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)

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)

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:

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 adopt and publish, by 28 February 2005 at the latest, the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith inform the Commission thereof.

They shall apply those provisions from 1 March 2005.

When Member States adopt those provisions, they shall contain a reference to this Directive or shall 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

1 Member States shall review the authorisation for each plant protection product containing quinoxyfen to ensure that the conditions relating to this active substance set out in Annex I to Directive 91/414/EEC are complied with. Where necessary, they shall amend or withdraw the authorisation in accordance with Directive 91/414/EEC before 28 February 2005.

[F1 2 For each authorised plant protection product containing quinoxyfen as either the only active substance or as one of several active substances all of which were listed in Annex I to Directive 91/414/EEC by 31 August 2004 at the latest, Member States shall re-evaluate the product in accordance with the uniform principles provided for in Annex VI to Directive 91/414/EEC, on the basis of a dossier satisfying the requirements of Annex III to that Directive. On the basis of that evaluation, they shall determine whether the product satisfies the conditions set out in Article 4(1)(b), (c), (d) and (e) of Directive 91/414/EEC.

Following that determination Member States shall:

a in the case of a product containing quinoxyfen as the only active substance, where necessary, amend or withdraw the authorisation by 28 February 2006 at the latest; or

b in the case of a product containing quinoxyfen as one of several active substances, where necessary, amend or withdraw the authorisation by 28 February 2006 or by the date fixed for such an amendment or withdrawal in the respective Directive or Directives which added the relevant substance or substances to Annex I to Directive 91/414/EEC, whichever is the latest.**]**

Textual Amendments

F1 Substituted by Commission Directive 2004/97/EC of 27 September 2004 amending Commission Directive 2004/60/EC as regards time limits (Text with EEA relevance).

Article 4

This Directive shall enter into force on 1 September 2004.

Article 5

This Directive is addressed to the Member States.