COMMISSION DIRECTIVE 2011/23/EU

of 3 March 2011

amending Council Directive 91/414/EEC to include triflumuron 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 triflumuron. By Commission Decision 2009/241/EC ([4]) it was decided not to include triflumuron in Annex I to Directive 91/414/EEC.

(2) Pursuant to Article 6(2) of Directive 91/414/EEC the original notifier (hereinafter 'the applicant') submitted a new application requesting the accelerated procedure to be applied, as 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 Italy, which had been designated rapporteur Member State by Regulation (EC) No 1490/2002. The time period for the accelerated procedure was respected. The specification of the active substance and the supported uses are the same as those that were the subject of Decision 2009/241/EC. That application also complies with the remaining substantive and procedural requirements of Article 15 of Regulation (EC) No 33/2008.

(4) Italy evaluated the new information and data submitted by the applicant and prepared an additional report. It communicated that report to the European Food Safety Authority (hereinafter 'the Authority') and to the Commission on 5 March 2010.

(5) The Authority communicated the additional report to the other Member States and the applicant for comments and forwarded the comments it had received to the Commission. In accordance with Article 20(1) of Regulation (EC) No 33/2008 and at the request of the Commission, the additional report was peer reviewed by the Member States and the Authority. The Authority then presented its conclusion on triflumuron to the Commission on 9 December 2010 ([6]). The draft assessment report, the additional report and the conclusion of the Authority were reviewed by the Member States and the Commission within the Standing Committee on the Food Chain and Animal Health and finalised on 28 January 2011 in the format of the Commission review report for triflumuron.

(6) The additional report by the rapporteur Member State and the new conclusion by the Authority concentrate on the concerns that lead to the non-inclusion. Those concerns were in particular that, based on the available information, it had not been demonstrated that the consumer exposure was acceptable due to lack of data in terms of nature and level of the relevant residues. In fact, it was not possible to perform an acute risk assessment for the metabolite M07 ([7]), because data was not sufficient to allocate an acute reference dose for this metabolite. Moreover, data was missing to determine an appropriate residue definition and to estimate the level of residues in processed fruit commodities.

(7) The new information submitted by the applicant enabled a consumer exposure assessment. The information currently available indicates that the consumer exposure is acceptable.

(8) Consequently, the additional data and information provided by the applicant permit to eliminate the specific concerns that led to the non-inclusion. No other open scientific questions have arisen.

([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 71, 17.3.2009, p. 59.
([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 triflumuron*; EFSA Journal 2011; 9(1):1941. [81 pp.]. doi:10.2903/j.efsa.2010.1941. Available online: www.efsa.europa.eu/efsajournal.htm.
([7]) 4-trifluoro-methoxyaniline

(9) It has appeared from the various examinations made that plant protection products containing triflumuron 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 triflumuron 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.

(10) Without prejudice to that conclusion, it is appropriate to obtain confirmatory information on certain specific points. Article 6(1) of Directive 91/414/EEC provides that the inclusion of a substance in Annex I may be subject to conditions. Therefore, it is appropriate to require that the applicant submit confirmatory information as regards the long-term risk to birds, the risk to aquatic invertebrates and the risk to bee brood development.

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

(12) 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 September 2011 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 April 2011.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 3 March 2011.

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
'328	Triflumuron CAS No: 64628-44-0 CIPAC No: 548	1-(2-chlorobenzoyl)-3-[4-trifluoromethoxyphenyl]urea	≥ 955 g/kg Impurities: — *N,N'*-bis-[4-(trifluoromethoxy)phenyl]urea: not more than 1 g/kg, — 4-trifluoro-methoxyaniline: not more than 5 g/kg.	1 April 2011	31 March 2021	PART A Only uses as insecticide may be authorised. PART B For the implementation of the uniform principles of Annex VI the conclusions of the review report on triflumuron, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 28 January 2011, shall be taken into account. In this overall assessment, Member States shall pay particular attention to: — the protection of the aquatic environment, — the protection of honeybees. Conditions of authorisation shall include risk mitigation measures, where appropriate. Conditions of authorisation shall include risk mitigation measures, where appropriate. The Member States concerned shall ensure that the applicant submits to the Commission confirmatory information as regards the long-term risk to birds, the risk to aquatic invertebrates and the risk to bee brood development. The Member States concerned shall ensure that the applicant submits such information to the Commission by 31 March 2013.'

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