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**ANSES France**  
**Chair of the Assessment Group on Glyphosate (AGG)**

**CC: EU Commission, DG SANTE,**  
**Head of Unit - Pesticides and biocides, ██████████**

**By e-mail**

### **Glyphosate renewal dossier submission – follow-up**

Dear ██████████, dear AGG,

this is with reference to our letter sent via e-mail on 23 March 2020, and AGG's reply (e-mail) from 1 April 2020.

GRG would like to sincerely thank AGG for sharing the concerns and exchanging information on the current situation due to the Covid-19 pandemic. GRG is diligently working towards submission of the dossier according to the legal deadline of 15 June 2020, and currently we are confident to be able to meet this deadline, but as of today we cannot ensure completeness of the dossier submitted, due to the given uncertainties and implications regarding Covid-19 development that are outside of our control.

GRG appreciates AGG's recommendation for the way forward, i.e.

- GRG will contact the AGG and Commission when serious deficiencies as a result of the Covid-19 crisis are foreseen
- GRG will inform AGG as early as possible about possible missing or deficient elements and at what date the final version could be submitted

As of today, we are confident that the impact of the Covid-19 pandemic on progress of dossier compilation can still be managed and that no significant delays are materializing that cannot be mitigated by the

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April 8, 2020

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measures that we have already instigated, such as involving additional colleagues and postponing holidays.

Having said that we recognize an impairment to working efficiently for an increasing number of colleagues in home-office situation and it remains to be seen in how far this can be completely mitigated. Most notably the preparation of the ecotox risk assessment section of the dossier is currently slightly behind schedule. GRG will keep AGG informed about the development of this situation.

Regarding still ongoing experimental studies GRG would like to share the overview in Appendix 1. In summary, a number of studies are still in the experimental phase and the smooth operating of the service provider's facilities is beyond GRG's influence. Once studies will enter the phase of report writing that can be done in home-office, then the situation should be better predictable. Again, GRG is monitoring the situation and will inform AGG in case any delay becomes evident.

GRG would be grateful for AGG's comments regarding electronic submission of the dossier to the four individual AGG Member States. The Knoell project leader just sent respective questions via e-mail to AGG (6 April 2020). Please kindly let us know about the preferred way of transferring the renewal dossier files, to guarantee timely submission and acknowledgement of receipt by 15 June 2020.

Finally, GRG would like to point out our recent communication (from the Knoell project leader, via e-mail, 31 March 2020) to AGG regarding preparation of a Glyphosate CLH dossier. Although, a full CLH dossier (according to Regulation (EC) N° 1272/2008 (SANCO/12592/2012 - rev. 2 22 March 2019)) is no requirement of the SANCO renewal dossier, GRG welcomes AGG's recommendation in this regard and hopes that the proposed way forward, i.e. submitting a full CLH dossier including physico-chemical, environmental safety and tox data by October 2020, will be acceptable for AGG under the current circumstances of limited resource availability and increased pressure and uncertainty for many colleagues.

Thank you for your kind consideration of our update, and GRG will keep AGG and Commission closely informed over the course of the coming weeks.

Meanwhile GRG welcomes AGG's comments.

Yours sincerely,

[Redacted signature]

[Redacted name]

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

Attachment: Appendix 1

**Appendix 1:**

Study	Contract lab	Finalization date	Experimental phase ongoing	Report writing ongoing	Comment
NNG method validation in formulated product	Bayer internal laboratory in St. Louis, USA	Beginning May	Yes, ongoing	No, not yet	Timely finalization of experimental phase dependent on local Covid-19 development.
Rate of degradation of ANPA in acidic soils incubated under aerobic conditions	Smithers Viscient, UK	Preliminary report and summary delivery: 31.5.2020	Sampling day 63 = 23 <sup>rd</sup> March; sampling day 92 = 21 <sup>st</sup> April	Scheduled for May	Timely finalization of experimental phase dependent on local Covid-19 development.
Glyphosate adsorption to soil according to OECD guideline 106	IES Ltd Basel, Switzerland	Draft: 20 <sup>th</sup> March 2020 Final report: 15 <sup>th</sup> April 2020	Finalized	Draft report to be issued shortly	Timely report finalization likely from home office.
Aerobic mineralisation in surface water	Charles River, UK	Draft report: end March Final report: mid April	Analytical work almost finalized	Almost finalized	Timely report finalization likely from home office.
Chironomus sediment dweller: spiked water test design	ECT, Germany	Finalization date: April	Ending 20 Mar 2020	Yes	Timely report finalization likely from home office.
Earthworm reproduction study with the representative formulation MON52276	BioChem Agrar, Germany	May	Ending 17 Apr 2020	Yes	Timely finalization of experimental phase dependent on local Covid-19 development.
Micronucleus Test in Human Lymphocytes in vitro with MON 52276	Covance, UK	May (final report)	Experimental phase in progress	Draft report in April	Timely finalization of experimental phase dependent on local Covid-19 development.