Commission Implementing Regulation (EU) 2016/872 of 1 June 2016 concerning the non-renewal of approval of the active substance isoproturon, 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) 2016/872

of 1 June 2016

concerning the non-renewal of approval of the active substance isoproturon, 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 2002/18/EC[(2)] included isoproturon 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 isoproturon, as set out in Part A of the Annex to Implementing Regulation (EU) No 540/2011, expires on 30 June 2016.

(4) An application for the renewal of the inclusion of isoproturon in Annex I to Directive 91/414/EEC was 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 applicant submitted the supplementary dossiers required in accordance with Article 9 of Regulation (EU) No 1141/2010. 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 (hereinafter ‘the Authority’) and the Commission on 28 February 2014.

Changes to legislation: *There are outstanding changes not yet made to Commission Implementing Regulation (EU) 2016/872. 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 5 August 2015 the Authority communicated to the Commission its conclusion[(6)] on whether isoproturon 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 isoproturon in situations represented by all pertinent groundwater scenarios. In addition, a high long-term risk to birds and wild mammals and a high risk to aquatic organisms from isoproturon were identified.

(9) Based on these identified risks, 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 isoproturon in accordance with Article 20(1)(b) of Regulation (EC) No 1107/2009.

(10) Additionally, isoproturon is classified as carcinogenic category 2 in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council[(7)] and in the conclusion of the Authority it is indicated that during the peer review it was proposed that isoproturon should be classified as toxic for reproduction category 2.

(11) Given the concerns detailed in recital 8, the derogation provided for in Article 4(7) to Regulation (EC) No 1107/2009 does not apply. The application of that derogation is also excluded on the grounds that it has not been established that any of the criteria set out in point 3.6.3, 3.6.4, 3.6.5 or 3.8.2 of Annex II to Regulation (EC) No 1107/2009 are not satisfied.

(12) The Commission invited the applicant to submit its comments on the conclusion of the Authority and, in accordance with Article 17(1) of Regulation (EU) No 1141/2010, on the draft review report. The applicant submitted its comments, which have been carefully examined.

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

(14) Member States should be provided with time to withdraw authorisations for plant protection products containing isoproturon.

(15) For plant protection products containing isoproturon, 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 30 September 2017.

(16) This Regulation does not prejudice the submission of a further application for isoproturon in accordance with Article 7 of Regulation (EC) No 1107/2009.

(17) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,