Conclusion regarding the peer review of the pesticide risk assessment of the active substance

tolylfluanid

finalized: 14 March 2005

(version of 20 April 2005 with minor editorial changes and modifications to respect confidentiality)

SUMMARY

Tolylfluanid is one of the 52 substances of the second stage covered by Commission Regulation (EC) No 451/2000[1], as amended by Commission Regulation (EC) No 1490/2002[2]. This Regulation requires the European Food Safety Authority (EFSA) to organise a peer review of the initial evaluation, i.e. the draft assessment report (DAR), provided by the designated rapporteur Member State and to provide within one year a conclusion on the risk assessment to the EU-Commission.

Finland being the designated rapporteur Member State submitted the DAR on tolylfluanid in accordance with the provisions of Article 8(1) of the amended Regulation (EC) No 451/2000, which was received by the EFSA on 13 June 2003. Following a quality check on the DAR, the peer review was initiated on 30 July 2003 by dispatching the DAR for consultation of the Member States and the sole notifier Bayer AG. Subsequently, the comments received were examined by the rapporteur Member State and the need for additional data was agreed in an evaluation meeting in 12 March 2004. Remaining issues as well as further data made available by the notifier upon request were evaluated in a series of scientific meetings with Member State experts in June and July 2004.

A final discussion of the outcome of the consultation of experts took place with representatives from Member States on 9 February 2005 leading to the conclusions as laid down in this report.

The conclusion was reached on the basis of the evaluation of the representative uses as a foliar fungicide as proposed by the notifier, which comprises spray treatment to foliar to control a wide range of fungicidal diseases such as apple scab, grey mould, leaf spot diseases and powdery and downy mildew in different fruits, vegetables and hops at application rate up 3 kg tolylfluanid per hectare. The representative formulated product for the evaluation was “Euparen M WG 50”, a water dispersible granule (WG), registered in almost all Member States of the EU.

[1] OJ No L 53, 29.02.2000, p. 25
[2] OJ No L 224, 21.08.2002, p. 25

Adequate methods are available to monitor all compounds given in the respective residue definition apart from food of animal origin.

Tolylfluanid is extensively and rapidly absorbed (>90%). Oral and dermal toxicity is low. However, toxicity during inhalation exposure was low to high which was related to the particle size leading to a differentiated proposal for classification i.e. tolylfluanid containing ≥ 0.1% particles < 50µm (T+; R26). Tolylfluanid has irritating properties in both eyes and skin (proposed classification: Xi; R36/37/38) and has sensitizing properties (proposed classification: R43). Main effects during short term oral exposure were functional disturbance of the thyroid, increased liver weights and decreased liver enzyme levels in the rat and dog and slight histopathological changes in the kidney in the dog at high dose levels. During inhalation exposure severe respiratory tract irritation including deaths was observed. Depending on the particle size, tolylfluanid containing ≥ 0.1% particles < 50µm is classified as toxic (proposed classification: T, R48/R23). Tolylfluanid is neither genotoxic nor carcinogenic. There were no effects on reproductive or developmental toxicity observed and no evidence of neurotoxicity was observed. The acceptable daily intake (ADI) is set to 0.1 mg/kg, the acceptable operator exposure level (AOEL) to 0.3 mg/kg bw/day and the acute reference dose (ARfD) to 0.25 mg/kg bw/day. The estimated operator, worker and bystander exposure is below the AOEL for proposed uses of Euparen M 50 WG.

The metabolism of tolylfluanid in plants proceeds through degradation to DMST[3], being the main metabolite in the majority of investigated crops. Moreover, under processing conditions tolylfluanid degrades rapidly and almost completely to DMST, that has a similar toxicity compared to tolylfluanid. The residue situation in food of plant origin was proved with a sufficient number of trials according to the critical GAP for a wide range of fruit and vegetable crops and for hops; and also with studies determining the level of residues in processed products.
In livestock tolylfluanid is rapidly metabolised to DMST that was detected in all organs and tissues as well as in eggs. Assuming fruit pomace as the only relevant feed item possibly containing residues from tolylfluanid treatment, no quantifiable residues are expected in edible products of animal origin.
The chronic and acute dietary exposure assessment for adult consumers indicates that the intake of residues via the total diet for food of plant origin or any individual food item considered does not exceed the ADI and the ARfD, respectively.
For toddlers and children the theoretical maximum daily residue intake from fruit and vegetables (TMDI) occupies no more than 70% of the ADI, indicating that long-term exposure to residues from tolylfluanid treated crops does not pose an adverse health risk to these consumer subgroups. The estimation of the short term exposure revealed that the ARfD is slightly exceeded (102%, WHO/GEMS Food data) for children consuming table grapes. However, Germany pointed out during the last discussion of tolylfluanid that a greater exceedance of the ARfD (121%) was obtained based on national consumption data for children.

[3] dimethylaminosulfotoluidide

Under aerobic conditions, tolylfluanid yields DMST that is subsequently degraded to other minor metabolites (none > 10 % AR) and ultimately bound residue and CO_2. Photolysis will not significantly contribute to the overall degradation of tolylfluanid under environmental conditions. Tolylfluanid is between very low to low persistent in soil and metabolite DMST is low persistent. Tolylfluanid should be classified as a slightly to low mobile compound and DMST can be classified as a medium to high mobile compound.
Hydrolysis of tolylfluanid is rapid and slightly pH dependent. DMST is stable in all range of environmental relevant pH. Direct photodegradation is not expected to contribute to the degradation of tolylfluanid or its metabolite DMST in the aqueous environment. Tolylfluanid is not ready biodegradable. In water sediment systems, tolylfluanid completely disappear from water phase in about three days mainly due to degradation. Levels of tolylfluanid found in the sediment never attained the 10 % of AR. Major metabolite, both in water and sediment, was DMST. DMST dissipates from the water phase by degradation and adsorption to the sediment.
On the basis of FOCUS-PELMO model simulations neither tolylfluanid nor DMST are expected to exceed the 0.1 µg / L trigger in ground water.

The risk to birds, bees, soil micro- and macro-organisms, including earthworms and non-target terrestrial plants is low with respect to tolylfluanid and the metabolites as far as investigated.
A high long term risk to mammals was identified. The toxicity exposure ratio (TER) values range from 0.84 to 2.78 depending on the representative use evaluated and therefore breaching the Annex VI trigger value of 5 for all the representative uses evaluated. Further data to address this risk is needed and the risk assessment can only be concluded when the outstanding data is evaluated.
High risk is identified for fish (being the most sensitive aquatic organism), which requires consideration of appropriate risk mitigation measures. Pending on the representative use, bufferzones of 5-20 metres are needed to respect the Annex VI trigger value. The toxicity to fish is higher at lower pH-values therefore it is proposed that Member States with surface water bodies of low pH (<6) associated with agricultural landscapes should consider the effect of pH on toxicity to fish at the local level.
Also for non-target arthropods (other than bees) a high risk was identified in-field however a recovery before the start of next season is considered possible.

Key words: tolylfluanid, peer review, risk assessment, pesticide, fungicide

TABLE OF CONTENTS

BACKGROUND

Commission Regulation (EC) No 451/2000 laying down the detailed rules for the implementation of the second and third stages of the work program referred to in Article 8(2) of Council Directive 91/414/EEC, as amended by Commission Regulation (EC) No 1490/2002, regulates for the European Food Safety Authority (EFSA) the procedure of evaluation of the draft assessment reports provided by the designated rapporteur Member State. Tolylfluanid is one of the 52 substances of the second stage covered by the amended Regulation (EC) No 451/2000 designating Finland as rapporteur Member State.

In accordance with the provisions of Article 8(1) of the amended Regulation (EC) No 451/2000, Finland submitted the report of its initial evaluation of the dossier on tolylfluanid, hereafter referred to as the draft assessment report, to the EFSA on 13 June 2003. Following an administrative evaluation, the EFSA communicated to the rapporteur Member State some comments regarding the format and/or recommendations for editorial revisions and the rapporteur Member State submitted a revised version of the draft assessment report. In accordance with Article 8(5) of the amended Regulation (EC) No 451/2000 the revised version of the draft assessment report was distributed for consultation on 30 July 2003 to the Member States and the main notifier Bayer AG as identified by the rapporteur Member State.

The comments received on the draft assessment report were evaluated and addressed by the rapporteur Member State. Based on this evaluation, representatives from Member States identified and agreed in an evaluation meeting on 12 March 2004 on data requirements to be addressed by the notifier as well as issues for further detailed discussion at expert level. A representative of the notifier was attending this meeting.

The discussion of the identified data requirements and/or issues took place in expert meetings organised on behalf of the EFSA by the Federal Office for Consumer Protection and Food Safety (BVL) in Braunschweig. The reports of these meetings have been made available to the Member States electronically.

A final discussion of the outcome of the consultation of experts took place with representatives from Member States on 09 February 2005 leading to the conclusion as laid down in this report.

During the peer review of the draft assessment report and the consultation of technical experts no critical issues were identified for consultation of the Scientific Panel on Plant Health, Plant Protection Products and their Residues (PPR).

In accordance with Article 8(7) of the amended Regulation (EC) No 451/2000, this conclusion summarises the results of the peer review on the active substance and the representative formulation

evaluated as finalised at the end of the examination period provided for by the same Article. A list of the relevant end points for the active substance as well as the formulation is provided in appendix 1.

The documentation developed during the peer review was compiled as a **peer review report** comprising of the documents summarising and addressing the comments received on the initial evaluation provided in the rapporteur Member State's draft assessment report:

- the comments received
- the resulting reporting table (rev. 1-2 of 26 March 2004)
- the consultation report

as well as the documents summarising the follow-up of the issues identified as finalised at the end of the commenting period:

- the reports of the scientific expert consultation
- the evaluation table (rev. 1-1 of 09 March 2005)

Given the importance of the draft assessment report including its addendum (compiled version of February 2005) and the peer review report with respect to the examination of the active substance, both documents are considered respectively as background documents A and B to this conclusion.

By the time of the presentation of this conclusion to the EU-Commission, the rapporteur Member State has made available amended parts of the draft assessment report which take into account mostly editorial changes. Since these revised documents still contain confidential information, the documents cannot be made publicly available. However, the information given can basically be found in the original draft assessment report together with the peer review report which both is publicly available.

THE ACTIVE SUBSTANCE AND THE FORMULATED PRODUCT

Tolylfluanid is the ISO common name for *N*-dichlorofluoromethylthio-*N′*,*N′*-dimethyl-*N*-*p*-tolylsulfamide (IUPAC).

Tolylfluanid, belonging to the class of phenylsulfamide fungicides and it is used to control a wide range of fungicidal diseases such as apple scab, grey mould, leaf spot diseases and powdery and downy mildew in different fruits, vegetables and hops. Tolylfluanid is taken up via foliar and it is a multi site SH-blocker interfering at many locations in the metabolism of fungi.

The representative formulated product for the evaluation was "Euparen M WG 50", a water dispersible granule (WG), registered in almost all Member States of the EU.

The representative uses evaluated comprise spray treatment to foliar to control a wide range of fungicidal diseases such as apple scab, grey mould, leaf spot diseases and powdery and downy mildew in different fruits, vegetables and hops at application rate up 3 kg tolylfluanid per hectare.

SPECIFIC CONCLUSIONS OF THE EVALUATION

1 IDENTITY, PHYSICAL/CHEMICAL/TECHNICAL PROPERTIES AND METHODS OF ANALYSIS

The minimum purity of tolylfluanid as manufactured should not be less than 960 g/kg, which is higher than the minimum purity given in the FAO specification 275/TC/S/P (1991) of 940 g/kg. The higher value relates to the submitted results of current batch analysis and not to any toxicological concern to increase the minimum purity. The technical material contains no relevant impurity.
Recently submitted study regarding batch analyses and the specification of the technical material were not peer reviewed by other MS or discussed in an EPCO expert meeting. However, the conclusion of the rapporteur Member State that this study fulfils the data gap is confirmed by EFSA. *(refer to the final addendum, addendum 5, Annex C, 08.11.04)*

The content of tolylfluanid in the representative formulation is 500 g/kg (pure).

The assessment of the data package revealed no particular area of concern in respect of the identity, physical, chemical and technical properties of tolylfluanid or the respective formulation.

The main data regarding the identity of tolylfluanid and its physical and chemical properties are given in appendix 1.

Adequate analytical methods are available for the determination of tolylfluanid in the technical material and in the representative formulation as well as for the determination of the respective impurities in the technical material and the relevant impurity in the formulation.
Analytical methods for the determination of residues of tolylfluanid and DMST are available for a range of food of plant origin, but no acceptable method was provided for hops. The acceptability of the analytical methods has not been evaluated during the expert meeting, due to the fact that the residue definition was changed at the end of the procedure. However, EFSA concluded that sufficient methods (HPLC-MS/MS) has been submitted and described in the DAR, except for hops, to ensure that the proposed MRLs can be monitored. In contrast to EFSA's opinion, the RMS has some doubts whether the methods under consideration fully address the requirements relating to the independence of the laboratories and the extent of the validation for the determination of DMST in commodities with high acid content**.** In soil and water (drinking and surface) the residues of tolylfluanid and its metabolite DMST can be determined with adequate analytical methods. However, it should be noted that the DT_{90} values for surface water are below the trigger value of 3 d as given in the guidance document SANCO/825/00 (rev.7, 17/03/2004). For the determination of tolylfluanid in air a validated method is available.
An analytical method for food of animal origin is not required due to the fact that no MRLs are proposed (see 3.4). However, only an acceptable analytical method for the determination of tolylfluanid in food of animal origin is available at the moment.

Recently submitted studies, regarding the enforcement method for the determination of residues in soil and water (drinking and surface) as well as analytical methods for the determination of tolylfluanid and impurities in the technical material were not peer reviewed by other MS or discussed in an EPCO expert meeting. However, the conclusion of the rapporteur Member State that these studies fulfil the data gap is confirmed by EFSA. *(refer to the final addendum, addendum 3, Annex B, 02.06.04 and addendum 5, Annex B, 08.11.04)*

2 MAMMALIAN TOXICOLOGY

2.1 ABSORPTION, DISTRIBUTION, EXCRETION AND METABOLISM (TOXICOKINETICS)

Tolylfluanid is rapidly and nearly completely absorbed, over 90% (based on urinary and biliary excretion) within 48 hours. The excretion is also rapid, 60-90% mainly in the urine. It is widely distributed and the highest concentration was found in liver, kidney and thyroids. There was no evidence of accumulation. Tolylfluanid is extensively metabolised. The parent compound is metabolised to dimethylaminosulfotoluidide (DMST). Other major metabolites are 4-(dimethylaminosulfonylamino)-benzoic acid, 4-(dimethylaminosulfonylamino)hippuric acid (TTCA) and thiazolidine-2-thione-4-carbonic acid. Parent compound was not found in milk.

2.2 ACUTE TOXICITY

The oral and dermal toxicity is low i.e. LD_{50} > 5000 mg/kg bw. However, the toxicity during inhalation exposure was *low to high*. This was related to the particle size (i.e. the amount that was ≤ 3 µm) and the LC_{50}-values varied from > 1.038 mg/l air (< 7% ≤ 3 µm), 0.383 mg/l air (35-39% ≤ 3 µm) and 0.160-0.200 mg/l air (64-74% ≤ 3 µm). This leads to a differentiated classification from *no classification to very toxic*. Thus, two proposals of classification were suggested that were based on the particle size. **Tolylfluanid containing ≤ 0.1% of 0-50 µm particles is not classified for inhalation whereas tolylfluanid containing ≥ 0.1% of 0-50 µm particles is classified with T+ R26 "Very toxic by inhalation".** See also section 2.3 below.

Tolylfluanid has irritating properties in both eyes and skin. **Thus the following symbol; risk phrases Xi; R36/37/38 "Irritating to eyes, respiratory system and skin"** are proposed.

Tolylfluanid was found to have sensitizing properties (Magnus and Kligman test) and should therefore be labelled as such. **The following risk phrase R43 "May cause sensitisation by skin contact"** was proposed.

2.3 SHORT TERM TOXICITY

The short term effects of tolylfluanid were studied in a 4-week study in rat, three 90-day studies (rat, and dog) and two 1-year dog studies. The dermal toxicity was studied in the rabbit. Four studies were evaluated on short-term inhalation toxicity (rat).

The main effects observed were functional disturbance of the thyroid, increased liver weights and decreased liver enzyme levels in the rat and dog and slight histopathological changes in the kidney in the dog at high dose levels.

The relevant oral NOAEL for short term studies was discussed at the Expert meeting (July 2004), see Addendum. The meeting agreed that the NOAEL of 1000 ppm based on a clinical signs, decreased body weight and increased liver and kidney weight at the highest dose 3000 ppm in the 90-day dog study, was the most appropriate (Hoffman and Mirea, 1974).

Thus, the relevant oral NOAEL is 1000 ppm (i.e. 33 mg/kg bw/day) in the 90-day dog study.

The relevant dermal NOAEL is 300 mg/kg bw/day in the rabbit, based on slight effects in haematological and clinical chemistry parameters. The NOAEL for local effects was < 1 mg/kg bw/day based on erythema and increased skin thickness.

During short term inhalation exposure of tolylfluanid severe respiratory tract irritation including deaths (secondary to irritation effects) was observed. Depending on the particle size, whether tolylfluanid was micronised or not, the outcome was some what different. **Therefore, the relevant inhalation NOAEL/NOEC is 0.001 mg/L for non-micronised dust (adequately respirable or < 3 µm) otherwise ≥ 0.004 mg/L based on the irritation effects observed,** see also 2.2 above.

Two proposals for classification were made based on the differentiated results obtained during acute inhalation exposure.

Tolylfluanid containing ≤ 0.1% of 0-50 µm particles is not classified for inhalation whereas tolylfluanid containing ≥ 0.1% of 0-50 µm particles is classified with T; R48/R23 Toxic "Danger of serious damage to health by prolonged exposure through inhalation".

2.4 GENOTOXICITY

In the DAR, 9 *in vitro* studies and 9 *in vivo* studies have been evaluated and presented. Many of the studies were according to the rapporteur Member State of poor quality or with deficiencies in the reporting. One *in vitro* study was not acceptable due to too low dose levels tested) and further one *in vivo* aberration assay in Hamster was not acceptable due to several deficiencies.

There were several positive responses in the *in vitro* studies (i.e. chromosome aberration study, TK +/- gene mutation test and ovary cell test). However, the other tests were negative (i.e. HGPRT test, Ames test, UDS test and gene mutation test in *Sacharomyces*). These studies indicated that tolylfluanid might have a clastogenic potential. Most of the *in vivo* tests with somatic cells were negative. There was however, weak clastogenic activity in a chromosome aberration assay. No indications of mutagenic effects on germ cells were observed. Overall, there were weak indications of mutagenicity both *in vitro* and *in vivo* and a new chromosome aberration study was required by the rapporteur Member State.

The new *in vivo* bone marrow cytogenic study in the mouse (Herbold, 2004) was evaluated and presented in the Addendum and discussed at the Expert meeting (July 2004). The rapporteur Member State concluded that no difference in metaphases with aberrations between control mice and mice exposed to Maximum Tolerated Dose of tolylfluanid implicating no clastogenic effects. The meeting agreed.

The overall conclusion was revised. **Tolylfluanid should not be classified as mutagenic,** based on the fact that the overall *in vivo* test data points towards negative results, although the clear or

equivocal genotoxicity results seen in the sole acceptable *in vitro* chromosome aberration test and in some tests for gene mutations in mammalian cells.

2.5 LONG TERM TOXICITY

Two studies in rats and two in mice were submitted in the dossier, evaluated and presented in the DAR. One of the mouse studies was not considered acceptable due that control animals were used from another study, low survival and deficiencies in the study design and reporting.

The main effects observed were increased fluoride levels, increased liver weights and slightly increased liver enzyme activities, slight effects on thyroid gland at high dose levels.

There were no indications of carcinogenic potential of tolylfluanid. The relevant long term NOAEL is 300 ppm (i.e. 18 mg/kg bw/day) in the rat based on increased treatment related changes in the osseous part of the muscular-skeletal system at 1500 ppm and 7500 ppm (Leser *et al*., 1996).

2.6 REPRODUCTIVE TOXICITY

Four studies were submitted in the dossier on rat in order to determine the reproductive effects of tolylfluanid (two-generation studies). Initially the rapporteur Member State suggested a relevant NOAEL of 100 ppm (i.e. 9 mg/kg bw/day) based on reductions in parental body weight and decreased survival rate of the pups. However, the notifier submitted a new two-generation study in the rat (Young and Fickbohm, 2004) which is presented in the Addendum and was discussed at the Expert meeting (July 2004). The meeting concluded that the NOAEL was 200 ppm (i.e. 12 mg/kg bw/day for males and 14.7 mg/kg bw/day for females during the premating period)

There were no direct effects on reproductive performance or fertility observed.

The meeting agreed on the relevant NOAEL for both systemic effects and reproduction was set to 12 mg/kg bw/day in the rat based on reduced body weight and pup spleen weight.

In order to examine teratogenic or developmental effects of tolylfluanid two studies in rat and two in the rabbit were presented in the DAR. Rabbit was more susceptible than the rat and effects observed were increased post implantation losses, slightly increased malformations and placental alterations at maternally toxic doses (i.e. decreased body weight).

It was concluded that tolylfluanid did not induce teratogenic or fetotoxic effects at non-maternally toxic doses.

The relevant developmental and maternal NOAEL is 25 mg/kg bw/day in the rabbit based on effects observed at 70 mg/kg bw/day (Holzum, 1991b).

2.7 NEUROTOXICITY

No studies performed on delayed neurotoxicity were performed. Studies on acute and repeated neurotoxicity was performed in the rat and reported under section B.6.8 “Further studies”. No evidence of neurotoxicity was observed, see 2.8 below.

2.8 FURTHER STUDIES

Studies on the metabolites KUE 5156 (TTCA), Dimethylamino-sulf-P-tuluidid (DMST), WAK 5818, WAK 6550, WAK 6676, WAK 6698 have been evaluated and is presented in the DAR. Oral LD50 for all metabolites was > 1000 mg/kg bw/day and all metabolites except TTCA were tested in Ames test with a negative result as outcome. DMST was also tested for acute dermal and inhalatory toxicity and the dermal LD50 was > 5000 mg/kg bw/day and the inhalatory LC50 was > 0.16 mg/L and it was neither an eye nor skin irritant.

The question was raised during the evaluation process whether the metabolites formed in plants (WAK 6550, WAK 6676 and WAK 6698) were of relevance for re-entry activities. It was agreed at the Expert meeting (July 2004) that they were of low toxicological concern based on the acute toxicity and *in vitro* genotoxicity data. Furthermore, the new risk assessment estimations presented in the Addendum was discussed. **It was concluded that the maximum exposure level is 4% for WAK 6550, 1% for WAK 6676 and < 0.1% for WAK 6698 of the exposure level of tolylfluanid and they are thus not considered as relevant regarding re-entry**, see also 2.10 below.

Studies on acute and repeated neurotoxicity were performed in the rat and reported under section B.6.8 "Further studies". No evidence of acute neurotoxicity was observed and the NOAEL is 2000 mg/kg bw/day, the highest dose tested. In the 90-day study, the NOAEL for neurotoxicity was 9000 ppm (i.e. 602 mg/kg bw/day and the NOAEL for general systemic toxicity was 1650 ppm (i.e. 109 mg/kg bw/day). According to a decision at the Expert meeting (July 2004) is a **conclusion that tolylfluanid is not neurotoxic** is presented in the List of Endpoint under section "Neurotoxicity" see also comment under 2.7 above.

Toxicological significance of different impurities Information was recently submitted regarding chemical structures of impurities concerning the similarity to the parent tolylfluanid but not peer reviewed by other MS nor discussed in an EPCO expert meeting. Quantitative structure activity analyses (DEREK) did reveal similar structural alerts for these compounds, indicating that the toxicity would be similar to tolylfluanid. The conclusion of the rapporteur Member State that it may be assumed that they are not of toxicological concern is confirmed by EFSA *(refer to addendum 5, Annex C, 08.11.04)*.

2.9 MEDICAL DATA

Several reports from plant employees exposed for tolylfluanid and tolylfluanid containing products are presented in the DAR and no effects of major concern were reported except that a few cases of allergic skin reactions. No poisoning incidents, epidemiological studies or clinical tests have been reported. The rapporteur Member State has made a refined search in the open literature upon request from other Member States. However, no further information seemed to be available. This was accepted at the Expert meeting (July 2004).

2.10 ACCEPTABLE DAILY INTAKE (ADI), ACCEPTABLE OPERATOR EXPOSURE LEVEL (AOEL) AND ACUTE REFERENCE DOSE (ARFD)

ADI

Initially in the DAR the rapporteur Member State proposed an ADI of 0.2 mg/kg bw/day based on the NOAEL of 18 mg/kg bw/day in the 2-year rat study (Leser *et al*., 1996).

The ADI value was discussed at the Expert meeting (July 2004). The meeting agreed that the ADI should be based upon the new multigeneration study, see Addendum, in the rat (Young and Fickbohm, 2004) where the NOAEL was 12 mg/kg bw/day based on histopathological changes observed at 19 mg/kg bw/day. The Safety factor of 100 was used and the ADI was rounded to 0.1 mg/kg bw/day.

The ADI is set to 0.1 mg/kg.

AOEL

The AOEL is based on the NOAEL of 33 mg/kg bw/day in the 90-day study in dogs (Hoffman and Mirea, 1974) with a safety factor of 100 and no correction for oral absorption required.

The AOEL is rounded to 0.3 mg/kg bw/day.

ARfD

No ARfD was originally allocated in the DAR. This was discussed at the Expert meeting (July 2004). The meeting agreed that the effects seen in the developmental rabbit study such as increased postimplantation losses and slightly increased malformations at 70 mg/kg bw/day might as a worst case scenario already be caused by a single dose. Thus, the meeting agreed to allocate an ARfD for tolylfluanid and that it is based on the NOAEL of 25 mg/kg bw/day with the safety factor of 100.

The ARfD is set to 0.25 mg/kg bw/day.

2.11 DERMAL ABSORPTION

The dermal absorption of Euparen M 50 WG was assessed in two *in vivo* studies on rat and rabbit and one *in vitro* study (on human and rat skin) which is presented in the DAR. Based on the results from the *in vivo* studies the rapporteur Member State suggested in the DAR that the dermal absorption should be equal to 1.3% for undiluted, 3.8% and 13% for the diluted formulation (1:10 and 1:100) based on the absorption evident at 8 hours of dermal exposure.

Some MS were concerned about the selected time point 8 hours, since the amount remaining in the skin after washing becomes systemically available subsequently. This issue was discussed at the Expert meeting (July 2004). New calculations were presented in the Addendum and the meeting agreed with the rapporteur Member State that it was appropriate to use amount absorbed from skin plus that remained in the skin after washing in the calculations. The estimated absorption at 8 hours was even higher than after 168 hours. The new proposal from the rapporteur Member State was 8% for undiluted, 7% and 27% for the diluted formulation (1:10 and 1:100).

The meeting agreed on this but in addition a correction factor for the flux ratio between rat and human skin determined in the *in vitro* study should also be applied. This does not completely comply

with the guidance document but would in this case be acceptable since the figures were nearly the same as for the absorption percentage. The flux rates (rat/human) were 1.67 for the concentrate and 3.67 for the 1:100 dilution.

Thus, the meeting agreed that the dermal absorption for Euparen M 50 WG was 5% for the concentrate and 7% for the 1:100 dilution, on the basis of the *in vivo* study in the rat and by using a correction factor for the *in vitro* rat/human comparison.

2.12 EXPOSURE TO OPERATORS, WORKERS AND BYSTANDERS

The representative plant protection product Euparen M 50 WG contains 500 g tolylfluanid/L. Depending on the crop, the applied doses are in the range of 1.5 to 2.5 kg a.i./kg and the application volumes ranges from 400 to 2000 L/ha. Between 2-7 sprayings/year are recommended.

The use scenarios include ground boom spraying for low crops, broadcast air assisted sprayers for high crops and portable or hand-held sprayers for field high crops and glasshouses.

The operator exposure assessments were estimated by using several models (UK-POEM, German model, Dutch model and EUROPOEM-model), for exposure assessments during orchard spraying also data from a field study was utilised. Bystander exposure was estimated by using spray-drift calculations and worker exposure was estimated by using recommendations present in the EUROPOEM II-re-entry working group report.

The dermal absorption value of 5% for the concentrate and 7% for the 1:100 dilutions and the AOEL of 0.3 mg/kg bw/day were used in the calculations.

Operator exposure

The estimated operator exposure is below the AOEL for proposed uses of Euparen M 50 WG according to UK-POEM if PPE (i.e. gloves) is used during mixing and loading (M/L) and without any PPE according to German model (i.e. ≤ 70% of AOEL), see calculations in the Addendum.

Worker exposure

The estimated worker exposure is below the AOEL even without wearing PPE (i.e. ≤ 66% of AOEL), with PPE the estimated exposure is ≤ 33% of AOEL, see calculations in the Addendum.

Bystander exposure

The estimated bystander exposure is below the AOEL (i.e. ≤ 3% of AOEL), see calculations in the Addendum.

3 Residues

3.1 NATURE AND MAGNITUDE OF RESIDUES IN PLANT

3.1.1 PRIMARY CROPS

The metabolism of tolylfluanid was studied in apples, grapes, strawberries and lettuce using two radiolabelled forms. The metabolic pathway proceeded through degradation of tolylfluanid to

dimethylaminosulfotoluidide (DMST), which was further metabolised by hydroxylation and by conjugation to glucosides that formed further glycosides. Radioactivity was detected mostly on the surface of the tested crops. Parent tolylfluanid was the most abundant residue in apple, strawberry and lettuce (>65 % of TRR) and DMST was a major metabolite also in apple, strawberry and lettuce (up to 15 % of TRR). In grapes the major residue besides tolylfluanid (13 % of TRR) has been identified as the metabolites 4-hydroxymethyl-DMST-glucoside (46 % of TRR) and 2-hydroxyphenyl-DMST-glucoside (13 % of TRR).

In order to investigate effects of industrial or household processing on the nature of the residue a study simulating normal processing practice was conducted applying representative hydrolytic conditions to a test solution. The study indicated that tolylfluanid degrades rapidly and almost completely to DMST, which was the only metabolite found.

Taking into account the results from the metabolism and hydrolysis studies as well as the similar toxicity of DMST compared to tolylfluanid (refer to point 2.8) the expert meeting on residues proposed to define the residue of concern for fruit and leafy crops as tolylfluanid and DMST for risk assessment and monitoring purposes. Moreover, for grapes it was proposed to include also the metabolites 4-hydroxymethyl-DMST-glucoside and 2-hydroxyphenyl-DMST-glucoside in the residue definition for risk assessment. Due to the fact, that the investigation of the metabolic behaviour of tolylfluanid is limited to two representative crop groups only, a residue definition for plants in general can not be proposed.

The magnitude of tolylfluanid residues was determined in a total of 218 supervised field and/or greenhouse residue trials in pome fruit, berries and small fruits, fruiting vegetables, lettuce, leek and hops, conducted over several growing seasons in representative locations in Northern and Southern European regions. The trials have been conducted consistent with critical GAP by using two different formulations considered to be interchangeable in terms of residue behaviour. All residues were analysed utilising validated methods. Tolylfluanid and DMST are the residues determined. With regards to grapes, two additional metabolites of tolylfluanid, i.e. 4-hydroxymethyl-DMST-glucoside and 2-hydroxyphenyl-DMST-glucoside are also reported. Significant amounts of residues were found at harvest in all crops studied in the residue trials.

Processing studies determining the level of residues in processed products have been performed on apples, grapes, strawberries, currants, tomatoes and hops. These studies confirm the results of the hydrolysis study and indicate that although residue levels predominantly decline during processing there are still significant residues, mainly of DMST, quantifiable in processed products.

3.1.2 SUCCEEDING AND ROTATIONAL CROPS

Studies on succeeding and rotational crops haven't been undertaken. Uptake of residues from soil by crops grown in rotation with tolyfluanid treated crops is not expected due to the low persistency of tolylfluanid and DMST in soil (refer to point 4.1.2).

3.2. NATURE AND MAGNITUDE OF RESIDUES IN LIVESTOCK

None of the crops currently intended for treatment with tolylfluanid is fed to poultry and pigs. Fruit pomace is the only commodity arising from the representative uses, which is relevant in nutrition of cattle.

Metabolism studies in lactating goats and laying hens indicate, that tolylfluanid is rapidly metabolised by cleavage of the N-S bond to form DMST, that is further metabolised via either hydroxylation or demethylation followed by oxidation and conjugation processes. Tolylfluanid was not detected in any of the edible tissues and organs of both species, nor in milk and eggs. In contrast, DMST was detected in all analysed organs and tissues as well as in eggs. DMST was the major metabolite in poultry fat (66% TRR) and a main metabolite in goat fat (15%TRR). Therefore, the expert meeting on residues proposed to define the residue of concern in food of animal origin as DMST for risk assessment and monitoring purposes. Although DMST has the highest lipophilicity of all compounds in the metabolic profile, its lipophilicity is assessed as moderate (logPow 1.99) and accumulation in fat is not expected. This is supported by the results of biokinetic, metabolism and autoradiography studies in the rat. (See points 2.1 and 2.8)

Assuming fruit pomace as the only relevant feed item containing residues from tolylfluanid treatment, the presented data indicate that no quantifiable residues are expected in edible products of animal origin.

3.3. CONSUMER RISK ASSESSMENT

The chronic dietary exposure assessment for consumers is based on consumption data from the WHO/GEMS Food European diet, on consumption data of UK consumers (adults, school children, toddlers, infants) and on the German model for a diet of a 4-6 year old girl. Assuming residue levels amounting to the proposed MRLs for food of plant origin, the Theoretical Maximum Daily Intake (TMDI) occupies no more than 70% of the ADI for the most highly exposed consumer subgroup of toddlers. A refinement of the assessment, considering results from processing studies and mean residue values obtained from supervised trails on representative crops, yielded 24% of the ADI at the maximum for toddlers.

The short term dietary exposure assessment for consumers was carried out with consumption data from the WHO/GEMS Food Database for adults and children and with consumption data of UK adult consumers and toddlers. The estimations revealed a moderate risk for adults. The highest occupations of the ARfD were consistently obtained for table grapes, lettuce and pome fruit from both of the two consumption data sets. The maximum value for European adult consumers was achieved from table grapes and is equal 25% ARfD. For children and toddlers the highest occupations of the ARfD were obtained from table grapes, pome fruit and tomatoes. The estimation of the short term exposure to residues from tolyfluanid treated fruits and vegetables leads to a maximum result for table grapes of 102% ARfD based on data for children from the WHO/GEMS Food Database and of 100.5% based on the UK consumption data for toddlers, followed by the results for apples with 94% and 59%, respectively and pears with 88% and 80%, respectively.

A late comment raised by Germany in the evaluation meeting on 7th February 2005 indicated that the dietary exposure of children to residues arising from tolylfluanid treatment of table grapes may be

even higher, in fact at 121% ARfD. This estimation is based on recently published German consumption data for children (age 2 to 4 years old).

3.4. PROPOSED MRLS

MRLs were proposed for the following crops or crop groups in which the use of tolyfluanid is intended: Pome fruit, Small fruit and berries, Solanacea, cucumbers, courgettes, melons, lettuce and hops. A detailed table with the individual proposed MRLs can be found in the attached Listing of endpoints.
MRLs for food of animal origin are currently not proposed.

There is a range of Codex MRLs in place and Tolylfluanid was fully reviewed at the 2003 JMPR meeting. Owing the differences in the residue definitions for food of plant and animal origin proposed by the JMPR and in the European Review Program, it is not possible to make any comparisons of the proposed MRLs.

4 Environmental fate and behaviour

4.1 FATE AND BEHAVIOUR IN SOIL

4.1.1. ROUTE OF DEGRADATION IN SOIL

Information on tolyfluanid metabolism in soil under dark aerobic conditions at 22 ^{o}C is provided by two studies one with phenyl labelled tolyfluanid in four soils and another with dichlorofluoromethyl labelled tolyfluanid in two soils. The soils covered a range of pH values (5.5-7.5), clay contents (8.3 – 13.2 %) and organic carbon content (0.9 -2.5 %).
Under aerobic conditions, the first step in the degradation of tolyfluanid is the loss of volatile **dichlorofluoromethane sulfenic acid** (postulated from the dichlorofluoromethyl tolyfluanid labelled study) to yield **DMST** (dimethylaminosulfotoluidide, maximum 73.7 % after 1 day) that decreases to levels below 3 % AR by the end of the study (99 d). Degradation of this metabolites produces other minor metabolites (none > 10 % AR) and ultimately bound residue (maximum 83.7 % after 15 d, 72.3 % after 99 d) and CO_2 (maximum 40 % after 99 d).
For one of the experiments, bound residue was fractioned between humic (39-44 %), fulvic (35-37.5 %) and humin fractions (20-21 %). Selected samples were also subjected to more rigorous extraction techniques. In these samples the soil was further extracted with 1 N HCl-acetone or 6N HCl. About half of the non extractable radioactivity at the end of the study (99 d) was demonstrated to be bounded DMST.
No anaerobic degradation study is available. It was considered that, under the representative uses proposed, tolyfluanid will be not exposed to anaerobic conditions. A soil photolysis study is available where it has been demonstrated that photolysis will not significantly contribute to the overall degradation of tolyfluanid under environmental conditions.

4.1.2. PERSISTENCE OF THE ACTIVE SUBSTANCE AND THEIR METABOLITES, DEGRADATION OR REACTION PRODUCTS

Degradation rate of tolyfluanid and its metabolite DMST was investigated with data from the study performed with the phenyl labelled tolyfluanid in four soils. Kinetic analysis was performed with SIMOSOLV v3.0 software assuming pseudo first order kinetics for all degradation steps. Concentration *vs.* time data are fitted to a model that considers direct transformation of tolyfluanid to DMST and of DMST to a sink compartment representing the rest of metabolites, un-extractable residue and CO_2. Degradation constants are obtained for each compound in each of the soils studied. These first order rate constants are employed to calculate the corresponding DT_{50} and DT_{90} at 22 ^oC (study temperature), 20 ^oC (transformed) and 10 ^oC (transformed).

Tolyfluanid is between very low to low persistent in soil ($DT_{50\ (20°C)}$ = 0.5 – 2.6 d). However, only one of the four degradation constants obtained resulted in an acceptable fitting to first order kinetics. Experts meeting (EPCO 7, June 2004) discussed the need of a degradation study in three additional soils. Meeting agreed that the available data clearly indicates that the half life of tolyfluanid was one day or less and that more accurate data will not change the risk assessment. Therefore, no further soil degradation studies were deemed necessary.

Metabolite DMST is low persistent with a $DT_{50\ (22°C)}$ = 1.3 – 6.7 d.

PEC soil presented in the DAR were calculated with mean DT_{50} instead of worst case. Evaluation meeting required the RMS to present an addendum where the use of the mean DT_{50} were clearly justified and the impact on the risk assessment analyzed (Open point 4.1). New calculations were provided instead in Addendum 2, which was reviewed by the experts meeting. In this case the 90th percentile DT_{50} was used instead of the worst case. Whereas a severe impact in the risk assessment was not expected, the RMS was required to provide the PEC soil values using the worst case DT_{50} to follow the same approach employed for other substances. These new PEC soil calculations have been presented in Addendum 5 (8.11.2004). Whereas not fully peer-reviewed, it is the EFSA opinion that these new calculations are in agreement with what was required by the experts meeting.

Evaluation meeting was also concerned on the scenarios chosen for the environmental risk assessment that not covered worst case application rates (eg. 15 applications for apples) proposed in the list of representative uses. In addendum 5, representative uses for apples have been amended with a maximum of seven applications per season. Therefore, the 15 application per season in apples should not be considered covered by this risk assessment.

4.1.3. MOBILITY IN SOIL OF THE ACTIVE SUBSTANCE AND THEIR METABOLITES, DEGRADATION OR REACTION PRODUCTS

According the adsorption coefficient estimated with a HPLC method, tolylfluanid should be classified as a slightly to low mobile compound (Koc = 2220 mL / g). The HPLC method is not considered reliable (SCP Opinion: SCP/KOC/002-final, 18 July 2002) and this value should be considered a mere estimation. However, due to the fast degradation of tolylfluanid the value was deemed acceptable for the risk assessment.

The adsorption / desorption behaviour of DMST was investigated by batch equilibrium experiments. DMST can be classified as a medium to high mobile compound (Koc = 56.1 – 118.3 mL / g).

An aged residue column leaching study is available. Major components in the leachate were an unknown (3 % AR), DMST (1.1 % AR) and 4-dimethylaminosulfonylamino benzoic acid (0.9 % AR). Parent tolylfluanid accounted for less than 0.1 % AR.

4.2 FATE AND BEHAVIOUR IN WATER

4.2.1. SURFACE WATER AND SEDIMENT

In sterile buffer aqueous solution, hydrolysis of tolylfluanid is rapid and slightly pH dependent. Half life is very short and not measurable at pH 9 (20 °C), 42.5 h at pH 7 (20 °C) and 5.6 d at pH 4 (30 °C). Extrapolated to 22 °C half life at pH 4 is 12 d. DMST is stable in all range of pH with an estimated half life longer than one year.

Direct photodegradation is not expected to contribute to the degradation of tolylfluanid or its metabolite DMST in the aqueous environment.

Tolylfluanid is not ready biodegradable.

Three water sediment studies are available with a total of five water sediment systems being investigated. Quality and duration of the studies is variable and results are difficult to compare. These studies cover a range of sediment pH ($pH_{sed.}$ = 5.4 – 7.4). However, water is slightly alkaline in all the systems (pH_{water} = 7.4 -8.0). When measurable (short term studies), tolylfluanid completely disappear from water phase in about three days (maximum $DT_{50\ water}$ = 6 h), mainly due to degradation. Maximum level of tolylfluanid found in sediment was 6.7 % AR, 12 h after application. Major metabolite, both in water and sediment, was DMST (maximum in water = 72.2 % AR after 24 h; maximum in sediment = 41.3 % AR after 7 d [end of corresponding study]). DMST dissipates from the water phase by degradation and adsorption to the sediment ($DT_{50\ (22°C)\ extrapolated}$ = 20.6 d – 75.8 d). When transformed to 20 ºC the worst case half life in water for DMST is 88.7 d. Levels of unextractable residue are high in the sediment at the end of the studies (maximum 40.1 % AR after 120 d). Levels of CO_2 evolved up to a maximum of 28 % AR.

Input parameters, scenarios and methodology employed for PECsw calculation was discussed in Evaluation and fate and behaviour in the environment experts meeting. The need for new calculations, more in line with current practices in EU, was agreed. These new calculations have been provided in Addendum 5 (8.11.2004). Worst case DT_{50} in water for tolylfluanid and DMST were used. PECsw have been provided for the representative uses apples, grapes and strawberries, as given in the updated table in Addendum 5. Spray drift rates with different risk mitigation buffers were used. Whereas not fully peer-reviewed EFSA agrees that these new calculations are in line with the conclusions of the experts meeting conclusions and its use for the risk assessment in the frame of Annex I inclusion is found acceptable.

4.2.2. POTENTIAL FOR GROUND WATER CONTAMINATION OF THE ACTIVE SUBSTANCE THEIR METABOLITES, DEGRADATION OR REACTION PRODUCTS

On the basis of FOCUS-PELMO model simulations neither tolylfluanid nor DMST are expected to exceed the 0.1 µg / L trigger in ground water.

4.3 FATE AND BEHAVIOUR IN AIR

Concentrations of tolylfluanid and DMST in the air compartment are expected to be negligible, due to low volatility and short persistence in the atmosphere.

5. Ecotoxicology

In the section on ecotoxicology the risk was evaluated for the following representative uses:

Apples/Pears (NE): 1.125 kg a.s./ha; 7 applications/ 7 d interval
Apples/Pears (SE): 1.5 kg a.s./ha; 3 applications/ 7 d interval
Grapes (NE): 1.8 kg a.s./ha; 8 applications/ 10 d interval
Grapes (SE): 2.0 kg a.s./ha; 3 applications/ 8 d interval
Strawberries (NE): 2.5 kg a.s./ha; 3 applications/ 8 d interval
Strawberries (SE): 1.25 kg a.s./ha; 3 applications/ 7 d interval

5.1 RISK TO TERRESTRIAL VERTEBRATES

A revised risk assessment is available in the addenda of February and November 2004. In the last addendum recommendations from EPCO Expert meetings 7, 8 and 9 are taken into account. The risk to birds and mammals is calculated according to the Guidance Document on Birds and Mammals (SANCO/4145/2000). The risk was calculated for a medium herbivorous and an insectivorous bird and a small and medium herbivorous mammal as foreseen in the above mentioned guidance document for a use in orchards, grapes and strawberries. In addition the risk was calculated for a bird and mammal with mixed diet feeding exclusively on fruits (fructivorous bird or mammal).

In the first tier risk assessment triggers were breached for insectivorous birds on a short term time scale for strawberries and on a long term time scale for all representative uses mentioned above. Also for herbivorous birds (only relevant in strawberries) triggers were breached in the first tier risk assessment at all time scales.

Therefore a tier 2 risk assessment was performed. The risk to insectivorous birds was refined by using the 50th percentile residue values for foliar insects from table 10 of Appendix 2 of Guidance document SANCO/4145/2000. Based on this tier 2 risk assessment the risk to insectivorous birds can be considered low. Also for herbivorous birds a tier 2 risk assessment was performed. In the addendum of February 2004 a PT-value of 0.6 was used. This was not accepted by the EPCO 8 Expert meeting unless data to support this is available. Data to support this was submitted by the notifier after the EPCO 8 Expert meeting and is consequently not taken into account in the risk assessment. This will not change the outcome of the risk assessment as it was decided in the EPCO 8 risk assessment that the scenario of herbivorous birds is not relevant for the representative uses evaluated in the section on ecotoxicology. In addition the risk for fructivorous birds in strawberries was calculated and this risk can be regarded as low (trigger not breached).

All calculated first tier acute TER values for herbivorous mammals do not breach the appropriate Annex VI trigger value and hence the acute risk to herbivorous mammals can be considered as low for the representative uses evaluated in the section on ecotoxicology.

The EPCO 8 Expert meeting had a discussion on the relevant NOAEL to be used for the long term risk assessment for mammals and decided that the NOEC of 9 mg/kg bw from the study by Pickel and Rincke study needs to be used. Meanwhile the EPCO 9 Expert meeting on toxicology decided that the value of 12 mg/kg bw/day on the basis of the new 2-generation reproduction study by Young & Fickbohm is the most appropriate NOAEL. Therefore the RMS revised the long term risk assessment for mammals in the addendum of November 2004 based on the NOAEL of 12 mg/kg bw/day. All calculated first tier long term TER-values for mammals breach the appropriate Annex VI trigger value and hence a refinement of the risk is considered necessary and is available. Also in this second tier the Annex VI trigger values are not met and the long term risk to herbivorous mammals still needs to be considered as high. The notifier submitted a refined risk assessment but due to the late submission this cannot be taken into account any more in the risk assessment at this stage. Therefore a data requirement is set to further address the long term risk for herbivorous mammals for all representative uses evaluated in the section on ecotoxicology. This refinement could include the relevance of the herbivorous mammal scenario in strawberries.
The long term risk to fructivorous mammals in strawberries can be regarded as acceptable.

As the logPow exceeds 3 the risk from secondary poisoning to birds and mammals was assessed.
The risk for earthworm eating birds and mammals was recalculated in the addendum of November 2004 as the PECs-values changed after the EPCO 7 Expert meeting on Fate and behaviour. In the same addendum the buffer zones taken into account to calculate the risk for fish eating birds and mammals are now clearly indicated as requested during the EPCO 8 Expert meeting. EFSA agrees with the revised risk assessment for earthworms eating birds and mammals in the addendum of November 2004 which was not peer reviewed in an EPCO Expert meeting. The risk for earthworm birds and mammals can be considered low for all the representative uses evaluated in the section on ecotoxicology. Also the risk for fish eating birds and mammals can be considered low if a buffer zone of 5 m from water bodies is taken into account for all the representative uses evaluated in the section on ecotoxicology.

5.2 RISK TO AQUATIC ORGANISMS

Onchorhynchus mykiss was the most sensitive species from all aquatic species tested with tolylfluanid and the lead formulation. The choice of endpoint was discussed during the EPCO 8 Expert meeting. It was decided that to assess the risk to fish, the outdoor microcosm study with rainbow trout was the most relevant study. From this study a NOEC of 60 µg/L could be defined. During this EPCO meeting it was decided that the uncertainty factor could be lowered to 5 as acute studies on several fish species were submitted, rainbow trout is the most sensitive species and the acute/chronic ratio is low. A lower uncertainty factor would only be warranted if indirect effects within the community would be covered by a study.
Only for the use in strawberries in Southern Europe the risk can be considered low (TER>5) without the need for risk mitigation measures. For all the other uses evaluated in the section on ecotoxicology TER-values exceed 5 indicating a low risk to aquatic organisms if buffer zones of 5-20 m are taken into account pending on the crop and the location (Northern or Southern Europe).

Furthermore an acute toxicity study to zebrafish conducted at different pH values was submitted. From this study it is clear that the toxicity to fish is higher at lower pH-values. This was discussed in the EPCO 8 Expert meeting and it was decided that MS with surface water bodies of low pH (<6) associated with agricultural landscapes should consider the effect of pH on toxicity to fish at the local level.

As the DT_{50} in water is 0.25 d no prolonged exposure is expected. The risk from repeated exposure was considered covered by the EPCO 8 Expert meeting as 4 applications were included in the outdoor microcosm studies. Even though only 4 applications were tested instead of 8, the uncertainty arising from that matter was considered low because the substance is very unstable in water and it was regarded unlikely that the highest PEC will reach one water body 8 times.

As in the water sediment study the content of active substance was less than 10% of the AR at or after 14 days no studies with the active substance on sediment dwelling organisms are considered necessary.

Furthermore the metabolite DMST was tested on fish (acute and long term), *Daphnia magna* (acute and long term), algae and sediment dwelling organisms as DMST could be found in concentrations above 10% of the AR in the sediment. The metabolite is less toxic to aquatic organisms than the compound. The risk from this metabolite was recalculated in addendum 5 of November 2004 due to a change in PECsw-values as decided during the EPCO 7 Expert meeting. In this addendum the risk was calculated taking into account a buffer zone of 5 m for all crops. For the information EFSA calculated the TER value for the acute endpoint for Daphnia magna (31000 µg/L) which, given the higher trigger value of 100, drives the risk assessment for DMST and the highest PECsw-value without buffer zone (=130.39 µg/L) which gives 238. This TER-value indicates that the risk from the metabolite can be considered as low (Annex VI trigger not breached) without the need for risk mitigation measures.

As the log Pow exceeds 3, a study on bioconcentration in fish is made available. The resulting BCF is below the Annex VI trigger value of 100 for not readily biodegradable compounds indicating a low risk for bioconcentration in fish.

5.3 RISK TO BEES

Acute contact and oral toxicity studies both with tolylfluanid and the lead formulation are available. The resulting HQ values do not breach the appropriate Annex VI trigger value indicating a low risk to bees.

5.4 RISK TO OTHER ARTHROPOD SPECIES

Toxicity to non-target arthropods was high in laboratory studies on the two indicator species *Aphidius rhopalosiphi* and *Typhlodromus pyri*.

A large data set was submitted to indicate the possibility for recovery. This is discussed by the RMS per group of non target arthropods.

For parasitoids studies on *Aphidius rhopalosiphi, Trichogramma dendrolimi* and *T. cacoeciae* are available. From these studies it is concluded the risk to parasitoids off-field can be considered as low and that recovery in-field could start at the latest after a period of 8 weeks after the last treatment.

For predatory mites studies were submitted with *Typhlodromus pyri*. Also field studies in vineyards are available. The risk to predatory mites off-field can be considered as low. A potential for within season effects was identified for predatory mites in-field but population recovery was demonstrated before the start of next season.

For ground dwelling predators studies on *Poecilus cupreus* and *Aleochara bilineata* were submitted. No effects were observed up to an application rate of 3 x 3.1 kg a.s./ha. The risk for ground dwelling predators is regarded as low.

For foliage dwelling predators studies on *Coccinella septempunctata*, *Orius insidiosus, O. laevigatus* and *Chrysoperla carnea*. The risk to foliage dwelling predators off-field can be considered as low. Only for the application in strawberries in northern Europe a short term risk can not be excluded. However, a recovery is possible, as the maximum residue level on the plant surface after the last application will degrade within less than a week below the residue levels that would cause adverse effects.

5.5 RISK TO EARTHWORMS

Studies on the acute toxicity to earthworms from tolylfluanid and the lead formulation are available. The acute toxicity for DMST is based on the 14 d NOEC of the long term toxicity study. Recalculated TER-values are available in the addendum of November 2004 as the PECs-values changed after the EPCO 7 Expert meeting on Fate and behaviour. EFSA noted that no correction factor for the LogPow exceeding 2 was taken into account in this risk assessment. The RMS corrected this in the final addendum (see corrections highlighted in red) and EFSA agrees with these corrections (final addendum has not been peer reviewed in an EPCO Expert meeting). Also the TER-values, based on the LC_{50} corrected for the LogPow, do not breach the Annex VI trigger value, indicating a low acute risk to earthworms for the representative uses evaluated in the section on ecotoxicology.

Studies on the long term toxicity to earthworms from the lead formulation and the metabolite DMST are available. As for the acute risk a revised risk assessment is available in the addendum of November 2004 and no correction factor was taken into account. The RMS corrected this in the final addendum (see corrections highlighted in red) and EFSA agrees with these corrections (final addendum has not been peer reviewed in an EPCO Expert meeting). Also the TER-values, based on the NOEC corrected for the LogPow, do not breach the Annex VI trigger value, indicating a low long term risk to earthworms for the representative uses evaluated in the section on ecotoxicology.

5.6 RISK TO OTHER SOIL NON-TARGET MACRO-ORGANISMS

Tolylfluanid is not expected to be persistent in soil. Therefore, no further testing on other soil non-target macro-organisms is considered necessary for the compound.

Also the metabolite DMST is not expected to be persistent in soil but a study on the effects of this metabolite on collembola was made available. It is noted by EFSA that this risk assessment was not revised after EPCO 7 Expert meeting during which a change to the PECs values was decided. The RMS corrected this in the final addendum (see corrections highlighted in red) and EFSA agrees with these corrections (final addendum has not been peer reviewed in an EPCO Expert meeting). Based on these TER-values the risk to collembola from the metabolite DMST can be regarded as low.

5.7 RISK TO SOIL NON-TARGET MICRO-ORGANISMS

The effects of the lead formulation and the soil metabolite DMST were tested on soil microbial respiration and nitrogen transformation. No deviations of more than 25% after 91 days were observed (i.e. no breaching of the Annex VI trigger value) at concentrations above the max. PECs and hence the risk to soil non-target micro-organisms is considered to be low.

5.8 RISK TO OTHER NON-TARGET-ORGANISMS (FLORA AND FAUNA)

Studies on the effects of the lead formulation on non-target terrestrial plants are available. The initial screening data (Study 1, Meisner & Kolb 2000) showed that no or only slight phytotoxic effects (< 50 %) occurred up to an application rate of 6 kg ai/ha (max. single application rate is 2.5 kg ai/ha). According to the Guidance Document on Terrestrial Ecotoxicology states: there is no need to provide further studies but a study on seedling emergence and vegetative vigor is available. All EC50-values from this study are above 15 kg/ha. It is noted by EFSA that no TER values were calculated in the DAR but overall the risk can be regarded as low.

5.9 RISK TO BIOLOGICAL METHODS OF SEWAGE TREATMENT

A study was made available with the a.s. and the metabolite DMST. The risk for biological methods of sewage treatment is considered to be low.

6 Residue definitions

Soil

Definitions for risk assessment: Tolylfluanid and DMST
Definitions for monitoring: Tolylfluanid

Water

Ground water

Definitions for risk assessment: Tolylfluanid and DMST
Definitions for monitoring: Tolylfluanid

Surface water

Definitions for risk assessment: Tolylfluanid and DMST

Definitions for monitoring: Tolylfluanid

Sediment:

Definition fort he risk assessment: DMST

Air

Definitions for risk assessment: Tolylfluanid

Definitions for monitoring: Tolylfluanid

Food of plant origin

Definitions for risk assessment: sum of tolylfluanid and DMST, expressed as tolylfluanid;

for grapes: sum of tolylfluanid, DMST, 4-hydroxymethyl-DMST-glucoside and 2-hydroxyphenyl-DMST-glucoside expressed as tolylfluanid

Definitions for monitoring: sum of tolylfluanid and DMST, expressed as tolylfluanid

Food of animal origin

Definitions for risk assessment: DMST

Definitions for monitoring: DMST

Overview of the risk assessment of compounds listed in residue definitions for the environmental compartments

Soil

Compound (name and/or code)	Persistence	Ecotoxicology
Tolylfluanid	very low to low persistent ($DT_{50\ (20°C)}$ = 0.5 – 2.6 d)	See points 5.5, 5.6 and 5.7.
DMST	low persistent ($DT_{50\ (22°C)}$ = 1.3 – 6.7 d)	Acute risk to earthworms is considered to be low (trigger not breached). Long term risk to earthworms is considered to be low. A low risk to collembolan was observed. The risk to soil non-target micro-organisms is considered to be low.

Ground water

Compound (name and/or code)	Mobility in soil	> 0.1 µg / L 1m depth for the representative uses	Pesticidal activity	Toxicological activity	Ecotoxicological activity
Tolylfluanid	estimated to be slightly to low mobile	No scenarios above trigger value	-	Yes, assessed in the DAR	Yes, assessed in the DAR
DMST	potentially high mobile	No scenarios above trigger value	-	Assessed not to be toxicologically relevant	Assessed not to be ecotoxicological relevant

Surface water and sediment

Compound (name and/or code)	Ecotoxicology
Tolylfluanid (only water phase)	See point 5.2.
DMST (water and sediment)	The risk to aquatic organisms is considered low (trigger not breached) based on an acute and long term toxicity study with fish, an acute and long term toxicity study with *Daphnia magna*, a toxicity study with algae and a toxicity study with *Chironomus riparius.*

Air

Compound (name and/or code)	Toxicology
Tolylfluanid	Air contamination not expected

LIST OF STUDIES TO BE GENERATED OR STILL ONGOING

- Notifier to submit a refined risk assessment for herbivorous mammals (relevant for all representative uses evaluated; submitted by the notifier: August 2004; not evaluated by the RMS; refer to point 5.1)

CONCLUSIONS AND RECOMMENDATIONS

Overall conclusions

The conclusion was reached on the basis of the evaluation of the representative uses as proposed by the applicant which comprises spray treatment to foliar to control a wide range of fungicidal diseases such as apple scab, grey mould, leaf spot diseases and powdery and downy mildew in different fruits, vegetables and hops at application rate up 3 kg tolylfluanid per hectare. The representative formulated product for the evaluation was "Euparen M WG 50", a water dispersible granule (WG), registered in almost all Member States of the EU.

Adequate methods are available to monitor all compounds given in the respective residue definition apart from food of animal origin.

Tolylfluanid is extensively and rapidly absorbed (>90%). It is widely distributed and the highest concentration was found in liver, kidney and thyroids but there is no evidence of accumulation. Tolylfluanid is extensively metabolised. The oral and dermal toxicity is low i.e. LD_{50} > 5000 mg/kg bw/day. However, the toxicity during inhalation exposure was low to high. This was related to the particle size that leads to two proposals of classification from **no classification** to very toxic. For **tolylfluanid containing ≥ 0.1% particles < 50µm; T+; R26 "Very toxic by inhalation"**. Tolylfluanid has irritating properties in both eyes and skin and the classification as **Xi; R36/37/38 "Irritating to eyes, respiratory system and skin" is** proposed. Tolylfluanid was found to have sensitizing properties and should be labelled as with **R43 "May cause sensitisation by skin contact"**. The main effects observed during short term exposure were functional disturbance of the thyroid, increased liver weights and decreased liver enzyme levels in the rat and dog and slight histopathological changes in the kidney in the dog at high dose levels and the relevant oral NOAEL is 1000 ppm (i.e. 33 mg/kg bw/day) in the 90-day dog study. The relevant dermal NOAEL is 300 mg/kg bw/day in the rabbit, based on slight effects in haematological and clinical chemistry parameters. During short term inhalation exposure severe respiratory tract irritation including deaths was observed. Depending on the particle size, the inhalation NOAEL/NOEC is 0.001 mg/L for respirable particles (i.e. < 3 µm) and for larger particles NOAEL/NOEC ≥ 0.004 mg/L based on the irritation effects observed. Two proposals for classification were made depending on the particle size with **no classification for tolylfluanid containing ≤ 0.1% of 0-50 µm particles** whereas for **tolylfluanid containing ≥ 0.1% particles < 50µm, classification with T; R48/R23 Toxic "Danger of serious damage to health by prolonged exposure through inhalation"** is proposed**.**

Tolylfluanid should not be classified as mutagenic, based on the fact that the overall *in vivo* test data points towards negative results, although some evidence of genotoxicity were seen in an *in vitro* chromosome aberration test and in some tests for gene mutations in mammalian cells.

There were no indications of carcinogenic potential of tolylfluanid. The relevant long term NOAEL is 300 ppm (i.e. 18 mg/kg bw/day) in the rat based on increased changes in the osseous part of the muscular-skeletal system.

There were no direct effects on reproductive performance or fertility observed. The relevant NOAEL for both systemic effects and reproduction was set to 12 mg/kg bw/day in the rat based on reduced body weight and pup spleen weight. **Tolylfluanid did not induce teratogenic or fetotoxic effects** at non-maternally toxic doses. The developmental and maternal NOAEL is 25 mg/kg bw/day in the rabbit based on post implantation losses and slightly increased malformations at maternally toxic doses.

No evidence of neurotoxicity was observed. Studies on the metabolites KUE 5156 (TTCA), dimethylaminosulfotoluidide (DMST), WAK 5818, WAK 6550, WAK 6676, WAK 6698 revealed that they were of low toxicological concern based on the acute toxicity and *in vitro* genotoxicity data. Risk assessment estimations for WAK 6550, WAK 6676 and WAK 6698 were all ≤ 4% of AOEL. Further, studies on impurities showed that they are not of toxicological concern.

The ADI is set to 0.1 mg/kg based on the NOAEL of 12 mg/kg bw/day in the rat multigeneration study. **The AOEL is 0.3 mg/kg bw/day** based on the NOAEL of 33 mg/kg bw/day in the 90-day study in dogs. **The ARfD is 0.25 mg/kg bw/day** based on the NOAEL of 25 mg/kg bw/day in the rabbit developmental study.

The dermal absorption for Euparen M 50 WG was 5% for the concentrate and 7% for the dilution, on the basis of the results in the *in vivo* study in the rat and by using the *in vitro* data rat/human for comparison. **The estimated operator exposure levels are below the AOEL for proposed uses of Euparen M 50 WG** according to UK-POEM if PPE (i.e. gloves) is used during mixing and loading (M/L) and without any PPE according to German model (i.e. ≤ 70% of AOEL). **The estimated worker and bystander exposure levels are also below the AOEL** i.e. ≤ 66% and ≤ 3% of AOEL, respectively without PPE.

The metabolism of tolylfluanid in plants proceeds through degradation to DMST, being the main metabolite in the majority of investigated crops. Moreover, under processing conditions tolylfluanid degrades rapidly and almost completely to DMST, that has a similar toxicity compared to tolylfluanid. The residue situation in food of plant origin was proved with a sufficient number of trials according to the critical GAP for a wide range of fruit and vegetable crops and for hops; and also with studies determining the level of residues in processed products.

In livestock tolylfluanid is rapidly metabolised to DMST that was detected in all organs and tissues as well as in eggs. Assuming fruit pomace as the only relevant feed item possibly containing residues from tolylfluanid treatment, no quantifiable residues are expected in edible products of animal origin.

The chronic and acute dietary exposure assessment for adult consumers indicates that the intake of residues via the total diet for food of plant origin or any individual food item considered does not exceed the ADI and the ARfD, respectively.

For toddlers and children the maximum daily residue intake from fruit and vegetables (TMDI) occupies no more than 70% of the ADI, indicating that long-term exposure to residues from tolylfluanid treated crops does not pose an adverse health risk to these consumer subgroups. The estimation of the short term exposure revealed that the ARfD is slightly exceeded (102%, WHO/GEMS Food data) for children consuming table grapes. However, Germany pointed out during the last discussion of tolylfluanid that a greater exceedance of the ARfD (121%) was obtained based on national consumption data for children.

Under aerobic conditions, the loss of volatile dichlorofluoromethane sulfenic acid yields DMST that decreases to levels below 3 % AR at the end of the study (99 d). Degradation of this metabolites produces other minor metabolites (none > 10 % AR) and ultimately bound residue (maximum 83.7 % after 15 d, 72.3 % after 99 d) and CO_2 (maximum 40 % after 99 d). About half of the non extractable radioactivity at the end of the study was demonstrated to be bounded DMST. Photolysis will not significantly contribute to the overall degradation of tolyfluanid under environmental conditions. Tolyfluanid is between very low to low persistent in soil. Metabolite DMST is low persistent. Tolyfluanid should be classified as a slightly to low mobile compound. DMST can be classified as a medium to high mobile compound.
Hydrolysis of tolyyfluanid is rapid and slightly pH dependent. DMST is stable in all range of environmentally relevant pH with an estimated half life longer than one year. Direct photodegradation is not expected to contribute to the degradation of tolyfluanid or its metabolite DMST in the aqueous environment. Tolyfluanid is not ready biodegradable. In water sediment systems, tolyfluanid completely disappear from water phase in about three days mainly due to degradation. Levels of tolyfluanid found in the sediment never attained the 10 % of AR. Major metabolite, both in water and sediment, was DMST. DMST dissipates from the water phase by degradation and adsorption to the sediment. Levels of unextractable residue are high in the sediment at the end of the studies (maximum 40.1 % AR after 120 d). Levels of CO_2 evolved up to a maximum of 28 % AR.
On the basis of FOCUS-PELMO model simulations neither tolylfluanid nor DMST are expected to exceed the 0.1 µg / L trigger in ground water.
Concentrations of tolyfluanid and DMST in the air compartment are expected to be negligible.

The risk to birds, bees, soil micro- and macro-organisms, including earthworms and non-target terrestrial plants is low with respect to tolylfluanid and the metabolites as far as investigated.

A high long term risk to mammals was identified. TER-values range from 0.84 to 2.78 pending on the representative use evaluated and therefore breaching the Annex VI trigger value of 5 for all the representative uses evaluated. Further data to address this risk is needed and the risk assessment can only be concluded when the outstanding data is evaluated.
High risk is identified for fish (being the most sensitive aquatic organism), which requires consideration of appropriate risk mitigation measures. Pending on the representative use bufferzones of 5-20 metres are needed to respect the Annex VI trigger value. The toxicity to fish is higher at lower

pH-values therefore it is proposed that MS with surface water bodies of low pH (<6) associated with agricultural landscapes should consider the effect of pH on toxicity to fish at the local level.
Also for non-target arthropods (other than bees) a high risk was identified in-field however a recovery before the start of next season is considered possible.

Particular conditions proposed to be taken into account to manage the risk(s) identified

- Appropriate risk mitigation measures (e.g. a 5-20 meter no spray bufferzone) are required with regard to the risk for fish eating birds and mammals and aquatic organisms (refer to points 5.1 and 5.2).
- MS with surface water bodies of low pH (<6) associated with agricultural landscapes should consider the effect of pH on toxicity to fish at MS level.
- Tolylfluanid use on grapes may be restricted to the use on wine grapes only with regard to the high acute risk identified for toddlers and children (refer to point 3.3)

CRITICAL AREAS OF CONCERN

- The estimate of the short term exposure of toddlers and children to residues on table grapes arising from tolylfluanid treatment revealed a slight exceedance of the ARfD (102 %, WHO/GEMS Food data). Germany indicated that based on national consumption data the exposure of children may be at 121% ARfD. Thus, an acute risk for individuals of the referred-to consumer subgroups cannot be entirely excluded.
- A high long term risk to mammals was identified. TER-values range from 0.84 to 2.78 pending on the representative use evaluated and therefore breaching the Annex VI trigger value of 5 for all the representative uses evaluated.
- The risk to aquatic organisms is high, in particular to fish. Pending on the representative use bufferzones of 5-20 metres are needed to respect the Annex VI trigger value. The toxicity to fish is higher at lower pH-values therefore it is proposed that MS with surface water bodies of low pH (<6) associated with agricultural landscapes should consider the effect of pH on toxicity to fish at the local level.

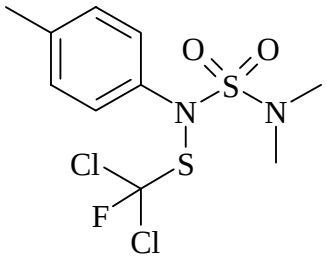
APPENDIX 1 – LIST OF ENDPOINTS FOR THE ACTIVE SUBSTANCE AND THE REPRESENTATIVE FORMULATION

(Abbreviations used in this list are explained in appendix 2)

Appendix 1.1: Identity, Physical and Chemical Properties, Details of Uses, Further Information

Active substance (ISO Common Name) ‡	Tolylfluanid
Function (e.g. fungicide)	Fungicide
Rapporteur Member State	Finland

Identity (Annex IIA, point 1)

Chemical name (IUPAC) ‡	*N*-dichlorofluoromethylthio-*N*',*N*'-dimethyl-*N*-*p*-tolylsulfamide
Chemical name (CA) ‡	Methanesulfenamide, 1,1-dichloro-*N*-[(dimethyl=amino)sulfonyl]-1-fluoro-*N*-(4-methylphenyl)-
CIPAC No ‡	275
CAS No ‡	731-27-1
EEC No (EINECS or ELINCS) ‡	EINECS: 211-986-9
FAO Specification ‡ (including year of publication)	960 ± 20 g/kg AGP:CP/332 (1995)
Minimum purity of the active substance as manufactured ‡ (g/kg)	min. 960 g/kg
Identity of relevant impurities (of toxicological, environmental and/or other significance) in the active substance as manufactured (g/kg)	none
Molecular formula ‡	$C_{10}H_{13}Cl_2FN_2O_2S_2$
Molecular mass ‡	347.3
Structural formula ‡	

‡ Endpoint identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Physical-chemical properties (Annex IIA, point 2)

Melting point (state purity) ‡	93 °C
Boiling point (state purity) ‡	Not measurable, decomposition above 200 °C
Temperature of decomposition	> 200 °C
Appearance (state purity) ‡	Whitesh crystalline powder with lumpy parts; weak characteristic odour (960 g/kg)
Relative density (state purity) ‡	1.520 g/cm^3 (density)
Surface tension	70 mN/m at 20 °C
Vapour pressure (in Pa, state temperature) ‡	$2 \cdot 10^{-4}$ Pa at 20 °C (extrapolated) tolylfluanid $2.5 \cdot 10^{-4}$ Pa at 20 °C (extrapolated) DMST
Henry's law constant (Pa m^3 mol $^{-1}$) ‡	$7.7 \cdot 10^{-2}$ at 20 °C tolylfluanid $7.7 \cdot 10^{-5}$ at 20 °C DMST
Solubility in water ‡ (g/l or mg/l, state temperature)	0.90 mg/L at 20°C
Solubility in organic solvents ‡ (in g/l or mg/l, state temperature)	*n*-heptane 54 xylene 190 dichloromethane > 250 2-propanol 22 1-octanol 16 polyethylen glycol (PEG) 56 acetone > 250 acetonitrile > 250 dimethylsulfoxide > 250 ethylacetate > 250 (all g/L at 20 °C)
Partition co-efficient (log POW) ‡ (state pH and temperature)	log P_{OW} = 3.9 at 21 °C (not dependent on pH)
Hydrolytic stability (DT50) ‡ (state pH and temperature)	pH 4: Tolylfluanid: 11.7 d (22 °C, extrapolated), 5.6 d (30 °C) (purity 99 %) DMST: >>1 yr (55 °C) (purity not reported) pH 7: Tolylfluanid: 42.5 h (20 °C), 29.1 h (22 °C, extrapolated), 7.9 h (30 °C) (purity 99%) DMST: >> 1 yr (55 °C) (purity not reported) pH 9: Tolylfluanid: <<10 min (20 °C) (purity 99 %) DMST: >> 1 yr (55 °C) (purity not reported)
Dissociation constant ‡	Tolylfluanid shows in aqueous solvents neither acidic nor basic properties. pK value not possible to specify.
UV/VIS absorption (max.) ‡ (if absorption > 290 nm state ε at wavelength)	Absorption maximum at 210 nm. No absorbance above 290 nm.

‡ Endpoint identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Photostability (DT50) ‡ (aqueous, sunlight, state pH)	Tolylfluanid: direct photodegradation is not expected to contribute to the elimination in the environment (no absorbance above 290 nm). DMST: minimum 56 days (at 30th degree latitude) or 69-82 days (at 50th degree latitude), maximum >1 year. (The estimates based on simulation models GC-SOLAR and Frank & Klöpffer and on the results obtained in phototransformation study, pH 5-9.)
Quantum yield of direct phototransformation in water at Σ > 290 nm ‡	Tolylfluanid: no absorbance above 290 nm. Quantum yield of DMST was calculated $4.66 \cdot 10^{-3}$.
Flammability ‡	Not flammable. Spontaneous ignition temp. 381 °C
Explosive properties ‡	Not explosive.

‡ Endpoint identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

List of representative uses evaluated*

Crop and/or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of a.s. (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	kg as/hl min max	water l/ha min max	kg as/ha min max		
Apples/Pears[I]	*NE SE	Euparen M	F F	VENTIN VENTPI	WG	50	SPI / SRU	/	7 3	7 – 14 7 - 14	0,15 – 0,2 -	max. 1500[a] max. 1500 [a]	- 1.125 - 1.5	7 3	*NE SE
Grapes[I]	*NE SE	Euparen M	F F	BOTRCI PLASVI	WG	50	SPI / SRU	/	8 3	10 – 14 8 – 19	0,225 – 0,4 -	max. 1600[b] 100 – 1000	up to 1.8 up to 2.0	35 21	
Strawberries[I]	NE SE	Euparen M	F F	BOTRCI SPHRMA	WG	50	SPI	/	3 3	8 – 12 7 – 10	/	300 – 2000 800 – 1000	2.5 1.25	7 3	
Rasp- and Blackberries	NE	Euparen M	F F	BOTRCI SPHRMA	WG	50	SPI	/	4	8 – 10	/	500 – 1500	1.7	14	
Currants / Gooseberries	NE	Euparen M	F F	BOTRCI SPHRMA	WG	50	SPI	/	2	14	/	500 – 1000	1.25	14	
Tomatoes	NE SE -	Euparen M	F F G	ALTESO BOTRCI PHYTIN	WG	50	SPI	/	6 3 – 4 4 – 6	8 – 10 7 – 10 8 – 10	0,2 0,3 0,2	300 – 1200 1000 max. 1500[c]	up to 1.2 up to 1.5 up to 1.5	3 3 3	
Peppers	-	Euparen M	G	ALTESO BOTRCI	WG	50	SPI	/	3	7	0,2	max. 1500[d]	1.3	3	

‡ Endpoint identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Appendix 1 – list of endpoints

Crop and/or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of a.s. (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	kg as/hl min max	water l/ha min max	kg as/ha min max		
Cucumber / Zucchini	NE -	Euparen M	F G	PSECU SPHRFU	WG	50	SPI	/	6 6	10 8 – 11	0,2 0,2	600 max. 1500[e]	0.6 up to 1.5	3 3	
Melons	NE SE	Euparen M	F F	ALTECU PSECU	WG	50	SPI	/	3 3	10 10	/	300 300	1.25 1.25	14 14	
Head Lettuce	NE SE	Euparen M	F F	BREMLA BOTRCI	WG	50	SPI	/	6 3	5 10 – 17	/	600 1000	0.6 1.0	21 7	
Leeks	NE	Euparen M	F	PHYTPO	WG	50	SPI	/	5	14	/	600	1.25	21	
Hops	*NE	Euparen M	F	BOTRCI PSPEHU	WG	50	SPI / SRU	/	6	8 – 24	0.2 -	1000 - 3000	up to 3.0	14	

Remarks:
(a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (*e.g.* fumigation of a structure)
(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
(c) *e.g.* biting and suckling insects, soil born insects, foliar fungi, weeds
(d) *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) GCPF Codes - GIFAP Technical Monograph No 2, 1989
(f) All abbreviations used must be explained
(g) Method, *e.g.* high volume spraying, low volume spraying, spreading, dusting, drench
(h) Kind, *e.g.* overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
(i) g/kg or g/l
(j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
(k) The minimum and maximum number of application possible under practical conditions of use must be provided
(l) PHI - minimum pre-harvest interval
(m) Remarks may include: Extent of use/economic importance/restrictions
(n) product concentration of spray liquid
(I) The uses for which environmental fate and ecotoxicological risk assessments have been conducted

‡ Endpoint identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Appendix 1.2: Methods of Analysis

Analytical methods for the active substance (Annex IIA, point 4.1)

Technical as (principle of method)	HPLC, UV-detection
Impurities in technical as (principle of method)	HPLC, UV-detection for organic impurities potentiometric, $AgNO_3$ for Cl^- ICP-OES, for MgO Karl Fischer titration for water
Plant protection product (principle of method)	HPLC, UV-detection

Analytical methods for residues (Annex IIA, point 4.2)

Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes)	GC-TID or ECD or FPD (method DFG S 19 and S 8) 0.01 mg/kg to 0.05 mg/kg tolylfluanid ; for all crops
Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes)	GC-ECD (method DFG S 19) 0.01 mg/kg tolylfluanid for milk, 0.05 mg/kg tolylfluanid for meat, egg, fat An analytical method is not required since no MRLs have been proposed.
Soil (principle of method and LOQ)	GC-MSD (method DFG S 19) 0.01 mg/kg tolylfluanid, GC-MSD (method DFG S 19) 0.01 mg/kg DMST
Water (principle of method and LOQ)	HPLC-MS/MS for surface and drinking water 0.05 µg/L tolylfluanid, 0.05 µg/L DMST
Air (principle of method and LOQ)	GC-TID 0.01 mg/m^3 tolylfluanid
Body fluids and tissues (principle of method and LOQ)	GC-MSD 0.05 mg/L tolylfluanid for blood

Classification and proposed labelling (Annex IIA, point 10)

with regard to physical/chemical data	Not classified

‡ Endpoint identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Appendix 1.3: Impact on Human and Animal Health

Absorption, distribution, excretion and metabolism in mammals (Annex IIA, point 5.1)

Rate and extent of absorption ‡	Over 90% within 48 h, based on urinary and biliary excretion
Distribution ‡	Widely distributed. Highest residue levels in liver, kidney and thyroids (24 – 48 h)
Potential for accumulation ‡	No evidence for accumulation
Rate and extent of excretion ‡	60 – 90% in urine, 12 – 36 % in feces with phenyl-ring labelled a.s. within 48 h. About 16% of dichloro-fluoromethyl-labelled a.s. is exhaled within 48 h.
Metabolism in animals ‡	Extensively metabolised (> 90 %). The parent is metabolised to DMST in one of two parallel pathways, followed by hydroxylation, demethylation and conjugation reactions. In the other pathway the dichlorofluoromethyl side chain is converted in a series of unknown reactions to TTCA.
Toxicologically significant compounds ‡ (animals, plants and environment)	Parent compound and metabolites. TTCA is identified as an antithyroideal metabolite. Release of fluoride causes hyperostosis. The plant metabolites WAK6550, WAK6676 and WAK6698 were not relevant.

Acute toxicity (Annex IIA, point 5.2)

Rat LD_{50} oral ‡	> 5000 mg/kg bw	
Rat LD_{50} dermal ‡	> 5000 mg/kg bw	
Rat LC_{50} inhalation ‡	> 1.038 mg/l (MMAD 16.8-19.8 µm, <7% ≤3 µm) 0.383 mg/l (MMAD 3.81-3.95 µm, 35-39% ≤ 3 µm) 0.160-0.200 mg/l (MMAD 2.1-2.5 µm, 64-74% ≤ 3 µm) (split classification and labelling, see point 5.10)	
Skin irritation ‡	Irritating to skin	**R38**
Eye irritation ‡	Irritating to eyes	**R36**
Skin sensitization ‡ (test method used and result)	Sensitizing (M & K)	**R43**

Short term toxicity (Annex IIA, point 5.3)

Target / critical effect ‡	Liver, kidneys, thyroids
Lowest relevant oral NOAEL / NOEL ‡	13-week dog: 1000 ppm (33 mg/kg bw/d)

‡ Endpoint identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Lowest relevant dermal NOAEL / NOEL ‡	17-18 day rabbit: 300 mg/kg bw/d, NOAEL for irritation <1 mg/kg bw/d
Lowest relevant inhalation NOAEL / NOEL ‡	0.001 mg/l (0.27 mg/kg bw/d, non-micronised dust), 4-wk rat. ≥ 0.004 mg/l; irritation of respiratory tract (split classification and labelling, see point 5.10)

Genotoxicity ‡ (Annex IIA, point 5.4)

.....	Some *in vitro* positives. Equivocal *in vivo* results. A new *in vivo* chromosome aberration test in mammalian bone marrow cells was required, evaluated and found to be negative. Tolylfluanid can not be classified as a mutagen.

Long term toxicity and carcinogenicity (Annex IIA, point 5.5)

Target/critical effect ‡	Increased fluoride levels, increased liver weights and slightly increased liver enzyme activities, slight effects on thyroid gland at high dose levels
Lowest relevant NOAEL / NOEL ‡	2-year rat: 300 ppm (18 mg/kg bw/d)
Carcinogenicity ‡	No carcinogenic potential

Reproductive toxicity (Annex IIA, point 5.6)

Reproduction target / critical effect ‡	Reduced pup body weights and pup spleen weights
Lowest relevant reproductive NOAEL / NOEL ‡	200 ppm (12 mg/kg bw/d), for both systemic and reproduction toxicity
Developmental target / critical effect ‡	Increased postimplantation loss, malformations and placental alterations at the maternal toxic dose
Lowest relevant developmental NOAEL / NOEL ‡	Rabbit: 25 mg/kg bw/d

Neurotoxicity / Delayed neurotoxicity ‡ (Annex IIA, point 5.7)

.....	No data on delayed neurotoxicity, data not required. Acute and subchronic neurotoxicity studies in rats showed no neurobehavioral changes

‡ Endpoint identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Other toxicological studies ‡ (Annex IIA, point 5.8)

.....	TTCA: TTCA was identified as an antithyroideal metabolite in a mechanistic study. The acute oral toxicity was low (LD50>1000 mg/kg bw) and mutagenicity (Ames test) showed no concerns. Triadimefon: A study of combined acute toxicity of tolylfluanid and triadimefon showed no synergistic effects WAK6550, WAK6676 and WAK6698: Plant metabolites. The acute toxicity was low (LD50>5000 mg/kg bw) and they were not genotoxic. DMST: Acute oral LD50 1600 mg/kg bw, dermal MD50 > 5000 mg/kg bw, inhalation LC50 > 0.16 mg/L, neither skin nor eye irritancy observed.

Medical data ‡ (Annex IIA, point 5.9)

.....	A few cases of allergic skin reactions are described among manufacturing plant personnel exposed to both tolylfluanid and dichlofluanid.

Summary (Annex IIA, point 5.10)	Value	Study	Safety factor
ADI ‡	0.1 mg/kg bw	rat, 2-generation study	100
AOEL ‡	0.3 mg/kg bw/d	dog, 13w study	100
ARfD ‡	0.25 mg/kg bw/day	rabbit, developmental	100

Dermal absorption (Annex IIIA, point 7.3)

.....	5 % for the concentrate and 7 % for 1:100 dilution, based on an *in vivo* study in rat and *in vitro* skin penetration data from rats and humans

Acceptable exposure scenarios (including method of calculation)

Operator	The estimated operator exposure was below the AOEL according to the UK-POEM model with PPE (i.e. gloves during M/L) and without PPE according to the German model (i.e. 70% of AOEL).
Workers	The estimated exposure is below the AOEL (i.e. 66% without PPE or 33% with PPE).

‡ Endpoint identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Bystanders	The estimated exposure is below the AOEL (i.e. 3%).

Classification and proposed labelling (Annex IIA, point 10)

With regard to toxicological data	Tolylfluanid (< 0.1 % of 0 to 50 µm particles): Xi; Irritant R36/37/38; Irritating to eyes, respiratory system and skin R43; May cause sensitisation by skin contact Tolylfluanid (≥ 0.1 % of 0 to 50 µm particles): T+; Very toxic R26; Very toxic by inhalation R48/23; Toxic: danger of serious damage to health by prolonged exposure through inhalation R36/37/38; Irritating to eyes, respiratory system and skin R43; May cause sensitisation by skin contact

‡ Endpoint identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Appendix 1.4: Residues

Metabolism in plants (Annex IIA, point 6.1 and 6.7, Annex IIIA, point 8.1 and 8.6)

Plant groups covered	Fruit crops (apple, grape, strawberry), leafy crops (lettuce)
Rotational crops	Not required
Plant residue definition for monitoring	Sum of tolylfluanid and DMST expressed as tolylfluanid
Plant residue definition for risk assessment	Sum of tolylfluanid and DMST for all supported crops, additionally 4-hydroxymethyl-DMST-glucoside and 2- hydroxyphenyl-DMST-glucoside for grapes, expressed as tolylfluanid.
Conversion factor (monitoring to risk assessment)	Only applicable for grapes; Conversion factor depending on progression in metabolism as with decreasing levels of tolylfluanid and DMST the level of the relevant glucosides is increasing to a certain degree until declining due to far advanced metabolism (conversion factors observed from supervised residue trials at PHI 35: Range 1.2-5.6; mean 2.3)

Metabolism in livestock (Annex IIA, point 6.2 and 6.7, Annex IIIA, point 8.1 and 8.6)

Animals covered	Goat and hen.
Animal residue definition for monitoring	DMST
Animal residue definition for risk assessment	DMST
Conversion factor (monitoring to risk assessment)	-
Metabolism in rat and ruminant similar (yes/no)	Yes
Fat soluble residue: (yes/no)	No, DMST (log Pow 1.99) considered more hydrophilic than untransformed tolylfluanid in line with metabolism studies in rats and goats.

Residues in succeeding crops (Annex IIA, point 6.6, Annex IIIA, point 8.5)

.....	Not required

‡ Endpoint identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Stability of residues (Annex IIA, point 6 introduction, Annex IIIA, point 8 introduction)

.....

Apple, fruit	1.5 years
Grape, fruit	2.2 years
Grape, juice	2.2 years
Grape, wine	2.2 years [1]
Tomato, fruit	1.5 years
Tomato, juice	4 months
Tomato, puree	4 months
Hops, green cones	1 year
Hops, dried cones	1 year

[1)] Applies to DMST; tolylfluanid is stable only for 29 days

Residues from livestock feeding studies (Annex IIA, point 6.4, Annex IIIA, point 8.3)

Intakes by livestock ≥ 0.1 mg/kg diet/day:	Ruminant: yes Beef Cattle 0.22 mg/kg/bw/d	Poultry: no	Pig: no
Muscle	<0.05 mg/kg [2]		
Liver	<0.05 mg/kg [2]		
Kidney	<0.05 mg/kg [2]		
Fat	<0.05 mg/kg [2]		
Milk	<0.05 mg/kg [2]		
Eggs			

[2)] Extrapolated from metabolism study, applies to DMST

‡ Endpoint identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Summary of critical residues data (Annex IIA, point 6.3, Annex IIIA, point 8.2)

Crop	Northern or Mediterranean Region	Trials results relevant to the critical GAP (a)	Recommendation/comments	MRL [3)]	STMR [4)] (b)
Pome fruit	N-EU S-EU	0.21, 0.22, 0.29, 0.41, 0.51, 0.74, 0.76, 1.86 0.33, 0.43, 0.47, 0.72, 0.86, 0.91, 1.0, 1.01, 2.45		3	0.46 0.86
Grapes	N-EU S-EU	0.14, 0.35, 0.46, 0.67, 0.83, 0.84, 1.19, 1.94 0.16, 0.41, 0.42, 0.61, 0.75, 1.51, 1.63, 2.38, 2.96, 3.82	MRL is based on S-EU data	5	
	S-EU	0.5, 1.24, 1.5, 2.12, 2.3, 2.42, 3.37, 3.41, 3.82, 4.61	Sum of tolylfluanid + relevant metabolites for risk assessment purposes		2.36
Strawberries	N-EU S-EU	0.15, 0.66, 0.99, 1.06, 1.1, 1.12, 1.2, 1.3, 1.81, 2.71 0.22, 0.35, 0.76, 0.77, 0.80, 0.87, 1.44, 2.31	MRL is based on both N-EU and S-EU data (Both data results in same MRL proposals)	3	1.1 0.79
Cane fruit	N-EU	0.48, 0.72, 1.55, 1.88, 2.04, 2.06, 2.19, 2.87		5	1.96
Other small fruit and berries	N-EU	0.37, 0.45, 0.63, 0.78, 0.80, 0.81, 1.37, 1.83		3	0.79

‡ Endpoint identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Crop	Northern or Mediterranean Region	Trials results relevant to the critical GAP (a)	Recommendation/comments	MRL [3)]	STMR [4)] (b)
Tomatoes and eggplants	N-EU S-EU Greenhouse Greenhouse[1)]	0.26, 0.30, 0.34, 0.35, 0.40, 0.49, 0.55, 1.27 0.07, 0.10, 0.24, 0.27, 0.29, 0.58, 0.60, 0.69 0.14, 0.22, 0.37, 0.40, 0.47, 0.67, 0.70, 0.77, 1.5, 1.56 0.47, 0.76, 0.98, 1.02, 1.06, 3 x 1.07, 1.96	MRL is based on greenhouse data	2	0.38 0.28 0.57 1.06
Peppers	Greenhouse	0.13, 0.34, 2 x 0.44, 0.62, 0.72, 0.85, 0.95, 1.41, 1.64		2	0.67
Cucumbers and Courgettes	N-EU Greenhouse	4 x 0.05 0.08, 0.16, 0.31, 0.34, 0.4, 0.67, 0.68, 0.96	MRL is based on greenhouse data	1	0.37
Melons (whole fruit)	N-EU S-EU	2 x 0.08, 0.17, 0.25 5 x 0.05, 0.07, 0.08, 0.16	MRL is based on N-EU and S-EU data as same GAP is intended for both region	0.3	0.08
Melons (pulp)	N-EU S-EU	3 x 0.05, 0.08 7 x 0.05, 0.08			0.05
Lettuce	N-EU N-EU[1)] S-EU S-EU[2)]	3 x 0.05, 4 x 0.13, 0.17 0.29, 0.54, 1.39, 1.71, 2.34, 2.36, 3.03, 4.53, 13.68 0.89, 1.19, 2.94, 3.05, 3.57, 3.91, 4.49, 7.12 0.21, 0.42, 1.49, 2.21, 2.71, 3.52, 10.44, 11.64	MRL is based on S-EU data and for use of tolylfluanid in mixture with tebuconazole	20	0.13 2.34 3.31 2.46

‡ Endpoint identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Crop	Northern or Mediterranean Region	Trials results relevant to the critical GAP (a)	Recommendation/comments	MRL [3)]	STMR [4)] (b)
Leeks	N-EU	0.25, 0.41, 0.45, 0.97, 1.07, 1.16, 1.52, 1.8		3	1.02
Hops	N-EU	8.79, 13.47, 17.78, 19.33, 29.96, 31.78, 32.06, 70.74		50	24.65

[1)] Tolylfluanid in mixture with iprovalicarb
[2)] Tolylfluanid in mixture with tebuconazole
[3)] MRL proposals refer to the sum of tolylfluanid and DMST expressed as tolylfluanid
[4)] STMR-values refer the sum of tolylfluanid and relevant metabolites for grapes and the sum of tolylfluanid and DMST for all other crops. The STMR value was calculated for each data set. The highest one was selected for dietary risk assessment.

(a) Numbers of trials in which particular residue levels were reported *e.g.* 3 x <0.01, 1 x 0.01, 6 x 0.02, 1 x 0.04, 1 x 0.08, 2 x 0.1, 2 x 0.15, 1 x 0.17
(b) Supervised Trials Median Residue *i.e.* the median residue level estimated on the basis of supervised trials relating to the critical GAP

‡ Endpoint identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Consumer risk assessment (Annex IIA, point 6.9, Annex IIIA, point 8.8)

ADI	0.1 mg/kg
TMDI (European Diet) (% ADI)	28 % (WHO European diet, adult – 60 kg) 29 % (German diet, female child –13.5 kg) 12 % (German diet, woman – 60 kg) 25 % (UK diet, adult – 70.1 kg) 15 % (UK diet, school child – 43.6 kg) 69 % (UK diet, toddler – 14.5 kg) 36 % (UK diet, infant – 8.7 kg)
NEDI (% ADI)	12 % (WHO European diet, adult – 60 kg) 9 % (German diet, female child –13.5 kg) 5 % (German diet, woman – 60 kg) 9 % (UK diet, adult – 70.1 kg) 4 % (UK diet, school child – 43.6 kg) 24 % (UK diet, toddler – 14.5 kg) 11 % (UK diet, infant – 8.7 kg)
Factors included in NEDI	Supervised Trials Median Residue values with processing factors Processing factors used depended on the consumption data: tomato juice, paste and raisins (WHO diet) wine, beer (UK diet, adults) apple juice, strawberry sauce/preserve, tomato paste, wine, beer (German diet, woman)
ARfD	0.25 mg/kg bw
Acute exposure (% ARfD)	NESTI for adults (UK consumption data) Apple (fruit) 14 % Black currant (fruit) 1 % Courgette 5 % Cucumber 2 % Grapes 25 % Leek 11 % Lettuce 19 % Melon 1 % Pear 16 % Pepper 6 % Strawberry 3 % Tomato 7 %

‡ Endpoint identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Acute exposure (% ARfD)	NESTI for children (UK consumption data) Apple (fruit) 60 % Black currant (fruit) 3 % Courgette 11 % Cucumber 11 % Grapes 100 % Leek 9 % Lettuce 24 % Melon 3 % Pear 80 % Pepper 16 % Strawberry 8 % Tomato 33 %

Processing factors (Annex IIA, point 6.5, Annex IIIA, point 8.4)

Crop/processed crop		Number of studies	Transfer factor Tolylfluanid + metabolite(s)	% Transference *
Pome fruit	sauce juice preserve pomace, wet pomace, dry	7 4 4 3 2	0.4 0.1 0.0 2.7 10.1	-
Grape	must wine juice raisin raisin waste pomace, wet pomace, dry	14/6[1] 14/6[1] 3 3 3 3 3	0.9 1.3 0.9 3.3 5.9 2 3.7	-
Strawberry	fruit, washed jam preserve	2 2 2	0.6 0.2 0.2	-
Currant	washed fruit juice jelly	1 1 1	0.8 0.6 0.3	-
Tomato	juice puree paste pomace, wet pomace, dry	5 5 5 3 3	0.4 1.1 2.2 3.4 28.3	-

‡ Endpoint identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Crop/processed crop		Number of studies	Transfer factor Tolylfluanid + metabolite(s)	% Transference *
Hops	spent hops hops draff beer brewers yeast	2 2 2 2	0.3 0.2 0.0 0.0	-

* Calculated on the basis of distribution in the different portions, parts or products as determined through balance studies
[1)] Transfer factors for tolylfluanid are based on the results of 14 studies, transfer factors for the sum of tolylfluanid and metabolites are based on the results of 6 studies

Proposed MRLs (Annex IIA, point 6.7, Annex IIIA, point 8.6)

Proposed MRLs	Pome fruit	3 mg/kg
	Grapes	5 mg/kg
	Strawberries	3 mg/kg
	Cane fruit	5 mg/kg
	Other small fruit and berries	3 mg/kg
	Tomatoes and eggplants	2 mg/kg
	Peppers	2 mg/kg
	Cucumbers and courgettes	2 mg/kg
	Melons	0.3 mg/kg
	Lettuce	20 mg/kg
	Leeks	3 mg/kg
	Hops	50 mg/kg

‡ Endpoint identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Appendix 1.5: Fate and Behaviour in the Environment

Route of degradation (aerobic) in soil (Annex IIA, point 7.1.1.1.1)

Mineralisation after 100 days ‡ at 22 °C	24.7-40.0 % after 99 d, [phenyl-UL-^{14}C]-label (n = 4); 64.8-76.7 % after 65 d, [dichlorofluoromethyl-^{13,14}C]-label (n = 2) Sterile conditions: no studies provided nor required
Non-extractable residues after 100 days ‡ at 22 °C	56.0-72.3 % after 99 d, [phenyl-UL-^{14}C]-label (n = 4); ~7- ~23 % after 65 d, [dichlorofluoromethyl-^{13,14}C]-label (n = 2) Sterile conditions: no studies provided nor required
Relevant metabolites ‡ - name and/or code, % of applied (range and maximum) at 22 °C	DMST (metabolite II): 0.6-2.8 % at 99 d, max. 73.7 % at 1 d, [phenyl-UL-^{14}C]-label (n = 4)

Route of degradation in soil - Supplemental studies (Annex IIA, point 7.1.1.1.2)

Anaerobic degradation ‡	No studies available.
Soil photolysis ‡	Mineralisation 2.8 % after 18 d [phenyl-UL-^{14}C]-label Non-extractable residues 39.3 % after 18 d [phenyl-UL-^{14}C]-label Metabolites: DMST (metabolite II): 20.2 % at 18 d, max. 50.8 % at 3 day [phenyl-UL-^{14}C]-label 4-(dimethylaminosulfonylamino) benzoic acid (metabolite XI) 10.6 % at 18 day, max. 10.6 % at 18 day [phenyl-UL-^{14}C]-label

Rate of degradation in soil (Annex IIA, point 7.1.1.2, Annex IIIA, point 9.1.1)

Method of calculation	Laboratory: first order kinetics (calculation by using SIMOSOLV V3.0 Software package) Field studies were not performed nor required.

‡ Endpoint identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Laboratory studies ‡ (range or median, with n value, with r^2 value)	DT_{50lab} (20°C, aerobic): **Tolylfluanid**: 0.5-2.6 d, mean 1.8 d (n=4, r^2=0.27-0.96) **DMST**: 1.3-6.7 d, mean 3.5 d (n=4, r^2=0.86-1.00) (Values were transformed by the notifier using the results obtained at 22 °C.) For FOCUS gw modelling – **Tolylfluanid** DT_{50lab} (aerobic, 1st order kinetics): mean DT_{50lab} 1.5 d (normalisation to 10kPa or pF2, 20°C with Q10 of 2.2) **DMST** DT_{50lab} (aerobic, 1st order kinetics): mean DT_{50lab} 2.8 d (normalisation to 10kPa or pF2, 20°C with Q10 of 2.2) DT_{90lab} (20°C, aerobic): **Tolylfluanid**: 1.7-8.6 d, mean 5.9 d (n=4, r^2=0.27-0.96) (Values were transformed by the notifier using the results obtained at 22 °C.) DT_{50lab} (10°C, aerobic): **Tolylfluanid**: 1.0-5.7 d, mean 3.8 d (n=4, r^2=0.26-0.96) **DMST**: 2.8-14.7 d, mean 7.7 d (n=4, r^2=0.86-1.00) (Values were transformed by the rapporteur using the results obtained at 22 °C.) DT_{50lab} (20°C, anaerobic): not applicable. The notifiers's justification: due to the proposed use pattern and rapid degradation no exposure to anaerobic conditions is to be expected.
	Degradation in the saturated zone: no data submitted nor required.
Field studies ‡ (state location, range or median with n value)	According to the notifier valid field studies were not performed, no data required.
Soil accumulation and plateau concentration ‡	No studies provided nor required

Soil adsorption/desorption (Annex IIA, point 7.1.2)

K_f /K_{oc} ‡ K_d ‡ pH dependence ‡ (yes / no) (if yes type of dependence)	K_{oc}: Tolylfluanid: 2200 (Value estimated by using HPLC-method) DMST: 56-118 (mean 76.4, 1/n=0.889-0.931, n=4) K_d 0.41-1.73 (mean 0.98, n=4) desorption: K_{oc} 110-311 (mean 176, 1/n=0.911-0.933, n=4) K_d 1.11-2.63 (mean 2.0, n=4) No pH dependence observed

‡ Endpoint identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

	For FOCUS gw modelling – Tolylfluanid: K_{oc}: 2200 DMST: K_{oc} : 76.4 (mean, 1/n=0.909)

Mobility in soil (Annex IIA, point 7.1.3, Annex IIIA, point 9.1.2)

Column leaching ‡	No studies provided nor required
Aged residues leaching ‡	Guideline: BBA IV, 4-2 (1986) Aged for: 12 and 40 days Time period: 2 d Precipitation: 200 mm Leachate: 4.9 % (aged 12 d) and 6.6 % (aged 40 d) of applied radioactivity in leachate <0.1 % active substance, 0.2-1.1 % DMST, <0.4 % Met IX, 0.9 % Met XI 61.4 % (aged 12 d) and 75.1 % (aged 40 d) of applied radioactivity retained in top 9 cm. (The half-life value of tolylfluanid is 1.8 d (mean 20 °C) thus the study gives information on the leaching properties of degradation products.)
Lysimeter/ field leaching studies ‡	No studies provided nor required

PEC (soil) (Annex IIIA, point 9.1.3)

Parent

Method of calculation	DT_{50} (d): 2.6 days Kinetics: 1st order (lab. studies) MICROSOFT EXCEL 2000
Application rate	The used application pattern for tolylfluanid taking into account minimum application intervals and maximum number of applications, and the corresponding amount of parent compound reaching the soil surface (based on interception data from FOCUS groundwater report, 2000) are given in table below.

‡ Endpoint identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Crop	Region	Assumed application period	Intended application rate (kg as/ha)	Shortest application interval (days)	Crop interception (%)	Amount of as reaching the soil (kg as/ha)
Apples	Northern Europe	April-June	7 x 1.125	7	50, 50, 70, 80, 80, 80, 80	2 x 0.563, 1 x 0.338, 4 x 0.225
	Southern Europe	June-July	3 x 1.5	7	80, 80, 80	3 x 0.300
Grapes	Northern Europe	April-July	0.6, 0.8, 1.2, 1.4, 1.6, 3 x 1.8	10	50, 50, 70, 85, 85, 85, 85, 85	0.3, 0.4, 0.36, 0.24, 0.21, 3 x 0.27
	Southern Europe	June-July	3 x 2.0	8	85, 85, 85	3 x 0.3
Strawberries	Northern Europe	May	3 x 2.5	8	60, 60, 60	3 x 1.0
	Southern Europe	April-May	3 x 1.25	7	60, 60, 60	3 x 0.5

Actual PEC_s values of tolylfluanid (upper 5 cm soil layer)

(The maximum actual PEC_s value occurring at any time during or after the application period is reported as value of day 0. Other PEC_s values refer to time after the maximum PEC_s. Due to fast degradation and increasing foliage the maximum PEC_s was not necessarily reached after the last application.)

Crop	Region	Actual concentration in soil on certain days after the maximum concentration (µg/kg)								
		0 d	1 d	2 d	4 d	7 d	21 d	28 d	50 d	100 d
Apples	NE	**866.8**	664.0	508.6	298.4	584.8	360.4	355.8	6.5	<0.05
	SE	**471.5**	361.1	276.6	162.3	72.9	1.7	0.3	<0.05	<0.05
Grapes	NE	**561.1**	429.8	329.2	277.2	86.8	242.1	37.5	386.7	<0.05
	SE	**453.0**	347.0	265.8	156.0	70.1	1.7	0.3	<0.05	<0.05
Strawberries	NE	**1510.1**	1156.7	886.0	519.8	233.6	5.6	0.9	<0.05	<0.05
	SE	**785.8**	601.9	461.0	270.5	121.6	2.9	0.5	<0.05	<0.05

Bold = values used for the risk assessment
NE = Northern Europe, SE = Southern Europe

Time weighted average (TWA) PEC_s values for tolylfluanid (upper 5 cm soil layer).

(The highest average concentrations during or after the application. Term time refers to the width of time window used for averaging.)

Crop	Region	TWA concentration in soil /time period (µg/kg)							
		1 d	2 d	4 d	7 d	21 d	28 d	50 d	100 d
Apples	NE	765.4	679.8	545.5	464.5	379.3	335.4	261.4	133.4
	SE	416.3	369.7	296.7	267.5	222.2	175.5	100.5	50.8

‡ Endpoint identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Crop	Region	TWA concentration in soil /time period (µg/kg)							
		1 d	2 d	4 d	7 d	21 d	28 d	50 d	100 d
Grapes	NE	495.5	440.1	353.1	264.2	220.6	201.3	174.2	130.9
	SE	400.0	355.3	285.1	213.3	215.3	174.7	100.5	50.8
Strawberries	NE	1333.4	1184.3	950.3	711.0	717.7	582.5	335.1	169.2
	SE	693.8	616.2	494.5	445.8	370.4	292.6	167.6	84.6

NE = Northern Europe, SE = Southern Europe

Metabolite

DMST (Metabolite II)	DT_{50}: 6.7 days
Method of calculation	Kinetics: 1st order (lab. studies) MICROSOFT EXCEL 2000
Application rate	See the application pattern of the active substance (formation rate out of parent substance 100 %)

Actual PEC_s values of DMST (upper 5 cm soil layer).

(The maximum actual PEC_s value occurring at any time during or after the application period is reported as value of day 0. Other PEC_s values refer to time after the maximum PEC_s. Due to fast degradation and increasing foliage the maximum PEC_s was not necessarily reached after the last application.)

Crop	Region	Actual concentration in soil on certain days after the maximum concentration (µg/kg)								
		0 d	1 d	2 d	4 d	7 d	21 d	28 d	50 d	100 d
Apples	NE	**522.7**	515.9	493.2	428.1	509.3	352.2	321.7	78.9	0.4
	SE	**336.3**	327.0	309.8	266.4	202.0	48.3	23.4	2.4	<0.05
Grapes	NE	**341.6**	335.8	320.2	277.2	211.0	240.8	218.0	266.3	1.9
	SE	**315.0**	307.5	292.0	251.7	191.1	45.7	22.1	2.3	<0.05
Strawberries	NE	**1050.1**	1024.9	973.4	838.9	636.9	152.3	73.8	7.6	<0.05
	SE	**560.5**	545.0	516.4	444.0	336.6	80.4	39.0	4.0	<0.05

Bold = values used for the risk assessment
NE = Northern Europe, SE = Southern Europe

Time weighted average (TWA) PEC_s values for DMST (upper 5 cm soil layer).

(The highest average concentrations during or after the application. Term time refers to the width of time window used for averaging.)

Crop	Region	TWA concentration in soil/time period (µg/kg)							
		1 d	2 d	4 d	7 d	21 d	28 d	50 d	100 d
Apples	NE	519.3	513.3	499.1	493.0	438.1	410.3	352.3	195.8
	SE	333.7	331.5	321.0	300.5	247.5	221.7	145.5	74.6

‡ Endpoint identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Crop	Region	TWA concentration in soil/time period (µg/kg)							
		1 d	2 d	4 d	7 d	21 d	28 d	50 d	100 d
Grapes	NE	338.7	335.8	325.5	306.0	275.3	261.7	240.3	190.6
	SE	311.6	310.2	299.8	281.7	236.3	216.0	145.1	74.6
Strawberries	NE	1038.6	1034.1	999.3	939.1	787.7	720.0	483.6	248.6
	SE	556.2	552.4	535.0	500.9	412.5	369.5	242.4	124.3

NE = Northern Europe, SE = Southern Europe

Route and rate of degradation in water (Annex IIA, point 7.2.1)

Hydrolysis of active substance and relevant metabolites (DT_{50}) ‡ (state pH and temperature)	pH 4: - **tolylfluanid**: 11.7 days (22 °C, extrapolated), 5.6 days (30 °C) - **DMST**: >> 1 year (55 °C) pH 7: - **tolylfluanid**: 42.5 hours (20 °C), 29.1 hours (22 °C, extrapolated), 7.9 hours (30 °C) - **DMST**: >> 1 year (55 °C) pH 9: - **tolylfluanid**: << 10 minutes (20 °C) - **DMST**: >> 1 year (55 °C)
Photolytic degradation of active substance and relevant metabolites ‡	- **tolylfluanid**: direct photodegradation is not expected to contribute the elimination in the environment (did not absorb light at wavelengths above 290 nm) - **DMST**: minimum 56 days (at 30th degree latitude) or 69-82 days (at 50th degree latitude), maximum >1 year (The estimates based on simulation models GC-SOLAR and Frank & Klöpffer and on the results obtained in phototransformation study, pH 5-9)
Readily biodegradable (yes/no)	no (The suitability of the method (OECD 301C, Modified MITI Test) was questionable. The results can be regarded as supporting data.)

‡ Endpoint identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Degradation in water/sediment - DT_{50} water - DT_{90} water - DT_{50} whole system - DT_{90} whole system Mineralisation Non-extractable residues in sediment	- tolylfluanid (20 °C): DT_{50} water: 1.4-6.0 hours DT_{90} water: 4.7-13.2 hours DT_{50} sediment: 2.6-4.8 hours DT_{50} whole system: 1.5-5.0 hours DT_{90} whole system 5.1-16.8 hours (2 systems) - **DMST** (20 °C): - DT_{50} water: 20.6-88.7 days - DT_{50} sediment: 39.7 ->365 days - DT_{50} whole system: 51.0-89.6 days - DT_{90} values were not applicable (2 systems at 20 °C and 2 systems at 22 °C, values obtained at 22 °C were normalised to e reference temperature by the notifier/the RMS) Mineralisation (22 °C): 14.5-32.7 % after 120 days, [phenyl-UL-^{14}C]label (n=3) Non-extractable residues: 24.2-40.1 % after 120 days, [phenyl-UL-^{14}C]label (n=3)

Distribution in water/sediment systems (**active substance**, % of applied radioactivity):

	System 1 [%]		System 2 [%]	
	Water	Sediment	Water	Sediment
0 days	99.2	-	99.3	-
5 hours	39.5	8.4	28.6	2.2
12 hours	17.4	6.7	8.4	1.5
24 hours	1.1	0.4	n.d.	n.d.
7 hours	n.d.	n.d.	n.d.	n.d.

n.d. = not detected

Distribution in water / sediment systems (**DMST**) % of applied radioactivity, 5 systems;

	System 1 [%]		System 2 [%]	
	Water	Sediment	Water	Sediment
0 d	0.6	-	0.6	-
5 h	36.5	9.5	53.4	10.6
12 h	56.0	14.2	71.4	12.1
24 h	66.0	24.3	72.2	20.8
7 h	46.6	41.3	46.7	39.3

‡ Endpoint identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

	System 3 [%]		System 4, 5 [%]	
	Water	Sediment	Water	Sediment
14 d	67.5	28.3	72.7	19.8
30 d	58.9	28.5	64.0	12.3
75 d	42.1	19.6	32.7 32.2	5.6 15.0
90 d	40.1	13.5	20.9	4.2
120 d	23.5	10.4	13.4 19.1	2.9 10.2

PEC (surface water) (Annex IIIA, point 9.2.3)

Parent

Method of calculation	DT_{50}: 0.25 days MICROSOFT EXCEL 2000
Main routes of entry	Spray drift (tolylfluanid realistically degrades completely between applicatios and thus the maximum values were obtained by calculations for single application

Application pattern of tolylfluanid used for calculation of $PEC_{sw.}$

Crop	Region	Assumed application period	Intended application rate (kg as/ha)	Shortest application interval (days)	Max. spray drift for single applications (%)*	Max. spray drift for multiple applications (%)*
Apples	Northern Europe	April-June	7 x 1.125	7	29.20 (pre-blossom) 15.73 (post-blossom)	22.69 (pre-blossom) 9.01 (post-blossom)
	Southern Europe	June-July	3 x 1.5	7	15.73	11.01
Grapes	Northern Europe	April-July	0.6, 0.8, 1.2, 1.4, 1.6, 3 x 1.8	10	8.02	6.26
	Southern Europe	June-July	3 x 2.0	8	8.02	6.90
Strawberries	Northern Europe	May	3 x 2.5	8	2.77	2.01
	Southern Europe	April-May	3 x 1.25	7	2.77	2.01

* = no extra buffer

‡ Endpoint identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Initial or Maximum PEC_{sw}

In all cases where the maximum PEC values were reached already during the application period, so that the PECs at day 0 after last application were not equivalent with the maximum PEC, the maximum PEC values instead of the initial PECs are given in this table. **The risk assessment for the aquatic toxicity was performed based on these values.**

Crop	Width of buffer strip (m)	PEC_{sw} of tolylfluanid (µg/L)	
		Northern Europe	Southern Europe
Apples	0	109.55	78.65
	5	74.62	42.05
	10	44.31	18.00
	15	20.82	9.05
	20	10.39	5.45
Grapes	0	48.12	53.47
	5	21.72	24.13
	10	7.38	8.20
	15	3.90	4.33
	20	2.52	2.80
Strawberries	0	23.08	11.54
	5	4.75	2.38
	10	2.42	1.21
	15	1.67	0.83
	20	1.25	0.63

Short and long term actual and time-weighted average PEC (surface water) with respect to different application scenarios (values are given in µg/L):

Actual PEC_{sw} values of tolylfluanid, no extra buffer

Crop	Region	Actual concentration on certain days after the maximum concentration (µg/L)									
		0 d	1 d	2 d	4 d	7 d	14 d	21 d	28 d	42 d	100 d
Apples	NE	109.55	33.02	10.11	1.06	59.01*	58.99*	58.99*	58.99*	<0.01	<0.01
	SE	78.65	4.92	0.31	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01
Grapes	NE	48.12	3.01	0.19	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01
	SE	53.47	3.34	0.21	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01
Strawberries	NE	23.08	1.44	0.09	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01
	SE	11.54	0.72	0.05	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01

* = concentrations caused by applications at days 7, 14, 21 and 28 after the maximum peak
NE = Northern Europe, SE = Southern Europe

‡ Endpoint identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Time-weighted average PEC_{sw} values of tolylfluanid, no extra buffer

Crop	Region	TWA concentration in surface water/time period (µg/L)								
		1 d	2 d	4 d	7 d	14 d	21 d	28 d	42 d	100 d
Apples	NE	71.29	50.90	31.40	27.05	19.95	17.05	15.46	12.48	5.31
	SE	26.59	14.13	7.09	4.05	2.03	1.35	1.01	0.68	0.28
Grapes	NE	25.56	17.11	10.27	6.42	3.42	2.33	1.77	1.19	0.51
	SE	18.08	9.60	4.82	2.75	1.38	0.92	0.69	0.46	0.19
Strawberries	NE	7.81	4.15	2.08	1.19	0.59	0.40	0.30	0.20	0.08
	SE	3.90	2.07	1.04	0.59	0.30	0.20	0.15	0.10	0.04

NE = Northern Europe, SE = Southern Europe

Metabolite

DMST	DT_{50}: 88.7 days
Method of calculation	MICROSOFT EXCEL 2000
Application rate	See the application rate of the active substance (formation 75.7 % of applied radioactivity (maximum rate occurred in water/sediment studies))
Main routes of entry	Spray drift (maximum values were obtained by the calculations for multiple applications)

Relevant metabolites: PEC (surface water) of DMST

Initial or Maximum PEC_{sw}

In all cases where the maximum PEC values were reached already during the application period, so that the PECs at day 0 after last application were not equivalent with the maximum PEC, the maximum PEC values instead of the initial PECs are given in this table. The risk assessment for the aquatic toxicity was performed based on these values.

Crop	Width of buffer strip (m)	PEC_{sw} of DMST (µg/L)	
		Northern Europe	Southern Europe
Apples	0	130.39	73.11
	5	77.65	40.11
	10	38.62	17.73
	15	18.82	9.23
	20	9.70	5.31

‡ Endpoint identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Crop	Width of buffer strip (m)	PEC_{sw} of DMST (µg/L)	
		Northern Europe	Southern Europe
Grapes	0	87.27	60.63
	5	38.76	26.98
	10	12.97	8.96
	15	6.83	4.75
	20	4.32	2.99
Strawberries	0	22.08	11.12
	5	4.50	2.27
	10	2.20	1.11
	15	1.54	0.77
	20	1.10	0.55

Actual PECsw values of DMST, no extra buffer

Crop	Region	Actual concentration on certain days after the maximum concentration (µg/L)									
		0 d	1 d	2 d	4 d	7 d	14 d	21 d	28 d	42 d	100 d
Apples	NE	130.39	129.38	128.37	126.38	123.45	116.88	110.66	104.77	93.91	59.69
	SE	73.11	72.54	71.97	70.86	69.22	65.53	62.04	58.74	52.65	33.46
Grapes	NE	87.27	86.59	85.92	84.59	82.63	78.23	74.06	70.12	62.85	39.95
	SE	60.63	60.16	59.69	58.77	57.41	54.35	51.46	48.72	43.67	27.75
Strawberries	NE	22.08	21.91	21.74	21.40	20.90	19.79	18.74	17.74	15.90	10.11
	SE	11.12	11.04	10.95	10.78	10.53	9.97	9.44	8.94	8.01	5.09

Time-weighted average PEC_{sw} values of DMST, no extra buffer

Crop	Region	TWA concentration in surface water/time period (µg/L)								
		1 d	2 d	4 d	7 d	14 d	21 d	28 d	42 d	100 d
Apples	NE	129.88	129.38	128.38	126.89	123.52	120.27	117.13	111.18	90.53
	SE	72.82	72.54	71.98	71.14	69.25	67.42	65.66	62.32	50.73
Grapes	NE	86.93	86.59	85.92	84.93	82.67	80.50	78.39	74.41	60.59
	SE	60.40	60.16	59.69	59.00	57.43	55.92	54.46	51.69	42.07
Strawberries	NE	21.99	21.91	21.74	21.49	20.91	20.36	19.83	18.82	15.32
	SE	11.08	11.04	10.95	10.82	10.54	10.26	9.99	9.48	7.72

‡ Endpoint identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

PEC (sediment)

Parent

Method of calculation	The calculations on predicted environmental concentrations of tolylfluanid in sediment were not performed. The notifier's justification: the calculations were not considered necessary due to the fact that the residues of tolylfluanid in sediment (in water/sediment tests) did not reach 10 % of the applied radioactivity at any time and due to the fast degradation of the parent compound in sediment.

PEC (sediment)

Metabolite

Metabolite DMST	MICROSOFT EXCEL 97
Method of calculation	Partitioning: see distribution in water/sediment
Application rate	See PEC (surface water)

Maximum initial PEC (sediment) of DMST:

Crop	Region	Maximum single application rate[a] (kg as/ha)	Buffer zone (m)	Maximum PEC_{sed} (mg DMST/kg)
Apples	Northern Europe	1.125	-	0.518
Apples	Southern Europe	1.5	-	0.297
Grapes	Northern Europe	1.8	-	0.346
Grapes	Southern Europe	2.0	-	0.246
Strawberries	Northern Europe	2.5	-	0.089
Strawberries	Southern Europe	1.25	-	0.045
Apples	Northern Europe	1.125	5	0.308
Apples	Southern Europe	1.5	5	0.163
Grapes	Northern Europe	1.8	5	0.154
Grapes	Southern Europe	2.0	5	0.109
Strawberries	Northern Europe	2.5	5	0.018
Strawberries	Southern Europe	1.25	5	0.045
Apples	Northern Europe	1.125	10	0.153
Apples	Southern Europe	1.5	10	0.072
Grapes	Northern Europe	1.8	10	0.051
Grapes	Southern Europe	2.0	10	0.036

‡ Endpoint identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Crop	Region	Maximum single application rate[a] (kg as/ha)	Buffer zone (m)	Maximum PEC_{sed} (mg DMST/kg)
Strawberries	Northern Europe	2.5	10	0.009
Strawberries	Southern Europe	1.25	10	0.004

a = refers to the maximum intended single application rate within an application season, i.e. the value does not represent the rate of every individual application within season.

PEC (ground water) (Annex IIIA, point 9.2.1)

Method of calculation and type of study (*e.g.* modelling, monitoring, lysimeter)	Modelling: FOCUS-PELMO, Version 1.1.1, Fraunhofer-Institut für Umweltchemie und Ökotoxikologie, Schmallenberg FOCUS-Scenarios (Châteaudun, Hamburg, Jokioinen, Kremsmünster, Okehampton, Piacenza, Porto, Sevilla, Thiva) -DT_{50}: tolylfluanid: 1.5 d (mean,lab. study) DMST: 2.8 d (mean, lab. study) - K_{oc} tolyfluanid 2220 (HPLC) DMST 76.4 (mean, ads./des. study)

Application pattern of tolylfluanid used for calculation of PEC_{gw}

Application pattern	Crop Simulation ID	Intended appl. rate (kg as/ha)	Amount of as reaching the soil (kg as/ha)	Dates of application	FOCUS scenarios
I	Apple #1-5	7 x 1.125	2 x 0.563 / 0.338/ 4 x 0.225	18.4. / 30.4. / 12.5. / 24.5 / 5.6. / 17.6. / 29.6.	Hamburg, Jokioinen, Kremsmünster, Okehampton, Châteaudun
II	Apple #6, 8-11	3 x 1.5	3 x 0.3	10.6. / 22.6. / 4.7.	Châteaudun, Piacenza, Porto, Sevilla, Thiva
III	Apple #7, 12-15	3 x 1.5	3 x 0.3	31.8. / 12.9. / 24.9.	Châteaudun, Piacenza, Porto, Sevilla, Thiva
IV	Grape #1-3	0.6 / 0.8 / 1.2 / 1.4 / 1.6 / 3 x 1.8	0.3 / 0.4 / 0.36 / 0.21 / 0.24 / 0.21/ 3 x 0.27	13.4. / 25.4. / 7.5. / 19.5. / 31.5. / 12.6. / 24.6. / 6.7.	Hamburg, Kremsmünster, Châteaudun
V	Grape #4-8	3 x 2.0	3 x 0.3	20.6. / 2.7. / 14.7.	Châteaudun, Piacenza, Porto, Sevilla, Thiva

‡ Endpoint identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Application pattern	Crop Simulation ID	Intended appl. rate (kg as/ha)	Amount of as reaching the soil (kg as/ha)	Dates of application	FOCUS scenarios
VI	Strawberry #1, 3	3 x 2.5	3 x 1.0	10.5. / 20.5. / 30.5.	Hamburg, Kremsmünster
VII	Strawberry #2	3 x 2.5	3 x 1.0	1.6. / 11.6. / 21.6.	Jokioinen
VIII	Strawberry #4	3 x 1.25	3 x 0.5	20.4. / 30.4. / 10.5.	Sevilla

$PEC_{(gw)}$

Maximum concentration	<0.001 µg/L (all scenarios, tolylfluanid and DMST)

Fate and behaviour in air (Annex IIA, point 7.2.2, Annex III, point 9.3)

Direct photolysis in air ‡	Not studied - no data requested
Quantum yield of direct phototransformation	No data available
Photochemical oxidative degradation in air ‡	**Tolylfluanid**: 7.2 h (chemical lifetime 10.4 h) **DMST**: 2.3 h (chemical halftime 3.3 h) (These estimations were carried out with respect to the OH-radical reaction, only, and using a 12-hours-day with 1.5 x 10^6 OH radicals/cm^3.)
Volatilization ‡	Not available

PEC (air)

Method of calculation	Not available

$PEC_{(a)}$

Maximum concentration	Not available

Definition of the Residue (Annex IIA, point 7.3)	
Relevant to the environment	Soil: Definitions for risk assessment: Tolylfluanid and DMST Definitions for monitoring: Tolylfluanid Water: Ground water: Definitions for risk assessment: Tolylfluanid and DMST

‡ Endpoint identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

	Definitions for monitoring: Tolylfluanid Surface water Definitions for risk assessment: Tolylfluanid and DMST Definitions for monitoring: Tolylfluanid Sediment: Definition fort he risk assessment: DMST Air: Definition for risk assessment and monitoring: tolylfluanid

Monitoring data, if available (Annex IIA, point 7.4)

Soil (indicate location and type of study)	No data available
Surface water (indicate location and type of study)	No data available
Ground water (indicate location and type of study)	No data available
Air (indicate location and type of study)	No data available

Classification and proposed labelling (Annex IIA, point 10)

with regard to fate and behaviour data	R53 has been removed (WG on classification and labelling, June 2002)

‡ Endpoint identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Appendix 1.6: Effects on non-target Species

Effects on terrestrial vertebrates (Annex IIA, point 8.1, Annex IIIA, points 10.1 and 10.3)

Acute oral toxicity to mammals ‡	LD_{50}	> 5000	mg ai/kg bw (rat)
Dietary toxicity to mammals (28 d) ‡	NOEC	1500	mg ai/kg diet (rat)
Reproductive toxicity to mammals ‡	NOAEL	12	mg ai/kg/bw/day (rat)
Acute oral toxicity to birds ‡	LD_{50}	> 2000	mg ai/kg bw (quail)
Dietary toxicity to birds (5 d) ‡	LC_{50}	> 5000	mg ai/kg diet (quail)
Reproductive toxicity to birds (21 w) ‡	NOEC	791	mg ai/kg diet (quail)

Toxicity/exposure ratios for terrestrial vertebrates (Annex IIIA, points 10.1 and 10.3)

Appl. rate (kg ai/ha)	Crops	Category	Time-scale	TER (tier 1)	TER Annex VI trigger[1)]	TER (tier 2)
1.125 – 2.5	apples, grapes straw-berries	herbivorous birds	acute	> 7.1	10	not necessary (unrealistic scenario)*
		insectivorous birds	acute	> 14.8 – 32.9		not necessary
		herbivorous birds	short-term	4.8 – 9.6	10	fructivorous: 77.9 herbivorous: 13.7
		insectivorous birds	short-term	9.6 – 21.4		103.5
		herbivorous birds	long-term	1.0 – 1.9	5	herbivorous: 3.3 – 6.5 fructivorous: 19
		insectivorous birds	long-term	1.0 – 2.3		11.1 – 24.7
		earthworm eating birds secondary poisoning	long-term	25.6 – 85.3	5	not necessary
		fish eating birds secondary poisoning	long-term	67 - 2112	5	not necessary
		herbivorous mammals	acute	12 - 97	10	not necessary
		herbivorous mammals	long-term	0.09 – 0.81	5	herbivorous: 0.84-2.78 fructivorous: 12.4
		earthworm eating mammals secondary poisoning	long-term	6.6 – 21.9	5	not necessary
		fish eating mammals secondary poisoning	long-term	16.7 - 522	5	not necessary

‡ Endpoint identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Toxicity data for aquatic species (most sensitive species of each group) (Annex IIA, point 8.2, Annex IIIA, point 10.2)

Group	Test substance	Time-scale	Endpoint	Toxicity (mg/l)
Laboratory tests ‡				
Oncorhynchus mykiss	active substance	96 h	LC50 static	45 µg ai/L
Oncorhynchus mykiss	WG 50	96 h	LC_{50} flow-through	16.0 µg ai/L
Pimephales promelas	WG 50	96 h	LC_{50} static	43.2 µg ai/L
Oncorhynchus mykiss	DMST	96 h	LC50 static	35000 µg/L
Fish	active substance, WG 50	21 d	Chronic NOEC	9.8 µg ai/L 9.3 µg ai/L
Oncorhynchus mykiss	DMST	32 d	ELS-NOEC	≥ 10000 µg/L
Daphnia magna	active substance	48 h	EC_{50} flow-through	190 µg ai/L
Daphnia magna	active substance	48 h	EC_{50} static	690 µg ai/L
Daphnia magna	DMST	48 h	EC_{50} static	31000 µg/L
Daphnia magna	active substance, WG 50	21 d	Chronic NOEC	100 µg ai/L 61 µg ai/L
Daphnia magna	DMST	21 d	Chronic NOEC	5600 µg/L
Chironomus riparius	DMST	28 d	Chronic EC_{15}	5750 µg/L
Scenedesmus subspicatus	active substance	72 h	E_rC_{50}	> 1000 µg ai/L
Pseudokirchneriella subcapitata	WG 50	72 h	E_rC_{50}	5010 µg ai/L
Pseudokirchneriella subcapitata	DMST	72 h	E_rC_{50}	71200 µg/L
Microcosm or mesocosm tests				
Oncorhynchus mykiss	WG 50	28 d	Laboratory microcosm NOEC	44.0 µg ai/L
Oncorhynchus mykiss	WG 50	35 d	Outdoor microcosm NOEC	60.0 µg ai/L
Daphnia magna	WG 50	40 d	Laboratory microcosm NOEAEC	180 µg ai/L

‡ Endpoint identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Group	Test substance	Time-scale	Endpoint	Toxicity (mg/l)
Daphnia magna	WG 50	51 d	Aquatic community –outdoor microcosm NOEAEC	99 µg ai/L

Toxicity/exposure ratios for the most sensitive aquatic organisms (Annex IIIA, point 10.2)

Appl. rate (kg ai/ha)	Crops	Organism	Time-scale	TER	TER Annex VI trigger[1)]	refined risk assessment
1.125 – 2.5	apples, grapes, straw-berries	fish	acute–flow-through	0.21 - 64	100	refined risk assessment necessary
			acute–static	0.58 - 173		
			laboratory microcosm	0.59 - 176	5[2)]	
			outdoor microcosm	5.2 - 143	5[2)]	final risk assessment all TER´s above trigger for buffer zones of 1 to 20 m (crop dependent)
		daphnia	acute–flow-through	2.5 – 760	100	refined risk assessment necessary
			acute–static	4.8 - 1440		
			laboratory microcosm	7.5 - 720	5[2)]	final risk assessment all TER´s above trigger for buffer zones of 5 to 15 m (crop dependent)
			aquatic community – outdoor microcosm	4.1 - 236	3-5[2)]	final risk assessment all TER´s above trigger for buffer zones of 5 to 15 m (crop dependent)
		algae	chronic, static	67 –20040	10	not necessary

[1)] a refined risk assessment is performed in case the TER-tier 1 is lower than the Annex VI-trigger.
[2)] refined TER trigger according EPCO 8 and HARAP for higher tier risk assessment.

‡ Endpoint identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Toxicity/exposure ratios for the most sensitive aquatic organisms - metabolites (Annex IIIA, point 10.2)

Name	Major metabolite in	Time-scale	Distance (m)	TER (tier 1)	TER Annex VI trigger[1)]	refined risk assessment
Fish						
DMST	water / water-sediment	acute	5	450 – 15217	100	not necessary
DMST	water / water-sediment	chronic	5	≥ 129 - ≥ 4348	10	not necessary
Aquatic invertebrates						
DMST	water / water-sediment	acute	5	399 – 13478	100	not necessary
DMST	water / water-sediment	chronic	5	72 – 2435	10	not necessary
Sediment dwelling organisms						
DMST	water / water-sediment	chronic	5	89 – 2396	10	not necessary
Green algae						
DMST	water / water-sediment	chronic	5	916 – 30967	10	not necessary

Bioconcentration

Bioconcentration factor (BCF) ‡	74 (whole fish)
Annex VI Trigger:for the bioconcentration factor	1000 for readily, 100 for not readily biodegradable
Clearance time (CT_{50})	0.38 days (whole fish)
Level of residues (%) in organisms after the 14 day depuration phase	< 10 %

Effects on honeybees (Annex IIA, point 8.3.1, Annex IIIA, point 10.4)

Acute oral toxicity ‡	LD_{50} oral > 197 µg ai/bee (active ingredient) LD_{50} oral > 222 µg ai/bee (WG 50)
Acute contact toxicity ‡	LD_{50} contact > 196 µg ai/bee (active ingredient) LD_{50} contact > 200 µg ai/bee (WG 50)

Hazard quotients for honey bees (Annex IIIA, point 10.4)

Application rate (kg ai/ha)	Crop	Route	Hazard quotient	Annex VI Trigger	refined risk assessment
Laboratory tests					
1.125	Apples / Pears North-Europe	oral contact	< 5.7 < 5.7	50 50	

‡ Endpoint identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Application rate (kg ai/ha)	Crop	Route	Hazard quotient	Annex VI Trigger	refined risk assessment
1.500	Apples / Pears South-Europe	oral contact	< 7.6 < 7.7	50 50	not necessary
1.800	Grapes North-Europe	oral contact	< 9.1 < 9.2	50 50	
2.000	Grapes South-Europe	oral contact	< 10.2 < 10.2	50 50	
2.500	Strawberries North-Europe	oral contact	< 12.7 < 12.8	50 50	
1.250	Strawberries South-Europe	oral contact	< 6.3 < 6.4	50 50	

Q_{HO} and Q_{HC} are calculated with the lower results of the studies with active ingredient.

Field or semi-field tests
not required

Effects on other arthropod species (Annex IIA, point 8.3.2, Annex IIIA, point 10.5)

Species	Stage	Test Substance	Dose (kg ai/ha)	Endpoint	Effect	Annex VI Trigger*	refined risk assessment
Laboratory tests ‡							
Parasitoids							
Aphidius rhopalosiphi	adults	WG 50	2.5 kg ai/ha	mortality	100 %	50 %	higher tier study required
Aphidius rhopalosiphi	adults	WG 50	40 – 2500 g ai/ha	ER50 (glass plates) effect on reproduction	303 g ai/ha 3 – 74 %	50 %	higher tier study required
Aphidius rhopalosiphi	pupae within host	WG 50	0.125 % ai spray solution	mortality effect on reproduction	11 % 26 %	50 %	not necessary
Aphidius rhopalosiphi	adults	WG 50	25 – 1000 g ai/ha	LR50 (apple leaves) at 0.1-0.5 kg ai/ha	0.912 kg ai/ha no adverse effect on reproduction	50 %	higher tier study required

‡ Endpoint identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Species	Stage	Test Substance	Dose (kg ai/ha)	Endpoint	Effect	Annex VI Trigger*	refined risk assessment
Aphidius rhopalosiphi	adults	WG 50	aged residues 3 x 2.545 kg ai/ha	21 DAT 31 mortality effect on parasitization	5 % 60 %	50 %	refined risk assessment required
Trichogramma cacoeciae	adults	WG 50	1.5 – 4.5 kg ai/ha	effect on parasitization	56 - 85 %	50 %	higher tier study required
Trichogramma cacoeciae	adults	WG 50	7 × 1.125 kg ai/ha	effect on mortality effect on reproduction	-17- 84 %1 4 - 64 %	50 %	higher tier study required
Predatory Mites							
Typhlodromus pyri	adults	WG 50	2.5 kg ai/ha	mortality effect on reproduction	85 % 100 %	50 %	higher tier study required
Typhlodromus pyri	adults	WG 50	4 – 600 g ai/ha	LR50 effect on reproduction	247 g ai/ha -15 - 59 %1	50 %	higher tier study required
Typhlodromus pyri	adults	WG 50	25 – 2545 g ai/ha	LR50 effect on reproduction	>2.545 g ai/ha 8 - 53 %	50 %	refined risk assessment required
Typhlodromus pyri	adults	WG 50	aged residues 3 x 2.545 kg ai/ha	mortality effect on reproduction	8 - 77 % 13 - 70 %	50 %	refined risk assessment required

*) 50 % effect threshold level according to ESCORT II (Candolfi et al. (2001): Guidance document on regulatory testing and risk assessment procedures for plant protection products with non-target arthropods). ESCORT I: 30 % Barrett et al. (1994): SETAC guidance document on regulatory testing procedures for pesticides with non-target arthropods.
[1] negative values indicate an effect below that of the control

Effects on other arthropod species (Annex IIA, point 8.3.2, Annex IIIA, point 10.5) continued

Species	Stage	Test Substance	Dose (kg ai/ha)	Endpoint	Effect	Annex VI Trigger*	refined risk assessment
Laboratory tests ‡							
Ground Dwelling Predators							
Poecillus cupreus	adults	WG 50	1.25 kg ai/ha	mortality effect on feeding rate	0 % -9 %[1]	50 %	not necessary

‡ Endpoint identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Species	Stage	Test Substance	Dose (kg ai/ha)	Endpoint	Effect	Annex VI Trigger*	refined risk assessment
Poecillus cupreus	adults	WG 50	2.5 kg ai/ha	mortality effect on feeding rate	0 % 25.9 %	50 %	not necessary
Poecillus cupreus	adults	WG 50	3 × 3.1 kg ai/ha	mortality effect on feeding rate	0 % 0 %	50 %	not necessary
Aleochara bilineata	adults	WG 50	2.5 kg ai/ha	mortality effect on reproduction	1.7 % 6.7 %	50 %	not necessary
Foliage Dwelling Predators							
Coccinella septempunctata	adults	WG 50	2.5 kg ai/ha	mortality effect on reproduction:	20 % no adverse effects	50 %	not necessary
Orius insidiosus	adults	WG 50	1.05 kg ai/ha	mortality effect on reproduction	15-24 % 30-50 %	50 %	see semi-field
Orius insidiosus	adults	WG 50	1.16 kg ai/ha	mortality effect on reproduction	19 % 46 %	50 %	see semi-field
Orius insidiosus	adults	WG 50	2.42 kg ai/ha	mortality effect on reproduction	4 % 46 %	50 %	see semi-field
Orius laevigatus	adults	WP 50	7 × 1.125 kg ai/ha	mortality effect on fecundity	-17 - 13 %[1] 4 - 32 %[1]	50 %	not necessary
Chrysoperla carnea	adults	WG 50	0.3 – 4.5 kg ai/ha	LR_{50} effect on reproduction:	>4.5 kg ai/ha no adverse effects	50 %	not necessary

*) 50 % effect threshold level according to ESCORT II (Candolfi et al. (2001): Guidance document on regulatory testing and risk assessment procedures for plant protection products with non-target arthropods). ESCORT I: 30 % Barrett et al. (1994): SETAC guidance document on regulatory testing procedures for pesticides with non-target arthropods.

[1] negative values indicate an effect below that of the control

‡ Endpoint identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Field or semi-field tests

Species	Stage	Test Substance	Dose (kg ai/ha)	Endpoint	Effect	Annex VI Trigger*)	refined risk assessment
Semi-field tests							
Parasitoids							
Trichogramma dendrolimi	adults	WP 50	1.123 kg ai/ha	no adverse effects	no adverse effects	50 %	not necessary
Trichogramma cacoeciae	within host egg and imagines	WP 50	up to 3 × 1.5 kg ai/ha	emergence (within host egg) parasitization (imagines)	no adverse effects no adverse effects	50 %	not necessary
Foliage Dwelling Predators							
Orius laevigatus	adults	WP 50	3 × 1.5 kg ai/ha	mortality effect on reproduction	no effect > 30 % no effect > 30 %	50 %	not necessary

Species	Stage	Test Substance	Dose (kg ai/ha)	Endpoint	Effect	Annex VI Trigger*)	refined risk assessment
Field tests							
Predatory Mites							
Typhlodromus pyri	adults	WP 50, apple orchard	7 × 1.125 kg ai/ha	Abundance	effects[1] not significant up to 54 %	50 %	not necessary
Typhlodromus pyri	adults	WG 50, vineyard	0.6 – 1.6 kg ai/ha, 4 applic.	Abundance	effects[1] -7.7[2] – 35.9 %	50 %	Find the refined risk assessment for predatory mites in detail under 10.5.d: only moderate risk, potential for with-in season effects, population recovery was demonstrated before
Typhlodromus pyri	adults	WG 50, vineyard	0.8 – 1.6 kg ai/ha, 4 applic.	Abundance	effects[1] 46.3 – 47.6 %	50 %	
Typhlodromus pyri	adults	WG 50, vineyard	0.4 – 1.8 kg ai/ha, 6 applic.	Abundance	effects[1] 71.2 – 75.9 %	50 %	
Typhlodromus pyri	adults	WG 50, vineyard	1.5 – 1.8 kg ai/ha, 6 applic.	Abundance	effects[1] 55.8 – 63.8 %	50 %	

‡ Endpoint identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Species	Stage	Test Substance	Dose (kg ai/ha)	Endpoint	Effect	Annex VI Trigger*)	refined risk assessment
Typhlodromus pyri	adults	WG 50, vineyard	0.6 – 1.68 kg ai/ha, 6 applic.	Abundance	effects[1] -8.5[2] – 42.5 %	50 %	beginning of the next season, thus effects are considered acceptable
Typhlodromus pyri	adults	WG 50, vineyard	1.19–1.53 kg ai/ha, 6 applic.	Abundance	effects[1] 4.9 – 11.7 %	50 %	
Typhlodromus pyri	adults	WG 50, vineyard	0.4 – 1.8 kg ai/ha, 6 applic.	Abundance	effects[1] 74.7 – 81.8 %	50 %	
Typhlodromus pyri	adults	WG 50, vineyard	1.2 – 2.0 kg ai/ha, 6 applic.	Abundance	effects[1] 42.3 – 52.8 %	50 %	
Typhlodromus pyri	adults	WG 50, vineyard	0.6 – 1.8 kg ai/ha, 6 applic.	Abundance	effects[1] 22.3 – 62.3 %	50 %	
Typhlodromus pyri	adults	WG 50, vineyard	1.04–1.46 kg ai/ha, 6 applic.	Abundance	effects[1] 58.8 – 63.8 %	50 %	

*) 50 % effect threshold level according to ESCORT II (Candolfi et al. (2001): Guidance document on regulatory testing and risk assessment procedures for plant protection products with non-target arthropods). ESCORT I: 30 % Barrett et al. (1994):
SETAC guidance document on regulatory testing procedures for pesticides with non-target arthropods.
[1]effects according to Henderson-Tilton

Effects on earthworms (Annex IIA, point 8.4, Annex IIIA, point 10.6)

Acute toxicity ‡	LC_{50}	> 1000 mg ai/kg d. wt. soil	(techn. ai)
Acute toxicity ‡	LC_{50}	> 961 mg ai/kg d. wt. soil	(WG 50)
	$LC_{50,corr.}$	> 480.5 mg ai/kg d. wt. soil	(WG 50)
Reproduction ‡	NOEC	24 kg ai/ha	(WG 50)
	$NOEC_{corr}$	12 kg ai/ha	(WG 50)

Appl. rate (kg ai/ha)	Crops	Time-scale	TER (tier 1)	TER Annex VI trigger[1)]	refined risk assessment
1.125 – 2.5	apples, grapes, strawberries	acute	> 318– > 1061	10	not necessary
		chronic	11 - 35	5	

1) a refined risk assessment is performed in case the TER-tier 1 is lower than the Annex VI-trigger.
The risk assessment for the acute toxicity is performed with the lower result of the study with the WG 50 formulation.

‡ Endpoint identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Effects of metabolites on earthworms (Annex II 8.4 and Annex III 10.6)

Acute toxicity to earthworms ‡	DMST	LC50	> 100	mg/kg dry weight soil
Chronic toxicity to earthworms ‡	DMST	NOEC	100	mg/kg dry weight soil

Name	Major metabolite in	Time-scale	TER (tier 1)	TER Annex VI trigger1)	refined risk assessment
DMST	soil	acute	> 95 - > 317	10	not necessary
DMST	soil	chronic	95 - 317	5	not necessary

1) a refined risk assessment is performed in case the TER-tier 1 is lower than the Annex VI-trigger.

Effects of metabolites on other soil non-target macro-organisms (Annex III 10.6.2)

Chronic toxicity to Folsomia candida	DMST	NOEC	250	mg/kg dry weight soil

Name	Major metabolite in	Time-scale	TER (tier 1)	TER Annex VI trigger[1)]	refined risk assessment
DMST	soil	chronic	238 – 794	5	not necessary

1) a refined risk assessment is performed in case the TER-tier 1 is lower than the Annex VI-trigger.

Effects on soil micro-organisms (Annex IIA, point 8.5, Annex IIIA, point 10.7)

Nitrogen mineralization ‡	DMST	no influence up to 8.9 kg/ha

For all intended application rates, no unacceptable influence of DMST on the microbial biomass under practical field conditions is to be expected.

Effects on non target terrestrial plants (Annex II 8.6 and Annex III 10.8)

biological screening	lowest EC_{50} lowest EC_{50}	~ 6 kg ai/ha (pre-emergence) ~ 10 kg ai/ha (foliar applied)
seedling emergence and vegetative vigor	EC_{50}	> 15.6 kg ai/ha

For all intended application rates, no unacceptable influence of tolylfluanid on non-target terrestrial plants under practical field conditions is to be expected.

Classification and proposed labelling (Annex IIA, point 10)

with regard to ecotoxicological data	N; R50 (agreed by ECB)

‡ Endpoint identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

APPENDIX 2 – ABBREVIATIONS USED IN THE LIST OF ENDPOINTS

ADI	acceptable daily intake
AOEL	acceptable operator exposure level
ARfD	acute reference dose
a.s.	active substance
bw	body weight
CA	Chemical Abstracts
CAS	Chemical Abstracts Service
CIPAC	Collaborative International Pesticides Analytical Council Limited
d	day
DAR	draft assessment report
DM	dry matter
DT_{50}	period required for 50 percent degradation / dissipation
DT_{90}	period required for 90 percent degradation / dissipation
ε	decadic molar extinction coefficient
EC_{50}	effective concentration, median
EEC	European Economic Community
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of New Chemical Substances
EMDI	estimated maximum daily intake
EU	European Union
FAO	Food and Agriculture Organisation of the United Nations
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
GAP	good agricultural practice
GCPF	Global Crop Protection Federation (formerly known as GIFAP)
GS	growth stage
h	hour(s)
ha	hectare
hL	hectolitre
HPLC	high performance liquid chromatography or high pressure liquid chromatography
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
K_{oc}	organic carbon adsorption coefficient
L	litre
LC	liquid chromatography
LC-MS	liquid chromatography-mass spectrometry
LC-MS-MS	liquid chromatography with tandem mass spectrometry
LC_{50}	lethal concentration, median
LD_{50}	lethal dose, median
LOAEL	lowest observable adverse effect level

LOD	limit of detection
LOQ	limit of quantification (determination)
µg	microgram
min	minute(s)
mN	milli-Newton
MRL	maximum residue limit or level
MS	mass spectrometry
NESTI	national estimated Short Term Intake
NIR	Near-Infrared-(Spectroscopy)
nm	nanometer
NOAEL	no observed adverse effect level
NOEL	no observed effect level
PEC	predicted environmental concentration
PEC_A	predicted environmental concentration in air
PEC_S	predicted environmental concentration in soil
PEC_{SW}	predicted environmental concentration in surface water
PEC_{GW}	predicted environmental concentration in ground water
PHI	pre-harvest interval
pK_a	negative logarithm (to the base 10) of the dissociation constant
PPE	personal protective equipment
ppm	parts per million (10^{-6})
PPP	plant protection product
r^2	coefficient of determination
SPI	spraying
SRU	low volume spraying
STMR	supervised trials median residue
TER	toxicity exposure ratio
TMDI	theoretical maximum daily intake
UV	ultraviolet
WHO	World Health Organisation
WG	water dispersible granule
yr	year