DIRECTIVES

COMMISSION DIRECTIVE 2010/27/EU

of 23 April 2010

amending Council Directive 91/414/EEC to include triflumizole as active substance

(Text with EEA relevance)

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 Article 6(1) thereof,

Whereas:

(1) Commission Regulations (EC) No 451/2000 [2] and (EC) No 1490/2002 [3] lay down the detailed rules for the implementation of the third stage of the programme of work referred to in Article 8(2) of Directive 91/414/EEC and establish a list of active substances to be assessed, with a view to their possible inclusion in Annex I to Directive 91/414/EEC. That list included triflumizole. By Commission Decision 2008/748/EC [4] it was decided not to include triflumizole in Annex I to Directive 91/414/EEC.

(2) Pursuant to Article 6(2) of Directive 91/414/EEC the original notifier submitted a new application requesting the application of the accelerated procedure provided for in Articles 14 to 19 of 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].

(3) The application was submitted to the Netherlands, which had been designated rapporteur Member State by Regulation (EC) No 451/2000. The time period for the accelerated procedure was respected. The specification of the active substance and the supported uses are the same as were the subject of Decision 2008/748/EC. That application also complies with the remaining substantive and procedural requirements of Article 15 of Regulation (EC) No 33/2008.

(4) The Netherlands evaluated the new information and data submitted by the notifier and prepared an additional report on 6 March 2009.

(5) The additional report was peer reviewed by the Member States and the EFSA and presented to the Commission on 14 December 2009 in the format of the EFSA Conclusions for triflumizole [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 12 March 2010 in the format of the Commission review report for triflumizole.

(6) The new assessment by the rapporteur Member State and the conclusion by the EFSA concentrated on the concerns that led to the non-inclusion. Those concerns were the unacceptable risk assessment for operators and workers.

(7) The new data submitted by the notifier show that the exposure of operators and workers may be considered as acceptable provided that additional protective equipment is worn.

(8) It has appeared from the various examinations made that plant protection products containing triflumizole may be expected to satisfy, in general, the requirements laid down in Article 5(1)(a) and (b) of Directive 91/414/EEC, in particular with regard to the uses which were examined and detailed in the Commission review report. It is therefore appropriate to include triflumizole in Annex I, in order to ensure that in all Member States the authorisations of plant protection products containing this active substance may be granted in accordance with the provisions of that Directive.

[1] OJ L 230, 19.8.1991, p. 1.
[2] OJ L 55, 29.2.2000, p. 25.
[3] OJ L 224, 21.8.2002, p. 23.
[4] OJ L 252, 20.9.2008, p. 37.
[5] OJ L 15, 18.1.2008, p. 5.

[6] European Food Safety Authority; Conclusion on the peer review of the pesticide risk assessment of the active substance triflumizole. *EFSA Journal* 2009; 7(12):1415. [49 pp.]. doi:10.2903/j.efsa.2009.1415. Available online: www.efsa.europa.eu

(9) It is therefore appropriate to amend Directive 91/414/EEC accordingly.

(10) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Annex I to Directive 91/414/EEC is amended as set out in the Annex to this Directive.

Article 2

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 30 November 2010 at the latest. They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

Article 3

This Directive shall enter into force on 1 July 2010.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 23 April 2010.

For the Commission
The President
José Manuel BARROSO

ANNEX

The following entry shall be added at the end of the table in Annex I to Directive 91/414/EEC:

No	Common Name, Identification Numbers	IUPAC Name	Purity [1]	Entry into force	Expiration of inclusion	Specific provisions
'311	Triflumizole CAS No: 99387-89-0 CIPAC No: 730	*(E)-4-chloro-α,α,α-trifluoro-N-(1-imidazol-1-yl-2-propoxy-ethylidene)-o-toluidine*	≥ 980 g/kg Impurities: Toluene: not more than 1 g/kg	1 July 2010	30 June 2020	PART A Only uses as fungicide in greenhouses on artificial substrates may be authorised. PART B For the implementation of the uniform principles of Annex VI, the conclusions of the review report on triflumizole, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 12 March 2010 shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the operator and worker safety: conditions of use shall prescribe the use of adequate personal protective equipment, — the potential impact on aquatic organisms and must ensure that the conditions of authorisation include, as appropriate, risk mitigation measures.'

[1] Further details on identity and specification of active substance are provided in the review report.