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1. Physical/Chemical Properties; Details of Uses and Further Information; Methods of Analysis

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
1(1)	Vol. 4, C.1.3.11 Technical specification	UK: CONFIDENTIAL INFORMATION – FAXED SEPARATELY TO RMS/EFSA	(ii): The notifier will submit a new analytical profile of batches.	Open point 1.1: - RMS to evaluate the new study on analytical profile of batches (taking into account specification and analytical method for impurities validation) and include this evaluation in an Addendum (B.1.11) - RMS to check validation for the analytical method for impurities in the new analysis of batches and include in the addendum Evaluation Meeting (12.03.2004): Notifier want to confirm the identity of impurities (data will be available within 1-2 months). Open point changed into data requirement **Data requirement** **Notifier to submit new study on analytical profile of batches (taking into account specification and validation of analytical methods for impurities)**

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1(2)	Vol. 4, C1.2, Batch profile	NL: The batches are from 1995. This is 8 years ago, and maybe they are no longer representative for the current production. Are there also new batches to confirm that the production still is the same? BAY: Certificates of analysis of 2001 show the same good quality; further new analytical data of production control are ordered.	(ii): The notifier will submit a new analytical profile of batches.	See open point 1.1.
1(3)	Vol. 4, C1.2, Specifications a.s.	NL: Please fill the complete table C2. with all the specifications. The specification for impurity 1, 2, 4 and 5 are too high compared to the content in the batches and should be lowered. BAY: New analytical data of production control are ordered to check the limits.	(ii): Table C2 will be completed, data is also available in Annex C, point 1.3.10. The notifier will submit a new analytical profile of batches.	See open point 1.1.
1(4)	Vol. 4, C1.4, Analytical methods impurities	NL: How is the accuracy determined? If this was not done by standard addition additional validation is required. BAY: Analyses of 5 samples of laboratory prepared (spiked) synthetic active ingredient containing known weight of analyte were used to check recovery.	(ii): Spiked samples were acceptably determined.	See open point 1.1.

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1(5)	Vol. 4, C1.4, Analytical methods impurities	NL: There is no indication that the identity of the impurities are confirmed. Also there is no confirmatory method submitted. Or the identity should be confirmed (using HPLC-MSMS with the same eluent and column) or a confirmatory method should be submitted. BAY: The identity is done by peak identification of individual impurities. The chromatographic data ensure the proper identification of the individual impurities reported in the material accountability study (see MA-study)	(ii): Identity of the impurities are not confirmed in an acceptable way. Confirmatory method for the impurities is required.	**Data requirement 1.1: Confirmatory method for the impurities is required.** Evaluation Meeting (12.03.2004): See open point 1.1. Notifier will confirm the identity of impurities (data will be available within 1-2 months). Data requirement still open.
1(6)	Vol. 3, B.2.1.14, Hydrolysis	NL: The purity of the active substance is missing BAY: The purity is 99.0 %.	(ii): This point is always fully evaluated in point B.8.4.1.1 in the DAR (purity given).	Addressed RMS to amend this point in the DAR. (B.2.9.1) if needed.
1(7)	Vol. 3, B2.1.21, Explosive properties	NL: Is this determined or by statement? If statement please give statement. BAY: Test according to EEC method A 14.	(ii): See point B.2.1.21 column Method (EEC method A 14) in the DAR. Method given.	Addressed.

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1(8)	Vol. 3, B.2.2.32, Chemical compatibility	NL: If there is no evidence that the product is compatible I suggest to remove this text and leave it open. BAY: No report available, only statement based on expert knowledge.	(ii): Statement is acceptable in this point.	Addressed RMS to amend the DAR to clarify that compatibility has not been actually tested but the statement based in expert knowledge is found acceptable.
1(9)	Vol. 3, B5.2.1, Residue methods	NL: Not all the methods are acceptable as monitoring methods (e.g. Vogeler 1967). For all those methods no data protection can be claimed. RMS is asked to see which methods are acceptable and to remove all the data protection form the other methods. BAY: In Vol.3 Annex B, B.5.2 (p.38) it is stated, which methods can be used for enforcement purposes. From all those methods data protection can be removed.	(ii): Data protection will be checked in the DAR.	Addressed. RMS to check data protection in the DAR and amend accordingly. (B.4.2)

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1(10)	Vol. 3, B5.2.1, Residue methods plants	NL: The residue definition for monitoring in plants is not clear. Is it only the parent (as in the list of endpoints) or with the metabolite DMST (and for grapes with the glycoside adducts)? In the end points no conversion factor is proposed, and still only the parent is proposed. Propose to use the parent and DMST as the residue definition for monitoring. BAY: Residue definition for monitoring in plants is proposed to be parent only. For justification see dossier point 6.7.1 p.173, DAR B.7.17. p.332.	(ii): Residue definition for monitoring in plants is proposed to be parent only.	Addressed. RMS to amend the DAR where and if necessary to avoid confusion on residue definition for monitoring in plants.
1(11)	Vol. 3, B5.2.1, Residue methods animal products	NL: the residue definition for monitoring in animal products is not clear. Is it only the parent (as in the list of endpoints) or with the metabolite DMST? In the end points no conversion factor is proposed, and still only the parent is proposed. It is strange to measure only the parent if the parent was not found in the residue trials! Propose to use the parent and DMST as the residue definition for monitoring. BAY: When defining the residue of concern a distinction was made by BCS with respect to the purpose of the definition. For enforcement (and control of misuse) parent compound only was proposed and for refined estimations of	(ii): Residue definition for monitoring in animal products is proposed to be parent only.	Addressed. RMS to amend the DAR where and if necessary to avoid confusion on residue definition for monitoring in animal products.

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	continued Vol. 3, B5.2.1, Residue methods animal products	dietary intake DMST, 4-(dimethylamino-sulfonyl-amino) benzoic acid, and 4-(dimethyl-aminosulfonylamino) hippuric acid. Residue analysis on tolylfluanid can be done conveniently (Maasfeld, 1996). But as MRL-setting for products of animal origin is not aimed at (see comments on comments relating to section 3 - Residues) and no MRLs are proposed, the need for routinely done enforcement does not arise. (In case misuse is to be conservatively monitored, a method is available for a "marker"-metabolite, which is included in the residue definition for refined risk assessment (4-(dimethyl-aminosulfonylamino) hippuric acid.)		

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
1(12)	Vol. 3, B.5.3.1 Residue method soil	UK: Volume 3, page 51 Only limited recovery data are available for soil – additional recovery data are required. BAY: The method proposed is a published modification of the well-known S-19 method. This method is used by official and independent laboratories also for plant materials and was validated for many different matrices. For this reason and because of the marginal relevance of tolylfluanid and DMST in soil, available recovery data were considered to show sufficiently the validity of the method. However, to meet also formalistic guideline requirements, a new method validation will be performed. The report of this method validation will be available in the first half of 2004.	(ii):Identical data point with data point No (13). Modification of DFG S 19 by replacing dichloromethane by ethyl acetate/cyclohexane was acceptably validated. RMS agrees with the notifier.	Open point 1.2: RMS to evaluate the new validation data for DFG S 19 –method and include this evaluation in an Addendum of the DAR. (B.4.2.2) Evaluation Meeting (12.03.2004): A data requirement was proposed at the meeting. Notifier states that the study will be available in April 2004. RMS to provide an addendum to the draft assessment report. **Date requirement 1.2:** **Notifier to submit the new validation data for DFG S 19 – method**

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
1(13)	Vol. 3, B5.3.1, Residue method soil	NL: The method proposed is not sufficient validated and therefore not acceptable. Additional validation is required, for the parent as well as for DMST. The individual results cannot be pulled together because there are different detectors used, and also different extraction solvents are used. BAY: The method proposed is a published modification of the well-known S-19 method. This method is also used by official and independent laboratories for plant materials and was validated for many different matrices. For this reason and because of the marginal relevance of tolylfluanid and DMST in soil, available recovery data were considered to show sufficiently the validity of the method. However, to meet also formalistic guideline requirements, a new method validation will be performed. The report of this method validation will be available in the first half of 2004.	(ii): Identical data point with data point No (12). Modification of DFG S 19 by replacing dichloromethane by ethyl acetate/cyclohexane was acceptably validated. RMS agrees with the notifier.	See open point 1.2.

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
1(14)	Vol. 3, B5.3.2, Residue method water	NL: I do not agree that the method is validate for drinking water because there is validation for surface water. From experience it is seen that this compound behaves very different if a matrix is present, and in drinking water almost no matrix is present. Validation in drinking water is required. BAY: We agree that due to very the pronounced adsorption and hydrolysis behaviour of tolylfluanid, the results of residue analyis are strongly influenced by the possible presence of matrix. Generally, presence of matrix, e.g. in surface water samples, can lead to even faster dissipation, may decrease recovery and enlarge scattering of recoveries, which overall makes method development more challenging. Absence of matrix reduces scattering of the values and leads to more consistent recoveries, and may reduce the need for clean-up. Therefore, it is not to be expected that the absence of matrix, e.g. in drinking or mineral water, reduces the validity of the method. It is not known to us that analysis of tolylfluanid in water of drinking water quality will be more difficult or sophisticated than in surface water owing to specific behaviour of this compound.	(ii): The method for surface water is validated at 0.05 µg/l then this fulfils the requirements for drinking water. Acceptable.	Open point 1.3: MS to discuss the acceptability of surface water as surrogate for drinking water and impact of matrix effects. Evaluation Meeting (12.03.2004): NL maintains their comment. Surface water can not be used instead of drinking water in this certain case. A data requirement was proposed at the meeting (see data requirement 1.3.) Open point needs to be discussed in an expert meeting. NL is asked to provide detailed information about their comment. Open point still open. **Open point 1.3:** **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.**

EFSA recommends the following modification in the list of endpoint:

- It should be mentioned that the value given for the FAO specification is the declared content and not the minimum purity.

2. Mammalian toxicology

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
2(1)	Vol. 3, B.6.3.2.1 Oral 90-day toxicity, feeding 3 months	NL: The NOAEL was based on increased organ weights in the absence of histopathological findings or changes in clinical biochemistry. A higher NOAEL might be considered, but cannot be established based on the present summary due to the absence of quantitative data on organ weight changes.	(ii): No other effects than retarded body weight gains and weight changes involving the liver, kidneys, suprarenal glands, thymus and lungs were observed. The NOAEL or NOEL for these effects was 150 ppm, which is approximately 18 mg/kg bw/day in females. This rather old (1976) study is not crucial for the overall risk assesment of subchronic effects caused by tolylfluanid.	--
2(2)	Vol. 3, B.6.3.2.2 Short-term toxicity studies	UK: Decreased activities of the liver enzymes AST, ALT and AP are not considered to represent an adverse effect.	(ii): The overall target/critical effects of tolylfluanid include liver effects in rodents. Effects on liver functions were observed in this study as decreased levels of ASAT, ALAT and AP in both sexes of rats at mid and high doses. Relative liver weights were increased in high dose males. The NOAEL is therefore the low dose of 300 ppm (20 mg/kg bw/day) based on an overall evaluation of liver toxicity.	Open Point 2.1: MS to discuss the setting of the NOAEL at dose of 300 ppm. Evaluation Meeting (12.03.2004): This topic needs to be discussed in general (see point under any other business on the agenda). Open point still open. **Open point 2.1:** **The setting of NOAEL for short**

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
	continued Vol. 3, B.6.3.2.2 Short-term toxicity studies			**term toxicity studies needs to be discussed in an expert meeting**
2(3)	Vol. 3, B.6.3.2.2 Oral 90-day toxicity, 13–weeks diet and 4 weeks recovery	NL: The NOAEL was based on a decrease in AP and calcium. No futher changes were noted. The establishement of a higher NOAEL might be considered.	(ii): The overall target/critical effects of tolylfluanid include liver effects in rodents. Effects on liver functions were observed in this study as decreased levels of ASAT, ALAT and AP in both sexes of rats at mid and high doses. Relative liver weights were increased in high dose males. The NOAEL is therefore the low dose of 300 ppm (20 mg/kg bw/day). The effects were overall slight, but in line with findings from other rodent studies. The long spacing (appr. 5x) between dose levels unavoidably makes the NOAEL fairly conservative.	see Open Point 2.1

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2(4)	Vol. 3, B.6.3.2.5 Short-term toxicity studies	UK: The RMS should justify the NOAEL proposed for this study (80 mg/kg bw/d), when elevated bone fluoride was seen at 20 mg/kg bw/d. BAY: Uptake of fluoride in bones per se is not a toxicological issue (dose dependancy). See Assessment of fluoride uptake, MO-02-009943, dated July 17, 2002 provided by separate document as well as with up-dated dossier (see page 73)	(ii): The relevance of fluoride incorporation in bones, without histopathological or gross necropsy changes, may be a suitable expert group discussion topic.	Open point:2.2: MS to discuss the relevance of fluoride incorporation in bones in an expert meeting see also No (10), (12), (17). Evaluation Meeting (12.03.2004): Open point needs to be discussed in an expert meeting (see also (12). Open point still open. **Open point 2.2:** **The** NOAELs from short-term toxicity studies and the **relevance of fluoride incorporation in bones needs to be discussed in an expert meeting.**

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
2(5)	Vol. 3, B.6.3.3.3 Percutaneous 28-day toxicity study	NL: Based on the observed moderate-to-severe skin irritation, tolylfluanid should be labelled with R66. BAY: Tolylfluanid is already labelled with R 38. In this case R 66 is not necessary according to the dangeroue substance directive.	(ii): The classification criteria in Annex VI of Dir 67/548/EEC states for R66: ”For substances and preparations which may cause concern as a result of skin dryness, flaking or cracking but which do not meet the criteria for R38 based on either: - practical observation after normal handling and use, or – relevant evidence concerning their predicted effects on the skin.” The effects seen in this study meet the criteria for R38, which in turn triggers recommendations for the use of PPE to avoid skin exposure. R66 is designed to cover effects seen in man which are based on practical observations in certain special cases not attributable to effects which merit R38 in animal studies.	Addressed.

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2(6)	Vol. 1, App. 3, Listing of endpoints, Chapter 2.3, Annex IIA, point 5.3 (Short term toxicity / Inhalation)	DE: Amend the box ”Lowest relevant inhalation NOAEC / NOEC as follows: 0.001 mg/L (0.27 mg/kg bw/d, not micronised dust), 4-wk rat = 0.004 mg/L: Irritation of respiratory tract Species tested, study duration, and findings are missing (rat, 4-wk, irritation in the respiratory tract at 0.004 mg/L and above). Furthermore, it should be mentioned that the study was performed with not micronised dust, because the relevance "micronised" or not for practical conditions is still in discussion, most of all with respect to labelling. (Most likely micronised dust is realistic.) BAY: Particle size decides whether a substance is inhalable/respirable or not. Therefore the split-entry rules should be used as it is foreseen by ECB.	(ii): The proposal is accepted. Listing of end points will be amended.	Open point 2.3: RMS to revise List of Endpoints. Evaluation Meeting (12.03.2004): RMS to amend the list of end points. Open point still open. **Open point 2.3:** **RMS to revise the List of Endpoints regarding the ”Lowest relevant inhalation NOAEC / NOEC”.**

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2(7)	Vol. 3, B.6.4.1.5 Genotoxicity studies	UK: A reduction in survival index at the highest concentration is considered to be sufficient indication of cytotoxicity; this study is therefore acceptable.	(ii): According to the OECD test guideline (473), the highest tested dose in the in vitro mammalian cytogenicity test should suppress mitotic activity by approximately 50%. The MI:s at the highest dose were between 90 and 113% of the control. ”Cytotoxicity” was expressed as ”survival indices” in the study report by a methodology which was not explained in detail. Anyway, also the ”survival indices” were reduced less than 30% at the highest dose. As MI:s were not reduced at the high dose as required by the test guideline, and not enough data is given on the methodology and relevance of the ”cytotoxicity test” which was reportedly done, the study remains unacceptable.	Addressed.

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2(8)	Vol. 3, B.6.4.1.6 Genotoxicity studies	UK: The RMS is asked to clarify whether any assessment of the number of small colonies was made in this mouse lymphoma assay, in order to clarify the mechanism of genotoxicity. BAY: Study was performed in 1984. Obviously no differentiation between big or small colonies were made. No hints were found in the report. However, both endpoints are covered by higher tiered studies.	(ii): Numbers of small colonies were not counted in this study.	Addressed.
2(9)	Vol. 3, B.6.5.1 Long-term toxicity and carcinogenicity studies	UK: The incidences of uterine tumours seen in the rat study are not considered to be treatment-related. There is no evidence of carcinogenicity in this study.	(ii): The overall conclusion of this study and other long-term and carcinogenicity studies is that tolylfluanid is not carcinogenic.	--
2(10)	Vol. 3, B.6.5.1 Long-term toxicity and carcinogenicity studies	UK: The RMS should justify the NOAEL proposed for this study (300 ppm), when elevated bone fluoride was seen at 60 ppm. BAY: See comment on UK comment No. (4).	(ii): This point refers to study B.6.5.2. Again, the relevance of fluoride incorporation in bones, without histopathological or gross necropsy changes, is a topic for peer-review discussions.	see open point 2.2

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2(11)	Vol. 3, B.6.5.3 Long-term toxicity and carcinogenicity studies	UK: Survival to 18 months in the mouse study should be reported to enable an assessment of the adequacy of this study.	(ii): Survival at 18 months was 75, 70, 76 and 72% in males, and 59, 40, 50 and 35% in females, at feeding levels of 0, 200, 1000 and 5000 ppm, respectively. At the 18 month time-point, low and high dose females had survival rates less than 50%. This underlines the fact that the study was found unacceptable, mainly because of the staggered study start for controls and treated groups, and overall deficiencies in study design and reporting.	--

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2(12)	Vol. 3, B.6.5.3 Long-term toxicity and carcinogenicity studies	UK: The RMS should justify the NOAEL proposed for this study (60 ppm), when elevated bone fluoride was seen in males at 60 ppm. BAY: See comment on the UK comment No. (4).	(ii): This point refers to study B.6.5.4. (second mouse oncogenicity study). Contrary to the information in the DAR, an increase in fluoride content in bone was observed in females at week 106. In males at the same time the NOEL for fluoride in bone was 300 ppm. At week 54 the NOEL for fluoride in bone was 60 ppm in both sexes. The NOELs for fluoride in teeth were 60 ppm in males and 300 ppm in females at weeks 54 and 106. The NOAEL of 60 ppm for the study is based on the overall evidence of fluoride incorporation in bone and corresponding hyperostotic changes observed in the sternum of females at 300 ppm and higher doses. The relevance of fluoride incorporation in bone as such is suggested again as a general discussion topic.	Open point 2.4: RMS to make corrections in the DAR. See open point 2.2 Evaluation Meeting (12.03.2004): The NOAEL from long-term toxicity and carcinogenicity studies in relation to the fluoride incorporation needs to be discussed in an expert meeting. Open point has been rephrased. **Open point:** **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.**

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2(13)	Vol 3, B.6.6.1 Two generation reproduction toxicity in the rat	NL: Based on the decreased lactation and/or viability index at doses at which very slight maternal toxicity was noted, labeling of tolylfluanide with R63 should be considered. BAY: With respect to the results of the 2-generation reproduction studies, the effects observed are not strong enough (see DAR pages 74 -77) to classify tolylfluanid with R 63. Furthermore a new study is underway showing only unspecific effects in a clear parental effect dose. The report on this new study will be available by the beginning of next year.	(ii): See Point 34 (Vol. 3, B.4.1 Proposals for the classification and labelling of the active substance) below.	--
2(14)	Vol. 1, App. 3, Listing of endpoints, Chapter 2.3, Annex IIA, point 5.6 (Reproductive toxicity) *continued*	DE: Amend the box "Lowest relevant reproductive NOAEL / NOEL" as follows: 100 ppm (7.9 mg/kg bw/d), 2-gen. rat As base for the NOAEL, another reproduction study is proposed: doses: 0-100-700-900 ppm, NOAEL: 7.9 mg/kg bw/d (100 ppm), based on labored breathing and reduced survival rate of the pups at 700 ppm (about 56 mg/kg bw/d). In the study chosen by the RMS, the only tested dose (180 ppm = 19 mg/kg bw/d) revealed labored breathing and reduced lactation indices in F2 pups.	(ii): Cyanotic pups with laboured breathing were not observed in all 2-generation studies, and these effects occurred at a high frequency also in controls in the study by Holzum (1991c). The critical study for assessment of an overall NOAEL for effects on reproduction is the Holzum study where the lactation index was decreased only in F1B pups (laboured breathing occurred among F2 pups). The relevance of the decreased lactation index in F1B pups only in the Holzum study as such is questionable and may be	Open point 2.5: MS to discuss the relevant NOAEL in 2-generation reproduction studies in rat. Evaluation Meeting (12.03.2004): RMS informs the meeting that the notifier has provided a new 2-generation study. Evaluation until the end of April 2004. Open point still open.

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	Vol. 1, App. 3, Listing of endpoints, Chapter 2.3, Annex IIA, point 5.6 (Reproductive toxicity)	This LOAEL is supported by a 3rd reproduction study with a LOAEL of 23 mg/kg bw/d (decreased viability and lactation indices), the lowest dose tested. Comment on Vol. 3, Annex B, B.6: The threshold values are noted correctly by the RMS in the Summary tables 2.3.7 (Vol. 1, level 2, page 23) and 6.6.9 (Vol. 3, Annex B, B.6, page 187), whereas under Conclusions of the study B.6.6.1.2, page 178, wrongly the reproductive LOAEL of 300 ppm is noted as NOAEL. A further contradictory conclusion is drawn on the finding *labored breathing* of the pups. In the Summary tables it is not noted and in the study B.6.6.1.3, page 179, this finding at 180 ppm is regarded as toxicologically not significant, justified in view of not occurring in the other reproduction studies. However, in the reproduction study B.6.6.1.4, page 180, labored breathing of the pups is one of the findings. BAY: The validity of the cited study suffers under an infection of the test animals. Therefore, the study was repeated and a NOEL of 31.5 mg/kg bw could be determined	considered incidental. There were, however, similar decreases in lactation and viability indices in the studies by Holzum and Kaliner (1989) and Pickel and Rinke (1995). Beacuse of the wide spacing between doses in the Pickel and Rinke study (100 – 700 – 4900 ppm), the Holzum study at 180 ppm becomes decisive for setting the overall NOAEL. A conservative view would therefore be to set the NOAEL from the Pickel and Rinke study as an overall reproductive value. The test compound intakes at 100 ppm were between 9.1 and 10.5 mg/kg bw/day in the F1B-generation. A conservative overall NOAEL for reproductive effects would thus be approximately 9 mg/kg bw/day.	**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.**

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		resulting in an AOEL of 0.3 mg/kg bw. The report on this new study will be available by the beginning of 2004.		
2(15)	Vol 3, B.6.8 Further toxicological studies	NL: Studies with several metabolites were performed. Studies included acute toxicity data and genotoxicity data. One should establish which of these metabolites are considered relevant in terms of exposure, e.g. exposure to plant metabolites during re-entry activities, exposure through drinking water, exposure through food, etc. For relevant metabolites additional data on repeated dose toxicity should be provided. BAY: See comments provided by separate document MEF-416/03.	(ii): Three preliminarily tested metabolites were found only in plants: WAK6550, WAK6676 and WAK6698. The other three; KUE5156 (TTCA), DMST and WAK5818 are formed in animal metabolism and therefore extensively tested as part of the evaluation of the a.s. The preliminary testing for acute oral toxicity in rat and mutagenicity in the Ames test indicate that also the three plant metabolites are of low toxicological concern. The notifier has supplied a written statement of the relevance of metabolites formed in plants for re-entry activities. The estimations presented in the statement can be evaluated in an Addendum to the DAR.	Open point 2.6: MS to discuss the relevance of metabolites, in particular those formed in plants Evaluation Meeting (12.03.2004): RMS to provide an addendum to the draft assessment report (in time before the expert meeting in May). Open point still open **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.**

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2(16)	Vol. 1, App. 3, Listing of endpoints, Chapter 2.3, Annex IIA, point 5.8 (Other toxicological studies)	DE: The last sentence relating to neurotoxicity, should be transferred to point 5.7. which should be renamed in Neurotoxicity / Delayed neurotoxicity	(ii) Agreed.	Open point 2.7: MS to revise List of Endpoints. Evaluation Meeting (12.03.2004): RMS to amend the list of end points regarding the last sentence relating to neurotoxicity. Open point still open. **Open point 2.7:** **RMS to revise the List of Endpoints regarding the last sentence relating to neurotoxicity.**

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
2(17)	Vol. 3, B.6.10.4 Proposed ADI	UK: The ADI derivation is not agreed. The RMS' proposal to base the ADI on a NOAEL from a chronic toxicity study is agreed, as the overall NOAEL from the reproductive toxicity studies is shown to be 23 mg/kg bw/d. However the NOAEL of 15 mg/kg bw/d from the mouse study should be used to derive the ADI, leading to a value of 0.15 mg/kg bw/d.	(ii): The relevance of fluoride incorporation must be discussed. Setting the ADI on the basis of fluoride incorporation and corresponding histopathological changes in bones in the 2-year mouse study by Leser and Ruehl-Fehlert (1996) may be supported depending on the outcome of discussions.	Open point 2.8: MS to discuss the setting of the ADI in an expert meeting. See open point 2.2 Evaluation Meeting (12.03.2004): Open point needs to be discussed in an expert meeting. Open point still open. **Open point 2.8:** **The setting of the ADI needs to be discussed in an expert meeting.**

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
2(18)	Vol. 1, App. 3, Listing of endpoints, Chapter 2.3, Annex IIA, point 5.10, (Summary, ADI)	DE: ADI: 0.08 mg/kg bw, 2-gen. rat, Safety factor 100 For deriving an ADI, the 2-generation study on rat with a NOAEL of 7.9 mg/kg bw/d (see comment (2)) instead of the NOAEL of the 2-yr rat study is proposed. The NOAEL (18 mg/kg bw/d) in the 2-yr rat study resembles the LOAELs (19 and 23 mg/kg bw/d) in two further reproduction studies with the effects labored breathing and reduced viability / lactation indices. BAY: As mentioned above, there will be a new 2-generation study on rat with a higher NOAEL than 18 mg/kg bw., i.e. 31.5 mg/kg bw.	(ii): As for using the 9 mg/kg bw/day NOAEL for setting an ADI, the RMS considers this to be a conservative alternative to be discussed at peer-review of tolylfluanid.	See Open points 2.5 and 2.8.

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2(19)	Vol 3, B.6.10.4 AOEL	NL: A rather large range of urinary excretion was given in the summary of toxicokinetics: 60-90% (B.6.1.9.). Furthermore, it is not clear whether the excreted radioactivity in bile had been systemically available. Therefore, one should consider correction for systemic availability for the derivation of the AOEL. BAY: In 11 of 12 groups of rats with low or medium dose urinary excretion was 72-86% (mean: 77%) of administered radio-activity. The lower rate of only 63% urinary excretion was found in an experiment with significantly lower overall recovery. Bile cannulation experiments are performed to investigate which part of the orally administered radioactivity excreted via faeces has been absorbed by liver and biliarily excreted. Accordingly, radioactivity excreted via bile after oral application has generally been systemically available. Systemical availability of tolylfluanid depended slightly on the radiolabel and amounted to 75% for [dichloro-fluoro-methyl-^{14}C]tolylfluanid (excretion via urine, bile and expired air) and to 85-99% for [phenyl-U-^{14}C]tolylfluanid (excretion via urine 72-86%; excretion via bile: 13.5%). Conclusion: systemic absorption of tolylfluanid is generally >80%.	(ii): Three different studies with phenyl ring labeled tolylfluanid were supplied. In the first study by Ecker et al. (1987) at 20 mg/kg bw, the absorption from the GI tract was >90% based on urinary excretion data. In the second study by Abbink and Weber (1988) excretion to bile was also studied, showing that the absorption was about 95% based on biliary and urinary excretion at a dose of 2 mg/kg bw. In the third study (Klein, 1991), with doses of 2 and 100 mg/kg bw, urinary excretion was between 61 and 87% and fecal excretion between 13 and 39%. As biliary excretion was not examined in the study by Klein, no complete data on absorption is available. Looking at the second study by Abbink and Weber with complete absorption data based on biliary and urinary excretion, one may assume that most (>90%) of the orally administered tolylfluanid is absorbed within 48 h. The data as a whole suggests that no correction for poor oral absorption is needed.	**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)** Evaluation Meeting (12.03.2004): 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). Open point still open.

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2(20)	Vol 3, B.6.10.4 AOEL	NL: The AOEL should be based on the overall NOAEL of approximately 20 mg/kg bw/day from the 2-generation reproduction studies. The NOAEL of 9 mg/kg bw/day is the lowest NOAEL from the 2-generation reproduction studies, but comparison of NOAELs and LOAELs results in an overall NOAEL of approximately 20 mg/kg bw/day. Application of a safetyfactor 100 results in an AOEL of 0.2 mg/kg bw/day. BAY: The validity of the cited study suffers under an infection of the test animals. Therefore, the study was repeated and a NOEL of 31.5 mg/kg bw could be determined resulting in an AOEL of 0.3 mg/kg bw. The report on this new study will be available by the beginning of next year.	(ii): Although studies on reproductive toxicity did not trigger enough concerns to classify tolylfluanid as toxic to reproduction, there were consistently slight effects in rat 2-generation studies, mainly showing decreased lactation indices, for which the overall LOAEL is about 70 mg/kg bw/day. It is a matter of discussion whether the overal NOAEL for reduced lactation index in 2-generation studies is 9 or 23 mg/kg bw/day. Taking a conservative approach to setting an overall NOAEL for reproductive effects would be to use 9 mg/kg bw/day (see also the discussion in Point 30 below concerning the use of the reproductive endpoint for setting the ADI). For setting of an AOEL the RMS is of the opinion that subchronic studies should be used as they are more relevant in terms of the length of occupational exposure. The proposed NOAEL for setting the AOEL is between 20 and 33 mg/kg bw/day, depending on whether fluoride incorporation in bones as such in dog is considered an adverse effect.	Open point 2.10: MS to discuss the setting of the AOEL in an expert meeting. Evaluation Meeting (12.03.2004): Open point needs to be discussed in an expert meeting. Open point still open. **Open point 2.10:** **The setting of the AOEL needs to be discussed in an expert meeting.**

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2(21)	Vol 3, B.6.10.4 AOEL *continued*	NL: Tolylfluanide is labeled with R26 (very toxic by inhalation). Although in most studies local effects were noted, one repeated dose inhalation study (B.6.3.3.1..3) showed systemic effects (increased thyroid weight) at 0.05 mg/L. Based on these findings, the derivation of a respiratory AOEL, based on inhalation data should be considered. BAY: The results of inhalation studies should not be considered because effects on thyroids are not relevant for man based on low storage capacity of T3/T4 and missing TBG in rats (see separate statement on Thyroid Disruption Mode of Action Analysis, MO-03-002440, dated 02 27, 2003, accepted within ECB).	(ii): Two repeated dose (20 x 6h/day) inhalation studies in rat were submitted. In one of the studies micronised, highly respirable, dust of tolylfluanid (particles = 3 µm constitute 59-83% of aerosol mass) was tested. The second study used non-micronised dust (particles = 3 µm constitute 37-44% of aerosol mass). The smaller particle size dust was more irritating for the lungs and airways, and caused death among the test animals. Systemic effects were more frequently observed with the smaller particle size dust which introduces a higher amount of particulate mass in to the lungs. A higher respirable mass leads to a higher systemic dose, which in case of the micronised material means that systemic effects such as thyroidal weight increase are observed. The RMS is of the opinion that inhalatory risk assessment should take into account the actual particle size distributions of the a.s. and formulations. In line with this, the RMS considers that inhalatory effects of tolylfluanid are taken into consideration by the classification for R37 (irritating to the respiratory system) at normal use and	--

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	Vol 3, B.6.10.4 AOEL		handling. A respiratory AOEL is not considered necessary.	
2(22)	Vol. 1, App. 3, Listing of endpoints, Chapter 2.3, Annex IIA, point 5.10, (Summary, AOEL inhalative) *continued*	DE: AOEL inhalative: 0.003 mg/kg bw/d; 4-week rat inhalation (dust not micronised), Safety factor 100 With regard to the high inhalative toxicity of tolylfluanid, the derivation of an AOEL inhalative is proposed. BAY: Particle size decides whether a substance is inhalable/respirable or not. Therefore the split-entry rules should be used as it is foreseen by ECB.	(ii): Two repeated dose (20 x 6h/day) inhalation studies in rat were submitted. In one of the studies micronised, highly respirable, dust of tolylfluanid (particles = 3 µm constitute 59-83% of aerosol mass) was tested. The second study used non-micronised dust (particles = 3 µm constitute 37-44% of aerosol mass). The smaller particle size dust was more irritating for the lungs and airways, and caused death among the test animals. Systemic effects were more frequently observed with the smaller particle size dust which introduces a higher amount of particulate mass in to the lungs. A higher respirable mass leads to a higher systemic dose, which in case of the micronised material means that systemic effects such as thyroidal weight increase are observed. The RMS is of the opinion that inhalatory risk assessment should take into account the actual particle size distributions of the a.s. and formulations. In line with this, the	--

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	Vol. 1, App. 3, Listing of endpoints, Chapter 2.3, Annex IIA, point 5.10, (Summary, AOEL inhalative)		RMS considers that inhalatory effects of tolylfluanid are taken into consideration by the classification for R37 (irritating to the respiratory system) at normal use and handling. A respiratory AOEL is not considered necessary.	
2(23)	Vol. 1, App. 3, Listing of endpoints, Chapter 2.3, Annex IIA, point 5.10, (Summary, ARfD) *continued*	DE: ARfD: 0.25 mg/kg bw, teratogenicity study rabbit, Safety factor 100 The derivation of an ARfD is proposed: With regard to adverse effects (postimplantation loss and malformations) in presence of only slight maternal toxic effects, the NOAEL of the teratogenicity study on rabbit is appropriate: 25 mg/kg bw/d and a safety factor of 100 result in an ARfD of 0.25 mg/kg bw. BAY: The malformations seen 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 the ArfD. Based on the results of toxicological studies, the short-term dietary intake of tolylfluanid residues is not considered to present a risk to	(ii) Risks for the consumer at acute dietary intake may be discussed. An ARfD based on the intake of fluoride may be proposed depending on peer-review discussions on the relevance of incorporation in bones as such. An NOAEL of about 20 mg/kg bw/day from repeated oral studies in dog and rat for fluoride incorporation may be suggested as a basis for an ARfD.	Open point 2.11: MS to discuss setting of an ARfD in an expert meeting. Evaluation Meeting (12.03.2004): Open point needs to be discussed in an expert meeting. Open point still open. **Open point 2.11:** **The setting of the ARfD needs to be discussed in an expert meeting.**

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	Vol. 1, App. 3, Listing of endpoints, Chapter 2.3, Annex IIA, point 5.10, (Summary, ARfD)	consumers. Thus, it is not considered necessary to establish an ARfD.		
2(24)	Vol. 3, B.6.12.4 Dermal absorption *continued*	UK: The predicted dermal absorption values for human skin *in vivo* should be calculated using the available comparative *in vitro* data, according to current EU guidance. The relevant figures from the rat study *in vivo* to use in this calculation are those from the 168 hour measurement. These figures clearly show that residual skin radioactivity following an 8-hour exposure is bioavailable. BAY: See comment on the Dutch comment No. (25) on dermal absorption.	(ii): The in vitro comparison of penetration through rat and human skin gave no reliable reasons to assume that there are differences between the two species in dermal penetration. Therefore, the results of the in vivo rat study after 8 hours of exposure were used to estimate dermal absorption as most relevant for workers. As a very conservative alternative, taking into account the skin lodged dose, we propose that the total percentages of cumulative radioactivity absorbed at 168 hours may be used, since they reflect the total amounts of actually absorbed radiolabel during 7 days. This would mean that dermal absorption percentages of 4, 7 and 22% for the dose levels of 0.75, 0.075 and 0.0075 mg/cm2, respectively, would be used.	Data requirement 2.1: The notifier should present data on the kinetics of absorption/ excretion during the 7 day follow up period in the in vivo rat study. Open point 2.12: MS to discuss the estimation of dermal absorption. Evaluation Meeting (12.03.2004): Data submitted previously according to the OECD guideline. Dermal rat and human skin were therefore regarded to be comparable by the company. The RMS considered these studies not to be reliable. Additional data on *the in vivo* study in rat would be helpful for the further discussions. The company will check the situation. Data requirement still open.

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	Vol. 3, B.6.12.4 Dermal absorption			Open point needs to be discussed in an expert meeting. Open point still open. See also No (25), (26) **Data requirement 2.1:** **Notifier to present additional data on the *in vivo* study in rat .** **Open point 2.12:** **The estimation of dermal absorption needs to be discussed in an expert meeting.**

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
2(25)	Vol 3, B.6.12.4 Summary of dermal absorption	NL: The percentage absorbed after 8 hours dermal exposure were selected. However, based on the 168 h. data from the in vivo dermal absorption study it should be noted that part of the amount remaining in the skin after washing becomes systemically available. Therefore, the amount potentially absorbed (absorbed dose and amount remaining in the skin) should be taken to established the percentage dermal absorption. This results in dermal absorption percentages of 8, 7 and 27% for the dose levels of 0.75, 0.075 and 0.0075 mg/cm^2, respectively. BAY: See comments provided by separate document MR-185/03. The *in vivo* human skin absorption calculated by the notifier, based on rat *in vivo* and *in vitro* rat and human skin penetration data, is 5% for the concentrate and 7% for a 1:100 field dilution.	(ii): Several possible interpretations from the rat in vivo data are possible, ranging from conservative to extremely conservative estimates. The data on absorption at 8 h exposure + 160 h observation (i.e. after 7 days) shows that practically all of the skin lodge dose is becoming systemically available and excreted or removed by desquamation within 7 days. In harmony with the guideline, as most of the skin lodged dose is becoming systemically available within 7 days, total amounts of absorbed material after 7 days can be used for estimation of skin absorption in humans. As a very conservative estimate we propose that the total percentages of cumulative radioactivity absorbed at 168 hours may be used, since they reflect the amounts of actually absorbed radiolabel. This would mean that the total amounts of absorbed a.s. during a period of 7 days after an 8 h exposure period would be 4, 7 and 22% of the for the dose levels of 0.75, 0.075 and 0.0075 mg/cm2.	See Open point 2.12.

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2(26)	Vol. 1, App. 3, Listing of endpoints, Chapter 2.3, Annex IIIA, point 7.3, (Dermal absorption)	DE: 4.2 % for the concentrate and 7.5 % for the dilution (*in vivo* rat and *in vitro* rat and human skin, 8 h exposure = collection period for absorbed radioactivity; fraction in / on washed skin included). Setting a dermal absorption rate on the base of the amount of radioactivity absorbed within 8 hours (1st sacrifice), the fraction in / on the washed skin should be included - as well as the relation rat / human skin. (The corresponding findings from the original reports are documented correctly in the monograph, Vol. 3, B6, page 224-228.) BAY: See comments provided by separate document MR-185/03.	(ii): As stated earlier, several possible interpretations from the rat in vivo data are possible, ranging from conservative to extremely conservative estimates. Taking into account all comments on the subject, we suggest as a conservative estimate to include the skin lodged dose as potentially absorbed material. The total percentages of cumulative radioactivity absorbed at 168 hours would thus be used, since they reflect the amounts of actually absorbed radiolabel. This would mean that dermal absorption percentages of 4, 7 and 22% for the dose levels of 0.75, 0.075 and 0.0075 mg/cm2, respectively, would be used.	See Open point 2.12.
2(27)	Vol. 3, B.6.14.1. Operator exposure and comparison to the AOEL. (Annex IIIA.7.2)	UK:Exposure estimates for this WG formulation have been predicted using UK POEM. As UK POEM does not have the appropriate data to estimate the level of exposure arising during mixing and loading a WG formulation these calculations may be unreliable. In these situations a combination of the German and UK POEM models may be used; the German model to obtain a figure for exposure during mixing and loading and POEM to derive an	(ii): We fully agree that the combination of the German and UK-POEM models would be an optimum solution for modelling WG- type products in M&L tasks. By using liquid product based data a certain amount of conservatism can, however, be achieved. In this case the operator exposures were at acceptable levels and from this point of view the model results do not necessarily need recalculations.	--

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	continued Vol. 3, B.6.14.1. Operator exposure and comparison to the AOEL. (Annex IIIA.7.2)	estimate for application exposure. The POEM data for mixing and loading are based on pouring data for liquid formulations. BAY: PSD published new spreadsheets of the UK-POEM in June 2003 to comply with data gaps for WP and WG formulations. At the time of compilation of the dossier these were not yet available. The new UK-POEM uses M/L-data for solid formulations from the German model. In contrast to the German model, where geometric mean values are taken to calculate exposure, maximum values are taken for the new UK-POEM. Moreover, the maximum values taken for inhalation exposure are derived from non-detects i.e. these data are theoretical values (1/2 of LOQ) from studies where LOQs were set too high. This is a very conservative approach.		

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2(28)	Vol. 3, B.6.14.1. Operator exposure and comparison to the AOEL. (Annex IIIA.7.2)	UK:For measurement of operator exposure, only limited details of three operator exposure studies are provided. Greater detail in terms of study design, methodology and results are required for this section to be transparent. It is also unclear whether these data have been generated in accordance with GLP principles. The studies referenced were conducted in the Netherlands, Belgium, and Germany.	(ii): More details of study design, methodology and GLP-issues will be added in the text.	Open point 2.13: RMS to amend the DAR. See also No (30) **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.**
2(29)	Vol. 3, B.6.14.2. Conclusions on operator exposure. (Annex IIIA.7.2)	UK:This section concludes 'in greenhouse applications a re-entry interval of 12 hours is recommended'. It is unclear from the exposure assessment what this recommendation is based on. BAY: BCS recommends that re-entry may start when spary deposit is dry.	(ii): There is no specific data for tolylfluanid degradation from the surface of the leafs and indoor air. The re-entry interval of 12 hours is an unspecific general assumption which was found to be relevant in a greenhouse study (Kangas, J., S. Laitinen, A. Jauhiainen and K. Savolainen. Exposure of Sprayers and plant Handlers to Mevinphos in Finnish Greenhouses. Am. Ind. Hyg. Assoc. J. (54).1993. pp. 150-175) for organophosphrous pesticides.	--

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2(30)	Vol 3, B.6.14 Exposure data	NL: The use of dermal absorption values of 8 and 27% for the undiluted and diluted formulation, respectively, for the calculation of internal exposure values should be considered.	(ii): Absorption values of 4% and 22% for the undiluted and diluted formulations may be used as a conservative estimate. See previous points on dermal absorption.	See Open point 2.13
2(31)	Vol. 1, App. 3, Listing of endpoints, Chapter 2.3, Annex IIIA, point 7.2, (Acceptable exposure scenarios)	DE: Considering the high inhalative toxicity of tolylfluanid (see comment (5), AOEL inhalation), the inhalation exposure should be assessed separately and RPE (respiratory protection equipment) should be recommended in all cases. BAY: Particle size decides whether a substance is inhalable/respirable or not. Therefore the split-entry rules should be used as it is foreseen by ECB. The hazard of irritant effects in the lung will be better adressed by R 37 as proposed.	(ii): Local pulmonary irritation is identified as the mechanism causing effects in inhalation studies. The pulmonary effects are directly related to particle size and thus the total inhalable mass. RMS is therefore of the opinion that the particle size distribution of the active substance and formulated products should be taken into consideration in the risk assessment and in classification and labelling. The notifier has shown that the masses of inhalable particles for the active substance and representative products are in ranges that do not under normal use and handling cause risks related to pulmonary toxicity to the operators. However, as the a.s. is a pulmonary irritant, measures to avoid inhalation exposure are recommended, as prompted also by labelling the product for R37.	--

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2(32)	Vol. 3, B.6.14.4 Re-entry exposure (Annex IIIA.7.2)	UK: The worker exposure assessment considers only exposure from crops treated with a single application of 'Euparen M 50 WG'. As crops may be treated with up to 7 applications of this product, systemic exposure for workers harvesting treated crops could be higher than that which has been predicted. The potential accumulation of DFR should be considered. BAY: See separate document MR-185/03.	(ii): We agree with the possibility of accumulation. The worker exposure is estimated in a standard and rather conservative way on the basis of a single treatment. Accumulation is difficult to take into consideration since there is no generally accepted method for estimating it. The assumption that the sum of tolylfluanid mass from seven treatments would yield the total mass for DFR may be far too conservative and therefore bias the conclusions. Furthermore, the notifier has not submitted any product specific data about tolylfluanid degradation from leafs. This issue may be suitable as a general peer-review discussion topic.	Data requirement 2.2: Worker exposure, taking into account potential accumulation at repeated treatments should be addressed by notifier. Evaluation Meeting (12.03.2004): Notifier states that they have additional data available which could be submitted. Data requirement still open. **Data requirement 2.2:** **Notifier to submit additional data on worker exposure.**

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
2(33)	Vol. 3, B.6.14.4 Re-entry exposure (Annex IIIA.7.2)	UK:In accordance with good hygiene standards, workers should not re-enter treated crops until spray deposits are dry. Workers exposed to dislodgeable foliar residues would therefore be expected to be exposed to a dry foliar deposit. The dermal absorption value which has been assumed for the worker exposure assessment (13%) relates to the spray dilution. This value may therefore be high. BAY: A dry spray deposit is assumed to penetrate skin with a lower rate than observed for a spray dilution or for a concentrate liquid. As no other data are available for dermal absorption of a dry deposit the dermal absorption of a concentrate (5%) should be taken to calculate re-entry exposure. (Calculations see separate document MR-185/03)	(ii) The current calculations in the DAR show that the systemic re-entry exposure is at its highest 43% of the AOEL when PPE are used. Dry spray deposits are not expected to be absorbed more efficiently than spray dilutions. Thus re-entry activities after foliar residues have dried are not expected to cause concerns, provided that safety measures are applied as recommended.	--

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
2(34)	Vol. 3, B.4.1 Proposals for the classification and labelling of the active substance	NL: Based on the results of the 28-day dermal toxicity study in rabbits tolylfluanid should be labeled with R66. Based on the results of the 2-generation reproduction studies, labeling of tolyfluanide with R63 should be considered. BAY: With respect to the results of the 2-generation reproduction studies, the effects observed are not strong enough (see DAR pages 74 -77) to classify tolylfluanid with R 63. Furthermore a new study is underway showing only unspecific effects in a clear parental effect dose. The report on this new study will be available by the beginning of next year. With respect to R 66 see comment on Dutch comment No. 5.	(ii): RMS feels that effects related to skin irritation, even at repeated exposure, are sufficiently covered by the proposed classification and labelling for R38. Survival and lactation indices were reduced in three two-generation studies in rats at maternotoxic dose levels. In one supplementary study with one dose level, the lactation index was reduced only in F1B pups; cold, cyanotic pups with laboured breathing were observed both among controls and treated pups (relevant study?). The overall evaluation of all multigeneration studies, including supplementary studies and prenatal toxicity studies, do not support classification and labelling for effects on reproduction.	--

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
2(35)	Vol. 1, 2.1.4 Classification and Labelling	UK:The active substance and products should be classified with regard to inhalation toxicity/irritation regardless of particle size. BAY: Particle size decides whether a substance is inhalable/respirable or not. Therefore the split-entry rules should be used as it is foreseen by ECB.	(ii): Local pulmonary irritation is identified as the mechanism causing effects in inhalation studies. The pulmonary effects are directly related to particle size and thus the total inhalable mass. RMS is therefore of the opinion that the partice size distribution of the active substance and formulated products should be taken into consideration in the risk assessment and in classification and labelling.	--
2(36)	Vol. 1, 2.1.4 Classification and Labelling	UK: The minimum purity of the manufactured material is 960 g/kg, whereas the genotoxicity studies were performed with material of higher purity (98-100%). The RMS is therefore requested to clarify whether all impurities associated with the manufactured material have been adequately tested for genotoxicity. BAY: Clarification of this issue is still ongoing.	(ii): The notifier may be asked to give a statement about the impurities in different tested batches of active substance, and the possible toxicological relevance of different impurity profiles.	Data requirement 2.3: Notifier to clarify the question of the toxicological significance of different impurities. Evaluation Meeting (12.03.2004): Notifier states that a study is ongoing and data may be available in 3 months. Data requirement still open. **Data requirement 2.3:** **Notifier to submit the ongoing study on the toxicological significance of different impurities.**

Evaluation Meeting (12.03.2004):

A data requirement (new chromosome aberration study *in vivo* in rodents) was transferred from the consultation report. Notifier states that studies are carried out and the report will be available in April/May 2004. The list of end points will be amended accordingly.

Data requirement still open.

Data requirement: 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.

Another data requirement (literature search on clinical cases etc.) given in consultation report was confirmed.

Data requirement still open.

Data requirement: 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.

3. Residue

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
3(1)	Vol. 3, B.7.3 Definition of the residue in plant	UK: Volume 3, page 269 The residues definition in plants for consumer risk assessment is parent plus the metabolite DMST. However the text indicates that the identified metabolites were not of toxicological significance, DMST was identified in the rat metabolism study and the majority of the residue in the crops samples from the residue trials is parent tolylfluanid. Therefore, consideration should be given to amending the residue definition to parent only.	(ii) identified metabolite DMST was present in significant amounts and so it was considered important to include it in dietary risk assessment, although studies on mammalian toxicology of the parent and specific tests of metabolites do not indicate any special concerns related to metabolites.	Addressed

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
3(2)	Vol. 3, B.7.3 Definition of the residue in plant	UK: Volume 3, page 269 In line with (1) above the residue definition for consumer risk assessment, should be amended to parent only. Neither of the 2 and 4-hydroxy metabolites were identified in the rat metabolism study, however the metabolic pathway indicates that the major metabolite 4-hydroxy is likely to have been present in the rat. BAY: There are no objections if the UK proposal would become applicable.The use of the same residue definition (parent only) for both purposes is possible.	(ii) identified 2 and 4-hydroxy metabolites metabolites were present in significant amounts and so it was considered important to include them in dietary risk assessment	Addressed

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
3(3)	Vol. 3, B.7.3 Residues definition rapporteur: FI	UK: A residues definition for animal products does not need to be set at this stage, as none of the crops for which continuing approval is sought, are fed to animals. If a residues definition is set, a method of analysis of determination residues in animal products will be required, analysing the products for the components of the residue definition (method of analysis for animal products is currently not available). The proposed residue definition is parent and its metabolites, this could be refined to the metabolites DMST (only included to the levels in hen fat, however it is a rat metabolite), 4(Dimethylaminosulfonylamino) hippuric acid and 4-(Dimethylaminosulfonylamino) benzoic acid, which are the three main components analysed in the animal products, BAY: No MRL-setting for products of animal origin is intended and no MRLs are proposed. The residue definition applicable only for refined estimations of dietary intake (e.g. WHO model) includes metabolites found in the presented metabolism study. Calculating the IEDI according to WHO guideline hypothetical residues in edible offals were taken into consideration (set at an LOQ of 0.05 mg/kg).	(ii): The residue definition in products of animal origin may be specified either as tolylfluanid alone, or tolylfluanid and the metabolite DMST, possibly incuding also 4-(dimethyl-aminosulfonylamino)benzoic acid and 4-(dimethyl-aminosulfonylamino)hippuric acid. An analysis method for animal products is available only for parent , thus the residue definition for products of animal origin is revised to be parent compound only. RMS to revise DAR For MRL setting see Points 20 and 24	Open point 3.1 MS to discuss in an expert meeting if a residue definition for animal products should be set according to the analytical method available, although no parent compound was detected in animal matrices in the metabolism studies Evaluation Meeting (12.03.2004): Notifier states that DMST is soluble in fat. A statement on the solubility of DMST in fat was included to the original dossier. Open point still open. **Open point 3.1:** **RMS to provide an addendum to the draft assessment report concerning the relevance of DMST as residue in animals products. Subsequently the necessity of setting of a residue definition for animal products needs to be discussed in the residue expert meeting.**

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
3(4)	Vol. 3, Point B.7.3, Definition of the residue	GR: The residue definition as stated for products of animal origin (parent compound and metabolites) is rather vague. The relevant metabolites should be specified in the residue definition.	(ii): In line with earlier point (3), the suggested residue definition for products of animal origin is parent compound only. RMS to revise DAR	See Open point 3.1 Depending from the decision of open point 3.1 the residue definition for products of animal origin has to be revised in the DAR
3(5)	Vol. 3, B.7.10	UK: Volume 3 on page 326 The case for none submission of rotational crop data needs to be expanded quoting the DT90's for tolylfluanid and its primary metabolite DMST. BAY: It is proposed to include in the monograph DT90 values at 10°C for parent and its metabolite DMST from Table B.8.1-11 and B.8.1-12 to show that both compounds are sufficiently degraded within one vegetation period. DT90 (10°C) of tolylfluanid: 3.4-18.8 days DT90 (10°C) of DMST: 9.5-48.7 days	(ii) Agreed. Tables B.8.-11 and – 12 can be quoted. It will be corrected in the revised DAR.	RMS to revise DAR
3(6)	Vol. 3, B.7.10	UK: Volume 3 on page 326 The MRL for grapes needs to be amended from 5 50 10 mg/kg (one of the trials gave a residue of 5.1 mg/kg). BAY: MRL-calculation was performed including	(ii) See applicant's comment no. 6 to Section 3 and rapporteur's comment no. 11 to Section 3.	Addressed

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
	continued Vol. 3, B.7.10	all values according to method I (Weinmann/ Nolting) resulting in a maximum residue value of 4.96 mg/kg. Furthermore, the result mentioned was identified as an statistical outlier.The calculation with elimination of outliers resulted in a maximum residue value of 3.78 mg/kg. The maximum residue value calculated according to method II (Wilkening) accouted for 4.00 mg/kg (cf. dossier p. 188). All results (with and witout the outlying figure of 5.1 mg/kg) lead to figures below the proposed MRL of 5 mg/kg. Investigating the specific conditions of this trial the following reasons, which contributed to the unusual high amount of residues can be given: - shorter spraying intervall (in comparison to trial No 0353-93 from the same data set - lower plant density (-25%) per ha - height of vines was one third less - nevertheless the same application rate/ha was applied - spraying was done manually Based on the rather large database for tolylfluanid residues in grapes and the above given rationale, an MRL of 5 mg/kg is considered to be an appropriate value.		
3(7)	Vol. 3, Point B.7.4, Use pattern	GR: The use in grapes should be more specific and should clarify whether it involves both	(ii) The use in grapes includes both table and wine grapes. Tolylfluanid is supported for	Addressed

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
		table and wine grapes. For strawberries it is not clarified if the use outdoors and/or indoors is intended. BAY: The use in grapes includes wine grapes and table grapes as well, as long as the PHI of 21/35 (southern/northern Europe) days is kept. For strawberries outdoor use is intended The use in grapes includes wine grapes and table grapes as well, as long as the PHI of 21/35 (southern/northern Europe) days is kept. For strawberries outdoor use is intended	use outdoors on strawberries.	RMS to clarify this point in the DAR. if necessary.
3(8)	Vol. 3, Point B.7.5, Identification of critical GAPs	GR: To out opinion the critical GAPs should be identified on the basis of the zones. Different critical GAPs should be identified for Southern and Northern Europe, if different GAPs are intended. In the cases where a greenhouse use is intended for a crop along to the outdoor uses, and this greenhouse use differs than that outdoors, then, a separate cGAP for this greenhouse use should be identified.	(ii) Agreed. It will be corrected in the revised DAR.	RMS to revise DAR
3(9)	Vol. 3, Point B.7.6, Residues arising from supervising trials	GR:: In Table B.7.6-1, 2 for pome fruits in Northern Europe, if the number of applications and the application rate per hl are taken to be within 25% of those in cGAP only seven trials	(ii) In 10 trials the number of application is 15. This was due to a specific request of German authorities to simulate a situation where a single product is used over an	RMS to revise DAR

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
		are according to the critical GAP for Northern Europe. If the trials with reduced over 25% number of application (7 instead of 15) are accepted that would raise the number of trials to nine, but a justification for this deviation for the number of applications based on the persistence of the a.s. should be provided. BAY: As high and low volume application are common agricultural practice it was intended to demonstrate that both techniques lead to comparable results. Therefore, evaluation of number of trials should be based on the criterion of application rate/ha (18 trials). Even if the number of applications is taken into consideration, sufficiant number of trials (10 trials with 15 appl. [according to German lable recommendation]; 8 trials with 7 appl.) is presented. Based on the residue behaviour of the compound, it is justifiable to combine both GAPs, because the crucial application,which determines the amount of residue at the day of harvest is the last one.	entire growing season to control the aimed pests. In 8 trials the number of application was 7. The supported use pattern for tolylfluanid in pome fruit grown in Northern Europe includes 7 applications. This figure is considered to represent a realistic worst case situation in regard to the max. number of applications per season. Therefore, only the trials conducted with 7 applications of tolylfluanid should be used for MRL calculation. An EU-MRL of 2 mg/kg is proposed to replace the previous one of 5 mg/kg given in the original DAR. The GAP table and new MRL proposal will be corrected in the revised DAR.	
3(10)	Vol. 3, Point B.7.6, Residues arising from supervising trials	GR: In relation to comment 2, in Table B.7.6-3 the type of grapes, wine or table should be stated as the MRLs are calculated on that basis. BAY: A common MRL for wine and table	(ii) The use in grapes includes both table and wine grapes. The MRL is intended to cover both table and wine grapes.	Addressed

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
		grapes is calculated and can be justified based on use pattern with a PHI of 21/35 days (southern/northern Europe).		
3(11)	Vol. 3, Point B.7.6, Residues arising from supervising trials	GR: The trials of Table B.7.6-6 for grapes cannot be used for MRL calculation as the application rate per ha is 50% below that in the critical GAP for Southern Europe.	(ii) Residue data based on the S-EU GAP represent the worst case scenario. In dossier and DAR the MRL proposal of 5 mg/kg was based on all 16 S-EU trials (See the applicant's comment no. 5 in Section 3). An abandonment of the results of trials given in Table B.7.6-5 does not have any effect on the MRL proposal. If a MRL is calculated by using only the results of 10 trials that were conducted exactly against the cGAP for S-EU (Table B.7.6-5), a MRL of 5 mg/kg can be proposed for grapes (R(max) = 4.61, R(ber) = 4.45).	Addressed
3(12)	Vol. 3, Point B.7.6, Residues arising from supervising trials	GR: In relation to comment 2, in Table B.7.6.-13, for strawberries, the field of use (outdoors or indoors) is not stated.	(ii) Tolylfluanid is supported for use outdoors on strawberries. The residue trials conducted with tolylfluadid on strawberries were outdoors trials.	Addressed
3(13)	Vol. 3, Point B.7.6, Residues arising from supervising trials	GR: On the basis of the residue levels presented in Tables B.6-17, 18, 19, 20 and 21, the greenhouse use appears to be more critical	(ii) See also comment No. 17 in Section 3. For tomatoes, the worst case situation is represented by the use of tolylfluanid in	Addressed

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
		than those in field. Therefore, the calculation of MRL for tomatoes and by extrapolation for aubergines, should be based only on this data from greenhouse trials.	the greenhouse. The MRL calculations using separately greenhouse data corresponding PHI of 3 and 7 days gave comparable results. Consequently, the MRL proposal for tomatoes of 2 mg/kg is based on the greenhouse trials.	
3(14)	Vol. 3, Point B.7.6, Residues arising from supervising trials	GR: Table B.6-22. For peppers only two trials in greenhouse are according to critical GAP (the two in the Netherlands). The rest of the trials are with very low compared to the critical application rate per ha (50% below). Six (6) more trials according to the cGAP for peppers indoors are required.	(ii) The notifier agreed to support a GAP up to 1.3 kg as/ha on peppers. This means that all trials are in acceptable range of 1.3 ± 25 % (0.98-1.63) kg as/ha. The GAP table will be corrected in the revised DAR.	RMS to revise DAR

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
3(15)	Vol. 3, Point B.7.6, Residues arising from supervising trials	GR: The trials of table B.7.6-.32 cannot be used for MRL calculation as the number of applications is reduced from 3 to 2 and there are enough (8) trials in table B.7.6.31 conducted according to the critical GAP for Southern Europe. BAY: MRLs were calculated for different use patterns. The worst case conditions are represented by the 8 trials in southern Europe (3 applications with the mixture of tolylfluanid & tebuconazole) which result in an MRL proposal of 15 mg/kg.	(ii) The MRL calculations for lettuce were performed separately for each data set: N-EU (tolylfluanid in mixture with iprovalicarb), S-EU (tolylfluanid as solo-product), S-EU (tolylfluanid in mixture with tebuconazole) and S-EU (sum of the results of tolylfluanid as solo-product and in mixture with tebuconazole). The use of tolylfluanid in mixture with tebuconazole represented the worst case situation and therefore these results were used for MRL proposal. In other words, the MRL proposal is based on the results shown in Table B.7.6-32.	Addressed
3(16)	Vol. 3, Point B.7.9, Livestock feeding studies	GR: For clarity and transparency reasons, the calculated by the Rapporteur intake of residues for beef and dairy cattles should be presented clearly, in a form that would enable the read to see the figures (residue levels, transfer factors) used for these calculations.	(ii) Agreed, the calculations of residue intake of tolylfluanid by dairy and beef cattle from apple pomace, supplied by the notifier, shall be added to the DAR.	RMS to revise DAR

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
3(17)	Vol. 3, Point B.7.13, Proposed EU MRLs and justification for the acceptability of those MRLs	GR: From Point B.7.6. as well as in this point it is not clear on which basis these MRLs were calculated by the Rapporteur. If they have been calculated by pooling the relevant data of the two zones (Northern and Southern Europe), we strongly oppose such an approach. On the contrary we would accept the approach and on the basis of our previous comments (2-10), i.e. to perform separate calculations of MRLs for Southern and Northern Europe and greenhouse and then for the MRL proposal, select the highest calculated. BAY: All MRL-calculations were specified for different zones (northern and southern Europe) and it is indicated if greenhouse use is intended. In each case the MRL proposal is based on the most cGAP, i.e. highest values.	(ii) MRLs were calculated separately for each data set (Southern Europe/Northern Europe/ greenhouse). If the data from all field trials were considered to be comparable e..g. concerning the PHI, calculation was also done based on the sum of all available data. For the MRL proposal the highest calculated MRL was selected.	Addressed For reasons of clarification the RMS should add a justification to the DAR.
3(18)	Vol. 3, Point B.7.13, Proposed EU MRLs and justification for the acceptability of those MRLs	GR: Were the average transfer factors obtained under point B.7.8 taken into account for the MRL proposals? BAY: MRLs were proposed for raw commodities only.	(ii) No.	Addressed

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
3(19)	Vol. 1, Level 4, Point 4.2.7	GR: Six (6) more residue trials according to the cGAP for peppers indoors are required. .	ii) The notifier agreed to support a GAP up to 1.3 kg as/ha on peppers. This means that all trials are in acceptable range of 1.3 ± 25 % (0.98-1.63) kg as/ha. The GAP table will be corrected in the revised DAR.	RMS to revise DAR
3(20)	Vol. 1, level 2, 2.4.2, Residues relevant for consumer safety	NL: It is questioned if the extrapolation from residue levels form the goat metabolism study performed at 45X to 1X is reliable. According to the Netherlands, it is quite uncertain that the LOQ will not be exceeded for liver and kidney tissue which are already *calculated* to be 0.03 mg/kg which is near to the LOQ. Furthermore it is questioned what happens if in future the MRL will be set at 0.01 mg/kg ('zero') after implementation of the new MRL regulation which is now under discussion, with respect to the calculated levels which are up to 0.03 mg/kg for liver. Therefore, it is proposed that a ruminant feeding study is needed to set MRLs for animal products. BAY: With respect to metabolism studies on farm animals, the trigger value for feeding studies is given as 0.01 mg/kg or above the limit of quantitation if this would be higher than 0.01 mg/kg in the relevant EU-guideline.	(ii) The observation that some of the calculated levels of residues in animal products are close to or just above the LOQ is correct. However, taking into account the conservatism built into the dietary intake calculations in domestic animals, and the overall fairly benign toxicological profile of tolylfluanid, as well as factors related to variation in analytical method tolerances at the low levels near the LOQ, it is still felt by the RMS that there are no health concerns related to dietary intake of feeding stuffs of animal origin. Feeding studies in ruminants would therby not be necessary in this particular case.	Addressed

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
	continued Vol. 1, level 2, 2.4.2, Residues relevant for consumer safety	Even though it is not expressly stated, in our opinion the wording implies that the value relates to a specific compound (for which an analytical method is available or could be developed) rather than to the TRR (total radioactive residue). Therefore, it is considered to be more accurate to calculate corrected metabolism data based on the values for the major specific metabolites (M XI and XIII, see AII, 6.4) rather than the TRR (DAR, B7.2.3). Following this approach 0.015 mg/kg (would be the highest residue to be expected in the excretory organs (kidney). Based on this deductive calculation no residues are expected in meat or milk. This extrapolation is considered to be reliable, because linearity can be assumed (justification dossier p. 134). excretory organs (kidney). Based on this deductive calculation no residues are expected in meat or milk. This extrapolation is considered to be reliable, because linearity can be assumed (justification dossier p. 134). The above mentioned metabolites are of no toxicological significance. The only feed item relevant for cattle possibly treated with tolylfluanid is apple pomace. The occurence		
	continued			

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
	Vol. 1, level 2, 2.4.2, Residues relevant for consumer safety	of the above mentioned metabolites in measurable amounts is to be expected only in excretory organs under worst case conditions. Even in the case (misuse) residues at a LOQ of 0.05 mg/kg would occur the impact of this residue intake via edible offals would be insignificant. Based on the ADI of 0.079 mg/kg bw for tolylfluanid and on calculations according to WHO guideline residue intake would account for <0.001% of ADI-exhaustion. The available data from the metabolism study are deemed sufficient to show that measurable tolylfluanid residues are not likely to occur in products of animal origin and would not result in an unacceptable risk to the consumer. Therefore, for this borderline case it is requested to waive the requirement for a feeding study. As a feeding study is not expected to reveal new information, to conduct one would mean a rather needless sacrifice of at least 12 cows. Thus, MRLs for products of animal origin are not proposed.		

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
3(21)	B5.4. Analysis method for plant and animal products	NL: As a consequence of the need for providing a ruminant feeding study and deducing MRLs for animal products (Vol 1, Level 2, 2.4.2), an analysis method (enforcement) for animal products is required for parent compound, 4-(dimethylaminosulfonyl amino) benzoic acid and 4-(dimethylaminosulfonyl) hypuric acid.	(ii) Refering to the previous point, the RMS is of the opinion that no further feeding studies in ruminants are necessary.	Addressed
3(22)	B7.6 Residue trials	NL: In table 7.6.4 for trial 8202-87, 8203-87, 0210-88, 0211-88, 0212-88 and 0213-88 the wrong PHI was selected (at the right PHI higher residues were found). BAY: DAR p.276: For northern Europe it is intended to support a PHI of 35 days for grapes. For MRL calculation values for 35 days were used, unless results from 42 days were higher. Table 7.4.1 (DAR p. 271) shows that different GAPs are intentended for northern and southern Europe (35 vs. 21 days).	(ii) The supported PHI for grapes in N-EU is 35 days (See Table B.7.4.1 in Vol. 3.) In Table B.7.6.4 for trials 8200-87 and 8201-87 the residue values corresponding to day 42 were selected for MRL calculation because of higher residues were found than at day 35.	Addressed

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
3(23)	B7.6 Residue trials	NL: In table 7.6.13 (strawberry) residue trials with PHI 3 days in stead of PHI 7 days were selected BAY: For southern Europe a GAP with PHI of 3 days, for northern Europe a GAP with PHI of 7 days is intended (DAR p.271, 283 – 286).	(ii) The supported PHI for strawberries in S-EU is 3 days and 7 days in N-EU (See Table B.7.4-1 in Vol 3.). Thus residue results at right PHI were selected.	Addressed
3(24)	B7.6 Residue trials	NL: In table 7.6.17 (tomatoes) residue trials with PHI 3 days in stead of PHI 7 days were selected BAY: For southern Europe, northern Europe, and greenhouse use a PHI of 3 days is intended and supported for the straight-formulation for tomatoes. For the in-can formulation with SZX 722 (Iprovalicarb) greenhouse use is intented with a PHI of 7 days. (DAR p. 289-293). MRL-calculations were conducted separately for the different GAPs and the proposed MRL (2 mg/kg) is based on the worst case conditions in the greenhouse.	(ii) The supported PHI for tomatoes in N-EU and S-EU is 3 days. The supported PHI for tomatoes is 7 days only in greenhouse application (See Table B.7.4-1 in Vol. 3). Thus residue results at right PHI were selected.	Addressed
3(25)	B7.6 Residue trials	NL: In table 7.6.22 residue trials (pepper) with a application rate of 1.0 kg ai/ha were selected while this is outsite the acceptable range of 1.5 ± 25% (1.11-1.88) kg ai/ha	(ii) The notifier agreed to support a GAP up to 1.3 kg as/ha on peppers. This means that all trials are in acceptable range of 1.3 ± 25 % (0.98-1.63) kg as/ha.	Addressed

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
3(26)	B7.6 Residue trials	NL: In table 7.6.24 residue trials (cucumber) with a application rate of 1.0 kg ai/ha were selected while this is outsite the acceptable range of 1.5 ± 25% (1.11-1.88) kg ai/ha BAY: For treatment in glasshouses , an application rate of either consistently 1.5 kg a.s./ha is envisaged or – especially for Germany – one which increases with the growth stage of the plants from 0.6 up to 1.2 kg a.s./ha. All trials a were performed with a consistant spray concentration of 0.1 kg as/hl. The described deviation in GAPs is not considered to be of relevance. This assessment is derived at by the following facts: - All trials were conducted with the same spray concentration. - Due to the short half-life time values it is indicated that the crucial application is the last one before harvest. In the German trials the last application was performed with 1.2 kg a.s./ha adjusted to plant height. Thus, resulting residue values for PHI 3 days from both trial sets can be combined, because the deviation for the last application rate does not exceed 25%. The results of all trials vary in the same order of magnitude.	(ii) The cGAP of supported use of tolylfluanid on cucumber/zucchini in greenhouse is 3 application up to 1.5 kg as/ha (spray conc. 0.1 kg as/hl) with PHI of 3 days. In the 2 Italian and the two Spanish trials, the application rate was consistently 1.5 kg as/ha, and the water volume was 1500 L/ha in 3 trials, and 1000 L/ha in 1 trial. In the four German studies, the dosage as well as the amount of water increased with the growth stage of the cucumbers in such a way that the first treatment was carried out with 0.9 kg as/ha in 900 L/a, and the second to sixth application with 1.2 kg as/ha in 1200 L/ha. However, why the deviation in the employed application rate was not considered to have significant effect on the amount of tolylfluanid residues detailed discussed in dossier. Therefore, it was considered that the data requirements were fulfilled.	Addressed

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
3(27)	B7.7 Storage stability data	NL: As a consequence of the need for providing a ruminant feeding study and deducing MRLs for animal products (Vol 1, Level 2, 2.4.2), storage stability data for animal products of parent compound, 4-(dimethylaminosulfonyl amino) benzoic acid and 4-(dimethylamino-sulfonyl) hypuric acid are needed. BAY: As a waiver for a feeding study is requested and thus, no MRLs for products of animal origin are proposed, storage stability data for animal products are considered to be not necessary.	(ii) Not agreed. Feeding studies in ruminants are not considered necessary.	Addressed
3(28)	Vol. 3, B. 7.13 Proposed MRLs	DK: It is considered that MRLs should not be proposed for non-cereal food crops or poultry products (as intakes in poultry are not significant) BAY: We agree that an MRL for poultry products is not necessary.	(ii) No MRLs for animal products is proposed as any measurable residues of tolylfluanid or relevant metabolites are not expected to occur. However, when calculating dietary risk including foodstuff of animal origin, the LOQs of the analytical methods were used.	Addressed

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
3(29)	Vol. 3, B.7.16.1, Chronic Exposure	DE: Due to the proposal in the toxicological section to lower the ADI a new intake assessment is necessary. BAY: In the AII dossier on tolylfluanid, the chronic exposure through diet was assessed based on an ADI value of 0.079 mg/kg body weight (German proposal). This ADI value represents the lowest value currently under discussion for an appropriate ADI for tolylfluanid.	(ii) A change of the ADI may be considered necessary depending on peer-review discussions. New calculations are supplied if needed.	**Open point 3.2** **(See open points 2.6 and 2.9)** **RMS to provide a revised intake calculation if ADI should be changed.** Evaluation Meeting (12.03.2004): Open point still open.
3(30)	Vol. 3, B.7.16.2, Acute Exposure	DE: Due to the proposal in the toxicological section to set an ARfD an intake assessment is necessary. BAY: Although it is recognised that the need toestablish an Acute Reference Dose still needs to be discussed, a statement on acute dietary exposure to tolylfluanid was prepared to support the review process (See separate document).	(ii) Acute dietary intake assessments for consumers may be necessary depending on a peer-review decision the necessity of setting an ARfD.	**Open point 3.3** **(See open point 2.1) RMS to provide an acute risk assessment if an ARfD should be derived** Evaluation Meeting (12.03.2004): Open point still open.

Section 3 – residues

Evaluation Meeting (12.03.2004)

Based on a comment of France another open point was identified:

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.

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.

-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.

4. Environmental fate and behaviour

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
4(1)	Vol. 1, 2.5, PEC values	SE: The scenarios chosen for PECsoil, groundwater, surface water and sediment do not appear to include the worst case scenarios, e.g. 15 applications in apples/pears at 1.125 kg as/ha and 6 applications in hops at 3 kg as/ha. BAY: 15 applications in pomefruit and 6 applications in hops are strictly a national issue, based on the former German requirement that biological and residue testing should cover full season disease control by use of one product. This very hypothetical use pattern does not cover the realistic safe use described in the EU dossier.	(ii): RMS agrees with the notifier. The revised use pattern in pome fruit will be presented in the DAR and in the list of end points. The uses supported by the notifier were, however, considered in the sections on environmental fate and behaviour and ecotoxicology of the DAR and thus no necessity for change of the scenarios is seen.	Open point 4.1: MS to discuss representative use taken for the Fate and Behaviour and Ecotoxicological assessment. If necessary, RMS to revise the DAR and the list of end point and check consistency between intended uses and the assessment. Evaluation Meeting (12.03.2004): The meeting agrees with the RMS's position. Open point fulfilled.
4(2)	Vol. 1, 2.5.2.3, PECsoil *continued*	SE: PECsoil should generally be calculated by use of realistic worst case DT50. In this case, mean DT50 values for a.s. and DMST were used. The FOCUS-scenarios used take worst-case conditions for leaching on board, by use of worst case weather and soil scenarios. Therefore, mean DT50 values are acceptable for PECgroundwater, but not for PECsoil. We realize though that in this case the risk assessment is not likely to change by this.	(ii): RMS agrees with the notifier. Additionally the calculated DT50 values of the active substance at 10 oC were 1.0-5.7 days (mean 3.8 days). Even these values are so low that the risk assessment would not be influenced by use of these parameters.	**Open point 4.2:** MS to discuss whether it is acceptable to use mean DT50 values for the PECsoil calculations Evaluation Meeting (12.03.2004): **RMS to provide an addendum to the draft assessment report on the use of mean DT50 values for the PECsoil calculations and the**

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
	Vol. 1, 2.5.2.3, PECsoil	BAY: The DT50 of tolylfluanid (0.5-2.6 days, geometric mean: 1.5 days, 90th percentile 2.4 days) is an order of magnitude shorter than and the period between 2 applications (7-12 days). Therefore, tolylfluanid is completely degraded between two applications and the choice of the mean or worst case degradation rate doesn't influence maximum PECsoil values. Due to the slightly longer DT50 of DMST (1.3-6.7 days, geometric mean: 2.8 days, 90th percentile 6.0 days) a slight influence of the previous application to the max. PECsoil after application has to be taken into account. However, independent on the use of mean or worst case DT50, significant degradation takes place between two applications. In any case, the terrestrial ecotoxicity of DMST is that low that TER values for soil organisms are far above the trigger values for refined risk assessment.		**impact with respect the use of worst case.** The addendum will then be discussed in the expert meeting. Open point still open.

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
4(3)	Vol. 1, level 2, 2.5.3.3	NL: Why is the high value for DT_{50} sediment DMST used for the calculations Because of the short incubation time of the test, the extrapolated value for DT_{50} sediment can not be guarded as reliable. BAY: In EXAMS degradation of tolylfluanid and formation and degradation of DMST depend from each other. Therefore, for sake of consistency DT_{50} values for both compounds derived from the same study were used. (It goes without saying that the study more reliable for the parent compound is used in this case.)	(ii): RMS considers the comments of the notifier satisfactory. Additionally sediment dwelling organisms are not very sensitive to DMST and the TER values calculated based on these DT50 values do not have influence on the final risk assessment for aquatic organisms.	**Open point 4.3:** MS to discuss **appropriateness of DT50 sediment DMST used for the calculations.** Evaluation Meeting (12.03.2004): Open point needs **to be discussed in an expert meeting.** Open point still open.
4(4)	Vol. 1, 2.5.3.3, PECsw	SE: Generally, realistic worst-case DT50 values should be used for calculation of PECsw. In this case, it appears that both mean and worst-case values were used. The use of mean values should be justified. BAY: Mean DT50 values were used to simulate representative conditions and thus to show the range of environmental concentrations which can be realistically expected. In any case, the ecotoxicological risk assessment was made on the basis of the worst case PEC values.	(ii): RMS considers the comments of the notifier satisfactory.	**Open point 4.4:** **MS to discuss whether the DT50 value and the method employed for the PECsw calculation is acceptable.** Evaluation Meeting (12.03.2004): Open point needs to be discussed **in an expert meeting.** Open point still open.

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
4(5)	Vol.1, Appendix 3, List of endpoints	NL: Koc; change text 'determined by HPLC-method' to 'estimated using HPLC-method'. The HPLC method provides only an estimated value (see SCP opinion). BAY: We agree with the Dutch proposal. (The OECD draft guideline which was followed in this study, has the title '*Estimation* of the Adsorption Coefficient (K_{OC}) on Soil and on Sewage Sludge using High Performance Liquid Chromatography (HPLC)'.)	(ii): RMS agrees with NL. The text will be changed in the endpoints list.	Addressed. RMS to amend the list of endpoints with respect method employed for Koc. Amendment already done.
4(6)	Vol. 3, B.8, PEC values	SE: The scenarios chosen for PECsoil, groundwater, surface water and sediment do not appear to include the worst case scenarios, e.g. 15 applications in apples/pears at 1.125 kg as/ha and 6 applications in hops at 3 kg as/ha. BAY: see comments to point vol.1, 2.5	(ii): RMS considers the comments of the notifier satisfactory. See comments to point vol. 1, 2.5.	See open point 4.1

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
4(7)	Vol. 3, B.8.1.1, Route of degradation in soil	NL: The analytical method used is not validated and not comparable to the method supposed in chapter B.5. Because of the low recovery of the parent on t=0 and the values for DMST serious doubts about the validity of the used method arise. BAY: Due to the known sensitivity to hydrolysis, stability of tolylfluanid during the extraction process was especially examined and demonstrated by comparing results from extraction with 1 x methanol/water (4:1) and 2 x 100% methanol with results from extraction with 1 x 100% dichloromethane and 2 x 100% methanol. Both extraction methods gave comparable results. Therefore, it can be concluded that fast degradation of tolylfluanid between application and the first sampling point took actually place in the incubated soil and was not an artefact of the analytical method.	(ii): RMS considers the comments of the notifier satisfactory.	Addressed. RMS to amend the DAR to include acceptability of analytical method employed in the studies of the route of degradation in soil.

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
4(8)	Vol. 3, B.8.1.3, Summary of degradation in soil.	NL: As just for one of the soils the data showed a good fit there is only 1 reliable DT_{50} value for the parent compound available instead of 4 required. For the parent 3 additional DT_{50} values in soil should be available unless the parent can be seen as a precursor. Data requirement to be added in volume 1, level 4. BAY: There is no doubt that 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. 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 show clearly a DT50 =1 day.	(ii): RMS considers the comments of the notifier satisfactory. Risk assessment would not be influenced by recalculation.	**Open point 4.5:** MS to discuss **the need of additional DT50 values for the degradation of tolylfluanid in soil.** Evaluation Meeting (12.03.2004): Open point needs **to be discussed in an expert meeting.** Open point still open.

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
4(9)	Vol. 3, B.8.2.1, Adsorption	NL: The determined Koc with HPLC-method is just an estimation. According to the SCP opinion (Opinion of the scientific committee on plants on methods for the determination of the organic carbon adsorption coefficient (Koc) for a plant protection product active substance, SCP/KOC/002-final, 18 July 2002) the result of the method is not a reliable value. Because of fast hydrolysis of the parent no batch method is possible. A column study as described in the SCP opinion is considered a better study method and required. BAY: According to OECD draft guideline 312 the leaching period of a column leaching study is 2 days. Therefore, column leaching studies are not reliable for unstable compounds. Due to the hydrolytic and biotic instability of tolylfluanid this test design would result in a nearly complete degradation of the test compound and thus give no better result. In case of a compound like tolylfluanid, the estimation of the Koc value is considered to be the only feasible and valid approach.	(ii): RMS considers the comments of the notifier satisfactory. Additionally according to the SCP opinion the underestimation of Koc becomes considerable if Koc exceeds 100 L/kg. RMS agrees with NL that the HPLC-method provides an estimated value and the comment will be added in the endpoint list.	**Open point 4.6:** MS to discuss the need of additional Koc values for the adsorption of tolylfluanid in soil. Evaluation Meeting (12.03.2004): The meeting agreed on the RMS's position. **RMS to amend the list of end points clarifying that the Koc values for the adsorption of tolylfluanid in soil is an estimation.** Open point still open.

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
4(10)	Vol. 3, B.8.2.1.1, Adsorption/desorption of active substance (Sommer 2000)	UK: Chemicals used as reference standards do not have similar characteristics to active substance. Suggest RMS adds comment to endpoints explaining that result from study is likely to be a rough estimate. BAY: Generally, the HPLC method can only be used as ”a last resort ” when the use of equilibration methods (batch or column leaching) is impossible. Reference substances were chosen from the list given in the OECD guideline. Compounds with very similar structural characteristics have often similar physico-chemical properties and thus similar problems with stability and cannot be used due to the lack of reliable batch experiments to determine their Koc values. However, in the endpoint list the comment to the Koc value of tolylfluanid (”value determined by using HPLC method”) could be changed to ”value *estimated* by .....”.	(ii): RMS considers the comments of the notifier satisfactory. RMS agrees with UK that the HPLC method provides an estimated value and the comment will be added in the endpoint list. See also comments to point vol 3, B.8.2.1.	Addressed. RMS to amend the list of endpoints with respect method employed for Koc.

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
4(11)	Vol. 3, B.8.2.2.2, Aged residue column leaching study (Scholz 1987a)	UK: Ageing periods used significantly in excess of one half-life. Suggest RMS clarifies by stating this, or by repeating half-life value, in endpoints for this study. BAY: It is correct that according to current proposal for OECD guideline 312 the ageing period should be 1 half-life and that in the BBA guideline valid in 1987 much longer ageing periods were proposed. However, the aim of this study type is only to supplement batch sorption experiments of degradation products (These batch experiments were provided for DMST).	(ii): RMS agrees with the notifier. The study gives information on the leaching properties of degradation products. The half-life value will be added in the DAR and in the endpoint list.	**Open point 4.7:** MS to discuss the acceptability of column leaching study (Scholz 1987a). RMS to revise the DAR and the list of end points if necessary. Evaluation Meeting (12.03.2004): **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).** Open point still open.
4(12)	Vol. 3, B.8.3 PECsoil	SE: PECsoil should generally be calculated by use of realistic worst case DT50 (see further comment on Vol.1). BAY: see comments to point vol. 1, 2.5.2.3.	(ii): RMS considers the comments of the notifier satisfactory. See also comments to point vol. 1, 2.5.2.3.	See open point 4.2

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
4(13)	Vol. 3, B.8.3, Predicted environmental concentration in soil (Schad 2001a, Schäfer 2001a)	UK: PECs not calculated in accordance with Commission doc 7617/VI/96 (FOCUS soil persistence guidance). Approach used may underestimate worst case PECs, particularly for mobile metabolite DMST. UK considers that PECs for endpoints should be recalculated in accordance with 7617/VI/96. BAY: In the document 7617/VI/96 basic characteristics, input parameters and validation status of different simulation models are discussed. In addition, some guidance is given for simple estimates as 1st tier approach. For the notifier it is not clear which part, input parameter etc. of PECsoil calculation is not accepted and is asked to be corrected.	(ii): RMS agrees with the notifier. Additionally RMS does not find it necessary to recalculate the PECs values due to fast degradation of active substance and low toxicity of DMST. The risk assessment is not likely to change by the new PECs value of the active substance. For DMST there should be slight differences by recalculation but the risk assessment would not be changed. See comments to point vol 1, 2.5.2.3.	See open point 4.2

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
4(14)	Vol. 3, B.8.3.1, PEC_s	NL: PEC_{soil} calculations should be performed with worst-case DT_{50} values. This should then also be corrected in Volume 1. BAY: Due to the very fast degradation of tolylfluanid which is an order of magnitude shorter than the time between two applications, the choice of the degradation rate (mean or 90th percentile) has no influence on maximum PEC_{soil}. For DMST the maximum PEC is slightly influenced by the degradation rate and thus by the choice of the mean or 90th percentile value. However, terrestrial ecotoxicity of DMST is so low that the risk assessment would not be influenced by these parameters.	(ii): RMS agrees with the notifier. See also comments to point vol. 1, 2.5.2.3 and vol. 3, B.8.3.	See open point 4.2

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
4(15)	Vol. 3, B.8.4.1 and B.8.4.2, Hydrolytic degradation and photochemical degradation (Wilmes 1982, Suzuki and Yoshida 1994, Hellpointer 1992 and 2000)	UK: Procedural recoveries for these cold studies were not stated. UK considers that levels (or acceptability) of recoveries should be stated. BAY: In the reports of hydrolysis (Wilmes, 1982 and Suzuki & Yoshida, 1994) recoveries were determined and stated in the reports (100 % and 106 %, respectively). In the study on photochemical degradation of tolylfluanid (Hellpointner, 1992) no degradation experiment and thus no residue analysis was needed due to the lack of light absorption. In the study on photochemical degradation of DMST (Hellpointner, 2000) recovery of 100 % was stated indirectly by measuring the concentration at 0 min irradiation, which was identical with the test concentration.	(ii): RMS considers the comments of the notifier satisfactory.	Addressed. RMS to amend DAR to include procedural recoveries of hydrolitical and photochemical degradation studies.

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
4(16)	Vol. 3, B.8.4.3.2, Water/sediment studies	NL: The DT_{50} value for DMST in sediment is much much longer than in the 1st experiment and seem urealistic. In the 3rd experiment sampling was performend until 7 days after application. There was only one sample point after the maximum was reached in the water and it is not clear that the maximum in the sediment has been reached. The extrapolation of DT_{50} in the sediment has led to unrealistic high values. BAY: We fully agree with this comment. However, from our point of view the fact that one study was performed for description of degradation of tolylfluanid and one for DMST, is also clearly explained in the monograph and the dossier.	(ii): RMS considers the comments of the notifier satisfactory. See also comments to point vol. 1, level 2, 2.5.3.3	See open point 4.3.
4(17)	Vol. 3, B.8.6 PECsw	SE: Generally, realistic worst-case DT50 values should be used for calculation of PECsw. (see further comment on Vol.1) BAY: see comments to point vol. 1, 2.5.3.3	(ii): RMS considers the comments of the notifier satisfactory. See also comments to point vol. 1, 2.5.3.3.	See open point 4.4.

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
4(18)	Vol. 3, B.8.6.1, PEC_{SW}	NL: temperature correction of the DT_{50} to 15ºC is not common in Tier 1 evaluation. PEC_{sw} should, to our opinion, be recalculated using the DT_{50} at 20ºC. BAY: According to EPA, the publisher of the model EXAMS, this model is a Tier 2 evaluation. In any case, it's not clear why the use of worst case data is criticised. No necessity for recalculation is seen.	(ii): RMS agrees with NL. PECsw should be calculated using the DT50 values obtained at 20 oC. However, tolylfluanid is unstable in water and a chronic risk assessment is not appropriate for this substance. Thus only maximum initial PECsw of a.s. were used for the risk assessment. Because of the fact that the DT50 values were not used for calculation of PECsw initial RMS doesn't find it necessary to recalculate the PECsw values of tolylfluanid. The aquatic toxicity of DMST is low and even the TER values calculated on the basis of DT50 values at 15 oC were over trigger values. Thus no necessity for recalculation of the PECsw values of DMST is seen.	See open point 4.4.

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
4(19)	Vol 3, B.8.6.1, PEC_{sw}	NL: Does the model EXAMS provide the same data as standard input calculations? It looks like the same dimensions are used as in the standard calculations, we would like a conformation on this. BAY: In addition to ”standard input calculations” EXAMS takes into account transport and transformation processes within the aquatic system. For tolylfluanid and DMST results from EXAMS should range in similar dimensions like ”standard input calculations” due to the very fast and complete transformation of tolylfluanid to DMST.	(ii): RMS considers the comments of the notifier satisfactory.	See open point 4.4.

5. Ecotoxicology

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
5(1)	Vol. 1, 2.6 Risk assessment scenarios	SE: The scenarios chosen for risk assessment do not appear to include the worst case scenarios, e.g. 15 applications in apples/pears at 1.125 kg as/ha and 6 applications in hops at 3 kg as/ha. BAYER answers: The use scenarios (max application rate/max number of treatments) used in the risk assessment remain unchanged, but reflect the worstcase scenarios in the revised GAP see general comments.	(ii): RMS considers the comments of the applicant satisfactory. See also comments to point Vol. 1, 2.5.	See open point 4.1
5(2)	Vol.1, 2.6.1 Effects on birds *continued*	SE: The toxicity endpoint from short-term dietary study and reproduction study should consistently be expressed as daily dose (mg as/kg bw per day), in order to take into account the different feed intake between laboratory and wild animals. The difference in feed intake depends mainly on different energy expenditure of the animals, and on different energy and moisture content of the food in the laboratory compared to that in the field. BAYER answers: The risk assessment for birds presented in the dossier was based on guidance that was appropriate at the time of dossier submission, however has been	(ii): RMS agrees with Sweden and considers the comments of the applicant satisfactory. The new risk assessment for birds is presented in the Addendum and the results are updated in the revised list of end points.	**Open point 5.1:** MS to discuss **the conclusions from the addendum regarding the risk assessment for birds.** Evaluation Meeting (12.03.2004): Open point needs **to be discussed in an expert meeting.** Open point still open.

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
	Vol.1, 2.6.1 Effects on birds	revised, based on the new SANCO Guidance Document (4145/2000), and is presented in Appendix 1. In line with the new guidance, the toxicity endpoints from the short-term dietary study and reproduction study have been expressed as a daily dose (mg as/kg bw per day).		
5(3)	Vol.1, 2.6.1 Effects on birds	SE: In the exposure assessment , RUD in accordance with Appendix II of Guidance Doc 4145 should have been used. BAYER answers: The risk assessment for birds presented in the dossier was based on guidance that was appropriate at the time of dossier submission, however has been revised, based on the new SANCO Guidance Document (4145/2000), using the relevant RUD values in accordance with Appendix II of Guidance Doc 4145 (see Appendix 1). In addition relevant data from residues trials have also been incorporated into the risk assessment as appropriate.	(ii): RMS agrees with Sweden and considers the comments of the applicant satisfactory. The new risk assessment for birds is presented in the Addendum and the results are updated in the revised list of end points.	See open point 5.1

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
5(4)	Vol. 1, 2.6.3 Effects on wild mammals	SE: The toxicity endpoints should consistently be expressed as daily dose (mg as/kg bw per day), in order to take into account the different feed intake between laboratory and wild animals. The difference in feed intake depends mainly on different energy expenditure of the animals, and on different energy and moisture content of the food in the laboratory compared to that in the field. BAYER answers: The risk assessment for mammals presented in the dossier was based on guidance that was appropriate at the time of dossier submission. Based on the new SANCO Guidance Document (4145/2000) the toxicity endpoints have been expressed as a daily dose (mg as/kg bw per day) in the up-dated risk assessment (see Appendix 1).	(ii): RMS agrees with Sweden and considers the comments of the applicant satisfactory. The new risk assessment for wild mammals is presented in the Addendum and the results are updated in the revised list of end points.	Open point 5.2: MS to discuss **the conclusions from the addendum regarding the risk assessment for mammals.** Evaluation Meeting (12.03.2004): Open point needs **to be discussed in an expert meeting.** Open point still open.

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
5(5)	Vol. 1, 2.6.3 Effects on wild mammals	SE: In the exposure assessment , RUD in accordance with Appendix II of Guidance Doc 4145 should have been used. BAYER answers: The risk assessment for mammals presented in the dossier was based on guidance that was appropriate at the time of dossier submission, however has been revised, based on the new SANCO Guidance Document (4145/2000), using the relevant RUD values in accordance with Appendix II of Guidance Doc 4145 (see Appendix 1). In addition relevant data from residues trials have also been incorporated into the risk assessment as appropriate.	(ii): RMS agrees with Sweden and considers the comments of the applicant satisfactory. The new risk assessment for wild mammals is presented in the Addendum and the results are updated in the revised list of end points.	See open point 5.2.
5(6)	Vol.1, Appendix 3 Effects on aquatic species *continued*	SE: Please include and make clear the RMS's final risk assessment with regard to fish in the list of endpoint. From pages 502-502 and Table B.9.2.10-24 in Annex B we understand that the RMS's final assessment applies an assessment factor of 3 to NOEC 60 µg/l, resulting in acceptable risk at 5-15 m sprayfree zones. We can agree to that conclusion. It is important however to point out that at lower pH conditions than used in the studies, and at > 4 applications/season, the conclusion is more uncertain. Use of assessment factor lower than, say 3-5, is not justified in this case, since the outdoor	(ii): RMS agrees with Sweden. Two outdoor microcosm studies were sent by applicant later than the other studies and the end point lists were unfortunately not dated…The mistake is corrected in the new list of endpoints.	RMS to revise the list of endpoints **Data requirement 5.1:** **Notifier to submit new acute toxicity test with zebrafish at different pH-values.** Evaluation Meeting (12.03.2004): Notifier states that the study is finished and can be submitted any time. RMS is asked to evaluate the data so that it can to be discussed in the expert meeting.

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
	Vol.1, Appendix 3 Effects on aquatic species *continued*	justified in this case, since the outdoor microcosm had some shortcomings and since the HC5 approach in itself has not yet been generally adopted. BAYER answers: BCS acknowledge that pH is important in determining the hydrolysis of tolylfluanid and therefore a new acute toxicity test with zebrafish at different pH-values is being conducted to GLP. This additional confirmatory study will clarify the RMSs final risk assessment with regard to fish. The higher tier aquatic data was subject to independent expert review (Ratte 2002) and found to be of high quality and sufficiently detailed to support the conclusions drawn. Based on i) the exposure regime is considered appropriate for the proposed GAP (4 applications made at weekly intervals in a 35 day study), particularly for tolylfluanid which is unstable in water, ii) evaluation of all of the available aquatic data (i.e. the HC5 approach is not used in isolation), and iii) the use of worst case instantaneous PECs to calculate TERs, the use of lower assessment factors is considered appropriate. BCS recommended an assessment factor of 1.5 to be applied to the study endpoint to extrapolate to lower pH ranges in natural water		Data requirement still open.

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
	Vol.1, Appendix 3 Effects on aquatic species			
5(7)	Vol. 1, appendix 3, list of endpoints. Toxicity data for aquatic species Toxicity/exposure ratios	DK: The NOEC HC_5 – acute studies value should be deleted and the results of the microcosm studies for fish and invertebrates should be included. BAYER: The list of endpoints, Page 102-103, AQUATICS, has to be revised in such a manner, that the list of endpoints reflects the results of the two outdoor-microcosm studies as well as the newly calculated TER and crop dependent buffer zones DK: The NOEC HC_5 – acute studies value should be deleted and the TERs should be revised to take into account further uncertainties. BAYER answers: See rationale and explanations above.	(ii) RMS agrees with DK and BAYER. Values are corrected in the new list of endpoints. (ii) RMS agrees with the NOEC HC_5 but thinks that the TER revisions should be discussed further with all member states.	RMS to revise list of endpoints **Open point 5.3:** MS to discuss **the TER revisions for aquatic organisms** in the Evaluation meeting. Evaluation Meeting (12.03.2004): The TER revisions for aquatic organisms should be assessed in combination with the new data on zebrafish. Open point needs **to be discussed in an expert meeting.** Open point still open.

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
5(8)	Vol 1 Appendix 3 Listing of Endpoints Effects on Non-Target species	UK: It is implied that the recommendations in HARAP and ESCORT 2 are Annex VI triggers. Unless and until they are formally incorporated into Annex VI they should be treated only as guidance for the possible refinement of first tier uncertainty triggers. BAYER answers: BCS acknowledge that the trigger values referred to in both HARAP and ESCORT 2 are not yet formally incorporated into Annex VI.	(ii) RMS agrees with UK. It is only for "technical" reasons why HARAP and ESCORT triggers are presented together with Annex VI triggers. There is also a reference (* or number) which tells that the trigger is not the Annex trigger but the trigger is taken from. e.g. HARAP.	
5(9)	Vol.1, Level 4 Bioconcentration study	SE: Bioconcentration studies should in accordance with OECD TG be performed at two concentrations to identify potential concentration dependency. The requirement can be dealt with as confirmatory. BAYER answers: The study was conducted in accordance with GLP and to the recommended test guideline at that time. The steady-state BCF was low (74 for whole fish) and the depuration was rapid (total residues in fish declined with a half-life of 0.38 days). For animal welfare reasons generation of additional data to confirm the study endpoints is considered unnecessary.	(ii) RMS agrees with the applicant.	-

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
5(10)	Vol. 3 General point	UK: The use scenarios (max application rate/max number of treatments) used in the risk assessment sections of Vol 3 do not appear to reflect the GAPs proposed in section 1.5.3.1 of Vol 1 Level 1. BAYER answers: The use scenarios (max application rate/max number of treatments) used in the risk assessment remain unchanged, but reflect the worst-case scenarios in the revised GAP see general comments.	(ii) RMS considers the comments of the applicant satisfactory. See also comments to point Vol. 1, 2.5.	See open point 4.1
5(11)	Vol. 3, B.9 Risk assessment	SE: The scenarios chosen for risk assessments do not appear to include the worst case scenarios, e.g. 15 applications in apples/pears at 1.125 kg as/ha and 6 applications in hops at 3 kg as/ha. BAYER answers: The use scenarios (max application rate/max number of treatments) used in the risk assessment remain unchanged, but reflect the worst-case scenarios in the revised GAP see general comments.	(ii) RMS considers the comments of the applicant satisfactory. See also comments to point Vol. 1, 2.5.	See open point 4.1.

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
5(12)	Vol.3, B.9.1.4 Risk assessment to birds	SE: The toxicity endpoint from short-term dietary study and reproduction study should consistently be expressed as daily dose (mg as/kg bw per day). BAYER answers: The risk assessment for birds presented in the dossier was based on guidance that was appropriate at the time of dossier submission, however has been revised, based on the new SANCO Guidance Document (4145/2000), and is presented in Appendix 1. In line with the new guidance, the toxicity endpoints from the short-term dietary study and reproduction study have been expressed as a daily dose (mg as/kg bw per day).	(ii): RMS agrees. The new risk assessment for birds is presented in the Addendum and the results are updated in the revised list of end points.	See open point 5.1

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
5(13)	Vol.3, B.9.1.4 Risk assessment to birds	SE: In the exposure assessment , RUD in accordance with Appendix II of Guidance Doc 4145 should have been used. BAYER answers: The risk assessment for birds presented in the dossier was based on guidance that was appropriate at the time of dossier submission, however has been revised, based on the new SANCO Guidance Document (4145/2000), using the relevant RUD values in accordance with Appendix II of Guidance Doc 4145 (see Appendix 1). In addition relevant data from residues trials have also been incorporated into the risk assessment as appropriate.	(ii): RMS agrees. The new risk assessment for birds is presented in the Addendum and the results are updated in the revised list of end points.	See open point 5.1.

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
5(14)	Vol.3, B.9.1.4 Risk assessment to birds	NL: It is recommended to base the risk assessment for birds on the Guidance Document on Risk Assessment for Birds and Mammals. For orchards and grapes only an insectivorous bird should be taken into account. According to the Guidance Document the averaging time for calculating a TWA should not be longer than the interval between two applications. So, in the case of tolylfluanide, an averaging time of 7 days must be taken instead of 21 days. BAYER answers: The risk assessment for birds presented in the dossier was based on guidance that was appropriate at the time of dossier submission, however has been revised, based on the new SANCO Guidance Document (4145/2000), and is presented in Appendix 1. In accordance with the guidance document the averaging time for calculating the TWAs has been revised using an averaging time of 7 days.	(ii): RMS agrees. The new risk assessment for birds is presented in the Addendum and the results are updated in the revised list of end points.	See open point 5.1

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
5(15)	Vol. 3, B.9.1.4 page 433-450. Long term risk to herbivorous birds	UK: UK agrees that further refinement of TERlt is necessary. However, the proposed refinement of residue levels using median 50% values requires further justification. Justification for the extrapolation from the DT50 of 3.1 days based on lettuce heads to outdoor short grasses must also be provided. BAYER answers: The risk assessment for birds presented in the dossier was based on guidance that was appropriate at the time of dossier submission, however has been revised based on the new SANCO Guidance Document (4145/2000) and is presented in Appendix 1. In-line with current guidance, median 50% values have only been used for calculation of short and long-term TER values. In addition, relevant data from residue trials on grass have also been incorporated into the risk assessment and confirm a mean DT_{50} value of 2.47 days.	(ii) RMS considers the comments of the applicant satisfactory. The new risk assessment for birds is presented in the Addendum and the results are updated in the revised list of end points.	See open point 5.1
5(16)	Volume 3, point B.9.2 Effects on aquatic organisms (fish, aquatic invertebrates, algae)	GR: When reviewing the reports it is clearly that the end points used for the risk assessment for Daphnia derives from the static test while for fish the notifier prefers end points from flow-through tests. We fully agree with the suggestions made from the RMS.		
5(17)	Vol. 3, B.9.2.4, Acute	BAYER: It is stated to the acute static study with	(ii) Acute static study with fish: RMS did	

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	toxicity to aquatic invertebrates	aquatic invertebrates (Page 468), that "…in principle, the results of the test should not be considered valid for the risk assessment or measured concentrations should be used for the calculation of LC_{50}. In contrast, is stated to the corresponding acute static study with fish, that "… results of the test can be considered valid for the risk assessment, as an appropriate risk assessment for substances being highly instable in water should be conducted by comparing the initial environmental concentrations after the application in the field versus the initial concentrations in the laboratory test system..." Are these two statements compatible?	change the text according to the comments given by the notifier in Spring 2003. Also the "However…" clause was added to the text concerning aquatic invertebrates. Does notifier now want to change their earlier comments?	
5(18)	Vol. 3, B.9.2.10, risk assessment to aquatic oganisms	BAYER: It is stated ahead of the TER calculation - acute static (Page 488), that "…the evaluator agrees to these statements but would like to use the results of static acute studies with caution because the nominal concentrations were used in calculations… " In view of the conclusions given by FIN to the acute static study with fish (see above), the two statement are not compatible.	(ii) RMS can delete the sentence in the revised DAR (it does not have any influence on the final risk assessment).	RMS to revise DAR

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5(19)	Vol. 3, B.9.2.10, Summary and risk assessment to aquatic organisms	BAYER: It is stated (Page 497), that "the assessment factor of 1.5… as proposed by the applicant… is considered not to be protective enough …as pH-values in surface water of lower than 6 are quite common in Northern Europe " However, according to the "Guidance Document on Aquatic Ecotoxicology, SANCO/3268/2001 rev. 4", the relevant pH range for Europe is 6-9.	(ii) Guidance Documents are meant to be for guidance, they are not statutory requirements. Furthermore, pH may be covered by AF 1.5, but there are also some other things in the outdoor microcosm studies that should be taken into account when deriving the AF (e.g. 4 applications when up to 8 is possible). Also recovery from effects may depend largely on the specific local conditions (e.g. generation time in aquatic organism population may be much longer in colder climates). Altogether, RMS is of opinion that in very rare cases NOEAEC can be used as EAC without any AF.	
5(20)	Vol. 3, B.9.2.10, Summary and risk assessment to aquatic organisms	BAYER: In the diagram on page 498: (i) row strawberries (Northern Europe), column "30 m buffer strip": the stated value of 200 is incorrect, as the correct value is 72.3; (ii) according to the assessments of FIN, the TER has to be > 3, however, in the row apples/pears (Northern Europe, reduced buffer zone scenario), column 10m, the value of 2.88 is considered to be still safe (which is inconsistent).	(ii) Agrees, corrected in the revised DAR. (ii) Agrees, corrected in the revised DAR (does not have any influence on the final risk assessment).	RMS to revise DAR

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
5(21)	Vol. 3, B.9.2.10, Summary and risk assessment to aquatic organisms	BAYER: In the diagram on page 500: (i) row strawberries (Northern Europe), column "30 m buffer strip": the stated value of 330 is incorrect, as the correct value is 119.	(ii) Agrees, corrected in the revised DAR.	RMS to revise DAR
5(22)	Vol. 3, B.9.2.10, risk assessment to aquatic oganisms *continued*	NL: Why the TER calculation starts with a distance of 5 m? The standard situation in orchards and grapes is 3 m and in strawberries 1 m. There is an outdoor microcosm study with algae and invertebrates available. The RMS has concluded that the NOEAEC of this study is 99 µg/L. This study has also been evaluated in NL and the conclusion was that the NOEAEC should be 46 µg/L, because at this concentration there is fast recovery. At 99 µg/L there is also recovery, but the duration of the effects is longer and more species are showing effects. Besides that the frequency of application in the test is only 4 times, while in practice 8 applications are possible. If an assessment factor of 3 is applied to the value of 46 µg/L the norm will be 15.3 µg/L. This is lower than the value which is based on the higher tier studies with fish (including an assessment factor of 3).	(ii) The TERs presented exceeded acceptable limits at 5 m distance. The TER data for the standard distances of 3 m in orchards and grapes and 1 m in strawberries can be provided if required. (ii) It is stated in the DAR that a conservative EAC (or NOEAEC as RMS would prefer to say) can be set at 46 µg/L. However, at this treatment level consistent effects on phytoplankton were transient and confined to one species, while treatment-related responses of other ecological endpoints that lasted longer than a single sampling date could not be demonstrated. However, if 46 µg/L (with assessment factor of 3) is used in the final risk assessment, only one buffer zone would change: In the southern Europe a buffer zone of 10 m would be needed in apples/pears.	**Open point 5.4:** MS to discuss which is **the relevant endpoint of an outdoor microcosm study.** Evaluation Meeting (12.03.2004): Open point needs **to be discussed in an expert meeting.** Open point still open.

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
	Vol. 3, B.9.2.10, risk assessment to aquatic oganisms	BAYER answers: The higher tier aquatic data was subject to independent expert review (Ratte 2002) and found to be of high quality and sufficiently detailed to support the conclusions drawn. Guidance on how to evaluate outdoor studies is available and according to this, the NOEAEC of this study is 99 µg/L based on recovery within an eight week period. Based on i) all of the available aquatic data, ii) the exposure regime (4 applications made at weekly intervals) is considered appropriate for the proposed GAP for tolylfluanid, which is unstable in water and iii) the use of worst case instantaneous PECs to calculate TERs, the use of lower assessment factors is considered appropriate. BCS recommended an assessment factor of 1.5 to be applied to the study endpoint to extrapolate to lower pH ranges in natural water bodies.		

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
5(23)	Vol 3, B.9.2.10 and Vol 1, 2.6.2 *continued*	DK: In our view some of the endpoints used for fish in the higher tier risk assessment for fish should be reconsidered. Re: Acute risk assessment based on HC_5 We have seen no information to validate the assumption that the higher values are outliers and therefore can be excluded from the HC5 calculation leading to a higher endpoint (33 micrg/l) than if all values are included (17,5 microg/l) – thus the later value should be used. Re Acute NOEC HC_5 We do not agree to this approach and find that this value should be deleted from the endpoint list. Furthermore it seems that the data are not normaly distributed and as such the analysis is invalid (In Table B.9.2.19-6 the Kolmogorov-S test is significant). BAYER answers: The data for the three species from the genera, *Scardinius*, *Cyprinus* and *Carassius*, are considered reliable and valid. Nevertheless, the rationale for exclusion of these three species is that they are signifi-cantly less sensitive than the other eight species and it is therefore appropriate to separate the total cohort into two sub groups. By focussing on the most sensitive fish species tested, an increase in the statistical power of the HC5 calculation was clearly demonstrated (R^2 of 0.8945).	(ii): Acute risk assessment based on HC_5 The value (33 µg/l) is not used in the final risk assessment. Furthermore, if the value of 17,5 µg/l was used in the TER calculations, the results would be the same as with 33 µg/l: a further refined risk assessment is necessary if smaller buffer zones are aspired. Acute NOEC HC_5 RMS agrees with DK. All results were copied by mistake in the list of endpoints (instead of only those which were used in the final risk assessment). The mistake is corrected in the new list of endpoints.	RMS to revise the list of endpoints See open point 5.3.

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
	Vol 3, B.9.2.10 and Vol 1, 2.6.2	The fish acute NOEC HC_5 data are considered both valid and relevant for the risk assessment. NOEC are derived from concentrations selected in the study design and therefore would not be expected to be normally distributed. Nevertheless the LC50 data and in this case, the very steep dose response justify the use of the NOEC HC_5. Tolylfluanid is unstable in water (mean DT_{50} 2.7 hour) and the steep dose response is commensurate with the rapid loss from the test system. This is a critical factor in assessing the possible environmental impact under realistic field conditions. Note that the NOEC HC_5 has not been used in isolation and the overall risk to fish is based even on higher tier data generated under field conditions.		
5(24)	Vol 3, B.9.2.10 and Vol 1, 2.6.2 *continued* Vol 3, B.9.2.10	DK: In our view the TER values accepted for the higher tier risk assessment for fish and invertebrates are too low – and thus the risk and the extend of needed buffer zones underestimated. Invertebrates: The indoor microcosm study with daphnids does only include daphnids and as such can not be used to lower the TER for invertebrates in general.	(ii) RMS disagrees with DK and agrees with the applicant what concerns the indoor microcosm study. The outdoor microcosm study was well conducted and reliable. RMS agrees that pH was high and only 4 applications were made. This is however taken into account in the TER value (higher than proposed by the notifier). Interpretation and	See open point 5.3.

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
	and Vol 1, 2.6.2	In our view a TER of 100 for acute effects would still apply for this study. The outdoor microcosm study on the other hand is an aquatic community study (this is not clear in volume 1) – and as such can be used to lower the TER, however as above there are limitations to the study (high pH – which increases hydrolysis) and only 4 applications were made. So again we find that a TER of 10 would be more appropriate for this study. Invertebrates: The TER of 100 is purported to allow for inter-species sensitivity, organism exposure, bioavailability and extrapolation to population level effects. This study address all of these with the exception of inter-species sensitivity. Nevertheless, the exposure regime (four applications were made at weekly intervals) is considered appropriate to assess the long-term effects on *Daphnia* populations over 40 days. The use of an acute TER of 10 is considered appropriate for this chronic endpoint.	extrapolation between different waters and regions is difficult based on one local study but RMS is of the opinion that TER between 3-5 is enough protective.	
	continued Vol 3, B.9.2.10 and	Furthermore the higher tier aquatic data was subject to independent expert review (Ratte 2002) and found to be of high quality and		

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
	Vol 1, 2.6.2	sufficiently detailed to support the conclusions drawn. Based on i) evaluation of all of the available aquatic data, ii) knowledge of the typical expected pH range for water bodies in agricultural areas in Europe and iii) the use of worst case instantaneous PECs to calculate TERs, the use of lower assessment factors is considered appropriate. BCS recommended an assessment factor of 1.5 to be applied to.		

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
5(25)	Vol. 3, B.9.1.4, risk assessment to mammals	NL: It is recommended to base the risk assessment for mammals on the Guidance Document on Risk Assessment for Birds and Mammals. According to the Guidance Document the averaging time for calculating a TWA should not be longer than the interval between two applications. So, in the case of tolylfluanide, an averaging time of 7 days must be taken instead of 21 days. BAYER answers: The risk assessment for mammals presented in the dossier was based on guidance that was appropriate at the time of dossier submission. The risk assessment for mammals has been revised based on the new SANCO Guidance Document (4145/2000) and is presented in Appendix 1. In accordance with the guidance document the averaging time for calculating the TWAs has been revised using an averaging time of 7 days.	(ii) RMS agrees. The new risk assessment for birds is presented in the Addendum and the results are updated in the revised list of end points .	See open point 5.1

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
5(26)	Vol 3, B.9.2.9 page 480-482	UK: The detail provided on the effects observed in Study 4 is insufficient to allow MSs to reach any conclusion as to the validity of the proposed endpoint from this study. Information on the species present and on the magnitude of any observed impacts should normally be included together with appropriate statistical analyses. In this case the UK is prepared to accept the RMS opinion that fish are the most sensitive group of aquatic organisms. BAYER answers: The full biological and statistical details are presented in the original report and are available if required.	(ii) The overall problem when preparing the DAR is that there is no clear guidance how detailed the evaluation should be. The RMS does not agree with UK that listing of > 100 species is necessary in DAR. The RMS has mentioned the most sensitive species and observed impacts in the same way as in some other DARs evaluated before.	
5(27)	Vol. 3, B.9.3 Risk assessment mammals	SE: The toxicity endpoints should consistently be expressed as daily dose (mg as/kg bw per day). BAYER answers: The risk assessment for mammals presented in the dossier was based on guidance that was appropriate at the time of dossier submission, however has been revised, based on the new SANCO Guidance Document (4145/2000), using toxicity endpoints expressed as a daily dose (mg as/kg bw per day) in the up-dated risk assessment (see Appendix 1).	(ii) RMS agrees. The new risk assessment for birds is presented in the Addendum and the results are updated in the revised list of end points.	See open point 5.2.
5(28)	Vol. 3, B.9.3	SE: In the exposure assessment , RUD in	(ii) RMS agrees. The new risk assessment for	See open point 5.2

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
	Risk assessment mammals	accordance with Appendix II of Guidance Doc 4145 should have been used. BAYER answers: The risk assessment for mammals presented in the dossier was based on guidance that was appropriate at the time of dossier submission, however has been revised, based on the new SANCO Guidance Document (4145/2000), using the relevant RUD values in accordance with Appendix II of Guidance Doc 4145 (see Appendix 1). In addition relevant data from residues trials have also been incorporated into the risk assessment as appropriate.	birds is presented in the Addendum and the results are updated in the revised list of end points.	
5(29)	Vol. 3, B.9.3.3 page 507-524. Long term risk to herbivorous mammals	UK: UK agrees that further refinement of TERlt is necessary. However, proposed refinement of residue levels using median 50% values requires further justification. Justification for the extrapolation from the DT50 of 3.1 days for lettuce heads to outdoor short grasses must also be provided. Further justification for not using the 2-gen rat NOEC (100 ppm = 9 mg a.s./kg bw/day) must be provided. The proposed use of the teratogenicity NOAEL (100 mg a.s./kg bw/day) is questionable given that frequent exposure may occur in certain use scenarios (i.e. apples/pears 15 applications @ 7 day intervals). It is important to consider in more detail the effects reported in the 2-gen rat study	(ii) RMS considers the comments of the applicant satisfactory. The new risk assessment for birds is presented in the Addendum and the results are updated in the revised list of end points.	See open point 5.2

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	continued Vol. 3, B.9.3.3 page 507-524. Long term risk to herbivorous mammals	detail the effects reported in the 2–gen rat study at the 700 ppm dose (= 70 mg a.s./kg bw/day), which appear to be related to maternal toxicity and which are otherwise not accounted for in the proposed refinement. BAYER answers: The risk assessment for mammals presented in the dossier was based on guidance that was appropriate at the time of dossier submission, however has been revised, based on the new SANCO Guidance Document (4145/2000), using the relevant RUD values in accordance with Appendix II of Guidance Doc 4145. In-line with current guidance, median 50% values have only been used for calculation of long-term TER values. Additional data are now available confirming a mean DT50 of 2.47 days on grass (Barfknecht 2003); these data have been incorporated into the revised risk assessment and used to refine the MAF and TWA residue concentrations. The GAP has now been clarified see general comments, therefore the use of the 20 day teratogenicity NOAEL (100 mg a.s./kg bw/day) with repeated daily dosing by gavage, is considered acceptable. However a new 2-gen rat study is currently in progress.		

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5(30)	Vol. 3, B.9.5, Risk assessment non-target arthropods	BAYER: FIN stated to the lab. study with *C. 7-punctata* (Page 530), that ”the reproductive output determined in the above mentioned laboratory study is well within the historical database for control beetles and hence this parameter is considered as not impacted by the treatment… as about trice the number of fertile eggs per viable female per day were observed with regard to the lower threshold stated for this testing endpoint…the residue levels resulting from applications up to 2.5 kg a.i./ha tolylfluanid can be regarded as safe when used as a single application”. Why does FIN considers then the residues caused by to 2.5 kg a.i./ha tolylfluanid ”to be in borderline of a safe residue level” in the risk assessment (Page 562)?	(ii) In comments (p. 531) RMS says that the effects are in borderline of harmless and slightly harmful when compared to IOBC classification. This statement has been transferred to risk assessment. RMS agrees that the final conclusion is that tolylfluanid can be regarded as safe when used as a single application. The sentence in page 562 is corrected in the revised DAR.	RMS to revise DAR

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5(31)	Vol. 3, B.9.5.4, Risk assessment to non-target terrestrial arthropods	NL: The risk assessment for parasitoids and predatory mites is based on extended lab tests with indicator species. To account for the range of species which could be expected in off-field habitats, a 5-fold correction (uncertainty) factor must be included. This is according to the Escort 2 Guidance Document. BAYER answers: The risk assessment presented in the dossier was based on guidance from ESCORT 1, which was appropriate at the time of dossier submission. However even with the inclusion of a 5-fold safety factor the risk to NTAs remains negligible, as shown below: At an application rate of 500 g ai/ha the corrected mortality for parasitoids was 10% with no adverse effects on reproduction. An application rate of 500 g ai/ha can therefore be considered as a safe application rate with no adverse effects on parasitoids. Similarly the NOER for predatory mites was determined as 458 g a.i./ha. With a 5-fold safety factor the No Effect Rates (NOER) are re-calculated as 100 g ai/ha and 92 g ai/ha for parasitoids and predatory mites respectively. When these are compared with a maximum off-crop PEC_{plant} max. of 32.9 g ai/ha, it is clear that even with a 5-fold safety factor the risk remains negligible.	(ii) RMS considers the answers of the applicant satisfactory.	

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5(32)	Vol. 3, B.9.9, Effects on other non-target organisms (flora and fauna)	NL: For estimating the exposure of non-target terrestrial plants to tolylfluanide the drift percentage at 1 m (strawberries) or 3 m (orchards and grapes) must be taken into account. For the risk assessment an assessment factor of 5 must be applied to the lowest EC50-value. BAYER answers: Based on drift values calculated according to the BBA (2000), the worst-case drift percentages at 1 m for strawberries and 3 m for late application orchards and grapes are 2.77, 15.73 and 8.02 kg a.i./ha respectively. ER_{50} values for all six species tested in the seedling emergence and vegetative vigour studies were >15.625 kg a.i./ha (the highest rate tested). Based on an ER_{50} of 15.625 kg a.i./ha as a worst-case end-point and using the drift values presented above, the TER values for strawberries, orchards and grapes are calculated as 226, 66 and 94 respectively. All TER values are well in excess of the trigger value of 5 and therefore no unacceptable effects on non-target plants are to be expected from the recommended uses of tolylfluanid.	(ii) RMS considers the answers of the applicant satisfactory.	