

[REDACTED]
CTGB Netherlands
Chair of the Assessment Group on Glyphosate (AGG)

CC:

- **AGG Member State competent authorities in France, Hungary, Sweden**

By e-mail

Glyphosate: Check of completeness of the supplementary dossier for renewal of approval under Commission Implementing Regulation (EU) No 844/2012 – Glyphosate Renewal Group (GRG) reply to the letters received from AGG on 10-July-2020

Dear **[REDACTED]**, dear AGG,

On 10-July-2020 the AGG competent authorities informed the GRG about the outcome of the check of completeness of the glyphosate supplementary dossier for renewal of approval under Commission Implementing Regulation (EU) No 844/2012.

In their respective letters the AGG requested the GRG to submit certain missing elements as a prerequisite to confirm admissibility of the application according to Article 8 of Regulation (EU) No 844/2012.

The GRG is submitting these elements by the deadline of 24-July-2020 to the AGG competent authorities.

In addition, the AGG provided a number of remarks that – although not leading to inadmissibility – warrant submission of further data or clarification.

The GRG has thoroughly evaluated each remark provided by the AGG and outlined in the second section of the enclosure to AGG's letters from 10-July-2020. The GRG appreciates the opportunity to submit further data

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July 21, 2020

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and clarification and prepared respective proposals to address each point, in the format of a commenting table in **Appendix 1** to this letter.

The GRG would like to provide some general comments regarding AGG's remarks.

- Finalization date of new studies that are currently still ongoing and submission of final study reports:

The GRG confirmed the latest status of the finalization of experimental studies with the involved Contract Research Organizations (CROs) again in July 2020. Due to several unforeseen delays in the experimental work performed by the CROs, new timelines had to be included in the latest update of the Application document (Revision 3). This updated Application Revision 3 document was submitted to the AGG on 20-July-2020.

The GRG is conscious of the fact that this unanticipated change in study finalization dates affects the update of the SANCO dossier. However, due to the still tense situation in the EU linked to COVID19 the GRG has limited influence on the CRO-internal organization of study workload and finalization timelines.

- AGG's requested submission dates for further data:

As discussed during the 4-June-2020 pre-submission call, the GRG has prepared and is submitting an updated CADDY dossier: SANCO Dossier Rev 1_version July 2020.

The GRG was able to already include in this updated CADDY dossier some of the data requested by AGG, although AGG's request was for a later submission date. This is indicated in the **Appendix 1** table for the respective points.

- Updated CADDY dossier for all the CA and CP sections:

Considering the finalization of currently still ongoing studies, as well as AGG's request for additional summaries and other data, a full update of M, N and L documents may be desirable, to properly include updated risk assessments and additional references. Based on the timelines for availability of new data (see **Appendix 1** table) the GRG's proposal is to submit individual study reports and study summaries upon individual study

completion and for the submission of an updated CADDY dossier for the CA and CP sections between 15-December-2020 and 15-January-2021.

The GRG is available for explaining any points in the **Appendix 1** table in more details in case this is requested by the AGG, and we are proposing a conference call to discuss any open topics.

Thank you for your kind consideration of our comments.

Yours sincerely,



Glyphosate EU Regulatory Lead, Bayer AG
Chair of GRG Regulatory Working Group

Attachment: **Appendix 1**

Appendix 1:

bility check Point No.	Topic	Section	AGG remark	AGG requested submission date	GRG comments - proposed timelines
Section I: Elements to be submitted in accordance with Article 8(2) of Regulation (EU) No 844/2012					
1	Toxicology	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 • Nordstrom 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. Please also submit an updated L-document.</p>	24-Jul-20	<p>In response to this point, the 14 PDF articles and corresponding Appendix E summaries are provided in a stand-alone document by 24-July-2020, as requested. In addition, an updated L-document, including the 14 publications, are provided in the updated SANCO Dossier Rev 1_version July 2020 that GRG is submitting to AGG by 24-July-2020.</p> <p>The GRG's proposal for updated M and N documents that include the additionally submitted data (updated CADDY dossier for the CA and CP sections), if requested by AGG, would be between 15-December-2020 and 15-January-2021.</p>

Admissi- bility check Point No.	Topic	Section	AGG remark	AGG requested submission date	GRG comments - proposed timelines
2	Residues	Residues	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-Jul-20	An MRL application form is submitted as a stand-alone document by 24-July-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	Feedback on this point will be provided by 24-July-2020 . The Application documents dated <ul style="list-style-type: none"> • 22-January-2020, as well as • Application document Rev 2 (dated 24-April-2020), and • Application document Rev 3 (dated 20-July-2020) will be provided in doc F Rev 1 in the updated SANCO Dossier Rev 1_version July 2020 that will be submitted to AGG by 24-July-2020 .
2	Confidential	Doc J	Delay previously communicated: Specifications for sources from AFRASA and Albaugh final reports and document	31-Jul-20	Feedback on this point will be provided on 24-July-2020 . The information will be included in the updated SANCO Dossier Rev 1_version July 2020 that GRG is submitting to AGG by 24-July-2020 .

Admissi- bility check Point No.	Topic	Section	AGG remark	AGG requested submission date	GRG comments - proposed timelines
3	Socioeconomics	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 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.	01-Sep-20	Feedback on this point will be provided by 24-July-2020 . The information will be included in the updated SANCO Dossier Rev 1_version July 2020 that GRG is submitting to AGG by 24-July-2020 .
4	Toxicology	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.	01-Sep-20	The PDF study reports submitted to the AGG are the only available files in the archives of GRG members. However, we will explore the options to provide enhanced quality of the submitted PDF study reports. Further feedback on this point will be provided by 01-September-2020, as requested .
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: • [REDACTED] 2020	01-Sep-20	Due to an unforeseen delay in the experimental work by the CRO commissioned to perform the studies relevant to this point,

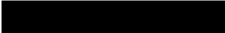
Admissi- bility check Point No.	Topic	Section	AGG remark	AGG requested submission date	GRG comments - proposed timelines
			<ul style="list-style-type: none"> • [REDACTED] 2020 • AMPA: [REDACTED] 2020 • [REDACTED] 2020 • [REDACTED] 2020 		<p>new timelines had to be included in Application document Revision 3.</p> <p>The Application Revision 3 document was submitted to the AGG on 20-July-2020. The updated status and new timelines for these 5 studies has been communicated to GRG by the CRO in July 2020, with planned finalization date by December 2020.</p> <p>Thus, GRG will only be able to submit the finalized study reports and summaries of these 5 studies to AGG during December 2020.</p> <p>The GRG's proposal for updated M, N and L documents that include the new data (updated CADDY dossier for the CA and CP sections), if requested by AGG, would be between 15-December-2020 and 15-January-2021.</p>

Admissi- bility check Point No.	Topic	Section	AGG remark	AGG requested submission date	GRG comments - proposed timelines
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	<p>In response to this point, PDF articles and short summaries will be provided in a stand-alone document by 01-September-2020.</p> <p>The GRG's proposal for updated M, N and L documents that include the additionally submitted data (updated CADDY dossier for the CA and CP sections), if requested by AGG, would be between 15-December-2020 and 15-January-2021.</p>

Admissi- bility check Point No.	Topic	Section	AGG remark	AGG requested submission date	GRG comments - proposed timelines
7	Toxicology	K-CA Section 5.6.1/010	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. [REDACTED] (1990). Two Generation Reproduction Feeding Study with Glyphosate in Sprague-Dawley Rats. MSL-10387 MON. Doc No. M-643937-01-1	01-Sep-20	Feedback on this point will be provided by 01-September-2020 .
8	Toxicology	K-CA Section 5.6.2/015	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. 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.	01-Sep-20	The historical control data [REDACTED] Rabbit 1989) will be provided as a stand-alone document by 01-September-2020 . The entire M-document will be screened for details provided on HCD and if applicable, the GRG will contact the CROs to obtain any additional data. The outcome of the M-document screen and any additional available data will be provided by 01-September-2020. The GRG's proposal for updated M, N and L documents that include the additionally submitted data (updated CADDY dossier for the CA and CP sections), if requested by AGG, would be between 15-December-2020 and 15-January-2021 .
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	Feedback on this point will be provided by 24-July-2020 . The information will be included in the updated SANCO Dossier Rev 1_version July 2020 that GRG is submitting to AGG by 24-July-2020 .

Admissi- bility check Point No.	Topic	Section	AGG remark	AGG requested submission date	GRG comments - proposed timelines
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	<p>In response to this point, PDF articles and short summaries will be provided in a stand-alone document by 01-September-2020.</p> <p>The GRG's proposal for updated M, N and L documents that include the additionally submitted data (updated CADDY dossier for the CA and CP sections), if requested by AGG, would be between 15-December-2020 and 15-January-2021.</p>
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	Feedback on this point will be provided by 01-September-2020 .

Admissi- bility check Point No.	Topic	Section	AGG remark	AGG requested submission date	GRG comments - proposed timelines
12	E-Fate	K-CA Section 7.1	Delay previously communicated: [REDACTED] 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	A PDF of the study report and study summary will be submitted by 24-July-2020 . The information will be included in the updated SANCO Dossier Rev 1_version July 2020 that GRG is submitting to AGG by 24-July-2020 . The GRG's proposal for updated M, N and L documents that include the new data of this study ([REDACTED], 2020) and updated risk assessment (updated CADDY dossier for the CA and CP sections) would be between 15-December-2020 and 15-January-2021 .
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	This study will be finalized by 31-August-2020, as previously communicated to the AGG in the Application document Revision 2 (dated 24-April-2020). Given the forecasted finalization date, the GRG proposes to provide the PDF study report and study summary to the AGG in a stand-alone document by 15-September-2020 . The GRG's proposal for updated M, N and L documents that include the new data and updated risk assessment (updated CADDY dossier for the CA and CP sections) would be between 15-December-2020 and 15-January-2021 .

Admissi- bility check Point No.	Topic	Section	AGG remark	AGG requested submission date	GRG comments - proposed timelines
14	E-Fate	K-CA Section 7.2	<p>Delay previously communicated:  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>Due to an unforeseen delay in the experimental work by the CRO commissioned to perform this study, new timelines had to be included in Application document Revision 3.</p> <p>The Application Revision 3 document was submitted to the AGG on 20-July-2020. The updated status and new timelines for this study has been communicated to GRG by the CRO in July 2020, with planned finalization date by end-August 2020.</p> <p>Given the forecasted finalization date, the GRG proposes to provide the PDF study report and study summary to the AGG in a stand-alone document by 15-September-2020.</p> <p>The GRG's proposal for updated M, N and L documents that include the new data and updated risk assessment (updated CADDY dossier for the CA and CP sections) would be between 15-December-2020 and 15-January-2021.</p>

Admissi- bility check Point No.	Topic	Section	AGG remark	AGG requested submission date	GRG comments - proposed timelines
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	<p>Study summaries and discussion will be provided in a stand-alone document by 01-September-2020.</p> <p>The GRG's proposal for updated M, N and L documents that include the new data and updated risk assessment (updated CADDY dossier for the CA and CP sections) would be between 15-December-2020 and 15-January-2021.</p>
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	<p>Due to an unforeseen delay in the experimental work by the CRO commissioned to perform this study, new timelines had to be included in Application document Revision 3.</p> <p>The Application Revision 3 document was submitted to the AGG on 20-July-2020. The updated status and new timelines for this study has been communicated to GRG by the CRO in July 2020, with planned finalization date by 15-December-2020.</p> <p>Given the forecasted finalization date, the GRG proposes to include the PDF study report and study summary in the updated CADDY dossier.</p>

Admissi- bility check Point No.	Topic	Section	AGG remark	AGG requested submission date	GRG comments - proposed timelines
					The GRG's proposal for updated M, N and L documents that include the new data and updated risk assessment (updated CADDY dossier for the CA and CP sections) would be between 15-December-2020 and 15-January-2021 .
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 [REDACTED], 2012) should be submitted and summarised in M-CA Section 8.	1-Sep-20	<p>Please note that the PDF Report of the study [REDACTED], 2012) was already submitted in the SANCO Dossier_version June 2020, as KCP 10.6.2/004.</p> <p>The PDF report, study summary, and updated LCA-document will be provided in a stand-alone document by 01-September-2020.</p> <p>The GRG's proposal for updated M, N and L documents that include the study summary (updated CADDY dossier for the CA and CP sections) would be between 15-December-2020 and 15-January-2021.</p>
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	<p>Due to an unforeseen delay in the experimental work by the CRO commissioned to perform this study, new timelines had to be included in Application document Revision 3.</p> <p>The Application Revision 3 document was submitted to the AGG on 20-July-2020. The updated status and new timelines for this study has been communicated to GRG by the CRO in July 2020, with planned finalization date by 01-October-2020.</p> <p>Given the forecasted finalization date, the GRG proposes to provide the PDF study</p>

Admissi- bility check Point No.	Topic	Section	AGG remark	AGG requested submission date	GRG comments - proposed timelines
					<p>report and study summary to the AGG in a stand-alone document by 15-October-2020.</p> <p>The GRG's proposal for updated M, N and L documents that include the new data and updated risk assessment (updated CADDY dossier for the CA and CP sections) would be between 15-December-2020 and 15-January-2021.</p>
19	Ecotoxicology	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-Oct-20	<p>Due to an unforeseen delay in the experimental work by the CRO commissioned to perform this study, new timelines had to be included in Application document Revision 3.</p> <p>The Application Revision 3 document was submitted to the AGG on 20-July-2020. The updated status and new timelines for this study has been communicated to GRG by the CRO in July 2020, with planned finalization date by 01-December-2020.</p> <p>Given the forecasted finalization date, the GRG proposes to include the PDF study report and study summary in the updated CADDY dossier.</p> <p>The GRG's proposal for updated M, N and L documents that include the new data and updated risk assessment (updated CADDY dossier for the CA and CP sections) would be between 15-December-2020 and 15-January-2021.</p>

Admissi- bility check Point No.	Topic	Section	AGG remark	AGG requested submission date	GRG comments - proposed timelines
20	Ecotoxicology	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 Louam 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	<p>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.</p> <p>The GRG proposes to submit the PDF study reports and corresponding study summaries of these 7 articles to the AGG in 2 batches:</p> <ul style="list-style-type: none"> • The PDF study reports and study summaries for a first batch of 3 articles will be provided to the AGG in a stand-alone document by 01-September-2020. • GRG proposes to provide the remaining 4 articles (batch 2) to the AGG in a stand-alone document by 01-October-2020. <p>The GRG's proposal for updated M, N and L documents that include the new data and updated risk assessment (updated CADDY dossier for the CA and CP sections) would be between 15-December-2020 and 15-January-2021.</p>

Admissi- bility check Point No.	Topic	Section	AGG remark	AGG requested submission date	GRG comments - proposed timelines
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 • Guiseppe 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 • D'Anieri et al 1987 • Edge et al 2011 • Edge et al 2012 • Edge et al 2013 	01-Sep-20	<p>The GRG proposes to submit the PDF study reports and corresponding study summaries of these 31 articles to the AGG in 3 batches:</p> <ul style="list-style-type: none"> • The PDF study reports and study summaries for a first batch of 10 articles will be provided to the AGG in a stand-alone document by 01-September-2020. • GRG proposes to provide the next 10 articles (batch 2) to the AGG in a stand-alone document by 01-October-2020. • GRG proposes to provide the remaining 11 articles (batch 3) to the AGG in a stand-alone document by 01-November-2020. <p>The GRG's proposal for updated M, N and L documents that include the new data and updated risk assessment (updated CADDY dossier for the CA and CP sections) would be between 15-December-2020 and 15-January-2021.</p>

Admissi- bility check Point No.	Topic	Section	AGG remark	AGG requested submission date	GRG comments - proposed timelines
			<ul style="list-style-type: none"> • 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	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>This request comprises the evaluation of approximately 22 study reports.</p> <p>The GRG proposes to submit position papers and updated study summaries (where appropriate) in a stand-alone document in 3 batches:</p> <ul style="list-style-type: none"> • Batch 1, to be provided to the AGG in a stand-alone document by 01-September-2020. • Batch 2, to be provided to the AGG in a stand-alone document by 01-October-2020. • Batch 3, to be provided to the AGG in a stand-alone document by 01-November-2020. <p>The GRG's proposal for updated M, N and L documents that include the updated summaries (updated CADDY dossier for the</p>

Admissi- bility check Point No.	Topic	Section	AGG remark	AGG requested submission date	GRG comments - proposed timelines
					CA and CP sections) would be between 15-December-2020 and 15-January-2021 .
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	The outcome of the evaluation, relevance assessment at title and abstract level, allocation of CA and CP data requirement points for relevant articles, and individual Appendix E summaries of relevant articles and update of the LRR document will be submitted by 30-October-2020 . The GRG's proposal for updated M, N and L documents that include the summaries (updated CADDY dossier for the CA and CP sections) would be between 15-December-2020 and 15-January-2021 .
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	These documents will be evaluated once the requested articles are communicated to the GRG.
25	L doc	General	Some studies are cited in documents M, but are not referenced in corresponding documents L. Please correct.	01-Sep-20	The updated L document will be submitted to the AGG in a stand-alone document by 01-September 2020 . The GRG's proposal for updated M, N and L documents that include the summaries (updated CADDY dossier for the CA and CP sections) would be between 15-December-2020 and 15-January-2021 .
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	01-Sep-20	The updated L document will be submitted to the AGG in a stand-alone document by 01-September 2020 .

Admissi- bility check Point No.	Topic	Section	AGG remark	AGG requested submission date	GRG comments - proposed timelines
			were actually performed on vertebrate animals and update the documents L accordingly.		The GRG's proposal for inclusion of the updated L document in the SANCO dossier (updated CADDY dossier for the CA and CP sections) would be between 15-December-2020 and 15-January-2021 .
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. 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	<p>The PDF articles will be provided in a stand-alone document by 31-July-2020. (Please note that 3 of the 4 outstanding articles are already included in the updated SANCO Dossier Rev 1_version July 2020 that GRG is submitting to AGG by 24-July-2020. The remaining article Marusca T., 2017, will be provided in a stand-alone document by 31-July-2020.)</p>
28	CLH	General	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.	30-Oct-20	As stated above under point 5 of this table, due to an unforeseen delay in the experimental work by the CRO commissioned to perform the studies pertaining to the CLP criteria (e.g., critical for the classification for the endpoint "Germ Cell Mutagenicity"), new

Admissi- bility check Point No.	Topic	Section	AGG remark	AGG requested submission date	GRG comments - proposed timelines
					<p>timelines had to be included in Application document Revision 3.</p> <p>The Application Revision 3 document was submitted to the AGG on 20-July-2020. The updated status and new timelines for ongoing genotox studies has been communicated to GRG by the CRO in July 2020, with planned finalization date by December 2020.</p> <p>In consequence, submitting a complete dataset in relation to CLP criteria by 30-October-2020 will not be possible because the new genotox data cannot be included.</p> <p>Furthermore, since the admissibility check contains requests for further clarification and information concerning carcinogenicity, this work will subsequently influence the work involved in preparation of the presentation of data in relation to CLP criteria.</p> <p>The GRG, would like to propose the following two options:</p> <ul style="list-style-type: none"> • Option A) to submit the data in relation to CLP criteria, based on the information available at that time for submission in October-2020, and to provide the updated and complete data in relation to CLP criteria by 16-December-2020. • Option B) to submit a complete dataset in relation to CLP criteria,

Admissi- bility check Point No.	Topic	Section	AGG remark	AGG requested submission date	GRG comments - proposed timelines
					including all newly available information by 16-December-2020 .
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 GRG will prepare and submit study summaries in a stand-alone document. The GRG's proposal for inclusion of the updated L document in the SANCO dossier (updated CADDY dossier for the CA and CP sections) would be between 15-December- 2020 and 15-January-2021 .