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)

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.

Changes to legislation: *There are outstanding changes not yet made to Commission Implementing Regulation (EU) 2018/1532. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

(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 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[(7)] the Authority confirmed the high risk to bystanders and residents for all scenarios. In addition a high risk to birds was identified[(8)].

(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: