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COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval period of the active substance glyphosate

(Text with EEA relevance)

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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 the first paragraph of Article 17 thereof,

Whereas:

(1) Part A of the Annex to Commission Implementing Regulation (EU) No 540/2011[2] sets out the active substances deemed to have been approved under Regulation (EC) No 1107/2009.

(2) The approval period of the active substance glyphosate will expire on 30 June 2016. An application for the renewal of the inclusion of that substance in Annex I to Council Directive 91/414/EEC[3] was submitted in accordance with Article 4 of Commission Regulation (EU) No 1141/2010[4].

(3) Due to the fact that the assessment of the substance and the decision on a renewal of the approval have been delayed for reasons beyond the control of the applicant, the approval of the active substance is likely to expire before a decision has been taken on its renewal.

(4) Following the findings of the International Agency for Research on Cancer as regards the carcinogenic potential of glyphosate, the Commission on 29 April 2015 mandated the European Food Safety Authority (hereinafter 'the Authority') to review the underlying information and to include those findings in its conclusion. In the context of the evaluation procedure under Regulation (EC) No 1107/2009, the Authority concluded that glyphosate is unlikely to pose a carcinogenic hazard to humans and that the available evidence would not support the harmonised classification of glyphosate

[1] OJ L 309, 24.11.2009, p. 1.

[2] Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances (OJ L 153, 11.6.2011, p. 1).

[3] Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market (OJ L 230, 19.8.1991, p. 1).

[4] Commission Regulation (EU) No 1141/2010 of 7 December 2010 laying down the procedure for the renewal of the inclusion of a second group of active substances in Annex I to Council Directive 91/414/EEC and establishing the list of those substances (OJ L 322, 8.12.2010, p. 10).

under Regulation (EC) No 1272/2008[5], as regards its carcinogenic potential. In this context the Authority recalled, however, that its proposals for classification made in the context of the evaluation procedure under Regulation (EC) No 1107/2009 are not formal proposals for harmonised classification in accordance with Regulation (EC) No 1272/2008.

(5) On 22 July 2015[6] the rapporteur Member State indicated its intention to submit a dossier concerning the harmonised classification of glyphosate, including for the hazard class on carcinogenicity, in accordance with Article 37 of Regulation (EC) No 1272/2008. On 17 March 2016 the rapporteur Member State submitted that dossier to the European Chemicals Agency, which is to give its opinion in accordance with Article 37(4) of Regulation (EC) No 1272/2008.

(6) The findings of the International Agency for Research on Cancer and the proposal for classification of the Authority as regards the carcinogenic potential of glyphosate are divergent. Morover, the procedure for harmonised classification of glyphosate was already initiated. 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 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.

(7) In view of the time required to assess the dossier concerning the harmonised classification, it is necessary to extend the approval period of the active substance until 6 months from the date of receipt of the opinion of the Committee for Risk Assessment of the European Chemicals Agency by the Commission but however until 31 December 2017 at the latest. Once the Commission receives the opinion of the Committee for Risk Assessment of the European Chemicals Agency, the Commission will communicate the date of the receipt in the *Official Journal of the European Union*.

(8) In view of the aim of the first paragraph of Article 17 of Regulation (EC) No 1107/2009, in the case where, following the receipt of the opinion of the Committee for Risk Assessment of the European Chemicals Agency, the Commission would adopt a Regulation providing that the approval of glyphosate is not renewed because the approval criteria are not satisfied, the Commission will set the expiry date of the approval period at the date of the entry into force of the Regulation providing that the approval of glyphosate is not renewed, even if that date is earlier than the expiry date of approval.

(9) Taking into account the extension of the approval period of glyphosate described in the preceding recitals, and in light of the concerns identified by the Authority as regards the use of the co-formulant POE-tallowamine (CAS No 61791-26-2) in plant protection products containing glyphosate, the Commission will initiate a review of

[5] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p.1).

[6] ECHA Registry of Intentions. Available online: echa.europa.eu/web/guest/addressing-chemicals-of-concern/registry-of-intentions.

the approval of glyphosate according to Article 21 of Regulation (EC) No 1107/2009, as soon as possible.

(10) Implementing Regulation (EU) No 540/2011 should therefore be amended accordingly.

(11) Taking into account that the current approval of glyphosate expires on 30 June 2016, this Regulation should enter into force as soon as possible.

(12) 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
Amendment to Implementing Regulation (EU) No 540/2011

In the sixth column, 'expiration of approval', of entry 25 on glyphosate in Part A of the Annex to Implementing Regulation (EU) No 540/2011, the words "30 June 2016" are replaced by the words "6 months from the date of receipt of the opinion of the Committee for Risk Assessment of the European Chemicals Agency by the Commission or 31 December 2017, whichever is the earlier".

Article 2
Entry into force

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

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

Done at Brussels,

For the Commission
The President
Jean-Claude JUNCKER.