European Parliament

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10 November 2022

Subject: Renewal of the approval of glyphosate

Dear Commissioner, dear Executive Directors,

We are writing to you jointly as the future decision by the Commission with regard to the renewal or non-renewal of the approval of glyphosate depends crucially on the future EFSA conclusions on this matter and the classification of the substance based on the opinion of the Risk Assessment Committee (RAC) at ECHA.

We are aware that the Commission intends to extend the approval period of glyphosate by one year based on Article 17 of Regulation (EC) No 1107/2009, and is about to go to the appeal committee for this following the 'no opinion' by the standing committee of 14 October 2022.

We would like to remind the Commission that in its resolution of 24 October 2017, the European Parliament called on the Commission "to adopt necessary measures to phase out the active substance glyphosate in the European Union no later than 15 December 2022, ensuring that no use of glyphosate is authorised after that date, which includes any possible extension period or period referred to in Article 32 of Regulation (EC) No 1107/2009".

We are very frustrated about this upcoming extension, as we consider that there is enough evidence on glyphosate to conclude that it does not meet the approval criteria, and that its approval should indeed have been withdrawn based on Article 21 of Regulation (EC) No 1107/2009.

We are setting out specific concerns in the Annex to this letter and would kindly ask you to provide us with an answer to our calls set out below and our questions and concerns raised in the Annex.

In case the Commission decides to go ahead with the extension, despite the lack of a qualified majority of Member States and despite the call of the European Parliament to phase out glyphosate no later than 15 December 2022, this risks damaging the confidence that EU citizens and the European Parliament have been putting in the European Commission. To mitigate this, we call on the Commission and EFSA to ensure that all relevant data be requested from, and provided by, the applicant. We also call on ECHA that RAC revisits its opinion on the classification of glyphosate (for more details, see the Annex), we call on EFSA that it makes a thorough assessment of all the data, and we call on ECHA and EFSA to give

equivalent weight to scientific peer-reviewed open literature as compared to regulatory studies in their respective assessments.

We thank you for your attention to this important matter and look forward to receiving your answers.

Yours sincerely,

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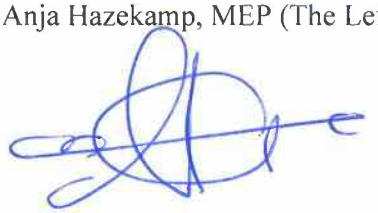
Martin Hojsik, MEP (Renew), ENVI contact person for ECHA

Tilly Metz, MEP (Greens/EFA)

Anja Hazekamp, MEP (The Left)



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Annex

1. Concerns with regard to admissibility of the dossier

Firstly, we would like to raise important concerns with regard to the work of the Assessment Group on Glyphosate (AGG). In the context of the Commission's REFIT evaluation of Regulation (EC) No 1107/2009[1], the Commission recommended the following:

> *"In line with the views of the European Parliament to avoid procedural delays leading to inefficiencies, the Commission recommends that Member States only accept complete dossiers of high quality as admissible - both for applications for first or renewed approval of active substance and PPP authorisation applications.* "

In its admissibility letter of 18 August 2020[2], the AGG found the application to be admissible, yet asked for more than 20 "elements" comprising inter alia more than 50 studies that were not yet included in the revised supplementary dossier to be provided by 1 September 2020. It is difficult to understand how the application could be considered admissible in light of all the missing elements. It is even more difficult to understand this in light of the 40-page long "list of studies to be generated" as identified in the draft Renewal Assessment Report (dRAR) of glyphosate, and as provided by the AGG on 2 June 2021[3]. And it becomes virtually impossible to understand this in light of the 388 [!] additional information points that EFSA has formally requested from the applicant on 14 March 2022 following the public consultation.

We would therefore like to ask the Commission whether it would consider the dossier that was submitted to the AGG "complete" and of "high quality" and as such admissible, or not.

2. Concerns with RAC opinion

There has undoubtedly been a major controversy about whether or not glyphosate and/or glyphosate-based pesticide formulations are causing cancer or not - and for us, this controversy has not been settled. While the International Agency for Research on Cancer (IARC) classified glyphosate as probably carcinogenic to humans in March 2015[4], and the relevant IARC Advisory Group in 2019 saw no need for IARC to re-evaluate this during 2020-2024[5], RAC did not consider such a classification to be warranted in 2017[6], and reconfirmed this stance in 2022[7].

However, a meta-analysis of 2019 found "*a compelling link between exposures to GBHs* [glyphosate-based herbicides] *and increased risk for NHL* [non-Hodkgin Lyphoma]" [8]. A comprehensive analysis published in 2020 "*clearly support*[s] *the IARC's conclusion that there*

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[1] COM(2020) 208 final, 20.5.2020
[2] available on https://www.glyphosate.eu/transparency/authority-communication/
[3] also available on https://www.glyphosate.eu/transparency/authority-communication/
[4] https://www.iarc.who.int/featured-news/media-centre-iarc-news-glyphosate/
[5] https://monographs.iarc.who.int/wp-content/uploads/2019/10/IARCMonographs-AGReport-Priorities_2020-2024.pdf
[6] https://echa.europa.eu/documents/10162/2f8b5c7f-030f-5d3a-e87e-0262fb392f38
[7] https://echa.europa.eu/documents/10162/882a2dc7-9e6f-b0ac-491a-ed3526b4018a
[8] https://pubmed.ncbi.nlm.nih.gov/31342895/

is sufficient evidence to say that glyphosate causes cancer in experimental animals"[9]. And a major review published in 2021 concluded that that there is "*compelling evidence that glyphosate and GBF [*Glyphosate-based formulations*] are a cause of NHL in humans exposed to these agents.*"[10]

Moreover, serious scientific shortcomings about the work of RAC with regard to the classification of glyphosate have been raised in a recent report of the Health and Environment Alliance[11].

A closer look into the RAC opinion of 2022 provides interesting insights. One key element for the assessment of carcinogenicity on which IARC and RAC disagree is genotoxicity - a key mode of action for carcinogenicity. RAC states the following:

> "*Due to the many cancer bioassays performed for glyphosate, RAC notes that* ***for the assessment of carcinogenicity the evaluation of biological relevance of an increased tumour incidence is critical*** *and is given more weight compared to statistically significance in the weight of evidence assessment.*" (page 57, own emphasis added)

> "*Glyphosate appears to induce transient DNA strand breaks as observed in the in vitro and in vivo Comet assays or by using the alkaline elution assay; however,* ***no reliable in vivo Comet assays were included in the CLH dossier in relevant target organs*** *e.g., liver and kidney or a TGR somatic and germ cell gene mutation assay. [...]* ***Noting the absence of a Comet assay conducted according to OECD TG 489 in relevant tissues as well as a TGR somatic and germ cell gene mutation assay conducted according to OECD TG 488, the biological importance of such DNA lesions in relation to mutagenicity is equivocal. Taking all data into account*** *and based on the overall negative responses in the existing gene mutation and oral mutagenicity tests, RAC concludes that* ***no classification of glyphosate for germ cell mutagenicity is warranted****."* (page 48, own emphasis added).

In summary, RAC stresses the biological relevance of an increased tumour incidence for the assessment of carcinogenicity. It refers to important findings with regard to genotoxicity, but then notes the absence of reliable tests in relevant target organs. For RAC, the lack of such tests make the biological relevance of the positive findings equivocal, resulting in the conclusion that no classification of glyphosate for germ cell mutagenicity is warranted.

We consider it unacceptable, firstly, that key tests have not been conducted and secondly, that the conclusion of no classification for germ cell mutagenicity is justified with the absence of such key tests.

Importantly, this is not just unacceptable politically and scientifically, but actually violating the provisions of Regulation (EC) No 1107/2009 as interpreted by the Court of Justice in Case C-616/17[12]. According to the Court,

> "*It is therefore the task of the competent authorities, when examining an application for the authorisation of a plant protection product, to verify that the material submitted by the*

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[9] https://ehjournal.biomedcentral.com/articles/10.1186/s12940-020-00574-1

[10] https://pubmed.ncbi.nlm.nih.gov/34052177/

[11] https://www.env-health.org/wp-content/uploads/2022/06/HEAL-How-the-EU-risks-greenlighting-a-pesticide-linked-to-cancer-2022.pdf

[12] https://curia.europa.eu/juris/document/document.jsf?text=&docid=218463&pageIndex=0&doclang=EN&mode=lst&dir=&occ=first&part=1&cid=3125950

applicant, and primarily the tests, analyses and studies of the product, is sufficient to exclude, in the light of current scientific and technical knowledge, the risk that that product exhibits such carcinogenicity or toxicity." (paragraph 116)

We therefore call on you to ensure that reliable assays are being requested from the applicant and that RAC revisits its opinion on the basis of such assays and in light of the concerns raised in the report of the Health and Environment Alliance. Failure to do the former would mean that you cannot exclude carcinogenicity, and therefore cannot conclude that the approval criteria of (EC) No 1107/2009 are met.

3. Concerns with AGG draft conclusions

On 15 June 2021, the AGG published "The procedure and outcome of the draft Renewal Assessment Report on glyphosate"[13] with the following overall conclusion: "*Based on the current assessment, the AGG considers that glyphosate does meet the approval criteria set in Regulation (EC) N° 1107/2009*".

Apart from suffering from the same fundamental flaw with regard to the conclusions on the classification of glyphosate as explained above, we would like to point to an additional serious problem in the AGG conclusions with regard to their assessment of ecotoxicology.

The AGG rightly points out that active substances can only be approved if, among others, plant protection products containing them have no unacceptable impacts on biodiversity and the ecosystem (Article 4(3)(e)(iii) of Regulation 1107/2009).

Glyphosate is a non-selective herbicide which kills all herbage. It acts by interfering with the so-called "shikimate" pathway, a metabolic pathway that is not only present in plants, but also in algae, bacteria and fungi. Given this mode of action of glyphosate, it risks having direct adverse effects on almost all living organisms other than animals and humans, and indirect effects on human and animal health via adverse effects of bacteria. Increasing evidence demonstrates that herbicides have profound effects on ecosystem functions via altered microbial communities[14].

Glyphosate does not only kill target weeds, but also useful herbage in and close to fields treated with glyphosate. These plants are an important source of food for insects and other wild animals. The German Environment Agency states that the widespread use of total herbicides such as glyphosate in intensive agriculture represents a significant danger for certain birds and is co-responsible for the continuous decrease of such populations[16].

In the document released by the AGG, they go on to explain that there "*is currently no validated tool nor a harmonised methodology for evaluating biodiversity in the context of approval of active substances*", that "[specific] *protection goals are to be set by the risk managers*" and thus propose that "*impacts on biodiversity are further considered during the peer review process , and if relevant, by risk managers*". Four paragraphs later, they come to their overall conclusion that "*glyphosate does meet the approval criteria set in Regulation (EC No 1107/2009*".

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[13] https://food.ec.europa.eu/system/files/2021-06/pesticides_aas_agg_report_202106.pdf
[14] https://www.sciencedirect.com/science/article/pii/S0169534722002294
[16] https://www.umweltbundesamt.de/themen/chemikalien/pflanzenschutzmittel/glyphosat

We fail to understand how AGG can come to such a conclusion on the approval criteria when it itself delegates the assessment of impacts on biodiversity and the ecosystem to the risk manager.

We would like to seek clarity from the Commission and EFSA how you intend to properly assess glyphosate and its representative formulation against the approval criteria in Article 4(3)(e) of Regulation (EC) No 1107/2009, including with regard to adverse effects on the microbiome.

4. Need to assess neurotoxicity

A recent systematic review on the toxic effects of glyphosate on the nervous system has found that "*exposure to glyphosate produces important alterations in the structure and function of the nervous system of humans, rodents, fish, and invertebrates*"[17].

We would like to seek clarity from the Commission and EFSA you how you intend to properly assess glyphosate and its representative formulation with regard to possible neurotoxic effects.

5. Need to assess the representative formulation with regard to long-term toxicity and carcinogenicity

Major pesticide formulations, including formulations containing glyphosate, have been found to be significantly more harmful than their active substance alone[18]. This has been confirmed by a recent study, which found significant differences observed in the cytotoxic and genotoxic pattern between glyphosate and glyphosate-based herbicide formulations[19].

According to Article 4(5) of Regulation (EC) No 1107/2009, for "*approval of an active substance, paragraphs 1, 2 and 3* [= the approval criteria] *shall be deemed to be satisfied where this has been established with respect to one or more representative uses* ***of at least one plant protection product*** *containing that substance*" (own emphasis added).

Moreover, according to the judgment in Case Case C-616/17,

> *"it must [...] be noted that Article 4(2) and (3) [...] explicitly provides that the possibility of [the] product or its residues having a harmful effect on human or animal health must be assessed taking into account 'known cumulative and synergistic effects', which implies [...] taking into consideration the effects caused by the interaction between a given active substance and, inter alia, the other constituents of the product. [...] As regards the procedure for the authorisation of a plant protection product, taking into account the known cumulative and synergistic effects of the constituents of that product is again required [...]"*

It is thus clear that the AGG and EFSA have to assess whether the representative formulation of glyphosate - with the co-formulants - meets the approval criteria.

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[17] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9101768/
[18] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3955666/
[19] https://pubmed.ncbi.nlm.nih.gov/34109144/

This issue has been subject to a recent exchange of correspondence between the chair of the Committee on the Environment, Public Health and Food Safety of the European Parliament and you, Commissioner Kyriakides. In your response of 20 October 2022, you state the following:

> *"I agree with you that the judgment of the Court of Justice in Case C-616/17 recalls the obligation of the Member States to thoroughly assess the long-term toxicity and carcinogenicity in the context of the assessment of potential impacts on human health of PPPs."*
>
> ...
>
> *"Therefore, and in particular, also in the light of the judgement in Case C-616/17, I agree with you that in case insufficient information is provided by applicants, the Member States and EFSA have an obligation to request further information. Regulation (EU) 284/2013 sets out the obligations for applicants in terms of data submission in their respective application dossiers, and these data requirements give scope to Member States to require additional data, and it is as an obligation to do so if such data are needed to ensure safety, as made clear in paragraph 116 of the Court's decision in Case C-616/17."*

In that context, we would like to stress that these requirements do not only apply for Member States when authorising pesticide formulations, but also for EFSA in the context of the approval of an active substance (see para 69 of the judgment in Case C-616/17). And excluding long-term toxicity and carcinogenicity of glyphosate and its representative formulation is a prerequisite for the Commission to be able to approve glyphosate, as provided in Regulation (EC) No 1107/2009 and as confirmed by the Court of Justice in its judgment in Case C-616/17.

We would therefore like to seek reassurance from EFSA a) that you have requested data on the long-term toxicity and carcinogenicity of the co-formulants in the representative formulation (if that was not already done by the AGG and provided by the GRG), and b) where such data is missing or insufficient, that EFSA has requested such data for the representative formulation as a whole and has received it.

We would like to similarly seek reassurance from the Commission that you will not grant approval of glyphosate if you cannot exclude long-term toxicity and carcinogenicity of the representative formulation (by taking into account the cumulative and synergistic effects of its constituents, including the effects of co-formulants), in line with the judgment in Case C-616/17.

6. Full consideration of scientific peer-reviewed open literature

Glyphosate is subject to a large amount of independent research. According to Article 8(5) of Regulation (EC) No 1907/2009, applicants are obliged to provide scientific peer-reviewed open literature, as determined by EFSA, on the active substance and its relevant metabolites dealing with side-effects on health, the environment and non-target species and published within the last 10 years before the date of submission of the dossier. According to Article 8(3) of that Regulation, the applicant shall provide an assessment of all information submitted. Unfortunately, applicants all too often systematically dismiss the findings of independent research.

We therefore call on you to ensure that scientific peer-reviewed open literature that is relevant for a thorough assessment of glyphosate and its representative formulation against all approval criteria is fully considered in your assessment and given equivalent

weight to regulatory studies in line with the request of the European Parliament in its resolution 16 January 2019 on the Union's authorisation procedure for pesticides[20].

[20] https://www.europarl.europa.eu/doceo/document/TA-8-2017-0395_EN.html