Commission Implementing Regulation (EU) 2017/2324 of 12 December 2017 renewing the approval of the active substance glyphosate 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 the Annex to Commission Implementing Regulation (EU) No 540/2011 (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2017/2324

of 12 December 2017

renewing the approval of the active substance glyphosate 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 the Annex to 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) thereof,

Whereas:

(1) Commission Directive 2001/99/EC[(2)] included glyphosate 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 glyphosate, as set out in Part A of the Annex to Implementing Regulation (EU) No 540/2011, expires on 15 December 2017.

(4) An application for the renewal of the inclusion of the active substance glyphosate 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 20 December 2013.

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(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) Following the findings of the International Agency for Research on Cancer published on 20 March 2015 as regards the carcinogenic potential of glyphosate, on 29 April 2015 the Commission mandated the Authority to review the underlying information and to include those findings in its conclusion by 13 August 2015.

(9) To allow for an appropriate evaluation of the information[(6)] from the International Agency for Research on Cancer and of the extraordinarily high number of comments received from Member States and the public, the Commission extended the deadline for the submission of the Authority's conclusion to 30 October 2015.

(10) On 30 October 2015[(7)], the Authority communicated to the Commission its conclusion on whether glyphosate can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009. The Commission presented the draft review report for glyphosate to the Standing Committee on Plants, Animals, Food and Feed on 28 January 2016.

(11) The applicant was given the possibility to submit comments on the draft review report.

(12) The discussions in the Standing Committee on Plants, Animals, Food and Feed on 18 and 19 May 2016 showed that in the specific situation of glyphosate a number of Member States, in their role as risk managers, considered that it was appropriate to have an opinion of the Committee for Risk Assessment of the European Chemicals Agency (hereinafter 'the Agency') on the harmonised classification as regards carcinogenicity of glyphosate, before taking a decision on a renewal of the approval because such an opinion could be relevant for the approval based on the criteria set out in Regulation (EC) No 1107/2009.

(13) The possible renewal of the approval of glyphosate was also extensively discussed outside of the Standing Committee on Plants, Animals, Food and Feed. On 13 April 2016[(8)] and on 24 October 2017[(9)], the European Parliament adopted Resolutions on the different draft Commission Implementing Regulations renewing the approval of the active substance glyphosate, and on 6 October 2017 the European Commission officially received a successful European Citizens' Initiative (ECI)[(10)], referring specifically to glyphosate in one of its three aims, with validated signatures from at least one million European citizens in at least seven Member States.

(14) As an opinion of the Committee for Risk Assessment of the Agency on the harmonised classification as regards carcinogenicity of glyphosate was deemed necessary, on 17 March 2016, the rapporteur Member State submitted a dossier in accordance with Article 37 of Regulation (EC) No 1272/2008 of the European Parliament and of the Council[(11)], including for the hazard class on carcinogenicity. In view of the time required to assess such a dossier, the approval period of the active substance was extended until 6 months from the date of receipt of the opinion of the Committee for Risk Assessment of the Agency by the Commission but however until 31 December 2017 at the latest by Commission Implementing Regulation (EU) 2016/1056[(12)]. In the

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meantime, the conditions of approval of the active substance were amended in the light of new scientific and technical knowledge by Commission Implementing Regulation (EU) 2016/1313[(13)].

(15) The Committee for Risk Assessment of the Agency adopted its opinion[(14)] on 15 March 2017 and forwarded it to the Commission on 15 June 2017. The Commission published a Notice[(15)] confirming the date of its receipt in the *Official Journal of the European Union* on 28 June 2017. In its opinion, the Committee for Risk Assessment of the Agency concluded by consensus that on the basis of the information currently available, no hazard classification for carcinogenicity is justified for glyphosate.

(16) In its conclusion of October 2015, the Authority identified a data gap to rule out potential endocrine activity observed in one study. Pertinent data became available too late to be included in the peer review. On 27 September 2016 the Commission asked the Authority to assess that additional information. On 7 September 2017[(16)] the Authority communicated to the Commission its conclusion on the potential endocrine disrupting properties of glyphosate. In its conclusion, the Authority confirmed that the data gap had been adequately addressed as the weight of evidence indicates that glyphosate does not have endocrine disrupting properties through oestrogen, androgen, thyroid or steroidogenesis mode of action based on a comprehensive database available in the toxicology area. The available ecotoxicology studies did not contradict this conclusion.

(17) It has been established with respect to one or more representative uses of at least one plant protection product containing the active substance glyphosate that the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are satisfied. Those approval criteria are therefore deemed to be satisfied.

(18) It is therefore appropriate to renew the approval of glyphosate.

(19) While a large amount of information on the active substance glyphosate already exists and has been assessed leading to the conclusion that the approval of the active substance glyphosate should be renewed, additional information on glyphosate is being published at an exceptionally high rate compared to other active substances. Therefore possibilities of rapid future developments in science and technology should be taken into account when deciding on the length of the approval period of glyphosate, also bearing in mind the fact that glyphosate is one of the most widely used herbicides in the Union.

(20) In light of these specificities and other legitimate factors referred to in the recitals above and bearing in mind the need to ensure a level of safety and protection consistent with the high level of protection that is sought within the Union, from a risk management perspective it is appropriate to provide for a renewal of the approval of glyphosate for a period of five years ensuring a priority re-assessment of glyphosate over other active substances.

(21) In accordance with Article 14(1) of Regulation (EC) No 1107/2009 in conjunction with Article 6 thereof and in the light of current scientific and technical knowledge, it is necessary to include certain conditions and restrictions.

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(22) In accordance with Article 20(3) of Regulation (EC) No 1107/2009, in conjunction with Article 13(4) thereof, the Annex to Implementing Regulation (EU) No 540/2011 should be amended accordingly.

(23) Taking into account that the current approval of glyphosate expires on 15 December 2017, this Regulation should enter into force as soon as possible.

(24) This Regulation should apply from the day after the date of expiry of the approval of the active substance glyphosate as referred to in recital 3.

(25) The Standing Committee on Plants, Animals, Food and Feed has not delivered an opinion within the time limit laid down by its Chairman. An implementing act was deemed to be necessary and the chair submitted the draft implementing act to the appeal committee for further deliberation. The measures provided for in this Regulation are in accordance with the opinion of the appeal committee,

HAS ADOPTED THIS REGULATION:

Article 1

Renewal of the approval of active substance

The approval of the active substance glyphosate, as specified in Annex I, is renewed subject to the conditions laid down in that Annex.

Article 2

Amendments to Implementing Regulation (EU) No 540/2011

The Annex to Implementing Regulation (EU) No 540/2011 is amended in accordance with Annex II to this Regulation.

Article 3

Entry into force and date of application

This Regulation shall enter into force on the day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 16 December 2017.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

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Done at Strasbourg, 12 December 2017.

For the Commission

The President

Jean-Claude JUNCKER