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[...] (2023) **XXX** draft

COMMISSION IMPLEMENTING REGULATION (EU) .../...

of **XXX**

renewing the approval of the active substance glyphosate in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council and amending Commission Implementing Regulation (EU) No 540/2011

(Text with EEA relevance)

This draft has not been adopted or endorsed by the European Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission.

COMMISSION IMPLEMENTING REGULATION (EU) .../...

of **XXX**

renewing the approval of the active substance glyphosate in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council 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/EEC¹, and in particular Article 20(1) thereof,

Whereas:

- (1) Commission Implementing Regulation (EU) 2017/2324² renewed the approval of the active substance glyphosate until 15 December 2022 and included it in the list in Part B of the Annex to Commission Implementing Regulation (EU) No 540/2011³.
- (2) On 13 December 2019, the applicant (the Glyphosate Renewal Group) submitted an application for the renewal of the approval of the active substance glyphosate to the Assessment Group on Glyphosate (AGG), composed of France, Hungary, the Netherlands and Sweden who were appointed to act jointly as rapporteur Member States⁴, in accordance with Article 1 of Commission Implementing Regulation (EU) No 844/2012⁵ and within the time period provided for in that Article.

¹ OJ L 309, 24.11.2009, p. 1.

² 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 (OJ L 333, 15.12.2017, p. 10).

³ 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).

⁴ 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).

⁵ 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), which continues to apply to the procedure for the renewal of the approval of this active substance pursuant to Article 17 of Commission Implementing Regulation (EU) 2020/1740 of 20 November 2020 setting out the provisions necessary for the implementation of the renewal procedure for active substances, as provided for in

- (3) The applicant submitted the supplementary dossiers to the AGG, the Commission and the European Food Safety Authority (the 'Authority') in accordance with Article 6 of Implementing Regulation (EU) No 844/2012. The application was found to be admissible by the AGG.
- (4) On 15 June 2021, the AGG submitted to the Authority and the European Chemicals Agency (the 'Agency') its assessments of the active substance glyphosate in the form of a draft renewal assessment report and a report containing a proposal for harmonised classification and labelling under Regulation (EC) No 1272/2008 of the European Parliament and of the Council⁶, respectively. In its draft renewal assessment report, the AGG proposed to renew the approval of glyphosate based on the risk assessment it performed.
- (5) The Authority made the supplementary summary dossier available to the public. It also circulated the draft renewal assessment report to the applicant and to the Member States for the submission of comments and launched a public consultation on it. The Authority forwarded the comments received to the Commission.
- (6) The AGG, together with the Authority, considered all comments received on the draft renewal assessment report and the responses of the applicant to them. In accordance with Article 13(3) of Implementing Regulation (EU) No 844/2012, the Authority requested additional information from the applicant.
- (7) Given the volume of new information received through the public consultation, the work required by the AGG following the evaluation of the comments received, and the need to evaluate the additional information requested from the applicant by the Authority, the AGG indicated that more time was needed to provide an updated draft renewal assessment report. Accordingly, on 10 May 2022, the Authority and the Agency announced that the delivery of the Authority's conclusion would be delayed until July 2023.
- (8) On 30 May 2022, the Committee for Risk Assessment of the Agency adopted its opinion on the harmonised classification and labelling of glyphosate⁷, in which it concluded that the existing classification of glyphosate, established under Regulation (EC) No 1272/2008, should be maintained. The Committee also confirmed that, based on the latest scientific and technical information available, and in light of the criteria laid down in that Regulation, glyphosate does not meet the criteria to be classified as carcinogenic, mutagenic or toxic for reproduction.
- (9) Given that the assessment of glyphosate was delayed for reasons beyond the control of the applicant, the Commission was obliged to extend, in accordance with Article 17 of

Regulation (EC) No 1107/2009 of the European Parliament and of the Council, and repealing Commission Implementing Regulation (EU) No 844/2012 (OJ L 392, 23.11.2020, p. 20).

⁶ 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).

⁷ European Chemicals Agency (2022). Opinion of the Committee for Risk Assessment proposing harmonised classification and labelling of glyphosate (ISO); N-(phosphonomethyl)glycine (EC Number: 213-997-4; CAS Number: 1071-83-6). <https://echa.europa.eu/registry-of-clh-intentions-until-outcome/-/dislist/details/0b0236e185e41a77>.

Regulation (EC) No 1107/2009, the approval period of glyphosate by a period of one year, until 15 December 2023⁸.

- (10) On 6 July 2023, the Authority communicated to the Commission the conclusion of its scientific risk assessment on whether the active substance glyphosate can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009⁹.
- (11) The Commission invited the applicant to submit its comments on the conclusion of the Authority and, in accordance with Article 14(1), third subparagraph, of Implementing Regulation (EU) No 844/2012, on the draft renewal report. The applicant submitted its comments, which have been carefully examined and taken into consideration.
- (12) The Commission presented the draft renewal report on glyphosate and a draft of this Regulation to the Standing Committee on Plants, Animals, Food and Feed on 13 July 2023 and on 22 September 2023, respectively.
- (13) 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. It is therefore appropriate to renew the approval of glyphosate.
- (14) 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 and the outcome of the risk assessment, it is, however, necessary to provide for certain conditions and restrictions, including the submission of confirmatory information.
- (15) It is, in particular, appropriate to set maximum limits for certain toxicologically relevant impurities that might be present in the technical material as manufactured to ensure that the active substance glyphosate used in plant protection products does not lead to any harmful effects on human health.
- (16) Based on the findings of the risk assessment, it is also necessary to require Member States to pay particular attention to certain technical aspects when carrying out assessments for the authorisation of plant protection products containing glyphosate.
- (17) In order to ensure that plant protection products containing glyphosate do not have harmful effects on human or animal health nor unacceptable effects on the environment, Member States should be required to pay particular attention that sufficient data is provided on co-formulants contained therein, taking into account in particular the criteria for identification of unacceptable co-formulants as set out in Commission Implementing Regulation (EU) 2023/574¹⁰.
- (18) Some crops may be grown in fields where glyphosate was used in the preceding growing season. Since the Authority could not finalise the consumer risk assessment of residues that might be present in those crops based on the available data,

⁸ Commission Implementing Regulation (EU) 2022/2364 of 2 December 2022 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval period of the active substance glyphosate (OJ L 312, 5.12.2022, p. 99).

⁹ European Food Safety Authority (EFSA), (2023). Peer review of the pesticide risk assessment of the active substance glyphosate. EFSA Journal, 21(7), 1-52. <https://doi.org/10.2903/j.efsa.2023.8164>.

¹⁰ Commission Implementing Regulation (EU) 2023/574 of 13 March 2023 setting out detailed rules for the identification of unacceptable co-formulants in plant protection products in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council (OJ L 75, 14.3.2023, p. 7).

Member States should be required when carrying out risk assessments for the authorisation of plant protection products containing glyphosate to pay particular attention to the consumer exposure assessment for succeeding crops.

- (19) No concern was identified for the risk of direct leaching of glyphosate and its metabolites into groundwater. However, during the peer review it was noted that groundwater may be exposed via bank infiltration and/or connectivity of surface water bodies to groundwater aquifers for which information was not available. Furthermore, it is possible that certain non-agricultural uses of glyphosate on sealed surfaces and in very permeable areas may lead to a higher risk of leaching into groundwater and surface waters. Therefore, when carrying out assessments for the authorisation of plant protection products containing glyphosate, Member States should be required to pay particular attention to the protection of groundwater in vulnerable areas, including very permeable areas, and in general to the protection of surface waters, in particular those used for the abstraction of drinking water, considering specifically uses on sealed surfaces.
- (20) For some uses of glyphosate assessed as part of the renewal process, a high risk to small herbivorous mammals was identified when applying a conservative assessment (Tier 1) without taking exposure refinements into account, since there were no reliable higher tier data suitable for that. When carrying out risk assessments for the authorisation of plant protection products containing glyphosate, Member States should therefore be required to pay particular attention to the assessment of the risk to small herbivorous mammals, in particular for those uses where such risk was identified by the Authority, and where necessary to impose appropriate mitigation measures, such as limiting the timing of use, the number of applications or the maximum dose rate. Based on the outcome of the risk assessment, it is also considered appropriate to set maximum rates of use that should normally apply unless the outcome of a risk assessment undertaken for a specific plant protection product use indicates that a higher rate does not lead to any unacceptable effects on small herbivorous mammals.
- (21) The Authority did not identify any unacceptable risks to non-target terrestrial plants when considering potential exposure from spray drift if certain mitigation measures are applied. Non-target aquatic plants may also be exposed to such drift. In order to avoid any unacceptable effects on non-target terrestrial and aquatic plants Member States should be required to take into account possible contact exposure from spray drift and to impose appropriate mitigation measures when carrying out assessments for the authorisation of plant protection products containing glyphosate.
- (22) While no direct impacts on biodiversity were identified as part of the renewal assessment of glyphosate, possible indirect effects could not be excluded. When carrying out assessments for the authorisation of plant protection products containing glyphosate Member States should therefore pay particular attention to any possible indirect impact on biodiversity via trophic interactions caused by the use of plant protection products containing glyphosate. When doing so they should take into account the specific agro-environmental conditions and, where necessary, impose risk mitigation measures and/or conditions and restrictions of use.
- (23) In the absence of methods and guidance agreed at EU level, which still need to be developed, Member States may apply methods which they consider appropriate to determine the potential indirect effects of plant protection products containing glyphosate and which take into account their specific agro-environmental conditions.

When doing so, if they identify any such possible indirect effects on biodiversity and if practical alternative control or prevention methods with lower impacts on biodiversity are available, Member States should set specific conditions or restrictions of use for plant protection products containing glyphosate, considering in particular if practical alternative control or prevention methods with lower impacts on biodiversity are available.

- (24) Given that no agreed methods or guidance on the assessment of indirect effects on biodiversity are currently available at Union level, confirmatory information on any possible indirect effects on biodiversity via trophic interactions, should be submitted by the applicant once suitable methods and guidance are available.
- (25) Furthermore, other Union provisions aimed at the protection and promotion of biodiversity in ecosystems, including agro-ecosystems might also be relevant when considering the reduction of any impacts of glyphosate on biodiversity. In particular, under Directive 2009/128/EC of the European Parliament and of the Council¹¹ in conjunction with Article 55 of Regulation (EC) No 1107/2009, Member States are obliged to encourage the development and implementation of integrated pest management and of alternative approaches or techniques in order to reduce their dependency on the use of pesticides.
- (26) Uses by non-professional users were not part of the representative uses submitted by the applicant and therefore have not been assessed. Therefore, Member States should be required to pay particular attention to uses by non-professional users when carrying out assessments for their authorisation.
- (27) The use of plant protection products containing glyphosate for pre-harvest uses may not always be compliant with Directive 2009/128/EC in conjunction with the provisions of Article 55 of Regulation (EC) No 1107/2009. Therefore, Member States should be required to pay particular attention to pre-harvest uses when carrying out assessments for their authorisation. Specifically, use of plant protection products containing glyphosate for desiccation to control the time point of harvest or to optimise threshing is not considered to comply with the provisions of Article 55 of Regulation (EC) No 1107/2009 and, therefore, should not be authorised.
- (28) As plant protection products containing glyphosate are also used for non-agricultural applications, Member States should, in accordance with Directive 2009/128/EC, ensure that the use of plant protection products containing glyphosate is minimised or prohibited in sensitive areas such as public parks and gardens, sports and recreation grounds, school grounds and children's playgrounds and in the close vicinity of healthcare facilities.
- (29) Directive 2000/60/EC¹² of the European Parliament and of the Council and Directive 2009/128/EC set out certain requirements for the monitoring of water status and use of plant protection products. Considering the importance of preventing contamination of the environment with glyphosate and/or its metabolites, and in particular surface waters, Member States may also set additional monitoring requirements when authorising plant protection products containing glyphosate.

¹¹ Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of pesticides (OJ L 309, 24.11.2009, p. 71).

¹² Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy (OJ L 327, 22.12.2000, p. 1).

- (30) Glyphosate has been subject to two comprehensive assessments since 2012, both of which have not identified concerns indicating that the approval criteria laid down in Regulation (EC) No 1107/2009 are not fulfilled. As such it cannot be expected that in the near term enough new information would be accumulated to result in a different outcome. At the same time, it is noted that research on glyphosate has intensified in recent years and new insights on the properties of glyphosate relevant for the protection of human health and environment might arise. In order to balance those considerations, it is appropriate to provide for a renewal of the approval of glyphosate for a period of 10 years. Furthermore, the active substance may be reviewed at any time pursuant to Article 21 of Regulation (EC) No 1107/2009.
- (31) Implementing Regulation (EU) No 540/2011 should be amended accordingly.
- (32) Taking into account that the current approval of glyphosate expires on 15 December 2023, and with a view to ensuring legal certainty, this Regulation should enter into force as soon as possible.
- (33) 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

Renewal of the approval of the active substance

The approval of the active substance glyphosate, as specified in Annex I to this Regulation, is renewed, subject to the conditions and restrictions 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 third day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 16 December 2023.

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