

Brussels, XXX SANTE/10395/2015 Rev. 1 [...](2016) XXX draft

COMMISSION IMPLEMENTING REGULATION (EU) .../...

of XXX

concerning the non-renewal of approval of the active substance diquat, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending Implementing Regulation (EU) No 540/2011

(Text with EEA relevance)

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(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC¹, and in particular Article 20(1) and Article 78(2) thereof,

Whereas:

- (1) Commission Directive 2001/21/EC² included diquat as an active substance in Annex I to Council Directive 91/414/EEC³.
- (2) Active substances included in Annex I to Directive 91/414/EEC are deemed to have been approved under Regulation (EC) No 1107/2009 and are listed in Part A of the Annex to Commission Implementing Regulation (EU) No 540/2011⁴.
- (3) The approval of the active substance diquat, as set out in Part A of the Annex to Implementing Regulation (EU) No 540/2011, expires on 30 June 2017.
- (4) An application for the renewal of the inclusion of diquat in Annex I to Directive 91/414/EEC was submitted in accordance with Article 4 of Commission Regulation (EU) No 1141/2010⁵ within the time period provided for in that Article.
- (5) The applicants submitted the supplementary dossiers required in accordance with Article 9 of Regulation (EU) No 1141/2010. The application was found to be complete by the rapporteur Member State.

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OJ L 309, 24.11.2009, p. 1.

Commission Directive 2001/21/EC of 5 March 2001 amending Annex I to Council Directive 91/414/EEC concerning the placing of plant protection products on the market to include amitrole, diquat, pyridate and thiabendazole as active substances (OJ L 69, 10.3.2001, p. 17–21).

Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market (OJ L 230, 19.8.1991, p. 1).

Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances (OJ L 153, 11.6.2011, p. 1).

Commission Regulation (EU) No 1141/2010 of 7 December 2010 laying down the procedure for the renewal of the inclusion of a second group of active substances in Annex I to Council Directive 91/414/EEC and establishing the list of those substances (OJ L 322, 8.12.2010, p. 10).

- (6) The rapporteur Member State prepared a renewal assessment report in consultation with the co-rapporteur Member State and submitted it to the European Food Safety Authority (hereinafter 'the Authority') and the Commission on 28 September 2014.
- (7) The Authority communicated the renewal assessment report to the applicant and to the Member States for comments and forwarded the comments received to the Commission. The Authority also made the supplementary summary dossier available to the public.
- (8) On 12 November 2015 the Authority communicated to the Commission its conclusion⁶ on whether diquat can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009. The Authority identified a high risk to workers, bystanders and residents. In addition a high risk to birds was identified.
- (9) The Commission invited the applicants to submit their comments on the conclusion of the Authority and, in accordance with Article 17(1) of Regulation (EU) No 1141/2010, on the draft review report. The applicants submitted their comments, which have been carefully examined.
- (10) However, despite the arguments put forward by the applicants, the concerns related to the substance could not be eliminated.
- (11) Consequently, it has not been established that it may be expected that, with respect to one or more representative uses of at least one plant protection product containing diquat, the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are satisfied. The approval of the active substance diquat should therefore not be renewed.
- (12) Member States should be provided with time to withdraw authorisations for plant protection products containing diquat.
- (13) For plant protection products containing diquat, where Member States grant any grace period in accordance with Article 46 of Regulation (EC) No 1107/2009, that period should, at the latest, expire on 31 March 2018.
- (14) This Regulation does not prejudice the submission of a further application for diquat in accordance with Article 7 of Regulation (EC) No 1107/2009.
- (15) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1 Non-renewal of approval of active substance

The approval of the active substance diquat is not renewed.

Article 2 Transitional measures

Member States shall withdraw authorisations for plant protection products containing diquat as active substance by 31 March 2017.

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EFSA (European Food Safety Authority), 2015. Conclusion on the peer review of the pesticide risk assessment of the active substance diquat. EFSA Journal 2015;13(11):4308, 127 pp. doi:10.2903/j.efsa.2015.4308

Article 3 Grace periods

Any grace period granted by Member States in accordance with Article 46 of Regulation (EC) No 1107/2009 shall be as short as possible and shall expire on 31 March 2018 at the latest.

Article 4
Amendments to Implementing Regulation (EU) No 540/2011

In Part A of the Annex to Implementing Regulation (EU) No 540/2011, row 15 on diquat is deleted.

Article 5
Entry into force

This Regulation shall enter into force on 1 January 2017.

This Regulation shall be binding in its entirety and directly applicable in all Member States. Done at Brussels,

For the Commission The President Jean-Claude JUNCKER