PEER REVIEW REPORT ON **PENOXSULAM** 18.04.2007

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REPORT OF PRAPeR EXPERT MEETING 01

PENOXSULAM

Rapporteur Member State: IT

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**
none		

3. Documents tabled at the meeting:

Date	**Supplier**	**File Name**
08.09.2006	Italy	Penoxsulam end point (Sept 2006).doc
08.09.2006	Italy	Praper_01_geneal_table Penoxsulam.doc
08.09.2006	Italy	Penoxsulam evaluation table rev0-1 (2006-09-04).doc

The conclusions of the meeting were as follows:

4. **Data on preparations:** Subject to an open point.

5. **Classification and labelling:** Not discussed.

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

Reference List: Not discussed.

Areas of concern: None

Appendix 1: Discussion table: PENOXSULAM

Appendix 2: Evaluation table

Appendix 1: Discussion Table, Penoxsulam (Hb)

1. Physical and Chemical Properties

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	Open point 1.1: RMS to amend the list of end points with respect to classification and labeling. (see reporting table 0(1))	The endpoints sheet tabled at the meeting has been corrected	Open point fulfilled.
	Open point 1.2: RMS to amend the list of end points with respect to the list of representative uses. (see reporting table 0(4) and 1(13))	The endpoints sheet tabled at the meeting has been corrected	Open point fulfilled.
	Open point 1.3: RMS to provide a corrigendum or revised Volume 4 to clarify the used codes. (see reporting table 0(5))	An addendum for volume 4 will be prepared and should be provided by the end of October 2006	Open point remains

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	Open point 1.4: RMS to amend the list of end points with respect to method for the determination of Bis-CHYMP. (see reporting table 1(1) and 1(10))	The endpoints sheet tabled at the meeting has been corrected	Open point fulfilled.
	Open point 1.5: RMS to amend the list of end points to indicate that a method for blood and tissues (Annex point 4.2.5) is not required. (see reporting table 1(3))	The endpoints sheet tabled at the meeting has been corrected	Open point fulfilled.
	Open point 1.6: RMS to amend the list of end points with respect to the validated matrices in food of plant origin. (see reporting table 1(11))	The endpoints sheet tabled at the meeting has been corrected	Open point fulfilled.

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
1.1	Applicant to provide a shelf-life study as well as data on the relative density. (see reporting table 1(12), 1(20) and 1(21))	2 studies submitted, evaluated by the RMS Relative density study has not been provided. As data on the density is available the experts agreed they are happy that the available data on density is sufficient. However, only the study for the representative formulation (GF-657) is needed. Therefore, the other study should not be listed in the references relied on.	Data requirement for relative density addressed. New open point (see o.p. 1.12) RMS to summarise and evaluate the shelf life study for the representative formulation in an addendum and remove the study for the GF-237 formulation from the references relied on.
	New open point 1.12: RMS to summarise and evaluate the shelf life study for the representative formulation in an addendum and remove the study for the GF-237 formulation from the references relied on.		Open point open.
1.2	Applicant to provide data on the oxidising properties of the formulation based on a theoretical assessment or on the EEC method A21. (see reporting table 1(12), 1(18) and 1(19))	A study has been evaluated by the RMS (column 3 of the evaluation table). It was concluded that formulation did not have oxidising properties.	Data requirement fulfilled New open point (see o.p 1.13) The evaluation in column 3 of the evaluation table to be transferred to an addendum.

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	New open point 1.13: The evaluation in column 3 of the evaluation table to be transferred to an addendum.		Open point open.
	Open point 1.7: RMS to remove confidential data form the box "Impurities in technical as" from the list of end points. (see reporting table 1(14)	The endpoints sheet tabled at the meeting has been corrected	Open point fulfilled
	Open point 1.8: RMS to report the purity of the starting material in a revised Volume 4 or a corrigendum. (see reporting table 1(28))	The purity of the starting material that has now been provided should be summarised in an addendum to volume 4	Open point open. RMS to provide the information on the purity of the starting material in an addendum to vol 4.

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
1.3	Applicant to provide actual batch analysis of the large scale production or a justification that specified limits above the maximum value found in the batch analyses is acceptable in respect to the toxicological and ecotoxicological assessment. (see reporting table 1(28))	Data on production scale batches are not available until 2007. The data requirement remains.	Data requirement open. Large scale batch data is required. A final specification is still required.

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	Open point 1.9: RMS to provide the specified maximum value of the relevant impurity in a revised Volume 4 or corrigendum. (see reporting table 1(29))	The experts discussed the specification proposed based on the pilot scale batch analysis and considered that the specification proposed based on this pilot plant production was unreliable. Therefore the ecotoxicology and toxicology experts should carry out an assessment comparing impurity levels in the pilot plant production batches with the material used in their studies as well as those in the proposed specification. Note for the relevant impurity Bis-CHYMP though the specification proposes a level of 0.5 g/kg in the pilot batches it was not determined (<26 mg/kg, method not fully validated).	Open point open the revised volume 4 or corrigendum was not provided. Message to tox and ecotox meeting of experts. The ecotoxicology and toxicology experts should carry out an assessment comparing impurity levels in the pilot plant production batches with the material used in their studies as well as those in the proposed specification. (See bottom of the table) Note for the relevant impurity Bis-CHYMP though the specification proposes a level of 0.5 g/kg in the pilot batches it was not determined (<26 mg/kg, method not fully validated)
	Open point 1.10: RMS to provide CAS numbers of formulants in a revised Volume 4 or corrigendum. (see reporting table 1(31))	This is still outstanding	Open point open. Information to be provided in a corrigendum.

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	Open point 1.11: RMS to provide validation data (incl. the used UV wavelength) for the analytical method used for the determination of the relevant impurity Bis-CHYMP in a revised Volume 4 or corrigendum. (see reporting table 1(32) and 1(33))	This data is still outstanding.	Open point open. Information to be provided in a corrigendum.
1.3	Data gap identified at PRAPeR 01: Applicant to clarify what happened to batches out of specification with respect to the specified minimum purity.	Applicant to clarify what happened to batches out of specification with respect to the specified minimum purity.	Data gap open.
	New open point 1.14 RMS to submit the updated versions of the end points and the evaluation table to the EFSA for distribution.	The meeting realised that the end points and evaluation table placed on CIRCA contain a footer "DOW RESTRICTED – For internal use only. However, IT tabled at the meeting new versions which were discussed by the experts.	Open point open.

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	New open point 1.15 RMS to amend the list of end points	RMS to confirm the end points and evaluation table placed on CIRCA was prepared by them and not Dow (subsequently replaced by new versions tabled at the meeting) Purity of material used for temperature of decomposition to be reported Method for the relevant impurity in the technical material to specify the identity of this impurity next to the entry. Amend the method information in soil to clarify LOQ for the soil metabolite and indicate its identity. In analytical methods remove each time mentioned “it was calculated as the lowest fortification level for recovery samples” Table of representative uses: clarify NN and NN* in the PHI column; product name to be clarified/provided. UV/VIS sorption where does A λ = 290 nm; ε = 8846 $L.mol^{-1}.cm^{-1}$originate from as it is not in the DAR.	Open point open. Noted changes / clarifications to be made to the end points

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	Message to tox and ecotox meeting of experts. The ecotoxicology and toxicology experts should carry out an assessment comparing impurity levels in the pilot plant production batches with the material used in their studies as well as those in the proposed specification. (See bottom of the table) Note for the relevant impurity Bis-CHYMP though the specification proposes a level of 0.5 g/kg in the pilot batches it was not determined (<26 mg/kg, method not fully validated)		Answer ecotox: Data gap (see 5.1) Notifier to provide the composition of the batches in order to assess the relevance of the impurities. New open point (see 5.4) RMS to check the comparability of the profiles. Answer tox: Data gap (2.2) Notifier to provide the composition of the batches in order to assess the relevance of the impurities. New open point (2.7) RMS to check the comparability of the batches used in the tox studies and the proposed specification

Appendix 2: Evaluation table

1. Physical and Chemical Properties

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

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 EPCO Expert Meeting / Conclusions of the Evaluation Meeting
	Section 1 Data requirements: ***3*** Open points: ***11***			
	Open point 1.1: RMS to amend the list of end points with respect to classification and labeling. (see reporting table 0(1))	Agreed. RMS to amend the list of end points with respect to classification and labeling.	List of end points updated by adding the missing statement.	PRAPeR 01 Meeting (6.– 8.9.2006): Open point fulfilled.
	Open point 1.2: RMS to amend the list of end points with respect to the list of representative uses. (see reporting table 0(4) and 1(13))	Headings should be changed according to the guidance document.	List of end points has been amended with respect to the list of representative uses.	PRAPeR 01 Meeting (6.– 8.9.2006): Open point fulfilled.
	Open point 1.3:	Monograph should be amended to clarify to which the codes are related.	A corrigendum of Volume 4 to clarify the used codes is in preparation.	PRAPeR 01 Meeting (6.– 8.9.2006):

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 EPCO Expert Meeting / Conclusions of the Evaluation Meeting
	RMS to provide a corrigendum or revised Volume 4 to clarify the used codes. (see reporting table 0(5))			Open point remains
	Open point 1.4: RMS to amend the list of end points with respect to method for the determination of Bis-CHYMP. (see reporting table 1(1) and 1(10))	List of end points should be updated to include this method.	List of end points has been updated to include this method.	PRAPeR 01 Meeting (6.– 8.9.2006): Open point fulfilled.
	Open point 1.5: RMS to amend the list of end points to indicate that a method for blood and tissues (Annex point 4.2.5) is not required. (see reporting table 1(3))	The submitter agrees.	List of end points has been amended to indicate that a method for blood and tissues is not required, due the low toxicity of the compound. However a method is described for urine and whole blood.	PRAPeR 01 Meeting (6.– 8.9.2006): Open point fulfilled
	Open point 1.6: RMS to amend the list of end points with respect to the	Agreed. List of end points should be updated.	List of end points has been corrected.	PRAPeR 01 Meeting (6.– 8.9.2006):

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 EPCO Expert Meeting / Conclusions of the Evaluation Meeting
	validated matrices in food of plant origin. (see reporting table 1(11))			Open point fulfilled.
1.1	Applicant to provide a shelf-life study as well as data on the relative density. (see reporting table 1(12), 1(20) and 1(21))	"Lindsay, D. A. (2004): Frozen Storage Stability of DE-638 in Rice (Raw Agricultural Commodities: Grain, Straw, Immature Forage) and its Processed Products (Bran, Hulls, Polished Rice), Dow AgroSciences unpublished report number 010100.01. Ref. A26" submitted on June 06	Study considered acceptable. Addendum in preparation. Residues of penoxulam are stable in rice grain, straw, and immature forage when stored frozen at -20°C for up to 732 days. Residues of penoxulam show to be stable in rice bran, hulls and polished rice when stored frozen at -20°C for up to 390 days.	PRAPeR 01 Meeting (6.– 8.9.2006): Data requirement for relative density addressed. New open point (see o.p. 1.12) RMS to summarise and evaluate the shelf life study for the representative formulation in an addendum and remove the study for the GF-237 formulation from the references relied on.
	New open point 1.12: RMS to summarise and evaluate the shelf life study for the representative formulation in an addendum and remove the study for the GF-237 formulation from the references relied on.			PRAPeR 01 Meeting (6.– 8.9.2006): 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 EPCO Expert Meeting / Conclusions of the Evaluation Meeting
1.2	Applicant to provide data on the oxidising properties of the formulation based on a theoretical assessment or on the EEC method A21. (see reporting table 1(12), 1(18) and 1(19))	"Nelson R.M (2006): Oxidising properties of GF 657 Ref. MA36 " submitted on June 06 IMPORTANT note by RMS: An insertion made by applicant has been removed as contained confidential information about the composition of formulated product.	The current EU test method A 21 to determine oxidizing properties has not to be performed when structural analysis allows to establish that an exothermal reaction with a combustible material is unlike to occur. An assessment of the structures of individual components of GF-657 as well as of penoxulam has been performed: none of the formulants nor penoxulam contain reactive chemical groups (as, for instance, N-halogen compounds, organ-nitro compounds and oxyhalogen compounds) that may give the substances oxidising potential. Therefore, none of the components of GF-657 demonstrate oxidising potential. Since the formulation is a simple blend of these components and exhibits good chemical and physical stability on storage, it is reasonable to conclude that GF-657 does not demonstrate oxidising properties.	PRAPeR 01 Meeting (6.– 8.9.2006): Data requirement fulfilled New open point (see o.p 1.13) The evaluation in column 3 of the evaluation table to be transferred to an addendum.
	New open point 1.13: The evaluation in column 3 of the evaluation table to be transferred to an addendum.			PRAPeR 01 Meeting (6.– 8.9.2006): Open point open.
	Open point 1.7: RMS to remove confidential	Agreed	The confidential information such as used columns or internal standards has been	PRAPeR 01 Meeting (6.– 8.9.2006):

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 EPCO Expert Meeting / Conclusions of the Evaluation Meeting
	data form the box "Impurities in technical as" from the list of end points. (see reporting table 1(14)		removed from the table.	Open point fulfilled.
	Open point 1.8: RMS to report the purity of the starting material in a revised Volume 4 or a corrigendum. (see reporting table 1(28))	Applicant provided actual batch analysis of the large scale production or a justification that specified limits above the maximum value found in the batch analyses is acceptable in respect to the toxicological and ecotoxicological assessment.	Acceptable. A table with the purity of the starting material during manufacturing will be added in a revised Volume 4.	PRAPeR 01 Meeting (6.– 8.9.2006): Open point open. RMS to provide the information on the purity of the starting material in an addendum to vol 4.
1.3	Applicant to provide actual batch analysis of the large scale production or a justification that specified limits above the maximum value found in the batch analyses is acceptable in respect to the toxicological and ecotoxicological assessment. (see reporting table 1(28))	Applicant stated that a large scale batch analysis will be available in 2007 meanwhile a 6 batches analysis is provided. “Six typical batches of penoxsulam (DE-638) Technical Grade of Active Ingredient were analyzed for active ingredient level, DE-638 related impurities, residual 3,5-lutidine, water and BIS-CHYMP [4(1H)-pyrimidinone, 2-chloro-5-methoxy-, 2-chloro-5-methoxy-4-pyrimidinylhydrazone].	Applicant stated that a large scale batch analysis will be available in 2007. A six batch analysis has been however provided confirming that specified limits above the maximum value found in the batch analyses is acceptable in respect to the toxicological and ecotoxicological assessment. The study is under assessment in an addendum to Volume 4.	PRAPeR 01 Meeting (6.– 8.9.2006): Data requirement open. Large scale batch data is required. A final specification is still 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 EPCO Expert Meeting / Conclusions of the Evaluation Meeting
		Active ingredient was determined by the internal standard liquid chromatographic (HPLC) method described in DAS-AM-02-003. DE-638 related impurities and 3,5-lutidine were determined by the internal standard liquid chromatographic method described in DAS-AM-01-051. The external standard HPLC method described in DECO GL-AL-MD-2002-002138 was used to measure BIS-CHYMP. Water levels in the 6 batches were measured using Karl Fischer titration. Active ingredient and impurity identification were determined by electrospray liquid chromatography-mass spectrometry (ESI/LC/MS) in the positive ion (PI) and (NI) modes."		
	Open point 1.9: RMS to provide the specified maximum value of the relevant impurity in a revised Volume 4 or corrigendum. (see reporting table 1(29))		A table with the purity of the starting material during manufacturing will be added in a revised Volume 4.	PRAPeR 01 Meeting (6.– 8.9.2006): Open point open the revised volume 4 or corrigendum was not provided. Message to tox and ecotox meeting of experts. The ecotoxicology and toxicology experts

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 EPCO Expert Meeting / Conclusions of the Evaluation Meeting
				should carry out an assessment comparing impurity levels in the pilot plant production batches with the material used in their studies as well as those in the proposed specification. (See bottom of the table) Note for the relevant impurity Bis-CHYMP though the specification proposes a level of 0.5 g/kg in the pilot batches it was not determined (<26 mg/kg, method not fully validated)
	Message to tox and ecotox meeting of experts. The ecotoxicology and toxicology experts should carry out an assessment comparing impurity levels in the pilot plant production batches with the material used in their studies as well as those in the proposed specification. (See bottom of the table) Note for the relevant impurity Bis-CHYMP though the specification proposes a level			Answer ecotox: Data gap (see 5.1) Notifier to provide the composition of the batches in order to assess the relevance of the impurities. New open point (see 5.4) RMS to check the comparability of the profiles. Answer tox:

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 EPCO Expert Meeting / Conclusions of the Evaluation Meeting
	of 0.5 g/kg in the pilot batches it was not determined (<26 mg/kg, method not fully validated)			Data gap (2.2) Notifier to provide the composition of the batches in order to assess the relevance of the impurities. New open point (2.7) RMS to check the comparability of the batches used in the tox studies and the proposed specification
	Open point 1.10: RMS to provide CAS numbers of formulants in a revised Volume 4 or corrigendum. (see reporting table 1(31))		Volume C being amended to include this information.	PRAPeR 01 Meeting (6.– 8.9.2006): Open point open. Information to be provided in a corrigendum.
	Open point 1.11: RMS to provide validation data (incl. the used UV wavelength) for the analytical method used for the determination of the relevant impurity Bis-CHYMP in a revised Volume 4 or corrigendum.		Summary of validation data (incl. the used UV wavelength) for the analytical method used for the determination of the relevant impurity Bis-CHYMP, will be part of a revised Volume 4.	PRAPeR 01 Meeting (6.– 8.9.2006): Open point open. Information to be provided in a corrigendum.

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 EPCO Expert Meeting / Conclusions of the Evaluation Meeting
	(see reporting table 1(32) and 1(33))			
1.3	Data gap identified at PRAPeR 01: Applicant to clarify what happened to batches out of specification with respect to the specified minimum purity.			PRAPeR 01 Meeting (6.– 8.9.2006): Data gap open.
	New open point 1.14 RMS to submit the updated versions of the end points and the evaluation table to the EFSA for distribution.			PRAPeR 01 Meeting (6.– 8.9.2006): Open point open.
	New open point 1.15 RMS to amend the list of end points			Open point open. Noted changes / clarifications to be made to the end points

List of representative uses evaluated*

Crop and / or situation (a)	**Member State or Country**	**Product name**	**F G or I** (b)	**Pests or Group of pests controlled** (c)	**Formulation**		**Application**				**Application rate per treatment**			**PHI** (days) (l)	**Remarks:** (m)
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	kg as/hl min max	water l/ha min max	kg as/ha min max		
Rice	Italy	Penoxsulam PENOXULAM	F	Echinochloa crus-galli, sedges and broad leaf weeds.	OD	20.4 g/L	Broadcast spray	BBCH 11-31 May-June	1	Not applicable	0.03-0.04	200-400	0.0075-0.02	N.N*	
Rice	Spain	Penoxsulam PENOXULAM	F	Echinochloa crus-galli, sedges and broad leaf weeds.	OD	20.4 g/L	Broadcast spray	BBCH 11-31 May-June	1	Not applicable	0.03-0.04	150-400	0.0075-0.027	N.N	
Rice	Portugal	Penoxsulam PENOXULAM	F	Echinochloa crus-galli, sedges and broad	OD	20.4 g/L	Broadcast spray	BBCH 11-31 May-June	1	Not applicable	0.03-0.04	150-400	0.0075-0.027	N.N	

Crop and / or situation (a)	**Member State or Country**	**Product name**	**F G or I** (b)	**Pests or Group of pests controlled** (c)	**Formulation**		**Application**				**Application rate per treatment**			**PHI** (days) (l)	**Remarks:** (m)
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	kg as/hl min max	water l/ha min max	kg as/ha min max		
				leaf weeds.											
Rice	Greece	Penoxsulam PENOXULAM	F	Echinochloa crus-galli, sedges and broad leaf weeds.	OD	20.4 g/L	Broadcast spray	BBCH 11-31 May-June	1	Not applicable	0.03-0.04	300-500	0.006-0.013	N.N	
Rice	France	Penoxsulam PENOXULAM	F	Echinochloa crus-galli, sedges and broad leaf weeds.	OD	20.4 g/L	Broadcast spray	BBCH 11-31 May-June	1	Not applicable	0.03-0.04	150-300	0.01-0.027	N.N	

Remarks: * Uses for which risk assessment could not been concluded due to lack of essential data are marked grey

(a) For crops, the EU and Codex classifications (both) should be used; where relevant,

(h) Kind, *e.g.* overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated

(i) g/kg or g/l

the use situation should be described (*e.g.* fumigation of a structure)

(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)

(c) *e.g.* biting and suckling insects, soil born insects, foliar fungi, weeds

(d) *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)

(e) GCPF Codes - GIFAP Technical Monograph No 2, 1989

(f) Method, *e.g.* high volume spraying, low volume spraying, spreading, dusting, drench

(g) All abbreviations used must be explained

(j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application

(k) The minimum and maximum number of application possible under practical conditions of use must be provided

(l) PHI - minimum pre-harvest interval

(m) Remarks may include: Extent of use/economic importance/restrictions

REPORT OF PRAPeR EXPERT MEETING 02

PENOXSULAM

Rapporteur Member State: IT

Specific comments on the active substance in the section

2. Environmental Fate and Behaviour

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**
none		

3. Documents tabled at the meeting:

Date	**Supplier**	**File Name**
none		

The conclusions of the meeting were as follows:

4. **Data on preparations:** Viper.

5. **Classification and labelling:** candidate for R53.

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

7. **Reference List** not discussed

Areas of concern: none identified

Appendix 1: Discussion table: PENOXSULAM

Appendix 2: Evaluation table

Appendix 1: Discussion Table, Pensoxsulam (Hb)

4. Environmental fate and behaviour

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
4.1	Applicant to provide argumentation on their selection of Koc values used to calculate a mean value for use in PEC calculations. (see reporting table 4(4))	In addition to 4 soils originating from the EU there were numerous values from soils from outside the EU. Though the argumentation was to use just EU soils, originally the mean was based on all soils. The applicant has used the Kdoc values of just the 4 EU soils in PEC calculations. Using the average value in MedRICE as done by the applicant is appropriate. The meeting is of the opinion that all appropriate soils can be used. But in this case the average value of 4 can be accepted, as the difference in the mean of all soils and just the 4 EU soils is small. Data requirement stays open for formal reasons.	Data requirement remains formally open. RMS to prepare an addendum on the position paper provided by the applicant.
	Open point 4.1: Endpoints for definition of the residue to be updated to include a list of all major residues that require risk assessments as well a relevant residues for monitoring. (see reporting table 4(9))	At the fate part of the endpoints list all compounds that need a risk assessment should be listed. The meeting confirmed these were: Soil:penoxsulam, 5-OH penoxsulam and BSTCA Surface- and groundwater: penoxsulam, 5-OH penoxsulam and BSTCA Sediment: penoxsulam and 5-OH penoxsulam Air: penoxsulam	Open point remains open. RMS to update the LoEP as indicated

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
4.2	Applicant to clarify all assumptions used to calculate metabolite PECgw, to include clear information on how $TWA_{pw,t(close)}$ for both 5-OH and BSTCA were estimated and to present new calculations that use a realistic worst case formation fraction of BSTCA. (see reporting table 4(10))	Applicant provided a position paper that should be assessed. The results are included in the LoEP already by RMS. An addendum will be provided.	Data requirement remains formally open. RMS to prepare an addendum on the position paper provided by the applicant.
	Open point 4.2: 'for phenyl and triazolopyrimidine ring radiolabels' still needs to be added to the endpoints to put the mineralization and NER values in context. (see reporting table 4(14))	Endpoints have been updated accordingly.	Open point fulfilled.

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	Open point 4.3: 'for phenyl and triazolopyrimidine ring radiolabels' and 'moist soil first order DT50 19 days at 25°C summer sunlight at 40°N (r^2=0.9)' still need to be added to the endpoints. (see reporting table 4(15))	Endpoints have been updated accordingly	Open point fulfilled.
	Open point 4.4: 'non linear first order Modelmaker compartment modelling' still need to be added to the endpoints in the context of the metabolites. (see reporting table 4(16))	Endpoints have been updated accordingly	Open point fulfilled.

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	Open point 4.5: The DT50 for the major metabolites (5-OH and BSTCA for aerobic studies and 5-OH for anaerobic studies) still need to be added to the endpoints. (see reporting table 4(17))	Endpoints have been updated accordingly	Open point fulfilled.
4.3	Applicant to provide an audited corrigendum to the original report to correct the Kf, 1/n and Kfoc values for the Amagon soil. Provision by the end of June 2006 would be appreciated. (see reporting table 4(21))	Applicant provided a statement that the Amagon soil is non EU and therefore considered supplementary. With reference to datarequirement 4.1 the value is the average of 4 European soils. Though there is no impact on the assessment the applicant needs to provide a study report with the correct numbers in.	Data requirement remains formally open.

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	Open point 4.6: RMS to check that Koc were not used to calculate the metabolite PEC. If they were used the values should be added to the method of calculation box. (see reporting table 4(25))	The values are not used for calulation of PECsoil. No change to endpoints list required.	Open point fulfilled.
	Open point 4.7: RMS to check that Koc were not used to calculate the metabolite PEC. If they were used the values should be added to the method of calculation box. (see reporting table 4(28))	The values are not used for calulation of PECsoil. No change to endpoints list required.	Open point fulfilled.

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	Open point 4.8: After data requirement 4.2 has been addressed the endpoints will need appropriately updating with the necessary information in the method of calculation box. (see reporting table 4(30))	The information provided by the applicant has not yet been assessed. The endpoints have been updated. The open point stays open for formal reasons to check the endpoints sheet against the data from data requirement 4.2.	Open point remains open.
	New open point 4.9: RMS to update LoEP as indicated.	Replace the code for the active with penoxsulam and consistently use the same codes for all metabolites. The column header for Koc should be changed to Kdoc for penoxsulam and metabolites. The product name in the list of representative uses should be changed to Viper. The ready biodegradability of the formulated product should be removed from the endpoints sheet. Classification and labelling: the S phrases are reported and should be substituted by R53 (candidate).	Open point open

Appendix 2: Evaluation table

4. Environmental Fate and Behaviour

4. Environmental fate and behaviour

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 EPCO Expert Meeting / Conclusions of the evaluation group
	Section 4 Data requirements: ***3*** Open points: ***8***			
4.1	Applicant to provide argumentation on their selection of Koc values used to calculate a mean value for use in PEC calculations. (see reporting table 4(4))	Provided.	Clarification provided by applicant, and summarized in the list of end point into the revised fate section attached. *[The attached list of end points has been removed by EFSA.]*	PRAPeR 02 Meeting (11.– 14.9.2006): Data requirement remains formally open. RMS to prepare an addendum on the position paper provided by the applicant.
	Open point 4.1: Endpoints for definition of the residue to be updated to include a list of all major residues that require risk assessments as well a relevant residues for monitoring.		Endpoints for definition of the residue has been updated to include a list of all major residues that require risk assessments as well relevant residues for monitoring.	PRAPeR 02 Meeting (11.– 14.9.2006): Open point remains open. RMS to update the LoEP as indicated

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 EPCO Expert Meeting / Conclusions of the evaluation group
	(see reporting table 4(9))			
4.2	Applicant to clarify all assumptions used to calculate metabolite PECgw, to include clear information on how $TWA_{pw,t(close)}$ for both 5-OH and BSTCA were estimated and to present new calculations that use a realistic worst case formation fraction of BSTCA. (see reporting table 4(10))	Provided.	Clarification provided by applicant, and summarized in the list of end point into the revised fate section. See open point 4.1.	PRAPeR 02 Meeting (11.– 14.9.2006): Data requirement remains formally open. RMS to prepare an addendum on the position paper provided by the applicant.
	Open point 4.2: 'for phenyl and triazolopyrimidine ring radiolabels' still needs to be added to the endpoints to put the mineralization and NER values in context. (see reporting table 4(14))		Clarification provided by applicant, and summarized in the list of end point into the revised fate section. See open point 4.1.	PRAPeR 02 Meeting (11.– 14.9.2006): 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 EPCO Expert Meeting / Conclusions of the evaluation group
	Open point 4.3: 'for phenyl and triazolopyrimidine ring radiolabels' and 'moist soil first order DT50 19 days at 25°C summer sunlight at 40°N (r^2=0.9)' still need to be added to the endpoints. (see reporting table 4(15))	.	Clarification provided by applicant, and summarized in the list of end point into the revised fate section. See open point 4.1.	PRAPeR 02 Meeting (11.– 14.9.2006): Open point fulfilled.
	Open point 4.4: 'non linear first order Modelmaker compartment modelling' still need to be added to the endpoints in the context of the metabolites. (see reporting table 4(16))		Clarification provided by applicant, and summarized in the list of end point into the revised fate section. See open point 4.1.	PRAPeR 02 Meeting (11.– 14.9.2006): Open point fulfilled.
	Open point 4.5: The DT50 for the major metabolites (5-OH and BSTCA for aerobic studies and 5-OH for anaerobic studies) still need to be added to the endpoints. (see reporting table 4(17))		Clarification provided by applicant, and summarized in the list of end point into the revised fate section. See open point 4.1.	PRAPeR 02 Meeting (11.– 14.9.2006): 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 EPCO Expert Meeting / Conclusions of the evaluation group
4.3	Applicant to provide an audited corrigendum to the original report to correct the Kf, 1/n and Kfoc values for the Amagon soil. Provision by the end of June 2006 would be appreciated. (see reporting table 4(21))	Amagon soil is non-EU and not used in calculations, provided as supplementary information.	Applicant has stated in its comments that the Kf and 1/n values for the Amagon soil reported in the original study were incorrectly calculated. Agreed.	PRAPeR 02 Meeting (11.– 14.9.2006): Data requirement remains formally open.
	Open point 4.6: RMS to check that Koc were not used to calculate the metabolite PEC. If they were used the values should be added to the method of calculation box. (see reporting table 4(25))		Clarification provided by applicant, and summarized in the list of end point into the revised fate section. See open point 4.1.	PRAPeR 02 Meeting (11.– 14.9.2006): Open point fulfilled.
	Open point 4.7: RMS to check that Koc were not used to calculate the metabolite PEC. If they were used the values should be added to the method of calculation box.		Clarification provided by applicant, and summarized in the list of end point into the revised fate section. See open point 4.1.	PRAPeR 02 Meeting (11.– 14.9.2006): 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 EPCO Expert Meeting / Conclusions of the evaluation group
	(see reporting table 4(28))			
	Open point 4.8: After data requirement 4.2 has been addressed the endpoints will need appropriately updating with the necessary information in the method of calculation box. (see reporting table 4(30))		Clarification provided by applicant, and summarized in the list of end point into the revised fate section. See open point 4.1.	PRAPeR 02 Meeting (11.– 14.9.2006): Open point remains open.
	New open point 4.9: RMS to update LoEP as indicated in the discussion table.			PRAPeR 02 Meeting (11.– 14.9.2006): Open point open

List of representative uses evaluated*

Crop and / or situation (a)	**Member State or Country**	**Product name**	**F G or I** (b)	**Pests or Group of pests controlled** (c)	**Formulation**		**Application**				**Application rate per treatment**			**PHI** (days) (l)	**Remarks:** (m)
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	kg as/hl min max	water l/ha min max	kg as/ha min max		
Rice	Italy	Penoxsulam PENOXULAM	F	Echinochloa crus-galli, sedges and broad leaf weeds.	OD	20.4 g/L	Broadcast spray	BBCH 11-31 May-June	1	Not applicable	0.03-0.04	200-400	0.0075-0.02	N.N*	
Rice	Spain	Penoxsulam PENOXULAM	F	Echinochloa crus-galli, sedges and broad leaf weeds.	OD	20.4 g/L	Broadcast spray	BBCH 11-31 May-June	1	Not applicable	0.03-0.04	150-400	0.0075-0.027	N.N	
Rice	Portugal	Penoxsulam PENOXULAM	F	Echinochloa crus-galli, sedges and broad	OD	20.4 g/L	Broadcast spray	BBCH 11-31 May-June	1	Not applicable	0.03-0.04	150-400	0.0075-0.027	N.N	

Crop and / or situation (a)	**Member State or Country**	**Product name**	**F G or I** (b)	**Pests or Group of pests controlled** (c)	**Formulation**		**Application**				**Application rate per treatment**			**PHI** (days) (l)	**Remarks:** (m)
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between application s (min)	kg as/hl min max	water l/ha min max	kg as/ha min max		
				leaf weeds.											
Rice	Greece	Penoxsulam PENOXULAM	F	Echinochloa crus-galli, sedges and broad leaf weeds.	OD	20.4 g/L	Broadcast spray	BBCH 11-31 May-June	1	Not applicable	0.03-0.04	300-500	0.006-0.013	N.N	
Rice	France	Penoxsulam PENOXULAM	F	Echinochloa crus-galli, sedges and broad leaf weeds.	OD	20.4 g/L	Broadcast spray	BBCH 11-31 May-June	1	Not applicable	0.03-0.04	150-300	0.01-0.027	N.N	

Remarks: * Uses for which risk assessment could not been concluded due to lack of essential data are marked grey

(a) For crops, the EU and Codex classifications (both) should be used; where relevant,

(h) Kind, *e.g.* overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated

(i) g/kg or g/l

the use situation should be described (*e.g.* fumigation of a structure)

(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)

(c) *e.g.* biting and suckling insects, soil born insects, foliar fungi, weeds

(d) *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)

(e) GCPF Codes - GIFAP Technical Monograph No 2, 1989

(f) Method, *e.g.* high volume spraying, low volume spraying, spreading, dusting, drench

(g) All abbreviations used must be explained

(j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application

(k) The minimum and maximum number of application possible under practical conditions of use must be provided

(l) PHI - minimum pre-harvest interval

(m) Remarks may include: Extent of use/economic importance/restrictions

REPORT OF PRAPeR EXPERT MEETING 03

PENOXSULAM

Rapporteur Member State: IT

Specific comments on the active substance in the section

3. 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
none		

3. Documents tabled at the meeting:

Date	Supplier	File Name
none		

The conclusions of the meeting were as follows:

4. **Data on preparations:** A complete Annex III data package has been submitted for the formulation DE-638:

5. **Classification and labelling:** R50/53 was proposed by the meeting.

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

7. **Reference List**

Areas of concern: risk to aquatic higher plants

Appendix 1: Discussion table: PENOXSULAM

Appendix 2: Evaluation table

Appendix 1: Discussion Table, Penoxsulam (Hb)

5. Ecotoxicology

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	Open point 5.1: RMS to present the revised assessment in a revised DAR/corrigendum. (see reporting table 5(3))	The list of end points has been amended, but an addendum has not been prepared. Therefore the RMS is kindly asked to submit a short addendum in relation to 5(3) of the reporting table.	Open point still open.
	Open point 5.2: The risk to aquatic plants to be discussed in an experts' meeting. (see reporting table 5(7), 5(9), 5(13) and 5(16))	The risk to aquatic plants has been discussed. The RMS explained the derivation of the EC50 for *Lemna gibba* on the basis of the current guidance. A standard toxicity study is available with the active substance. The RMS proposed to refine the risk assessment for *Lemna gibba* using the results from another study available with the formulation (with *Lemna gibba*, sediment, prolonged observation period). This study was an outdoor study The study gives as well some indication of recovery (compensation) or "re-colonisation". Growth rate should be the appropriate parameter to conclude on recovery instead of biomass. (comment from DE) The appropriate end point to be selected was discussed (EC50 or NOEC). The appropriate end point could be the EC50 based on bio-mass derived from the study with the formulation. (DE) The option to use the NOEC was discussed and what trigger value should be used in that case. The trigger value of 10 was discussed related to this study, which is not a standard study. The approach was considered to be too conservative. Therefore a trigger	Open point open From the available information a risk to non-target aquatic plants could not be excluded.Therefore further data on recovery potential and variability of sensitivity between aquatic plants could be explored. Data gap see 5.1: Applicant to provide data to demonstrate the recovery potentia also for other aquatic plants besides *Lemna*

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
		value of less than 10 should be applied, if a NOEC is chosen (proposal from GR). The results from the two studies at 14 days have been compared, which result in 3.3 ug/L (a.s) and 4.74 ug/L (formulated product). Except for the potential of re-colonisation the second study does not provide results being so different. It was concluded that these studies are comparable and therefore the lowest value at 14 days was chosen (3.29 ug/L). A TER of 2.9 was calculated based on this end point. The effects of recovery observed for one species does not necessarily indicate a recovery for other species. Therefore further refinement of recovery potential and variability of sensitivity between species should be explored.	
5.1	Data gap identified a PRAPeR 03: Applicant to provide data to demonstrate the recovery potentia also for other aquatic plants besides *Lemna*		Data gap open
	Open point 5.3: RMS to clearly indicate in the list of intended uses that the assessment only covers tractor application technology. (see reporting table 5(12))	The information should show up as a footnote to the table. The RMS is asked to insert the information.	Open point still open RMS to add information to the list of intended uses.

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	Message from the phys-chem meeting: Ecotoxicology and toxicology experts should carry out an assessment comparing impurity levels in the pilot plant production batches with the material used in their studies as well as those in the proposed specification.	To discuss this point information on the composition of the batches in needed, which is not available at the moment. No conclusion can be drawn at this stage and new information is necessary.	Answer: No conclusion can be drawn at this stage and new information is necessary. Data gap (see 5.2) Notifier to provide the composition of the batches in order to assess the relevance of the impurities. New open point (see 5.4) RMS to check the comparability of the profiles.
5.2	Data gap identified at PRAPeR 03: Notifier to provide the composition of the batches in order to assess the relevance of the impurities.		Data gap open.
	New open point 5.4 proposed at PRAPeR 03: RMS to check the comparability of the profiles.		Open point open.

Appendix 2: Evaluation table

5. Ecotoxicology

5. Ecotoxicology

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 EPCO Expert Meeting / Conclusions of the evaluation group
	Section 5 Data requirements: **-** Open points: ***3***			
	Open point 5.1: RMS to present the revised assessment in a revised DAR/corrigendum. (see reporting table 5(3))		DAR has amended.	PRAPeR 03 Meeting (11.– 15.9.2006): Open point still open. The list of end points has benn amended, but an addendum has not been prepared.
	Open point 5.2: The risk to aquatic plants to be discussed in an experts' meeting. (see reporting table 5(7), 5(9), 5(13) and 5(16))	The study should be considered as a single species study performed with more realistic exposure conditions, as it is aimed to refine the EC50 value of Lemna. A single species study with a modified exposure regime may be used to refine the risk assessment, provided the initial PEC is used and there is no modification of the trigger TER value of 10 (as stated in Guidange document on Aquatic	The study should be considered as a single species study with more realistic exposure conditions . It is aimed to refine the EC50 value of Lemna. A single species study with a modified exposure regime may be used to refine the risk assessment, provided the initial PEC is used and there is no modification of the trigger TER value of 10 (SANCO/3268/2001 and HARAP). The duration of the test was 28 days. It is longer than the standard test "to	PRAPeR 03 Meeting (11.– 15.9.2006): Open point open From the available information a risk to non-target aquatic plants could not be excluded.Therefore further data on recovery potential and variability of sensitivity between aquatic plants could be explored.

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 EPCO Expert Meeting / Conclusions of the evaluation group
		Toxicology, SANCO/3268/2001 and HARAP). The duration of the test was 14 days longer than the standard test (in accordance to point 5.4.2.1 of the guidance document SANCO/3268/2001) in order to allow a certain environmental fate to take place and also in order to take account of the recovery. Growth rate generate more relevant information on recovery potential than frond count. The refined TERlt exceeds the uncertainty factor of 10, associated with protection of untested species ********** We are not fully agree. Please refer also to comment to Point 9.Tthe objective of the higher tier Lemna study was not intended to be a meso/microcosm one; we are of the opinion that it is not necessary to test the whole aquatic plant community as the first step in the refinement of the risk assessment for aquatic plants. is no modification of the TER trigger. Both of these above said provisions were followed in the refined risk assessment, showing any unacceptable risk to aquatic plants and the demonstrating a safe use of the	allow a certain environmental fate to take place" (SANCO/3268/2001 Sect. 5.4.2.1) and in order to take account of the recovery. Growth rate generate more relevant information on recovery potential than frond count. The refined TERlt exceeds the uncertainty factor of 10, associated with protection of untested species. Nevertheless, considered the study duration in order to evaluate the recovery potential of Lemna, the use of EC50 as endpoint, instead of the NOEC can be questionable.	Data gap see 5.1: Applicant to provide data to demonstrate the recovery potentia also for other aquatic plants besides *Lemna*

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 EPCO Expert Meeting / Conclusions of the evaluation group
		product. ********** Please refer also to comment to Point 9. The frond number is not a population level endpoint with ecological relevance to populations. In fact, this is a similar situation with the algal toxicity bioassays, where it may be considered that effects on individual algal cells are not relevant to population level risk assessment, but rather effects on populations of cells. The persistence of populations in the natural environment depends also upon the dynamic parameter of the growth rate of the population which is a factor that counterbalances the death rate of the population. Actually, the individual counts of organisms, fronds or algal cells are static measures of the population size at a particular time and, hence, do not reflect the ongoing growth rate of the population, which is necessary to maintain the species in the environment. Therefore, effects on the growth rate of the population are considered as necessary, as relevant, in the risk assessment of adverse effects of exposure to pesticides on the long term persistence of the species in the environment. **********		

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 EPCO Expert Meeting / Conclusions of the evaluation group
		Add any other supports if needed		
5.1	Data gap identified a PRAPeR 03: Applicant to provide data to demonstrate the recovery potentia also for other aquatic plants besides *Lemna*			PRAPeR 03 Meeting (11.– 15.9.2006): Data gap open.
	Open point 5.3: RMS to clearly indicate in the list of intended uses that the assessment only covers tractor application technology. (see reporting table 5(12))		Supported intended uses for Annex I listing only covers tractor application technology. Additional application technologies could be examined at Annex III level depending on local uses.	PRAPeR 03 Meeting (11.– 15.9.2006): Open point still open RMS to add information to the list of intended uses.
	Message from the phys-chem meeting: Ecotoxicology and toxicology experts should carry out an assessment comparing impurity levels in the pilot plant production batches with the material used in their studies as well as those in the proposed specification.			Answer: No conclusion can be drawn at this stage and new information is necessary. Data gap (see 5.2) Notifier to provide the composition of the batches in order to assess the relevance

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 EPCO Expert Meeting / Conclusions of the evaluation group
				of the impurities. New open point (see 5.4) RMS to check the comparability of the profiles.
5.2	Data gap identified at PRAPeR 03: Notifier to provide the composition of the batches in order to assess the relevance of the impurities.			PRAPeR 03 Meeting (11.– 15.9.2006): Data gap open.
	New open point 5.4 proposed at PRAPeR 03: RMS to check the comparability of the profiles.			PRAPeR 03 Meeting (11.– 15.9.2006): Open point open

List of representative uses evaluated*

Crop and / or situation (a)	**Member State or Country**	**Product name**	**F G or I** (b)	**Pests or Group of pests controlled** (c)	**Formulation**	**Application**	**Application rate per treatment**	**PHI** (days) (l)	**Remarks:** (m)

					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	kg as/hl min max	water l/ha min max	kg as/ha min max		
Rice	Italy	Penoxsulam PENOXULAM	F	Echinochloa crus-galli, sedges and broad leaf weeds.	OD	20.4 g/L	Broadcast spray	BBCH 11-31 May-June	1	Not applicable	0.03-0.04	200-400	0.0075-0.02	N.N *	
Rice	Spain	Penoxsulam PENOXULAM	F	Echinochloa crus-galli, sedges and broad leaf weeds.	OD	20.4 g/L	Broadcast spray	BBCH 11-31 May-June	1	Not applicable	0.03-0.04	150-400	0.0075-0.027	N.N	
Rice	Portugal	Penoxsulam PENOXULAM	F	Echinochloa crus-galli, sedges and broad leaf weeds.	OD	20.4 g/L	Broadcast spray	BBCH 11-31 May-June	1	Not applicable	0.03-0.04	150-400	0.0075-0.027	N.N	
Rice	Greece	Penoxsulam PENOXULAM	F	Echinochloa crus-galli, sedges and broad	OD	20.4 g/L	Broadcast spray	BBCH 11-31 May-June	1	Not applicable	0.03-0.04	300-500	0.006-0.013	N.N	

Crop and / or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	kg as/hl min max	water l/ha min max	kg as/ha min max		
				leaf weeds.											
Rice	France	Penoxsulam PENOXULAM	F	Echinochloa crus-galli, sedges and broad leaf weeds.	OD	20.4 g/L	Broadcast spray	BBCH 11-31 May-June	1	Not applicable	0.03-0.04	150-300	0.01-0.027	N.N	

Remarks:

* Uses for which risk assessment could not been concluded due to lack of essential data are marked grey

(a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (*e.g.* fumigation of a structure)

(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)

(c) *e.g.* biting and suckling insects, soil born insects, foliar fungi, weeds

(d) *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)

(e) GCPF Codes - GIFAP Technical Monograph No 2, 1989

(f) Method, *e.g.* high volume spraying, low volume spraying, spreading,

(h) Kind, *e.g.* overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated

(i) g/kg or g/l

(j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application

(k) The minimum and maximum number of application possible under practical conditions of use must be provided

(l) PHI - minimum pre-harvest interval

dusting, drench

(g) All abbreviations used must be explained

(m) Remarks may include: Extent of use/economic importance/restrictions

REPORT OF PRAPeR EXPERT MEETING 04

PENOXSULAM

Rapporteur Member State: IT

Specific comments on the active substance in the section

4. 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**
none		

3. Documents tabled at the meeting:

Date	**Supplier**	**File Name**
none		

The conclusions of the meeting were as follows:

4. **Data on preparations:** GF-657

5. **Classification and labelling:** R 40?

6. **Recommended restrictions/conditions for use:** none proposed (risk assessment missing)

7. **Reference List**

Areas of concern: risk assessment inconclusive, possible carcinogen in rat

Appendix 1: Discussion table: PENOXSULAM

Appendix 2: Evaluation table

Appendix 1: Discussion Table, Penoxsulam (Hb)

2. Mammalian toxicology

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	Open point 2.1: RMS to provide a revised Vol.1, level 3. AOEL to be confirmed in an experts' meeting. (see reporting table 2(5))	The revised Vol. 1, level 3 has not been submitted. The lowest short term NOAEL is from the mouse study, mainly because of dose spacing; furthermore, a major sensitivity of the mouse was not demonstrated. Thus, the AOEL of 0,18 mg/kg bw/day based on the 90 d dog study, SF 100, was confirmed.	Open point open, AOEL confirmed, but revised Vol. 1, level 3 not submitted.
	Open point 2.2: RMS to provide a separate addendum 1 with revised dermal absorption. Dermal absorption to be discussed in an experts' meeting. (see reporting table 2(7))	No addendum is available at the moment. For the dermal absorption the values of 0,04% (dilution) and 2% (concentrate), based on the *in vivo* rat study, are proposed by the RMS, see DAR 106. The value of 2% could be agreed, but for the dilution the value of 0,04% was questioned. More data are necessary for a proper conclusion. Therefore, an addendum has to be available before a final conclusion. It should be clarified, whether the substance is accumulated in the stratum corneum and if a skin depot is available. In this case it might be difficult to calculate the correct value for the dilution. . BE: taking into account the treated skin a default value of 10% could be suitable. DE: as not precise data are available, the worst case should be assumed. This would result in 18% for the dilution as a worst case assumption of 100% absorption.	Open point fulfilled. Dermal absorption 10% default value for concentrate and dilution.

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
		The *in vivo* study shows 24h exposure and a 72 h measure time. Looking at all the data a worst case value of 10% is reasonable. Due to lack of data the 100% default value might be overestimated and a 10% default value could be appropriate. NL supports the proposal taken for the concentrate already in the DAR and not to use a 10% default value, as the study available gives indication of 2% over a longer time (72 h) . As well for the dilution 10% would be overestimated. Nevertheless data presented in an addendum are needed for confirmation. Pending on further explanation in the addendum, a 10% default value was agreed for the concentrate, as well as for the dilution, based on the information available.	
	Open point 2.3: According to the agreed AOEL and dermal absorption, a confirmation/revision of the exposure estimates will be needed. (see reporting table 2(7))	The estimates have to be re-calculated. This point could be closed by the submission of an addendum, if the reference values are agreed during the meeting.	Open point still open.

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	Open point 2.4: RMS to provide an addendum with the argumentation related to the ARfD. ARfD to be confirmed in an experts' meeting. (see reporting table 2(8))	The RMS is asked to present the information presented in column 3 of the evaluation table into an addendum. The RMS's proposal that a ARfD is not needed, has been agreed by the experts.	Open point open for formal reasons (the addendum is still missing). The arguments provided by the RMS that an ARfD is not needed were agreed on by the experts.
2.1	Notifier to provide a position paper on the relevance of large granular lymphocytic leukaemia in Fisher rats treated with penoxsulam. (see reporting table 2(9))	The information is available, but the addendum has not been submitted. The information on historical control data should be presented in an addendum, as well as the information on cited publications. New open point for the RMS to prepare an addendum.	Data requirement fulfilled. New open point (see open point 2.6) RMS to prepare an addendum on the relevance of large granular lymphocytic leukaemia in Fisher rats treated with penoxsulam..

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	Open point 2.5: Carcinogenicity of penoxsulam to be discussed in an experts' meeting. (see reporting table 2(9))	The detailed presentation of the historical background data of LGL leukemia should be submitted in an addendum. NL: as the incidences in the study are above the historical control data, these data will not present any new information. The experts had the feeling that the finding is not treatment related, what should be supported by data presented in an addendum. DE: in principle the information presented in the DAR should be sufficient, but a confirmation is needed. Therefore the addendum is needed and the situation like it is now is very uncomfortable. BE expressed concerns with regard to the margin of safety. It is likely that the findings are not dose related, but confirmation is needed in this case. It was discussed whether this problem could be solved by setting a higher safety factor. DK: in this case the most prudent decision has to be taken. NL: being aware that no addenda are available the substance should not have been scheduled for this meeting. If this point will be kept open, the results from the addendum may be taken up in the EFSA conclusion. Because of non availability of data this point could not be concluded.	Open point open. No conclusion on the carcinogenicity.
	New open point 2.6: RMS to prepare an addendum on the relevance of large granular lymphocytic leukaemia in Fisher rats treated with penoxsulam..		Open point open.

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	Message from phys-chem: The experts discussed the specification proposed based on the pilot scale batch analysis and considered that the specification proposed based on this pilot plant production was unreliable. Therefore the ecotoxicology and toxicology experts should carry out an assessment comparing impurity levels in the pilot plant production batches with the material used in their studies as well as those in the proposed specification. Note for the relevant impurity Bis-CHYMP though the specification proposes a level of 0.5 g/kg in the pilot batches it was not determined (<26 mg/kg, method not fully validated).	No information is available at this stage. Therefore a data gap was identified and a new open point has been proposed.	Data gap: Notifier to provide the composition of the batches in order to assess the relevance of the impurities. New open point: RMS to check the comparability of the batches used in the tox studies and the proposed specification

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
2.2	Data gap identified at PRAPeR 04: Notifier to provide the composition of the batches in order to assess the relevance of the impurities.		Data gap open.
	New open point: 2.7: RMS to check the comparability of the batches used in the tox studies and the proposed specification		Open point open.

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	The experts discussed setting ADI, AOEL, ARfD	It has been discussed whether higher safety factors should be applied due to some uncertainties. NL raised a concern to conclude on the reference values, because at the moment these values can not be established, due to lack of information, which should have been submitted in an addendum. For this substance several experts expressed their opinion not to increase the safety factor, due to many reasons: lack of NOAEL, insufficient information available, carcinogenicity mechanism not known. The ADI and AOEL were not concluded due to the fact that the carcinogenicity could not be concluded. The experts agreed that the ARfD is not affected by the conclusion on carcinogenicity. GR proposed to provide ECB with the addendum, as soon as it is available, because a meeting is scheduled there in spring. GR: EFSA should think about the possibility of a second discussion in an expert meeting in those cases! GR: it should be in the RMS's responsibility to exchange the most recent documents (e.g. list of end points) to ECB and EFSA as well.	
	Message from Residues to tox:	Two metabolites were found at high levels in rotational crops: BST and BSTCA. Can the tox meeting examine their relevance and recommend toxicological end points to be used in risk assessment (end points of the parent compound or and other end point)? For chemical structures of metabolites BST and BSTCA please refer to DAR, p 38, residue section.	No conclusion.

Appendix 2: Evaluation table

2. Mammalian Toxicology

2 Mammalian toxicology

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 EPCO Expert Meeting / Conclusions of the Evaluation Meeting
	Section 2 Data requirements: ***1*** Open points: ***5***			
	Open point 2.1: RMS to provide a revised Vol.1, level 3. AOEL to be confirmed in an experts' meeting. (see reporting table 2(5))	Applicant position paper attached *[Attachment has been removed by EFSA for confidentiality reason.]*	Position paper from notifier received on July 2006. RMS does not understand the question raised by the notifier, since in the monograph and in the list of end-points the proposed AOEL is 0.18 mg/kg bw/d based on a 90 day study on dog. However, if other MSs think that the AOEL needs to be confirmed, then RMS agrees that the matter should be discussed in an experts' meeting.	PRAPeR 04 Meeting (25. - 29.9.2006): Open point open, AOEL confirmed, but revised Vol. 1, level 3 not submitted.
	Open point 2.2: RMS to provide a separate addendum 1 with revised dermal absorption. Dermal absorption to be discussed in an experts' meeting.	Applicant position paper attached *[Attachment has been removed by EFSA for confidentiality reason.]*	Position paper Position paper from notifier received on July 2006. RMS agrees that the matter should be discussed in an experts' meeting. If the results of the meeting will require a review of dermal absorption, then an addendum will be prepared.	PRAPeR 04 Meeting (25. - 29.9.2006): Open point fulfilled. Dermal absorption 10% default value for concentrate and dilution.

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 EPCO Expert Meeting / Conclusions of the Evaluation Meeting
	(see reporting table 2(7))			
	Open point 2.3: According to the agreed AOEL and dermal absorption, a confirmation/revision of the exposure estimates will be needed. (see reporting table 2(7))	According to the agreed AOEL and dermal absorption, a confirmation/revision of the exposure estimates will be needed. See above	According to the agreed AOEL and dermal absorption in an experts' meeting, a confirmation/revision of the exposure estimates will be needed. See above	PRAPeR 04 Meeting (25. - 29.9.2006): Open point still open.
	Open point 2.4: RMS to provide an addendum with the argumentation related to the ARfD. ARfD to be confirmed in an experts' meeting. (see reporting table 2(8))		Under the conditions of the acute oral toxicity study in Fischer 344 rats (Bonnette, K. L., 2000), the acute oral median lethal dose (LD_{50}) of penoxulam was greater than 5000 mg/kg bw in males and females. In addition, there are no effects on relevant endpoints such as developmental toxicity, neurotoxicity, mutagenicity or specific organ toxicity following repeated exposure to warrant establishment of an ARfD. In accordance with Directive criteria 93/21/EEC, penoxulam is not classified on the basis of acute oral toxicity. Therefore, an acute reference dose (ARfD) is considered as not necessary for penoxulam. If the expert's meeting will result in a different opinion, then an addendum will be prepared.	PRAPeR 04 Meeting (25. - 29.9.2006): Open point open for formal reasons (the addendum is still missing). The arguments provided by the RMS that an ARfD is not needed were agreed on by the experts.

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 EPCO Expert Meeting / Conclusions of the Evaluation Meeting
2.1	Notifier to provide a position paper on the relevance of large granular lymphocytic leukaemia in Fisher rats treated with penoxsulam. (see reporting table 2(9))	Range of historical control data from the performing laboratory are stated in the dossier. Notifier provided on June 2006 a collection of 7 publication.	Position paper on leukaemia was provided, reference publications were provided. Historical control incidences for LGL leukemia within the reporting laboratory ranged from 8–20 of 50 control males with a mean of 14 of 50 rats/group.	PRAPeR 04 Meeting (25. - 29.9.2006): Data requirement fulfilled. New open point (see open point 2.6) RMS to prepare an addendum on the relevance of large granular lymphocytic leukaemia in Fisher rats treated with penoxsulam..
	New open point 2.6: RMS to prepare an addendum on the relevance of large granular lymphocytic leukaemia in Fisher rats treated with penoxsulam..			PRAPeR 04 Meeting (25. - 29.9.2006): Open point open.
	Open point 2.5: Carcinogenicity of penoxsulam to be discussed in an experts' meeting. (see reporting table 2(9))	Notifier position paper attached *[Attachment has been removed by EFSA for confidentiality reason.]*	In the chronic toxicity/oncogenicity study in Fischer 344 rats with penoxsulam, statistically significant, non-dose related increases in the incidence of large granular lymphocytic (LGL) leukemia were observed in male rats at all dose levels tested when compared to concurrent controls. However, considering:	PRAPeR 04 Meeting (25. - 29.9.2006): Open point open. No conclusion on the carcinogenicity.

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 EPCO Expert Meeting / Conclusions of the Evaluation Meeting
			• the high spontaneous incidence of LGL leukemia in Fischer rats, especially males • the increase in LGL leukemia being limited to one sex (male) and one species (rat) • the lack of a dose-response in both incidence and severity • the lack of any other tumors in either rats or mice • the lack of genotoxicity • the lack any increases in LGL leukemia in rats administered with structural analogs of penoxsulam the LGL leukemia found in this study was considered spontaneous in origin and unrelated to exposure to penoxsulamthe increases in LGL leukemia in male rats following exposure to penoxsulam. In line with the scientific literature, the finding of an increase in LGL leukemia in one sex in a non-dose related incidence, even when statistically significantly identified, is not considered toxicologically relevant for human risk assessment. Leukaemia not relevant.	
	Message from phys-chem: The experts discussed the specification proposed based on the pilot scale batch			PRAPeR 04 Meeting (25. - 29.9.2006): Data gap:

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 EPCO Expert Meeting / Conclusions of the Evaluation Meeting
	analysis and considered that the specification proposed based on this pilot plant production was unreliable. Therefore the ecotoxicology and toxicology experts should carry out an assessment comparing impurity levels in the pilot plant production batches with the material used in their studies as well as those in the proposed specification. Note for the relevant impurity Bis-CHYMP though the specification proposes a level of 0.5 g/kg in the pilot batches it was not determined (<26 mg/kg, method not fully validated).			Notifier to provide the composition of the batches in order to assess the relevance of the impurities. New open point: RMS to check the comparability of the batches used in the tox studies and the proposed specification
2.2	Data gap identified at PRAPeR 04: Notifier to provide the composition of the batches in order to assess the relevance of the impurities.			PRAPeR 04 Meeting (25. - 29.9.2006): 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 EPCO Expert Meeting / Conclusions of the Evaluation Meeting
	New open point: 2.7: RMS to check the comparability of the batches used in the tox studies and the proposed specification			PRAPeR 04 Meeting (25. - 29.9.2006): Open point open.
	Message from residues to tox: Two metabolites were found at high levels in rotational crops: BST and BSTCA. Can the tox meeting examine their relevance and recommend toxicological end points to be used in risk assessment (end points of the parent compound or and other end point)? For chemical structures of metabolites BST and BSTCA please refer to DAR, p 38, residue section.			PRAPeR 04 Meeting (25. - 29.9.2006): No conclusion.

List of representative uses evaluated*

Crop and / or situation (a)	**Member State or Country**	**Product name**	**F G or I** (b)	**Pests or Group of pests controlled** (c)	**Formulation**		**Application**				**Application rate per treatment**			**PHI** (days) (l)	**Remarks:** (m)
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	kg as/hl min max	water l/ha min max	kg as/ha min max		
Rice	Italy	Penoxsulam PENOXULAM	F	Echinochloa crus-galli, sedges and broad leaf weeds.	OD	20.4 g/L	Broad cast spray	BBCH 11-31 May-June	1	Not applicable	0.03-0.04	200-400	0.0075-0.02	N. N*	
Rice	Spain	Penoxsulam PENOXULAM	F	Echinochloa crus-galli, sedges and broad leaf weeds.	OD	20.4 g/L	Broad cast spray	BBCH 11-31 May-June	1	Not applicable	0.03-0.04	150-400	0.0075-0.027	N. N	
Rice	Portugal	Penoxsulam PENOXULA	F	Echinochloa crus-galli,	OD	20.4 g/L	Broad cast spray	BBCH 11-31 May-	1	Not applicable	0.03-0.04	150-400	0.0075-0.027	N. N	

Crop and / or situation (a)	**Member State or Country**	**Product name**	**F G or I** (b)	**Pests or Group of pests controlled** (c)	**Formulation**		**Application**				**Application rate per treatment**			**PHI** (days) (l)	**Remarks:** (m)
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	kg as/hl min max	water l/ha min max	kg as/ha min max		
		M		sedges and broad leaf weeds.				June							
Rice	Greece	Penoxsulam PENOXULAM	F	Echinochloa crus-galli, sedges and broad leaf weeds.	OD	20.4 g/L	Broad cast spray	BBCH 11-31 May-June	1	Not applicable	0.03-0.04	300-500	0.006-0.013	N.N	
Rice	France	Penoxsulam PENOXULAM	F	Echinochloa crus-galli, sedges and broad leaf weeds.	OD	20.4 g/L	Broad cast spray	BBCH 11-31 May-June	1	Not applicable	0.03-0.04	150-300	0.01-0.027	N.N	

Remarks:

* Uses for which risk assessment could not been concluded due to lack of essential data are marked grey

(a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (*e.g.* fumigation of a structure)

(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)

(c) *e.g.* biting and suckling insects, soil born insects, foliar fungi, weeds

(d) *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)

(e) GCPF Codes - GIFAP Technical Monograph No 2, 1989

(f) Method, *e.g.* high volume spraying, low volume spraying, spreading, dusting, drench

(g) All abbreviations used must be explained

(h) Kind, *e.g.* overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated

(i) g/kg or g/l

(j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application

(k) The minimum and maximum number of application possible under practical conditions of use must be provided

(l) PHI - minimum pre-harvest interval

(m) Remarks may include: Extent of use/economic importance/restrictions

Report of PRAPeR Expert MEETING 14

PENOXSULAM

Rapporteur Member State: IT

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**
none		

3. Documents tabled at the meeting:

Date	**Supplier**	**File Name**
none		

The conclusions of the meeting were as follows:

4. **Data on preparations:** see report on PRAPeR 04

5. **Classification and labelling:** see report on PRAPeR 04

6. **Recommended restrictions/conditions for use:** see report on PRAPeR 04

7. **Reference List:** not discussed

Areas of concern: see report on PRAPeR 04

Appendix 1: Discussion table: PENOXSULAM

Appendix 2: Evaluation table

Appendix 1: Discussion Table, penoxsulam (Hb)

2. Mammalian toxicology

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	Open point 2.1: RMS to provide a revised Vol.1, level 3. AOEL to be confirmed in an experts' meeting. (see reporting table 2(5)) <u>PRAPeR 04 Meeting (25. - 29.9.2006):</u> Open point open, AOEL confirmed, but revised Vol. 1, level 3 not submitted.	Information was presented in an addendum. The resulting AOEL was agreed: 0.18 mg/kg bw/d, 90 d dog, sf 100 Open point fulfilled.	Open point fulfilled.

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	Open point 2.3: According to the agreed AOEL and dermal absorption, a confirmation/revision of the exposure estimates will be needed. (see reporting table 2(7)) <u>PRAPeR 04 Meeting (25. - 29.9.2006):</u> Open point still open.	The RMS agreed on a value for dermal absorption of 10%. The calculations have been performed accordingly and were submitted recently to EFSA. For the UK and the DE model, without PPE, a safe use has been identified.	Open point fulfilled.

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	Open point 2.4: RMS to provide an addendum with the argumentation related to the ARfD. ARfD to be confirmed in an experts' meeting. (see reporting table 2(8)) <u>PRAPeR 04 Meeting (25. - 29.9.2006):</u> Open point open for formal reasons (the addendum is still missing). The arguments provided by the RMS that an ARfD is not needed were agreed on by the experts.	The addendum has now been submitted. Open point fulfilled.	Open point fulfilled.

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	New open point 2.6: RMS to prepare an addendum on the relevance of large granular lymphocytic leukaemia in Fisher rats treated with penoxsulam.. <u>PRAPeR 04 Meeting (25. - 29.9.2006):</u> Open point open.	This point refers to the data requirement 2.1. The addendum has now been submitted and the results were presented during the meeting. The RMS explained that the tumors are not dose related, although the findings are slightly above the historical control data of the laboratory. The values are within the historical control range provided by NTP. The meeting agreed to the conclusions. Open point fulfilled.	Open point fulfilled.
	Open point 2.5: Carcinogenicity of penoxsulam to be discussed in an experts' meeting. (see reporting table 2(9)) <u>PRAPeR 04 Meeting (25. - 29.9.2006):</u> Open point open. No conclusion on the carcinogenicity.	The meeting concluded that penoxsulam is not carcinogenic (why?) Open point fulfilled.	Open point fulfilled.
2.2	Data gap:	No information has been submitted. Data gap still open.	Data gap still open.

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	Notifier to provide the composition of the batches in order to assess the relevance of the impurities.		
	New open point: 2.7: RMS to check the comparability of the batches used in the tox studies and the proposed specification	see above. Open point open.	Open point still open.

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	Message from residues to tox: Two metabolites were found at high levels in rotational crops: BST and BSTCA. Can the tox meeting examine their relevance and recommend toxicological end points to be used in risk assessment (end points of the parent compound or and other end point)? For chemical structures of metabolites BST and BSTCA please refer to DAR, p 38, residue section. <u>PRAPeR 04 Meeting (25. - 29.9.2006):</u> No conclusion.	The metabolites exceed the threshold for ground water. In the addendum a statement has been submitted with regard to their toxicity. An AMES test is available, showing negative results. There was no genotoxic activity observed. They are not relevant for ground water. Therefore it is assumed that the parent compound covers the metabolites as well and the metabolites do not contribute to the toxicity. BST and BSTCA were not found in the rat. The substance itself does not show any indication of reproductive, genotoxic and carcinogenic toxicity. Based on the data available a conclusion could not be drawn with regard to their relevance. It was highlighted during the meeting that guidelines are missing for theses cases.	No conclusion.

Appendix 2: Evaluation table

2. Mammalian Toxicology

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 EPCO Expert Meeting / Conclusions of the Evaluation Meeting
	Section 2 Data requirements: ***1*** Open points: ***5***			Section 2 Data requirements: ***0*** Data gaps: ***1*** Open points: ***1***
	Open point 2.1: RMS to provide a revised Vol.1, level 3. AOEL to be confirmed in an experts' meeting. (see reporting table 2(5))	Applicant position paper attached *[Attachment has been removed by EFSA for confidentiality reason.]* *December 06: position paper contained in the removed attachement*	Position paper from notifier received on July 2006. RMS does not understand the question raised by the notifier, since in the monograph and in the list of end-points the proposed AOEL is 0.18 mg/kg bw/d based on a 90 day study on dog. However, if other MSs think that the AOEL needs to be confirmed, then RMS agrees that the matter should be discussed in an experts' meeting. December 06: An AOEL of 0.18 mg/kg bw/d based on a NOAEL of 18 mg/kg/bw/d from the 90 day study is proposed: see addendum.	PRAPeR 04 Meeting (25. - 29.9.2006): Open point open, AOEL confirmed, but revised Vol. 1, level 3 not submitted. PRAPeR 14 (22. – 26.1.2007): Open point fulfilled.
	Open point 2.2: RMS to provide a separate addendum 1 with revised dermal absorption. Dermal absorption to be discussed in an experts'	Applicant position paper attached *[Attachment has been removed by EFSA for confidentiality reason.]*	Position paper Position paper from notifier received on July 2006. RMS agrees that the matter should be discussed in an experts' meeting. If the results of the meeting will require a review of dermal absorption, then an addendum will be	PRAPeR 04 Meeting (25. - 29.9.2006): 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 EPCO Expert Meeting / Conclusions of the Evaluation Meeting
	meeting. (see reporting table 2(7))	*December 06:position paper contained in the removed attachment*	prepared. December 06: Based on results from an in vivo study in rats, a 2.0% dermal absorption for the undiluted formulation (GF-657) and 0.4% of the 1:100 dilution of the formulation over a 24-hr *in vivo* are considered as the appropriate values for dermal absorption. See addendum	Dermal absorption 10% default value for concentrate and dilution.
	Open point 2.3: According to the agreed AOEL and dermal absorption, a confirmation/revision of the exposure estimates will be needed. (see reporting table 2(7))	According to the agreed AOEL and dermal absorption, a confirmation/revision of the exposure estimates will be needed. See above	According to the agreed AOEL and dermal absorption in an experts' meeting, a confirmation/revision of the exposure estimates will be needed. See above December 06: see addendum	PRAPeR 04 Meeting (25. - 29.9.2006): Open point still open. PRAPeR 14 (22. – 26.1.2007): Open point fulfilled.
	Open point 2.4: RMS to provide an addendum with the argumentation related to the ARfD. ARfD to be confirmed in an experts' meeting. (see reporting table 2(8))		Under the conditions of the acute oral toxicity study in Fischer 344 rats (Bonnette, K. L., 2000), the acute oral median lethal dose (LD_{50}) of penoxulam was greater than 5000 mg/kg bw in males and females. In addition, there are no effects on relevant endpoints such as developmental toxicity, neurotoxicity, mutagenicity or specific organ toxicity following repeated exposure to warrant establishment of an ARfD. In accordance with Directive criteria 93/21/EEC, penoxulam is not classified on the basis of acute oral toxicity. Therefore, an acute reference dose (ARfD) is	PRAPeR 04 Meeting (25. - 29.9.2006): Open point open for formal reasons (the addendum is still missing). The arguments provided by the RMS that an ARfD is not needed were agreed on by the experts. PRAPeR 14 (22. – 26.1.2007):

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 EPCO Expert Meeting / Conclusions of the Evaluation Meeting
			considered as not necessary for penoxulam. If the expert's meeting will result in a different opinion, then an addendum will be prepared. December 06: see addendum	Open point fulfilled.
2.1	Notifier to provide a position paper on the relevance of large granular lymphocytic leukaemia in Fisher rats treated with penoxsulam. (see reporting table 2(9))	Range of historical control data from the performing laboratory are stated in the dossier. Notifier provided on June 2006 a collection of 7 publication. :	Position paper on leukaemia was provided, reference publications were provided. Historical control incidences for LGL leukemia within the reporting laboratory ranged from 8–20 of 50 control males with a mean of 14 of 50 rats/group. December 06: information assessed in the addendum.	PRAPeR 04 Meeting (25. - 29.9.2006): Data requirement fulfilled. New open point (see open point 2.6) RMS to prepare an addendum on the relevance of large granular lymphocytic leukaemia in Fisher rats treated with penoxsulam..
	New open point 2.6: RMS to prepare an addendum on the relevance of large granular lymphocytic leukaemia in Fisher rats treated with penoxsulam..		December 06: see addendum	PRAPeR 04 Meeting (25. - 29.9.2006): Open point open. PRAPeR 14 (22. – 26.1.2007): Open point fulfilled.
	Open point 2.5:	Notifier position paper attached	In the chronic toxicity/oncogenicity study in	PRAPeR 04 Meeting (25. -

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 EPCO Expert Meeting / Conclusions of the Evaluation Meeting
	Carcinogenicity of penoxsulam to be discussed in an experts' meeting. (see reporting table 2(9))	*[Attachment has been removed by EFSA for confidentiality reason.]* *December 06: Attachments where provided timely, together with a position paper*	Fischer 344 rats with penoxsulam, statistically significant, non-dose related increases in the incidence of large granular lymphocytic (LGL) leukemia were observed in male rats at all dose levels tested when compared to concurrent controls. However, considering: • the high spontaneous incidence of LGL leukemia in Fischer rats, especially males • the increase in LGL leukemia being limited to one sex (male) and one species (rat) • the lack of a dose-response in both incidence and severity • the lack of any other tumors in either rats or mice • the lack of genotoxicity • the lack any increases in LGL leukemia in rats administered with structural analogs of penoxsulam the LGL leukemia found in this study was considered spontaneous in origin and unrelated to exposure to penoxsulamthe increases in LGL leukemia in male rats following exposure to penoxsulam. In line with the scientific literature, the finding of an increase in LGL leukemia in one sex in a non-dose related incidence, even when statistically significantly identified, is not considered toxicologically relevant for human risk assessment.	29.9.2006): Open point open. No conclusion on the carcinogenicity PRAPeR 14 (22. – 26.1.2007): 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 EPCO Expert Meeting / Conclusions of the Evaluation Meeting
			Leukaemia not relevant.	
	Message from phys-chem: The experts discussed the specification proposed based on the pilot scale batch analysis and considered that the specification proposed based on this pilot plant production was unreliable. Therefore the ecotoxicology and toxicology experts should carry out an assessment comparing impurity levels in the pilot plant production batches with the material used in their studies as well as those in the proposed specification. Note for the relevant impurity Bis-CHYMP though the specification proposes a level of 0.5 g/kg in the pilot batches it was not determined (<26 mg/kg, method not fully validated).			PRAPeR 04 Meeting (25. - 29.9.2006): Data gap: Notifier to provide the composition of the batches in order to assess the relevance of the impurities. New open point: RMS to check the comparability of the batches used in the tox studies and the proposed specification.
2.2	Data gap identified at PRAPeR 04: Notifier to provide the composition of the batches in			PRAPeR 04 Meeting (25. - 29.9.2006): 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 EPCO Expert Meeting / Conclusions of the Evaluation Meeting
	order to assess the relevance of the impurities.			PRAPeR 14 (22. – 26.1.2007): Data gap open.
	New open point: 2.7: RMS to check the comparability of the batches used in the tox studies and the proposed specification		December 2006: It is commonly accepted that for Annex I listing purposes for new active ingredient,there is no need to submit contextually the 5 batches on a large scale plant. As soon as they will be available all related cross checking will be done, and the end points if necessary changed	PRAPeR 04 Meeting (25. - 29.9.2006): Open point open. PRAPeR 14 (22. – 26.1.2007): Open point open.
	Message from residues to tox: Two metabolites were found at high levels in rotational crops: BST and BSTCA. Can the tox meeting examine their relevance and recommend toxicological end points to be used in risk assessment (end points of the parent compound or and other end point)? For chemical structures of metabolites BST and BSTCA please refer to DAR, p 38,	December06; new studies were provided	December 06: new studies assessed in the addendum.	PRAPeR 04 Meeting (25. - 29.9.2006): No conclusion. PRAPeR 14 (22. – 26.1.2007): No conclusion possible on the data available.

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 EPCO Expert Meeting / Conclusions of the Evaluation Meeting
	residue section.			

REPORT OF PRAPeR EXPERT MEETING 05

PENOXSULAM

Rapporteur Member State: IT

Specific comments on the active substance in the section

5. Residues

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

1. Comments submitted for this meeting: None

Date	Supplier	File Name
xx Month xxxx	Name	

2. Documents submitted for meeting: None

Date	Supplier	File Name
xx Month xxxx	Name	

3. Documents tabled at the meeting: 1

Date	Supplier	File Name
29.09.2006	tabled by EFSA but submitted by RMS.	Table B.7.9-1 - future addendum B.7.doc

The conclusions of the meeting were as follows:

4. **Data on preparations:** Viper.

5. **Classification and labelling:** none proposed

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

7. **Reference List:** not discussed

Areas of concern: none

Appendix 1: Discussion table: PENOXSULAM

Appendix 2: Evaluation table

Appendix 1: Discussion Table, Penoxsulam (Hb)

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	Open point 3.1: RMS to include TMDI according to WHO/FAO European diet and worst case national diet in the listing of end-points. (see reporting table 3(1))	The list of endpoints has not been amended as final end-points have not been derived yet. Open point still open as no tox reference values derived in the tox meeting.	Open point still open. Open point still open as no tox reference values yet derived in the tox meeting.
	Open point 3.2: RMS provide an addendum on consideration of possible impacts of a later application in practice on the qualitative and quantitative findings in the rice metabolism study. (see reporting table 3(2))	RMS reported why it is considered that different application timings would not yield significantly different qualitative or quantitative results. That is because the conditions chosen for the rice metabolism study provided the maximum possibility of identifying all potentially significant components of the crop residue. The meeting accepted the comprehensive statement presented by RMS in the evaluation table. EFSA requests RMS to report this explanation in an addendum before the final discussion of penoxulam in the evaluation meeting. RMS indicated that an addendum is in preparation. Open point still open.	Open point still open. Open point remains open as RMS to transfer into an addendum the explanation why different results are not expected if the metabolism study was carried out at different application timings.
	Open point 3.3: RMS to propose a	RMS informed that the major component of the residue in plant and animal products is parent compound. RMS proposes a residue definition for risk assessment to be set as	Open point fulfilled.

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	residue definition for risk assessment in an addendum (see reporting table 3(8))	parent compound only. Experts agreed the proposal made by RMS. Furthermore, experts agreed that a residue definition for animal products it is not needed. However, there is an indication that a possible definition can be parent only. It was pointed out that it is not sure whether the crop rice can be considered as a permanent crop (grown as a monoculture) or there is crop rotation. EFSA informed that it is possible to grow other crops in rotation with rice (e.g. leguminous crops). IT reported that in Italy it is common to grow maize in rotation with rice. It was agreed that MS with rice cultivation have to consider and verify if crops other than rice are rotated after rice harvesting when granting national authorization. EFSA raised a question as to whether rice can be considered as a feeding item. A residue definition was discussed and agreed. Therefore the open point is considered fulfilled.	The residue definition for risk assessment in plant products to be set as the parent compound only. For animal products, a residue definition is not deemed necessary in terms of the use evaluated.

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	Open point 3.4: RMS to summarize additional storage stability data covering a period of 24 month in an addendum. (see reporting table 3(11))	RMS informed that a report has been submitted by the applicant. RMS informed that it can be considered that the residue is stable up to 732 days in raw rice and for rice processed products up to 390 days. The meeting took note of the information given by the RMS on the evaluation of additional storage stability data. EFSA requests RMS to present the evaluation of this additional storage stability data in an addendum before the final discussion of penoxulam in the evaluation meeting. RMS indicated that an addendum is in preparation. The list of end-points should be amended accordingly. Open point still open.	Open point still open. RMS to present the evaluation of the additional storage stability data of raw and processed rice samples under frozen conditions.in an addendum and amend the list of end-points accordingly.

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	Open point 3.5: RMS to present total radioactive residues (TRR) in rotational crops in an addendum. (see reporting table 3(13))	A table summarizing data on TRR in rotational crops has been presented at the meeting. The table reports results from a crop rotation study performed with radiolabelled penoxulam at 1X and 2X rate. Penoxulam was applied to bare soil, which was aged 90 days before planting different crops (wheat, kale and potatoes). Results with a 30 days planting back interval are not available. From the residue trials it has been found that a shorter period than 90 days is possible between application and a potential replanting. RMS was therefore requested to provide data on a 30 days planting back interval, if available. However, the experts agreed that after a planting back interval of 90 days still low residues are expected (e.g. wheat straw 0.024 mg equ./kg at 1X rate) but that it is most likely that no livestock studies are triggered. Based on the data available, the meeting concluded that if cereals are grown as rotational crops no significant residue levels in terms of consumer and livestock exposure are expected. EFSA pointed out that with the data available it is not possible to exclude that residues can occur in rotational crops other than cereals. A total residue of 0.5 mg/kg was found in foliage of potatoes planted 90 days after a soil application at 1X rate. As potato was chosen only as a model crop for the root/tuber crop group in the submitted crop rotation study, a similar residue situation in leaves and tops of other root/tuber crops potentially fed to livestock has to be assumed. Therefore reconsideration of the aspect might be needed at MS level if rice growing practice in the respective MS deviates from the practice assessed by the meeting. (i.e. cereals as following crop) EFSA requests RMS to summarise all additional information with regard to residues in rotational crops including the presented table B.7.9-1 and possibly data on a 30 days planting back interval in an addendum before the final discussion of penoxulam in the evaluation meeting. Open point remains open.	Open point still open. RMS should summarise all additional information with regard to residues in rotational crops including the table presented in the experts' meeting in an addendum. The addendum should also include data on a planting back interval of 30 days, if available.

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	Open point 3.6: RMS to discuss the role of metabolites BST and BSTCA not found in primary but in rotational crops in an addendum. (see reporting table 3(14))	RMS informed that the information of the metabolites in the rotational crops has been included in the list of end-points. BSTCA and BST were found in soil metabolism studies. Metabolite BSTCA represented 25% of the TRR in potato foliage and is expected to be further metabolised to BST. Attempts of identification of residues in the other rotational crops were not successful due to the low total residue levels. Concerning the relevance of two metabolite (BSTCA and BST) found in rotational crops but not in primary crops, it was decided to send the following massage to the tox meeting: "Two metabolites were found at high level in rotational crops: BST and BSTCA. Can the tox meeting examine the relevance and recommend toxicological endpoints to be used in risk assessment (end point of the parent compound or any other end point)? For the chemical structures of the metabolites to be discussed please refer to pag.38, residue section, of the DAR – January 2005" The experts' meeting of toxicology responded as follows: "Metabolites BST and BSTCA were not detected in the rat metabolism and therefore no data are available. In this case the notifier is asked to provide information on whether or not BST and BSTCA are of toxicological relevance and to provide the related data. " It was agreed by the experts that MS with rice cultivation have to verify if crops other than rice are rotated after rice harvesting and consider whether further data are needed when granting national authorization. Open point still open.	Open point still open. The relevance of metabolites BST and BSTCA has not yet been agreed. Consideration of the relevance of metabolites, residues levels and livestock exposure is needed with regard to a particular crop rotation practice in the rice growing MS when authorisation is sought on MS level. It might be necessary to request additional data to address the issue sufficiently. (Data requirement on MS level ???)

No.	Subject	Discussion Expert Meeting	Conclusions Expert Meeting
	Open point 3.7: RMS to perform a new consumer exposure/risk assessment in an addendum by taking into account the most recent GEMS/food diet figures and also consumption figures for young children. (see reporting table 3(17))	The list of end point has been amended with a new TMDI calculation. However, as the final tox reference values are not yet known it is not possible to finalize the calculation of the TMDI. Open point still open pending the final version of the tox reference values.	Open point still open. The calculation of the TMDI can not be finalized as no agreed tox reference values are available.
	Message from residues to tox: New message for tox meeting: Two metabolites were found at high level in rotational crops: BST and BSTCA. Can the tox meeting examine the relevance and recommend toxicological endpoints to be used in risk assessment (end point of the parent compound or any other end point)?	New message for tox meeting: Two metabolites were found at high level in rotational crops: BST and BSTCA. Can the tox meeting examine the relevance and recommend toxicological endpoints to be used in risk assessment (end point of the parent compound or any other end point)? For the chemical structures of the metabolites to be discussed please refer to pag.38, residue section, of the DAR – January 2005	Answer from tox: Metabolites BST and BSTCA were not detected in the rat metabolism and therefore no data are available. In this case the notifier is asked to provide information on whether or not BST and BSTCA are of toxicological relevance and to provide the related data.

Appendix 2: Evaluation table

3. Residues

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 EPCO Expert Meeting / Conclusions of the Evaluation Meeting
	Section 3 Data requirements: **-** Open points: ***7***			Section 3 Data requirements: **-** Open points: ***6***
	Open point 3.1: RMS to include TMDI according to WHO/FAO European diet and worst case national diet in the listing of end-points. (see reporting table 3(1))		TMDI according to WHO/FAO European diet and worst case national diet has been included in the list of end-points.	PRAPeR 05 Meeting (27 – 29 09.2006): Open point still open. Open point still open as no tox reference values yet derived in the tox meeting.
	Open point 3.2: RMS provide an addendum on consideration of possible impacts of a later application in practice on the qualitative and quantitative findings in the rice metabolism study. (see reporting table 3(2))		^{14}C-Penoxsulam was applied in a single application at a rate of approximately 100 g ai/ha or equivalent to 2.5x the maximum use rate on rice (40 g/ha) to both, the paddy water and the rice foliage at the 5 to 6 leaf stage of development, being this application method considered as the worst-case scenario. Due to the relatively small size of the	PRAPeR 05 Meeting (27 – 29 09.2006): Open point still open. Open point remains open as RMS to transfer into an addendum the explanation why different results are not expected if the metabolism study was carried out at different application timings.

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 EPCO Expert Meeting / Conclusions of the Evaluation Meeting
	continued: Open point 3.2: RMS provide an addendum on consideration of possible impacts of a later application in practice on the qualitative and quantitative findings in the rice metabolism study. (see reporting table 3(2))		plants at the time of application, penoxsulam was liberally applied to the water as well as to the rice foliage. Since penoxsulam is rapidly photodegraded in aquatic systems, this application timing maximized the potential exposure of the rice plants to parent penoxsulam and the possibility of photoproduct uptake—both through the root system and through the leaf surface. No photoproducts were observed in the plant tissues (extracted) or the surface rinses conducted at 0 days after treatment (DAT), 3, 7, 14 and 30 DAT, due to the primary photodegradation route, which involves breaking the sulfonamide bridge. Immature samples were analyzed at 0, 3, 7, 14 and 30 DAT to elucidate the metabolicpathway while mature samples were harvested at 134 DAT. The same residue profile was observed in the immature samples and at harvest. The residue profile consisted primarily of parent penoxsulam, the 5-OH metabolite of penoxsulam and two other minor metabolites. The 5-OH metabolite reached levels of 30% of the TRR at 30 DAT and remained at 30% of the TRR in the mature straw. However,	

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 EPCO Expert Meeting / Conclusions of the Evaluation Meeting
	continued: Open point 3.2: RMS provide an addendum on consideration of possible impacts of a later application in practice on the qualitative and quantitative findings in the rice metabolism study. (see reporting table 3(2))		the concentration of 5-OH decreased to less than 0.010 µg/g in mature straw. The other two metabolites reached levels of about 10-20% of the TRR in the mature straw; corresponding to approximately 0.005 µg/g. Due to their low levels in the mature samples, no attempt was made to identify either of these components. In addition to maximizing the potential uptake of photoproducts, the early application timing also increased the time for the rice plants to metabolize penoxsulam. Less than 10% of the TRR remained parent penoxsulam in the mature straw. The remainder of the TRR was equally divided among the 5-OH metabolite and the two minor metabolites. Neither penoxsulam nor its metabolites were present in the mature straw at levels greater than 0.010 µg/g (penoxsulam equivalents) and no compounds were detected at greater than 0.001 µg/g in the rice grain. Panicle initiation, the latest application timing, is approximately 30 days later than the application timing in the current study (5 to 6 leaf stage). No differences expected in the residue profiles for rice treated with penoxsulam at either an early (5 to 6	

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 EPCO Expert Meeting / Conclusions of the Evaluation Meeting
	continued: Open point 3.2: RMS provide an addendum on consideration of possible impacts of a later application in practice on the qualitative and quantitative findings in the rice metabolism study. (see reporting table 3(2))		leaf stage) or a later growth stage (panicle initiation), since the pathway of penoxsulam rice metabolism is well established. Total residue levels in rice tissues rapidly decline during the first 30 days after application—parent and metabolite concentrations at 30 DAT were all less than 0.02 µg/g. Application at panicle initiation should not result in a significant increase in residue levels at harvest. This is confirmed by magnitude of residue studies where no detectable residues of penoxsulam following either application scenario in rice grain were found. The conditions chosen for the rice metabolism study, provided the maximum possibility of identifying all potentially significant components of the crop residue. Different application timings would not yield significantly different qualitative or quantitative results.	

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 EPCO Expert Meeting / Conclusions of the Evaluation Meeting
	Open point 3.3: RMS to propose a residue definition for risk assessment in an addendum (see reporting table 3(8))		Plants: penoxulam Animal: penoxulam Soil: penoxulam Surface water: penoxulam Ground water: penoxulam Sediment: penoxulam Air: penoxulam	PRAPeR 05 Meeting (27 – 29 09.2006): Open point fulfilled. The residue definition for risk assessment in plant products to be set as the parent compound only. For animal products, a residue definition is not deemed necessary in terms of the use evaluated.
	Open point 3.4: RMS to summarize additional storage stability data covering a period of 24 month in an addendum. (see reporting table 3(11))	"Lindsay, D. A. (2004): Frozen Storage Stability of DE-638 in Rice (Raw Agricultural Commodities: Grain, Straw, Immature Forage) and its Processed Products (Bran, Hulls, Polished Rice), Dow AgroSciences unpublished report number 010100.01. Ref. A26" submitted on June 06	Report received, addendum in preparation. Control samples of rice grain, straw, immature forage, and the rice processed products bran, hulls, and polished rice were fortified at 0.10 mg/kg (a concentration tenfold above the validated analytical method limit of quantisation of 0.01 mg/kg) with penoxulam and stored in polypropylene containers. The fortified samples were stored frozen at –20 ± 5°C. Residues of penoxulam are stable in rice grain, straw, and immature forage when stored frozen at -20°C for up to 732 days. Residues of penoxulam are stable in rice bran, hulls and polished rice when stored frozen at -20°C for up to 390 days.	PRAPeR 05 Meeting (27 – 29 09.2006): Open point still open. RMS to present the evaluation of the additional storage stability data of raw and processed rice samples under frozen conditions.in an addendum and amend the list of end-points accordingly.

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 EPCO Expert Meeting / Conclusions of the Evaluation Meeting
	Open point 3.5: RMS to present total radioactive residues (TRR) in rotational crops in an addendum. (see reporting table 3(13))		Tables summarized in the DAR. *[Attachment has been removed by EFSA.]*	PRAPeR 05 Meeting (27 – 29 09.2006): Open point still open. RMS should summarise all additional information with regard to residues in rotational crops including the table presented in the experts' meeting in an addendum. The addendum should also include data on a planting back interval of 30 days, if available.
	Open point 3.6: RMS to discuss the role of metabolites BST and BSTCA not found in primary but in rotational crops in an addendum. (see reporting table 3(14))		The structure for BST being corrected in a corrigendum to DAR	PRAPeR 05 Meeting (27 – 29 09.2006): Open point still open. The relevance of metabolites BST and BSTCA has not yet been agreed. Consideration of the relevance of metabolites, residues levels and livestock exposure is needed with regard to a particular crop rotation practice in the rice growing MS when authorisation is sought on MS level. It might be necessary to request additional data to address the issue sufficiently. (Data requirement on MS level ???)

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 EPCO Expert Meeting / Conclusions of the Evaluation Meeting
	Open point 3.7: RMS to perform a new consumer exposure/risk assessment in an addendum by taking into account the most recent GEMS/food diet figures and also consumption figures for young children. (see reporting table 3(17))	A report has been submitted in June 2006 with an assessment performed considering the regional GEMS diet.	New exposure risk assessment performed: higher exposure is for toddler and accounts to 0.1% of ADI. It can be concluded that it is extremely unlikely that, in the requested condition of use, any European could ingest enough residues of penoxsulam to exceed the ADI. Therefore, the risk to consumers can be regarded as low.	PRAPeR 05 Meeting (27 – 29 09.2006): Open point still open. The calculation of the TMDI can not be finalized as no agreed tox reference values are available.
	Message from residues to tox: New message for tox meeting: Two metabolites were found at high level in rotational crops: BST and BSTCA. Can the tox meeting examine the relevance and recommend toxicological endpoints to be used in risk assessment (end point of the parent compound or any other end point)?			PRAPeR 05 Meeting (27 – 29 09.2006): Answer from tox: Metabolites BST and BSTCA were not detected in the rat metabolism and therefore no data are available. In this case the notifier is asked to provide information on whether or not BST and BSTCA are of toxicological relevance and to provide the related data.