15 June 2021

Glyphosate: questions and answers

1. What is ECHA's role in the glyphosate assessment?

ECHA implements the harmonised classification and labelling (CLH) process for hazardous chemical substances. The aim is to protect human health and the environment from those hazards that matter the most.

In 2019, a group of companies (the Glyphosate Renewal Group GRG) applied under the Plant Protection Products (PPP) Regulation to renew the approval of glyphosate for use after the current approval expires at the end of 2022. The application is first assessed by a group of four EU Member States (France, Hungary, the Netherlands and Sweden – called the Assessment Group on Glyphosate, AGG) and will then be peer reviewed by the European Food Safety Authority EFSA.

In parallel with the EFSA peer review risk assessment, ECHA's Committee for Risk Assessment (RAC) will adopt an opinion on the proposal for harmonised classification of glyphosate. This opinion is based on a proposal prepared by the same group of four Member States that assess the industry renewal application.

The harmonised classification and labelling focuses solely on the hazardous properties of the substance: its potential to cause harm. It does not assess the exposure of humans or the environment to glyphosate. This will be part of the peer review of the risk assessment by EFSA.

EFSA's assessment: https://www.efsa.europa.eu/en/topics/topic/glyphosate

2. What is the timeline for the assessment?

The Assessment Group on Glyphosate (France, Hungary, the Netherlands and Sweden) has prepared a harmonised classification and labelling proposal under the CLP Regulation and submitted it to ECHA in June 2021.

ECHA will start a consultation on the proposal in early September 2021 and encourages stakeholders and interested parties to provide comments to it.

The final opinion of ECHA's Committee for Risk Assessment (RAC) is foreseen to be adopted in March 2022, but this could be postponed to June 2022 if new data becomes available and RAC is required to review and include it in its assessment.

ECHA's opinion will feed into EFSA's risk assessment, which is expected later in 2022 and then sent to the European Commission. Based on EFSA's risk assessment report, the Commission will decide whether or not to renew glyphosate.

European Commission: https://ec.europa.eu/food/plants/pesticides/approval-active-substances/renewal-approval/glyphosate_en

3. What are the current classifications for glyphosate?

Glyphosate already has harmonised classifications. It is classified as a substance which causes serious eye damage and is toxic to aquatic life with long-lasting effects. No classification for germ cell mutagenicity, carcinogenicity or reproductive toxicity was warranted in 2017.

The classification is based solely on the hazardous properties of the substance. It does not take into account the likelihood of exposure to the substance and, therefore, does not address the risks of exposure. It also does not take into account socio-economic consequences or any potential impacts in downstream legislation, e.g. risk management, as a result of the proposed classification.

The risks posed by exposure are considered under the Plant Protection Products (PPP) Regulation.

More information about glyphosate and links to further information on the PPP processes:
EFSA: https://www.efsa.europa.eu/en/topics/topic/glyphosate

ECHA's Harmonised classification and labelling (CLH): https://echa.europa.eu/regulations/clp/harmonised-classification-and-labelling

4. What does the proposal to harmonise classification contain?

We have received a scientific proposal from the Assessment Group on Glyphosate (France, Hungary, the Netherlands and Sweden) which does not propose to change the existing classification from 2017.

The CLH report includes summaries of relevant studies, a comparison of the data with the criteria for classification which are described in the CLP Regulation, and an assessment of the evidence and arguments leading to the conclusion on classification.

The next step is for RAC to evaluate the new analyses contained in the classification proposal and to evaluate whether there is any reason to change its previous opinion. There will be a 60-day consultation on the proposal, starting in early September.

Assessment Group on Glyphosate: https://ec.europa.eu/food/plants/pesticides/approval-active-substances/renewal-approval/glyphosate/assessment-group_en

5. What information will ECHA publish?

The CLH report from the Assessment Group on Glyphosate will be published on ECHA's website for a consultation, starting in early September 2021. Interested parties are invited to provide comments and scientific data to ECHA.

The report includes summaries of studies, a comparison of the data with the criteria for classification which are described in the CLP Regulation, and an assessment of the evidence and arguments leading to the conclusion on classification. ECHA will not publish the full study reports, which are the intellectual property of the companies who paid for them.

The Glyphosate Renewal Group has listed the studies on their website and their website indicates that it is possible to "request a copy of all the reports of the additional glyphosate

studies that were commissioned by the Glyphosate Renewal Group or its member companies for the 2020 Scientific Dossier". RAC has access to relevant full study reports.

Glyphosate Renewal Group: Owned Studies Archive

6. How does ECHA avoid conflicts of interest?

ECHA is an organisation that issues decisions, opinions and recommendations strictly based on science. Therefore, it is important for the Agency to guarantee the independence of its work from private interests.

To safeguard its independence, ECHA has established a comprehensive policy which obliges anyone taking up a position in ECHA to complete a detailed declaration of interests before they can start to work for the Agency.

On glyphosate, staff of the ECHA secretariat perform an accordance check of an incoming proposal from the Member States and provide administrative support throughout the process. The ECHA secretariat does not provide any opinion on the classification and labelling proposal itself. Staff members assigned to the dossier have filled out an annual declaration of interest (like all ECHA staff members) and have also been checked for any potential personal interest in the file.

The scientific opinion on glyphosate will be prepared by ECHA's Committee for Risk (RAC), which is composed of independent scientific experts nominated by the Member States and appointed by the Management Board (or co-opted by the Committee); most of them are public officials, or academics from universities.

Before being appointed by ECHA's Management Board, all Committee members are screened against five generic exclusion criteria. Once appointed they also submit updated declarations of interest annually, which are reviewed by the Chair of the Committee and published on ECHA's website for transparency reasons and peer review. Furthermore, each meeting of RAC starts with an oral declaration of specific interests with regard to the agenda items to be discussed. These oral declarations are recorded in the meeting minutes and members with conflicting interests abstain from decision making.

RAC is a collegial decision-making body (decisions built mainly on consensus), which means that no single individual could influence the outcome of the process by him or herself.

With all these checks and controls, ECHA is confident that no-one that has an apparent conflict of interest has participated in the decision-making process.

ECHA's Conflict of Interest Prevention policy is available at:
https://echa.europa.eu/documents/10162/13608/mb_07_2014_pro_coi_management_en.pdf/c4082b12-5830-4647-abf7-47c4a0879c86