Commission Implementing Regulation (EU) 2017/2091 of 14 November 2017 concerning the non-renewal of approval of the active substance iprodione, 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) 2017/2091

of 14 November 2017

concerning the non-renewal of approval of the active substance iprodione, 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 2003/31/EC[(2)] included iprodione 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 iprodione, as set out in Part A of the Annex to Implementing Regulation (EU) No 540/2011, expires on 31 October 2018.

(4) An application for the renewal of the approval of iprodione 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 3 November 2015.

Changes to legislation: *There are outstanding changes not yet made to Commission Implementing Regulation (EU) 2017/2091. 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 8 June 2016 the Authority communicated to the Commission its conclusion[6] on whether iprodione can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009. The Authority concluded that there is a high potential for the representative uses assessed to result in groundwater exposure above the parametric drinking water limit of 0,1 μg/l by the relevant metabolites of iprodione in situations represented by all pertinent groundwater scenarios; one relevant metabolite is even predicted to exceed 0,75 μg/l in all pertinent groundwater scenarios. In addition, the Authority also concluded that there is a high long-term risk to aquatic organisms.

(9) Furthermore, in respect of one metabolite, found as a residue in plants and as an impurity in the technical material, the Authority concluded that the genotoxic potential cannot be excluded and therefore the setting of reference values for that metabolite cannot be confirmed based on the information available. Moreover, based on the available information, the dietary risk assessment could not be finalised as it is not possible to establish residue definitions for risk assessment; nevertheless, an acute consumer risk could not be excluded. Finally, the long-term risk assessment for wild mammals for all the relevant routes of exposure could not be finalised, based on the information submitted in the dossier.

(10) Additionally, iprodione 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 iprodione should be classified as carcinogen category 1B and as toxic for reproduction category 2. For the representative uses considered, residue levels exceed the default value as referred to in point (b) of Article 18(1) of Regulation (EC) No 396/2005 of the European Parliament and of the Council[8]. Consequently, the requirement set out in Points 3.6.3 and 3.6.5 of Annex II to Regulation (EC) No 1107/2009 is not fulfilled.

(11) The Commission invited the applicant to submit its comments on the conclusion of the Authority and, in accordance with the third paragraph 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.

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

(13) Based on the concerns identified, 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 iprodione in accordance with Article 20(1)(b) of that Regulation.

(14) Member States should be given time to withdraw authorisations for plant protection products containing iprodione.

***Changes to legislation:** There are outstanding changes not yet made to Commission Implementing Regulation (EU) 2017/2091. 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) For plant protection products containing iprodione, 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 5 June 2018.

(16) Commission Implementing Regulation (EU) 2017/1511[(9)] extended the expiry date of iprodione to 31 October 2018 in order to allow the renewal process to be completed before the expiry of the approval of that substance. However, given that a decision has been taken ahead of that extended expiry date, this Regulation should apply as soon as possible.

(17) This Regulation does not prejudice the submission of a further application for the approval of iprodione pursuant to Article 7 of Regulation (EC) No 1107/2009.

(18) 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 iprodione 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 50, on iprodione, is deleted.

Article 3

Transitional measures

Member States shall withdraw authorisations for plant protection products containing iprodione as active substance by 5 March 2018 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 5 June 2018 at the latest.