

COMMISSION IMPLEMENTING REGULATION (EU) 2018/1532**of 12 October 2018****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 Commission Implementing Regulation (EU) No 540/2011****(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/EEC ⁽¹⁾, and in particular Article 20(1) and Article 78(2) thereof,

Whereas:

- (1) Commission Directive 2001/21/EC ⁽²⁾ included diquat as an active substance in Annex I to Council Directive 91/414/EEC ⁽³⁾.
- (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 540/2011 ⁽⁴⁾.
- (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 2019.
- (4) Two applications for the renewal of the inclusion of diquat in Annex I to Directive 91/414/EEC were submitted in accordance with Article 4 of Commission Regulation (EU) No 1141/2010 ⁽⁵⁾ 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 applications were found to be complete by the rapporteur Member State.
- (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 ('the Authority') and the Commission on 19 September 2014.
- (7) The Authority communicated the renewal assessment report to the applicants 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 conclusion ⁽⁶⁾ 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. The Authority and one applicant had a technical discussion on the non-dietary risk assessment after the publication of this conclusion. In November 2017, EFSA informed the applicant that the assessment was finalised considering the most appropriate scientific

⁽¹⁾ OJ L 309, 24.11.2009, p. 1.

⁽²⁾ 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).

⁽³⁾ 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).

⁽⁴⁾ 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).

⁽⁵⁾ 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⁾ 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.

approach but that the Commission might consider the need to reassess the non-dietary exposure to diquat by sending a mandate to EFSA. The Commission mandated the EFSA for this reassessment of the non-dietary exposure to diquat on 19 February 2018. On 17 April 2018 ⁽¹⁾ the Authority confirmed the high risk to bystanders and residents for all scenarios. In addition a high risk to birds was identified ⁽²⁾.

- (9) The Commission invited the applicants to submit their comments on the conclusion of the Authority, the statement by the Authority of 2018 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 with respect to one or more representative uses of at least one plant protection product containing diquat, that the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are satisfied. It is therefore appropriate not to renew the approval of the active substance diquat in accordance with Article 20(1)(b) of that Regulation.
- (12) Member States should be provided with sufficient 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 4 February 2020.
- (14) This Regulation does not prevent the submission of a further application for the approval of diquat in accordance with Article 7 of Regulation (EC) No 1107/2009.
- (15) The Standing Committee on Plants, Animals, Food and Feed has not delivered an opinion within the time limit laid down by its Chairman. An implementing act was deemed to be necessary and the chair submitted the draft implementing act to the appeal committee for further deliberation. The appeal committee did not deliver an opinion,

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 4 May 2019 at the latest.

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 by 4 February 2020 at the latest.

Article 4

Amendment 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.

⁽¹⁾ EFSA (European Food Safety Authority), 2018. Statement on non-dietary exposure on diquat. *EFSA Journal* 2018;16(4):5260, 111 pp.

⁽²⁾ 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.

*Article 5***Entry into force**

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 12 October 2018.

For the Commission
The President
Jean-Claude JUNCKER
