

Date: 18 August 2020

Ref.nr: 6300/2175-7/2020

Sent by e-mail to:

Glyphosate Renewal Group (GRG)

European Commission, DG SANTE

European Food Safety Authority (EFSA)

Glyphosate: Check of completeness of the supplementary dossier for renewal of approval under Commission Implementing Regulation (EU) No 844/2012

Dear Applicant,

Hungary is one of the members of the Assessment Group on Glyphosate (AGG). The National Food Chain Safety Office (Nébih), being the competent authority for Regulation (EC) No 1107/2009 received the supplementary dossier for the application for renewal of the approval of Glyphosate on the 9 June 2020. The application was already received on 24 January 2020.

The applicant Glyphosate Renewal Group (GRG) was asked to submit at the latest by 24 July 2020 an updated supplementary dossier to include all elements provided for in Article 7 of Regulation (EU) No 844/2012. A revised supplementary dossier was received on the 23rd of July 2020.

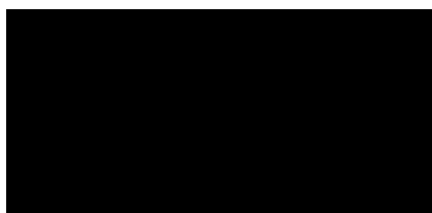
We have assessed the completeness of the updated supplementary dossier on Glyphosate, and found that it contains all the elements provided for in Article 7 (reference to section 1 of the enclosure to this letter). The application is found **admissible**. The evaluation process can start.

We invite the applicant to forward the updated supplementary dossier to the other Member States, the European Commission and EFSA according to Article 8 (3) of Regulation (EU) No 844/2012.

As already mentioned in our letter to the applicant, dated 10 July 2020, we have remarks that need further clarification. In addition, we took note that some final reports or studies are not yet available. We request these clarifications/reports in accordance with Article 11(5) of Regulation (EU) No 844/2012. These data are outlined in section 2 of the enclosure to this letter, together with a deadline for submission.

GRG already commented on the deadlines for submission in their response of 23rd July 2020 and proposed some alternative submission dates. Due to the regulatory deadline for AGG to submit their Renewal Assessment Report (RAR), the requested postponements cannot be accepted. Please note that if a submission deadline cannot be met, the first possibility to submit additional data is on request of EFSA in accordance with Article 13(3) of Regulation (EU) No 844/2012.

Yours sincerely,



Section 1: Elements to be submitted in accordance with Article 8(2) of Regulation (EU) No 844/2012

No.	Section	Issue	Submission date	AGG comment
1.	M-CA Section 5.5 Carcinogenicity	<p>In the M-document in the part of the carcinogenicity section where the available epidemiological studies are described (starting from page 1642 in the pdf version) it seems only a few new public literature studies were actually submitted. For most of the studies cited in this section the publication could not be found in the dossier. For the following studies the GRG is requested to submit the publications:</p> <ul style="list-style-type: none"> • Blair et al 2009 • De Roos et al 2005 • De Roos et al. 2003 • McDuffie et al. 2001 • Freeman 2009 • Hardell et al, 2002 • Erikson et al. 2008 • Orsi et al. 2009 • Lee et al. 2005 • Monge et al. 2007 • Hardell and Erikson, 1999 • Nordström et al. 1998 • Fritschi et al. 2005 • Alavanja et al. 2013 <p>In addition, a more extensive summary than is currently provided in the M-document or the Appendix is requested similar to the summaries that were provided for the publications found in the new literature search.</p> <p>Please also submit an updated L-document.</p>	24 July 2020	The request is fulfilled.

2.	-	An MRL application form should be submitted, indicating that an MRL in honey is requested (according to Art 7(i) of Regulation (EU) No 844/2012).	24 July 2020	The request is fulfilled.
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Section 2: Elements to be submitted in accordance with Article 11(5) of Regulation (EU) No 844/2012

No.	Section	Issue	Submission date	AGG comment
1.	Doc F	<p>The GRG updated their application on 24th April 2020. This application was not checked by the AGG as a correct application dated 22nd January 2020 was already agreed on.</p> <p>GRG only submitted the updated application dated 24th April 2020 in the supplementary dossier.</p> <p>GRG is requested to also submit the application dated 22nd January 2020 or at least make a reference to this document.</p>	1 September 2020	Already included in revised supplementary dossier Rev 1_version July 2020.
2.	Doc J	<p>Delay previously communicated:</p> <p>Specifications for sources from AFRASA and Albaugh</p> <p>Final reports and document</p>	31 July 2020	Already included in revised supplementary dossier Rev 1_version July 2020.
3.	M-CA Section 3 L-CA Section 3 K-CA Section 3.4/005 - 3.4/010	Document M-CA section 3.4 briefly summarises six reports describing “smart spray technologies”. M-CA section 3, page 42 and 44 refers to J-CP p. 1.4.1 for location of two of these documents. However, all six documents are filed under K-CA 3.4 in the CADDY CA, in red colour indicating that they are to be treated as	1 September 2020	Already included in revised supplementary dossier Rev 1_version July 2020.

		<p>confidential. The reports are listed in document L-CA section 3 without any indication that that they should be treated as confidential.</p> <p>Please clarify whether you consider reports K-CA 3.4/005 to K-CA 3.4/010 as confidential or not. If so, please consider to delete summaries of the studies in document M-CA section 3, and instead include these summaries in document J. Please also consider to delete these studies from reference list L-CA section 3, and instead include them in the reference list of document J. (Similar to handling of studies KCA 5/001 - KCA 5/036.) In case studies K-CA 3.4/005 to K-CA 3.4/010 should not be treated as confidential, the red colour in CADDY should preferably be changed to black.</p>		
4.	K-CA Section 5.2.2/025, K-CA Section 5.2.5/026	Two acute toxicity studies: [REDACTED] (1983- K-CA 5.2.2./026) and [REDACTED] (K-CA 5.2.5./025) are hardly readable. Documentation with enhanced quality should be submitted.	1 September 2020	Submission date confirmed by GRG.
5.	M-CA Section 5, K-CA Section 5.4	<p>Five studies on mutagenicity that were reported to be delayed should be submitted together with study summaries:</p> <ul style="list-style-type: none"> • [REDACTED] 2020 • [REDACTED] 2020 <p><u>AMPA:</u></p> <ul style="list-style-type: none"> • [REDACTED] 2020 • [REDACTED] 2020 • [REDACTED] 2020 	1 September 2020	<p>New submission date proposed by GRG: December 2020.</p> <p>Not accepted.</p>

6.	M-CA Section 5.5 Carcinogenicity	<p>Besides the studies listed in Section 1, a number of studies are also mentioned which are indicated to not reveal an association between glyphosate and specific cancer types. The GRG is requested to submit the following publications as well as a short summary of each of these studies:</p> <ul style="list-style-type: none"> • Alavanja et al. 2003 • Multigner et al 2008 • Band et al. 2011 • Lee et al. 2004 • Carreon et al. 2005 • Engel et al 2005 • Flower et al. 2004 • Andreotti et al. 2009 • Landgren et al. 2009 • Karunanayake et al. 2011 • Pahwa et al. 2011 • Schinasi and Leon 2014 • Kachuri et al. 2013 • Cocco et al. 2014 • Alavanja and Bonner 2012 • El-zaemey and Heyworth 2013 • Koutros et al. 2011 • Weichental et al. 2010 • Mink et al. 2012 <p>Please make sure no other studies referred to in the M-document are missing.</p> <p>Please also submit an updated doc L.</p>	1 September 2020	Submission date confirmed by GRG.
7.	K-CA Section 5.6.1/010	<p>The study report for the two-generation reproduction feeding study in rats conducted by [REDACTED] (1990)* is not complete (Vol II submitted only). Please submit the complete study</p>	1 September 2020	Submission date confirmed by GRG.

		<p>report.</p> <p>* (1990). Two Generation Reproduction Feeding Study with Glyphosate in Sprague-Dawley Rats. MSL-10387 MON. Doc No. M-643937-01-1</p>		
8.	K-CA Section 5.6.2/015	<p>The Historical control data (Rabbit 1989) is not described in sufficient detail (e.g. the time period for the studies reported, animal strain and if derived from the same laboratory and thus if laboratory conditions, study conditions, animal suppliers, husbandry etc is comparable). Without further information we expect it will be difficult to assess the relevance of this information. Please submit the missing data if available.</p> <p>The GRG is advised to check the entire M-document to see if sufficient details are provided on the historical control data for each case where HCD is used.</p>	1 September 2020	Submission date confirmed by GRG.
9.	K-CA Section 5.8.3	<p>The GRG is requested to provide a Word version of the document KCA 5.8.3/010 Assessment on the endocrine disruption properties of the active substance glyphosate.</p>	1 September 2020	Already included in revised supplementary dossier Rev 1_version July 2020.
10.	M-CA Section 5.9.7	<p>In the M-document on page 2651-2652 of the pdf version a number of references are listed which RMS could not find in the dossier.</p> <p>The following relevant studies were noted to be missing by the AGG:</p> <ul style="list-style-type: none"> • Acquavella et al. 1999 • Acquavella et al. 2004 	1 September 2020	Submission date confirmed by GRG.

		<ul style="list-style-type: none"> • Bradberry et al. 2004 • Bando et al. 2010 • Barbosa et al. 2001 • Brunetti et al. 2020 • Chang et al. 1999 • Goldstein et al. 1999 • Goldstein et al. 2002 • Kamijo et al. 2012 • Khot et al. 2012 • Lee et al. 2000 • Pushnoy et al. 1998 • Sawada et al. 1987 • Sawada et al. 1988 • Tominack et al. 1989 • Wang et al. 2011 • Zheng et al. 2018 <p>The GRG is requested to provide <u>all</u> references and include short summaries for these studies as they are currently only very briefly mentioned in the M-document</p> <p>Please make sure no other studies referred to in the M-document are missing.</p>		
11.	L-CA Section 5	The GRG is requested to provide a reference list sorted by author names. This will aid the AGG to prepare Volume 2 of the RAR.	1 September 2020	Submission date confirmed by GRG.
12.	K-CA Section 7.1	<p>Delay previously communicated:</p> <p>██████ 2020</p> <p>AMPA – Rate Degradation of Aminomethylphosphonic Acid (AMPA) in Aerobic Soil.</p> <p>This study should be provided together with an updated Document M-CA Section 7 (study summary + risk assessment if necessary).</p>	31 July 2020	Already included in revised supplementary dossier Rev 1_version July 2020.

13.	K-CA Section 7.1.3	<p>An adsorption study on AMPA is ongoing but not available yet.</p> <p>This study should be provided at the expected date together with an updated Document M-CA Section 7 (study summary + risk assessment if necessary).</p>	1 September 2020	<p>New submission date proposed by GRG: 15 September 2020.</p> <p>Not accepted.</p>
14.	K-CA Section 7.2	<p>Delay previously communicated:</p> <p>██████████ 2020</p> <p>Characterisation of the material in unidentified peak from study CRO-2019-268, Glyphosate – Aerobic mineralisation of [14C]Glyphosate in Surface Water.</p> <p>This study should be provided together with an updated Document M-CA Section 7 (study summary + risk assessment if necessary).</p>	31 July 2020	<p>New submission date proposed by GRG: 15 September 2020.</p> <p>Not accepted.</p>
15.	M-CA Section 8, 8.1.1.2	<p>Studies on avian short term dietary toxicity for glyphosate were available for the original Annex I inclusion. Based on the Regulation 283/2013 these data are not required anymore, provided that there is sufficient reason to assume that the dietary route of exposure is less severe than acute oral exposure. In the previous evaluation for renewal of approval, avian short term dietary data were not included. It is noted, however, that no attempt was made to convert the dietary endpoints (in ppm diet) to daily dietary dose</p>	1 September 2020	<p>Submission date confirmed by GRG.</p>

		(mg/kg bw per day), which is necessary in order to compare the toxicity endpoints from the different studies. Since the studies are available they should be included in the dossier. Appropriate study summaries including conversion of endpoints should be added to document M-CA Section 8.		
16.	K-CA Section 8.2	<p>Delay previously communicated:</p> <p>Algae study (freshwater green) with the metabolite AMPA.</p> <p>This study should be provided together with an updated Document M-CA Section 8 (study summary + risk assessment if necessary).</p>	31 July 2020	<p>New submission date proposed by GRG: between 15 December 2020 and 15 January 2021.</p> <p>Not accepted.</p>
17.	M-CA Section 8, K-CA Section 8.6	Please submit data on the herbicidal effect of the main metabolite AMPA. AGG noted that screening data on the biological activity of AMPA was summarised and evaluated in the revised RAR (2015), Vol 3, B.9. The study (██████████, 2012) should be submitted and summarised in M-CA Section 8.	1 September 2020	Submission date confirmed by GRG.
18.	K-CP Section 10.4.2	<p>For soil macroorganisms (<i>Folsomia candida</i> and <i>Hypoaspis aculeifer</i>), studies (new requirements) are ongoing but not available yet.</p> <p>These studies should be provided together with an updated Document M-CP</p>	31 July 2020	<p>New submission date proposed by GRG: 15 October 2020.</p> <p>Not accepted.</p>

		Section 10 (study summary + risk assessment if necessary).		
19.	K-CP Section 10.6.2	<p>It is noted that a vegetative vigor study on terrestrial plants is ongoing.</p> <p>This study should be provided together with an updated Document M-CP Section 10 (study summary + risk assessment if necessary).</p>	30 October 2020	<p>New submission date proposed by GRG: between 15 December 2020 and 15 January 2021.</p> <p>Not accepted.</p>
20.	M-CP Section 10.1.2	<p>Please provide full text versions and at least short summaries of the studies referred to in the higher tier risk assessment for wild mammals:</p> <ul style="list-style-type: none"> • Ebeling and Wang, 2018 • Le Louarn et al 2003 • Stein 1958 • Jacob and Halle 2001 • Jacob et al 2014 • Frank 1957 • Briner et al 2005 • Jacob et al 2014 	1 September 2020	<p>Submission date partly confirmed by GRG.</p> <p>New submission date proposed by GRG for part of the studies: 1 October 2020.</p> <p>Not accepted.</p>
21.	M-CP Section 10.1.1 and 10.1.2	<p>Please provide full text versions and at least short summaries of the studies referred to in the biodiversity assessment for birds and wild mammals.</p> <p><u>References relied upon for assessment of Indirect effects via trophic interaction for Birds discussion:</u></p> <ul style="list-style-type: none"> • Boatman et al 2004 • Bright et al 2008 • Burfeld 2005 • Campbell and Cooke 1997 • Cunningham et al 2005 • DEFRA 2005 • Donald et al 2006 • Easton and Martin 1998 	1 September 2020	<p>Submission date partly confirmed by GRG.</p> <p>New submission dates proposed by GRG for part of the studies: 1 October 2020 and 1 November 2020.</p> <p>Not accepted.</p>

		<ul style="list-style-type: none"> • Guiseppe et al 2006 • Guvnn et al 2004 • Jahn et al 2013 • Marshall et al 2001 • McLaughlin and Mineau 1995 • Santillo et al 1989b • Sullivan and Sullivan 2003 • Traba and Morales 2019 <p><u>Additional References relied upon for assessment of Indirect Effects via Trophic Interactions Discussions (make cross-references as appropriate, since some studies should be summarised already for the bird discussion):</u></p> <ul style="list-style-type: none"> • Anthony and Morrison 1985 • D'Anieri et al 1987 • Edge et al 2011 • Edge et al 2012 • Edge et al 2013 • Edge et al 2014 • Edge et al 2020 • Gagné et al 1999 • Guvnn et al 2004 • Guiseppe et al 2006 • Santillo et al 1989a • Santillo et al 1989b • Sullivan and Sullivan 2000 • Sullivan and Sullivan 2003 • McLaughlin and Mineau 1995 		
22.	<p>M-CA Section 8</p> <p>M-CP Section 10</p>	<p>No EC10 and EC20 were derived from some chronic studies – related to both the aquatic and terrestrial area. According to the Commission Regulations (EU) No 283/2013 and 284/2013 for all chronic/long term/reproductive toxicity studies, next to the NOEC an EC10 and EC20 should be provided, or at least a</p>	1 September 2020	<p>Submission date partly confirmed by GRG.</p> <p>New submission dates proposed by GRG for part of the studies: 1 October 2020 and 1 November 2020.</p>

		justification should be given why no, or no reliable EC10 and EC20 values can be derived.		Not accepted.
23.	M-CA Section 9 K-CA Section 9 M-CA Section 5, 6, 7, 8 as necessary	Top-up literature search. Scientific peer-reviewed open literature, published within the last 10 years before the date of submission of the dossier, shall be submitted (Article 8(5) of Regulation (EC) No 1107/2009). The current literature search covers the period Jan 2010 - Dec 2019. An additional search for open literature, covering the period Dec 2019 - June 2020 must be submitted.	30 October 2020	Submission date confirmed by GRG.
24.	M-CA Section 9 K-CA Section 9 M-CA Section 5, 6, 7, 8 as necessary	Study summaries or full-text articles and study summaries for potentially relevant/reliable articles that GRG initially has discarded. This will be requested by letter by the end of August.	30 October 2020	Pending
25.	General	Some studies are cited in documents M, but are not referenced in corresponding documents L. Please correct.	1 September 2020	Submission date confirmed by GRG.
26.	General	Some studies referenced as “vertebrate studies” in documents L may not be performed on vertebrate animals. Please check if the studies were actually performed on vertebrate animals and update the documents L accordingly.	1 September 2020	Submission date confirmed by GRG.
27.	General	Delay previously communicated: 4 scientific articles: Boscardin J. et al.,2014 -	31 July 2020	Submission date confirmed by GRG.

		<p>Relationship between ant communities and environmental quality in <i>Eucalyptus grandis</i> submitted to different weedy species control in the south of Brazil. (original in Portuguese language)</p> <p>Burstyn I. et al.,2017 - Visualizing the heterogeneity of effects in the analysis of associations of multiple myeloma with glyphosate use. Comments on Sorahan, T. Multiple myeloma and glyphosate use: A re-analysis of us agricultural health study (AHS) data.</p> <p>Marusca T.,2017 - Oversowing or resowing of subalpine grassland appointed after the dynamics of floristic composition.</p> <p>Shimina V. S. et al.,2010 - Effect of Herbicide Excel Mera-71 (Glyphosate) Treatment on Seed Germination and Early Seedling Growth of Black Gram (<i>Vigna mungo</i>, Hepper.) var. T-9.</p>		
28.	General	<p>Request on top of the dossier required in accordance with SANCO/10181/2013: Detailed presentation of data in relation to CLP criteria using format for tables and comparison with CLP criteria provided in SANCO/12592/2012.</p>	30 October 2020	<p>Submission date confirmed by GRG.</p> <p>Any additional material relevant for the comparison to the CLP criteria can be submitted during public consultation</p>

				of AGG's proposal for classification.
29.	General	Possibly study summaries of the old studies that will be submitted by our German colleagues. This will be communicated separately.	Deadline will be provided in separate request.	-