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REPORT OF EPCO EXPERT MEETING 06

TOLYLFLUANID

Rapporteur Member States: Finland

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:

None.

2. Documents submitted for this meeting:

Date	Supplier	File Name
19 February 2004	RMS/Finland	Tolylfluanid consultation report
26 March 2004	RMS/Finland	Tolylfluanid reporting table rev1-2
30 April 2004	RMS/Finland	Tolylfluanid evaluation table rev0-1
19 May 2004	RMS/Finland	Tolylfluanid end points
02 June 2004	RMS/Finland	Tolylfluanid addendum 3
02 June 2004	RMS/Finland	Tolylfluanid addendum 3 vol4

3. Documents tabled at the meeting

None.

The conclusions of the meeting were as follows:

4. **Data on preparations:** Euparen M WG 50.

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

6. **Recommended restrictions/conditions for use:** not discussed

Areas of concern: none

Appendix 1: EPCO discussion table: TOLYLFLUANID
Appendix 2: Evaluation table

Appendix 1: Discussion Table, Tolylfluanid (Ac, Fu)

1. Physical and Chemical Properties

No.	Subject	Discussion EPCO Expert Meeting	Conclusions EPCO Expert Meeting
1.1	Notifier to submit new study on analytical profile of batches (taking into account specification and validation of analytical methods for impurities) (Vol. 4, C.1.3.11 – see reporting table 1(1))	New validation data was requested. Unfortunately, the notifier submitted results from an older study to the RMS, which were not acceptable. Therefore, the RMS propose to leave the data requirement open. The meeting agreed on this proposal.	Data requirement still open. A new study on analytical profile of batches (incl. a proper identification of the impurities, e.g. by MS or NMR) using validated analytical method(s).
1.2	Confirmatory method for the impurities is required. (Vol. 4, C1.4 – see reporting table 1(5))	This data requirement can be covered by the data requirement 1.1. It was not clear whether only 5-batch data performed with validated analytical methods should be submitted by the notifier. A discussion came up on a general need of a confirmatory method for impurities and whether a fully validated method will be sufficient instead of a new confirmatory method. The meeting agreed that the confirmatory method should be used on the basis of the current guideline to identify the impurities. The nofitier originally used HPLC - UV measuring at 254 nm for identification of the impurities, which is not regarded as a highly specific method. Therefore, depending on the primary method there is a need to ask for a confirmatory method since the UV spectrum must be specific to the specific compound. The meeting agreed that a new open point should be set for this issue.	Data requirement can be covered by the data requirement 1.1. New open point 1.2 was proposed at the meeting: Depending on the new study required in 1.1 a confirmatory method may be necessary to demonstrate the specificity of the analytical method.

No.	Subject	Discussion EPCO Expert Meeting	Conclusions EPCO Expert Meeting
1.3	Notifier to submit the new validation data for DFG S 19 –method. (Vol. 3, B.5.3.1 - see reporting table 1(12))	The RMS proposed that new validation data for DFG S´19-method submitted by the notifier can be accepted. The meeting agreed on this proposal. Therefore, this data requirement is fulfilled.	Data requirement fulfilled.
	Open point 1.1: The acceptability of surface water as surrogate for drinking water for this certain compound to be discussed in the expert meeting. NL to provide additional background information. (Vol. 3, B5.3.2 - see reporting table 1(14))	The concerned MS still had doubts regarding the acceptability of surface water as surrogate for drinking water. The detailed information supporting the position of the concerned MS was submitted only to the notifier. Thus, the concerned MS was asked to distribute the required information to all MS. In this case, EFSA will contact the concerned MS regarding the submission of the background information. Nevertheless, the RMS stated that a study concerning the determination of residues of tolylfluanid in drinking water is ongoing and is supposed to be finished in August 2004. Therefore, the meeting agreed that this open point has been changed into a data requirement.	This open point has been changed into a data requirement. Data requirement 1.4: A study for the determination of residues of tolylfluanid in drinking water (taking the potential problems of the analysis of tolylfluanid into consideration). Note of the meeting: It would have been helpful for the expert meeting if the Netherlands had not only provided the notifier with the backgound information, but also the Member States.
	New Open point 1.3: List of representative uses	The table for the representative uses as stated in EPCO manual E4 should be used.	Open point still open.

No.	Subject	Discussion EPCO Expert Meeting	Conclusions EPCO Expert Meeting
	New Open point 1.4: List of end points: Page 2 relative density has no unit.	In this case the value for density was included and not for relative density. Therefore, this should be amended.	Open point still open.
	New Open Point 1.5: List of end points: FAO specifications	The value of 960 g/kg +/- 20 should be mentioned.	Open point still open.

Appendix 2: Evaluation table

1. Physical and Chemical Properties

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: 2 Open points: 4
1.1	Notifier to submit new study on analytical profile of batches (taking into account specification and validation of analytical methods for impurities) (Vol. 4, C.1.3.11 – see reporting table 1(1))	New analytical data out of production control will be submitted in May.	30.4.2004 Notifier will submit a new study on analytical profile of batches (taking into account specification and validation of analytical methods for impurities) in May. Acceptable. Data have to be awaited.	EPCO 6 (15.-16.06.2004): Data requirement still open. A new study on analytical profile of batches (incl. a proper identification of the impurities, e.g. by MS or NMR) using validated analytical method(s).
1.2	Confirmatory method for the impurities is required. (Vol. 4, C1.4 – see reporting table 1(5))	Further identification of impurities will be submitted in May.	30.4.2004 Notifier will submit a confirmatory method for the impurities in May. Acceptable. Data have to be awaited.	EPCO 6 (15.-16.06.2004): Data requirement can be covered by the data requirement 1.1.

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 1.2: Depending on the new study required in 1.1 a confirmatory method is maybe necessary to demonstrate the specificity of the analytical method. This new open point was proposed at the EPCO 6 Meeting.			EPCO 6 (15.-16.06.2004): Open point still open.
1.3	Notifier to submit the new validation data for DFG S 19 – method. (Vol. 3, B.5.3.1 - see reporting table 1(12))	Report on new validation data for DFG S 19-method will be finalised end of April or - at the latest - in May.	30.4.2004 Notifier will submit a report on new validation data for DFG S´19-method in May. Acceptable. Data have to be awaited.	EPCO 6 (15.-16.06.2004): Data requirement fulfilled.
	Post-meeting note after EPCO 6 from the RMS regarding data requirement 1.3: The submitted method (in addendum 3) was valid for the determination of residues of tolylfluanid in soil.			

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 1.1: The acceptability of surface water as surrogate for drinking water for this certain compound to be discussed in the expert meeting. NL to provide additional background information. (Vol. 3, B5.3.2 - see reporting table 1(14))	Clarification on the nature of the problem concerning the analysis of tolylfluanid in drinking water is still ongoing. Once this has been accomplished, Bayer CropScience (BCS) will either submit a statement on how to overcome these problems or develop a new method.	30.4.2004 Additional background information on comments by NL is awaited. Acceptable. Data have to be awaited.	EPCO 6 (15.-16.06.2004): This open point has been changed into data requirement 1.4.
1.4	A study for the determination of residues of tolylfluanid in drinking water (taking the potential problems of the analysis of tolylfluanid into consideration). This new data requirement was proposed at the EPCO 6 Meeting			EPCO 6 (15.-16.06.2004): Data requirement still open.
	Open point 1.3: RMS to revise list of representative uses: The table for the representative uses as stated in EPCO manual E4 should be used. This new open point was proposed at the EPCO 6 Meeting.			EPCO 6 (15.-16.06.2004): Open point still 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
	Open point 1.4: RMS to revise the list of end points: Page 2 relative density has no unit. In this case the value for density was included and not for relative density. Therefore, this should be amended in the list of end points. This new open point was proposed in the EPCO 6 Meeting.			EPCO 6 (15.-16.06.2004): Open point still open.
	Open point 1.5: RMS to revise the list of end points: FAO specifications The value of 960 g/kg +/- 20 should be mentioned.			EPCO 6 (15.-16.06.2004): Open point still open.

List of representative uses evaluated - Tolylfluanid / Euparen M WG 50

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)	Re-marks (m)
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	% product min max (n)	water L/ha min max	kg as/ha min max		
Apples/Pears	*NE SE	Euparen M	F F	VENTIN VENTPI	WG	50	SPI / SRU	/	7 (15*) 3	7 – 14 7 - 14	0,15 – 0,2 -	max. 1500[a] max. 1500[a]	- 1.125 - 1.5	7 3	**Safe Use**
Grapes	*NE SE	Euparen M	F F	BOTRCI PLASVI	WG	50	SPI / SRU	/	8 3	10 – 14 8 – 19	0,225 – 0,4 -	max. 1600[b] 100 – 1000	up to 1.8 up to 2.0	35 21	**Safe Use**
Strawberries	NE SE	Euparen M	F F	BOTRCI SPHRMA	WG	50	SPI	/	3 3	8 – 12 7 – 10	/	300 – 2000 800 – 1000	2.5 1.25	7 3	**Safe Use**
Rasp- and Blackberries	NE	Euparen M	F F	BOTRCI SPHRMA	WG	50	SPI	/	4	8 – 10	/	500 – 1500	1.7	14	
Currants / Gooseberries	NE	Euparen M	F F	BOTRCI SPHRMA	WG	50	SPI	/	2	14	/	500 – 1000	1.25	14	
Tomatoes	NE SE -	Euparen M	F F G	ALTESO BOTRCI PHYTIN	WG	50	SPI	/	6 3 – 4 4 – 6	8 – 10 7 – 10 8 – 10	0,2 0,3 0,2	300 – 1200 1000 max. 1500[c]	up to 1.2 up to 1.5 up to 1.5	3 3 3	
Peppers	-	Euparen M	G	ALTESO BOTRCI	WG	50	SPI	/	3	7	0,2	max. 1500[d]	1.3	3	
Cucumber / Zucchini	NE -	Euparen M	F G	PSECU SPHRFU	WG	50	SPI	/	6 6	10 8 – 11	0,2 0,2	600 max. 1500[e]	0.6 up to 1.5	3 3	**Safe Use**

Melons	NE SE	Eupare n M	F F	ALTECU PSECU	WG	50	SPI	/	3 3	10 10	/	300 300	1.25 1.25	14 14	
Head Lettuce	NE SE	Eupare n M	F F	BREMLA BOTRCI	WG	50	SPI	/	6 3	5 10 – 17	/	600 1000	0.6 1.0	21 7	
Leeks	NE	Eupare n M	F	PHYTPO	WG	50	SPI	/	5	14	/	600	1.25	21	
Hops	*NE	Eupare n M	F	BOTRCI PSPEHU	WG	50	SPI / SRU	/	6*	8 – 24	0.2 -	1000 - 3000	up to 3.0	14	

Remarks:

"Safe Use" indicates the uses for which operator exposure, environmental fate and ecotoxicology risk assessments were conducted on EU level; additionally, reports on residue trials and dietary risk assessments were submitted for all other uses with the Annex II dossier

* Relevant to national (German) use pattern only

(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

[a]: SPI: max. 1500 l/ha with 500 l/ha/m; SRU: max. 500 l/ha with 167 l/ha/m
[b]: SPI: 1600 l/ha; SRU: 333 l/ha
[c]: SPI: max. 1500 l/ha with 1000 l/ha/m
[d]: SPI: max. 1500 l/ha with 1000 l/ha/m
[e]: SPI: max. 1500 l/ha with 750 l/ha/m

REPORT OF EPCO EXPERT MEETING 07

TOLYLFLUANID

Rapporteur Member State: Finland

Specific comments on the active substance in the section

4. 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:

None.

2. Documents submitted for meeting:

Date	**Supplier**	**File Name**
19 February 2004	RMS/Finland	Tolylfluanid consultation report
26 March 2004	RMS/Finland	Tolylfluanid reporting table rev1-2
30 April 2004	RMS/Finland	Tolylfluanid evaluation table rev0-1
19 May 2004	RMS/Finland	Tolylfluanid end points
19 May 2004	RMS/Finland	Tolylfluanid addendum 2

3. Documents tabled at the meeting:

Date	**Supplier**	**File Name**
23 June 2004	company	excel spread sheet for PEC callculations

The conclusions of the meeting were as follows:

4. **Data on preparations:** The data set was submitted for the formulation Euparen M WG 50

5. **Classification and labelling:** R53 was proposed by the EPCO 7 meeting
RMS post meeting note:
No classification with regard to fate and behaviour data is proposed by the RMS since R53 has been removed by wg of classification and labelling in June 2002.

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

Areas of concern: none for the fate section

Appendix 1: EPCO discussion table: TOLYLFLUANID
Appendix 2: Evaluation table

Appendix 1: Discussion Table, Tolylfluanid (Fu)

4. Environmental Fate and Behaviour

No.	Subject	Discussion EPCO Expert Meeting	Conclusions EPCO Expert Meeting
		The RMS informed the meeting that the intended use in cucumber and zucchini is not safe. The uses evaluated are the ones in grapes, apples and strawberries. (The Notifier informed after the EPCO meeting that the use in cucumber and zucchini is supported only in greenhouses.) The worst case use scenario taken by the RMS is an application raqte ofis 2.5 kg/ ha in strawberries. The number of applications will not be taken into account for the active substance due to fast degradation.	
	Open point 4.1: RMS to provide an addendum to the draft assessment report on the use of mean DT50 values for the PEC soil calculations and the impact with respect the use of worst case. (Vol. 1, 2.5.2.3 - see reporting table 4(2))	In the DAR, the RMS had used the mean DT50 for the calculations of PEC soil values, which was regarded not to be appropriate. The notifier submitted recalculations using a 90th percentile DT50 of 2.4 days instead of realistic worst case value of 2.6 days. In this case it will not have any severe effect on the risk assessment, but in general the realistic worst case values should be used. The experts expressed their reservations against using other values (mean DT50, 90th percentile) for the PEC soil calculations. The PEC values presented in table B 8.3-2 in the addendum show some inconsistency. It was not quite understandable how these values were calculated. The PEC values would have been expected to reach their maximum at the time of a later application rather at the day of the first application (initial PEC at day 0). There were some concerns whether multiple application had actually been accounted for in the calculations. These calculations are based on an excel spread sheet. The original excel spread sheet was submitted by the company during the meeting. The data presented there are correct and include also values missing in the table in the addendum. That table has to be amended accordingly. In addition the PEC values have to be recalculated using the worst case DT50 (2.6 days for the parent and 6.7 days for the metabolite DMST). The recalculation is not expected to change the overall conclusion.	<u>EPCO 7 (22. – 23.06.2004):</u> The RMS has to recalculate the PEC soil values using the worst case DT50 values for tolylfluanid and DMST (tables B.8.3-2 – B.8.3-5) .and amend the tables B8.3-2 according to the data presented in the excel spread sheet (add information on the moment when the highest value have been achieved). Open point still open

No.	Subject	Discussion EPCO Expert Meeting	Conclusions EPCO Expert Meeting
	Open point 4.2: Appropriateness of DT50 sediment DMST used for the calculations to be discussed in an expert meeting. (Vol. 1, level 2, 2.5.3.3 - see reporting table 4(3))	There is a scientific reason for using the worst case values. The need to use the different values derived from one study was not seen.	EPCO 7 (22. – 23.06.2004): Open point closed.

No.	Subject	Discussion EPCO Expert Meeting	Conclusions EPCO Expert Meeting
	Open point 4.3: MS to discuss whether the DT50 value and the method employed for the PECsw calculation is acceptable in an expert meeting. (Vol. 1, 2.5.3.3 - see reporting table 4(4))	For the active substance and the metabolite the mean values used by the notifier were recalculated for a temperature of 15°C instead of the standard worst case at a temperature of 20°C. In the case of the active substance the worst case DT50 values at 20°C are quite similar to those used by the notifier. This will therefore not affect the risk assessment of the parent compound. However, the worst case DT50 for the metabolite was longer than the employed in the calculations presented in the DAR. The experts do not understand why these non standard methods have been used. For the ecotox risk assessment PEC values that have been used were not located by the experts in the fate section. It was discussed what was really meant by “worst case” DT50 - the highest DT50 overall or the worst case DT50 at 20°C – in order to get some clarification on the discrepancy between the values presented in chapter B8 and B9 of the draft assessment report. Again, the necessity of using worst case values under standard conditions was emphasised. The ecotoxicological risk assessment should only be based on the PEC values reported in the fate section. A recalculation of the PEC surface water is necessary using the values from the water sediment study conducted at 20°. The worst case DT50 for the rpatent is 6 hoursfor the metabolite 75.8 days. Post meeting note: Various PECsw calculations are presented in B8 following different assumptions. Therefore, it is not easy to identify which ones have been used for the ecotoxicological risk assessment. As a consequence, the meeting was not capable to locate the right table during the discussion. In fact, PEC used in ecotoxicological risk assessment (Tables B.9.2.10-2a and B.9.2.10-2b) may be actually found in chapter B.8 (under tables B.8.6-8 and B.8.6-11). These values correspond to the maximum PEC sw during the application pattern and may be affected by the change in the DT_{50} to be used for the calculations proposed by the meeting. The results have to be the basis for new TER calculations (See open point 4.7 and 4.9). The recalculation is not expected to change the ecotoxicological risk assessment, because there is a large safety margin.	<u>EPCO 7 (22. – 23.06.2004):</u> The RMS has to recalculate the PEC surface water values using the worst case DT50 of 6 hours for the parent and 75.8 days for the metabolite. Open point still open.

No.	Subject	Discussion EPCO Expert Meeting	Conclusions EPCO Expert Meeting
	Open point 4.7: The TER values have to be recalculated on the basis of the new PEC surface water values. This open point was proposed at the EPCO 7 meeting		EPCO 7 (22. – 23.06.2004): Open point still open.
	Open point 4.8: The list of end points has to be amended according to the PEC surface water values. This open point was proposed at the EPCO 7 meeting		EPCO 7 (22. – 23.06.2004): Open point still open.
	Open point 4.9: The list of end points has to be amended according to the TER values in the ecotox section. This open point was proposed at the EPCO 7 meeting		EPCO 7 (22. – 23.06.2004): Open point still open.

No.	Subject	Discussion EPCO Expert Meeting	Conclusions EPCO Expert Meeting
	Open point 4.4: The need of additional DT50 values for the degradation of tolylfluanid in soil to be discussed in an expert meeting. (Vol. 3, B.8.1.3 - see reporting table 4(8))	With respect to this point, the RMS position, which had already been presented in the reporting table, was supported. Submission of additional data will not influence the risk assessment.	EPCO 7 (22. – 23.06.2004): Open point fulfilled.
	Open point 4.5: RMS to amend the list of end points clarifying that the Koc values for the adsorption of tolylfluanid in soil is estimation. (Vol. 3, B.8.2.1 - see reporting table 4(9))	The list of end points has been amended in the related parts.	EPCO 7 (22. – 23.06.2004): Open point fulfilled.
	Open point 4.6: RMS to amend the list of end points regarding the leaching properties of degradation products (half-life value to be added to the list of end points). (Vol. 3, B.8.2.2.2 - see reporting table 4(11))	The list of end points has been amended in the related parts.	EPCO 7 (22. – 23.06.2004): Open point fulfilled.

No.	Subject	Discussion EPCO Expert Meeting	Conclusions EPCO Expert Meeting
	Other issues	One MS arise the issue that bounded residues in soil are > 70 % in some cases for this substance. Another MS informed that bounded residues need to be considered together with mineralization rates when assessing persistence. The meeting agreed that in this case this is not associated with very low mineralization and that it does not needs to be considered further.	

Appendix 2: Evaluation table

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-Peer Review Meeting / Conclusions of the evaluation group
				Section 4 Data requirements: 0 Open points: 6
	Open point 4.1: RMS to provide an addendum to the draft assessment report on the use of mean DT50 values for the PECsoil calculations and the impact with respect the use of worst case. (Vol. 1, 2.5.2.3 - see reporting table 4(2))	-	The addendum will be provided before the expert meeting.	EPCO 7 (22. – 23.06.2004): The RMS has to recalculate the PEC soil values using the worst case DT50 values for tolylfluanid and DMST (tables B.8.3-2 – B.8.3-5) .and amend the tables B8.3-2 according to the data presented in the excel spread sheet (add information on the moment when the highest value have been achieved). Open point still open
	Open point 4.2: Appropriateness of DT50 sediment DMST used for the calculations to be discussed in an expert meeting. (Vol. 1, level 2, 2.5.3.3 - see reporting table 4(3))	BCS will provide an explanatory statement in May.	New information will be included in the addendum.	EPCO 7 (22. – 23.06.2004): Open point closed.

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO-Peer Review Meeting / Conclusions of the evaluation group
	Open point 4.3: MS to discuss whether the DT50 value and the method employed for the PECsw calculation is acceptable in an expert meeting. (Vol. 1, 2.5.3.3 - see reporting table 4(4))	BCS will provide an explanatory statement in May.	New information will be included in the addendum.	EPCO 7 (22. – 23.06.2004): The RMS has to recalculate the PEC surface water values using the worst case DT50 of 6 hours for the parent and 75.8 days for the metabolite. Open point still open.
	Open point 4.7: The TER values have to be recalculated on the basis of the new PEC surface water values. This open point was proposed at the EPCO 7 meeting			EPCO 7 (22. – 23.06.2004): Open point still open.
	Open point 4.8: The list of end points has to be amended according to the PEC surface water values. This open point was proposed at the EPCO 7 meeting			EPCO 7 (22. – 23.06.2004): Open point still open.
	Open point 4.9: The list of end points has to be amended according to the TER values in the ecotox section. This open point was proposed at the EPCO 7 meeting			EPCO 7 (22. – 23.06.2004): Open point still 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-Peer Review Meeting / Conclusions of the evaluation group
	Open point 4.4: The need of additional DT50 values for the degradation of tolylfluanid in soil to be discussed in an expert meeting. (Vol. 3, B.8.1.3 - see reporting table 4(8))	DT50 values were calculated from data from 4 soils. Without doubt, the fit of the curves is not very good. 1st order kinetics may be not appropriate for description of the degradation curve when a compound decreases very fast at the very beginning of the study as tolylfluanid does. Nevertheless 1st order kinetic degradation rates were calculated since they are required for modelling. However, regardless of the correlation coefficient of the kinetic curves, experimental data for all 4 soils clearly show a DT50 ≤1 day.	RMS agrees with the notifier.	EPCO 7 (22. – 23.06.2004): Open point fulfilled.
	Open point 4.5: RMS to amend the list of end points clarifying that the Koc values for the adsorption of tolylfluanid in soil is estimation. (Vol. 3, B.8.2.1 - see reporting table 4(9))	-	The list of end points has been amended.	EPCO 7 (22. – 23.06.2004): 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-Peer Review Meeting / Conclusions of the evaluation group
	Open point 4.6: RMS to amend the list of end points regarding the leaching properties of degradation products (half-life value to be added to the list of end points). (Vol. 3, B.8.2.2.2 - see reporting table 4(11))	-	The list of end points has been amended.	EPCO 7 (22. – 23.06.2004): Open point fulfilled.

REPORT OF EPCO EXPERT MEETING 08

TOLYLFLUANID

Rapporteur Member State: Finland

Specific comments on the active substance in the section

5. Ecotoxicology

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

1. Comments submitted for this meeting:

None.

2. Documents submitted for meeting:

Date	Supplier	File Name
19 February 2004	RMS/Finland	Tolylfluanid consultation report
19 February 2004	RMS/Finland	Tolylfluanid addendum 1
26 March 2004	RMS/Finland	Tolylfluanid reporting table rev1-2
30 April 2004	RMS/Finland	Tolylfluanid evaluation table rev0-1
19 May 2004	RMS/Finland	Tolylfluanid end points
19 May 2004	RMS/Finland	Tolylfluanid addendum 2

3. Documents tabled at the meeting:

None.

The conclusions of the meeting were as follows:

4. **Data on preparations:** Euparen M WG 50.

5. **Classification and labelling:** N, R50 (agreed by ISPRA)

6. **Recommended restrictions/conditions for use:**

Areas of concern: the risk to fish at lower pH values has to taken into account at member state level. Risk mitigation measures to protect aquatic live should be set at member state level

Appendix 1: EPCO discussion table: TOLYLFLUANID
Appendix 2: Evaluation table

Appendix 1: Discussion Table, Tolylfluanid (Ac, Fu)

5. Ecotoxicology

No.	Subject	Discussion EPCO Expert Meeting	Conclusions EPCO Expert Meeting
	Open point 5.1: The conclusions from the addendum regarding the risk assessment for birds to be discussed in an expert meeting. (Vol.1, 2.6.1 - see reporting table 5(2))	Notifier has revised the risk assessment and it is presented in the addendum 1. RMS states that there is no risk for birds and mammals Meeting: The proposed revision of PT (1-0,6) could not be accepted unless based on supporting data.? Meeting: RMS should check if there are data in support of the proposed PT value of 0.6 available. If not the RMS should use a factor of 1. In this case the TER will be below the relevant trigger value. However the scenario with herbivorous birds is not relevant for the intended uses and overall there remains no problem. Meeting: in connection with the assessment of secondary poisoning of birds it should be clearly stated which distance between application area and water body was taken into account. A buffer zone is needed to protect aquatic life !	Open point still open: RMS should check if there are data in support of the proposed PT value of 0.6 available. If not the RMS should change the PT-value to 1 in a revised addendum. In connection with the assessment of secondary poisoning of birds it should be clearly stated which distance between application area and water body was taken into account. A buffer zone is needed to protect aquatic life !
	Open point 5.2: The conclusions from the addendum regarding the risk assessment for mammals to be discussed in an expert meeting. (Vol. 1, 2.6.3 - see reporting table 5(4))	NOT has revised the risk assessment and it is presented in the addendum 1. Table 9.3.5 in the addendum was discussed. The MAF value was discussed but the one that is mentioned is acceptable because of the new DT50 was considered. This point 5(15) of the reporting table as regards the relevant endpoint for the chronic risk assessment on mammals was discussed again. One MS states that refinement of this endpoint is necessary. The meeting agreed to use the NOAEL of 100 ppm or 9 mg/kg bw from the study by Pickel and Rinke. The Notifier should refine the long term risk assessment of mammals and use this reproNOEC. The new value should be amended in the list of endpoints Risk refinement is necessary and should be done by the Notifier.	New data requirement for the Notifier to refine the risk assessment for mammals Open point for the RMS The NOEC for mammals should be amended in the list of endpoints. A revised long term risk assessment for mammals based on a NOAEL Of 9 mg/kg bw should be made available in an addendum.

No.	Subject	Discussion EPCO Expert Meeting	Conclusions EPCO Expert Meeting
5.1	Notifier to submit new acute toxicity test with zebra fish at different pH-values. (Vol.1, Appendix 3 - see reporting table 5(6))	RMS: new study confirmed the earlier results and has been accepted by the RMS. Meeting agreed. The range of the pH-values used was discussed. In different states can be found different pH-values in surface water. According to the aquatic guidance document a range of 6-7 pH (areas of concern!) should be considered. This is typical for water bodies in the agricultural landscape. In toxicity tests pH is usually 7 – 9. Microcosm and mesocosm testing at other ph-values are difficult to conduct. MS's with surface water bodies of low pH (<6) associated with agricultural landscapes should consider the effect of pH on toxicity to fish at the local level.	Data requirement fulfilled.
	Open point 5.3: The TER revisions for aquatic organisms to be discussed in an expert meeting. (Vol. 1, appendix 3 - see reporting table 5(7))	RMS: The NOEC HC5 value should be deleted from the list of endpoints because it is not generally adopted yet. The TER calculations including different buffer zones have to be recalculated . RMS will do this. As regards classification and labelling the R 53 is not relevant . ISPRA has decided upon this. In June 2002, it was concluded that the revised agreed proposal with N; R50 would be included to a next draft of 29th ATP. Also specific concentration limits have been agreed (Cn > 2.5 % for N; R50). Should this also be included?	Open point still open List of endpoints should be revised: The NOEC HC5 value should be deleted from the list of endpoints and the TER calculations including different buffer zones have to be recalculated and inserted in the list of endpoints
	Open point 5.4: The relevant endpoint of an outdoor microcosm study to be discussed in an expert meeting. (Vol. 3, B.9.2.10 - see reporting table 5(18))	The NOEAEC of the study on invertebrates and primary producers is 99 μg/L based on the recovery within eight weeks period and was discussed. This endpoint was confirmed by the meeting because in the aquatic guidance document recovery in this period is regarded as acceptable. An independent and well recognised expert confirmed the high quality of the study. Even though only 4 applications were tested the uncertainty arising from this matter was regarded as low because the substance is very unstable in water - it is unlikely that the highest PEC will reach one water body 8 times. Additionally a lot of species were tested and consequently the relevant uncertainty value of ten should be lowered considerably. The recovery in relation to climatic conditions of the different regions (north and south) is discussed. So far there are no clear indications that recovery in the south is slower. On the other hand several species have more generations per year there and this would lead to a faster recovery. No clear conclusions were made with respect to this point. To assess the risk to fish it was considered that the outdoor micrcosm study with rainbow trout was more relevant. From this study a NOEC of 60 µg/L could be defined. Additionally acute tests on several fish species were submitted and rainbow trout is the most sensitive species. Furthermore the Acute/chronic ratio is low. Taking this information together it is	Open point still open: RMS to redraft the risk assessment for aquatic organisms taking into account the outcome of the EPCO expert meeting. RMS to include the outcome of the meeting to the list of end points (NOEAEC of 99 μg/L with an uncertainty factor of 3-5)

No.	Subject	Discussion EPCO Expert Meeting	Conclusions EPCO Expert Meeting
		warranted to lower the uncertainty factor to 5. A lower value would only be warranted if indirect effects within the community would be covered by a study. RMS to redraft the risk assessment and endpoints.	
	New open point	The remark that cucumber and zucchini represent a safe use should be deleted from the list of intended uses.	New open point The remark that cucumber and zucchini represent a safe use should be deleted from the list of intended uses.
	New open point Amend the list of endpoints concerning classification and labelling	Classification and labelling should be included in the list of endpoints and it should be noted that it has already been agreed on by ISPRA (see open point 5.3).	New open point Classification and labelling should be included in the list of endpoints indicating that it is agreed already by ISPRA.
	New open point	New PECsw should be calculated due to the new water/sediment study in 20°C.	New open point Pending on the PECsw to be recalculated in the fate and behaviour section due to the new water/sediment study at 20°C, a revision of the aquatic risk assessment may be necessary.
		EFSA: All data requirements and open points should be mentioned even if more than 12 month are needed to fulfil all requirements. This deadline is only relevant for EFSA to submit risk assessments to the Commission. The Commission might prolong this period for the notifiers. In any case there is a need for decision makers to know how severe are the remaining problems.	
		MS did not have any other remarks on the list of endpoints than the remarks already mentioned above.	

Appendix 2: Evaluation table

1. 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-Peer Review Meeting / Conclusions of the evaluation group
				Section 5 Data requirements: 1 Open points: 7
	Open point 5.1: The conclusions from the addendum regarding the risk assessment for birds to be discussed in an expert meeting. (Vol.1, 2.6.1 - see reporting table 5(2))	-	-	EPCO 8 (22.-23.06.2004): Open point still open. RMS should check if there are data in support of the proposed PT value of 0.6 available. If not the RMS should change the PT-value to 1 in a revised addendum. In connection with the assessment of secondary poisoning of birds it should be clearly stated which distance between application area and water body was taken into account. A buffer zone is needed to protect aquatic life ! Open point was amended at the EPCO 8 Meeting.

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-Peer Review Meeting / Conclusions of the evaluation group
	Open point 5.2: The conclusions from the addendum regarding the risk assessment for mammals to be discussed in an expert meeting. (Vol. 1, 2.6.3 - see reporting table 5(4))	-	-	EPCO 8 (22.-23.06.2004): Open point still open. The NOEC for mammals should be amended in the list of endpoints. A revised long term risk assessment for mammals based on a NOAEL of 9 mg/kg bw should be made available in an addendum. Open point was amended at the EPCO 8 Meeting. See new data requirement 5.2
5.1	Notifier to submit new acute toxicity test with zebrafish at different pH-values. (Vol.1, Appendix 3 - see reporting table 5(6))	Acute toxicity of Tolylfluanid WG 50 to fish (Danio rerio) at different pH-values of test water under static conditions by M Dorgerloh, report no. DOM 23100 of 2004-02-05 is available.	RMS evaluates the study and the Addendum will be provided before the expert meeting.	EPCO 8 (22.-23.06.2004): Data requirement 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-Peer Review Meeting / Conclusions of the evaluation group
	Open point 5.3: The TER revisions for aquatic organisms to be discussed in an expert meeting. (Vol. 1, appendix 3 - see reporting table 5(7))	The notifier likes to highlight that an extensive data base was generated in order to assess the effects on aquatic organisms, e.g. sensitivity distribution on fish, indoor microcosm study under more realistic exposure conditions, fish outdoor microcosm study, aquatic invertebrate laboratory studies and aquatic invertebrate outdoor microcosm study, pH-dependent toxicity in fish (most sensitivity species), independent expert statement on aquatic toxicity of tolylfluanid.	RMS agrees that all the data needed for risk assessment was provided. While there is no clear guidance available on TER values calculated from mesocosm studies, RMS is open for discussion with other member states in EPCO-Peer Review Meeting. RMS is still at the moment of the opinion that the proposed TER in the DAR is protective enough.	EPCO 8 (22.-23.06.2004): Open point still open. List of endpoints should be revised: The NOEC HC5 value should be deleted from the list of endpoints and the TER calculations including different buffer zones have to be recalculated and inserted in the list of endpoints Open point was amended at the EPCO 8 Meeting.
	Open point 5.4: The relevant endpoint of an outdoor microcosm study to be discussed in an expert meeting. (Vol. 3, B.9.2.10 - see reporting table 5(18))	BCS used recognised guidance on how to evaluate outdoor microcosm studies. According to this, the NOEAEC of this study is 99 µg/L based on recovery within an eight weeks period. The use of a low assessment factor is considered appropriate based on all of the available aquatic data, the employed exposure regime in the outdoor microcosm study which is considered appropriate for the proposed GAP of tolylfluanid (highly instable in water) and based on the use of worst case initial PECs. BCS recommends an assessment factor of 1.5 (to be applied to the study endpoint in order to extrapolate to lower pH ranges in natural water bodies).	RMS agrees with the applicant with the NOEAEC of 99 µg/L but prefers the assessment factor of 3 instead of 1.5 (see the explanation in the reporting table No. 20).	EPCO 8 (22.-23.06.2004): Open point still open. RMS to redraft the risk assessment for aquatic organisms taking into account the outcome of the EPCO expert meeting. RMS to include the outcome of the meeting to the list of end points (NOEAEC of 99 µg/L with an uncertainty factor of 3-5) Open point was amended at the EPCO 8 Meeting.

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-Peer Review Meeting / Conclusions of the evaluation group
5.2	Notifier to refine the risk assessment for mammals Data requirement was proposed in the EPCO 8 meeting.			EPCO 8 (22.-23.06.2004): Data requirement still open.
	New open point 5.5: The remark that cucumber and zucchini represent a safe use should be deleted from the list of intended uses. New open point was proposed in the EPCO 8 meeting.			EPCO 8 (22.-23.06.2004): Open point still open.
	New open point 5.6: Classification and labelling should be included in the list of endpoints indicating that it is agreed already by ISPRA. New open point was proposed in the EPCO 8 meeting.			EPCO 8 (22.-23.06.2004): Open point still 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-Peer Review Meeting / Conclusions of the evaluation group
	New open point 5.7: Pending on the PECsw to be recalculated in the fate and behaviour section due to the new water/sediment study at 20°C, a revision of the aquatic risk assessment may be necessary. New open point was proposed in the EPCO 8 meeting.			EPCO 8 (22.-23.06.2004): Open point still open.

List of representative uses evaluated - Tolylfluanid / Euparen M WG 50

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)	% product min max (n)	water L/ha min max	kg as/ha min max		
Apples/Pears	*NE SE	Euparen M	F F	VENTIN VENTPI	WG	50	SPI / SRU	/	7 (15*) 3	7 – 14 7 - 14	0,15 – 0,2 -	max. 1500[a] max. 1500[a]	- 1.125 - 1.5	7 3	**Safe Use**
Grapes	*NE SE	Euparen M	F F	BOTRCI PLASVI	WG	50	SPI / SRU	/	8 3	10 – 14 8 – 19	0,225 – 0,4 -	max. 1600[b] 100 – 1000	up to 1.8 up to 2.0	35 21	**Safe Use**
Strawberries	NE SE	Euparen M	F F	BOTRCI SPHRMA	WG	50	SPI	/	3 3	8 – 12 7 – 10	/	300 – 2000 800 – 1000	2.5 1.25	7 3	**Safe Use**
Rasp- and Blackberries	NE	Euparen M	F F	BOTRCI SPHRMA	WG	50	SPI	/	4	8 – 10	/	500 – 1500	1.7	14	
Currants / Gooseberries	NE	Euparen M	F F	BOTRCI SPHRMA	WG	50	SPI	/	2	14	/	500 – 1000	1.25	14	
Tomatoes	NE SE -	Euparen M	F F G	ALTESO BOTRCI PHYTIN	WG	50	SPI	/	6 3 – 4 4 – 6	8 – 10 7 – 10 8 – 10	0,2 0,3 0,2	300 – 1200 1000 max. 1500[c]	up to 1.2 up to 1.5 up to 1.5	3 3 3	
Peppers	-	Euparen M	G	ALTESO BOTRCI	WG	50	SPI	/	3	7	0,2	max. 1500[d]	1.3	3	
Cucumber / Zucchini	NE -	Euparen M	F G	PSECU SPHRFU	WG	50	SPI	/	6 6	10 8 – 11	0,2 0,2	600 max. 1500[e]	0.6 up to 1.5	3 3	**Safe Use**

Melons	NE SE	Eupare n M	F F	ALTECU PSECU	WG	50	SPI	/	3 3	10 10	/	300 300	1.25 1.25	14 14	
Head Lettuce	NE SE	Eupare n M	F F	BREMLA BOTRCI	WG	50	SPI	/	6 3	5 10 – 17	/	600 1000	0.6 1.0	21 7	
Leeks	NE	Eupare n M	F	PHYTPO	WG	50	SPI	/	5	14	/	600	1.25	21	
Hops	*NE	Eupare n M	F	BOTRCI PSPEHU	WG	50	SPI / SRU	/	6*	8 – 24	0.2 -	1000 - 3000	up to 3.0	14	

Remarks:

"Safe Use" indicates the uses for which operator exposure, environmental fate and ecotoxicology risk assessments were conducted on EU level; additionally, reports on residue trials and dietary risk assessments were submitted for all other uses with the Annex II dossier

* Relevant to national (German) use pattern only

(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

[a]: SPI: max. 1500 l/ha with 500 l/ha/m; SRU: max. 500 l/ha with 167 l/ha/m

[b]: SPI: 1600 l/ha; SRU: 333 l/ha

[c]: SPI: max. 1500 l/ha with 1000 l/ha/m

[d]: SPI: max. 1500 l/ha with 1000 l/ha/m

[e]: SPI: max. 1500 l/ha with 750 l/ha/m

REPORT OF EPCO EXPERT MEETING 09

TOLYLFLUANID

Rapporteur Member State: Finland

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:

None.

2. Documents submitted for meeting:

Date	**Supplier**	**File Name**
19 February 2004	RMS/Finland	Tolylfluanid consultation report
26 March 2004	RMS/Finland	Tolylfluanid reporting table rev1-2
30 April 2004	RMS/Finland	Tolylfluanid evaluation table rev0-1
19 May 2004	RMS/Finland	Tolylfluanid end points
22 June 2004	RMS/Finland	Tolylfluanid addendum 4

3. Documents tabled at the meeting:

None.

The conclusions of the meeting were as follows:

4. **Data on preparations:** EUPAREN M WG 50

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

6. **Recommended restrictions/conditions for use:** not discussed.

Areas of concern:

Appendix 1: EPCO discussion table: TOLYLFLUANID

Appendix 2: Evaluation table

Appendix 1: Discussion Table, Tolylfluanid (Ac/Fu)

2. Mammalian Toxicology

No.	Subject	Discussion EPCO Expert Meeting	Conclusions EPCO Expert Meeting
	Open point 2.1: The setting of NOAEL for short-term toxicity studies needs to be discussed in an expert meeting. (Vol. 3, B.6.3.2.2 - see reporting table 2(2))	It was discussed which study should be used for the setting of the overall NOAEL. For the 13-week rat study the NOAEL is 20 mg/kg bw/d (300 ppm) and the LOAEL is 108 mg/kg bw/d (1650 ppm), based on changes in clinical chemistry parameters which indicates impairment of the liver. For the dog, the 13-week study gave a NOAEL of 33 mg/kg bw/d (1000 ppm) and a LOAEL of 93 mg/kg bw/d (3000 ppm), while the 1-year studies provided a NOAEL of 20 mg/kg bw/d and a LOAEL of 62.5 mg/kg bw/d, on the basis of effects on liver and kidney. When comparing the NOAELs and LOAELs, the dog studies were considered to be the most appropriate for establishing the lowest relevant NOAEL for short term toxicity. The meeting agreed with the proposal of the RMS to set an overall NOAEL of 33 mg/kg bw/d (1000 ppm) from the 13-week dog study.	Open point fulfilled. The overall NOAEL for the short term toxicity is 33 mg/kg bw/d for the 13-week dog study.
	Open point 2.2: The relevance of fluoride incorporation in bones needs to be discussed in an expert meeting. (Vol. 3, B.6.3.2.5 - see reporting table 2(4))	In the one-year dog study, a statistically significant increase of fluoride levels in bone and teeth was observed at 80 mg/kg bw/d in both sexes. Since there were no gross or histopathological findings related to increased fluoride incorporation in bones at this dose level, the meeting established a NOAEL of 80 mg/kg bw/d and a NOEL of 20 mg/kg bw/d for this study.	Open point fulfilled. For the one-year dog study the NOAEL for fluoride incorporation in bones and teeth is 80 mg/kg bw/d, the NOEL is 20 mg/kg bw/d.

No.	Subject	Discussion EPCO Expert Meeting	Conclusions EPCO Expert Meeting
	Open point 2.3: RMS to revise the List of Endpoints regarding the ”Lowest relevant inhalation NOAEC / NOEC”. (see reporting table 2(6))	One MS remarked that the particle should be included. The RMS has already amended the box in the list of end points according to the proposal in the reporting table. Additionally, the risk phrase R37 has been proposed.	Open point fulfilled.
	Open point 2.4: The NOAELs from long-term toxicity and carcinogenicity studies and the relevance of fluoride incorporation in bones needs to be discussed in an expert meeting. (Vol. 3, B.6.5.3 - see reporting table 2(12))	The experts discussed the NOAEL/NOEL for the 2-year rat study. At 300 ppm, two cases of teeth discoloration as well as increased fluoride levels in bone and teeth have been observed. However, there were no histopathological findings related to increased fluoride incorporation in bones at this dose level. Therefore, the meeting agreed with the proposal of the RMS to set the NOAEL at 300 ppm (18 mg/kg bw/d). For the mouse, the overall NOAEL was agreed at 60 ppm (15.3 mg/kg bw/d), on the basis of hyperostosis in the sternum of females at 300 ppm and above.	Open point fulfilled. The meeting agreed with the proposed NOAEL of 300 ppm (18 mg/kg bw/d) for the 2-year rat study.
	Open point 2.5: RMS to evaluate the new 2-generation study until the expert meeting. The relevant NOAEL in 2-generation reproduction rat study needs to be discussed in an expert meeting. (see reporting table 2(14))	The experts discussed the appropriate NOAEL/NOEL for the 2-generation reproduction studies. In the old 2-generation studies, histopatological effects in bones were not extensively measured. However, in the supplementary study, thickened craniums were observed in most male and female F0 parent animals at 180 ppm (ca. 19 mg/kg bw/d). In the new 2-generation study, no histopathological changes and no systemic or reproductive toxic effects were observed at 200 ppm, equal to 12 mg/kg bw/d for males and 14.7 mg/kg bw/d for females during the premating period. On the basis of the new 2-generation study, the meeting proposed a NOAEL of 200 ppm (12 mg/kg bw/d) for systemic toxicity as well as for reproduction toxicity. One MS proposed to take this NOAEL as basis for the ADI.	Open point fulfilled. proposed NOEL is 200 ppm = 12 mg/kg bw/d. This NOEL is valid for systemic toxicity as well as for reproduction toxicity. New open point 2.14: RMS to amend the list of end point regarding the NOAEL of 200 ppm (12 mg/kg bw/d) for systemic toxicity as well as for reproduction toxicity.

No.	Subject	Discussion EPCO Expert Meeting	Conclusions EPCO Expert Meeting
	Open point 2.6: RMS to evaluate the statement of the notifier, regarding the relevance of the three plant metabolites (WAK6550, WAK6676 and WAK6698), in an addendum. (Vol. 3, B.6.8 – see reporting table 2(15))	The exposure assessment for re-entry activities for the metabolites was presented in the addendum (p.22). All three metabolites were tested for acute oral toxicity, which is lower or comparable to the parent compound. Furthermore, the Ames tests were performed for all three metabolites. No genotoxicity were was observed. The metabolite WAK6698 has been also tested in mouse lymphoma test, no mutagenic potential was recorded. According to the estimation presented in the addendum, the maximal exposure level is 4 % for WAK6550 of the exposure level for tolylfluanid, 1 % for WAK6676 and <0.1 % for WAK6698. As the exposure is lower than for tolylfluanid, these metabolites are not considered to be relevant regarding re-entry. Conclusion of the meeting: All three plant metabolites are of low toxicological concern based on acute oral toxicity and in vitro genotoxicity data. Re-entry exposure is significantly lower than for the parent compound.	Open point fulfilled. All three plant metabolites are of low toxicological concern based on acute oral and in vitro genotoxicity data. Re-entry exposure is significantly lower than for the parent compound.

No.	Subject	Discussion EPCO Expert Meeting	Conclusions EPCO Expert Meeting
	Open point 2.7: RMS to revise the list of end points regarding the last sentence relating to neurotoxicity. (see reporting table 2(16))	As suggested by one MS, the RMS has amended the list of end points accordingly.	Open point fulfilled.
	Open point 2.8: The setting of the ADI needs to be discussed in an expert meeting. (Vol. 3, B.6.10.4 - see reporting table 2(17))	The 2-year rat study was proposed as basis for the ADI by the RMS. The meeting discussed whether the new multigeneration rat study with a NOAEL of 12 mg/kg should be used as basis for the ADI since at 19 mg/kg bw/d (180 ppm) histopathological changes (thickened craniums) were observed in the supplementary 2-generation study (see open point 2.5). One MS proposed to use the NOAEL of 15 mg/kg bw/d from the long-term mouse study to derive the ADI. The experts agreed that the NOAEL from the new multigeneration rat study was the lowest relevant overall NOAEL and, thus, should be used as basis for the ADI. The ADI changed from 0.2 mg/kg bw to 0.1 mg/kg bw.	Open point fulfilled. The meeting agreed to take the NOAEL from the new multigeneration rat study as basis for ADI of 0.1 mg/kg bw. New open point 2.15 RMS to amend the list of end points regarding the ADI of 0.1 mg/kg bw.
	Open point 2.9: RMS to amend the list of end points concerning the rate and extent of absorption (Over 90% within 48 h, based on urinary and biliary excretion) (Vol 3, B.6.10.4 - see reporting table 2(19))	As suggested by one MS, the RMS has amended the list of end points accordingly.	Open point fulfilled.

No.	Subject	Discussion EPCO Expert Meeting	Conclusions EPCO Expert Meeting
	Open point 2.10: The setting of the AOEL needs to be discussed in an expert meeting. (Vol 3, B.6.10.4 - see reporting table 2(20))	One MS submitted a comment where they proposed to take the NOAEL of 20 mg/kg bw/d from the 2-generation study. The meeting concluded that the overall NOAEL of 33 mg/kg bw/d (1000 ppm) from the short-term toxicity studies (see open point 2.1) was the most appropriate basis for setting the AOEL. The proposed AOEL of 0.3 mg/kg bw/d was accepted by the experts.	Open point fulfilled. Proposed AOEL of 0.3 mg/kg bw/d was accepted by experts.
	Open point 2.11: The setting of the ARfD needs to be discussed in an expert meeting. (see reporting table 2(23))	In the DAR there was no ARfD allocated. The need for setting an ARfD was discussed. If the criteria from JMPR were taken into consideration, an ARfD could be set, due to the effects in the developmental toxicity study in rabbits. The LOAEL in the rabbit developmental study is 70 mg/kg bw/d. At this dose there is an indication of a clearly increased post-implantation loss and a slightly increased incidence of spontaneous malformations. These effects could (as a worst-case assumption) already be caused by a single dose. The developmental NOAEL in this study is 25 mg/kg bw/d. The meeting proposed to set an ARfD of 0.25 mg/kg bw based on developmental toxicity study in rabbits using a safety factor of 100.	Open point fulfilled Proposal: ARfD of 0.25 mg/kg bw based on developmental toxicity study in rabbits using a safety factor of 100. New open point 2.16 RMS to amend the list of end points: ARfD of 0.25 mg/kg bw based on developmental toxicity study in rabbits using a safety factor of 100.
2.1	Notifier to present additional data on the *in vivo* study in rat. (Vol. 3, B.6.12.4 - see reporting table 2(24))	The data was submitted to the RMS and was evaluated in addendum 4. See also discussion at open point 2.12.	Data requirement fulfilled.
	Open point 2.12: The estimation of dermal absorption needs to be discussed	According to the comments from some MS there are concerns about the 8 h time point selected by the RMS to estimate the dermal absorption figures in the in vivo study since the amount remaining in the skin after washing becomes systemically available subsequently.	Open point fulfilled. The proposal for the dermal

No.	Subject	Discussion EPCO Expert Meeting	Conclusions EPCO Expert Meeting
	in an expert meeting. (Vol. 3, B.6.12.4 - see reporting table 2(24))	The RMS explained that due to the non-linearity of the absorption figures, the amount absorbed from skin plus the one that remained in washed skin after 8 hours of exposure was used for the calculations. The meeting concluded that the proposal of the RMS is acceptable since the estimated absorption in the in vivo study was higher after 8 h than after 168 h. The following absorption figures were agreed on for the formulation Euparen M 50 WG: For the concentrate: 1.3 % absorbed radioactivity + 6.7 % remained in washed skin = 8 %. For the 1:100 dilution: 13 % absorbed + 14 % remaining in washed skin = 27 %. For the assessment of the in vitro rat and human skin penetration data, the use of the flux ratio was supported by several experts. One MS mentioned that using the flux ratio did not comply with the guidance document but would be acceptable in this case as the figures were nearly the same as for the absorption percentage. For the Euparen M 50 WG formulation, the differences in flux rates (rat/human) were 1.67 for the concentrate and 3.67 for the 1:100 dilution. The meeting supported the proposal of the RMS for a dermal absorption of 5 % for the concentrate and 7 % for the 1:100 dilution, on the basis of the in vivo study in the rat and the in vitro rat/human comparison with the formulated product.	absorption is 5 %. for the concentrate and 7 % for the 1:100 dilution. New open point 2.17 RMS to amend the list of end points: dermal absorption is 5 %. for the concentrate and 7 % for the 1:100 dilution.

No.	Subject	Discussion EPCO Expert Meeting	Conclusions EPCO Expert Meeting
	Open point 2.13: RMS to amend the DAR or to provide an addendum, regarding the measurement of operator exposure, to add more details of study design, methodology and GLP-issues. (Vol. 3, B.6.14.1. - see reporting table 2(28))	This open point refers to a comment from the UK where it was mentioned that there was not enough detailed information for the 3 operator exposure studies with tolylfluanid. The RMS stated that he had no updated addendum with more confirmatory data, which did not lead to a change of the conclusion. Due to new dermal absorption data the RMS has to recalculate the estimations. For concentrate the dermal absorption is now 5 % (formerly 1.3 %), for the dilution it changed from 13 % to 7 %. At the moment operator exposure is expected to stay clearly below the AOEL if PPE is used. The meeting concluded that the RMS has to provide more detailed information in an addendum. The estimations of operator and bystander exposure have to be recalculated using the new dermal absorption figures proposed during this meeting.	Open point still open RMS to provide more detailed information in an addendum. The estimations of operator and bystander exposure have to be recalculated using the new dermal absorption figures proposed during this meeting.
2.2	Notifier to submit additional data on worker exposure. (Vol. 3, B.6.14.4 - see reporting table 2(32))	The worker exposure was addressed in the addendum. Instead of doing a very conservative calculation (adding all amounts from leaves after every spraying) the notifier provided data on the decline of residues. The percentages for the decline were calculated and are based on this data. The RMS considers the exposure for re-entry workers as acceptable. The estimations of exposure cover the worst case of the supported uses (in grapes: 8 treatments = worst case). Even for cumulative spraying the values are acceptable, with gloves the highest value is 33 % of the AOEL and without gloves 66 % of the AOEL. The RMS stated that for this calculations the new dermal absorption figures have been used. Safe uses were identified for outdoor and indoor applications, and as there was no exceedance of the AOEL for workers, even without PPE.	Data requirement fulfilled. The worker exposure (for re-entry workers) is acceptable, even without wearing PPE it is below the AOEL.

No.	Subject	Discussion EPCO Expert Meeting	Conclusions EPCO Expert Meeting
2.3	Notifier to submit the ongoing study on the toxicological significance of different impurities. (Vol. 1, 2.1.4 – see reporting table 2(36))	The RMS explained that the data came just two days before addendum 4 had to be submitted, therefore it could not be evaluated. Most of the studies are for substance 1 (in tableC1 of addendum 5, Vol.4, Annex C), others for substance 2 and substance 3. Substance 1 explains some genotoxicity because the chromosome aberration test was positive, the micronucleus test with substance 1 was negative. The technical active substance is 960 g/l, and the company now changed the limits and increased the purity. The maximum level of substance 1 is now [redacted] g/kg (former specification [redacted] g/kg). The notifier stated that substance 2 and substance 3 chemically only differ little from tolylfluanid (2 chlorines, one fluorine), so they concluded that the toxicological properties should not differ very much. The RMS will check if this statement is reliable, otherwise more data on these impurities is needed. Conclusion: Data has been submitted, but not yet evaluated. Whereas the data package contains only substance 1, no data is available for the other two impurities. The notifier stated that due to the similarity to the active substance no further data is necessary. The data requirement still remains open, RMS has to present an addendum.	Data requirement still open. RMS to present the evaluation of the data in an addendum. Data has been submitted, but not yet evaluated. The data package contains only substance 1, no data is available for the other two impurities. The notifier stated that due to the similarity to the active substance no further data is necessary. If this is reliable, no further data is necessary.

No.	Subject	Discussion EPCO Expert Meeting	Conclusions EPCO Expert Meeting
2.4	A new chromosome aberration study *in vivo* in rodents (OECD Test Guideline 475) is required using relevant dose levels and with three sampling times between 6 and 48 h after dosage. (AII, B.5.4. - see reporting table at the end of section 2)	The *in vivo* bone marrow cytogenetic study using male mice has been performed with a purity of 96.2 %. It was questioned if this is still a valid specification. The amount of substance 1 (in tableC1 of addendum 5, Vol.4, Annex C) in the batch used is [redacted] g/kg which is lower than the former specification. Only one intraperitoneally administered dose of 16 mg/kg bw was used which was considered to be the MTD. No increase in the number of cells with chromosome aberrations has been observed. The study is acceptable, although only one dose level was used. The results are clearly negative. The experts considered the study as acceptable. At the tested dose no *in vivo* genotoxicity was observed and the data requirement was considered as fulfilled.	Data requirement fulfilled. The experts considered the study as acceptable, at the tested dose no *in vivo* genotoxicity was observed.
2.5	More data on possible reports of clinical cases, poisoning incidents, exposure of the general population and epidemiological studies must be supplied by doing extensive literature searches. Data on search terms and sources used in the literature searches must be reported. (AII, B.5.9. - see reporting table at the end of section 2)	The notifier has checked the relevant data bases, the results are included in addendum 4 (p. 26). According to this searches, no adverse effects of tolylfluanid or Euparen M to humans were reported in the literature. Due to the fact that the data bases *Medline* and *Toxline* were included in the search, the experts assume that no relevant information on clinical cases seems to be available. The search terms are acceptable. Therefore the meeting considered the data requirement as fulfilled. No cases of intoxication have been reported in literature.	Data requirement fulfilled. No cases of intoxication have been reported in literature.

No.	Subject	Discussion EPCO Expert Meeting	Conclusions EPCO Expert Meeting
	Comment from UK regarding fluoride generating pesticides	At the moment the discussion concentrates on single active compounds, but there are other active substances where fluoride is released and incorporated into bones and teeth. The MS asks if there is a model for providing a cumulative risk assessment? The meeting is of the opinion that this is an academic question. The main concerns focus on the risk assessment of the residues of the active substance, since the fluoride released from active substances in food commodities would normally contribute only little to the total amount of fluoride that can be safely ingested per day. It was proposed that EFSA should make a suggestion if this issue could be forwarded to the scientific panel. EFSA agreed to take this point into consideration but stressed that the panel is normally asked to focus on more specific questions.	

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
	Open point 2.1: The setting of NOAEL for short-term toxicity studies needs to be discussed in an expert meeting. (Vol. 3, B.6.3.2.2 - see reporting table 2(2))	-		EPCO 9 (06.-07.07.2004): Open point fulfilled. The overall NOAEL for the short term toxicity is 33 mg/kg bw/d for the 13-week dog study.
	Open point 2.2: The relevance of fluoride incorporation in bones needs to be discussed in an expert meeting. (Vol. 3, B.6.3.2.5 - see reporting table 2(4))	BCS statement on relevance of fluoride incorporation in bones is found in 'Assessment of fluoride uptake after prolonged administration of tolylfluanid' by K.G. Heimann, report no MO-02-009943 of 2000-04-04, revised, 2002-07-17 as well as in the dossier.	6.5.2004 The question will be addressed in an Addendum to the DAR, and later discussed at an expert meeting.	EPCO 9 (06.-07.07.2004): Open point fulfilled. For the one-year dog study the NOAEL for fluoride incorporation in bones and teeth is 80 mg/kg bw/d, the NOEL is 20 mg/kg bw/d.
	Open point 2.3: RMS to revise the List of Endpoints regarding the "Lowest relevant inhalation NOAEC / NOEC". (see reporting table 2(6))	-		EPCO 9 (06.-07.07.2004): 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
	Open point 2.4: The NOAELs from long-term toxicity and carcinogenicity studies and the relevance of fluoride incorporation in bones needs to be discussed in an expert meeting. (Vol. 3, B.6.5.3 - see reporting table 2(12))	BCS statement on carcinogenicity is found in 'Tolylfluanid – Thyroid effects' by K. G. Heimann report no MO-00-006460 of 2000-01-24 as well as in the dossier. BCS statement on relevance of fluoride incorporation in bones is found in 'Assessment of fluoride uptake after prolonged administration of tolylfluanid' by K.G. Heimann, report no MO-02-009943 of 2000-04-04, revised, 2002-07-17 as well as in the dossier	6.5.2004 The question will be addressed in an Addendum to the DAR, and later discussed at the expert meeting.	EPCO 9 (06.-07.07.2004): Open point fulfilled. The meeting agreed with the proposed NOAEL of 300 ppm (18 mg/kg bw/d) for the 2-year rat study.
	Open point 2.5: RMS to evaluate the new 2-generation study until the expert meeting. The relevant NOAEL in 2-generation reproduction rat study needs to be discussed in an expert meeting. (see reporting table 2(14))	-		EPCO 9 (06.-07.07.2004): Open point fulfilled. proposed NOEL is 200 ppm = 12 mg/kg bw/d. This NOEL is valid for systemic toxicity as well as for reproduction toxicity. See new open point 2.14
	Open point 2.6: RMS to evaluate the statement of the notifier, regarding the relevance of the three plant metabolites (WAK6550, WAK6676 and WAK6698), in an addendum. (Vol. 3, B.6.8 – see reporting table 2(15))	-		EPCO 9 (06.-07.07.2004): Open point fulfilled. All three plant metabolites are of low toxicological concern based on acute oral and in vitro genotoxicity data. Re-entry exposure is significantly lower than for the parent compound.

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 2.7: RMS to revise the list of end points regarding the last sentence relating to neurotoxicity. (see reporting table 2(16))	-		EPCO 9 (06.-07.07.2004): Open point fulfilled.
	Open point 2.8: The setting of the ADI needs to be discussed in an expert meeting. (Vol. 3, B.6.10.4 - see reporting table 2(17))	BCS proposal: ADI of 0.3 mg/kg bw/day based on the new two-generation study.	6.5.2004 The new 2-generation reproduction toxicity study in rat will be evaluated and presented in an Addendum to the DAR. The question of setting the ADI will be later discussed at the expert meeting.	EPCO 9 (06.-07.07.2004): Open point fulfilled. The meeting agreed to take the NOAEL from the new multigeneration rat study as basis for ADI of 0.1 mg/kg bw. See new open point 2.15
	Open point 2.9: RMS to amend the List of Endpoints concerning the rate and extent of absorption (Over 90% within 48 h, based on urinary and biliary excretion) (Vol 3, B.6.10.4 - see reporting table 2(19))	-		EPCO 9 (06.-07.07.2004): Open point fulfilled.
	Open point 2.10: The setting of the AOEL needs to be discussed in an expert meeting. (Vol 3, B.6.10.4 - see reporting table 2(20))	For the setting of the AOEL for tolylfluanid, BCS is of the opinion, that subchronic studies with dog as test species are relevant (NOAEL in dogs, subchronic, = 33 mg/kg bw/day; AOEL = 0.33 mg/kg bw/day).	6.5.2004 RMS agrees with Notifier's original proposal which is also presented in the current DAR version. The issue is to be discussed at an expert meeting.	EPCO 9 (06.-07.07.2004): Open point fulfilled. Proposed AOEL of 0.3 mg/kg bw/d was accepted by 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
	Open point 2.11: The setting of the ARfD needs to be discussed in an expert meeting. (see reporting table 2(23))	Based on the results of toxicological studies, the short-term dietary intake of tolylfluanid residues is not considered to present a risk to consumers by BCS. Furthermore, the malformation seen in the teratogenicity study rabbit are common and can occur spontaneously. There are clear hints of maternal toxicity (bw gain/food consumption decreased; hepatotoxicity). Therefore, the NOAEL of this study is not appropriate to set an ARfD. Thus, BCS does not consider it necessary to establish an ARfD.	6.5.2004 The question of setting the ARfD is to be discussed at an expert meeting, based also on data from a new 2-generation reproduction toxicity study in rats.	EPCO 9 (06.-07.07.2004): Open point fulfilled Proposal: ARfD of 0.25 mg/kg bw based on developmental toxicity study in rabbits using a safety factor of 100. See new open point 2.16
2.1	Notifier to present additional data on the *in vivo* study in rat. (Vol. 3, B.6.12.4 - see reporting table 2(24))	Information was supplied to RMS.	6.5.2004 The data on excretion kinetics in the rat *in vivo* dermal absorption study will be considered in an Addendum to the DAR. A new proposal for the potential dermal absorption in humans will be presented.	EPCO 9 (06.-07.07.2004): Data requirement 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
	Open point 2.12: The estimation of dermal absorption needs to be discussed in an expert meeting. (Vol. 3, B.6.12.4 - see reporting table 2(24))	BCS statement on the estimation of dermal absorption is found in 'Tolylfluanid – Response to RMS Finland on Member States comments to the Draft Assessment Report, Section 2 – Mammalian toxicology (B.6)' by H. Wicke, report no. MR-185/03 of 2003-11-19.	6.5.2004 A new proposal for the potential dermal absorption in humans will be presented in an Addendum to the DAR.	EPCO 9 (06.-07.07.2004): Open point fulfilled. The proposal for the dermal absorption is 5 %. for the concentrate and 7 % for the 1:100 dilution. See new open point 2.17
	Open point 2.13: RMS to amend the DAR or to provide an addendum, regarding the measurement of operator exposure, to add more details of study design, methodology and GLP-issues. (Vol. 3, B.6.14.1. - see reporting table 2(28))	-		EPCO 9 (06.-07.07.2004): Open point still open RMS to provide more detailed information in an addendum. The estimations of operator and bystander exposure have to be recalculated using the new dermal absorption figures proposed during this meeting.

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
2.2	Notifier to submit additional data on worker exposure. (Vol. 3, B.6.14.4 - see reporting table 2(32))	With respect to the potential accumulation of DFR, a new residue report is available: 'Residues of tolylfluanid on grass after spray application of Euparen M WG 50' by R. Barfknecht, report no. BAR/FS 012 of 2003-06-02. Furthermore, an assessment by BCS is found in 'Tolylfluanid – Response to RMS Finland on Member States comments to the Draft Assessment Report, Section 2 – Mammalian toxicology (B.6)' by H. Wicke, report no. MR-185/03 of 2003-11-19.	6.5.2004 The issue of accumulation of dry residues is going to be addressed in an Addendum to the DAR. Re-calculations of operator, worker and bystander exposure is suggested to be performed after expert discussions on setting the AOEL and dermal absorption values.	EPCO 9 (06.-07.07.2004): Data requirement fulfilled. The worker exposure (for re-entry workers) is acceptable, even without wearing PPE it is below the AOEL.
2.3	Notifier to submit the ongoing study on the toxicological significance of different impurities. (Vol. 1, 2.1.4 – see reporting table 2(36))	Assessment of the toxicological significance of different impurities will be available in May.	6.5.2004 The data on impurities will be assessed when received and the results presented in an Addendum to the DAR.	EPCO 9 (06.-07.07.2004): Data requirement still open. RMS to present the evaluation of the data in an addendum. Data has been submitted, but not yet evaluated. The data package contains only substance 1 (in tableC1 of addendum 5, Vol.4, Annex C), no data is available for the other two impurities. The notifier stated that due to the similarity to the active substance no further data is necessary. If this is reliable, no further data is necessary.

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
2.4	A new chromosome aberration study *in vivo* in rodents (OECD Test Guideline 475) is required using relevant dose levels and with three sampling times between 6 and 48 h after dosage. (AII, B.5.4. - see reporting table at the end of section 2)	Report on new chromosome aberration study *in vivo* in rodents will be submitted in April or - at the latest - in May.	6.5.2004 The study has been received. The results will be presented in an Addendum after evaluation of data.	EPCO 9 (06.-07.07.2004): Data requirement fulfilled. The experts considered the study as acceptable, at the tested dose no *in vivo* genotoxicity was observed.
2.5	More data on possible reports of clinical cases, poisoning incidents, exposure of the general population and epidemiological studies must be supplied by doing extensive literature searches. Data on search terms and sources used in the literature searches must be reported. (AII, B.5.9. - see reporting table at the end of section 2)	Document on literature search will be available in May.	6.5.2004 The data pertaining to data requirement point AII, B.5.9 will be evaluated when received and included in an Addendum to the DAR.	EPCO 9 (06.-07.07.2004): Data requirement fulfilled. No cases of intoxication have been reported in literature.
	New open point 2.14: RMS to amend the list of end point regarding the NOAEL of 200 ppm (12 mg/kg bw/d) for systemic toxicity as well as for reproduction toxicity. New open point was proposed in the EPCO 9 meeting.			EPCO 9 (06.-07.07.2004): Open point still 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 2.15 RMS to amend the list of end points regarding the ADI of 0.1 mg/kg bw. New open point was proposed in the EPCO 9 meeting.			EPCO 9 (06.-07.07.2004): Open point still open.
	New open point 2.16 RMS to amend the list of end points: ARfD of 0.25 mg/kg bw based on developmental toxicity study in rabbits using a safety factor of 100. New open point was proposed in the EPCO 9 meeting.			EPCO 9 (06.-07.07.2004): Open point still open.
	New open point 2.17 RMS to amend the list of end points: dermal absorption is 5 %. for the concentrate and 7 % for the 1:100 dilution. New open point was proposed in the EPCO 9 meeting.			EPCO 9 (06.-07.07.2004): Open point still open.

List of representative uses evaluated - Tolylfluanid / Euparen M WG 50

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)	% product min max (n)	water L/ha min max	kg as/ha min max		
Apples/Pears	*NE SE	Euparen M	F F	VENTIN VENTPI	WG	50	SPI / SRU	/	7 (15*) 3	7 – 14 7 - 14	0,15 – 0,2 -	max. 1500[a] max. 1500[a]	- 1.125 - 1.5	7 3	**Safe Use**
Grapes	*NE SE	Euparen M	F F	BOTRCI PLASVI	WG	50	SPI / SRU	/	8 3	10 – 14 8 – 19	0,225 – 0,4 -	max. 1600[b] 100 – 1000	up to 1.8 up to 2.0	35 21	**Safe Use**
Strawberries	NE SE	Euparen M	F F	BOTRCI SPHRMA	WG	50	SPI	/	3 3	8 – 12 7 – 10	/	300 – 2000 800 – 1000	2.5 1.25	7 3	**Safe Use**
Rasp- and Blackberries	NE	Euparen M	F F	BOTRCI SPHRMA	WG	50	SPI	/	4	8 – 10	/	500 – 1500	1.7	14	
Currants / Gooseberries	NE	Euparen M	F F	BOTRCI SPHRMA	WG	50	SPI	/	2	14	/	500 – 1000	1.25	14	
Tomatoes	NE SE -	Euparen M	F F G	ALTESO BOTRCI PHYTIN	WG	50	SPI	/	6 3 – 4 4 – 6	8 – 10 7 – 10 8 – 10	0,2 0,3 0,2	300 – 1200 1000 max. 1500[c]	up to 1.2 up to 1.5 up to 1.5	3 3 3	
Peppers	-	Euparen M	G	ALTESO BOTRCI	WG	50	SPI	/	3	7	0,2	max. 1500[d]	1.3	3	
Cucumber / Zucchini	NE -	Euparen M	F G	PSECU SPHRFU	WG	50	SPI	/	6 6	10 8 – 11	0,2 0,2	600 max. 1500[e]	0.6 up to 1.5	3 3	**Safe Use**

Melons	NE SE	Eupare n M	F F	ALTECU PSECU	WG	50	SPI	/	3 3	10 10	/	300 300	1.25 1.25	14 14	
Head Lettuce	NE SE	Eupare n M	F F	BREMLA BOTRCI	WG	50	SPI	/	6 3	5 10 – 17	/	600 1000	0.6 1.0	21 7	
Leeks	NE	Eupare n M	F	PHYTPO	WG	50	SPI	/	5	14	/	600	1.25	21	
Hops	*NE	Eupare n M	F	BOTRCI PSPEHU	WG	50	SPI / SRU	/	6*	8 – 24	0.2 -	1000 - 3000	up to 3.0	14	

Remarks:

"Safe Use" indicates the uses for which operator exposure, environmental fate and ecotoxicology risk assessments were conducted on EU level; additionally, reports on residue trials and dietary risk assessments were submitted for all other uses with the Annex II dossier

* Relevant to national (German) use pattern only

(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

[a]: SPI: max. 1500 l/ha with 500 l/ha/m; SRU: max. 500 l/ha with 167 l/ha/m
[b]: SPI: 1600 l/ha; SRU: 333 l/ha
[c]: SPI: max. 1500 l/ha with 1000 l/ha/m
[d]: SPI: max. 1500 l/ha with 1000 l/ha/m
[e]: SPI: max. 1500 l/ha with 750 l/ha/m

REPORT OF EPCO EXPERT MEETING 10

TOLYLFLUANID

Rapporteur Member State: Finland

Specific comments on the active substance in the section

3. Residues

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

1. Comments submitted for this meeting:

None.

2. Documents submitted for meeting:

Date	Supplier	File Name
19 February 2004	RMS/Finland	Tolylfluanid consultation report
26 March 2004	RMS/Finland	Tolylfluanid reporting table rev1-2
30 April 2004	RMS/Finland	Tolylfluanid evaluation table rev0-1
19 May 2004	RMS/Finland	Tolylfluanid end points
22 June 2004	RMS/Finland	Tolylfluanid addendum 4

3. Documents tabled at the meeting:

None.

The conclusions of the meeting were as follows:

4. **Data on preparations:** not discussed

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

6. **Recommended restrictions/conditions for use:** not discussed

Areas of concern: none

Appendix 1: EPCO discussion table: TOLYLFLUANID
Appendix 2: Evaluation table

Appendix 1: Discussion Table, Tolylfluanid (Ac/Fu)

3. Residues

No.	Subject	Discussion EPCO Expert Meeting	Conclusions EPCO Expert Meeting
	Open point 3.1: RMS to provide an addendum to the draft assessment report concerning the relevance of DMST as residue in animal's products. Subsequently the necessity of setting of a residue definition for animal products needs to be discussed in the residue expert meeting. (Vol. 3, B.7.3 - see reporting table 3(3))	The RMS presented the results of the addendum and stated that the expected DMST residues are below the level of LOQ in animal fat according to representative uses evaluated in the DAR and therefore this metabolite is not relevant. There is no significant accumulation of DMST. In plants both, tolylfluanid and DMST were detected. In animals only DMST was detected. Thus, the question rose whether tolylfluanid is the correct marker. The problem of finding tolylfluanid in raw agricultural products was discussed. In some trials DMST was detected in equal or higher amounts in plant material than tolylfluanid. In processed products DMST is the relevant major component. Therefore, DMST seems to be the better marker (e.g. DMST can be detected in wine, tolylfluanid not). One MS stated that in storage tolylfluanid decrease whereas DMST increase so that the sum of the tolylfluanid and DMST is always about the same (study of Brennecke in the DAR), which underlines the proposal that DMST should be included in the residue definition. This is only valid for wine. Furthermore, it should be checked whether the methods of analysis for DMST are sufficiently validated. The meeting proposed to change the residue definition for monitoring in plant that way that DMST has to be taken into account as sum of tolylfluanid and DMST expressed as tolylfluanid. But, no further metabolism studies are necessary. For risk assessment the same residue definition as given above applies. In grapes and wine furthermore 2- and 4-hydroxy compounds including glucosides have been detected. Therefore, in the risk assessment of grapes the 2- and 4-hydroxy compounds including glucosides have to be taken into account. The toxicological experts decided that these components are not toxicological relevant. Nevertheless, they are major metabolites in grapes (sum comprise for more than 50% of TRR). In the list of end points the critical residue data are shown for tolylfluanid (MRL) and for	Open point fulfilled. For products of animal origin only DMST should be relevant to enclose in the residue definition for monitoring and risk assessment. For beef cattle the residues in feeding item are above the trigger value, but no residues are expected in products of animal origin on the basis of the representative uses. The meeting agrees that for future developments methods of analysis for DMST in products of animal origin and a feeding study may be required.

No.	Subject	Discussion EPCO Expert Meeting	Conclusions EPCO Expert Meeting
	continued Open point 3.1: RMS to provide an addendum to the draft assessment report concerning the relevance of DMST as residue in animal's products. Subsequently the necessity of setting of a residue definition for animal products needs to be discussed in the residue expert. (Vol. 3, B.7.3 - see reporting table 3(3))	tolylfluanid plus DMST (STMR). The data have to be amended according to the residue definition. For beef cattle the residues in feeding item are above the trigger value. For products of animal origin only DMST should be relevant for monitoring and the risk assessment. At the moment no residues are expected in products of animal origin, but the meeting agrees that for future developments methods of analysis for DMST in products of animal origin and a feeding study maybe required.	
	Open point 3.2 (See open points 2.6 and 2.9) RMS to provide a revised intake calculation if ADI should be changed. (Vol. 3, B.7.16.1 - see reporting table 3(29))	Depends on the outcome of the EPCO 9 meeting. After the end of EPCO 10 meeting the toxicological experts in EPCO 9 have established a revised (lower) ADI of 0.1 mg/kg.	Open point still open.

No.	Subject	Discussion EPCO Expert Meeting	Conclusions EPCO Expert Meeting
	Open point 3.3 (See open point 2.1) RMS to provide an acute risk assessment if an ARfD should be derived. (Vol. 3, B.7.16.2 - see reporting table 3(30))	Depends on the outcome of the EPCO 9 meeting. After the end of EPCO 10 meeting the toxicological experts in EPCO 9 agreed on an ARfD of 0.25 mg/kg.	Open point still open.
	Open point 3.4: The parent compound is degraded rapidly and therefore DMST should be included in the plant residue definition for monitoring purposes. This point should then be discussed in an expert meeting. (see reporting table at the end of section 3)	See discussion at open point 3.1.	Open point fulfilled. The meeting proposed to change the residue definition for monitoring in plant that way that DMST has to be taken into account as sum of tolylfluanid and DMST expressed as tolylfluanid. New Open point 3.5: RMS to check whether the methods of analysis for DMST in plant matrices are sufficiently validated.

No.	Subject	Discussion EPCO Expert Meeting	Conclusions EPCO Expert Meeting
	New Open point 3.6: RMS to revise the list of end points in accordance with the agreements of the meeting	• Metabolism in plants/ Plant residue definition for monitoring: To be amended into "sum of tolylfluanid and DMST expressed as tolylfluanid". • Metabolism in plants/Conversion factor (monitoring to risk assessment): To be added where applicable • Metabolism in livestock/ Animal residue definition for monitoring and risk assessment: It should be DMST • Stability of residues: It should be clearly stated that in wine in contrast to DMST tolylfluanid is not stable. • Residues from livestock feeding studies: This issue should be changed to DMST instead of tolylfluanid. • Summary of critical residues data: The list has to be revised according to the residue definition. • Consumer risk assessment: • Processing factors/Transfer factor: The column tolylfluanid can be deleted. • Proposed MRLs: Have to be revised in view of the changed residue definition	Open point still open.

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-Peer Review Meeting / Conclusions of the Evaluation Meeting
				Section 3 Data requirements: 0 Open points: 4
	Open point 3.1: RMS to provide an addendum to the draft assessment report concerning the relevance of DMST as residue in animal's products. Subsequently the necessity of setting of a residue definition for animal products needs to be discussed in the residue expert. (Vol. 3, B.7.3 - see reporting table 3(3))	Relevance of DMST as residue in animal's products is addressed in the dossier: AII, 6.4.1, page 136ff.	6.5.2004 DMST occurred mainly in the fat of the treated goat. The highest level of DMST in fat (out of three analyses) was 0.26 mg/kg in a metabolism study with a dose level of 10 mg/kg bw/day. As the realistic intake levels for tolylfluanid in goat through feed are expected to be about 45 times lower than in the metabolism study, the expected level of DMST in fat in a feeding study would be 0.006 mg/kg. This level may be considered low, and does not indicate accumulation of DMST in fat of goats. An Addendum addressing this issue will be provided before the expert meeting.	EPCO 10 (06.-07.07.2004): Open point fulfilled. For products of animal origin only DMST should be relevant to enclose in the residue definition for monitoring and risk assessment. For beef cattle the residues in feeding item are above the trigger value, but no residues are expected in products of animal origin on the basis of the representative uses. The meeting agrees that for future developments methods of analysis for DMST in products of animal origin and a feeding study may be required.

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO-Peer Review Meeting / Conclusions of the Evaluation Meeting
	Open point 3.2 (See open points 2.6 and 2.9) RMS to provide a revised intake calculation if ADI should be changed. (Vol. 3, B.7.16.1 - see reporting table 3(29))	-	6.5.2004 Comment depends on the expert meeting (tox) decision on the ADI	EPCO 10 (06.-07.07.2004): Open point still open.
	Open point 3.3 (See open point 2.1) RMS to provide an acute risk assessment if an ARfD should be derived. (Vol. 3, B.7.16.2 - see reporting table 3(30))	-	6.5.2004 Comment depends on the expert meeting (tox) decision on the ARfD	EPCO 10 (06.-07.07.2004): Open point still 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-Peer Review Meeting / Conclusions of the Evaluation Meeting
	Open point 3.4: The parent compound is degraded rapidly and therefore DMST should be included in the plant residue definition for monitoring purposes. This point should then be discussed in an expert meeting. (see reporting table at the end of section 3)	For reasons given briefly below, BCS is not of the opinion that DMST needs to be included in the plant residue definition for monitoring purposes (for more detail see dossier: AII; 6.7.1, pages 173 -175) The residue definition of tolylfluanid alone for monitoring purposes is in good accordance with guideline requirements. The definition is justified based on data from toxicology and metabolism studies and is most convenient for the practical handling in monitoring laboratories. The amount of tolylfluanid residues found in/on MRL relevant commodities is sufficient for analysis purposes (e.g. STMRs range from 0.37 - 3.74 mg/kg for 10 of 12 crops/crop groups supported in AII, chapter 6; additionally there are melons with an STMR of 0.05 mg/kg, and hops with 24.65 mg/kg). Furthermore the definition of parent alone corresponds to the already established definition relevant in most countries (EU and others), in which tolylfluanid is registered. This holds also true for the US (import tolerances) and JMPR (Codex MRLs). With respect to refined dietary risk assessments, the residue definition should include both parent compound and DMST as well as two further metabolites in the special case of grapes.	In plant metabolism studies the amounts of DMST were 0.04 – 1.13 mg/kg, corresponding to 3.4 – 14.9 % of TRR. Highest amounts were found in metabolism study with strawberries, 14.9 % of TRR. According to residue trials, the amount of DMST was significantly less than of tolylfluanid in all other crops except melons and strawberries. The residues of tolylfluanid and DMST were on equal levels in melons, however at levels about the LOQ of 0.02 mg/kg. In strawberries, the amount of DMST were generally clearly less than of tolylfluanid, but were at equal levels with tolylfluanid in few cases. This is considered to be due to the fact of that picked strawberries tend to produce sap, in which tolylfluanid degrades to DMST. The studies of nature of the residue indicated that tolylfluanid degrades well by hydrolysis and the metabolite DMST is formed. However, the studies on the effects on residue levels demonstrated that the levels of the sum of tolylfluanid and metabolites, relevant for risk assessment, clearly decrease during processing in most commodities relevant for human consumption. Concentration was observed only in wine, raisin and tomato paste. The DMST is not considered to be toxicologically significant.	EPCO 10 (06.-07.07.2004): Open point fulfilled. The meeting proposed to change the residue definition for monitoring in plant that way that DMST has to be taken into account as sum of tolylfluanid and DMST expressed as tolylfluanid.
	continued Open point 3.4: The parent compound is degraded rapidly and			

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-Peer Review Meeting / Conclusions of the Evaluation Meeting
	Open point 3.5: RMS to check whether the methods of analysis for DMST in plant matrices are sufficiently validated. This new open point was proposed at the EPCO 10 meeting.			EPCO 10 (06.-07.07.2004): Open point still open.
	Open point 3.6: RMS to revise the list of end points in accordance with the agreements of the EPCO 10 meeting (Metabolism in plant and livestock; Stability of residues; Residues from livestock feeding studies; Summary of critical residues data; Consumer risk assessment; Processing factors; Proposed MRLs) This new open point was proposed at the EPCO 10 meeting.			EPCO 10 (06.-07.07.2004): Open point still open.

Concerning the list of endpoints EFSA is recommending the following:

-It is noted that the table of intended uses has changed. For apples/pears (N-EU) the number of applications was reduced from 15 to 7. This should be highlighted in the revised list of endpoints. Owing to this the cGAP and the relevant residue data for pome fruit have changed.

-Because the residue definition for monitoring is different from that for risk assessment an indication/statement concerning the application of conversion factors should be provided.

Conversion factor –**plant** (monitoring to risk assessment)

DMST x 1.62 = parent compound equivalents (pce.)
4-Hydroxymethyl-DMST x 1.51 = pce
2-Hydroxyphenly-DMST x 1.51 = pce

Tolylfluanid = 347,3 g/mol,
DMST = 214.3 g/mol,
4-Hydroxymethyl-DMST = 230.3 g/mol,
2-Hydroxyphenly-DMST= 230.3 g/mol

Conversion factor **livestock**(monitoring to risk assessment)

4-(Dimethyl-aminosulfonylamino)benzoic acid x 1.42 = pce,
4-(Dimethyl-aminosulfonylamino)hippuric acid x 1.15 = pce

Tolylfluanid = 347.3 g/mol
4-(Dimethyl-aminosulfonylamino)benzoic acid = 244.27 g/mol,
4-(Dimethyl-aminosulfonylamino)hippuric acid = 301.32 g/mol

-The change of the Summary table with the critical residue data refers to a lack of information and transparency. The STMR values are detached from the provided residue data in the table.

-Further on it is noted that values were deleted as outliers in 30% of the provided residue data sets. This high rate is not plausible anymore. It is clearly stated in the Guidance Document 7039/VI/95 that the elimination of outliers should be considered with extreme caution particularly with small data sets. Otherwise the loosing of real residue values can easily occur.
BCS will provide a statement on submitted residue data in May.

List of representative uses evaluated - Tolylfluanid / Euparen M WG 50

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)	% product min max (n)	water L/ha min max	kg as/ha min max		
Apples/Pears	*NE SE	Euparen M	F F	VENTIN VENTPI	WG	50	SPI / SRU	/	7 (15*) 3	7 – 14 7 - 14	0,15 – 0,2 -	max. 1500[a] max. 1500[a]	- 1.125 - 1.5	7 3	**Safe Use**
Grapes	*NE SE	Euparen M	F F	BOTRCI PLASVI	WG	50	SPI / SRU	/	8 3	10 – 14 8 – 19	0,225 – 0,4 -	max. 1600[b] 100 – 1000	up to 1.8 up to 2.0	35 21	**Safe Use**
Strawberries	NE SE	Euparen M	F F	BOTRCI SPHRMA	WG	50	SPI	/	3 3	8 – 12 7 – 10	/	300 – 2000 800 – 1000	2.5 1.25	7 3	**Safe Use**
Rasp- and Blackberries	NE	Euparen M	F F	BOTRCI SPHRMA	WG	50	SPI	/	4	8 – 10	/	500 – 1500	1.7	14	
Currants / Gooseberries	NE	Euparen M	F F	BOTRCI SPHRMA	WG	50	SPI	/	2	14	/	500 – 1000	1.25	14	
Tomatoes	NE SE -	Euparen M	F F G	ALTESO BOTRCI PHYTIN	WG	50	SPI	/	6 3 – 4 4 – 6	8 – 10 7 – 10 8 – 10	0,2 0,3 0,2	300 – 1200 1000 max. 1500[c]	up to 1.2 up to 1.5 up to 1.5	3 3 3	
Peppers	-	Euparen M	G	ALTESO BOTRCI	WG	50	SPI	/	3	7	0,2	max. 1500[d]	1.3	3	
Cucumber / Zucchini	NE -	Euparen M	F G	PSECU SPHRFU	WG	50	SPI	/	6 6	10 8 – 11	0,2 0,2	600 max. 1500[e]	0.6 up to 1.5	3 3	**Safe Use**

Melons	NE SE	Eupare n M	F F	ALTECU PSECU	WG	50	SPI	/	3 3	10 10	/	300 300	1.25 1.25	14 14	
Head Lettuce	NE SE	Eupare n M	F F	BREMLA BOTRCI	WG	50	SPI	/	6 3	5 10 – 17	/	600 1000	0.6 1.0	21 7	
Leeks	NE	Eupare n M	F	PHYTPO	WG	50	SPI	/	5	14	/	600	1.25	21	
Hops	*NE	Eupare n M	F	BOTRCI PSPEHU	WG	50	SPI / SRU	/	6*	8 – 24	0.2 -	1000 - 3000	up to 3.0	14	

Remarks:

"Safe Use" indicates the uses for which operator exposure, environmental fate and ecotoxicology risk assessments were conducted on EU level; additionally, reports on residue trials and dietary risk assessments were submitted for all other uses with the Annex II dossier

* Relevant to national (German) use pattern only

(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

[a]: SPI: max. 1500 l/ha with 500 l/ha/m; SRU: max. 500 l/ha with 167 l/ha/m

[b]: SPI: 1600 l/ha; SRU: 333 l/ha

[c]: SPI: max. 1500 l/ha with 1000 l/ha/m

[d]: SPI: max. 1500 l/ha with 1000 l/ha/m

[e]: SPI: max. 1500 l/ha with 750 l/ha/m