Commission Implementing Regulation (EU) 2017/1496 of 23 August 2017 concerning the non-renewal of approval of the active substance DPX KE 459 (flupyrsulfuron-methyl), 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) 2017/1496

of 23 August 2017

concerning the non-renewal of approval of the active substance DPX KE 459 (flupyrsulfuron-methyl), 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 2001/49/EC[(2)] included DPX KE 459 (flupyrsulfuron-methyl) 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 DPX KE 459 (flupyrsulfuron-methyl), as set out in Part A of the Annex to Implementing Regulation (EU) No 540/2011, expires on 30 June 2018.

(4) An application for the renewal of the inclusion of DPX KE 459 (flupyrsulfuron-methyl) 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.

Changes to legislation: *There are outstanding changes not yet made to Commission Implementing Regulation (EU) 2017/1496. 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*

(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 17 September 2013.

(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 30 September 2016 the Authority communicated to the Commission its conclusion[(6)] on whether DPX KE 459 (flupyrsulfuron-methyl) can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009. Based on the studies assessed, the Authority concluded that the parent substance has certain intrinsic toxicological properties, in particular as regards to carcinogenicity and reproductive toxicity. In the view of the Authority this information even justifies the classification as carcinogen category 2 and as toxic for reproduction category 2 in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council[(7)]. The Authority concluded that considering the representative uses assessed, there is a high potential to result in groundwater exposure above the parametric drinking water limit of 0,1 μg/L by several metabolites of DPX KE 459 (flupyrsulfuron-methyl) in situations represented by all pertinent groundwater scenarios.

(9) Regardless of the classification proposed by the Authority, given the intrinsic toxicological properties of the parent substance shown in the studies, in particular in relation to carcinogenicity and reproductive toxicity, the presence of the metabolites in groundwater is of particular concern since it has not be demonstrated that these metabolites do not share the same intrinsic properties. Therefore it cannot currently be established that the presence of the metabolites in groundwater will not result in unacceptable effects on groundwater and in harmful effects on human health.

(10) Furthermore, the Authority concluded that the groundwater exposure assessment could not be finalised based on the available information for metabolite IN-JE127, the genotoxic potential of which cannot be excluded.

(11) Given the uncertainty about the presence of that metabolite in groundwater, unacceptable effects on groundwater and harmful effects on human health cannot currently be excluded.

(12) Moreover, the Authority concluded that there is a high risk to aquatic organisms, in particular for algae and aquatic plants, from exposure to DPX KE 459 (flupyrsulfuron-methyl).

(13) Based on these risks identified in recitals 9, 11 and 12, 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 DPX KE 459 (flupyrsulfuron-methyl) in accordance with Article 20(1)(b) of that Regulation.

(14) Given the risks detailed in recitals 9, 11 and 12, the derogation provided for in Article 4(7) of Regulation (EC) No 1107/2009 does not apply. The application of that

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derogation is also excluded on the grounds that it has not been established that any of the criteria set out in points 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.

(15) 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.

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

(17) Member States should be given time to withdraw authorisations for plant protection products containing DPX KE 459 (flupyrsulfuron-methyl).

(18) For plant protection products containing DPX KE 459 (flupyrsulfuron-methyl), 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 13 December 2018.

(19) This Regulation does not prejudice the submission of a further application for DPX KE 459 (flupyrsulfuron-methyl) 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 DPX KE 459 (flupyrsulfuron-methyl) 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 19 on DPX KE 459 (flupyrsulfuron-methyl) is deleted.

Article 3

Transitional measures

Member States shall withdraw authorisations for plant protection products containing DPX KE 459 (flupyrsulfuron-methyl) as active substance by 13 December 2017 at the latest.