PEER REVIEW REPORT ON **TOLYLFLUANID** 04.04.2005

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1. Physical and chemical Properties

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	Section 1 Data requirements: 2 Open points: 4			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. 08.11.2004 New study on analytical profile of batches (taking into account specification and validation of analytical methods for impurities) was submitted and acceptably validated. Data is presented in Addendum 5. Data requirement fulfilled.	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). Evaluation Meeting (09.-10.02.2005): Study has been submitted and evaluated by the RMS in an addendum. RMS and EFSA are of the opinion that this data requirement is fulfilled. In the EFSA conclusion it will be highlighted that this issue has not been peer reviewed. Data requirement fulfilled.
1.2	Confirmatory method for the	Further identification of impurities will	30.4.2004	EPCO 6 (15.-16.06.2004):

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	impurities is required. (Vol. 4, C1.4 – see reporting table 1(5))	be submitted in May.	Notifier will submit a confirmatory method for the impurities in May. Acceptable. Data have to be awaited. 08.11.2004 The submitted HPLC-DAD- method is regarded as highly specific (guideline). Confirmatory method is not necessary.	Data requirement can be covered by the data requirement 1.1. Evaluation Meeting (09.-10.02.2005): Study has been submitted and evaluated by the RMS in an addendum. RMS and EFSA are the opinion that this data requirement is fulfilled. In the EFSA conclusion it will be highlighted that this issue has not been peer reviewed. Data requirement fulfilled.
	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.		08.11.2004 See point 1.2: Confirmatory method is not necessary, because the submitted HPLC-DAD- method is highly specific. Open point fulfilled.	EPCO 6 (15.-16.06.2004): Open point still open. Evaluation Meeting (09.-10.02.2005): Open point fulfilled.

section 1 - Identity, Physical and Chemical properties, Details of uses and further information, Methods of analysis

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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. 08.11.2004 See Post-meeting note below.	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.		08.11.2004 The submitted method (presented in addendum 3) was valid for the determination of residues of tolylfluanid in soil. The submitted method (presented in addendum 5) was valid for the determination of residues of DMST metabolite in soil. Data requirement fulfilled.	

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	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. 08.11.2004 See point 1.4	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.		08.11.2004 The new residue method for water was acceptably validated for both surface and drinking water. Data presented in Addendum 5. Data requirement fulfilled	EPCO 6 (15.-16.06.2004): Data requirement still open. Evaluation Meeting (09.-10.02.2005): Data has been submitted and evaluated by the RMS in an addendum. RMS and EFSA are the opinion that this Data requirement is fulfilled. In the EFSA conclusion it will be highlighted that this issue has not been peer reviewed. Data requirement fulfilled.

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	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.		08.11.2004 List of representative uses revised. Open point fulfilled.	EPCO 6 (15.-16.06.2004): Open point still open. Evaluation Meeting (09.-10.02.2005): Open point fulfilled.
	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.		17.06.2004 The list of end points revised. 08.11.2004 The list of end points revised. Open point fulfilled.	EPCO 6 (15.-16.06.2004): Open point still open. Evaluation Meeting (09.-10.02.2005): Open point fulfilled.

section 1 - Identity, Physical and Chemical properties, Details of uses and further information, Methods of analysis

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	Open point 1.5: RMS to revise the list of end points: FAO specifications The value of 960 g/kg +/- 20 should be mentioned.		17.06.2004 The list of end points revised. 08.11.2004 The list of end points revised. Open point fulfilled.	EPCO 6 (15.-16.06.2004): Open point still open. Evaluation Meeting (09.-10.02.2005): Open point fulfilled.

2. Mammalian Toxicology

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting/ Conclusions of the Evaluation Meeting
	Section 2 Data requirements: 1 Open points: 5			Section 2 Data requirements: 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))	-	8.11.2004 See Addendum 4 from 22 June 2004	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. 8.11.2004 See Addendum 4 from 22 June 2004	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.

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	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. 8.11.2004 See Addendum 4 from 22 June 2004	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))	-	8.11.2004 See Addendum 4 from 22 June 2004	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))	-	8.11.2004 See Addendum 4 from 22 June 2004	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.

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	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. 8.11.2004 See Addendum 4 from 22 June 2004	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.

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 2.10: 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.
	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.

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2.1	*continued* Notifier to present additional data on the *in vivo* study in rat. (Vol. 3, B.6.12.4 - see reporting table 2(24))		8.11.2004 See Addendum 4 from 22 June 2004.	
	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. 8.11.2004 See Addendum 4 from 22 June 2004.	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))	-	8.11.2004 Data will be presented in Addendum 5	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. Evaluation Meeting (09.-10.02.2005): Data has been provided in an addendum. Open point fulfilled.

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	continued 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))			In the EFSA conclusion it will be highlighted that this addendum has not been peer reviewed.
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. 8.11.2004 See Addendum 4 from 22 June 2004.	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.

section 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
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. 8.11.2004 The data has been evaluated. Toxicological studies and structure-active analyses using DEREK indicate that the toxicological significance of the impurities and the parent substance are similar. The evaluation is presented in Addendum 5, Volume 4, Annex C, and is therefore only available from RMS or EFSA.	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 DMST, 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. Evaluation Meeting (09.-10.02.2005): Data has been evaluated by the RMS in an addendum. RMS is on the opinion that the data requirement is fulfilled. In the EFSA conclusion it will be highlighted that this issue has not been peer reviewed. Data requirement fulfilled.

section 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
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. 8.11.2004 See Addendum 4 from 22 June 2004.	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. 8.11.2004 See Addendum 4 from 22 June 2004.	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.		8.11.2004 List of end points has been amended.	EPCO 9 (06.-07.07.2004): Open point still open. Evaluation Meeting (09.-10.02.2005): Open point fulfilled.

section 2 - Mammalian toxicology

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	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.		8.11.2004 List of end points has been amended.	EPCO 9 (06.-07.07.2004): Open point still open. Evaluation Meeting (09.-10.02.2005): Open point fulfilled.
	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.		8.11.2004 List of end points has been amended.	EPCO 9 (06.-07.07.2004): Open point still open. Evaluation Meeting (09.-10.02.2005): Open point fulfilled.
	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.		8.11.2004 List of end points has been amended.	EPCO 9 (06.-07.07.2004): Open point still open. Evaluation Meeting (09.-10.02.2005): Open point fulfilled.

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			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.

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	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 8.11.2004 A revised intake calculation is presented in Addendum to tolylfluanid.	EPCO 10 (06.-07.07.2004): Open point still open. Evaluation Meeting (09.-10.02.2005): Open point fulfilled.
	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 8.11.2004 An acute risk assessment is presented in Addendum to tolylfluanid	EPCO 10 (06.-07.07.2004): Open point still open. Evaluation Meeting (09.-10.02.2005): Open point fulfilled.
	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	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	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.

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	continued 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.	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.	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. Thus RMS agrees with the notifier that the plant residue definition for monitoring purposes should be parent only.	

section 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
	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.		08.11.2004 Methods of analysis in plant matrices are presented in the DAR in point B.5.2. DFG S 19 and DFG S 8 methods were validated only for parent compounds. The point B.5.2, however, contains a multitude of methods validated for parent and DMST metabolite for various plants. It would be the task of the notifier to decide whether to validate DFG methods also for DMST metabolite or to check the other submitted methods and conduct necessary further minor validations (e.g. ILV and confirmation methods) so that the requirements are met. The RMS wants still retain the original residue definition referring parent only for monitoring purposes and the sum of tolylfluanid and DMST for the dietary risk assessment due to the following reasons: a)The residue definition of parent compound only is in compliance with current guidelines b)The establishment of MRLs in processed commodities has not been decided on within the EC and may concern commodities only which the processing procedure requires concentration and not dilution steps	EPCO 10 (06.-07.07.2004): Open point still open. Evaluation Meeting (09.-10.02.2005): Open point closed. EFSA is of the opinion that the point is fulfilled whereas the RMS is of the opinion that the point is not fulfilled. The concerns of the RMS will be pointed out in the EFSA conclusion.

section 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
	continued 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.		c)The residue definition for the purpose of dietary risk assessment already includes DMST d) The residue definition for tolylfluanid for enforcement purposed is set as parent compound only e.g. by the Codex Alimentarius, US EPA, Australian APVMA and in many of the EU Member States.	
	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.		8.11.2004 RMS has revised the list of end points.	EPCO 10 (06.-07.07.2004): Open point still open. Evaluation Meeting (09.-10.02.2005): Open point fulfilled.

section 4 – Environmental fate an behaviour

4. Environmental fate and behaviour

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO-Peer Review Meeting / Conclusions of the evaluation group
	Section 4 Data requirements: 0 Open points: 65			Section 4 Data requirements: 0 Open points: 65
	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))	-	30.4.2004: The addendum will be provided before the expert meeting. 8.11.2004: The notifier has recalculated the PECsoil values using the worst case DT50 values. The recalculated values have been included in the addendum and in the list of end points.	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 Evaluation Meeting (09.-10.02.2005): Open point fulfilled.
	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.	30.4.2004: New information will be included in the addendum.	EPCO 7 (22. – 23.06.2004): Open point closed.

section 4 – Environmental fate an 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
	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.	30.4.2004: New information will be included in the addendum 8.11.2004: The notifier has recalculated the PECsw values using the worst case DT50 values. The recalculated values have been included in the addendum and in the list of end points.	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. Evaluation Meeting (09.-10.02.2005): Open point fulfilled.
	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		8.11.2004: The notifier has recalculated the TER values on the basis of the new PECsw values. The recalculated values have been included in the addendum and in the list of end points.	EPCO 7 (22. – 23.06.2004): Open point still open. Evaluation Meeting (09.-10.02.2005): Open point fulfilled.

section 4 – Environmental fate an 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
	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		8.11.2004: The list of end points has been amended.	EPCO 7 (22. – 23.06.2004): Open point still open. Evaluation Meeting (09.-10.02.2005): Open point fulfilled.
	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		8.11.2004: The list of end points has been amended.	EPCO 7 (22. – 23.06.2004): Open point still open. Evaluation Meeting (09.-10.02.2005): Open point fulfilled.
	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	30.4.2004: RMS agrees with the notifier.	EPCO 7 (22. – 23.06.2004): Open point fulfilled.

section 4 – Environmental fate an 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
	continued 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))	coefficient of the kinetic curves, experimental data for all 4 soils clearly show a DT50 ≤1 day.		
	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))	-	30.4.2004: The list of end points has been amended.	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))	-	30.4.2004: The list of end points has been amended.	EPCO 7 (22. – 23.06.2004): Open point fulfilled.

5. Ecotoxicology

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO-Peer Review Meeting / Conclusions of the evaluation group
	Section 5 Data requirements: 1 Open points: 7			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))	-	8.11.2004: The notifier provided a refined risk assessment in August 2004 supporting the PT of < 0.6. This data, however, was submitted after the EPCO 8 meeting and according to EFSA cannot be taken into account for the risk refinement. Therefore the risks are calculated using the PT of 1 in a revised addendum. In connection with the assessment of secondary poisoning of birds it is now stated in an addendum which distance between application area and water body was taken into account.	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. Evaluation Meeting (09.-10.02.2005): Open point fulfilled.

section 5 – Ecotoxicology

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO-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))	-	8.11.2004: The NOEC for mammals is amended in the list of endpoints. A revised long term risk assessment for mammals based on a NOAEL of 12 (the decision of EPCO 9) instead of 9 mg/kg bw is updated in an addendum. Open point is still open, because there is long-term risk for mammals.	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 Evaluation Meeting (09.-10.02.2005): RMS provided the addendum. Open point fulfilled.

section 5 – Ecotoxicology

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO-Peer Review Meeting / Conclusions of the evaluation group
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.
	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. 8.11.2004: For the outdoor microcosm study with rainbow trout, an uncertaintity factor of 5 was agreed in the EPCO 8 meeting. It is inserted in the list of endpoints. The NOEC HC5 value is deleted from the list of endpoints.	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. Evaluation Meeting (09.-10.02.2005): Open point fulfilled.
	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	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). 8.11.2004:	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

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
	continued 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))	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).	The endpoint of 99 µg/L with the uncertaintity factor of 3-5 is included in the list of endpoints.	of 99 µg/L with an uncertainty factor of 3-5) Open point was amended at the EPCO 8 Meeting. Evaluation Meeting (09.-10.02.2005): Open point fulfilled.
5.2	Notifier to refine the risk assessment for mammals Data requirement was proposed in the EPCO 8 meeting.		8.11.2004: Open point is still open.	EPCO 8 (22.-23.06.2004): Data requirement still open. Evaluation Meeting (09.-10.02.2005): 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.		8.11.2004: Safe uses supported for cucumber and zucchini are greenhouse use only.	EPCO 8 (22.-23.06.2004): Open point still open. Evaluation Meeting (09.-10.02.2005): Open point fulfilled.

section 5 – Ecotoxicology

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO-Peer Review Meeting / Conclusions of the evaluation group
	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.		8.11.2004: Classification and labelling is included in the list of endpoints.	EPCO 8 (22.-23.06.2004): Open point still open. Evaluation Meeting (09.-10.02.2005): Open point fulfilled.
	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.		8.11.2004: PEC_{sw} were recalculated (but there was no new water/sediment study!) and new TERs were accordingly updated when necessary and presented in the addendum.	EPCO 8 (22.-23.06.2004): Open point still open. Evaluation Meeting (09.-10.02.2005): Open point fulfilled.

List of representative uses
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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)	kg as/ha min max (n)	water L/ha min max	kg as/ha min max		
Apples/Pears	NE SE	Euparen M	F F	VENTIN VENTPI	WG	500	SPI / SRU	/	7 3	7 – 14 7 - 14	0.15 – 0.2 -	max. 1500[a] max. 1500 [a]	- 1.125 - 1.5	7 3	
Grapes	NE SE	Euparen M	F F	BOTRCI PLASVI	WG	500	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	
Strawberries	NE SE	Euparen M	F F	BOTRCI SPHRMA	WG	500	SPI	/	3 3	8 – 12 7 – 10	/	300 – 2000 800 – 1000	2.5 1.25	7 3	
Rasp- and Blackberries	NE	Euparen M	F F	BOTRCI SPHRMA	WG	500	SPI	/	4	8 – 10	/	500 – 1500	1.7	14	
Currants / Gooseberries	NE	Euparen M	F F	BOTRCI SPHRMA	WG	500	SPI	/	2	14	/	500 – 1000	1.25	14	
Tomatoes	NE SE -	Euparen M	F F G	ALTESO BOTRCI PHYTIN	WG	500	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	500	SPI	/	3	7	0.2	max. 1500[d]	1.3	3	
Cucumber / Zucchini	NE -	Euparen M	 G	PSECU SPHRFU	WG	500	SPI	/	6 6	10 8 – 11	0.2 0.2	600 max. 1500[e]	0.6 up to 1.5	3 3	
Melons	NE SE	Euparen M	F F	ALTECU PSECU	WG	500	SPI	/	3 3	10 10	/	300 300	1.25 1.25	14 14	
Head Lettuce	NE SE	Euparen M	F F	BREMLA BOTRCI	WG	500	SPI	/	6 3	5 10 – 17	/	600 1000	0.6 1.0	21 7	
Leeks	NE	Euparen M	F	PHYTPO	WG	500	SPI	/	5	14	/	600	1.25	21	

* Uses for which the risk assessment can not be concluded are marked grey.

List of representative uses

Hops	*NE	Euparen M	F	BOTRCI PSPEHU	WG	500	SPI / SRU	/	6	8 – 24	0.2 -	1000 - 3000	up to 3.0	14	

Remarks:

(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) All abbreviations used must be explained
(g) Method, *e.g.* high volume spraying, low volume spraying, spreading, dusting, drench
(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
(n) product concentration of spray liquid

SPI = spraying SRU = low volume spraying

[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