Commission Implementing Regulation (EU) 2019/677 of 29 April 2019 concerning the non-renewal of the approval of the active substance chlorothalonil, 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) 2019/677

of 29 April 2019

concerning the non-renewal of the approval of the active substance chlorothalonil, 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 2005/53/EC[(2)] included chlorothalonil 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 chlorothalonil, as set out in Part A of the Annex to Implementing Regulation (EU) No 540/2011, expires on 31 October 2019.

(4) An application for the renewal of the approval of chlorothalonil 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 applicants 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 2 September 2016.

Changes to legislation: *There are outstanding changes not yet made to Commission Implementing Regulation (EU) 2019/677. 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 6 December 2017 the Authority communicated to the Commission its conclusion[6] on whether chlorothalonil can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009.

(9) A critical concern was identified by the Authority in relation to the contamination of groundwater by metabolites of chlorothalonil. In particular, metabolites R417888, R419492, R471811, SYN507900, M3, M11, M2, M7 and M10 are predicted to occur above the parametric value of 0,1 μg/L in all pertinent scenarios for all proposed uses of chlorothalonil. Therefore, it cannot currently be established that the presence of metabolites of chlorothalonil in groundwater will not result in unacceptable effects on groundwater and in harmful effects on human health as required by Article 4(3)(b) of Regulation (EC) No 1107/2009. Furthermore, the Authority could not exclude a genotoxicity concern for residues to which consumers will be exposed and identified a high risk to amphibians and fish for all the uses evaluated.

(10) Furthermore, several areas of the risk assessment could not be finalised due to insufficient data in the dossier. In particular, the assessment of consumer risk from dietary exposure could not be completed because of lack of data to confirm the definition of the residue in plants and the livestock exposure assessment, including the toxicological assessment of a metabolite.

(11) Additionally, chlorothalonil is classified as carcinogen category 2 in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council[7] while in the conclusion of the Authority it is indicated that chlorothalonil should be classified as carcinogen category 1B. For the representative uses considered, residue levels as referred to in point (b) of Article 18(1) of Regulation (EC) No 396/2005 could not be confirmed for plant and animal products due to lack of data on the magnitude and toxicity of metabolites that are included in the residue definition for risk assessment. Consequently, the requirement set out in Point 3.6.3 of Annex II to Regulation (EC) No 1107/2009 is not fulfilled.

(12) The Commission invited the applicants to submit their 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, to submit comments on the draft renewal report. The applicants submitted comments, which have been carefully examined.

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

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

***Changes to legislation:** There are outstanding changes not yet made to Commission Implementing Regulation (EU) 2019/677. 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*

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

(16) Member States should be allowed sufficient time to withdraw authorisations for plant protection products containing chlorothalonil.

(17) For plant protection products containing chlorothalonil, 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 20 May 2020.

(18) Commission Implementing Regulation (EU) 2018/1262[8] extended the approval period of chlorothalonil to 31 October 2019 in order to allow the renewal process to be completed before the expiry of the approval of that substance. However, given that a decision on the non-renewal of the approval is taken ahead of that extended expiry date, this Regulation should apply as soon as possible.

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

(20) 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 chlorothalonil is not renewed.

Article 2

Amendments to Implementing Regulation (EU) No 540/2011

In Part A of the Annex to Implementing Regulation (EU) No 540/2011, row 101, on chlorothalonil, is deleted.

Article 3

Transitional measures

Member States shall withdraw authorisations for plant protection products containing chlorothalonil as active substance by 20 November 2019 at the latest.

Article 4

Grace period

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 20 May 2020 at the latest.