

COMMISSION DECISION

of 25 June 2010

concerning the non-inclusion of trifluralin in Annex I to Council Directive 91/414/EEC

(notified under document C(2010) 4199)

(Text with EEA relevance)

(2010/355/EU)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market ⁽¹⁾, and in particular the fourth subparagraph of Article 8(2) thereof,

Whereas:

- (1) By Commission Decision 2007/629/EC ⁽²⁾ it was decided not to include the active substance trifluralin in Annex I to Directive 91/414/EEC. That Decision was taken within the framework of the second stage of the programme of work provided for in Commission Regulations (EC) No 451/2000 ⁽³⁾ and (EC) No 703/2001 ⁽⁴⁾ which lay down the detailed rules for the implementation of the second stage of the programme of work referred to in Article 8(2) of Directive 91/414/EEC and which establish a list of active substances to be assessed, with a view to their possible inclusion in Annex I to Directive 91/414/EEC.
- (2) The original notifier submitted a new application pursuant to Article 6(2) of Directive 91/414/EEC and Commission Regulation (EC) No 33/2008 of 17 January 2008 laying down detailed rules for the application of Council Directive 91/414/EEC as regards a regular and an accelerated procedure for the assessment of active substances which were part of the programme of work referred to in Article 8(2) of that Directive but have not been included into its Annex I ⁽⁵⁾. It requested the application of the accelerated procedure pursuant to Articles 13 to 19 of Regulation (EC) No 33/2008 and submitted an updated dossier. The application was submitted to Greece, which had been designated rapporteur Member State by Regulation (EC) No 451/2000.
- (3) That application complies with the substantive and procedural requirements of Article 15 of Regulation

(EC) No 33/2008 and was submitted within the time period provided for in the second sentence of Article 13 of that Regulation.

- (4) Greece evaluated the new information and data submitted by the notifier and prepared an additional report on 7 January 2009.
- (5) The additional report was peer reviewed by the Member States and the European Food Safety Authority, hereinafter EFSA, and presented to the Commission on 14 July 2009 in the format of the EFSA Scientific Report for trifluralin ⁽⁶⁾. This report was reviewed by the Member States and the Commission within the Standing Committee on the Food Chain and Animal Health and finalised on 11 May 2010 in the format of the Commission review report for trifluralin.
- (6) The new assessment by the rapporteur Member State and the new conclusion by the EFSA concentrated on the concerns that lead to the non-inclusion, which were due to the high risk for aquatic organisms, especially fish, the toxicity of metabolites to sediment dwelling organisms, the consumer exposure for non-cereal applications, the high persistence in soil, the high potential for bioaccumulation, and the potential for long range transport via air.
- (7) New data and information were submitted by the notifier in the updated dossier, in particular as regards the aquatic risk assessment, especially fish, the toxicity of metabolites to sediment dwelling organisms, the high persistence in soil and the high potential for bioaccumulation. In order to reduce the risk to consumers, the notifier, in the context of the resubmission, only supported applications on oil seed rape. As regards the potential for long range transport via air, the submitted data simply reproduced a monitoring report which already figured in the original dossier. A new assessment was performed, as included in the additional report and in the EFSA Scientific Report for trifluralin.
- (8) However, the additional data and information provided by the notifier did not permit to eliminate all the specific concerns that led to the non-inclusion.

⁽¹⁾ OJ L 230, 19.8.1991, p. 1.

⁽²⁾ OJ L 255, 29.9.2007, p. 42.

⁽³⁾ OJ L 55, 29.2.2000, p. 25.

⁽⁴⁾ OJ L 98, 7.4.2001, p. 6.

⁽⁵⁾ OJ L 15, 18.1.2008, p. 5.

⁽⁶⁾ EFSA Scientific Report (2009) 327 — Conclusion regarding the peer review of the pesticide risk assessment of the active substance trifluralin (re-issued on 14 July 2009).

- (9) In particular, the concern on potential high risk for aquatic organisms, especially fish, could not be solved due to shortcomings in the newly submitted studies. As a consequence, the surface water risk assessment could not be finalised. Furthermore, the potential for long range transport via air has not been adequately elucidated by the produced information which was of an obsolete nature.
- (10) The Commission invited the notifier to submit its comments on the results of the peer review. Furthermore, in accordance with Article 21(1) to Regulation (EC) No 33/2008, the Commission invited the notifier to submit comments on the draft review report and in particular on the remaining concerns for the aquatic risk and the potential for long range transport. The notifier submitted its comments, which have been carefully examined.
- (11) However, despite the arguments put forward by the notifier, the concerns identified could not be eliminated, and assessments made on the basis of the information submitted and evaluated during the EFSA expert meetings have not demonstrated that it may be expected that, under the proposed conditions of use, plant protection products containing trifluralin satisfy in general the requirements laid down in Article 5(1)(a) and (b) of Directive 91/414/EEC.
- (12) Trifluralin should therefore not be included in Annex I to Directive 91/414/EEC.
- (13) Decision 2007/629/EC should be repealed.
- (14) This Decision does not prejudice the submission of a further application for trifluralin pursuant to Article 6(2) of Directive 91/414/EEC and Chapter II of Regulation (EC) No 33/2008.
- (15) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS DECISION:

Article 1

Trifluralin shall not be included as active substance in Annex I to Directive 91/414/EEC.

Article 2

Decision 2007/629/EC is repealed.

Article 3

This Decision is addressed to the Member States.

Done at Brussels, 25 June 2010.

For the Commission

John DALLI

Member of the Commission