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DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Food Safety, Sustainability, and Innovation
Pesticides and biocides

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Discussion at the Standing Committee on Plants, Animals, Food and Feed (PAFF Committee), section Phytopharmaceuticals - Legislation on Agenda item A.04.05

Exchange of views on EFSA's conclusions on the peer review of the risk assessment for glyphosate

12 July 2023

Summary Report

The Commission services recalled that on 6 July 2023 EFSA transmitted its Conclusion on the peer review of the risk assessment for glyphosate to the European Commission and Member States, as well as to the applicant.

The Commission services expressed their appreciation for the Member States acting jointly as Rapporteur (the AGG), EFSA and all Member State experts involved in the peer review for their thorough and comprehensive work, the huge resources made available, and the dedication shown during the evaluation of the dossier, which had allowed to finalise the EFSA Conclusion without further delay in addition to what had been announced last year.

EFSA provided a summary of the key findings in the EFSA Conclusion on the peer review of the risk assessment for glyphosate and explained that the full Conclusion would be published at the end of July, following a check for removal of confidential information as required under EU legislation. The background documents will be published successively thereafter, also following a check for removal of confidential information.

The Commission services noted that the EFSA Conclusion does not identify any critical areas of concern that would prevent the renewal of the approval of glyphosate as an active substance for use in plant protection products, provided that certain conditions and risk mitigation measures are set in order to address a number of issues that could not be finalised and other outstanding issues (data gaps), which are the following:

Issues not finalised:

- the assessment of one of the impurities in the EU reference specification, for which a clastogenic potential could not be excluded;
- consumer dietary risk assessment for some crops (carrot, lettuce and wheat) grown in the first year of rotation on a plot where glyphosate was used in the preceding year;
- risk assessment for aquatic plants due to contact exposure via spray drift;

Outstanding issues:

- for one of the co-formulants in the product for representative uses information on the short- and long-term was not available, while data on acute toxicity and genotoxicity for the product (including the co-formulant) did not identify concerns;
- while there is no indication that glyphosate as an active substance has neurotoxic potential, data from the public literature on glyphosate-based formulations and a study with glyphosate-trimesium (which is not approved in the EU) show effects of developmental neurotoxicity;
- the potential risks to biodiversity via indirect effects and trophic interactions, which the experts recognised as being complex and dependent on multiple factors.

Other issues:

- high long-term risk to wild mammals for some representative uses that were identified as a result of a conservative risk assessment due to lack of data for further refinement;
- the potential effects on the microbiome where no definitive conclusions could be drawn due to lack of standardised regulatory guidance and/or established harmonised criteria;
- potential relevance of possible groundwater exposure via bank infiltration and the connectivity of surface water bodies to groundwater aquifers;
- the need for mitigation measures to ensure an acceptable risk to non-target terrestrial plants.

The Commission services explained their analysis of the relevance of the issues listed above and informed that detailed considerations to address them would be included in the draft Renewal Report for glyphosate, which will be provided for comments to the Member States on 13 July and, as legally required by Article 14(1) of Regulation (EU) No 844/2012 to the applicant. Comments should be submitted no later than 27 July 2023. The Commission services will consider all comments in view of preparing an updated draft Renewal Report and a draft Implementing Regulation, which will be sent to Member States ahead of a special meeting of this Committee that is tentatively planned for 15 September 2023, subject to confirmation. The vote on the draft Regulation is planned for the meeting of this Committee scheduled for 12-13 October 2023, in view of finalising the decision-making procedure before the expiry of the current approval of glyphosate on 15 December 2023.

The Commission services further informed that they had not yet finalised reflections on the appropriate length of a renewed approval, while noting that the substance had now been assessed two times within a rather short period of time, each time necessitating a high amount of resources while coming to similar results. The Commission services invited Member States to also share their views on this matter when providing comments on the draft renewal report by 27 July 2023.

Two Member States inquired if the impurity present in the reference specification can be excluded or if it needs to be monitored. The Commission services explained that changes in the manufacturing process that will eliminate the impurity might be possible. As the impurity will be considered toxicology relevant and its content will be limited to levels

that are considered safe in the renewed approval, methods for detection and quantification will have to be presented by the applicant.

Another Member State noted that no firm conclusion was drawn by EFSA on the risks to biodiversity based on the available data. It considered that a guidance document on this issue needs to be developed and suggested to set a confirmatory data requirement in the renewed approval to further assess the issue once guidance would become available. The same Member State announced that it will send comments to request that harmonised conditions and restrictions will be set for all Member States, including for conducting comparative assessments in order to reduce the overall use of glyphosate. It also suggested that limits to the maximum amount of glyphosate that can be applied per hectare should be considered, in particular taking into account the uses where a risk to wild mammals was identified. The Commission services explained that imposing mandatory comparative risk assessment in the case of glyphosate might not be compatible with Article 50(2) of Regulation (EC) No 1107/2009, which entitles Member States to conduct voluntary comparative assessments prior to granting product authorisations. Member States are also empowered to set maximum application rates in product authorisations. The Commission services also noted that the risk to mammals was identified only for some, but not all, representative uses and was based on the results of a conservative first tier assessment - therefore there is a possibility for applicants for product authorisation to provide further data to be evaluated by Member States to verify whether the uses concerned are safe.

A Member State expressed concerns that requests for access to documents might force them to disclose the whole file on glyphosate. The Commission services reminded that granting such access needs be done in full compliance with the applicable legislation, especially protection of personal and where applicable commercial data, and considering that the decision-making process is still ongoing. EFSA recalled that it would publish the Conclusion and its background documents in full as soon as practically possible so that they will be accessible for everyone.

Another Member State asked if information for the general public will be provided in a format that is comprehensible by non-experts. EFSA and the Commission services noted that they had made available on their respective websites information specifically addressed to non-experts which is regularly updated.