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ANSES France

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Assessment Group on Glyphosate (AGG)

CC: EU Commission, DG SANTE,

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By e-mail

Glyphosate renewal dossier submission

Dear ^{5.1.2.e} dear AGG,

The Glyphosate Renewal Group (GRG) would like to share with AGG our concern regarding the increase in number of covid-19 infected people throughout Europe as the pandemic increases pace. Whilst we currently still have no known case of coronavirus infection among the GRG and ^{5.1.2.e} team, and continue to work diligently on dossier preparation, we acknowledge the seriousness of this situation and are highlighting our concern that at one point during the coming weeks the smooth progress of dossier preparation and timely dossier submission may be impacted by the pandemic.

GRG would like to emphasize that we are fully committed to timely finalization and submission of the renewal dossier. GRG continues to monitor the situation closely and is committed to complying with requirements as defined by authorities. GRG has undertaken comprehensive mitigation measures to avoid a delay in dossier preparation and submission, in particular home office of all team members and no travelling or face-to-face meeting activities anymore. However, as a consequence of the various mitigation measures there is obviously a significant and increasing impairment to working efficiently. In addition, ongoing experimental work depends on well-operating contractor facilities, which is beyond our influence.

As AGG is aware, the Glyphosate EU renewal dossier is of (most likely) unprecedented size and complexity, due to the high number of studies,

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public literature and involved companies. This task requires a broad network of service provider and contributors, which increases the risk that one or the other part of this network may be negatively affected by the current pandemic.

GRG is committed to keeping the AGG informed about any new development and we welcome a cooperation so that the regulatory process for the evaluation of glyphosate can take place in the most robust manner. Thus, GRG would be interested in how AGG assesses the current situation and the measures taken or to be taken on AGG's side to jointly deal with a potential delay due to covid-19. Specifically, GRG would like to know if the deadline for the submission of the dossier can be extended, should there be a delay as a result of covid-19.

GRG would be grateful for an indication by AGG during the coming days about the concrete mitigation options that seem realistic. On the part of GRG, we believe, in case the situation will get worse, that a delay corresponding to the time of emergency measures implemented by country authorities needs to be considered, i.e. a time period of 4 to 8 weeks which could then result in a delay of dossier submission of equally 4 to 8 weeks (current best guess).

GRG will closely monitor the development of the covid-19 situation and its impact on the dossier preparation team, and we will come back to AGG, at the latest by April 2nd with an updated picture of what can be realistically achieved and a proposal of concrete options.

Meanwhile GRG welcomes AGG's comments.

Yours sincerely,

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