



EUROPEAN COMMISSION
HEALTH & CONSUMERS DIRECTORATE-GENERAL

Directorate E – Safety of the food chain
Unit E.3 - Chemicals, contaminants and pesticides

Trifluralin
SANCO/10089/2010 final
1 July 2010

Review report for the active substance **trifluralin**

finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on
11 May 2010
in support of a decision concerning the non-inclusion of trifluralin in Annex I of Directive
91/414/EEC

1. Procedure followed for the re-evaluation process

This review report has been established as a result of the re-evaluation of trifluralin, made in the context of a new application by the data submitter after the non-inclusion of this substance.

Trifluralin is a substance that was covered by the second stage of the work programme for review of existing active substances provided for in Article 8(2) of Directive 91/414/EEC concerning the placing of plant protection products on the market, with a view to the possible inclusion of this substance in Annex I to the Directive.

At the outcome of that evaluation, trifluralin has not been included through Commission Decision 2007/629/EC¹ as, on the basis of the available information, it has not been demonstrated that, amongst other, the risk to aquatic organisms was acceptable. Moreover, concerns had been raised as regards the substance's high persistence in soil, its potential to bioaccumulate and to migrate over long distance via air. All information as regards this initial evaluation is recorded in the relevant Commission Review Report (document SANCO/10443/2006 final of 29 September 2007).

In accordance with Article 13 of Regulation (EC) No 33/2008, Dow Agro Sciences (representative of Dintec) on behalf of the European Union Trifluralin Task Force (EUTTF) comprising of Dintec Agroquímica Produtos Químicos Lda and Agan Chemicals Manufacturers Ltd., presented on 14 July 2008 a request to Greece, the original rapporteur Member State, for a new application aiming at Annex I inclusion of the substance.

Greece finalised in January 2009 its examination, in the form of an additional report to the original Draft Assessment Report. This Report was received by the Commission and the European Food Safety Authority on 19 January 2009.

¹ OJ No L 255, 29.9.2007, p. 42.

In accordance with the provisions of Article 19 of Regulation (EC) No 33/2008, the EFSA organised the consultation on the draft assessment report by all the Member States as well as by the EUTTF, being the sole data submitter, on 22 January 2009 by making it available.

The EFSA organised an intensive consultation of technical experts from a certain number of Member States, to review the draft assessment report and the comments received thereon (peer review).

In accordance with the provisions of Article 20 of Regulation (EC) No 33/2008 the EFSA sent to the Commission its conclusion on the risk assessment [Conclusions regarding the peer review of the pesticide risk assessment of the active substance trifluralin (re-issued on 14 July 2009²). This conclusion refers to background document A (draft assessment report) and background document B (EFSA peer review report).

In accordance with the provisions of Article 21 of Regulation (EC) No 33/2008, the Commission referred a draft review report to the Standing Committee on the Food Chain and Animal Health, for final examination. The draft review report was finalised in the meeting of the Standing Committee on 11 May 2010.

The present review report contains the conclusions of the final examination by the Standing Committee. Given the importance of the conclusion of the EFSA, and the comments and clarifications submitted after the conclusion of the EFSA (background document C), these documents are also considered to be part of this review report.

2. Purposes of this review report

This review report, including the background documents and appendices hereto, has been developed and finalised in support of Commission Decision 2010/355/EU concerning the non-inclusion of trifluralin in Annex I to Directive 91/414/EEC.

In accordance with the provisions of Article 22 of Regulation (EC) No 33/2008, this review report will be made available for public consultation by any interested parties.

3. Overall conclusion in the context of Directive 91/414/EEC

The overall conclusion of this evaluation, based on the information available and the proposed conditions of use, is that:

- **the information available is insufficient** to satisfy the requirements set out in Annex II and Annex III Directive 91/414/EEC in particular with regard to
 - the surface water exposure which could not be finalised;
 - the chronic risk which could not be finalised;
 - the assessment of the potential for long-range transport which could not be finalised.
- **concerns were identified with regard to**

² EFSA Scientific Report (2009) 327 – Conclusion on pesticide peer review - Peer review of the pesticide risk assessment of the active substance trifluralin (re-issued on 14 July 2009).

- the risk to aquatic organisms, in particular the risk for fish;
- the potential for long-range transport via air.

In conclusion from the assessments made on the basis of the submitted information, no plant protection products containing the active substance concerned is expected to satisfy in general the requirements laid down in Article 5 (1) (a) and (b) of Council Directive 91/414/EEC.

Trifluralin should therefore not be included in Annex I to Directive 91/414/EEC.