

## COMMISSION DECISION

of 3 March 2011

## concerning the non-inclusion of ethoxyquin in Annex I to Council Directive 91/414/EEC and amending Commission Decision 2008/941/EC

(notified under document C(2011) 1265)

(Text with EEA relevance)

(2011/143/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 <sup>(1)</sup>, and in particular the fourth subparagraph of Article 8(2) thereof,

Whereas:

- (1) Commission Regulations (EC) No 1112/2002 <sup>(2)</sup> and (EC) No 2229/2004 <sup>(3)</sup> lay down the detailed rules for the implementation of the fourth 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 ethoxyquin.
- (2) In accordance with Article 24e of Regulation (EC) No 2229/2004 the notifier withdrew its support of the inclusion of that active substance in Annex I to Directive 91/414/EEC within 2 months from receipt of the draft assessment report. Consequently, Commission Decision 2008/941/EC of 8 December 2008 concerning the non-inclusion of certain active substances in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing these substances <sup>(4)</sup> on the non-inclusion of ethoxyquin was adopted.
- (3) 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 <sup>(5)</sup>.

- (4) The application was submitted to Germany, which had been designated rapporteur Member State by Regulation (EC) No 2229/2004. 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 2008/941/EC. That application also complies with the remaining substantive and procedural requirements of Article 15 of Regulation (EC) No 33/2008.
- (5) Germany evaluated the additional 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 16 October 2009. 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 Authority presented its conclusion on ethoxyquin to the Commission on 20 August 2010 <sup>(6)</sup>. 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 ethoxyquin.
- (6) During the evaluation of this active substance, a number of concerns have been identified. In particular, it was not possible to perform a reliable consumer, operator and worker exposure assessment, due to the limited toxicological data package, considered insufficient to set the Acceptable Daily Intake (ADI), the Acute Reference Dose (ARfD) and the Acceptable Operator Exposure Level (AOEL). Furthermore, the data submitted were insufficient to set a residue definition for ethoxyquin and its metabolites. In addition, data were missing to conclude on the genotoxic potential and the ecotoxicity of an impurity in the technical specifications, for confidentiality reasons referred to as impurity 7. Finally, the data available were not sufficient to fully assess the risks to the environment and to non-target organisms. Consequently, it was not possible to conclude on the basis of the information available that ethoxyquin met the criteria for inclusion in Annex I to Directive 91/414/EEC.

<sup>(1)</sup> OJ L 230, 19.8.1991, p. 1.

<sup>(2)</sup> OJ L 168, 27.6.2002, p. 14.

<sup>(3)</sup> OJ L 379, 24.12.2004, p. 13.

<sup>(4)</sup> OJ L 335, 13.12.2008, p. 91.

<sup>(5)</sup> OJ L 15, 18.1.2008, p. 5.

<sup>(6)</sup> European Food Safety Authority; Conclusion on the peer review of the pesticide risk assessment of the active substance ethoxyquin. *EFSA Journal* 2010;8(9):1710. [38 pp.]. doi:10.2903/j.efsa.2010.1710. Available online: [www.efsa.europa.eu/efsajournal.htm](http://www.efsa.europa.eu/efsajournal.htm)

- (7) The Commission invited the applicant to submit its comments on the results of the peer review. Furthermore, in accordance with Article 21(1) of Regulation (EC) No 33/2008, the Commission invited the applicant to submit comments on the draft review report. The applicant submitted its comments, which have been carefully examined.
- (8) However, despite the arguments put forward by the applicant, the concerns identified could not be eliminated, and assessments made on the basis of the information submitted and evaluated during the Authority expert meetings have not demonstrated that it may be expected that, under the proposed conditions of use, plant protection products containing ethoxyquin satisfy in general the requirements laid down in Article 5(1)(a) and (b) of Directive 91/414/EEC.
- (9) Ethoxyquin should therefore not be included in Annex I to Directive 91/414/EEC.
- (10) This Decision does not prejudice the submission of a further application for ethoxyquin pursuant to Article 6(2) of Directive 91/414/EEC and Chapter II of Regulation (EC) No 33/2008.
- (11) In the interest of clarity, the entry for ethoxyquin in the Annex to Decision 2008/941/EC should be deleted.
- (12) It is therefore appropriate to amend Decision 2008/941/EC accordingly.
- (13) 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*

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

*Article 2*

Member States shall ensure that:

- (a) authorisations for plant protection products containing ethoxyquin are withdrawn by 3 September 2011;
- (b) no authorisations for plant protection products containing ethoxyquin are granted or renewed from the date of publication of this Decision.

*Article 3*

Any period of grace granted by Member States in accordance with the provisions of Article 4(6) of Directive 91/414/EEC, shall be as short as possible and shall expire on 3 September 2012 at the latest.

*Article 4*

In the Annex to Decision 2008/941/EC, the entry for 'ethoxyquin' is deleted.

*Article 5*

This Decision is addressed to the Member States.

Done at Brussels, 3 March 2011.

*For the Commission*

John DALLI

*Member of the Commission*

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