soils might be corrected based on the open point for the comment 4(5) (rounding) g) DT_{50} and kinetic formation fraction for IN-KE121 from the Theis study should not be used h) DT_{50} and kinetic formation fraction for the metabolites derived from the Whimle soil should be used (currently missing from the LoEP) See reporting table 4(13)		
	Open point: 4.2 MS experts to agree on the DT50 and kinetic formation fractions for use in FOCUS simulations (PECsw & PECgw) for lenacil, IN-KF313 and IN-KE121. See reporting table 4(13)	The requested information is provided in the chapter in the revised DAR (March 2009) called „Derivation of the DT50 soil used for the PEC calculations'. Experts confirm that the following values are to be used. Geomean DT50 value — formation fraction (arithmetic mean) Parent only for EU soils: 14.4 d / - IN-KF313 all available soils: 40.9 d / 0.4391 IN-KE121/M15.0 all available soils*: 6.4 d / 0.4766 *DT50 for IN-KE121 only derived from studies dosed with parent (hence EU soils) Open point fulfilled.	Open point fulfilled.

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	Open point: 4.3 Experts to discuss the validity of the studies by Berg 1994a and 1994b and the possible use of the results in the risk assessment. RMS to provide scientifically relevant details of the studies by Berg (1994a and 1994b) (e.g. preparation and storage of the soils, microbial biomass) in an addendum which can facilitate the discussion of experts about the validity of these studies. See reporting table 4(14)	During the commenting round some MS and EFSA doubted on the exclusion of these studies. In the original DAR, comments were made on the experimental design and the studies were discarded, because the use of methylene chloride as a solvent may have compromised the validity (see Column B of the reporting table). For study Berg 1994a (parent), the solvent volume was furthermore small and therefore homogeneous distribution was probably not achieved (as stated by the applicant in the reporting table). RMS considers that microbial activity only started at Day 30 (in the 1994a parent study). Therefore originally both studies were considered not valid by the RMS. In the addendum (which in fact is an updated B.8 of the original DAR with changes in yellow, dated to March 2009) the absence of degradation in the initial stage of the study was shown (for Berg 1994a). Recovery of the microbial biomass was discussed. The kinetic fit seems OK but there are only 4 data points after the degradation starts (in 1994a which is the parent study). Discarding the parent study seems appropriate in view of the all above considerations. For the 1994b study which considers the metabolite IN-KF313, no methylene-chloride was used (probably it was only used for parent lenacil in study 1994a in view of the limited solubility in water) and there is no lag phase for this study (1994b). The slower degradation of IN-KF313 as compared to other studies with IN-KF313 could not be clearly elucidated. However, there is no clear indication that the storage conditions were very inappropriate and hence there is no strong reason why the study should be discarded. Overall, this 1994b study is considered acceptable by the meeting. Therefore the corresponding DT50 values for IN-KF313 should be retained (and added to the LoEP) and used for calculation of a new geomean would be 41 days as opposed to the current geomean of 11 days. This would affect the groundwater and surface water/sediment modelling. Open point fulfilled.	Open point fulfilled. New open point proposed, see below.

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
		New open point for updated PEC groundwater and surface water calculations for IN-KF313.	
	New open point 4.22: RMS to update PEC groundwater and surface water calculations for IN-KF313.		Open point open.
	Open point: 4.4 RMS to provide information on the used kinetic model and the assessment of the goodness of fit for the field dissipation study in an addendum. Note: in the study description FOMC kinetic model is referred, however the ratio between the reported DT_{50} and DT_{90} values indicate SFO kinetics for all the 4 experiments. In the LoEP SFO kinetics are indicated, however the DT_{50} and DT_{90} values are not the same. See reporting table 4(17)	Information is presented in the revised DAR and the latest version of the list of endpoints was amended (April 2009). The kinetic model used for field data is SFO. Fits (checked during the meeting, using the FOCUS kinetics approach) are poor to moderate (chi2 about 20-30) due to the fact that the second day residue is higher than the first day residues (which is a commonly observed phenomenon in field studies). Other kinetic models do not improve the fit. The experts agreed with the presented values. Open point fulfilled.	Open point fulfilled.

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	Open point: 4.5 MS to discuss in a meeting of expert whether the field experiment in Spain is considered as representative to European conditions and the DT_{50} of 88 days (alternatively 52 days) should be used or not for PECsoil calculations for lenacil. MS to discuss moreover the used application intervals, and that the PECsoil for the metabolites should be recalculated using the maximum observed instead of the kinetic formation fractions. See reporting table 4(21)	The application interval was not an issue since the single application is worst-case. The value of 88 days was discarded by the RMS because of the extended dry period. Some member states commented that the value should be retained since these conditions may occur in reality. The study summary does not clearly indicate if irrigation has been applied. For the intended use a period of low precipitation of the initial 3 months would not be very common. However if other uses were to be applied for the value could be more relevant. It is noted that the degradation just followed SFO kinetics despite of the low precipitation at the beginning of the study and there is no reason from a kinetic point of view to discard the site. Experts consider that the value should be retained, but this will not affect the initial PECsoil. In this case, the single application (all 500 g a.s./ha at once) gave the worst-case PECsoil and no DT50 is needed for the initial PEC after a single application. RMS to delete the TWA values from the LoEP and only retain the single application initial PECsoil (since the multiple split application initial PEC after the last application is affected by a change in DT50 value). For metabolites PECsoil calculations it was discussed whether the formation fraction or the max. observed % is to be used. The experts agreed that it should be the maximum observed % from the lab studies. As it appears that the metabolites are less toxic than lenacil they might be assessed on a qualitative basis using the PEC of the a.s.. Open point fulfilled.	Open point fulfilled.
	Open point: 4.6 MS to discuss whether any requirement of additional data for the degradation of lenacil and its metabolites in soil at higher pH is	The pH range tested in the lab studies now is 5.4-6.6 (different matrices). Based on the lab data, it appears that at higher pH the DT50 would be lower. The Spanish field trial had a higher pH and resulted in higher DT50. Based on one observation at a higher pH (7.5) it cannot be stated if pH dependency is an issue. Some pH dependent processes were noted at the phys-chem section. The pKa of the a.s. is 10.	Open point fulfilled. New open point proposed, see below.

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	necessary. See reporting table 4(27)	Open point fulfilled. New open point: EFSA to indicate in the conclusion that pH range of the soils investigated for aerobic degradation rate is limited.	
	New open point 4.23: EFSA to indicate in the conclusion that pH range of the soils investigated for aerobic degradation rate is limited.		Open point open.
4.2	Point of clarification for the applicant: To provide a table of OM% and OC% content, the maximum water holding capacity and the actual wet content (used in the degradation studies) for the soils used in all Berg studies (list references). See reporting table 4(31)	This was presented in the revised DAR. Point of clarification addressed.	Point of clarification addressed.
4.3	Point of clarification to the applicant: Applicant to clearly clarify that the exact identity or structures of the metabolites M14.0	This was clarified to some extent in a position paper presented in the addendum/revised DAR. M15.0 is minor/non-transient (2* > 5%) in soil (therefore needs groundwater exposure assessment). Based on the information available the experts considered it likely that M15.0 is either	Point of clarification addressed.

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	and M15.0 are not available (however their structure are similar to IN-KE121) and confirm that the metabolite IN-KE121 was identified to be 3-cyclohexyl-6,7-dihydro-7-1H-cyclo pentapyrimidine-2,4,5(3H)-trione. Clearly indicate moreover, where the position of metabolite IN-KE121 is in the degradation pathway in soil. See reporting table 4(32)	identical to IN-KE121 or a positional isomer of IN-KE121 with the keto-function on the cyclohexane ring. M14.0 appears to be another positional isomer having the same key features (i.e., oxo-substituted at the cyclohexane ring) as IN-KE121. With respect to phys-chem properties these positional isomers are expected to be very similar. However biodegradation potential may well be different between IN-KE121, M15.0 and M14.0. Point of clarification fulfilled.	
	Open point: 4.7 RMS to remove the DT_{50} of IN-KE121 for the Speyer soil from the LoEP. The PEC values for the metabolite IN-KE121 without using this DT_{50} or the formation fraction calculated from the Theis study might need to be recalculated.	The DT50 for the metabolite in the Speyer soil is a DT50 for M15.0 (identity not fully confirmed), which was characterised as likely to be IN-KE121. IN-KE121 is the second most important metabolite. Main question is whether M15.0 is sufficiently similar to IN-KE121 in terms of degradation characteristics. The experts agreed on balance that the exposure assessment for IN-KE121 would probably cover the assessment for M15.0 even with respect to degradation. Inclusion of the DT50 of M15.0 for assessment of IN-KE121 is considered appropriate since it does not clearly belong to a different moiety. Open point becomes obsolete, the Speyer soil DT50 value should be retained.	Open point becomes obsolete, the Speyer soil DT50 value should be retained.

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	See reporting table 4(32)		
	Open point: 4.8 MS to discuss in a meeting of experts whether to address the leaching potential of M15.0 is necessary. See reporting table 4(32)	This is covered by the leaching assessment for IN-KE121 as discussed above (point of clarification 4.3 and open point 4.7). Open point fulfilled.	Open point fulfilled.
4.4	Point of clarification for the applicant: to clarify whether Polar B, Met.B, category „Polars' or „other polars' from the studies by Berg (1994a) and Girkin, R. (2003) contain any common transformation products. See reporting table 4(36)	NB The Berg 1994a study is not relied on anymore and is not discussed further. There is no clear explanation about the identity or nature of the polar fractions. It is not clear if the polar fraction consists of one or more compounds. Apparently no further analytical attempts were made. There are also some unknown compounds in the lysimeter studies. These are proposed to be pyrimidine ring-opening products. If these lysimeter unknowns are the same as the ones observed in the aerobic rate of degradation study (of Girkin, 2003) then this reinforces the need for further adequate characterisation. Data gap: notifier to provide further characterisation of „Polar B' and/or „polars' from the Girkin study or new incubations with comparable soil types having a proper material balance and characterisation of the radio-activity.	Data gap proposed instead, see below.
	New data gap identified at the PRAPeR 67 meeting: Notifier to provide further characterisation of „Polar B' and/or „polars' from the Girkin		Data gap open.

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	study or new incubations with comparable soil types having a proper material balance and characterisation of the radio-activity.		
	Open point: 4.9 Experts to discuss whether further consideration of Polar B and „Polars' from the study by Girkin, R., 2003 and category „Other polars' and the Met.B from the study by Berg (1994a) is needed. See reporting table 4(36)	See discussion above under point of clarification 4.4. Open point closed.	Open point closed.
	Open point: 4.10 RMS to include the statistical and visual assessment of the fit of the parent compounds and metabolites of the kinetic analysis for each experiment, where the formation fractions and degradation rates of the metabolites were	Some statistical information was presented in the revised DAR. However this was not done according to FOCUS kinetics. No chi2 values are calculated and no visual fits are shown. Although it was not sufficient on its own for the experts to conclude on this point, further analysis during the meeting enabled the experts to conclude that the DT50 values and formation fractions reported were acceptable. Open point open.	Open point open.

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	calculated in an addendum. See reporting table 4(40)		
	Open point: 4.11 RMS to include the DT_{50} values from the Whimle soils in the LoEP. The PEC values using these DT_{50} values and the pertaining to formation fractions might need to be recalculated. See reporting table 4(41)	The DT50 values are now added to the latest LoEP. The experts agreed that the data should be included in the exposure assessment. The formation fractions per soil are presented in the revised DAR. However they are not in the LoEP yet. Open point fulfilled.	Open point fulfilled.
	Open point: 4.12 RMS to include information about the preliminary test to determine the adsorption of the test substance on the surface of the test vessels and its results. See reporting table 4(46)	This refers to page 22 in the original DAR and concerns parent lenacil. Additional information is provided in Column C of the evaluation table regarding the preliminary test. Recoveries in the final test appear to be ranging from 94-105 % for the absorption phase (stated in the original and revised DAR) so losses to the vessel walls do not appear to be a concern in this study. Open point fulfilled.	Open point fulfilled.
	Open point: 4.13 In relation of the adsorption/desorption	a + b) total pH range is 6.3 – 6.8 for the three soils which is very narrow. Experts consider the range too narrow (does not comply with OECD 106) and furthermore consider that the tested pH is not representative of the agronomic conditions favourable for sugar beet	Open point fulfilled. New open point proposed, see

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	study of the metabolite IN-KF313 (Berg, D. S., 1996c), MS to discuss in a meeting of experts: a) similarity of Sassafras and Hillsdale soils b) narrow range of the pH of the used soils c) dependence of the adsorption to any soil parameter (pH, CEC, clay) d) to use the arithmetic mean or the (any) worst case K_{Foc} value for PEC calculations, and/or e) the need of additional adsorption data See reporting table 4(47)	cultivation. c) pH dependency cannot be established nor excluded based on the available data with a narrow pH range. No other soil properties require additional explanation. d) the current groundwater exposure assessment in the revised DAR is based on the 10th-percentile Koc value of 217 L/kg for IN-KF313 as well as on the lowest Koc of 79 L/kg (only mentioned in results table but not the box input parameters) and the arithmetic mean of 557 l/kg (original PEC calculations). The surface water/sediment exposure assessment is not revised and still is based on the arithmetic mean of 557 L/kg for IN-KF313. Preferably the lowest Koc should be used for PECsurface water and sediment at the appropriate STEP required to complete the risk assessment. Possibly STEP 2 might be sufficient. Redo the groundwater PEC calculations and amend the LoEP to only represent the lowest Koc input value and subsequent results also taking into account the new geomean DT50soil of 41 days for IN-KF313. e) a more alkaline soil batch adsorption study would be needed. Therefore a data gap is agreed. Open point fulfilled. New open point: RMS to redo the groundwater PEC calculations and amend the LoEP to only represent the lowest Koc input value and subsequent results also taking into account the new geomean DT50soil of 41 days for IN-KF313, and redo the PEC surface water and sediment calculations for IN-KF313 using the lowest Koc value of 79 L/kg and the new geomean DT50soil of 41 days for IN-KF313. For 1/n see open point 4.14. Data gap: a soil batch adsorption study in one soil for IN-KF313 under environmentally relevant alkaline conditions.	below. New data gap proposed, see below.
	New open point 4.24:		Open point open.

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	RMS to redo the groundwater PEC calculations and amend the LoEP to only represent the lowest Koc input value and subsequent results also taking into account the new geomean DT50soil of 41 days for IN-KF313, and redo the PEC surface water and sediment calculations for IN-KF313 using the lowest Koc value of 79 L/kg and the new geomean DT50soil of 41 days for IN-KF313. For 1/n see open point 4.14.		
	New data gap identified at the PRAPeR 67 meeting: A soil batch adsorption study in one soil for IN-KF313 under environmentally relevant alkaline conditions is missing.		Data gap open.
	Open point: 4.14	Lenacil	Open point fulfilled.

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	MS experts to agree on the K_{Foc} and 1/n values for use in FOCUS simulations for lenacil, IN-KF313 and IN-KE121. See reporting table 4(47)	Kfoc median (n=7) 83 L/kg as proposed by notifier and more conservative than the arithmetic mean. 1/n 0.88 (value associated with the median Kfoc) IN-KF313 Kfoc lowest value 79 L/kg (for now, in the absence of alkaline testing, see OP 4.13) 1/n 1.0 IN-KE121 Kfoc there is an indication of possible pH dependency. Range 30.5-43.5 L/kg which is narrow. Because the Koc range is quite narrow and the pH range is quite wide (5.6-7.3) the mean value is acceptable. Arithmetic mean = 38 L/kg 1/n 0.95 Open point fulfilled.	
	Open point: 4.15 MS to discuss in a meeting of experts whether there is a need for further information for the unidentified lysimeter metabolites M1, M2 and M3 for the EU level assessment. See reporting table 4(50)	The comment made in the peer review is: identification is needed since these metabolites (or molecule fragments) show a high potential for leaching. Now there is only an indication that this concerns ring-opening products. It is a 2004 study so further identification could have been possible. The compound M3 may not be as polar as indicated (in view of the retention time). RMS states that the lysimeter soil is quite vulnerable and the leachate concentrations decrease in the second year. However they are still above 0.1 µg/L in the third year for some of the metabolites. Column B in the evaluation table states that the addendum to the lysimeter study (Schnöder, 2004) contains a thorough assessment of the identity of polar metabolites and is considered sufficient to conclude they are of no concern (included in the revised DAR). This statement did not clarify fully the open point. The meeting is of the opinion that the matter should be resolved at the EU level. Open point fulfilled. Data gap: notifier to provide further (details of) characterisation of M1, M2, and M3 found	Open point fulfilled. New data gap proposed, see below.

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
		in the lysimeter study.	
	New data gap identified at the PRAPeR 67 meeting: Notifier to provide further (details of) characterisation of M1, M2, and M3 found in the lysimeter study.		Data gap open.
	Open point: 4.16 RMS to check the classification of the soils used in the adsorption/desorption studies and change the names of the soils with the soil types based on the USDA classification system in the relevant boxes of the LoEP. See reporting table 4(51)	The LoEP was not amended. Normally in the LoEP the soil types are provided instead of the site names. Since the textural classes are subdivided differently in the two classification systems it is not possible to convert the UK/BBA classification into the USDA classification. As there is no need for this property to be taken into account in the assessment, this is not considered absolutely necessary. Open point fulfilled.	Open point fulfilled.
4.5	Point of clarification for the applicant: to clarify whether is it correct that the Elmton soil in the study by Kane, T., 2004 had a $CaCO_3$ content of	It was confirmed that the CaCO3 content was indeed 263.1 g/kg. Point of clarification addressed.	Point of clarification addressed.

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	263.1 g/kg. See reporting table 4(53)		
	Open point: 4.17 RMS to amend the LoEP taking into consideration all the inconsistency identified in the reporting table. RMS to highlight all the changes in the LoEP with a colour (yellow is already proposed by the RMS for changes in February 2009) as part of the track changes procedure. See reporting table 4(55)	Open point still open. Please consider all further remarks made during the meeting.	Open point still open.
	Open point: 4.18 MS to discuss in a meeting of experts whether additional PECsw and PECsed calculation is needed or not with the option of DT50 of 1000 days for the sediment phase and geomean DT50 of the total system for the water phase.	Degradation DT50 from the whole system has been used for the sediment phase and 1000 days for the water phase. The water-sediment study did not indicate that degradation did occur in the sediment. However, as the aquatic risk assessment is driven by the aquatic plants the provided calculation is regarded as worst-case. Therefore no reverse calculation is deemed necessary. Open point fulfilled.	Open point fulfilled.

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	See reporting table 4(62)		
	Open point: 4.19 RMS to indicate in the LoEP the washoff factor used in the FOCUS calculations. See reporting table 4(67)	The wash-off factor was indicated in the box for new groundwater calculations. However for the surface water PEC calculations it should still be added in the LoEP. Open point open.	Open point open.
	Open point: 4.20 RMS to clarify that the crop washoff factor was used only for SW calculations or for the GW calculations as well and that whether the crop half-life was or was not changed for the modelling in an addendum. See reporting table 4(67)	The substance is applied in the first stage of plant growth in which interception will be limited. RMS therefore considers that the factor will have low impact on the modelling. For surface water a value of 0.03 was used instead of 0.026 (which would have been the right value because of the water solubility using the FOCUS guidance); the use of 0.03 was considered worst-case and therefore is acceptable. NB the interception in groundwater modelling was 20 %, the application rate was corrected to net application rate directly to soil before groundwater modelling; so no plant processes are used in the simulations. Agreed. RMS could not confirm whether the crop half-life (in FOCUS surface water and groundwater) was left at default for the new modelling. Open point still open with regard to the crop half-life value.	Open point still open with regard to the crop half-life value.
	Open point: 4.21 The studies by Berg (Berg, D. S. 1994a and Berg, D. S. 1994b) should be removed from the list of	Berg 1994b should be retained following the meeting's discussion. Berg 1994a should be removed from the list of studies relied on. To be done after the meeting. Open point open.	Open point open.

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	references relied on depending on the discussions on the validity of these studies during the peer review. See reporting table 4(68)		
	Discussion of definition of residues for further assessment.	Agreed in the meeting (provisionally, pending on further identification/characterisation of the unknowns): Soil: lenacil, IN-KE121, IN-KF313 + polar B, „polars' Groundwater: lenacil, IN-KE121, IN-KF313 + polar B, „polars„ and M1, M2, M3 (lysimeter) Surface water: lenacil, IN-KE121, IN-KF313 + polar B, „polars' (entry via soil) Sediment: lenacil, IN-KE121, IN-KF313 Air: lenacil	

Appendix 2: Evaluation table

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations PRAPeR Expert Meeting / Conclusions of the evaluation group
	Section 4 Open points: ***21*** Points for clarification: ***5*** Data gaps: ***0***			Section 4 Open points: ***8*** Data gaps: ***3***
	Open point: 4.1 RMS to clarify which DT_{50} values for IN-KE121 are the proper values for Sheringham and Wick soils and if necessary, to normalize these values to FOCUS reference conditions in an addendum. Note: the „k' values of these DT_{50} values are reported in Table B.8.1.2.1-13 originating from the report of Shaw (2004). See reporting table 4(5)	Only correction of the observed DT_{50} values for the Sheringham and Wick soils is necessary. The remainder of Table B8.1.2.1-16 is correct. Further normalisation of the DT_{50} values for IN-KE121 is not necessary.	See below	PRAPeR 67 (20 -24 April.2009): Open point fulfilled.
4.1	Point of clarification for the applicant: Regarding the studies by Theis (2003), Girkin (2003), Berg (1994a) and Berg (1994b): i) correctly classify the soils	The requested information is provided in the attached position paper for environmental fate.	The information has been included in the updated chapter B.8.	PRAPeR 67 (20 -24 April.2009): Point of clarification addressed.

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations PRAPeR Expert Meeting / Conclusions of the evaluation group
	j) appropriately normalize the soils to soil moisture (e.g without normalization, where the soils were wet enough) and to temperature where necessary k) calculate the geometric mean values of the normalized DT_{50} values from the studies by Theis (2003) and Girkin (2003) l) calculate the geometric mean values of the normalized DT_{50} values considering all studies m) calculate the mean values of the kinetic formation fractions of the metabolites Before the normalization procedure and derivation of the mean values it should be considered that n) DT_{50} values for IN-KE121 for Sheringham and Wick soils might be corrected based on the open point for the comment 4(5) (rounding) o) DT_{50} and kinetic formation fraction for IN-KE121 from the Theis study should not be used			

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations PRAPeR Expert Meeting / Conclusions of the evaluation group
	p) DT_{50} and kinetic formation fraction for the metabolites derived from the Whimle soil should be used (currently missing from the LoEP) See reporting table 4(13)			
	Open point: 4.2 MS experts to agree on the DT50 and kinetic formation fractions for use in FOCUS simulations (PECsw & PECgw) for lenacil, IN-KF313 and IN-KE121. See reporting table 4(13)	It is considered that the data analysis provided by Shaw (2004) is sufficient and the values given for lenacil, IN-KE313 and IN-KE121 should be referred to as the definitive end-points.	The information has been added in the DAR	PRAPeR 67 (20 -24 April.2009): Open point fulfilled.
	Open point: 4.3 Experts to discuss the validity of the studies by Berg 1994a and 1994b and the possible use of the results in the risk assessment. RMS to provide scientifically relevant details of the studies by Berg (1994a and 1994b) (e.g. preparation and storage of the soils, microbial biomass) in an addendum which can facilitate the discussion of experts about the validity of these studies.	It should be noted that in the Berg (1994a) study the test item was applied using methylene chloride (0.25 mL) as the carrier solvent. The use of this solvent may have adversely affected soil microbial populations. Also addition of a water immiscible solvent to the soil may have affected the distribution of the test item resulting in „hot-spots' which could have affected the subsequent degradation rate.	The notifier indicated that the test item was applied using methylene chloride (0.25 mL) as the carrier solvent. The use of this solvent may have adversely affected soil microbial populations. Also addition of a water immiscible solvent to the soil may have affected the distribution of the test item resulting in „hot-spots' which could have affected the subsequent degradation rate. There are no detailed information on the biomass evolution. The soils were taken from field sites and storted moist under refrigeration at 4°C for less than 90 days.	PRAPeR 67 (20 -24 April.2009): Open point fulfilled. New open point proposed, see below.

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations PRAPeR Expert Meeting / Conclusions of the evaluation group
	See reporting table 4(14)		The graphs showing the evolution of the as and metabolites show that metabolite formation and mineralisatioan were very limited in this study. Bound residue formation is the main process of this study.	
	New open point 4.22: RMS to update PEC groundwater and surface water calculations for IN-KF313.			PRAPeR 67 (20 -24 April.2009): Open point open.
	Open point: 4.4 RMS to provide information on the used kinetic model and the assessment of the goodness of fit for the field dissipation study in an addendum. Note: in the study description FOMC kinetic model is referred, however the ratio between the reported DT_{50} and DT_{90} values indicate SFO kinetics for all the 4 experiments. In the LoEP SFO kinetics are indicated, however the DT_{50} and DT_{90} values are not the same. See reporting table 4(17)	The field study data are evaluated in the report by Shaw (2004) using first order kinetics. Goodness of fit data is adequately presented in the report and is reproduced in Table B 8.1.3.1-2.	Sufficient information is available in the report by Shaw (2004) and in the DAR.	PRAPeR 67 (20 -24 April.2009): Open point fulfilled.

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations PRAPeR Expert Meeting / Conclusions of the evaluation group
	Open point: 4.5 MS to discuss in a meeting of expert whether the field experiment in Spain is considered as representative to European conditions and the DT_{50} of 88 days (alternatively 52 days) should be used or not for PECsoil calculations for lenacil. MS to discuss moreover the used application intervals, and that the PECsoil for the metabolites should be recalculated using the maximum observed instead of the kinetic formation fractions. See reporting table 4(21)	The soil studied at the site in Spain indicates an extreme condition with respect to degradation. The data point is an outlier in the overall behaviour of lenacil in field soil, which was noted by the RMS. The risk assessment is based on maximum initial PEC values so there will be no impact if a different DT50 is used.	The RMS considers that the long DT50 that has been observed in the study performed in Spain can be explained by the negligible degradation on a very dry soil during the 3 first months after application. The RMS considers that this study cannot be used to derive a meaningful DT50 for PEC assessment. The risk assessment is based on maximum initial PEC values so there will be no impact if a different DT50 is used.	PRAPeR 67 (20 -24 April.2009): Open point fulfilled.
	Open point: 4.6 MS to discuss whether any requirement of additional data for the degradation of lenacil and its metabolites in soil at higher pH is necessary. See reporting table 4(27)	The range of soils tested is considered adequate to determine the route and rate of degradation of lenacil and metabolites.	Point to be discussed in PRAPER meeting.	PRAPeR 67 (20 -24 April.2009): Open point fulfilled. New open point proposed, see below.
	New open point 4.23: EFSA to indicate in the			PRAPeR 67 (20 -24 April.2009): Open point open.

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations PRAPeR Expert Meeting / Conclusions of the evaluation group
	conclusion that pH range of the soils investigated for aerobic degradation rate is limited.			
4.2	Point of clarification for the applicant: To provide a table of OM% and OC% content, the maximum water holding capacity and the actual wet content (used in the degradation studies) for the soils used in all Berg studies (list references). See reporting table 4(31)	Berg 1994a (AMR 2400-92) Lenacil Soil Degradation Sassafras OM% = 1.3 OC% = 0.75 (by calculation) MWHC = 12.1 Hillsdale OM% = 2.0 OC% = 1.16 (by calculation) MWHC = 17.5 Tama OM% = 2.3 OC% = 1.33 (by calculation) MWHC = 28.2 Study conducted at pF 2.5. Study initiated 28/8/1992 Berg 1994b (AMR 2545-92) IN-KF313 Soil Degradation Sassafras OM% = 0.9 OC% = 0.52 (by calculation) MWHC = 8.5 Hillsdale OM% = 1.0 OC% = 0.58 (by calculation) MWHC = 8.2 Tama	The information has been included in the updated chapter B.8.	PRAPeR 67 (20 -24 April.2009): Point of clarification addressed.

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations PRAPeR Expert Meeting / Conclusions of the evaluation group
		OM% = 2.4 OC% = 1.39 (by calculation) MWHC = 23.5 Study conducted at pF 2.5. Study initiated 17/11/1993 Berg 1996 (AMR 2948-94) IN-KF313 Adsorption/Desorption Sassafras OM% = 0.9 OC% = 0.52 (by calculation) MWHC = 8.5 Hillsdale OM% = 1.0 OC% = 0.58 (by calculation) MWHC = 8.2 Tama OM% = 2.4 OC% = 1.39 (by calculation) MWHC = 23.5 Study initiated 23/5/1994 The soils used were taken from the same location and in all probability were the same batch. Reduction in OM content between 28/8/1992 and 17/11/1993 would appear to be consistent with storage of the soil. The same characterisation results were used for the adsorption/desorption study suggesting that the same batch of soil was tested.		
4.3	Point of clarification to the	Identity of M14/M15 as IN-KE121 in	The information has been included in	PRAPeR 67 (20 -24 April.2009):

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations PRAPeR Expert Meeting / Conclusions of the evaluation group
	applicant: Applicant to clearly clarify that the exact identity or structures of the metabolites M14.0 and M15.0 are not available (however their structure are similar to IN-KE121) and confirm that the metabolite IN-KE121 was identified to be 3-cyclohexyl-6,7-dihydro-7-1H-cyclo pentapyrimidine-2,4,5(3H)-trione. Clearly indicate moreover, where the position of metabolite IN-KE121 is in the degradation pathway in soil. See reporting table 4(32)	the study by Theis (2003) was indicated by MS analysis but the assignment was not definitive. Conclusion described M14/M15 as oxo-lenacil. Study by Girkin gives a better understanding of the metabolite profile in soil. 3-cyclohexyl-6,7-dihydro-7-1H-cyclo pentapyrimidine-2,4,5(3H)-trione is the chemical name for IN-KF313. IN-KF313 (5-oxo-lenacil) results from oxidation of the cyclopentapyrimidine ring moiety. IN-KE121 (7-oxo-lenacil) results from oxidation of the cyclohexyl ring moiety. Both processes can occur simulataneously. Further degradation probably occurs by opening of the pyrimidine ring to produce a number of unidentified polar fragments prior to mineralisation.	the updated chapter B.8.	Point of clarification addressed.
	Open point: 4.7 RMS to remove the DT_{50} of IN-KE121 for the Speyer soil from the LoEP. The PEC values for the metabolite IN-KE121 without using this DT_{50} or the formation fraction calculated from the Theis study might need to be recalculated.	From the known degradation profile it is reasonable to conclude that M15 is equivalent to IN-KE121 and the data from the Speyer soil may be used.	From the known degradation profile it is reasonable to conclude that M15 is equivalent to IN-KE121 and the data from the Speyer soil may be used. An assessment of the metabolites that are present in the environment has been performed in the toxicological chapter.	PRAPeR 67 (20 -24 April.2009): Open point becomes obsolete, the Speyer soil DT50 value should be retained.

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations PRAPeR Expert Meeting / Conclusions of the evaluation group
	See reporting table 4(32)			
	Open point: 4.8 MS to discuss in a meeting of experts whether to address the leaching potential of M15.0 is necessary. See reporting table 4(32)	M15 is considered to be equivalent to IN-KE121 and the leaching potential of this metabolite has been addressed.	According to the RMS, sufficient information on the leaching potential of the metabolites is available: detailed information in the lysimeter study, assessment of the toxicological relevance, detailed PECgw calculations for the a.s. and 2 main metabolites) metabolites.	PRAPeR 67 (20 -24 April.2009): Open point fulfilled.
4.4	Point of clarification for the applicant: to clarify whether Polar B, Met.B, category „Polars' or „other polars' from the studies by Berg (1994a) and Girkin, R. (2003) contain any common transformation products. See reporting table 4(36)	It is not possible to conclude whether the named fractions contain common products. The fractions in question are areas of unresolved radioactivity eluting at T_0 by HPLC or remaining at the origin by TLC. The indication is that the material is highly polar. Inspection of the structure of lenacil and its known metabolites suggests that the polar material must result from a significant breakdown of the lenacil molecule. A large number of fragments are possible but none will be significant as a percent of applied.	The RMS considers that the study of Berg (1994a) is not acceptable and cannot be used in the risk assessment. In this study no degradation has been observed for at least 14 days According to the RMS, sufficient information on the leaching potential of the metabolites is available: detailed information in the lysimeter study, assessment of the toxicological relevance, detailed PECgw calculations for the a.s. and 2 main metabolites) metabolites.	PRAPeR 67 (20 -24 April.2009): Data gap proposed instead, see below.
	New data gap identified at the PRAPeR 67 meeting: Notifier to provide further characterisation of „Polar B' and/or „polars' from the Girkin study or new incubations with comparable soil types having a proper material balance			PRAPeR 67 (20 -24 April.2009): Data gap open.

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations PRAPeR Expert Meeting / Conclusions of the evaluation group
	and characterisation of the radio-activity.			
	Open point: 4.9 Experts to discuss whether further consideration of Polar B and „Polars' from the study by Girkin, R., 2003 and category „Other polars' and the Met.B from the study by Berg (1994a) is needed. See reporting table 4(36)	See above comment.	See above comment.	PRAPeR 67 (20 -24 April.2009): Open point closed.
	Open point: 4.10 RMS to include the statistical and visual assessment of the fit of the parent compounds and metabolites of the kinetic analysis for each experiment, where the formation fractions and degradation rates of the metabolites were calculated in an addendum. See reporting table 4(40)	Exisiting statistical assessment presented in the report by Shaw (2004) is sufficient. Further recalculation is not considered necessary.	Sufficient information is available in the report by Shaw (2004) and in the DAR.	PRAPeR 67 (20 -24 April.2009): Open point open.
	Open point: 4.11 RMS to include the DT_{50} values from the Whimle soils in the LoEP. The PEC values using these DT_{50} values and the pertaining to formation fractions might need to be	Whimple soil omitted because the statistical fit was poor in the analysis performed by Shaw (2004). Inclusion of this soil will give a lower mean DT50 for the metabolites and hence a less conservative risk assessment.	The Whimple soil has been added in the DAR	PRAPeR 67 (20 -24 April.2009): Open point fulfilled.

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations PRAPeR Expert Meeting / Conclusions of the evaluation group
	recalculated. See reporting table 4(41)			
	Open point: 4.12 RMS to include information about the preliminary test to determine the adsorption of the test substance on the surface of the test vessels and its results. See reporting table 4(46)	Recoveries were quantitative in preliminary tests indicating no adsorption to the test vessels.	Recoveries were quantitative in preliminary tests indicating no adsorption to the test vessels.	PRAPeR 67 (20 -24 April.2009): Open point fulfilled.
	Open point: 4.13 In relation of the adsorption/desorption study of the metabolite IN-KF313 (Berg, D. S., 1996c), MS to discuss in a meeting of experts: f) similarity of Sassafras and Hillsdale soils g) narrow range of the pH of the used soils h) dependence of the adsorption to any soil parameter (pH, CEC, clay) i) to use the arithmetic mean or the (any) worst case K_{Foc} value for PEC calculations, and/or j) the need of additional adsorption data	Additional sorption data are available from the lysimeter study which shows no movement of lenacil or its significant metabolites. Further data are not considered necessary.	According to the RMS, sufficient information on the leaching potential of the metabolites is available: detailed information in the lysimeter study, assessment of the toxicological relevance, detailed PECgw calculations for the a.s. and 2 main metabolites) metabolites.	PRAPeR 67 (20 -24 April.2009): Open point fulfilled. New open point proposed, see below. New data gap proposed, see below.

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations PRAPeR Expert Meeting / Conclusions of the evaluation group
	See reporting table 4(47)			
	New open point 4.24: RMS to redo the groundwater PEC calculations and amend the LoEP to only represent the lowest Koc input value and subsequent results also taking into account the new geomean DT50soil of 41 days for IN-KF313, and redo the PEC surface water and sediment calculations for IN-KF313 using the lowest Koc value of 79 L/kg and the new geomean DT50soil of 41 days for IN-KF313. For 1/n see open point 4.14.			PRAPeR 67 (20 -24 April.2009): Open point open.
	New data gap identified at the PRAPeR 67 meeting: A soil batch adsorption study in one soil for IN-KF313 under environmentally relevant alkaline conditions is missing.			PRAPeR 67 (20 -24 April.2009): Data gap open.
	Open point: 4.14 MS experts to agree on the K_{Foc} and 1/n values for use in FOCUS simulations for	Exisiting adsorption data in conjunction with the short DT_{50} and lysimeter information are sufficient to determine a low risk from leaching. Additional	According to the RMS, sufficient information on the leaching potential of the metabolites is available: detailed information in the lysimeter study,	PRAPeR 67 (20 -24 April.2009): Open point fulfilled.

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations PRAPeR Expert Meeting / Conclusions of the evaluation group
	lenacil, IN-KF313 and IN-KE121. See reporting table 4(47)	modelling with PEARL to confirm this point is provided in the attached position paper for environmental fate. Further studies to calculate additional adsorption data for lenacil and metabolites is not considered necessary.	assessment of the toxicological relevance, detailed PECgw calculations for the a.s. and 2 main metabolites) metabolites.	
	Open point: 4.15 MS to discuss in a meeting of experts whether there is a need for further information for the unidentified lysimeter metabolites M1, M2 and M3 for the EU level assessment. See reporting table 4(50)	The addendum to the lysimeter study (Schnöder, 2004) contains a thorough assessment of the identity of polar metabolites and is considered sufficient to conclude they are of no concern.	The addendum to the lysimeter study (Schnöder, 2004) has been included in the DAR.	PRAPeR 67 (20 -24 April.2009): Open point fulfilled. New data gap proposed, see below.
	New data gap identified at the PRAPeR 67 meeting: Notifier to provide further (details of) characterisation of M1, M2, and M3 found in the lysimeter study.			PRAPeR 67 (20 -24 April.2009): Data gap open.
	Open point: 4.16 RMS to check the classification of the soils used in the adsorption/desorption studies and change the names of the soils with the soil types based on the USDA classification system	Soils characterised in the study by Girkin (2002) used the UK/BBA classification scheme and the results should be reported as such. USDA classification is not possible from the data available for these soils.	Soils characterised in the study by Girkin (2002) used the UK/BBA classification scheme and the results should be reported as such. USDA classification is not possible from the data available for these soils.	PRAPeR 67 (20 -24 April.2009): Open point fulfilled.

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations PRAPeR Expert Meeting / Conclusions of the evaluation group
	in the relevant boxes of the LoEP. See reporting table 4(51)			
4.5	Point of clarification for the applicant: to clarify whether is it correct that the Elmton soil in the study by Kane, T., 2004 had a $CaCO_3$ content of 263.1 g/kg. See reporting table 4(53)	The value of 263.1 g/kg is correct as shown in the original study report.	Addressed	PRAPeR 67 (20 -24 April.2009): Point of clarification addressed.
	Open point: 4.17 RMS to amend the LoEP taking into consideration all the inconsistency identified in the reporting table. RMS to highlight all the changes in the LoEP with a colour (yellow is already proposed by the RMS for changes in February 2009) as part of the track changes procedure. See reporting table 4(55)	No further comment.	The information has been included in the listing of endpoints.	PRAPeR 67 (20 -24 April.2009): Open point still open.
	Open point: 4.18 MS to discuss in a meeting of experts whether additional PECsw and PECsed calculation is needed or not with the option of DT50 of	Using the default value of 1000 days for the water phase will give worst-case values for PECsw compared to PECsed. The ecotox risk from the use of lenacil is associated with aquatic plants and therefore a worst-case		PRAPeR 67 (20 -24 April.2009): Open point fulfilled.

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations PRAPeR Expert Meeting / Conclusions of the evaluation group
	1000 days for the sediment phase and geomean DT50 of the total system for the water phase. See reporting table 4(62)	assessment has already been conducted. Revision of the PEC values is not considered necessary.		
	Open point: 4.19 RMS to indicate in the LoEP the washoff factor used in the FOCUS calculations. See reporting table 4(67)	A value of 0.03 cm^{-1} was used for the surface water calculations only.	The washoff factor of 0.03 cm^{-1} has been added in the listing of endpoints	PRAPeR 67 (20 -24 April.2009): Open point open.
	Open point: 4.20 RMS to clarify that the crop washoff factor was used only for SW calculations or for the GW calculations as well and that whether the crop half-life was or was not changed for the modelling in an addendum. See reporting table 4(67)	A value of 0.03 cm^{-1} was used for the surface water calculations only. This represents a change from the default value of 0.05 cm^{-1}, however it is not expected to make a significant change to the resulting PEC values.	The washoff factor of 0.03 cm^{-1} has been added in the listing of endpoints	PRAPeR 67 (20 -24 April.2009): Open point still open with regard to the crop half-life value.
	Open point: 4.21 The studies by Berg (Berg, D. S. 1994a and Berg, D. S. 1994b) should be removed from the list of references relied on depending on the discussions on the validity of these studies during the peer review.	The studies in question should be removed.	The change has been done in the updated chapter B.8.	PRAPeR 67 (20 -24 April.2009): Open point open.

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations PRAPeR Expert Meeting / Conclusions of the evaluation group
	See reporting table 4(68)			

REPORT OF PRAPeR EXPERT MEETING 68

LENACIL

Rapporteur Member State: BE

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
14.04.2009	BE	Lenacil evaluation table rev1-0 (2009-04-14).doc
April 2009	BE	Lenacil List of endpoints (April 2009).doc
April 2009	BE	Lenacil Addendum to Vol3_B9 (April 2009).doc
Nov 2007	BE	Lenacil list of data relied on (Nov 2007) ver1.doc
02.03.2007	BE	Lenacil reporting table rev1-1 (2009-03-02).doc
April 2009	BE	Lenacil updated DAR Vol3 (B9)_April 2009.doc
April 2009	BE	Lenacil VOL4(C1-C2)_update March 2009_cover page.doc

3. Documents tabled at the meeting:

Date	Supplier	File Name
none		

The conclusions of the meeting were as follows:

4. **Data on preparations:** Venzar 80WP

5. **Classification and labelling:** N, R50/53

6. **Recommended restrictions/conditions for use:** aquatic (algae, aquatic plants) risk assessment not finalised

7. **Reference list:** Not discussed.

Areas of concern: risk to aquatic organisms (algae, aquatic plants)

Appendix 1: Discussion table: LENACIL

Appendix 2: Evaluation table

Appendix 1: Discussion Table, Lenacil (Hb)

5. Ecotoxicology

	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	Open Point: 5.1 B.9.2.12, Effects on primary productivity and macrophyte biomass in field-based microcosms, (Jenkins, 2005). Several uncertainties (is not clear where the study was conducted, results of statistical analysis are not presented, the study was performed with a single application) can be observed in the outdoor microcosm study. Furthermore, some MS did not agree with the NOEAEC = 22.1 µg a.s./L, proposed by the RMS considering that at this endpoint it was noted that there were effects on *Elodea*	RMS revised the DAR, adding the requested information (location, water quality parameters, weather conditions, result graphs especially for *Elodea canadensis* and Charophyta). The notifier presented more information on the microcosm, which was presented in the addendum (nominal/measured concentrations, timing of application, frequency of application). RMS finally agreed to the NOAEC of 22.1 ug/L with a safety factor of 5. The concentrations after 3 d were higher than after 3 h, how is this possible? The presence of macrophytes might have caused slow mixing, which could explain the increasing concentration after 3 days. However, the maximum concentration measured was 10.17 ug/L, which is much lower than the NOAEC. The safety factor is not normally used to cover discrepancies between nominal and measured concentrations. The notifier addresses this in the addendum: application by spraying, reducing drift. Reason for low initial measured concentrations is unknown, however the spraying solution was confirmed to contain the correct concentration. The macrophyte cover of the microcosm cannot fully explain the low measurement. The meeting agrees that the NOAEC should be based on the measured concentration, not on the nominal. Initial, mean or maximum measured? At nominal conc of 22.1, the initial measured concentration is 7.66, after 3 d it is 10.17. The routes of exposure according to the fate LoE are spray drift, run-off and drainage. In that case, mean measured is preferred? Time frame over which the measured concentration should be calculated should include recovery. Therefore, mean measured concentration over whole duration should be calculated.	Open point fulfilled. New data gap proposed, see below. New Open point proposed, see below.

	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	canadensis and Charophyta. The endpoint for the microcosm study (Jenkins, 2005) as well as the assessment factor to be applied should be discussed by the MS experts in a meeting. See reporting table 5(7)	<u>Macrophytes :</u> Competition is not addressed in this type of microcosm with potted plants. In reality, a small effect on one species might already cause it to be outcompeted. Therefore, recovery should be considered with care. Also, the study was performed quite late in the season (application late in July). The control shows a decline in some species, therefore the observed recovery might be questionable. Recovery in the study takes 8 weeks, so with four applications you would not see recovery within 8 weeks. NOECs are more easily extrapolated to different climatic systems than NOEAECs. Because of these reasons, the NOEC is a better endpoint. However, for one species a NOEC could not be determined (Charophyta). This species was not introduced but arrived by itself. It was mainly present in the control, less in the treatments. RMS argued that, there were 12 macrophyte species tested in the mesocosm; Charophyta NOEC < 0.4 µg as/L; Elodea NOEC = 5.81 µg as/L; other 10 species NOEC >= 22.1 µg as/L and so the functioning of the system would not be affected. However, usually species are considered individually. Also, the fact that plants were potted makes it difficult to talk about functioning of the system. Macrophytes provide habitat structure to many other species. The fact that a non-potted species (Charophyta) showed most effect is worrying. There is another study (not considered valid for risk assessment) in which Elodea was the most sensitive species. Not all species showed recovery. Quite some introduced species are only partly submerged. Is this worst-case for exposure or would fully submerged species be preferred? No clear recommendation from AMRAP on this. The notifier argues that the effect seen on Charophyta might not be treatment related but be caused by its random distribution over the cosms. This could be proven by doing a toxicity study with Charophyta to show its relative sensitivity.	

	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
		Conclusion: the NOEAEC cannot be used. A NOEC cannot be determined at the moment, a study on Charophyta on its relative sensitivity is necessary. Depending on the outcome of that study: 1) Charophyta is sensitive: the microcosm cannot be used since a NOEC cannot be determined, but the risk assessment should take into account the information from the microcosm that the first tier endpoint might not be conservative enough. 2) Charophyta is not sensitive: the endpoint from the microcosm that can be used in the risk assessment is the NOEC for Elodea of 2.43 (max. measured) with a safety factor (of 2-5, to be determined at MS level). A safety factor of 1 is not recommend because (some points are discussed further below): - potted plants were used, so competition was not addressed - application late in the season - variability in measured concentration from the beginning of the study - NOEC could not be determined for Charophyta and algae - indirect effects on zooplankton were not monitored - many plant species were not fully submerged - substance is persistent NB first tier macrophyte endpoint is Lemna: 19 ug as/L so higher tier is more conservative. It was questioned whether algae, which are sensitive, were included in the mesocosm. RMS explained that they were. Lowest first tier EC50 for algae is 7.7 ug/L (mm). From the microcosm we can conclude on a NOEC for algae of 83.7 based on clorophyll and biomass, but for the PRC the NOAEC is 83.7 based on recovery (the NOEC for phytoplankton would be <0.4 ug/L nom.). Algae recover more easily than macrophytes, however, the time needed for recovery in the study is long (8 weeks), and the study does not take into account the multiple applications. Therefore it is uncertain that recovery in the field will occur within a reasonable time (8 weeks after the first application). So also for algae, the meeting concludes that the NOEC should be used instead of an endpoint based on recovery. If there would be only one application in the field, the meeting could agree to use the NOEAEC of 83.7 ug/L for algae. Zooplankton was not affected despite the initial decline in algae (only sampled on day 62	

	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
		in the cosm, but daphnids were also followed from day 16 till day 36 in the lab). It was questioned whether indirect effects were sufficiently addressed. Some MS would not use the microcosm at all because of all the deficiences. They would ask for a test with a second macrophyte species (which?) and perform the risk assessment based on the first tier data. Others would take the information from the microcosm into account. From the cosm we now know that the chronic route is more important, and that algal recovery takes a long time. At calculated PEC levels there were effects in the cosm and this should not be ignored. The route of exposure is more covered in microcosm, than in the lab studies. . Should a new micro/mesocosm study be required? This was not considered necessary. Addendum page 3-4: notifier did a calculation for multiple applications of concentrations that could be expected in the cosm: max. 2.43 ug as/L after 4 applications. However, all these concentrations are higher than the concentrations at which effects were found in the cosm. Due to the issues identified in the microcosm, the meeting agreed that it would not be possible to exclude it from the risk assessment and it is not possible to use first tier data only. Therefore the risk assessment cannot be finalised at the moment. Data gap: The relative sensitivity of Charophyta should be determined. If it turns out to be not sensitive, we can use the NOEC for Elodea (2.43 max.measured) and the NOEAEC of 48.32 (max.measured) for algae in the case of a single application (so the GAP should be restricted). If it is sensitive, could the lab NOEC be used for risk assessment over the microcosm NOEC? According to AMRAP this is sometimes acceptable. We know that Lemna has equal sensitivity in the lab and the cosm. However algae are more sensitive in the cosm than in the lab. If multiple applications are still intended, then a NOEC for algae should be defined. Lab NOECs are already available so it would have to be explained why the microcosm NOEC	

	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
		is lower than the lab NOECs (which are 11(mm), 3.4(mm), 10(n) (the latter is from a study not accepted see o.p. 5.2). New open point: RMS to update LoE: Perform first tier risk assessment for fish and daphnids. Delete first tier TERs for algae and macrophytes (because these indicate low risk, which may be confusing for the risk managers). State with a footnote that the first tier endpoints are not protective enough for algae and macrophytes. Remove the metabolites from the section „ecotoxicologically relevant compounds'.	
	New data gap identified at PRAPeR 68 meeting: The relative sensitivity of Charophyta should be determined.		Data gap open
	New open point identified at PRAPeR 68 meeting: RMS to update LoE: Perform first tier risk assessment for fish and daphnids. Delete first tier TERs for algae and macrophytes (because these indicate low risk, which may be confusing for the risk managers). State with a footnote that the first tier endpoints are not protective enough for algae and		Open point open

	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	macrophytes. Remove the metabolites from the section „ecotoxicologically relevant compounds'.		
	Open point: 5.2 B.9.2 Effects on aquatic organisms, B.9.2.8 Effects on algae. The study by Douglas M.T. and Handley J.W., 1988 is regarded as not acceptable and should only be used as additional information. The endpoints of this study should be deleted from the list of endpoint by the RMS. See reporting table 5(9)	This study is not fully reliable as concentrations were not measured. However, RMS has kept its results in the LoE as its results were in close agreement with another, reliable study with the same species. Meeting agrees that non-reliable studies should not be included in the LoE even if they are in the same range as reliable studies. Two valid studies on algae are available. Open point still open: RMS to delete the study by Douglas M.T. and Handley J.W., 1988 from the LoE and the list of studies relied on.	Open point open. RMS to delete the study by Douglas M.T. and Handley J.W., 1988 from the LoE and the list of studies relied on.
	Open point: 5.3 B.9.2.8, effects on algae, *Navicula pelliculosa* study. According to guidance SANCO/3268/2001 if the measured	This point is based on a misunderstanding. Mean measured concentrations in the study were in fact 98-104% of nominal. Open point closed.	Open point closed.

	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	concentrations are very low compared to the nominal the validity of the test might be questionable. MS to discuss in an expert meeting the acceptability of Flatman D., 2003b" study. See reporting table 5(25)		
	Open point: 5.4 B.9.2.8, effects on algae, *Selenastrum capricornutum* study. According to guidance SANCO/3268/2001 if the measured concentrations are very low compared to the nominal the validity of the test might be questionable. MS to discuss in an expert meeting the acceptability of Flatman D., 2003c" study. See reporting table 5(26)	This point is based on a misunderstanding. Mean measured concentrations in the study were in fact 86-103% of nominal. Open point closed.	Open point closed.
	Open point: 5.5	This point is based on a misunderstanding. Mean measured concentrations in the study	Open point closed.

	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	B.9.2.10, effects on aquatic plants, *Lemna* study. According to guidance SANCO/3268/2001 if the measured concentrations are very low compared to the nominal the validity of the test might be questionable. MS to discuss in an expert meeting the acceptability of Flatman D., 2003d" study. See reporting table 5(27)	were in fact 96-102% of nominal. Open point closed.	
	Open point: 5.6 Vol. 3, B.9.2.11, acute toxicity of the preparation, *Selenastrum capricornutum* study. The validity of the study should be discussed by the experts in a PRAPeR meeting. See reporting table 5(28)	Concentrations were not measured. Effects were seen so the substance has clearly been applied. However, analysis of the concentration is generally required. RMS kept the study in the LoE because the risk assessment would be based on the microcosm anyway. Meeting agrees that the study should be deleted from the LoE. Open point closed. New open point: RMS to delete the endpoint from the acute toxicity study with the preparation on *Selenastrum capricornutum*. New data gap: notifier to submit the study with the Venzar 500 SC formulation on *Selenastrum capricornutum.*	Open point fulfilled. New open point proposed, see below. New data gap proposed, see below.
	New open point		Open point open.

	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	identified at PRAPeR 68 meeting: RMS to delete the endpoint from the acute toxicity study with the preparation on *Selenastrum capricornutum*.		
	New data gap identified at PRAPeR 68 meeting: notifier to submit the study with the Venzar 500 SC formulation on *Selenastrum capricornutum.*		Data gap open.
	Open point: 5.7 B.9.2.12, aquatic organisms, microcosm and mesocosm study (Taylor S.A., 2004). The acceptability of the (Taylor S.A. 2004) should be discussed in an experts meeting. See reporting table 5(29)	Indoor microcosm test with only four macrophyte species tested. RMS considered it not relevant since a more elaborate, outdoor microcosm is available. The NOEC for Elodea from this study is 10 ug/L (nom.). Exposure concentrations in this study were not measured however. Therefore, the study is not considered valid. Open point closed.	Open point fulfilled.

Appendix 2: Evaluation table

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations PRAPeR Expert Meeting / Conclusions of the evaluation group
	Section 5 Open points: ***7*** Points for clarification: ***0*** Data gaps: ***0***			Section 5 Open points: ***3*** Data gaps: ***2***
	Open Point: 5.1 B.9.2.12, Effects on primary productivity and macrophyte biomass in field-based microcosms, (Jenkins, 2005). Several uncertainties (is not clear where the study was conducted, results of statistical analysis are not presented, the study was performed with a single application) can be observed in the outdoor microcosm study. Furthermore, some MS did not agree with the NOEAEC = 22.1 µg a.s./L, proposed by the RMS considering that at this endpoint it was noted that there were effects on *Elodea canadensis* and Charophyta.	Notifier has submitted a proposal for the endpoint and an appropriate assessment factor to be applied to take account of uncertainty (see accompanying position paper <<Lenacil mesocosm position paper_TSGE 30Mar09.doc>>).	**RMS (April 2009):** The report of the microcosm study (Jenkins C. A., 2005) has been revised, taking into account the comments raised in the reporting table. Some essential raw data have been added to the study summary in the updated DAR. An overall NOEAEC = 22.1 µg a.s./L was established. A NOEC of 22.1 µg a.s./L or higher has been identified for periphyton, phytoplankton, zooplankton and 10 out of 12 macrophyte species. A NOEAEC of 22.1 µg a.s./L has been determined for *Eleodea Canadensis*. Charophyta was the only macrophyte species with a NOEC < 0.4 µg a.s./L. RMS considers that setting the NOEAEC at 5.81 or 0.4 µg a.s./L is not appropriate since the functioning of the mesocosm is not impaired at 22.1 µg a.s./L. The position paper of the notifier is presented in an addendum. The RMS agrees with the conclusions of the notifier; the endpoint NOEAEC of 22.1	PRAPeR 68 (4 – 8 May 2009) Open point fulfilled. New data gap proposed, see below. New Open point proposed, see below.

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations PRAPeR Expert Meeting / Conclusions of the evaluation group
	The endpoint for the microcosm study (Jenkins, 2005) as well as the assessment factor to be applied should be discussed by the MS experts in a meeting. See reporting table 5(7)		µg a.s./L is maintained and a safety factor of 5 in stead of 3 can be applied (nominal and measured exposure, inter-species sensitivity, multiple applications).	
	New data gap identified at PRAPeR 68 meeting: The relative sensitivity of Charophyta should be determined.			PRAPeR 68 (4 – 8 May 2009) Data gap open
	New open point identified at PRAPeR 68 meeting: RMS to update LoE: Perform first tier risk assessment for fish and daphnids. Delete first tier TERs for algae and macrophytes (because these indicate low risk, which may be confusing for the risk managers). State with a footnote that the first tier endpoints are not protective enough for algae and macrophytes. Remove the metabolites from the section „ecotoxicologically relevant compounds'.			PRAPeR 68 (4 – 8 May 2009) Open point open

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations PRAPeR Expert Meeting / Conclusions of the evaluation group
	Open point: 5.2 B.9.2 Effects on aquatic organisms, B.9.2.8 Effects on algae. The study by Douglas M.T. and Handley J.W., 1988 is regarded as not acceptable and should only be used as additional information. The endpoints of this study should be deleted from the list of endpoint by the RMS. See reporting table 5(9)	The issue concerning the validity of the Douglas & Handley/ *S. capricornutum* study hangs on the absence of any analytical confirmation that exposure concentrations were a) achieved and b) satisfactorily maintained for the duration of the exposure. Although other algal studies and the *Lemna* study performed with the technical a.s. provide a weight of evidence that suggests lenacil concentrations will have remained at close-to-initial levels for at least 72 h (covering 2 of the 3 reported endpoints), it is not possible to make any convincing claim as to whether or not condition a) is likely to have been satisfied.	**RMS (April 2009):** The RMS confirms that the E_rC_{50} is calculated for the period 24-48 hours. No further explanation is given in the study why it was calculated as such and not for the period 0-72 hours. The endpoints are in close agreement with the study of Flatman D., 2003c and are not deleted from the List of Endpoints.	PRAPeR 68 (4 – 8 May 2009) Open point open. RMS to delete the study by Douglas M.T. and Handley J.W., 1988 from the LoE and the list of studies relied on.
	Open point: 5.3 B.9.2.8, effects on algae, *Navicula pelliculosa* study. According to guidance SANCO/3268/2001 if the measured concentrations are very low compared to the nominal the validity of the test might be questionable. MS to discuss in an expert meeting the acceptability of Flatman D., 2003b" study. See reporting table 5(25)	This issue is an artefact of the way the information has been presented in the summary and the inappropriate and misleading use of the term "nominal". In this study lenacil dissolved in DMF was dispersed in a primary stock at 10 mg a.s./L algal medium: a loading that exceeded the aqueous solubility of the test substance, but nevertheless afforded the opportunity to maximise dissolution in the aqueous medium over the course of 22 h stirring, followed by 2 h settlement. The portion of the stock preparation transferred to the algal test was taken from mid-water, post-settlement, to confine exposure to the test substance dissolved in the test	**RMS (April 2009):** Please refer to the explanation of the notifier in the column B. The mean measured lenacil concentrations represent 98 – 104 % of t_0 measured concentrations at mean measured concentrations of 11, 22, 47, 105, 219 and 468 µg a.s./L, respectively. The results are based on mean measured concentrations. More details are presented in the updated DAR.	PRAPeR 68 (4 – 8 May 2009) Open point closed.

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations PRAPeR Expert Meeting / Conclusions of the evaluation group
		medium. The degree of dissolution achieved under these conditions is shown in APPENDIX 2 (p. 25) of the study report: at t_0 the top-dose medium comprising 100% primary stock contained only 476.1 µg a.s./L, *i.e*. just 4.76% of the unachievable "nominal" 10 mg/L. Other t_0 measured concentrations are similarly low, since all the other tested concentrations were derived by serial dilution of the primary medium. It is essential to note that no "nominal" target exposure concentrations were set in this study. Report APPENDIX 2 shows that the lenacil concentrations measured after 72 h are close to the t_0 values; in media inoculated with algae the 72 h measured lenacil concentrations represent 102%, 107%, 99%, 95% and 97% of the corresponding t_0 concentrations of 10.57, 21.24, 46.95, 107.5, 221.6 and 476.1 µg a.s./L, respectively. The notifier therefore proposes that it would be more meaningful to express mean measured concentrations in terms of measured t_0 concentrations rather than spurious, notional "nominal" values. The former demonstrates clearly that the achieved exposure concentrations were adequately maintained for the duration of the algal study, whereas the latter is misleading		

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations PRAPeR Expert Meeting / Conclusions of the evaluation group
		and capable of being misinterpreted as an indication that substantial lenacil degradation occurred. Doubts about the validity/acceptability of the study are not justified. The mean measured lenacil concentrations represent 104%, 104%, 100%, 98%, 99% and 98% of t_0 measured concentrations at mean measured 11, 22, 47, 105, 219 and 468 µg a.s./L, respectively.		
	Open point: 5.4 B.9.2.8, effects on algae, *Selenastrum capricornutum* study. According to guidance SANCO/3268/2001 if the measured concentrations are very low compared to the nominal the validity of the test might be questionable. MS to discuss in an expert meeting the acceptability of Flatman D., 2003c" study. See reporting table 5(26)	As above, this issue is an artefact of the way the information has been presented in the summary and the inappropriate and misleading use of the term "nominal". Lenacil dissolved in DMF was dispersed in a primary stock at 10 mg a.s./L algal medium: a loading that exceeded the aqueous solubility of the test substance, but nevertheless afforded the opportunity to maximise dissolution in the aqueous medium over the course of overnight stirring, followed by 10 min settlement. The portion of the stock preparation transferred to the algal test was taken from mid-water, post-settlement, to confine exposure to the test substance dissolved in the test medium. The degree of dissolution achieved under these conditions is shown in APPENDIX 3 (p. 24) of the study report: at t_0 the top-dose medium comprising a 1.0% dilution of the primary stock contained only	**RMS (April 2009):** Please refer to the explanation of the notifier in the column B. The mean measured lenacil concentrations represent 86 – 103 % of t_0 measured concentrations at mean measured concentrations of 0.41, 0.79, 1.5, 3.4, 8.1, 17 and 36 µg a.s./L, respectively. The results are based on mean measured concentrations. More details are presented in the updated DAR.	PRAPeR 68 (4 – 8 May 2009) Open point closed.

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations PRAPeR Expert Meeting / Conclusions of the evaluation group
		34.88 µg a.s./L, *i.e.* just 34.88% dissolution was achieved in the primary stock at the unachievable "nominal" 10 mg/L. Other t_0 measured concentrations are similarly low, since all the other tested concentrations were derived by serial dilution of the primary medium. It is essential to note that no "nominal" target exposure concentrations were set in this study. Report APPENDIX 3 shows that the lenacil concentrations measured after 96 h are close to the t_0 values; in media inoculated with algae the 96 h measured lenacil concentrations represent 97%, 82%, 103%, 89%, 98%, 103% and 109% of the corresponding t_0 concentrations of 0.4127, 0.8678, 1.453, 3.962, 8.234, 16.52 and 34.88 µg a.s./L, respectively. The notifier therefore proposes that it would be more meaningful to express mean measured concentrations in terms of measured t_0 concentrations rather than spurious, notional "nominal" values. The former demonstrates clearly that the achieved exposure concentrations were adequately maintained for the duration of the algal study, whereas the latter is misleading and capable of being misinterpreted as an indication that substantial lenacil degradation occurred. Doubts about the validity/acceptability of the study are		

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations PRAPeR Expert Meeting / Conclusions of the evaluation group
		not justified. Expressed in terms of t_0 measured concentrations, the mean measured lenacil concentrations represent 99%, 91%, 103%, 86%, 98%, 103% and 103% at mean measured 0.41, 0.79, 1.5, 3.4, 8.1, 17 and 36 µg a.s./L, respectively.		
	Open point: 5.5 B.9.2.10, effects on aquatic plants, *Lemna* study. According to guidance SANCO/3268/2001 if the measured concentrations are very low compared to the nominal the validity of the test might be questionable. MS to discuss in an expert meeting the acceptability of Flatman D., 2003d" study. See reporting table 5(27)	As above, this issue is an artefact of the way the information has been presented in the summary and the inappropriate and misleading use of the term "nominal". In this study lenacil dissolved in DMF was dispersed in a primary stock at 10 mg a.s./L *Lemna* medium: a loading that exceeded the aqueous solubility of the test substance, but nevertheless afforded the opportunity to maximise dissolution in the aqueous medium by stirring, followed by 10 min settlement. The portion of the stock preparation transferred to the algal test was taken from mid-water, post-settlement, to confine exposure to the test substance dissolved in the test medium. The degree of dissolution achieved under these conditions is shown in APPENDIX 6 (pp. 25&26) of the study report: at t_0 (fresh media at each renewal during the semi-static exposure) the top-dose medium comprising a 1.8% dilution of the saturated primary stock contained	**RMS (April 2009):** Please refer to the explanation of the notifier in the column B. The mean measured lenacil concentrations represent 96 – 102 % of t_0 measured concentrations at mean measured concentrations of 3.7, 8.8, 15, 24 and 71 µg a.s./L, respectively. The results are based on mean measured concentrations. More details are presented in the updated DAR.	PRAPeR 68 (4 – 8 May 2009) Open point closed.

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations PRAPeR Expert Meeting / Conclusions of the evaluation group
		67.44, 69.85 and 73.29 µg a.s./L (mean = 70.19 µg a.s./L). Therefore, just 38.99% dissolution was achieved in the primary stock at the unachievable "nominal" 10 mg/L. Other t_0 measured concentrations are similarly low, since all the other tested concentrations were derived by serial dilution of the primary medium. It is essential to note that no "nominal" target exposure concentrations were set in this study. Report APPENDIX 6 shows that the lenacil concentrations measured in expired media on Days 2, 5 and 7 are close to the corresponding t_0 values for the Days 0, 2 and 5 fresh media, respectively. Thus the measured lenacil concentrations in Day 2 expired samples represent 108%, 94%, 101%, 105% and 108% of the corresponding Day 0 fresh concentrations of 3.508, 8.431, 15.22, 23.73 and 67.44 µg a.s./L, respectively. Similarly, the measured lenacil concentrations in Day 5 expired samples represent 108%, 94%, 101%, 105% and 108% of the corresponding Day 2 fresh concentrations of 3.392, 8.916, 15.64, 23.11 and 69.85 µg a.s./L, respectively, and measured lenacil concentrations in Day 7 expired samples represent 110%, 92%, 95%, 99% and 105% of the corresponding Day 5 fresh concentrations of 3.391, 9.831, 15.93,		

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations PRAPeR Expert Meeting / Conclusions of the evaluation group
		23.96 and 73.29 µg a.s./L, respectively. The notifier therefore proposes that it would be more meaningful to express overall mean measured concentrations (all data for fresh and expired media) in terms of mean measured t_0 concentrations in freshly prepared media (Days 0, 2 and 5 combined) rather than spurious, notional "nominal" values. Mean measured t_0 concentrations in freshly prepared media are not presented in the report, but have been calculated for this purpose (in ascending order) as 3.610, 9.059, 15.60, 23.60 and 70.19 µg a.s./L. The proposed comparison demonstrates clearly that the achieved exposure concentrations were adequately maintained for the duration of the *Lemna* study, whereas the current alternative is misleading and capable of being misinterpreted as an indication that substantial lenacil degradation occurred. Doubts about the validity/acceptability of the study are not justified. Expressed in terms of mean measured t_0 concentrations in freshly prepared media, the mean measured lenacil concentrations represent 102%, 97%, 96%, 102% and 101% at overall mean measured 3.7, 8.8, 15, 24 and 71 µg a.s./L, respectively.		

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations PRAPeR Expert Meeting / Conclusions of the evaluation group
	Open point: 5.6 Vol. 3, B.9.2.11, acute toxicity of the preparation, *Selenastrum capricornutum* study. The validity of the study should be discussed by the experts in a PRAPeR meeting. See reporting table 5(28)	The question mark over the validity of the Venzar 80% WP/ *S. capricornutum* study hangs on the absence of any analytical confirmation that exposure concentrations were a) achieved and b) satisfactorily maintained for the duration of the exposure. Although other algal studies and the *Lemna* study with the technical a.s. provide a weight of evidence that suggests lenacil concentrations will have remained at close-to-initial levels for at least 72 h (covering the reported E_bC_{50} and E_rC_{50} endpoints), it is not possible to make any convincing claim as to whether or not condition a) is likely to have been satisfied. EFSA have suggested elsewhere (reporting table 5(28)) that a "new, valid study could be useful to address potential highest sensitivity of algae to the formulation with respect to the active ingredient." Alternatively, the notifier is able to offer data from a more recent study of the effects of Venzar 500 SC (lenacil a.s.) on the same algal species and this could be offered to avoid having to perform a new study with Venzar 80% WP. Venzar 500 SC may be considered to be a suitable surrogate for Venzar 80% WP.	**RMS (April 2009):** Please refer to the explanation of the notifier in the column B. Three studies with *Pseudokirchneriella subcapitata* were conducted (Flatman D., 2003c; Douglas M.T. and Handley J.W., 1988; Douglas M.T. and Halls R.W.S, 1993), leading to similar endpoints. Moreover, a microcosm study (Jenkins C.A., 2005) is available. The effects of lenacil on algae are investigated. The endpoint is acceptable and therefore not deleted from the List of Endpoints.	PRAPeR 68 (4 – 8 May 2009) Open point fulfilled. New open point proposed, see below. New data gap proposed, see below.
	New open point identified at PRAPeR 68 meeting:			PRAPeR 68 (4 – 8 May 2009)

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations PRAPeR Expert Meeting / Conclusions of the evaluation group
	RMS to delete the endpoint from the acute toxicity study with the preparation on *Selenastrum capricornutum*.			Open point open.
	New data gap identified at PRAPeR 68 meeting: notifier to submit the study with the Venzar 500 SC formulation on *Selenastrum capricornutum.*			PRAPeR 68 (4 – 8 May 2009) Data gap open.
	Open point: 5.7 B.9.2.12, aquatic organisms, microcosm and mesocosm study (Taylor S.A., 2004). The acceptability of the (Taylor S.A. 2004) should be discussed in an experts meeting. See reporting table 5(29)		**RMS (April 2009):** As indicated in the DAR, only 4 macrophyte species were tested in a laboratory microcosm test. Since an outdoor, more elaborated microcosm study (Jenkins C.A., 2005) is available, RMS decided to base the risk assessment on the last one. RMS would welcome discussion in the expert meeting.	PRAPeR 68 (4 – 8 May 2009) Open point fulfilled.

Report of PRAPeR Expert MEETING 69

LENACIL

Rapporteur Member State: BE

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
April 2009	BE	Lenacil Addendum to Vol3_B6 (April 2009).doc
2009-04-14	BE	Lenacil evaluation table rev1-0 (2009-04-14).doc
Nov 2007	BE	Lenacil list of data relied on (Nov 2007) ver1.doc
April 2009	BE	Lenacil List of endpoints (April 2009).doc
2009-03-02	BE	Lenacil reporting table rev1-1 (2009-03-02).doc
March 2009	BE	Lenacil VOL4(C1-C2)_update March 2009_cover page.doc

3. Documents tabled at the meeting:

Date	Supplier	File Name
none		

The conclusions of the meeting were as follows:

4. **Data on preparations:** Venzar 80 WP

5. **Classification and labelling:** R40 proposed

6. **Recommended restrictions/conditions for use:** None

7. **Reference List:** Not discussed

Areas of concern: None

Appendix 1: Discussion table: LENACIL

Appendix 2: Evaluation table

Appendix 1: Discussion Table, Lenacil (Hb)

2. Mammalian toxicology

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	Open point: 2.1 Oral absorption to be discussed at an expert's meeting. See reporting table 2(1)	As the AOEL is based on a repeated dose study the experts agreed to use the results obtained after application of repeated low dose in the toxicokinetic study. A value of at least 80% was agreed. This is based on the results obtained after repeated low dose application and also a single low dose application in the toxicokinetic study considering that there is excretion via bile. 80% was calculated considering the excretion in urine and faeces minus parent compound. Open point fulfilled.	Open point fulfilled. A value of at least 80% was agreed.
	Open point: 2.2 The NOAEL of 15.5 mg/kg bw/d from the 90-day mouse toxicity study to be discussed by the experts. See reporting table 2(9)	The experts agreed that the NOAEL is 1000 ppm corresponding to 157 mg-kg bw-d. This is based on increased liver weight in females. Open point fulfilled.	Open point fulfilled. Agreed NOAEL is 1000 ppm corresponding to 157 mg-kg bw-d
	Open point: 2.3 Carcinogenic properties and proposal for classification and labelling for carcinogenicity (R40) to be discussed in an experts' meeting. See reporting table 2(13)	The RMS presented an Addendum to the DAR dated April 2009 with further historical control data in rat and mouse. Based on the mammary gland tumours in the rat and lung tumours in mice which are of equivocal relevance to humans the experts agreed to propose the classification with R40. Open point fulfilled.	Open point fulfilled. R40 agreed.
	Open point: 2.4 Proposal for classification	The experts discussed the data presented in the DAR considering the very high dose level applied in the study (50000 ppm = 4300 mg/kg bw/d which exceeds the 1000	Open point fulfilled.

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	and labelling with R64 based on reduction in body weight gain in offspring during lactation to be discussed in an expert's meeting. See reporting table 2(13)	mg/kg bw/d limit dose for reproductive toxicity studies). The decrease in offspring weight gain was deemed insufficient to justify R64 at this very high dose level. Experts agreed it was not appropriate to propose the classification with R64. Open point fulfilled.	R64 not agreed.
2.1	Point of clarification for the applicant: Applicant to submit laboratory control data including all details (dates, strain, number of animals, etc) for liver and lung tumours in mice and for mammary gland tumours in rats. See reporting table 2(18)	The data has been presented in an Addendum to the DAR dated April 2009. Point of clarification addressed.	Point of clarification addressed.
	Open point: 2.5 The setting of references values to be confirmed in an experts' meeting See reporting table 2(28)	ADI agreed by experts = 0.12 mg/g/kg bw/d based on long term study in the rat and a safety value of 100. AOEL agreed by experts = 0.4 mg/kg bw/d based on 90 day rat study supported by the 90 day dog study and a safety value of 100. With respect to the LOAEL in carcinogenicity studies there is a safety margin of 400. Experts agreed there was no need to set an ARfD. Open point fulfilled.	Open point fulfilled. Experts agreed: ADI = 0.12 mg/g/kg bw/d AOEL = 0.4 mg/kg bw/d ARfD – not required
	Open point 2.6 Operator, worker and bystander exposure to be confirmed at a meeting of	It was suggested by experts to use 2 hour exposure for crop inspection activities and 60 kg for bystanders. In addition, the most recent UK POEM Model (2007) should be used.	Open point fulfilled. New open point proposed, see

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	experts. See reporting table 2(38)	Open point fulfilled. New open point proposed – RMS to provide an Addendum to the DAR with revised exposure assessments taking into account agreed on input parameters and the agreed on AOEL of 0.4 mg/kg bw/d.	below
	New open point identified at PRAPeR 69 meeting: RMS to provide an Addendum to the DAR with revised operator, worker and bystander exposure to be recalculated taking into account agreed on input parameters and the agreed on AOEL of 0.4 mg/kg bw/d.		Open point open
	Message to the tox meeting: 1/3 of the identified total residue in sugar beet leaves (0.01 -0.02 mg/kg) was 7-OH-lenacil (IN-KC943) and its conjugates. Should 7-OH-lenacil (IN-KC943) be regarded as less, equally or more toxic than parent lenacil? Residue meeting	The experts agreed that the metabolite is structurally closely related to the major metabolite (P5) of lenacil in the rat (found in urine and faeces in rat) and therefore is covered by the toxicological studies of the parent compound. If the metabolite is included in the residues definition the same trigger values can be applied.	

Appendix 2: Evaluation table

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations PRAPeR Expert Meeting / Conclusions of the Evaluation Meeting
	Section 2 Open points: ***6*** Points for clarification: ***1*** Data gaps: ***0***			Section 2 Open points: ***1*** Points for clarification: ***0*** Data gaps: ***0***
	Open point: 2.1 Oral absorption to be discussed at an expert's meeting. See reporting table 2(1)	Notifier agrees with RMS position set out in reporting table. The use of an oral absorption value of greater than 80% has been justified by RMS. Further discussion of this point is presented in the attached position paper. See: <<Lenacil toxicology position paper_TSGE 30Mar09.doc>>	**04.2009:** The oral absorption is usually calculated based on the results obtained after application of a single low dose. The absorption of a compound is largely determined by the capacity to cross semi permeable membranes and depends strongly from its physic chemical properties, concentration at the site of contact, dissolution of the substance, gastric empting rate and intestinal motility. In the repeat study, the same low dose as in the single dose study was used but administered 7x with a time interval of 24h. Therefore, RMS considers that repeated dose study is well adapted for estimation of oral absorption. After a single oral low dose of lenacil, oral absorption= 63% (females) and 82% (males) increasing to 85-89% after repeated low dose. Females excrete more unchanged parent compound after a single low dose, an effect disappearing after repeated dosing. This could suggest that lenacil induces its own metabolism and therefore bioavailability. When the mean value of the different oral	PRAPeR 69 (4 – 8 May 2009) Open point fulfilled. A value of at least 80% was agreed.

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations PRAPeR Expert Meeting / Conclusions of the Evaluation Meeting
			absorption (see table B.6.1-4) is calculated, a value of about 80% is obtained. If bile excretion is added to urinary excretion, after single low dose administration, an oral absorption value of 64-73% of the dose is obtained. The latter approach was not followed as bile and urinary excretion were not measured in the same study.	
	Open point: 2.2 The NOAEL of 15.5 mg/kg bw/d from the 90-day mouse toxicity study to be discussed by the experts. See reporting table 2(9)	Derivation of the appropriate AOEL is discussed in attached position paper. Notifier agrees with DE: the 100 ppm dose level is an NOEL rather than NOAEL and a higher value should be investigated for setting the AOEL. See discussion in attached position paper and addendum produced by RMS.	**04.2009:** At the tested doses, it is probable that oral absorption of lenacil is low as suggested in the ADME part of the DAR, where at doses of 1000 mg/kg bw (= 5000 ppm) oral absorption is strongly reduced. Therefore, the lack of dose response starting at 1000 ppm onwards results from a low oral absorption at high dose with as a consequence a plateau in the toxic effects.	PRAPeR 69 (4 – 8 May 2009) Open point fulfilled. Agreed NOAEL is 1000 ppm corresponding to 157 mg-kg bw-d
	Open point: 2.3 Carcinogenic properties and proposal for classification and labelling for carcinogenicity (R40) to be discussed in an experts' meeting. See reporting table 2(13)	Notifier agrees with RMS, Proposal to classify with R40 cannot be justified from available data. Further discussions of the mammary adenocarcinoma, thyroid adenoma and mouse lung tumour incidence are set out in the attached position paper to demonstrate the absence of any treatment related increase in tumour incidence. In the absence of any new data, the incidence of these findings are not considered indicative of human carcinogenic potential.	**04.2009:** Allocation of R40 was not proposed as RMS considered that : (i) The incidence of malignant mammary adenocarcinoma was outside the historical control data of the laboratory but within the data of Charles River Han Wistar rats in 2003 and therefore considered **questionable**. (ii) Thyroid adenoma are not a basis for classification: the adenoma are within historical control data. (iii) Lung tumors in male mice: Incidences of adenoma and adenocarcinoma, taken separately, were not statistically increased. There was no statistical significance with the	PRAPeR 69 (4 – 8 May 2009) Open point fulfilled. R40 agreed.

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations PRAPeR Expert Meeting / Conclusions of the Evaluation Meeting
			Fisher exact test at p=0.05 for any dose group. There was no decrease in alveolar tumor latency; most tumors were observed in mice killed at terminal sacrifice. There was no increase in focal hyperplasia of type II alveolar cells. There was no shift in tumor cell anaplasia.	
	Open point: 2.4 Proposal for classification and labelling with R64 based on reduction in body weight gain in offspring during lactation to be discussed in an expert's meeting. See reporting table 2(13)	Notifier agrees with DE: the proposed classification with R64 is not supported since bodyweight effects in offspring were only apparent at very high doses, were not accompanied by other developmental effects and only occurred at parentally toxic doses. This point is further clarified in the attached position paper.	**04.2009:** Allocation of R64: we agree that the effects are confined to a very high dose but classification is hazard- and not risk-based. Parental toxicity was not evident in the 2 generation studies. However, as proposed in the DAR this point should be discussed in the PRAPeR meeting.	PRAPeR 69 (4 – 8 May 2009) Open point fulfilled. R64 not agreed.
2.1	Point of clarification for the applicant: Applicant to submit laboratory control data including all details (dates, strain, number of animals, etc) for liver and lung tumours in mice and for mammary gland tumours in rats. See reporting table 2(18)	This has been requested from the Contract Laboratories and will be submitted as soon as possible.	**04.2009:** This information could be helpful for further discussion.	PRAPeR 69 (4 – 8 May 2009) Point of clarification addressed.
	Open point: 2.5 The setting of references	A revised table of endpoints for short term and long term toxicity studies	**04.2009:** RMS agrees with the company that Lenacil	PRAPeR 69 (4 – 8 May 2009)

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations PRAPeR Expert Meeting / Conclusions of the Evaluation Meeting
	values to be confirmed in an experts' meeting See reporting table 2(28)	has been presented in the attached position paper to take account of the adaptive nature of liver effects. The implication of taking these effects into account in deriving the AOEL/ADI is discussed in the position paper and a revised value reached that takes account MS comments in the reporting table.	increases metabolic workload leading to adaptation of liver (increased weight, centrilobular hypertrophy…); however, enzyme induction was never measured. Therefore, RMS cannot exclude another mechanism for the observed liver effects.	Open point fulfilled. Experts agreed: ADI = 0.12 mg/g/kg bw/d AOEL = 0.4 mg/kg bw/d ARfD – not required
	Open point 2.6 Operator, worker and bystander exposure to be confirmed at a meeting of experts. See reporting table 2(38)	Revised exposure calculations have been prepared by the RMS. The notifier would like to point out that the version of UK POEM used by the RMS has been superseded by a 2007 version of the UK model. Calculations using UK POEM 2007 are presented by the Notifier in the attached position paper: << Lenacil tox position paper_TSGE 24Mar09.doc>> Calculations using UK POEM 2007 model demonstrate that exposure is below the AOEL for operators wearing gloves during mixing/loading and application. The Notifier has no other comments on the revised calculations presented by the RMS.	**04.2009:** It is correct that new generic values were introduced into the original „merged' UK-POEM and BBA model. RMS used the version with the original German generic value (75th %ile) for dust inhalation during mixing and loading, i.e. 0.659 mg/kg a.s. handled, while in the new version, the value is reduced to 0.21 mg/kg a.s. handled. This explains the different results in the UK model. However, as the German model predicts an acceptable exposure (30-40% of the proposed AOEL), the evaluation remained unaltered. In the addendum, it was also demonstrated that the worker and the bystander exposure was below the proposed AOEL.	PRAPeR 69 (4 – 8 May 2009) Open point fulfilled. New open point proposed, see below
	New open point 2.7 identified at PRAPeR 69 meeting: RMS to provide an			PRAPeR 69 (4 – 8 May 2009) Open point open.

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations PRAPeR Expert Meeting / Conclusions of the Evaluation Meeting
	Addendum to the DAR with revised operator, worker and bystander exposure to be recalculated taking into account agreed on input parameters and the agreed on AOEL of 0.4 mg/kg bw/d.			
	Message from PRAPeR 70 to PRAPeR 69: 1/3 of the identified total residue in sugar beet leaves (0.01 -0.02 mg/kg) was 7-OH-lenacil (IN-KC943) and its conjugates. Should 7-OH-lenacil (IN-KC943) be regarded as less, equally or more toxic than parent lenacil?			PRAPeR 69 (4 – 8 May 2009) The experts agreed that the metabolite is covered by the toxicological studies of the parent compound, and if it is included in the residues definition the same trigger values can be applied.

REPORT OF PRAPeR EXPERT MEETING 70

LENACIL

Rapporteur Member State: BE

Specific comments on the active substance in the section

3. Residues

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
April 2009	BE	Lenacil Addendum to Vol3_B7 (April 2009).doc
2009-04-14	BE	Lenacil evaluation table rev1-0 (2009-04-14).doc
Nov. 2007	BE	Lenacil list of data relied on (Nov 2007) ver1.doc
April 2009	BE	Lenacil List of endpoints (April 2009).doc
2009-03-02	BE	Lenacil reporting table rev1-1 (2009-03-02).doc
March 2009	BE	Lenacil VOL4(C1-C2)_update March 2009_cover page.doc

3. Documents tabled at the meeting:

Date	Supplier	File Name
none		

The conclusions of the meeting were as follows:

4. **Data on preparations:** VENZAR 80 WP

5. **Classification and labelling:** none

6. **Recommended restrictions/conditions for use:** none

7. **Reference List:** not discussed

Areas of concern: none

Appendix 1: Discussion table: LENACIL

Appendix 2: Evaluation table

Appendix 1: Discussion Table, Lenacil (Hb)

3. Residues

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	Data gap: 3.1 Frozen storage stability data covering the 26 months to be submitted if the trials can be considered as acceptable. See reporting table 3(1)	Residue trials referenced F-95-001-RES (French trials) and characterized by a frozen storage period of 26 months were not used to set the MRL since these trials were not performed at the critical growth stage of application but at BBCH 14. Data gap obsolete.	Data gap obsolete.
	Open point: 3.1 Experts meeting to discuss if metabolism studies on livestock are required. See reporting table 3(6)	Residues in sugar beet in GAP trials are <0.01 mg/kg in the tops and in the roots, but these trials are not supported by storage stability data and were performed at GS BBCH 14 (GAP is up to BBCH 31). Residues in tops up to 0.04 mg/kg are found in trials that are non GAP trials (too late application at GS 37/38). The intake is 0.105 mg/kg diet (DM) for dairy cattle and 0.135 mg/kg diet (DM) for beef cattle on the basis of these trials performed at a more critical GS (BBCH 37/38) with residues in the foliage of 0.04 mg/kg and 0.02 mg/kg (LOQ) in the roots. Residues in the roots are likely to be much lower than 0.02 mg/kg, and considering the significant contribution of root residues to the total livestock dietary burden (50%) the intake is probably over-estimated. Moreover, the nature of residues in sugar beet is polar and thus accumulation of lenacil residues is not expected in livestock. This is indicated by the metabolism data in rats. Therefore significant residues in animal matrices are not very likely. The majority of experts agreed that a livestock metabolism study should not be required.	Open point fulfilled. The majority of experts agreed a ruminant livestock metabolism study should not be required.
	Open point: 3.2 Meeting of experts to discuss the residue definition in plant matrices.	Plant metabolism study was performed at earlier GS than notified with GAP. There was a metabolite 7-OH-lenacil that may have to be included in the residue definition based on the tox properties of lenacil (classified as carcinogenic). The metabolite plus conjugates accounts for approx. 50% of the levels of parent in leaves. At a later time of application according to GAP criteria parent is expected to be more prevalent in the crops.	Open point fulfilled. For root crops the relevant residue for risk assessment and monitoring purposes should be lenacil alone.

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	See reporting table 3(8)	Nevertheless should the tox meeting be consulted on the properties of 7-OH-lenacil (the metabolite was not recovered in the rat study). For the current use in sugar beet parent lenacil is the most prevalent residue (in leaves) and thus should be defined as the relevant residue for risk assessment and monitoring purposes. Total residues in roots were below 0.01 mg/kg at harvest. The experts discussed whether the study can be considered representative for other uses in root crops (smaller root crops, later applications or higher application rates where residues might be expected in the roots). The experts do not expect a different metabolic pathway in the roots than in the leaves. However, for such future uses (other root crops, or spinach) it might be useful to clarify the tox relevance of 7-OH-lenacil (IN-KC943). Upon clarification the metabolism study could be considered representative for all root crops. Message to the tox meeting: 1/3 of the identified total residue in sugar beet leaves (0.01 - 0.02 mg/kg) was 7-OH-lenacil (IN-KC943) and its conjugates. Should 7-OH-lenacil (IN-KC943) be regarded as less, equally or more toxic than parent lenacil? The tox experts agreed that the metabolite is structurally closely related to the major metabolite (P5) of lenacil in the rat (found in urine and faeces in rat) and therefore is covered by the toxicological studies of the parent compound. If the metabolite were included in the residues definition the same reference values could be applied.	
	Open point: 3.3 Meeting of experts to discuss acceptability of the residue trials carried out in Northern Europe. See reporting table 3(11)	3 trials (France) in sugar beet were performed within GAP (BBCH 14) but not according to cGAP (BBCH 31). No residues were found in roots and leaves (<0.01 mg/kg). However the trials are not covered by storage stability data. In 4 additional trials (Germany) at a later GS BBCH 37 (non GAP trials) residues were below LOQ in the roots (<0.02 mg/kg) but positive residues were found in the leaves in one trial (0.04 mg/kg). Taking into account the discussion on OP 3.1 the trials from Germany can be used to support the notified use in the North. It was noted that monitoring data in the UK indicated that residues in sugar beet roots occurred, however further clarification with regard to the GAP in the UK is necessary.	Open point fulfilled. Though application was at a later stage than BBCH 31 the 4 trials conducted in Germany (BBCH 37) can be used to support the notified use in the North.
	Data gap: 3.2 Further trials covering SE necessary to	3 trials from Spain and Portugal were submitted with application at BBCH 31 and BBCH 38, respectively. No residues <0.02 mg/kg were found in the roots but positive residues (0.03 mg/kg) were found in the leaves in one trial performed at BBCH 38.	Data gap closed. Taking into account the overall data set from North and South the

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	complete the residue database. (Meeting of experts to discuss the number of trials necessary). See reporting table 3(12)	Taking into account the discussion on OP 3.1 and the overall data set from North and South the available trials are sufficient to support the notified use in the South.	available trials are sufficient to support the notified use in the South.
3.1	Point for clarification: Spray concentration does not agree with application rate and water volumes for use pattern provided in Table B.7.4-1. Notifier to clarify. See reporting table 3(13)	The maximum rate is 0.5 kg as/ha and year, which can be split into up to 4 applications at an individual rate of 0.125 kg as/ha. The critical GAP would be 1 application of 0.5 kg as/ha at the latest GS BBCH 31. The amount of water applied is 200-400 L/ ha / application. The overall range of concentration is stated in the GAP table in the list of endpoints.	Point of clarification addressed.
	Open point: 3.4 RMS to consider presenting relevant validation data for method Hamburger R., 2002 in an addendum to the DAR. See reporting table 3(14)	The validation data of the analytical methods used to generate the residue trials were reported in the Addendum to the DAR-April 2009. 1st method used in French trials that are no longer considered in the evaluation is no longer relevant 2nd method used in 2 reports by Mende, 2002 and Hamburger, 2002 was evaluated in Vol.3 B5.2 and is sufficiently validated (LC-MS/MS with LOQ 0.02 mg/kg) 3rd method by Witte, 2006 was evaluated in Vol.3 B5.2 is sufficiently validated (HPLC-MS/MS with LOQ 0.02 mg/kg) The experts agreed all methods used to generate residue trial results are sufficiently validated and comply with guidance document SANCO/3029/99.	Open point fulfilled. All methods used to generate residue trial results that were considered in the assessment are sufficiently validated.
	Open point: 3.5 Meeting of experts to discuss if methods used in residue trials (Tillkes, 1998; Mende	See open point 3.4	Open point fulfilled. All methods used to generate residue trial results that were considered in the assessment are sufficiently validated.

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	2002; Hamburger, 2002; Witte, 2006) comply with guidance document SANCO/3029/99 concerning methods of analysis in support of pre-registration requirements and therefore are suitable to support the respective residue trials. See reporting table 3(14)		
	Open point: 3.6 Meeting of experts to discuss if further information or studies concerning rotational/succeeding crops are required. See reporting table 3(22)	According to the RMS the notifier recommended succeeding crops should not be planted or drilled until at least 120 days have elapsed after application because of phytotoxicity. If crop failure occurred during this period only sugar beet, red beet, or spinach could be drilled or planted. The RMS has not received data on phytotoxicity tests and thus it is assumed that the 120 days recommendation by the applicant is based on the mean DT90 found in the studies from Germany, France and Spain (107.9 days). However the DT90 was found to be up to 291 days in the Spanish study (extreme case but considered possible by the e-fate meeting). Based on the findings and information currently available residues in rotational crops should be addressed by a complete study taking into account possible phytotoxicity problems.	Open point fulfilled. New data gap proposed, see below:
	New data gap identified at PRAPeR 70 meeting: A rotational crop metabolism study is necessary to address residues in rotational		Data gap open.

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	crops.		
	Open point: 3.7 Meeting of experts to discuss the requirement of a re-entry period and/or the prohibition of the feeding of sugar beet tops after thinning and crop failure taking into account the practices in different countries. See reporting table 3(25)	The meeting considered that thinning and grazing should not be a problem. Livestock are not supposed to graze on such an area. Thinning out the sugar beet crop is not relevant anymore nowadays (seeds selection). The experts are of the opinion that the crop is not fed to livestock in the case of crop failure but remains on the field and is ploughed. No re-entry period and/or the prohibition of the feeding of sugar beet tops is required for the situations discussed.	Open point fulfilled.
	New open point identified: RMS to update the LoEP according to the agreements of the meeting and for the revised ADI	RMS to update the LoEP according to the agreements of the meeting and for the revised ADI	

Appendix 2: Evaluation table

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations PRAPeR Expert Meeting / Conclusions of the Evaluation Meeting
	Section 3 Open points: ***7*** Points for clarification: ***1*** Data gaps: ***2***			Section 3 Data gaps: ***1***
	Data gap: 3.1 Frozen storage stability data covering the 26 months to be submitted if the trials can be considered as acceptable. See reporting table 3(1)	Samples from the 2001, 2002 and 2005 trials (4 North EU, 3 South EU) were stored for 1 to 7 months and are covered by the existing storage stability study. In all these trials residues in roots were <LOQ. Therefore, sufficient data are available to support the MRL proposal in sugar beet. Three additional trials from 1995 (North EU) were submitted with samples stored for 26 months. These were submitted as supporting data and are not required to set the MRL. Therefore additional storage data are not required.	**04.2009:** RMS agrees that the residue trials referenced F-95-001-RES and characterized by a frozen storage period of 26 months are supporting data and were not used to set the MRL since these trials were not performed at the critical growth stage of application (BBCH 31). No additional frozen storage stability data are required.	PRAPeR 70 (5 – 8 May 2009) Data gap obsolete.
	Open point: 3.1 Experts meeting to discuss if metabolism studies on livestock are required. See reporting table 3(6)	In 7 trials covering North and South EU residues in sugar beet roots were <0.02 mg/kg and residues in sugar beet tops were <0.02 to 0.04 mg/kg. (In 5 trials residues in tops were <0.02 mg/kg.) Therefore, dietary intake for all livestock is less than 0.1 mg/kg total diet as received (the EU trigger value	**04.2009:** a) The way the residue dietary burden has to be estimated for animals was considered during the PRAPeR Expert Meeting 65. It was reminded that the intake by animals should always be taken into account on a dry matter basis and not	PRAPeR 70 (5 – 8 May 2009) Open point fulfilled. The majority of experts agreed a ruminant livestock metabolism study should not be required.

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations PRAPeR Expert Meeting / Conclusions of the Evaluation Meeting
		according to Working Document 7030/VI/95 rev 3 and Commission Directive 96/68/EC) and consequently metabolism studies in livestock are not required. The calculations presented in the DAR are based on a dry weight basis which is not consistent with Working Document 7030/VI/95 rev 3 and Commission Directive 96/68/EC. Copies of the calculations in the DAR which now include intake on a fresh weight basis are submitted. See: <<Lenacil livestock intake calculations_27Mar09.doc>>	"as received" as stated in the guideline 7031/VI/95 rev. 4. The calculation on the dry matter basis is the lonely way to obtain comparable figures and the trigger value of "0.1 mg/kg total diet" has to be understood "on the dry matter basis". b) Although the trigger value is exceeded, this case is border line since the feed intake was calculated using the residue values of 0.04 and 0.03 mg/kg on sugar beet tops with leaves generated by trials performed at BBCH GS 37, 38. Based on the available residue trials, there is a non-residue situation in the roots and a very low residue situation in the leaves with tops. Lenacil is not fat-soluble. RMS is of the opinion that a metabolism study on ruminants is not required. A metabolism study on pigs is therefore also not required.	
	Open point: 3.2 Meeting of experts to discuss the residue definition in plant matrices.	The notifier agrees with the comments made by the RMS in the reporting table. Lenacil is metabolised in both plants and mammals via hydroxylation of the pyrimidine ring. The resulting	**04.2009:** a) RMS refers to the detailed metabolism study presented in the Addendum to the DAR-April 2009. The metabolite IN-KC961 was not recovered in the sugar beet leaves as it	PRAPeR 70 (5 – 8 May 2009) Open point fulfilled. For root crops the relevant residue for risk assessment and monitoring purposes

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations PRAPeR Expert Meeting / Conclusions of the Evaluation Meeting
	See reporting table 3(8)	metabolites are therefore structurally the same and any toxicity will be apparent in the available toxicology studies. There are no metabolites that are unique to plants and the residue definition as parent only is considered valid.	is explained in the DAR – Table B.7.1.1-1: HPLC analyses showed a peak that matched the retention time of IN-KQ961 (hydroxylated Lenacil on C2), indicating the presence of this metabolite. Later results indicated that IN-KQ961 showed a similar retention time to that of IN-KC 943-glucoside and the peak corresponding to IN-KQ961 could be IN-KC943-glucoside or a mixture of the 2. Therefore, the peak was isolated for further β-glucosidase hydrolysis and this peak matched the retention time of IN-KC943, indicating the existence of IN-KC943 glucose conjugate before hydrolysis with no detectable amount of the metabolite IN-KQ961. This metabolite should not be included in the residue definition both for monitoring and risk assessment. b) The metabolites IN-KC943 and IN-KQ961 were generated by hydroxylation of the parent compound on the C5 cycle of the molecule. This is a step of detoxification in plants. Those metabolites are structurally similar to the metabolites recovered in the rat. In rat metabolism, hydroxylation on C5 and C6 cycles is the main step of degradation of the parent Lenacil. IN-KC943 and IN-KQ961 can therefore	should be lenacil alone.

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations PRAPeR Expert Meeting / Conclusions of the Evaluation Meeting
			be considered as covered by the available toxicological dossier. These metabolites are as toxic as the parent or less toxic. In the frame of the representative use on sugar beet only, the exhaustion of the ADI is very low (max. 0.11 % of the ADI), the DOR both for monitoring and risk assessment can be established as the parent compound alone.	
	PRAPeR 70 message to PRAPeR 69 (tox): 1/3 of the identified total residue in sugar beet leaves (0.01 -0.02 mg/kg) was 7-OH-lenacil (IN-KC943) and its conjugates. Should 7-OH-lenacil (IN-KC943) be regarded as less, equally or more toxic than parent lenacil?			PRAPeR 70 (5 – 8 May 2009) Reply from PRAPeR 69: The experts agreed that the metabolite is covered by the toxicological studies of the parent compound, and if it is included in the residues definition the same trigger values can be applied.
	Open point: 3.3 Meeting of experts to discuss acceptability of the residue trials carried out in Northern Europe. See reporting table 3(11)	Samples from the 2001, 2002 and 2005 trials (4 North EU, 3 South EU) were stored for 1 to 7 months and are covered by the existing storage stability study. In all these trials residues in roots were <LOQ. Therefore, sufficient data are available to support the MRL proposal in sugar beet.	**04.2009:** RMS agrees not to accept the trials referenced F-95-001-RES for MRL setting. So, the actual valid database is presented as follows: *North*: -Roots:4x<0.02 mg/kg	PRAPeR 70 (5 – 8 May 2009) Open point fulfilled. Though application was at a later stage than BBCH 31 the 4 trials conducted in Germany (BBCH 37) can be used to support the notified use in the North.

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations PRAPeR Expert Meeting / Conclusions of the Evaluation Meeting
			-Leaves:<0.02-<0.02-<0.02-0.04 mg/kg *South*: -Roots:3x<0.02 mg/kg -Leaves:<0.02-<0.02-0.03 mg/kg These trials are covered by acceptable storage stability data.	
	Data gap: 3.2 Further trials covering SE necessary to complete the residue database. (Meeting of experts to discuss the number of trials necessary). See reporting table 3(12)	According to the guidelines (7525/VI/95 rev 8) when residues are expected to be <LOQ and this is confirmed in 2 trials, further trials are not required. Lenacil is used early in the season and residues in the sugar beet roots are not expected. This has been confirmed in 7 trials over three seasons (4 North and 3 South, all supported by adequate storage stability data) in which residues in sugar beet roots were <0.02 mg/kg in all trials. These trials are sufficient to propose a MRL for sugar beet roots. In the same 7 trials residues in sugar beet tops were <0.02 to 0.04 mg/kg. (In 5 trials residues in sugar beet tops were <0.02 mg/kg.) Therefore, additional trials are not required.	**04.2009:** To clarify the situation: -In the guideline 7029/VI/95 rev.6, it is stated that the number of residue trials can be reduced if it can be justified that the residue levels in plants will be lower than the Limit of Quantification (LoQ). -In the guideline 7525/VI/95-rev.8, it is stated in section 2.6 that when residues are foreseen to be under the LoQ and at least 2 residue trials confirm this then no further trials are normally necessary. In that specific case, a low residue situation is encountered since residue levels of 0.03 and 0.04 mg/kg were recovered in sugar beet tops and leaves. These residue values were generated from trials performed at BBCH GS 37-39. It is very unlikely that further data both for Northern and Southern Europe will	PRAPeR 70 (5 – 8 May 2009) Data gap closed. Taking into account the overall data set from North and South the available trials are sufficient to support the notified use in the South.

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations PRAPeR Expert Meeting / Conclusions of the Evaluation Meeting
			change the residue levels recovered both in the roots and in the leaves. RMS proposes not to require additional residue trials for N and S Europe.	
3.1	Point for clarification: Spray concentration does not agree with application rate and water volumes for use pattern provided in Table B.7.4-1. Notifier to clarify. See reporting table 3(13)	The spray concentration range in the GAP table is correct. The rate/ha and spray volume are independent. The maximum rate is 0.~~25~~ 5kg as/ha, which at the minimum spray volume of 200 L/ha is 0.25 kg as/hL. The minimum rate is 0.125 kg as/ha which at the maximum spray volume of 400 L/ha is 0.03125 kg as/hL.	**04.2009:** RMS notes the comment.	PRAPeR 70 (5 – 8 May 2009) Point of clarification addressed.
	Open point: 3.4 RMS to consider presenting relevant validation data for method Hamburger R., 2002 in an addendum to the DAR. See reporting table 3(14)	The notifier agrees that the relevant validation data should be presented as proposed.	**04.2009:** The validation data of the analytical methods used to generate the residue trials were reported in the Addendum to the DAR-April 2009.	PRAPeR 70 (5 – 8 May 2009) Open point fulfilled. All methods used to generate residue trial results that were considered in the assessment are sufficiently validated.
	Open point: 3.5 Meeting of experts to discuss if methods used in residue trials (Tillkes, 1998; Mende 2002; Hamburger, 2002; Witte, 2006) comply with guidance document SANCO/3029/99 concerning		**04.2009:** The validation data of the analytical methods used to generate the residue trials were reported in the Addendum to the DAR-April 2009.	PRAPeR 70 (5 – 8 May 2009) Open point fulfilled. All methods used to generate residue trial results that were considered in the assessment are sufficiently validated.

<table>
<tr><th>No.</th><th>Column A
Conclusions of the EFSA Evaluation Meeting</th><th>Column B
Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion</th><th>Column C
Rapporteur Member State comments on main data submitter / applicant comments</th><th>Column D
Recommendations PRAPeR Expert Meeting / Conclusions of the Evaluation Meeting</th></tr>
<tr><td></td><td>methods of analysis in support of pre-registration requirements and therefore are suitable to support the respective residue trials.

See reporting table 3(14)</td><td></td><td></td><td></td></tr>
<tr><td></td><td>Open point: 3.6
Meeting of experts to discuss if further information or studies concerning rotational/succeeding crops are required.

See reporting table 3(22)</td><td>The notifier agrees with the comments made by the RMS in the reporting table.</td><td><u>04.2009</u>:
a) Succeeding crops should not be planted or drilled until at least 4 months have elapsed after application and ploughing and cultivation to a depth of at least 15 cm should be carried out. When Venzar 80 WP is applied and crop failure occurs for any reason during this period only sugar beet, red beet, or spinach should be drilled or planted. No further application of Venzar 80 WP should be made for at least 4 months.
b)
<table>
<tr><th></th><th>DT_{50} (Lab)</th><th>DT_{50} (Field)</th><th>DT_{90} (Field)</th></tr>
<tr><td>Lenacil</td><td>11-18</td><td>18-28</td><td>61-91</td></tr>
<tr><td>IN-KF 313</td><td>3-20</td><td></td><td></td></tr>
<tr><td>IN-KE 121</td><td>4-11</td><td></td><td></td></tr>
</table></td><td><u>PRAPeR 70 (5 – 8 May 2009)</u>

Open point fulfilled.

New data gap proposed, see below.</td></tr>
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			The DT_{50}/DT_{90} values: 88/291 days from a fourth study (Spain) were discounted as there was no rainfall after application and no irrigation was applied. These conditions would not apply to sugar beets that require regular rainfall or irrigation for development. Based on these DT_{50}/DT_{90} values, no further information on rotational crops is required.	
	New data gap identified at PRAPeR 70 meeting: A rotational crop metabolism study is necessary to address residues in rotational crops.			PRAPeR 70 (5 – 8 May 2009) Data gap open.
	Open point: 3.7 Meeting of experts to discuss the requirement of a re-entry period and/or the prohibition of the feeding of sugar beet tops after thinning and crop failure taking into account the practices in different countries. See reporting table 3(25)	The notifier agrees with the comments made by the RMS in the reporting table.	**04.2009:** No re-entry period was proposed since Lenacil is intended to be used on sugar beet. Livestock are not supposed to be grazed on such an area. Thinning out the sugar beet crop is not relevant anymore nowadays (seeds selection). It is not expected that sugar beet leaves after the crop failure (30 days) will be fed to livestock.	PRAPeR 70 (5 – 8 May 2009) Open point fulfilled.