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

# trifluralin

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(version of 13 April 2005 with minor editorial changes)


## SUMMARY

Trifluralin 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.

Greece being the designated rapporteur Member State submitted the DAR on trifluralin in accordance with the provisions of Article 8(1) of the amended Regulation (EC) No 451/2000, which was received by the EFSA on 11 July 2003. Following a quality check on the DAR, the peer review was initiated on 24 July 2003 by dispatching the DAR for consultation of the Member States and the notifier, the European Union Trifluralin Taskforce comprising of Agan Chemical Manufacturers Ltd. and Dintec Agroquímica Produtos Químicos Lda. at the time of finalisation of the conclusion. Subsequently, the comments received were examined by the rapporteur Member State and the need for additional data was agreed in an evaluation meeting on 15 January 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 April, May and June 2004.

A final discussion of the outcome of the consultation of experts took place with representatives from Member States on 10 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 herbicide as proposed by the notifier which comprises spraying to bare soil to control grass and broad-leaved weeds in oilseed rape, sunflowers, cotton and winter cereals at application rate up 1.2 kg trifluralin per hectare. The representative formulated product for the evaluation was “EF-1521” ("Treflan"), an emulsifiable concentrate (EC), registered under different trade names in Europe. In case of oilseed rape, sunflowers, cotton, incorporation into soil takes place after the application. Trifluralin can be used only as pre-emergence herbicide.


[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.

Trifluralin is extensively and rapidly metabolised and absorbed. It has a low acute toxicity, but has sensitising properties (proposed classification: R43). Trifluralin induced neoplastic changes and carcinogenic effects were seen in rats such as Leydig cell tumours, thyroid tumours and renal carcinoma (proposed classification: R40). A no observed adverse effect level (NOAEL) could not be established but the lowest observed adverse effect level (LOAEL) of 30 mg/kg bw/day in the rat was assigned as the most relevant effect level. There were no direct effects on reproductive performance or fertility.
The acceptable daily intake (ADI) is 0.015 mg/kg bw/day based on the LOAEL in the rat carcinogenicity study with a margin of safety between LOAEL and ADI of 2000.
The acceptable operator exposure level (AOEL) is 0.026 mg/kg bw/day and no acute reference dose (ARfD) was allocated. The estimated operator exposure was below the AOEL only if personal protective equipment (PPE) is worn both during mixing/loading and during application.

The metabolism of trifluralin in cereals is extensive and does not yield metabolites of toxicological concern. No residues of trifluralin were quantified in any of the cereal grain or straw samples from field trials conducted according the critical good agricultural practise (GAP) in Northern Europe. Further information is needed to conclude on the residue situation in cereals for Southern European uses.
For oilseed crops the present studies do not fully address consumer exposure via seeds. Therefore a further metabolism study is required for oilseeds to support uses on these crops. Subsequently the applicability of the submitted residue trials in oilseed crops has to be reviewed.
Due to the above mentioned requirements a final conclusion on the livestock dietary burden and on the possibly occurrence of residues in food of animal origin cannot be drawn at this stage.
The chronic dietary exposure assessment for consumers based on the currently available information in line with the Northern European GAP on cereals leads to estimated intakes less than 4% of the proposed ADI for the consumer subgroups of infants and young children. However, this assessment needs to be reviewed upon receipt of the outstanding data. An ARfD was not allocated, thus there is no acute risk for consumers arising from trifluralin residues in food.

In aerobic conditions degradation of trifluralin in soil did not lead to any major metabolite. Under flooded anaerobic conditions a major metabolite TR-4[3] is formed. Furthermore, metabolite TR-14[4] was formed at amounts above 5 % at the end of the study in all three anaerobic soils tested. Due to its potential degradation under aerobic conditions, TR-4 may be addressed by Member States where anaerobic conditions are envisaged to be relevant. Whereas not discussed in particular during the Peer Review, it is EFSA's opinion that the same conclusion may be reached for metabolite TR-14.

[3] α, α, α-trifluoro-5-nitro-$N^4$, $N^4$-dipropyl-toluene-3, 4-diamine 3-nitro-$N^2$-dipropyl-5-(trifluoromethyl)-1, 2-benzenediamine
[4] 7-amino-2-ethyl-1-propyl-5-(trifluromethyl)-bendimidazole

Under aerobic laboratory conditions trifluralin is medium to highly persistent with half-lives between 81 to 356 d at 22 °C. The degradation under anaerobic conditions was faster than under aerobic conditions. Data indicate that trifluralin is strongly adsorbed to soil and could be classified as immobile. Trifluralin is hydrolytically stable under environmental relevant conditions. Aqueous photolysis may contribute to the environmental degradation of trifluralin producing TR-6[5] and TR-15[6] metabolites. Trifluralin is not readily biodegradable. During the Peer Review, it was agreed that worst case $DT_{50}$ = 13 d should be employed for the risk assessment performed in the context of Annex I inclusion and that a $DT_{50}$ = 2 d could be used to refine risk assessment when appropriate. Due to the potential contribution of photolysis to the dissipation of trifluralin in water, the fate and behaviour in the environment expert meeting confirmed the need of a water sediment study conducted in the presence of light that could be used by MS to refine the risk assessment performed in the context of Annex I inclusion. Neither trifluralin nor its anaerobic metabolite TR-4 are expected to contaminate ground water at levels above 0.1 µg / L under the proposed conditions of use.
Trifluralin was designated as a "priority substance" under the Water Framework Directive[7] but has not been identified as a "priority hazardous substance". However, trifluralin has been added to the OSPAR (Convention for the Protection of the Marine Environment of the North-East Atlantic) List of Chemicals for Priority action in 2002 because it is considered to be a PBT substance fulfilling the criteria for Persistence, Bioaccumulation and Toxicity.
Because of its high volatility the occurrence of trifluralin in air and transport trough air is possible. However, photochemical half life in air is estimated to be short.

The risk to insectivorous and fish-eating birds and mammals, bees, ground dwelling arthropods, soil micro- organisms, including earthworms is low with respect to trifluralin and the metabolites as far as investigated.
High risks were identified for aquatic organisms, in particular the chronic risk to fish, which require consideration of appropriate risk mitigation measures. Using the initial predicted environmental concentrations (PEC's) together with the no observed effect level (NOEC) of 0.3 µg/L leads to a toxicity exposure ratio (TER)-value of 0.38 when a bufferzone of 15 metres is taken into account which is below the Annex VI trigger value of 10 (without detailed calculations, a bufferzone of 50 m should lead to a TER-value of approximately 1). Further data to address this risk is needed and the risk assessment can only be concluded when the outstanding data is evaluated.
The EPCO expert meeting (section ecotoxicology, June 2004) considered the risk to earthworm eating birds and mammals as low, based on the TER value reflecting the soil accumulation plateau. EFSA would like to highlight that the risk to earthworm eating birds and mammals should be considered further at MS-level when the product is applied after this plateau value is reached. EFSA proposes that a new litterbag study should be made available in which the tested dose rate reflects the concentration in the soil after a single application when the accumulation plateau has been reached as

[5] α, α, α-trifluoro-5-nitrotoluene-3,4-diamine 3-nitro-5-(trifluromethyl)-1,2-benzenediamine
[6] 2-ethyl-7-nitro-5-(trifluoromethyl) benzimidazole
[7] OJ No L 327, 22.12.2000, p.1

the study which is available at present was performed at a lower dose rate. This data requirement has not been discussed in an EPCO expert meeting

The risk to non-target plants could not be calculated with the appropriate endpoint (median emergence rate (ER50) value) as this value is not reported in the DAR. Based on a conservative no observed effect concentration (NOEC), the risk to non-target plants can be certainly regarded as low if a bufferzone of 5 metres is taken into account.

Regulation (EC) No 850/2004[8] of the European Parliament and of the Council on persistent organic pollutants and amending Directive 79/117/EEC[9] entered into force when the Peer Review of trifluralin was in an advanced stage. For this reason, EFSA's conclusion does not specifically assess trifluralin against the criteria set in the paragraph 1 of Annex D of the Stockholm Convention[10]. However, available information assessed during the Peer Review and provided in this conclusion should allow the Commission and the Member States to conduct the assessment of trifluralin with respect to Regulation (EC) No 850/2004. As this conclusion only considers a limited range of representative uses, other information may need to be considered by the Commission and the Member States when assessing trifluralin with respect to Regulation (EC) No 850/2004.

**Key words: trifluralin, peer review, risk assessment, pesticide, herbicide**

[8] OJ No L 158, 30.04.2004, p. 21
[9] OJ No L 33, 08.02.1979, p. 36
[10] http://www.pops.int/default.htm