



**Appendix 1: Request for further elements to add to the dossier
on Glyphosate – Reply by GRG on 01-September-2020**

Doc ID: 110054-029

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The table below is copied from AGG's letter dated 18-August-2020 (Subject: Glyphosate: Check of completeness of the supplementary dossier for renewal of approval und Commission Implementing Regulation (EU) No 844/2012), section 2 of the enclosure to that letter). GRG added the column "GRG reply (01-September-2020)".

For better visibility those items where information has already been submitted by the GRG to the AGG and where the AGG confirmed that the requested information was "already included in revised supplementary dossier Rev 1_version July 2020" the text is in light grey colour to indicate that these lines are just included for the sake of completeness.

Admissi- bility check Point No.	Topic	Section	Issue	Submission date	AGG comment	GRG reply (01-September-2020)
Section 2: Elements to be submitted in accordance with Article 11(5) of Regulation (EU) No 844/2012						
1	Administrative	Doc F	The GRG updated their application on 24 th April 2020. This application was not checked by the AGG as a correct application dated 22 nd January 2020 was already agreed on. GRG only submitted the updated application dated 24 th April 2020 in the supplementary dossier. GRG is requested to also submit the application dated 22 nd January 2020 or at least make a reference to this document.	01-Sep-20	Already included in revised supplementary dossier Rev 1_version July 2020	
2	Confidential	Doc J	Delay previously communicated: Specifications for sources from AFRASA and Albaugh final reports and document	31-Jul-20	Already included in revised supplementary dossier Rev 1_version July 2020	
3	Socioeconomics	M-CA Section 3	Document M-CA section 3.4 briefly summarises six reports describing "smart spray technologies". M-CA	01-Sep-20	Already included in revised supplementary	

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		L-CA Section 3 K-CA Section 3.4/005 - 3.4/010	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 confidential. The reports are listed in document L-CA section 3 without any indication that that they should be treated as confidential. 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.		dossier Rev 1_version July 2020	
4	Toxicology	K-CA Section 5.2.2/026, K-CA Section 5.2.5/025	Two acute toxicity studies: (1983- K-CA 5.2.2./026) and (K-CA 5.2.5./025) are hardly readable. Documentation with enhanced quality should be submitted.	01-Sep-20	Submission date confirmed by GRG.	The documents are submitted by 01-Sep-20. Please refer to folder No 4_KCA 5.2 on the submitted CD.


Admissi- bility check Point No.	Topic	Section	Issue	Submission date	AGG comment	GRG reply (01-September-2020)
5	Toxicology	M-CA Section 5, K-CA Section 5.4	Five studies on mutagenicity that were reported to be delayed should be submitted together with study summaries: <ul style="list-style-type: none"> • [REDACTED] 2020 • [REDACTED] 2020 • AMPA: [REDACTED] 2020 • [REDACTED] 2020 • [REDACTED] 2020 	01-Sep-20	New submission date proposed by GRG: December 2020. Not accepted.	Available study status reports are submitted by 01-Sep-20. Please refer to the document CA 5.4_5.8_Status genotox studies_110054-23.docx in folder No 5_MCA Sec 5 on the submitted CD. GRG cannot submit the entire requested information at the requested date since the studies are still ongoing and are not yet finalized.

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6	Toxicology	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. Please also submit an updated doc L.</p>	01-Sep-20	Submission date confirmed by GRG.	<p>The publications and requested short summaries are submitted by 01-Sep-20.</p> <p>Please refer to folder No 6_MCA Sec 5.5 on the submitted CD.</p> <p>GRG cannot submit the updated doc L at the requested date but will provide it with an updated dossier on request of EFSA in accordance with Article 13(3) of Regulation (EU) No 844/2012.</p>

Admissi- bility check Point No.	Topic	Section	Issue	Submission date	AGG comment	GRG reply (01-September-2020)
7	Toxicology	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 report.</p> <p>[REDACTED] (1990). Two Generation Reproduction Feeding Study with Glyphosate in Sprague-Dawley Rats. MSL-10387 MON. Doc No. M-643937-01-1</p>	01-Sep-20	Submission date confirmed by GRG.	<p>The combined study report Vol. 1+2 is submitted by 01-Sep-20.</p> <p>Please refer to folder No 7_KCA 5.6.1-010 on the submitted CD.</p>
8	Toxicology	K-CA Section 5.6.2/015	<p>The Historical control data [REDACTED] 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>	01-Sep-20	Submission date confirmed by GRG.	<p>The requested missing data is submitted by 01-Sep-20.</p> <p>For the Historical control data [REDACTED] Rabbit 1989), please refer to folder No 8_KCA Sec 5.6.2-015 on the submitted CD.</p> <p>Regarding the advice to check the entire M-document, the GRG has reviewed the glyphosate AIR 5 MCA 5 submission document and has not identified any studies where doses in the range of likely endpoint selections for risk assessment rely on historical control data (HCD) to</p>

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						contextualize reported findings. Therefore, the only HCD update will be submitted in response to the AGG request in support of dossier points 5.6.2/014 & 015, Brooker (1991) range finder and definitive rabbit developmental toxicity studies.
9	Toxicology	K-CA Section 5.8.3	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.	01-Sep-20	Already included in revised supplementary dossier Rev 1_version July 2020	

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10	Toxicology	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. 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 • 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 all references and include short summaries for these studies as they are currently only very briefly mentioned in the M-document. Please make sure no other studies referred to in the M-document are missing.</p>	01-Sep-20	Submission date confirmed by GRG.	<p>The requested documents and short summaries are submitted by 01-Sep-20.</p> <p>Please refer to folder No 10_MCA Sec 5.9.7 (Medical data) on the submitted CD.</p>

Admissi- bility check Point No.	Topic	Section	Issue	Submission date	AGG comment	GRG reply (01-September-2020)
11	L doc	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-Sep-20	Submission date confirmed by GRG.	All L documents sorted by author name are submitted by 01-Sep-20. Please refer to folder No 11_LCA_Sec 5 Reference list on the submitted CD.
12	E-Fate	K-CA Section 7.1	Delay previously communicated:  2020 AMPA – Rate Degradation of Aminomethylphosphonic Acid (AMPA) in Aerobic Soil. This study should be provided together with an updated Document M-CA Section 7 (study summary + risk assessment if necessary).	31-Jul-20	Already included in revised supplementary dossier Rev 1_version July 2020	
13	E-Fate	K-CA Section 7.1.3	An adsorption study on AMPA is ongoing but not available yet. This study should be provided at the expected date together with an updated Document M-CA Section 7 (study summary + risk assessment if necessary).	1-Sep-20	New submission date proposed by GRG: 15 September 2020. Not accepted.	The finalized study report and study summary are submitted by 01-Sep-20. Please refer to folder No 13_KCA Sec 7.1.3 on the submitted CD. The GRG was able to obtain the finalized study report in time for inclusion in the submission by 01-Sep-20.

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14	E-Fate	K-CA Section 7.2	<p>Delay previously communicated: [REDACTED] 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-Jul-20	<p>New submission date proposed by GRG: 15 September 2020.</p> <p>Not accepted.</p>	GRG cannot submit the requested information at the requested date since the study is still ongoing and is not yet finalized.

Admissi- bility check Point No.	Topic	Section	Issue	Submission date	AGG comment	GRG reply (01-September-2020)
15	Ecotoxicology	M-CA Section 8, 8.1.1.2	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 (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.	1-Sep-20	Submission date confirmed by GRG.	The requested studies and study summaries are submitted by 01-Sep-20. Please refer to folder No 15_MCA Sec 8, 8.1.1.2 on the submitted CD.
16	Ecotoxicology	K.CA Section 8.2	Delay previously communicated: Algae study (freshwater green) with the metabolite AMPA. This study should be provided together with an updated Document M-CA Section 8 (study summary + risk assessment if necessary).	31-Jul-20	New submission date proposed by GRG: between 15 December 2020 and 15 January 2021. Not accepted.	GRG cannot submit the requested information at the requested date since the study is still ongoing and is not yet finalized.

Admissi- bility check Point No.	Topic	Section	Issue	Submission date	AGG comment	GRG reply (01-September-2020)
17	Ecotoxicology	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-Sep-20	Submission date confirmed by GRG.	The requested data, study and study summary are submitted by 01-Sep-20. Please refer to folder No 17_MCA Sec 8, K-CA Sec 8.6 (Herb screen) on the submitted CD.
18	Ecotoxicology	K-CP Section 10.4.2	For soil macroorganisms (<i>Folsomia candida</i> and <i>Hypoaspis aculeifer</i>), studies (new requirements) are ongoing but not available yet. These studies should be provided together with an updated Document M-CP Section 10 (study summary + risk assessment if necessary).	31-Jul-20	New submission date proposed by GRG: 15 October 2020. Not accepted.	GRG cannot submit the requested information at the requested date since the studies are still ongoing and are not yet finalized.
19	Ecotoxicology	K-CP Section 10.6.2	It is noted that a vegetative vigor study on terrestrial plants is ongoing. This study should be provided together with an updated Document M-CP Section 10 (study summary + risk assessment if necessary).	30-Oct-20	New submission date proposed by GRG: between 15 December 2020 and 15 January 2021. Not accepted.	GRG cannot submit the requested information at the requested date since the study is still ongoing and is not yet finalized.

Admissi- bility check Point No.	Topic	Section	Issue	Submission date	AGG comment	GRG reply (01-September-2020)
20	Ecotoxicology	M-CP Section 10.1.2	Please provide full text versions and at least short summaries of the studies referred to in the higher tier risk assessment for wild mammals: <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 	01-Sep-20	Submission date partly confirmed by GRG. New submission date proposed by GRG for part of the studies: 1 October 2020. Not accepted.	The entire requested information, documents and summaries, are submitted by 01-Sep-20. Please refer to folder No 20_MCP Sec 10.1.2 (Mammal lit.) on the submitted CD. <i>As mentioned before in the official GRG reply to AGG (21st of July) the GRG notes that one of the requested studies seems to appear in duplication (Jacob et al. 2014), so the GRG's understanding is that the AGG is requesting overall 7 studies under this point.</i> <i>Please note that the article Jacob et al. 2014 is not provided but Jacob et al. 2013. Possible typo in the year cited in the admissibility check table (Version 18-August-2020).</i>

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21	Ecotoxicology	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>References relied upon for assessment of Indirect effects via trophic interaction for Birds discussion:</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 • Guisepppe et al 2006 • Guvrin 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>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):</p> <ul style="list-style-type: none"> • Anthony and Morrison 1985 	01-Sep-20	<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>	<p>The entire requested information, documents and summaries, are submitted by 01-Sep-20.</p> <p>Please refer to folder No 21_MCP Sec 10.1.1 and 10.1.2 (Biodiversity lit.) on the submitted CD.</p>

Admissi- bility check Point No.	Topic	Section	Issue	Submission date	AGG comment	GRG reply (01-September-2020)
			<ul style="list-style-type: none"> • 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 • Guynn 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	Ecotoxicology	M-CA Section 8 M-CP Section 10	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 justification should be given why no, or no reliable EC10 and EC20 values can be derived.	01-Sep-20	<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>	<p>The entire requested information is submitted by 01-Sep-20.</p> <p>Please refer to folder No 22_MCA Sec 8_MCP Sec 10 on the submitted CD.</p>

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23	LRR	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-Oct-20	Submission date confirmed by GRG.	
24	LRR	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-Oct-20	Pending	
25	L doc	General	Some studies are cited in documents M, but are not referenced in corresponding documents L. Please correct.	01-Sep-20	Submission date confirmed by GRG.	A statement to address this request is submitted by 01-Sep-20. Please refer to folder No 25_General on the submitted CD.
26	L doc	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.	01-Sep-20	Submission date confirmed by GRG.	Updated documents LCA are submitted by 01-Sep-20. Please refer to folder No 26_Corrected vertebrate status in LCA documents on the submitted CD.

Admissi- bility check Point No.	Topic	Section	Issue	Submission date	AGG comment	GRG reply (01-September-2020)
27	LRR	General	<p>Delay previously communicated: 4 scientific articles:</p> <p>Boscardin J. et al.,2014 - Relationship between ant communities and environmental quality in Eucalyptus grandis 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.</p> <p>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 alter 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 (Vigna mungo, Hepper.) var. T-9.</p>	31-Jul-20	Submission date confirmed by GRG.	
28	CLH	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-Oct-20	<p>Submission date confirmed by GRG.</p> <p>Any additional material relevant for the comparison to the CLP criteria can be</p>	

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					submitted during public consultation of AGG's proposal for classification.	
29	Ad-hoc	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.	-	

The following information has not been requested by the AGG in their letter "Check of completeness of the supplementary dossier for renewal of approval under Commission Implementing Regulation (EU) No 844/2012" dated 18-August-2020. However, this supportive information on the acute endpoint selection based on the available acute toxicology (rodent) studies, to support the use of a geometric mean acute endpoint in the acute mammalian risk assessment has been updated in the Annex M-CA 8-02 of the SANCO M-CA document. This updated annex is submitted here for the consideration of AGG during the evaluation of the AIR 5 dossier.

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Not part of AGG admissibility check request	Ecotoxicology	M-CA Section 8	Updated version of Annex M-CA 8-02 – Acute mammal endpoint	01-Sep-20	Not relevant.	Please refer to folder No 99_Additional ecotox update Annex M-CA 8-02 on the submitted CD (Doc ID: M-CA 8-02_Update annex Acute Mammal Endpoint 110054-032).