



Glyphosate
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Renewal report for the active substance glyphosate
finalised in the Standing Committee on Plants, Animals, Food and Feed
at its meeting on **XX XXXX** 2023
in view of the renewal of the approval of glyphosate
in accordance with Regulation (EC) No 1107/2009¹

1. Procedure followed for the re-evaluation process

This renewal report has been established as a result of the evaluation of an application for the renewal of approval of glyphosate, in accordance with Regulation (EC) No 1107/2009² and Commission Implementing Regulation (EU) No 844/2012³.

Glyphosate was included in Annex I to Council Directive 91/414/EEC concerning the placing of plant protection products on the market, by Commission Directive 2001/99/EC⁴ and was subsequently deemed to have been approved under Regulation (EC) No 1107/2009 and listed in Part A of the Annex to Commission Implementing Regulation (EU) No 540/2011⁵.

The approval of the active substance glyphosate was renewed with Commission Implementing Regulation (EU) 2017/2324⁶ and it was listed in Part B of the Annex to Commission Implementing Regulation (EU) No 540/2011.

The Glyphosate Renewal Group⁷ (GRG) submitted an application for the renewal of approval of glyphosate in accordance with Article 1 of Regulation (EU) No 844/2012.

¹ Renewal Report established in accordance with Article 14 of Regulation (EU) No 844/2012; does not necessarily represent the views of the European Commission.

² OJ L 309, 24.11.2009, p. 1.

³ OJ L 252, 19.9.2012, p. 26.

⁴ OJ L 304, 21.11.2001, p. 14.

⁵ OJ L 153, 11.6.2011, p. 1.

⁶ OJ L 333, 15.12.2017, p. 10.

⁷ The Glyphosate Renewal Group consists of Bayer Agriculture BV (lead registrant of behalf of GRG), Barclay Chemicals Manufacturing Ltd., CIECH Sarzyna S.A., Albaugh Europe SARL, Nufarm UK Ltd., SINON Corporation, Industrias Afrasa, S.A. and Syngenta Crop Protection AG.

The Commission extended the approval period of glyphosate, originally expiring on 15 December 2022 for one year⁸ to allow for the completion of the scientific assessment process, in accordance with Article 17 of Regulation (EC) No 1107/2009.

Commission Implementing Regulation (EU) 2019/724⁹ appointed France, Hungary, the Netherlands, and Sweden to act jointly as rapporteurs, known as the Assessment Group on Glyphosate (AGG), which had to submit the relevant renewal assessment report and recommendations to the European Food Safety Authority (EFSA).

On 15 June 2021, the AGG submitted to EFSA and the European Chemicals Agency (ECHA) its assessments in the form of a draft Renewal Assessment Report (dRAR) and a CLH Report containing a proposal for harmonised classification and labelling, respectively.

On 23 September 2021, EFSA and ECHA launched public consultations on the reports delivered by the AGG, which ended on 22 November 2021.

In accordance with Article 13 of Implementing Regulation (EU) No 844/2012, EFSA organised a consultation of technical experts from Member States, to review the draft RAR and the comments received thereon (peer review).

EFSA sent to the Commission its Conclusion on the peer review of the pesticide risk assessment of the active substance glyphosate¹⁰ on 6 July 2023. This Conclusion refers to several background documents: the RAR including its revisions and the peer review report.

In accordance with the provisions of Article 14 of Implementing Regulation (EU) No 844/2012, the Commission referred a draft renewal report on the renewal of approval to the Standing Committee on Plants, Animals, Food and Feed, for examination on 13 July 2023. A draft Regulation was presented to the Committee on XX September 2023. The renewal report was finalised in the meeting of the Standing Committee on <date final vote at SCoPAFF meeting>.

The present renewal report contains the outcome of the final examination by the Standing Committee. Given the importance of the EFSA Conclusion, and its background documents, these documents are also considered to be part of this renewal report.

2. Purposes of this renewal report

This renewal report, including the background documents and appendices hereto, has been developed and finalised in support of Commission Implementing Regulation (EU) xxxx/xxxx¹¹ concerning the renewal of approval of glyphosate as active substance under Regulation (EC) No 1107/2009, and to assist the Member States in decisions on individual plant protection products containing glyphosate they have to take in accordance with the provisions of that Regulation, and in particular the provisions of Article 29(1) of Regulation (EC) No 1107/2009 and the uniform principles laid down in Regulation (EU) No 546/2011¹².

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 OJ L 124, 13.5.2019, p. 32.

¹⁰ TO ADD, once published.

¹¹ OJ L xxxx, p.XX.

¹² OJ L 155, 11.6.2011, p. 127.

This renewal report provides for the evaluation required under the above-mentioned uniform principles. The uniform principles require that Member States, when evaluating applications for authorisations, shall consider the information concerning the requirements of Regulation (EU) No 283/2013¹³, submitted for the purpose of (renewal of) approval of the active substances, as well as the result of the evaluation of those data.

This renewal report will be made available to the public.

The information in this renewal report is, at least partly, based on information which is confidential and/or protected under the provisions of Regulation (EC) No 1107/2009. It is therefore recommended that this renewal report would not be accepted to support any registration outside the context of that Regulation, e.g., in third countries, for which the applicant has not demonstrated to have rightful access to the information on which this renewal report is based.

3. Overall conclusion in the context of Regulation (EC) No 1107/2009

The overall conclusion from the evaluation is that it may be expected that plant protection products containing glyphosate will still fulfil the safety requirements laid down in Article 4(1) to (3) of Regulation (EC) No 1107/2009. This conclusion is however subject to compliance with the particular requirements in sections 4, 5, 6 and 7 of this report, as well as to the implementation of the provisions of Article 29(1) of Regulation (EC) No 1107/2009 and the uniform principles laid down in Regulation (EU) No 546/2011, for each glyphosate containing plant protection product for which Member States will grant or review the authorisation.

Furthermore, these conclusions were reached within the framework of the uses which were proposed and supported by the applicant and mentioned in the list of representative uses supported by available data (attached as Appendix II to this renewal report).

Although none of the representative uses are for application pre-harvest, plant protection products containing glyphosate might also be used for pre-harvest applications. In certain situations, pre-harvest uses to check or prevent undesired growth of weeds are in line with good agricultural practices. Nevertheless, it appears that plant protection products containing glyphosate are also used with the intention to control the time point of harvest or to optimise the threshing, although these uses may not be considered within good agricultural practices. Such uses may therefore not be compliant with the provisions of Article 55 of Regulation (EC) No 1107/2009. Member States should therefore pay particular attention to compliance of pre-harvest uses with good agricultural practices when authorising plant protection products.

The following health-based **reference values** have been set as part of this evaluation:

ADI: 0.5 mg/kg bw per day,
ARfD: 1.5 mg/kg bw,
AOEL: 0.1 mg/kg bw per day,
AAOEL: 0.3 mg/kg bw.

¹³ Commission Regulation (EU) No 283/2013 of 1 March 2013 setting out the data requirements for active substances, 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 Text with EEA relevance (OJ L 93, 3.4.2013, p. 1)

NB: the ARfD has increased compared to the previous EU agreed reference value; the ADI and AOEL remain the same; an AAOEL was not previously set.

The following **residue definitions for consumer risk assessment** have been set as part of this evaluation:

- Residue definition for risk assessment in commodities of plant, animal origin and honey and bee products: sum of glyphosate and (aminomethyl)phosphonic acid (AMPA), expressed as glyphosate;
- Residue definition for risk assessment in processed commodities: sum of glyphosate and AMPA, expressed as glyphosate;
- Residue definition for risk assessment in rotational crops: sum of glyphosate and AMPA, expressed as glyphosate.

The residue definitions for risk assessment have not changed compared to the previous EU agreed residue definitions.

It is noted that the representative uses of glyphosate assessed in the renewal evaluation are for use on conventional crops. In addition, information on residues was also submitted and evaluated for uses of glyphosate on genetically modified crops tolerant to glyphosate (crops with CP4-EPSPS, with GOX and with GAT modifications). The residue definitions for risk assessment in such crops are different to those for conventional crops:

- Residue definition for risk assessment in commodities of plant and animal origin and honey and bee products: Sum of glyphosate, AMPA, N-acetyl glyphosate and N-acetyl AMPA, expressed as glyphosate.

The residue definitions for monitoring are set in the Annexes to Regulation (EC) No 396/2005.

With particular regard to residues, no areas of concern were identified by EFSA. The Theoretical Maximum Daily Intake (TMDI) for the critical consumer group is 3 % of the Acceptable Daily Intake (ADI), based on EFSA PRIMo Model rev. 3. The highest International Estimated Short-Term Intake (IESTI) is 2 % of the Acute Reference Dose (ARfD), based on the same model.

As regards the criteria to identify endocrine disrupting properties introduced by Commission Regulation (EU) 2018/605¹⁴ which became applicable on 10 November 2018, EFSA concluded that glyphosate is unlikely to have endocrine disrupting properties. Furthermore, the ECHA confirmed that based on the available evidence glyphosate does not meet the criteria to be classified as carcinogenic, mutagenic or toxic for reproduction.

In its Conclusion, EFSA did not identify any critical areas of concern.

In the EFSA Conclusion some points were not finalised, which are however not considered critical for the renewal of the approval, in particular:

- *The assessment of the reference specification cannot be finalised since one of the impurities showed a potential for clastogenicity in an in vitro chromosome aberration test that was not appropriately followed up in vivo. Although some batches used in the toxicological studies*

¹⁴ Commission Regulation (EU) 2018/605 of 19 April 2018 amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties. (OJ L 101, 20.4.2018, p. 33).

contained this impurity at levels representative of the proposed reference specification, a conclusion on the maximum level of this impurity in any reference specification cannot be drawn without a clarification on its clastogenic potential

The presence of impurities in the material manufactured in production facilities (sources) can be influenced by the manufacturing process. The technical material from several sources of glyphosate manufactured by members of the GRG contained levels of the impurity (N,N-bis-phosphonomethylglycine, also known as 'glyphosine') below the limit of quantification (LOQ) i.e. present at levels less than 0.1 % in the final manufactured material. However, the issue is considered not finalised by EFSA given that a common reference specification for all sources was proposed by the GRG and since the presence of the impurity cannot be excluded, even if at very low levels.

It must also be underlined that glyphosine has not been confirmed to have clastogenic properties. Rather, based on the available studies carried out on glyphosine, a clastogenic potential cannot be excluded. Two *in vitro* tests investigating clastogenicity were carried out on glyphosine and were submitted and evaluated: the *in vitro* micronucleus test was negative, whereas the *in vitro* chromosome aberration study was positive.

Importantly, glyphosine was present in the batches of glyphosate tested in two *in vivo* micronucleus tests (an appropriate test to investigate clastogenicity) at levels of ~10 g/kg and of ~21 g/kg, respectively. Results of both *in vivo* micronucleus tests were negative, i.e. there was no evidence of clastogenicity.

EFSA noted in its Conclusion that the AGG disagrees with the conclusion that the issue could not be finalised and "*considers the genotoxic potential not to be of toxicological concern at the level of the proposed reference specification, since the impurity was present at a 7-fold higher level than that proposed for the reference specification in one in vivo micronucleus test performed with glyphosate*". The AGG proposed a level of 3 g/kg in the reference specification.

Given that the impurity has been tested twice *in vivo* at levels exceeding up to seven-fold the proposed limit and that both tests showed no indications of clastogenic potential, and given that there are mixed findings from the *in vitro* studies, the limit proposed by the AGG of 3 g/kg of glyphosine in the technical material as manufactured is considered to be sufficiently protective. Therefore, a maximum level of 3 g/kg for glyphosine will be set in the approval.

Finally, since the impurity profile is dependent on the manufacturing process, including the starting materials used, applicants for product authorisation may also consider changing the production process or starting materials to produce glyphosate that does not contain glyphosine.

- *The consumer dietary risk assessment could not be finalised since the data set on magnitude of residues in rotational crops is not complete*

This issue is only relevant for some crops (e.g. carrot, lettuce, wheat) grown in rotation i.e. succeeding crops grown in fields where glyphosate was used in the preceding growing season. Based on the studies available, residues of AMPA may occur above the LOQ of 0.025 mg/kg in some crops grown in rotation although in some trials on these crops residues were below LOQ.

It is also important to recall that, as mentioned above, based on the consumer risk assessment carried out for the representative uses, overall exposure of humans to residues of glyphosate through the diet is at levels far below the health-based reference values established for glyphosate and that EFSA indicated that it is not expected that the toxicological reference values will be exceeded.

Nevertheless, Member States should ensure that a full assessment of possible residues is undertaken before authorising uses on crops grown in rotation.

- *The risk assessment for aquatic macrophytes due to contact exposure via spray drift could not be finalised*

Based on the standard risk assessment, no risk to aquatic macrophytes was identified. However, EFSA concluded that exposure of the parts of aquatic macrophytes above the water surface via spray drift may lead to larger effects when compared to other routes of exposure, including the normally considered exposure via contaminated surface water, and that since glyphosate is an herbicide, exposure to drift should be additionally considered.

Member States should therefore pay attention to potential exposure of macrophytes via drift from spray applications, when carrying out assessments for authorisation of plant protection products and, where relevant, require mitigation measures to prevent contact exposure via spray drift.

Furthermore, in its Conclusion, EFSA identified a number of data gaps that require some specific consideration:

- *A data gap is set to identify whether the DNT findings reported in the studies with glyphosate-trimesium and with GBHs are due to glyphosate*

In a regulatory study conducted with glyphosate-trimesium (which is no longer approved in the EU), or in studies published in scientific literature with other glyphosate salts or glyphosate-based products for which full composition details are unknown because they were not reported, some findings were observed.

In contrast, the studies on glyphosate available for the peer review did not show any neurotoxicity effects, and the experts concluded that a specific study for developmental neurotoxicity (DNT) on glyphosate is therefore not needed.

In addition, EFSA concluded that the toxicological reference values set for glyphosate ensure adequate protection for potential DNT effects. Therefore, no specific requirement needs to be set as a condition in the approval.

- *For one of the components of the formulation for representative uses 'MON 52276', repeated-dose toxicity information over short- and long term was not available, therefore in order to allow a final conclusion on the risk assessment of 'MON 52276', repeated dose toxicity data for this component (short- and long term) should be assessed*

Although EFSA concluded that there is a data gap for one co-formulant in the formulated product for the representative uses (for which specific repeated dose toxicity data was not available), all Member State experts who took part in the expert discussions, as well as the AGG, agreed that the available toxicological information is sufficient to conclude on the

safety of 'MON 52276', for which acute toxicity and genotoxicity data exist and indicate no concern.

In addition, it is noted that this particular co-formulant is exempt from registration under Regulation (EC) No 1907/2006¹⁵ (REACH) due to its chemical nature (it is a polymer) and the applicant was not requested by neither AGG nor EFSA to provide any data on this co-formulant.

Nevertheless, Member States should pay particular attention to the assessment of co-formulants used in glyphosate-containing plant protection products when evaluating applications for authorisation and – according to the provisions in Regulation (EU) No 284/2013¹⁶ - request additional data if considered necessary.

- *For further addressing the risk to biodiversity via indirect effects and trophic interactions it was considered needed 1) to perform a systematic literature search for data collection; 2) to quantify, in a spatial and temporal context, the direct effects on the weeds (including the impact on the seed bank), non-target plants, non-target arthropods and bees in order to inform the extent of potential indirect effects via trophic interactions; 3) to demonstrate how both specific and general mitigation measures may address the impact due to indirect effects*

As part of the renewal review of glyphosate a comprehensive assessment of the possible impacts of the use of glyphosate on biodiversity was undertaken and no direct effects on non-target organisms are expected for a number of representative uses. However, the experts in the peer review highlighted that there are currently no agreed harmonised methodologies for carrying out assessments of indirect effects and trophic interactions, and that considering such kind of potential impacts is complex and multi-factorial. In addition, the experts noted that indirect impacts on biodiversity due to removal of weeds is not a glyphosate-specific issue, as other broad-spectrum herbicides and also non-chemical removal of weeds are also expected to lead to impacts via trophic food chain interactions.

During the peer review, Member State experts noted that risk mitigation measures including use of drift reduction nozzles, buffer zones, or the implementation of multi-functional field margins (MFFM) could be beneficial for biodiversity – however no quantification was possible and a consideration of effectiveness of such measures at landscape level is needed by Member States.

In fact, due to the complex and multifactorial elements, Member States are best positioned to assess indirect effects on their territory considering their national and regional specific environmental conditions, and to impose where relevant appropriate risk mitigation measures, conditions and restrictions of use. This applies both to professional and amateur uses.

In addition, Article 55 of Regulation (EC) No 1107/2009 obliges that the use of plant protection products complies with the general principles of integrated pest management as referred to in Article 14 and Annex III to the Directive on the Sustainable Use of Pesticides (SUD)¹⁷, i.e. biological, physical and other non-chemical methods must be preferred to

¹⁵ Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency (OJ L 396, 30.12.2006, p.1).

¹⁶ Commission Regulation (EU) No 284/2013 of 1 March 2013 setting out the data requirements for plant protection products, 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 (OJ L 93, 3.4.2013, p. 85).

¹⁷ 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).

chemical methods if they provide satisfactory pest control, and the use of pesticides must be kept at levels that are necessary.

Furthermore, other provisions of the SUD and other existing Union legislation, including the Birds¹⁸ and Habitats¹⁹ Directives, and the Common Agricultural Policy (CAP) contain provisions that contribute to the protection and promotion of biodiversity in agro-ecosystems.

Member States may also conduct comparative assessments in accordance with Article 50(2) of Regulation No 1107/2009 and may refuse authorisation of glyphosate-containing products if more selective herbicides, mechanical weeding or other non-chemical alternatives with less impacts on biodiversity are available.

Furthermore, if a Member State has justified concerns about impacts that cannot be controlled by the establishment of the national risk mitigation measures it may also restrict or refuse authorisation of plant protection products in its territory.

EFSA also identified a long-term risk to mammals for 12 out of 23 representative uses - a risk was identified for some representative uses following a first tier assessment²⁰ without taking into account possible refinements that may be applicable if additional data would be available (i.e. the assessment was based on conservative assumptions and may be refined further). As there are representative uses for which no risk was identified, the renewal of approval is not precluded.

The representative uses for which long-term risk to mammals was identified were removed from the list of representative uses supported by available data in Appendix II to this renewal report, and are therefore not underpinning the renewal of approval. For these uses, product authorisations can only be granted by Member States following a new risk assessment demonstrating the absence of unacceptable risks, for which further data can be submitted and assessed as part of the respective applications for the renewal of product authorisations that are mandatory after the renewal of approval.

Member States should therefore pay attention to the risk to mammals when carrying out assessments for authorisation of plant protection products.

EFSA also concluded that, based on the current state of scientific knowledge the available data support a sufficiently protective assessment for any health impact possibly mediated by the microbiome on humans, livestock and pet animals.

Experts noted that further research is needed to identify dedicated methodologies to better integrate microbiome into chemical risk assessment. EFSA is working to advance the understanding of possible impacts of exposure to food and substances on the microbiome and how to integrate such knowledge into risk assessment.

For groundwater, EFSA highlighted that in some small hydrological catchments and some larger river systems, the route of groundwater exposure via bank infiltration and the connectivity of surface water bodies to groundwater aquifers may be relevant and that further information would

¹⁸ Council Directive 92/43/EEC of 21 May 1992 on the conservation of natural habitats and of wild fauna and flora (OJ L 206, 22.7.1992, p. 7).

¹⁹ Directive 2009/147/EC of the European Parliament and of the Council of 30 November 2009 on the conservation of wild birds (OJ L 20, 26.1.2010, p. 7).

²⁰ i.e. a risk assessment using conservative assumptions and default values rather than information on actual and realistic field exposure.

be useful for Member States to assess groundwater concentrations that may result from this exposure pathway.

Therefore, Member States should pay particular attention to the protection of groundwater that may be exposed via bank infiltration and/or connectivity of surface water bodies to groundwater aquifers when carrying out assessments for plant protection products. This applies both to professional and amateur uses.

A low risk for non-target terrestrial plants was identified for all representative uses only by implementing appropriate risk mitigation measures. The required risk mitigation measures (e.g. for sprayed applications a 5 to 10 meters in-field non-sprayed buffer strip without or with combination of other drift reducing technology) vary with the different representative uses.

Member States should therefore pay attention to the risk to non-target terrestrial plants when carrying out assessments for authorisation of plant protection products.

The review has identified several acceptable exposure scenarios for operators, workers, residents, bystanders and groundwater which require however to be confirmed for each plant protection product in accordance with the relevant sections of the above mentioned uniform principles.

The review has also concluded that under the proposed and supported conditions of use there are no unacceptable effects on the environment, as provided for in Article 4(3)(e) of Regulation (EC) No 1107/2009, provided that certain conditions are taken into account as detailed in section 6 of this report.

Extension of the use pattern beyond those described in Annex II will require an evaluation at Member State level in order to establish whether the proposed extensions of use can satisfy the requirements of Article 29(1) of Regulation (EC) No 1107/2009 and of the uniform principles laid down in Regulation (EU) No 546/2011.

4. Identity and Physical/chemical properties

The identity of glyphosate is given in Appendix I.

5. Endpoints and related information

In order to facilitate Member States, in granting or reviewing authorisations, to apply adequately the provisions of Article 29(1) of Regulation (EC) No 1107/2009 and the uniform principles laid down in Regulation (EU) No 546/2011, the most important endpoints were identified during the re-evaluation process. These endpoints are listed in the EFSA Conclusion.

6. Particular conditions to be taken into account on short term basis by Member States in relation to the granting of authorisations of plant protection products containing glyphosate

On the basis of the representative uses (as listed in Appendix II), only uses as herbicide may be authorised and the following issues have been identified as requiring particular attention from all Member States, in the framework of any authorisations to be granted, amended or withdrawn, as appropriate.

Member States shall pay particular attention to:

- the co-formulants present in glyphosate-containing plant protection products;
- the consumer exposure assessment with regards to residues that may be present in succeeding crops grown in rotation;
- the protection of groundwater that may be exposed via bank infiltration and/or connectivity of surface water bodies to groundwater aquifers;
- the risk to terrestrial vertebrates;
- the risk to non-target terrestrial plants and non-target aquatic plants from contact exposure by spray drift;
- the risk of indirect effects on biodiversity at landscape level, in particular via trophic interactions;
- the protection of the environment related to use by non-professionals;
- compliance of pre-harvest uses with good agricultural practices.

Conditions of use shall include risk mitigation measures, including combinations thereof, as required.

Member States may also conduct comparative assessments in accordance with Article 50(2) of Regulation 1107/2009 and refuse authorisation of glyphosate-containing products if more selective herbicides, mechanical weeding or other non-chemical alternatives with less impacts on biodiversity are available.

7. List of studies to be generated

No further information was identified which is at this stage considered necessary in relation to the approval of glyphosate under the current approval conditions.

Some endpoints however may require the generation or submission of additional studies to be submitted to the Member States in the context of applications for authorisations for certain uses.

A complete list of studies to be generated, still ongoing or available but not peer reviewed can be found in the relevant part of the EFSA Conclusion (pages 42-45).

8. Information on studies with claimed data protection

For information of any interested parties, the rapporteur Member State will keep available a document, which gives information about the studies for which the applicant has claimed data

protection and which during the re-evaluation process were considered as essential with a view to approval under Regulation (EC) No 1107/2009. This information is only given to facilitate the operation of the provisions of Article 62 of Regulation (EC) No 1107/2009 in the Member States. It is based on the best information available, but it does not prejudice any rights or obligations of Member States or operators with regard to its uses in the implementation of the provisions of Article 62 of Regulation (EC) No 1107/2009 and neither does it commit the Commission.

9. Updating of this renewal report

The information in this report may require to be updated from time to time in order to take account of technical and scientific developments as well as of the results of the examination of any information referred to the Commission in the framework of Articles 13, 21, 38, 44, 56 of Regulation (EC) No 1107/2009. Any such adaptation will be finalised in the Standing Committee on Plants, Animals, Food and Feed, in connection with any amendment of the approval conditions for glyphosate.

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APPENDIX I

Identity

GLYPHOSATE

Chemical name (IUPAC)	<i>N</i> -(phosphonomethyl)glycine
Chemical name (CA)	glycine, <i>N</i> -(phosphonomethyl)-
CIPAC No	284
CAS No	1071-83-6
EC No (EINECS or ELINCS)	213-997-4
FAO Specification (including year of publication)	284/TC (2016) covering technical material of Monsanto, Cheminova, Syngenta and Helm Glyphosate: ≥ 950 g/kg Formaldehyde: maximum 1.3 g/kg of the glyphosate acid <i>N</i> -nitroso-glyphosate: maximum 1 mg/kg of the glyphosate acid
Minimum purity of the active substance as manufactured	950 g/kg
Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured	<i>N</i> -nitroso-glyphosate (NNG): < 1 mg/kg Formaldehyde: < 1 g/kg Formic acid: ≤ 4 g/kg Triethylamine: ≤ 2 g/kg <i>N,N</i> -bis-phosphonomethylglycine (glyphosine): ≤ 3 g/kg
Location of the (proposed) reference specification (for significant impurities)	RAR Volume 4 Equivalence (2023) It is noted that the proposed reference specification was not considered finalised by EFSA due to the need to exclude the clastogenic potential of one impurity, glyphosine. However, a maximum level has been established for glyphosine, therefore the reference specification is considered to be acceptable.
Molecular formula	C ₃ H ₈ NO ₅ P
Molar mass	169.1 g/mol
Structural formula	

APPENDIX II

List of representative uses supported by available data

GLYPHOSATE

Crop and/or situation (a)	Member State or Country	Product name	F, G or I (b)	Pests or Group of pests controlled (c)	Preparation		Application				Application rate per treatment			PHI (days) (m)	Remarks
					Type (d-f)	Conc. a.s. (i)	method kind (f-h)	range of growth stages & season (j)	Number min-max (k)	Interval between application (min)	kg a.s./hL min-max (l)	Water L/ha min-max	kg a.s./ha min-max (l)		
PRE-SOWING and/or PRE-PLANTING and/or PRE-EMERGENCE															
Root vegetable plants (NNNVW) & tuberous plants (NNNZK), bulb plants (NNNZJ), fruit-vegetable plants (NNNVF), Brassica (1BRSG), leaf and stem vegetable plants (NNNVL), Sugar beet (BEAVA)	EU	MON 52276	F	Emerged annual weeds (3ANMNT, 3ANDIT), emerged perennial and biennial weeds (3PEDIT, 3PEMNT) (BBCH > 13)	SL	360 g/L	Tractor mounted broadcast spray	Pre-emergence of the crop	1-1	NA	0.36 - 1.44	100-400	1.44	N/A	Also applicable to renovation / change of land use applications. Application to 100 % of the field. Use at least 75 % drift reducing nozzles. Maximum application rate of 1.44 kg as/ha glyphosate in any 12 months period.

Crop and/or situation (a)	Member State or Country	Product name	F, G or I (b)	Pests or Group of pests controlled (c)	Preparation		Application				Application rate per treatment			PHI (days) (m)	Remarks
					Type (d-f)	Conc. a.s. (i)	method kind (f-h)	range of growth stages & season (j)	Number min-max (k)	Interval between application (min)	kg a.s./hL min-max (l)	Water L/ha min-max	kg a.s./ha min-max (l)		
Root vegetable plants (NNNVW) & tuberous plants (NNNZK), bulb plants (NNNZJ), fruit-vegetable plants (NNNVF), Brassica (1BRSG), leaf and stem vegetable plants (NNNVL), Sugar beet (BEAVA)	EU	MON 52276	F	Emerged annual weeds (3ANMNT, 3ANDIT), emerged perennial and biennial weeds (3PEDIT, 3PEMNT) (BBCH 13-21)	SL	360 g/L	Tractor mounted broadcast spray	Pre-emergence of the crop	1-1	NA	0.27 - 1.08	100-400	1.08	N/A	Also applicable to renovation / change of land use applications. Application to 100 % of the field. Use at least 75 % drift reducing nozzles. Maximum application rate of 1.08 kg as/ha glyphosate in any 12 months period.
Root vegetable plants (NNNVW) & tuberous plants (NNNZK), bulb plants (NNNZJ), fruit-vegetable plants (NNNVF), Brassica (1BRSG), leaf and stem vegetable plants (NNNVL), Sugar beet (BEAVA)	EU	MON 52276	F	Emerged annual weeds (3ANMNT, 3ANDIT)	SL	360 g/L	Tractor mounted broadcast spray	Pre-sowing, Pre-planting, Pre-emergence of the crop	1-1	NA	0.18 - 0.72	100-400	0.72	N/A	Also applicable to renovation / change of land use applications. Application to 100 % of the field. Use at least 75 % drift reducing nozzles. Maximum application rate of 0.72 kg as/ha glyphosate in any 12 months period.
POST-HARVEST, PRE-SOWING, PRE-PLANTING															

Crop and/or situation (a)	Member State or Country	Product name	F, G or I (b)	Pests or Group of pests controlled (c)	Preparation		Application				Application rate per treatment			PHI (days) (m)	Remarks
					Type (d-f)	Conc. a.s. (i)	method kind (f-h)	range of growth stages & season (j)	Number min-max (k)	Interval between application (min)	kg a.s./hL min-max (l)	Water L/ha min-max	kg a.s./ha min-max (l)		
Root vegetable plants (NNNVW) & tuberous plants (NNNZK), bulb plants (NNNZJ), fruit-vegetable plants (NNNVF), Brassica (1BRSG), leaf and stem vegetable plants (NNNVL), Sugar beet (BEAVA)	EU	MON 52276	F	Emerged annual weeds (3ANMNT, 3ANDIT), emerged perennial and biennial weeds (3PEDIT, 3PEMNT)	SL	360 g/L	Tractor mounted broadcast spray	Post-harvest, pre-sowing, pre-planting	1	28 days	0.18 - 1.08	100-400	0.72	N/A	Application to existing row cropland after harvest for removal of remaining crop / stubble and for control of actively growing weeds. Application to 100 % of the field. Use at least 75 % drift reducing nozzles. Maximum application rate of 2.16 kg as/ha glyphosate in any 12 months period.
Root vegetable plants (NNNVW) & tuberous plants (NNNZK), bulb plants (NNNZJ), fruit-vegetable plants (NNNVF), Brassica (1BRSG), leaf and stem vegetable plants (NNNVL), Sugar beet (BEAVA)	EU	MON 52276	F	Emerged annual weeds (3ANMNT, 3ANDIT)	SL	360 g/L	Tractor mounted broadcast spray	Post-harvest, pre-sowing, pre-planting	1	28 days	0.18 - 0.72	100-400	0.72	N/A	Application to existing row cropland after harvest for removal of remaining crop / stubble and for control of actively growing annual weeds. Application to 100 % of the field. Use at least 75 % drift reducing nozzles. Maximum application rate of 2.16 kg as/ha glyphosate in any 12 months period.
Root vegetable plants (NNNVW) & tuberous plants (NNNZK), bulb plants	EU	MON 52276	F	Cereal volunteers (NNNGA)	SL	360 g/L	Tractor mounted broadcast spray	Post-harvest, pre-sowing, pre-planting	1	NA	0.135-0.54	100-400	0.54	N/A	Application to existing row cropland after harvest for removal of cereal volunteers. Maximum application rate of 0.54 kg as/ha glyphosate in any 12 months period. Use at least 75% drift reducing nozzles.

Crop and/or situation (a)	Member State or Country	Product name	F, G or I (b)	Pests or Group of pests controlled (c)	Preparation		Application				Application rate per treatment			PHI (days) (m)	Remarks
					Type (d-f)	Conc. a.s. (i)	method kind (f-h)	range of growth stages & season (j)	Number min-max (k)	Interval between application (min)	kg a.s./hL min-max (l)	Water L/ha min-max	kg a.s./ha min-max (l)		
(NNNZJ), fruit-vegetable plants (NNNVF), Brassica (IBRSG), leaf and stem vegetable plants (NNNVL), Sugar beet (BEAVA)															
Root vegetable plants (NNNVW) & tuberous plants (NNNZK), bulb plants (NNNZJ), fruit-vegetable plants (NNNVF), Brassica (IBRSG), leaf and stem vegetable plants (NNNVL), Sugar beet (BEAVA)	EU	MON 52276	F	Cereal volunteers (NNNGA)	SL	360 g/L	Tractor mounted broadcast spray	Post-harvest, pre-sowing, pre-planting	1	NA	0.135-0.54	100-400	0.54	N/A	Application to existing row cropland after harvest for removal of cereal volunteers once every three years. Maximum application rate of 0.54 kg as/ha glyphosate in any 36 months period. Use at least 75% drift reducing nozzles.
POST-EMERGENCE OF WEEDS															
Orchard crops: citrus (3CITC), stone (3STFC) and pome (3PMFC) fruits, kiwi (ATIDE), nut crops (3NUTC), banana	EU	MON 52276	F	Emerged annual weeds (3ANMNT, 3ANDIT), emerged perennial and biennial weeds	SL	360 g/L	Ground directed, fully-shielded (hooded) spray, band application	Post-emergence of weeds throughout the year	1	28 days	0.18 - 1.08	100-400	0.72	7	Avoid crop contamination during treatment. Maximum application rate of 2.88 kg as/ha treated area glyphosate in any 12 months period. Use at least 75% drift reducing nozzles. Band application in the rows below the trees or as spot treatments. The treated area represents not more than 50 % of the total orchard area. The

Crop and/or situation (a)	Member State or Country	Product name	F, G or I (b)	Pests or Group of pests controlled (c)	Preparation		Application				Application rate per treatment			PHI (days) (m)	Remarks
					Type (d-f)	Conc. a.s. (i)	method kind (f-h)	range of growth stages & season (j)	Number min-max (k)	Interval between application (min)	kg a.s./hL min-max (l)	Water L/ha min-max	kg a.s./ha min-max (l)		
(MUBPA), and table olives (OLVEU)*				(3PEDIT, 3PEMNT)											application rate with reference to the total orchard surface area is not more than 50 % of the stated dose rate.
Orchard crops: citrus (3CITC), stone (3STFC) and pome (3PMFC) fruits, kiwi (ATIDE), nut crops (3NUTC), banana (MUBPA), and table olives (OLVEU)*	EU	MON 52276	F	Emerged annual weeds (3ANMNT, 3ANDIT)	SL	360 g/L	Ground directed, fully-shielded (hooded) spray, band application	Post-emergence of weeds throughout the year	1	28 days	0.18 - 0.72	100-400	0.72	7	Avoid crop contamination during treatment. Maximum application rate of 2.16 kg as/ha treated area glyphosate in any 12 months period. Use at least 75% drift reducing nozzles. Band application in the rows below the trees or as spot treatments. The treated area represents not more than 50 % of the total orchard area. The application rate with reference to the total orchard surface area is not more than 50 % of the stated dose rate.
Vines (VITVI) (table and wine grape, leaves not intended for human consumption)	EU	MON 52276	F	Emerged annual weeds (3ANMNT, 3ANDIT), emerged perennial and biennial weeds (3PEDIT, 3PEMNT)	SL	360 g/L	Ground directed, fully-shielded (hooded) spray, band application	Post-emergence of weeds throughout the year	1	28 days	0.18 - 1.08	100-400	0.72	7	Avoid crop contamination during treatment. Maximum application rate of 2.88 kg as/ha treated area glyphosate in any 12 months period. Use at least 75% drift reducing nozzles. Band application in the rows below the vine stock or as spot treatments. The treated area represents not more than 50 % of the total vineyard area. The application rate with reference to the total vineyard surface area is not more than 50 % of the stated dose rate.
Vines (VITVI) (table and wine grape, leaves not intended for human consumption)	EU	MON 52276	F	Emerged annual weeds (3ANMNT, 3ANDIT)	SL	360 g/L	Ground directed, fully-shielded (hooded) spray, band application	Post-emergence of weeds throughout the year	1	28 days	0.18 - 0.72	100-400	0.72	7	Avoid crop contamination during treatment. Maximum application rate of 2.16 kg as/ha treated area glyphosate in any 12 months period. Use at least 75% drift reducing nozzles. Band application in the rows below the vine stock or as spot treatments. The treated area represents not more than 50 % of the total vineyard area. The application rate with reference to the total vineyard surface area is not more than 50 % of the stated dose rate.

Crop and/or situation (a)	Member State or Country	Product name	F, G or I (b)	Pests or Group of pests controlled (c)	Preparation		Application				Application rate per treatment			PHI (days) (m)	Remarks
					Type (d-f)	Conc. a.s. (i)	method kind (f-h)	range of growth stages & season (j)	Number min-max (k)	Interval between application (min)	kg a.s./hL min-max (l)	Water L/ha min-max	kg a.s./ha min-max (l)		
Vegetables (Root vegetable plants (NNNVW) & tuberous plants (NNNZK), bulb plants (NNNZJ), fruit-vegetable plants (NNNVF), Legume vegetables (3LEVC), Leafy vegetables (3LEAC))	EU	MON 52276	F	Emerged annual weeds (3ANMNT, 3ANDIT), emerged perennial and biennial weeds (3PEDIT, 3PEMNT)	SL	360 g/L	Inter-row application: ground directed, fully-shielded (hooded) spray	Crop BBCH < 20	1	NA	0.27 - 1.08	100-400	1.08	60	Avoid crop contamination during treatment. Maximum application rate of 1.08 kg as/ha glyphosate in any 12 months period. Use at least 75% drift reducing nozzles. Applications are made between the crop rows. The rate refers to the treated area only, which represents not more than 50 % of the total area. The application rate with reference to the total surface area is not more than 50 % of the stated dose rate.
Vegetables (Root vegetable plants (NNNVW) & tuberous plants (NNNZK), bulb plants (NNNZJ), fruit-vegetable plants (NNNVF), Legume vegetables (3LEVC), Leafy vegetables (3LEAC))	EU	MON 52276	F	Emerged annual weeds (3ANMNT, 3ANDIT)	SL	360 g/L	Inter-row application: ground directed, fully-shielded (hooded) spray	Crop BBCH < 20	1	NA	0.18 - 0.72	100-400	0.72	60	Avoid crop contamination during treatment. Maximum application rate of 0.72 kg as/ha glyphosate in any 12 months period. Use at least 75% drift reducing nozzles. Applications are between the crop rows. The rate refers to the treated area only, which represents not more than 50 % of the total area. The application rate with reference to the total surface area is not more than 50 % of the stated dose rate.
Railway tracks (3RAILO)	EU	MON 52276	F	Emerged annual weeds (3ANMNT, 3ANDIT), emerged perennial and	SL	360 g/L	Ground directed, spray	Post-emergence of weeds throughout the year / no crop presnet	2	90 days	0.45 - 1.8	100-400	1.8	N/A	Application by spray train Drift reducing nozzles should be used or curtailment measures of the potential for drift should be used – e.g., shielded spray, incorporating targeted / direct application with at least 75% potential for drift reduction.

Crop and/or situation (a)	Member State or Country	Product name	F, G or I (b)	Pests or Group of pests controlled (c)	Preparation		Application				Application rate per treatment			PHI (days) (m)	Remarks
					Type (d-f)	Conc. a.s. (i)	method kind (f-h)	range of growth stages & season (j)	Number min-max (k)	Interval between application (min)	kg a.s./hL min-max (l)	Water L/ha min-max	kg a.s./ha min-max (l)		
				biennial weeds (3PEDIT, 3PEMNT)											Maximum application rate of 3.6 kg as/ha glyphosate in any 12 months period.
Railway tracks (3RAILO)	EU	MON 52276	F	Emerged annual weeds (3ANMNT, 3ANDIT), emerged perennial and biennial weeds (3PEDIT, 3PEMNT)	SL	360 g/L	Ground directed, spray	Post-emergence of weeds throughout the year / no crop presnet	1	NA	0.45 - 1.8	100-400	1.8	N/A	Application by spray train Drift reducing nozzles should be used or curtailment measures of the potential for drift should be used – e.g., shielded spray, incorporating targeted / direct application with at least 75% potential for drift reduction. Maximum application rate of 1.8 kg as/ha glyphosate in any 12 months period.
Invasive species in agricultural (3CRGK) and non-agricultural (YNKKX) areas	EU	MON 52276	F	Giant hogweed (<i>Herculeum mantegazzianum</i>) (HERMZ)	SL	360 g/L	Spot treatment (shielded)	Post-emergence of invasive species throughout the year	1	NA	0.45 - 36	5-400	1.8	N/A	Maximum application rate of 1.8 kg as/ha glyphosate in any 12 months period. Use at least 75% drift reducing nozzles.
Invasive species in agricultural (3CRGK) and non-agricultural (YNKKX) areas	EU	MON 52276	F	Japanese knotweed (<i>Reynoutria japonica</i>) (POLCU)	SL	360 g/L	Spot treatment (shielded), cut stem: spray application	Late summer, early fall	1	NA	0.45 - 36	5-400	1.8	N/A	Maximum application rate of 1.8 kg as/ha glyphosate in any 12 months period. Use at least 75% drift reducing nozzles.

Crop and/or situation (a)	Member State or Country	Product name	F, G or I (b)	Pests or Group of pests controlled (c)	Preparation		Application				Application rate per treatment			PHI (days) (m)	Remarks
					Type (d-f)	Conc. a.s. (i)	method kind (f-h)	range of growth stages & season (j)	Number min-max (k)	Interval between application (min)	kg a.s./hL min-max (l)	Water L/ha min-max	kg a.s./ha min-max (l)		
Root vegetable plants (NNNVW) & tuberous plants (NNNZK), bulb plants (NNNZJ), fruit-vegetable plants (NNNVF), Brassica (IBRSG), leaf and stem vegetable plants (NNNVL), Sugar beet (BEAVA)	EU	MON 52276	F	Couch grass (<i>Elymus repens</i>) (AGRRE)	SL	360 g/L	Spot treatment (shielded)	Post-harvest, pre-sowing, pre-planting	1	NA	0.18 - 0.72	100-400	0.72	N/A	Application to existing row cropland after harvest for removal of couch grass. Maximum application rate of 0.72 kg as/ha glyphosate in any 12 months period. Use at least 75% drift reducing nozzles. The treated area represents not more than 20 % of the cropland.
Root vegetable plants (NNNVW) & tuberous plants (NNNZK), bulb plants (NNNZJ), fruit-vegetable plants (NNNVF), Brassica (IBRSG), leaf and stem vegetable plants (NNNVL), Sugar beet (BEAVA)	EU	MON 52276	F	Couch grass (<i>Elymus repens</i>) (AGRRE)	SL	360 g/L	Spot treatment (shielded)	Post-harvest, pre-sowing, pre-planting	1	NA	0.18 - 0.72	100-400	0.72	N/A	Application to existing row cropland after harvest for removal of couch grass once every three years. Maximum application rate of 0.72 kg as/ha glyphosate in any 36 months period. Use at least 75% drift reducing nozzles The treated area represents not more than 20 % of the cropland.

Remarks:

- (a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (e.g. fumigation of a structure)
- (b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
- (c) e.g. biting and suckling insects, soil born insects, foliar fungi, weeds
- (d) e.g. wettable powder (WP), watersoluble granule (WG)
- (e) CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide formulation types and international coding system
- (f) All abbreviations used must be explained
- (g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
- (h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
- (i) g/kg or g/l
- (j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
- (k) The minimum and maximum number of application possible under practical conditions of use must be provided
- (l) PHI - minimum pre-harvest interval
- (m) Remarks may include: Extent of use/economic importance/ restrictions