

Brussels, **XXX**
PLAN/2023/1497 ANNEX
(POOL/E4/2023/1497/1497-EN
ANNEX.docx)
[...] (2023) **XXX** draft

ANNEXES 1 to 2

ANNEXES

to the

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

**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**

ANNEX I

Common Name, Identification Numbers	IUPAC Name	Purity ¹	Date of approval	Expiration of approval	Specific provisions
Glyphosate CAS No: 1071-83-6 CIPAC No: 284	N-(phosphonomethyl)glycine	<p>≥ 950 g/kg</p> <p>The following impurities are of toxicological concern and shall not exceed the following levels in the technical material:</p> <ul style="list-style-type: none"> - N-nitroso-glyphosate (NNG): < 1 mg/kg - formaldehyde: < 1 g/kg - triethylamine: ≤ 2g/kg - formic acid: ≤ 4 g/kg - N,N-bis(phosphonomethyl)glycine (glyphosine) : ≤ 3 g/kg 	16 December 2023	15 December 2033	<p>Only uses as herbicide may be authorised.</p> <p>For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on glyphosate, and in particular Appendices I and II thereof, shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to:</p> <ul style="list-style-type: none"> - the co-formulants present in glyphosate-containing plant protection products, taking into account in particular the criteria for identification of unacceptable co-formulants as set out in Commission Implementing Regulation (EU) 2023/574; - the consumer exposure assessment with regards to residues that may be present in succeeding crops grown in rotation; - the protection of groundwater in vulnerable areas and of surface waters, in particular those used for the abstraction of drinking water, considering specifically uses on sealed surfaces;

¹ Further details on the identity and specification of the active substance are provided in the renewal report.

Common Name, Identification Numbers	IUPAC Name	Purity ¹	Date of approval	Expiration of approval	Specific provisions
					<ul style="list-style-type: none"> - the protection of small herbivorous mammals. Member States shall, where considered necessary impose mitigation measures such as limiting the timing of use, the number of applications or the maximum dose rate. The following maximum application rates shall not be exceeded unless the outcome of the risk assessment undertaken for the specific uses for which authorisation is applied for demonstrates that a higher rate does not lead to any unacceptable effects on small herbivorous mammals: <ul style="list-style-type: none"> – For use in agriculture: 1.44 kg glyphosate per hectare, per year; – For use to control invasive species in agricultural and non-agricultural areas: 1.8 kg glyphosate per hectare, per year; – For use in non-agricultural areas: 3.6 kg glyphosate per hectare, per year; - the protection of non-target terrestrial and aquatic plants from exposure by spray drift; - indirect effects on biodiversity via trophic interactions once relevant methods and guidance to identify such effects are agreed at Union level. In the absence of such methods and guidance, 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

Common Name, Identification Numbers	IUPAC Name	Purity ¹	Date of approval	Expiration of approval	Specific provisions
					<p>any such possible indirect effects on biodiversity, Member States shall 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;</p> <ul style="list-style-type: none"> - uses by non-professional users; - compliance of pre-harvest uses with the provisions of Directive 2009/128/EC in conjunction with Article 55 of Regulation (EC) No 1107/2009. Uses for desiccation to control the time point of harvest or to optimise threshing shall not be authorised. <p>Conditions of use shall include risk mitigation measures, including combinations thereof, as required. In particular, drift shall be reduced for spray applications made by professional users in agricultural fields. By default, to protect non-target terrestrial plants, an in-field non-sprayed buffer strip of at least 5 to 10 m from the field border depending on the particular use and drift reduction nozzles reducing spray drift by at least 75%, or other risk mitigation measures with equivalent reduction of drift, shall be required, unless the outcome of the risk assessment undertaken for the specific plant protection product use indicates that such risk mitigation measures are not needed or can be lowered because there are no unacceptable risks caused by spray drift.</p> <p>In addition, Member States may set monitoring</p>

Common Name, Identification Numbers	IUPAC Name	Purity ¹	Date of approval	Expiration of approval	Specific provisions
					<p>requirements when granting authorisations, in order to complement the monitoring under Directives 2000/60/EC² and 2009/128/EC.</p> <p>Member States shall ensure that use of plant protection products containing glyphosate is minimised or prohibited in the specific areas listed in Article 12(a) of Directive 2009/128/EC.</p> <p>The applicant shall submit to the Commission, the Member States and the Authority confirmatory information as regards the possible indirect effects on biodiversity via trophic interactions, within three years from the date of applicability of a relevant guidance document endorsed by the Standing Committee on Plants, Animals, Food and Feed.</p>

² 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).

ANNEX II

The Annex to Commission Implementing Regulation (EU) No 540/2011 is amended as follows:

In Part B, entry 118 on glyphosate is substituted with the following:

No	Common Name, Identification Numbers	IUPAC Name	Purity ¹	Date of approval	Expiration of approval	Specific provisions
"118	Glyphosate CAS No: 1071-83-6 CIPAC No: 284	N-(phosphonomethyl)glycine	≥ 950 g/kg The following impurities are of toxicological concern and shall not exceed the following levels in the technical material: - <i>N</i> -nitroso-glyphosate (NNG): < 1 mg/kg - formaldehyde: < 1 g/kg - triethylamine: ≤ 2g/kg - formic acid: ≤ 4 g/kg - <i>N,N</i> -bis(phosphonomethyl) glycine (glyphosine) : ≤ 3 g/kg	16 December 2023	15 December 2033	Only uses as herbicide may be authorised. For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on glyphosate, and in particular Appendices I and II thereof, shall be taken into account. In this overall assessment Member States shall pay particular attention to: - the co-formulants present in glyphosate-containing plant protection products, taking into account in particular the criteria for identification of unacceptable co-formulants as set out in Commission Implementing Regulation (EU) 2023/574; - the consumer exposure assessment with regards to residues that may be present in succeeding crops grown in rotation; - the protection of groundwater in vulnerable areas and of surface waters, in particular

¹ Further details on the identity and specification of the active substance are provided in the renewal report.

No	Common Name, Identification Numbers	IUPAC Name	Purity ¹	Date of approval	Expiration of approval	Specific provisions
						<p>those used for the abstraction of drinking water, considering specifically uses on sealed surfaces;</p> <ul style="list-style-type: none"> - the protection of small herbivorous mammals. Member States shall, where considered necessary impose mitigation measures such as limiting the timing of use, the number of applications or the maximum dose rate. The following maximum application rates shall not be exceeded unless the outcome of the risk assessment undertaken for the specific uses for which authorisation is applied for demonstrates that a higher rate does not lead to any unacceptable effects on small herbivorous mammals: <ul style="list-style-type: none"> – For use in agriculture: 1.44 kg glyphosate per hectare, per year; – For use to control invasive species in agricultural and non-agricultural areas: 1.8 kg glyphosate per hectare, per year; – For use in non-agricultural areas: 3.6 kg glyphosate per hectare, per year; - the protection of non-target terrestrial and aquatic plants from exposure by spray drift; - indirect effects on biodiversity via trophic interactions once relevant methods and guidance to identify such effects are agreed at Union level. In the absence of such methods and guidance, 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 local agro-environmental conditions. When

No	Common Name, Identification Numbers	IUPAC Name	Purity ¹	Date of approval	Expiration of approval	Specific provisions
						<p>doing so, if they identify any such possible indirect effects on biodiversity, Member States shall 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;</p> <ul style="list-style-type: none"> - uses by non-professional users; - compliance of pre-harvest uses with the provisions of Directive 2009/128/EC in conjunction with Article 55 of Regulation (EC) No 1107/2009. Uses for desiccation to control the time point of harvest or to optimise threshing shall not be authorised. <p>Conditions of use shall include risk mitigation measures, including combinations thereof, as required. In particular, drift shall be reduced for spray applications made by professional users in agricultural fields. By default, to protect non-target terrestrial plants, an in-field non-sprayed buffer strip of at least 5 to 10 m from the field border depending on the particular use and drift reduction nozzles reducing spray drift by at least 75%, or other risk mitigation measures with equivalent reduction of drift, shall be required, unless the outcome of the risk assessment undertaken for the specific plant protection product use indicates that such risk mitigation measures are not needed or can be lowered because there are no unacceptable risks caused by spray drift.</p> <p>In addition, Member States may set monitoring requirements when granting authorisations, in</p>

No	Common Name, Identification Numbers	IUPAC Name	Purity ¹	Date of approval	Expiration of approval	Specific provisions
						<p>order to complement the monitoring under Directives 2000/60/EC² and 2009/128/EC.</p> <p>Member States shall ensure that use of plant protection products containing glyphosate is minimised or prohibited in the specific areas listed in Article 12(a) of Directive 2009/128/EC.</p> <p>The applicant shall submit to the Commission, the Member States and the Authority confirmatory information as regards the possible indirect effects on biodiversity via trophic interactions, within three years from the date of applicability of a relevant guidance document endorsed by the Standing Committee on Plants, Animals, Food and Feed.’</p>

² 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).