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

tolylfluanid

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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