Commission Implementing Regulation (EU) 2018/1865 of 28 November 2018 concerning the non-renewal of approval of the active substance propiconazole, 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) 2018/1865

of 28 November 2018

concerning the non-renewal of approval of the active substance propiconazole, 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 2003/70/EC[(2)] included propiconazole as 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 propiconazole, as set out in Part A of the Annex to Implementing Regulation (EU) No 540/2011, expires on 31 January 2019.

(4) An application for the renewal of the approval of propiconazole was submitted in accordance with Article 1 of Commission Implementing Regulation (EU) No 844/2012[(5)] within the time period provided for in that Article.

(5) The applicant submitted the supplementary dossiers required in accordance with Article 6 of Implementing Regulation (EU) No 844/2012. The application was 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 15 April 2015.

Changes to legislation: *There are outstanding changes not yet made to Commission Implementing Regulation (EU) 2018/1865. 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 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 14 June 2017, the Authority communicated to the Commission its conclusion[6] on whether propiconazole can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009.

(9) The Authority referred to the opinion[7] of the Risk Assessment Committee of the European Chemicals Agency, adopted on 9 December 2016 pursuant to Article 37(4) of Regulation (EC) No 1272/2008 of the European Parliament and of the Council[8], which proposed that propiconazole be classified as toxic for reproduction category 1B in accordance with that Regulation. Commission Regulation (EU) 2018/1480[9] consequently amended Annex VI to Regulation (EC) No 1272/2008 and classified propiconazole as toxic for reproduction category 1B.

(10) Based on the data available in the dossier the Authority concluded that Maximum Residue Levels ('MRLs') in accordance with Regulation (EC) No 396/2005 of the European Parliament and of the Council[10] could not be confirmed for plant and animal products since data on the magnitude and toxicity of metabolites that are included in the residue definition for risk assessment was not available. The current MRLs for the proposed uses of propiconazole are above the default value in the meaning of Article 18(1)(b) of Regulation (EC) No 396/2005. For those reasons, it cannot be considered that exposure of humans to the active substance is negligible. Therefore, the requirements set out in Point 3.6.4 of Annex II to Regulation (EC) No 1107/2009 are not fulfilled.

(11) A critical concern was identified by the Authority in relation to the contamination of groundwater by metabolites of propiconazole. In particular, metabolite NOA436613 is predicted to occur above the parametric value of 0,1 μg/L in all pertinent scenarios for all proposed uses of propiconazole, even when the substance is used biennially. Two other metabolites are predicted to occur in groundwater above 0,1 μg/L in the majority of pertinent scenarios. These metabolites are considered *a priori* of concern since it can not be excluded that they do not share the same potential for reproductive toxicity as parent propiconazole. Therefore, it cannot currently be established that the presence of metabolites of propiconazole in groundwater will not result in unacceptable effects on groundwater and in harmful effects on human health in the meaning of Article 4(3)(b) and (e) of Regulation (EC) No 1107/2009.

(12) Additionally, the Authority concluded that propiconazole caused toxic effects on endocrine organs. However, the scientific assessment to determine the endocrine disrupting potential of propiconazole could not be finalised by the Authority based on the information available in the dossier. Furthermore, the assessment of several aspects necessary to conclude on the risk to consumers through dietary intake could not be finalised based on the information available in the dossier.

(13) Given these concerns, it is not possible to provide for an approval in accordance with Article 4(7) to Regulation (EC) No 1107/2009.

***Changes to legislation:** There are outstanding changes not yet made to Commission Implementing Regulation (EU) 2018/1865. 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*

(14) The Commission invited the applicant to submit its comments on the conclusion of the Authority and, in accordance with the third subparagraph of Article 14(1) of Implementing Regulation (EU) No 844/2012, on the draft renewal report. The applicant submitted its comments, which have been carefully examined.

(15) However, despite the arguments put forward by the applicant, the concerns related to the substance could not be eliminated.

(16) Consequently, it has not been established with respect to one or more representative uses of at least one plant protection product containing propiconazole 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 propiconazole in accordance with Article 20(1)(b) of that Regulation.

(17) Implementing Regulation (EU) No 540/2011 should therefore be amended accordingly.

(18) Member States should be given sufficient time to withdraw authorisations for plant protection products containing propiconazole.

(19) For plant protection products containing propiconazole, 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 19 March 2020.

(20) Commission Implementing Regulation (EU) 2018/84[(11)] extended the expiry date of propiconazole to 31 January 2019 in order to allow the renewal process to be completed before the expiry of the approval period of that substance. Given that a decision is taken ahead of this extended expiry date, this Regulation should apply as soon as possible.

(21) This Regulation does not prevent the submission of a further application for the approval of propiconazole in accordance with Article 7 of Regulation (EC) No 1107/2009.

(22) 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 propiconazole is not renewed.

Article 2

Amendment to Implementing Regulation (EU) No 540/2011

In Part A of the Annex to Implementing Regulation (EU) No 540/2011, row 58, on propiconazole, is deleted.