

COMMISSION IMPLEMENTING DECISION

of 1 June 2011

concerning the non-inclusion of dicloran in Annex I to Council Directive 91/414/EEC

(notified under document C(2011) 3731)

(Text with EEA relevance)

(2011/329/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 ⁽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 second and third stages 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 dicloran.
- (2) In accordance with Article 11f of Regulation (EC) No 1490/2002 and Article 12(1)(a) and Article 12(2)(b) of that Regulation, Commission Decision 2008/744/EC of 18 September 2008 concerning the non-inclusion of dicloran in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing that substance ⁽⁴⁾ was adopted.
- (3) The original notifier (hereinafter 'the applicant') submitted a new application pursuant to Article 6(2) of Directive 91/414/EEC 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⁾.
- (4) The application was submitted to Spain, 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 were the subject of Decision 2008/744/EC. That application also complies with the remaining substantive and procedural requirements of Article 15 of Regulation (EC) No 33/2008.

- (5) Spain 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 6 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 dicloran to the Commission on 21 July 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 the Animal Health and finalised on 5 May 2011 in the format of the Commission review report for dicloran.
- (6) The additional report by the rapporteur Member State and the conclusion by the Authority concentrate on the concerns that lead to the non-inclusion; in particular, there was a concern with regard to worker exposure. More concerns were identified in the review report for dicloran.
- (7) Additional information was submitted by the applicant, in particular as regards the specification of the technical material, the equivalence of the test materials used in the toxicity studies and the technical material; as commercially manufactured, the mammalian toxicity, the operator and worker exposure and the degradation pathways.
- (8) However, the additional information provided by the applicant did not permit to eliminate all of the specific concerns arising in respect of dicloran.

⁽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 251, 19.9.2008, p. 43.

⁽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 dicloran. *EFSA Journal* 2010;8(8):1698. [110 pp.]. doi:10.2903/j.efsa.2010.1698. Available online: www.efsa.europa.eu/efsajournal.

- (9) In particular, there were the following concerns. It was not demonstrated that the specification of the technical material, as commercially manufactured, is equivalent with those of the test materials used in the toxicological and ecotoxicological studies. The data available were insufficient to conclude on the toxicological relevance of two impurities present in the technical material, for confidentiality reasons referred to as impurities 3 and 4. Harmful effects on human health were identified. In particular, worker exposure was found to exceed 100 % of the acceptable operator exposure level (AOEL). The consumer risk assessment could not be finalised due to unknown amounts of residues in succeeding crops. Information on risks to aquatic organisms from unidentified degradation products of the aqueous photolysis and to non target soil macro-organisms was not sufficient.
- (10) The Commission invited the applicant to submit its comments on the conclusion by the Authority. Furthermore, in accordance with Article 21(1) to 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.
- (11) 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 expert meetings of the Authority have not demonstrated that it may be expected that, under the proposed conditions of use, plant protection products containing dicloran satisfy in general the requirements laid down in Article 5(1)(a) and (b) of Directive 91/414/EEC.
- (12) Dicloran should therefore not be included in Annex I to Directive 91/414/EEC.
- (13) In the interest of clarity, Decision 2008/744/EC should be repealed.
- (14) This Decision does not prejudice the submission of a further application for dicloran pursuant to Article 6(2) of Directive 91/414/EEC and Chapter II of Regulation (EC) No 33/2008.
- (15) 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*
- Dicloran shall not be included as active substance in Annex I to Directive 91/414/EEC.
- Article 2*
- Decision 2008/744/EC is repealed.
- Article 3*
- This Decision is addressed to the Member States.
- Done at Brussels, 1 June 2011.
- For the Commission*
John DALLI
Member of the Commission
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