

Commission Directive 2004/60/EC of 23 April 2004 amending Council Directive 91/414/EEC to include quinoxyfen as active substance (Text with EEA relevance)

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THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market⁽¹⁾, as last amended by Commission Directive 2003/82/EC⁽²⁾, and in particular Article 6(1) thereof,

Whereas:

- (1) In accordance with Article 6(2) of Directive 91/414/EEC the United Kingdom received on 1 August 1995 an application from Dow Elanco Europe (now Dow Agro Sciences), for the inclusion of the active substance quinoxyfen in Annex I to Directive 91/414/EEC. Commission Decision 96/457/EEC⁽³⁾ confirmed that the dossier was 'complete' in the sense that it could be considered as satisfying, in principle, the data and information requirements of Annexes II and III to Directive 91/414/EEC.
- (2) For this active substance, the effects on human health and the environment have been assessed, in accordance with the provisions of Article 6(2) and (4) of Directive 91/414/EEC, for the uses proposed by the applicant. The nominated rapporteur Member State, submitted a draft assessment report concerning the substance to the Commission on 11 October 1996.
- (3) The draft assessment report has been reviewed by the Member States and the Commission within the Standing Committee on the Food Chain and Animal Health. The review was finalised on 28 November 2003 in the format of the Commission review report for quinoxyfen.
- (4) The documents and information were also submitted to the Scientific Committee for Plants for separate consultation. The Committee was asked to comment on the accumulation of the substance in soil and on its potential environmental impact. In its opinion⁽⁴⁾, the Committee noted that the available studies and the field study on organic matter degradation (litter bag study) in particular did not convincingly demonstrate an acceptable impact on the environment, mainly due to insufficient statistical power of the experimental design. The Committee further noted that a fraction of the applied quinoxyfen may volatilise after application to a crop. Although available results indicate a rapid decomposition of the substance in air, the Committee suggested that measurements of the half-life should be repeated after appropriate schemes have

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been developed for assessing the environmental risks of atmospheric transport of plant protection products. This recommendation of the Committee was taken into account in the review report of the active substance.

The insufficient field study on organic matter breakdown was repeated with an upgraded test protocol. No effect of quinoxyfen on organic matter decomposition was detected.

- (5) In accordance with Article 6(4) of Directive 91/414/EEC and in view of a possible unfavourable decision for quinoxyfen the Commission organised a tripartite meeting with the main data submitter and the rapporteur Member State on 13 February 2003. The main data submitter provided further data in order to meet the initial concerns.
- (6) It has appeared from the various examinations made that plant protection products containing quinoxyfen may be expected to satisfy, in general, the requirements laid down in Article 5(1)(a) and (b) and Article 5(3) 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 quinoxyfen in Annex I, in order to ensure that in all Member States the authorisations of plant protection products containing this active substance can be granted in accordance with the provisions of that Directive.
- (7) The Commission review report is required for the proper implementation by the Member States, of several sections of the uniform principles laid down in Directive 91/414/EEC. It is, therefore, appropriate to provide that the finalised review report, except for confidential information within the meaning of Article 14 of Directive 91/414/EEC, should be kept available or made available by the Member States for consultation by any interested parties.
- (8) After inclusion, Member States should be allowed a reasonable period to implement the provisions of Directive 91/414/EEC as regards plant protection products containing quinoxyfen and in particular to review existing provisional authorisations and, by the end of this period at the latest, to transform those authorisations into full authorisations, to amend them or to withdraw them in accordance with the provisions of Directive 91/414/EEC.
- (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:

- (1) [OJ L 230, 19.8.1991, p. 1.](#)
- (2) [OJ L 77, 13.3.2004, p. 50.](#)
- (3) [OJ L 189, 30.7.1996, p. 112.](#)
- (4) Opinion of the Scientific Committee on Plants regarding the inclusion of quinoxifen in Annex I to Council Directive 91/414/EEC concerning the placing of plant protection products on the market. (SCP/QUINOX/002-final, adopted 7 March 2001).