EFSA explains the **scientific assessment of**

GLYPHOSATE

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GLYPHOSATE is an active substance that is widely used in herbicide products. Glyphosate-based pesticides (formulations containing glyphosate and other chemicals as co-formulants) are used in agriculture and horticulture to combat weeds that compete with cultivated crops, and in the maintenance of railway lines, amongst other uses.

What has EFSA done?

EFSA and EU Member States carried out a risk assessment and peer review thereof for the active substance glyphosate.

It is the most comprehensive and transparent assessment of a pesticide that EFSA and the EU Member States have ever carried out, taking into account thousands of studies related to human and animal health and the environment, and involving dozens of scientists from EFSA and national authorities across Europe. Draft documents related to the risk assessment have been made publicly available at different stages of the process.

What are the main conclusions?

- The assessment of the impact of glyphosate on the health of humans, animals and the environment **did not identify critical areas of concern**. A concern is defined as critical when it affects **all** proposed uses of the pesticide under evaluation (e.g., pre-sowing uses, post-harvest uses etc.), thus preventing its approval or renewal.
- In 2022, the European Chemicals Agency (ECHA) carried out a hazard assessment of glyphosate and concluded that it did not meet the scientific criteria to be classified as a carcinogenic, mutagenic or reprotoxic substance. EFSA used ECHA's hazard classification for the purposes of the EU risk assessment on glyphosate.
- With respect to ecotoxicology, the data package allowed a conservative risk assessment approach, which identified a high long-term risk to mammals in 12 out of 23 proposed uses of glyphosate.

Issues that could not be finalised

- The assessment of one of the impurities in glyphosate could not be finalised without further information about its clastogenic potential [i.e. potential to cause DNA breakages]. The presence of impurities can be influenced by the manufacturing process.
- The consumer dietary risk assessment could not be finalised due to incomplete data about the amount of glyphosate residues in rotational crops such as carrots, lettuce and wheat. However, this is not expected to lead to an exceedance of toxicological safety levels and so no critical concern was identified.
- The assessment of risks for aquatic plants could not be finalised due to a lack of data about their exposure to glyphosate via spray drift.

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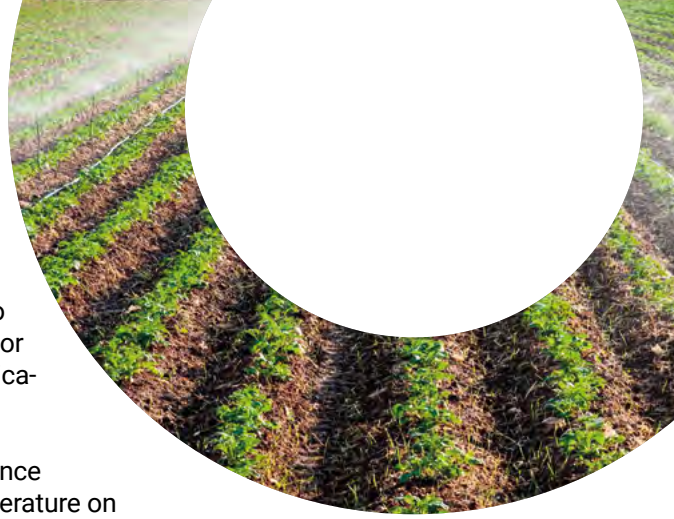

Outstanding issues

The outstanding issues of note are:

- Information on the short- and long-term toxicity of one of the components present in the formulation evaluated for representative uses was not available and is needed to conclude the risk assessment of the formulated product for representative use. For this formulation there were no indications of acute toxicity and genotoxicity.
- There is no indication that glyphosate as an active substance has neurotoxic potential. However, data from the public literature on glyphosate-based formulations and a study with a glyphosate salt (not approved in the EU) show effects of developmental neurotoxicity. A recommendation is made in the conclusions for the applicant to provide clarifications on this issue.
- Experts recognised that the risks for biodiversity associated with the representative uses of glyphosate are complex and depend on multiple factors. They also noted a lack of harmonized methodologies and agreed specific protection goals. Overall, the available information does not allow firm conclusions to be drawn on this aspect of the risk assessment and risk managers can consider mitigation measures.
- Studies reporting effects on microbiome were taken into account. Currently, no internationally agreed guidelines for the risk assessment of microbiome are in place in the pesticide area. Further research is needed to identify dedicated methodologies to better integrate microbiome into chemical risk assessment.

Glyphosate peer review in numbers

32
Months
Dec. 2019 - Jul. 2023

180,000
Pages dossier

2,400
Total studies assessed

Overall pages of initial dossier amount to circa 180,000 pages, containing 2-4 times more information than a typical renewal dossier.

400
Total entries received from public consultation

27
National authorities

90
Experts appointed by EU Member States authorities

What happens next?

Glyphosate is currently approved for use in the EU until 15 December 2023. EFSA's conclusions will be used by the European Commission and Member States to decide whether to keep glyphosate on the EU list of approved pesticide active substances.

The European Commission will submit to the Member States a draft renewal report and a draft Regulation deciding on the renewal of approval to the Member States, which they will discuss and vote on in the Standing Committee on Plants, Animals, Food and Feed (PAFF Committee).

How is the safety of pesticides assessed in the EU?

Under EU legislation, the burden of proof of safety for pesticides lies with the company that seeks to place (or renew the presence of) their product on the market. Applicants are required to present a dossier containing a set of mandatory studies and to carry out a literature review of scientific studies published in the last 10 years, among other requirements. The evaluation by regulatory authorities of both existing and new active substances follows a phased approach:

1. For each substance an initial draft assessment report (DAR) or renewal assessment report (RAR) is produced by a designated rapporteur Member State (RMS) based on the dossier submitted by the applicant. In the case of glyphosate, there were four Member States jointly acting as rapporteur: France, Hungary, the Netherlands and Sweden.

2. Once the DAR or RAR is drafted and submitted, EFSA organises a public consultation allowing all interested parties to scrutinise the work carried out by the RMS, provide comments, and highlight additional scientific evidence and academic studies they deem relevant for the risk assessment.

3. The RMS updates the DAR/RAR following the public consultation and the peer review by EFSA and all Member States begins. Additional information can be requested from the applicant if needed following the public consultation.

4. EFSA drafts a report ("Conclusion") on the active substance. The EFSA Conclusion informs the European Commission and Member States in deciding whether to include the substance in the EU's list of approved active substances. This determines whether the substance can be used in pesticides in the EU.

5. The Conclusion is available for EU Member States to assess or re-assess the safety of pesticide products (formulations) containing the active substance.

What was the role of EFSA and ECHA in the process?

- EFSA and ECHA hold two different and complementary roles in the assessment of pesticide active substances.
  - ECHA is responsible for carrying out the **hazard assessment** of chemical substances in the EU, and for proposing how they should be classified and labelled in relation to different environmental and health effects such as carcinogenicity, genotoxicity, and reproductive and developmental toxicity.
  - EFSA is responsible for **assessing the risks** that exposure to a given substance may pose for humans, animals and the environment. The hazard assessment of a substance is the first step in any risk assessment.
  - When evaluating the safety of pesticide active substances, EFSA uses the hazard assessment carried out by ECHA, where this is available.
- In the case of glyphosate, ECHA carried out a new hazard assessment in 2022 and concluded that it did not meet the scientific criteria to be classified as a carcinogenic, mutagenic or reprotoxic substance.

A highly transparent process

- In the EU, the risk assessment of pesticides and the subsequent peer review by EFSA is a highly transparent process. Interested parties are kept informed about each step of the process.
- In the case of glyphosate, this began with the draft renewal assessment report (RAR) which was prepared by the national competent authorities of Hungary, France, the Netherlands and Sweden, known collectively as the Assessment Group on Glyphosate (AGG), jointly acting as rapporteurs. The AGG published a summary of the RAR in June 2021.
- EFSA and ECHA held parallel public consultations (PCs) on the draft RAR prepared by the AGG, which ran from September to November 2021. Comments received during the public consultation were published on the open.efsa platform immediately after it closed.
- Following the public consultation, EFSA held a series of meetings with scientific experts from national competent authorities on different aspects of the risk assessment as part of the peer review process. EFSA has published high-level reports from each of these meetings and detailed accounts of the expert discussions will be published as background information.
- Once finalised, the peer review conclusions on glyphosate and all related background documents will be published on EFSA's website. This will include:
  - a record of all comments provided by Member States, the Glyphosate Renewal Group (industry), and EFSA on the RAR;
  - comments received during the public consultation on the RAR and the way the EU experts addressed them;
  - reports from all the expert meetings held with Member State scientists;
  - the comments received from the AGG and Member States on EFSA's draft peer review conclusions.

Timeline

2019

December
Glyphosate Renewal Group (GRG) submits an application for renewal of approval.

2020

June
GRG submits the full renewal dossier, and the Assessment Group on Glyphosate (AGG) starts working on the initial assessments.

2021

June
AGG submits the draft renewal assessment report (dRAR) and Harmonised Classification and Labelling (CLH) report to EFSA and ECHA, respectively.

August
AGG submits updated dRAR and CLH report to EFSA and ECHA following qualitative and administrative checks.

September
EFSA and ECHA launch parallel consultations.

November
The parallel consultations close.

2022

First quarter
AGG provides its considerations to the comments received during the consultations, also taking into account the responses of the GRG to each of the comments.
EFSA and ECHA review the comments and the information received during the consultations, including the AGG considerations to the comments.
EFSA requests the GRG to provide additional information to complete the data package and sends agreed action points for follow up by the AGG.

21 - 22 April
The Working Group of ECHA's Committee for Risk Assessment (RAC) discusses the proposal for harmonised classification and labelling (CLH).

30 May
Meeting of ECHA's RAC and adoption of RAC opinion on glyphosate classification.

30 September
AGG submits updated dRAR to EFSA in response to the identified action points and following evaluation of the additional information provided by the GRG.

14 November - 2 December
EFSA and EU Member State experts meet to peer review the updated renewal assessment report (RAR). Following these meetings, the AGG reviews the RAR in light of the outcome of the experts' discussions and then EFSA drafts the peer review conclusions, in consultation with the AGG and Member State experts.

22 December
The high-level reports (HLR) of peer-review expert meetings are published on EFSA's website.

2023

July
Conclusions of EFSA's peer review expected to be made available to the European Commission, Member States and the GRG.