

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

CC:

- **European Food Safety Authority (EFSA),  
Head of Pesticide Peer Review Unit, [REDACTED]**
- **EU Commission, DG SANTE,  
Head of Unit – Pesticides and biocides, [REDACTED]**

By e-mail

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June 17, 2020

**Disclosure of the AIR5 Glyphosate renewal dossier**

[REDACTED]

Bayer AG  
Crop Science Division  
Global Regulatory Affairs

Postal address:  
Alfred-Nobel-Str. 50  
40789 Monheim  
Germany

Dear [REDACTED], dear AGG,

Thank you for your letter from 11-June-2020 about the disclosure of the AIR5 Glyphosate renewal dossier and for requesting certain action from the Glyphosate Renewal Group (GRG).

[REDACTED]

[www.bayer.com](http://www.bayer.com)

The GRG would like to provide some comments for the sake of clarification.

Board of Management:  
Werner Baumann,  
Chairman of the Board  
Liam Condon  
Wolfgang Nickl  
Stefan Oelrich  
Heiko Schipper

Chairman of the  
Supervisory Board:  
Norbert Winkeljohann

Registered Office:  
Leverkusen  
Registered at the  
Local Court of Cologne  
HRB 48248

<b>AGG request</b>	<b>GRG comment</b>
<i>“As applicant and/or authorization holder we ask you to mark all items in the complete dossier you regard as confidential as stated in art 63 of Reg. (EC) No 1107/2009 . We will assess your proposal and your argumentation of confidentiality per item.”</i>	The GRG included a sanitized version of the summary dossier in our AIR5 glyphosate renewal dossier that was submitted recently to AGG. The justification form with our argumentation of confidentiality per item is included and was part of our submission.

AGG request	GRG comment
<p><i>“Since deadlines for decisions on requests for information are relatively short in view of the amount of dossier items, we would kindly request you to submit by July 1st 2020 a duplicate dossier where all confidential parts are highlighted using a specific color, which is not black, and the markings are motivated based on the relevant regulations and case law.”</i></p>	<p>The GRG would like to clarify the exact meaning of “duplicate dossier”. Is AGG referring to the summary dossier when talking about a “duplicate dossier”, or is AGG referring to the summary dossier <u>and</u> all full study reports?</p> <p>As commented above, the GRG included a sanitized version of the summary dossier in our AIR5 glyphosate renewal dossier that was submitted recently to AGG. In addition the GRG can provide a “marked for redaction” version of the summary dossier where all confidential parts are highlighted by a red box around the confidential parts and the content in the red box is still visible, by 1-July-2020. (This is the “marked for redaction” version prepared in Adobe Acrobat before actually applying the redaction and blackening the text.) The marked items will be the same as in the already provided sanitized version of the summary dossier that AGG recently received from us.</p> <p>In case AGG is referring to the summary dossier <u>and</u> all full study reports when talking about a “duplicate dossier”, then the GRG needs to inform that we are not planning to pro-actively sanitize all the old full study reports that are part of our renewal dossier, i.e. all those study reports that were part of the previous EU submissions. The GRG is only planning to pro-actively sanitize the approx. 100 new study reports that are listed in our updated Application document. The sanitization of these approx. 100 new study reports is currently scheduled to be finalized by mid-July.</p> <p>Sanitizing all the old study reports means a significant effort in case of working hours and associated cost, and the GRG is of the opinion that this sanitization work should be done on-demand in case a justified request for parts of the full study reports is received.</p>

AGG request	GRG comment
<p><i>“Specifically, you are asked to provide the AGG with the following information per item/phrase for which confidentiality is claimed:</i></p> <ul style="list-style-type: none"> <li>• <i>To describe in detail and with a thorough substantiation which interests are at stake and why these are protected by the relevant legislation,</i></li> <li>• <i>The risk for the GRG when these items are disclosed,</i></li> <li>• <i>The amount of damage for GRG when the risk materialize,</i></li> <li>• <i>If and how far the interests for disclosure is already met.”</i></li> </ul>	<p>The GRG’s understanding is that the request of AGG is in the direction of the GFL provisions which legally apply from March 2021, especially in terms of demonstrating potential harm. It is our understanding that the details of these AGG requests are currently still under discussion on European level, and the GRG cannot preempt these ongoing discussions. Thus, the GRG is of the opinion that the justification form with our argumentation of confidentiality per item, that is part of our recent submission, is sufficient to justify all confidentiality claims in our sanitized dossier.</p>
<p><i>“Please confirm whether it would be possible for you to submit the requested information and if so whether July 1st 2020 would be manageable or when it could be expected.”</i></p>	<p>As discussed above the GRG is of the opinion that the AGG’s request is already in essence addressed with our recent submission.</p> <p>The GRG can provide a “marked for redaction” version of the summary dossier where all confidential parts are highlighted by a red box around the confidential parts and the content in the red box is still visible, by 1-July-2020.</p>

In case AGG has a different understanding and expectation, then the GRG would like to respectfully request a conference call to quickly clarify any open topic and to come to a mutual agreement about the way forward.

Thank you for considering our comments.

Yours sincerely,

[Redacted signature]

[Redacted name]

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