Glyphosate Renewal Group

By e-mail

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Ju y 26, 2023

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Glyphosate (AIR V): EFSA-Q-2020-00140
Procedure for renewal of the approval of active substance glyphosate in accordance with Commission Implementing Regulation (EU) No. 844/2012
Applicant comments on EFSA conclusion

Dear [redacted],

The Glyphosate Renewal Group (GRG) is grateful for the opportunity to submit our comments on European Food Safety Authority's (EFSA) conclusion on the peer review of the pesticide risk assessment of the active substance glyphosate.

With the following executive summary, we would like to draw your attention to some key elements which we consider of relevance in the process of drafting the review/renewal report. Further, for your reference, our comments are addressed in technical details in the Annex to this letter.

GRG wishes to address the concerns, related data gaps, and outstanding issues identified by EFSA in its conclusion and highlight some key aspects for your kind attention.

It is notable that **no critical areas of concern** have been identified. Additionally, it has been concluded that glyphosate **has not met the scientific criteria** to be classified as a carcinogen, mutagen, or a reprotox. Glyphosate is unlikely to be genotoxic, does not indicate any immunotoxic potential, has no indication of neurotoxicity, and does not meet the ED criteria set in Commission Regulation (EU) No 2018/605.

Remaining data gaps and outstanding issues, which, although not critical, may lead to uncertainties in the risk assessment and are considered relevant for representative uses assessed at EU level. These are addressed as below:

- *Aneugenic potential of metabolite* [redacted] *could not be finalized without further information.*

GRG Comment: [redacted] should not be listed as a relevant impurity since the in-vivo micronucleus assay of [redacted] demonstrated a margin of safety above the current specifications which sufficiently addressed any ambiguity in the in-vitro clastogenecity screening data. The RMS is also of the opinion that "the genotoxic potential of [redacted] is not of toxicological concern at the level of the proposed reference specification." Therefore, there is no evidence that this is a data gap.

- *EFSA concludes that repeated-dose toxicity data for a component should be assessed to reach a final conclusion on the risk of MON 52276 and a data gap has been identified.*

  GRG Comment: The component in question is a polymer which is not required to be REACH registered under the current regulation and is in the list of permitted co-formulants. All Member State experts who took part in the expert discussions, as well as the AGG, agreed that the available toxicological information is sufficient to conclude on the safety of 'MON 52276', for which acute toxicity and genotoxicity data exist and indicate no concern.

- *Consumer dietary risk assessment could not be finalized due to incomplete data about the magnitude of residues in rotational crops.*

  GRG Comment: The limited field rotational study for which an interim report was submitted to AGG during stop-the-clock has now been completed and the final report can be made available to the risk managers upon request. The new results are in line with the previous ones and do not necessitate an update to the consumer risk assessment conducted based on the interim report. An extended set of field rotational crop trials is currently being performed to fully address the data gap set for "sufficient [supplementary] studies investigating the magnitude of residues in rotational crops (i.e. carrot, lettuce, wheat) including additional crops (as appropriate)." As the need for supplementary trials is a consequence of the limited field rotational crop study, these trials could only be initiated in 2022 and are still ongoing (with an expected completion date of 31.01.2025). It is important to note that according to EFSA "it is not expected that [the data gap for further residue trials in field rotational crops] might lead to an exceedance of toxicological reference values." GRG fully shares this opinion. Indeed, based on the interim results of the limited field rotational crop study, EFSA estimated the chronic and acute exposures at no more than 3% of ADI and 2% of ARfD, respectively. These estimates are provisional and more accurate estimates can be derived once the extended residue data package for field rotational crops is available. However, due to the wide margin of safety demonstrated by the preliminary estimates it is already possible to conclude that the supported representative uses (including the uses in annual crops) present no unacceptable risk to consumers.

- *A high long-term risk to mammals was concluded for 12 of 23 representative uses, driven by small herbivore mammal, based on tier 1 assumptions*.

  GRG Comment: During Annex I commenting to RMS and EFSA, GRG had indicated that additional residue decline trials will be conducted to address the concerns raised in historical plant residue decline studies. In 2022, nine glyphosate residue decline studies were conducted across [redacted] spanning the [redacted] and [redacted]. These studies have been subjected to kinetics data evaluation to determine residue decline 'half-life' values (DT_{50}) for glyphosate on/in monocotyledons and dicotyledons plant types. The data are considered 'sufficient' to support a quantitative refinement of DT_{50} value (to refine fTWA) used in the dietary exposure calculations in the long-term mammal risk assessment and demonstrates that a low and acceptable long-term dietary exposure risk to mammals for all the proposed representative uses can be achieved.

- *The assessment of risks for aquatic plants could not be finalized due to a lack of data about their exposure to glyphosate via spray drift.*

  GRG Comment: As appropriate test guidelines and defined risk assessment approach are not currently available for the route of exposure in the EU, the GRG would like to respectfully disagrees the need to conduct an overspray exposure study and corresponding risk assessment with an emergent macrophyte species.

- *Insufficient information was provided to draw a firm conclusion on the impact to* ***biodiversity*** *via indirect effects and trophic interactions for the representative uses*.

  GRG Comment: GRG appreciates that EFSA experts acknowledge the current lack of a harmonized approach to assess biodiversity within the prospective risk assessment. GRG also agrees with EFSA experts that any risk associated with the representative uses of glyphosate and any indirect effects for biodiversity are complex and depend on multiple factors. Additionally, indirect effects following removal of the target weeds are likely to be similar for any broad-spectrum herbicide and other herbicidal methods used in the same manner.

- *Additional information to help with assessment of groundwater concentrations that may result from exposure via bank infiltration could be useful.*

  GRG Comment: EFSA conclusion highlights that, given the extent of use of glyphosate, potential groundwater exposure from riverbank infiltration and connectivity with surface water bodies may occur in some susceptible locations.

However, from the groundwater monitoring database submitted with the dossier and updated during stop-the-clock, it can be concluded that groundwater recharge from surface water bodies is overall not a significant exposure pathway. In detail, no systematic exceedances of the regulatory threshold of 0.1 µg/L for glyphosate were observed for sampling locations close to surface water (based on proximity to surface water analysis). Further, it should be noted that bank filtration (among many other steps in drinking water processing) effectively contributes to the elimination of glyphosate residues from the raw water. This has been demonstrated by various investigations available as published literature as well as submitted as particular information in the dossier.

The overall EFSA assessment outcome merits the renewal of the approval of active substance glyphosate. We kindly ask the European Commission and the Member States to take the additional information provided with this letter into consideration when drafting the renewal regulation.

Kindly confirm receipt of this submission.

For and on behalf of the Glyphosate Renewal Group,

Respectfully yours,

[redacted]

[redacted]

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

Enclosed:

- GRG detailed comments on EFSA conclusion
    - Section I: Mammalian Toxicity
    - Section II: Residues
    - Section III: Environmental fate and behavior
    - Section IV: Ecotoxocology