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[...] (2022) **XXX** draft

**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)

# 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)

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<sup>1</sup>, and in particular Article 17, first paragraph, thereof,

Whereas:

- (1) Part B of the Annex to Commission Implementing Regulation (EU) No 540/2011<sup>2</sup> sets out the active substances that have been approved under Regulation (EC) No 1107/2009.
- (2) The approval of the active substance glyphosate expires on 15 December 2022. An application for the renewal of the approval of that substance was submitted pursuant to Article 1 of Commission Implementing Regulation (EU) No 844/2012<sup>3</sup> on 12 December 2019.
- (3) Commission Implementing Regulation (EU) 2019/724<sup>4</sup> appointed France, Hungary, the Netherlands and Sweden to act jointly as rapporteur Member State for the renewal of approval procedure for glyphosate. The four Member States formed the Assessment Group on Glyphosate ('AGG'). On 18 August 2020, the AGG confirmed the admissibility of the application for renewal. The AGG submitted its initial draft Renewal Assessment Report (RAR) to the European Food Safety Authority ('the Authority') on 15 June 2021.

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<sup>1</sup> OJ L 309, 24.11.2009, p. 1.

<sup>2</sup> 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).

<sup>3</sup> Commission Implementing Regulation (EU) No 844/2012 of 18 September 2012 setting out the provisions necessary for the implementation of the renewal procedure for active substances, as provided for in Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market (OJ L 252, 19.9.2012, p. 26).

Although Implementing Regulation (EU) No 844/2012 was repealed, it continues to apply to the procedure for the renewal of the approval of glyphosate in accordance with Article 17 of Implementing Regulation (EU) 2020/1740 (OJ L 392, 23.11.2020, p. 20).

<sup>4</sup> Commission Implementing Regulation (EU) 2019/724 of 10 May 2019 amending Implementing Regulation (EU) No 686/2012 as regards the nomination of rapporteur Member States and co-rapporteur Member States for the active substances glyphosate, lambda-cyhalothrin, imazamox and pendimethalin and amending Implementing Regulation (EU) No 844/2012 as regards the possibility that a group of Member States assumes jointly the role of the rapporteur Member State (OJ L 124, 13.5.2019, p. 32).

- (4) During the public consultation on the initial draft Renewal Assessment Report on glyphosate, a very high number of comments were submitted to the Authority. Furthermore, on 14 March 2022, the Authority requested a significant amount of additional information from the applicant, which has been submitted in due time. In addition, the AGG and the Authority identified a very high number of points to be discussed by experts during the peer review. The evaluation of the additional information by the AGG and the peer review carried out pursuant to Article 13(1) of Regulation (EU) No 844/2012 by the Authority requires significantly more time to be completed.
- (5) Accordingly, on 10 May 2022, the Authority and the European Chemicals Agency ('ECHA') informed the Commission that the adoption of the conclusion on the peer review of the risk assessment of glyphosate by the Authority would be delayed with the adoption date foreseen not before July 2023. This means that no decision on the renewal of the approval of glyphosate can be taken before 15 December 2022.
- (6) Given that the assessment of the active substance glyphosate has therefore been delayed for reasons beyond the control of the applicant, it is necessary to extend the approval period of that active substance to provide the time necessary to complete the assessment required in order to take a decision on the application for a renewal of its approval.
- (7) In case the Commission is to adopt a Regulation providing that the approval of glyphosate is not renewed because the approval criteria are not satisfied, the Commission is to set the expiry date at the same date as before this Regulation or at the date of the entry into force of the Regulation providing that the approval of glyphosate is not renewed, whichever date is later. In case the Commission is to adopt a Regulation providing for the renewal of the approval of glyphosate, the Commission will endeavour to set, as appropriate under the circumstances, the earliest possible application date.
- (8) Implementing Regulation (EU) No 540/2011 should therefore be amended accordingly.
- (9) Taking into account that the current approval of glyphosate expires on 15 December 2022, this Regulation should enter into force as soon as possible.
- (10) 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 Part B of the Annex to Implementing Regulation (EU) No 540/2011, in the sixth column 'Expiration of approval' of entry 118, glyphosate, the date is replaced by '15 December 2023'.

*Article 2*

***Entry into force***

This Regulation shall enter into force on the seventh day following 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*  
*Ursula VON DER LEYEN*