Commission Implementing Regulation (EU) 2016/864 of 31 May 2016 concerning the non-renewal of approval of the active substance triasulfuron, 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) 2016/864

of 31 May 2016

concerning the non-renewal of approval of the active substance triasulfuron, 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 2000/66/EC[(2)] included triasulfuron 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 triasulfuron, 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 triasulfuron 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 14 October 2013.

Changes to legislation: *There are outstanding changes not yet made to Commission Implementing Regulation (EU) 2016/864. 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 January 2015 the Authority communicated to the Commission its conclusion[(6)] on whether triasulfuron can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009. The Authority concluded that, due to an incomplete genotoxicity assessment of triasulfuron and its manufacturing impurity CGA 150829, it has not been possible to set the health based toxicological reference values. As a consequence, the assessment of the risk to consumers, operators, workers and bystanders could not be conducted. Furthermore, the Authority concluded that in specific geoclimatic situations 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, either by triasulfuron itself or by its soil metabolite CGA 150829. In addition, a high risk to aquatic plants was identified.

(9) 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.

(10) However, despite the arguments put forward by the applicant, the concerns referred to in recital 8 could not be eliminated.

(11) Consequently, it has not been established that it may be expected that, with respect to one or more representative uses of at least one plant protection product containing triasulfuron, the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are satisfied. The approval of the active substance triasulfuron should therefore not be renewed.

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

(13) For plant protection products containing triasulfuron, 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.

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

(15) 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 triasulfuron is not renewed.