30 May 2022

Glyphosate: questions and answers

1. Why didn't the current classification change?

ECHA's Risk Assessment Committee formed its independent scientific opinion based on their evaluation of a new proposal prepared by the Assessment Group on Glyphosate - Sweden, France, The Netherlands and Hungary: the current classification of glyphosate does not change.

The committee's independent experts assessed a large number of scientific studies and information received from our consultation against criteria in the EU's classification, labelling and packaging regulation.

They found that the available scientific evidence did not meet the criteria to classify glyphosate for specific target organ toxicity, or as a carcinogenic, mutagenic or reprotoxic substance under the EU's CLP regulation.

This is in line with the previous RAC opinion from 2017.

Assessment Group on glyphosate

2. On what data is RAC's opinion based? Did the committee take into account all available new studies?

The harmonised classification and labelling proposal takes into account a broad range of scientific studies: all data that was included in the previous assessment (for the opinion adopted in 2017) as well as both published and unpublished data since then addressing all the required CLP hazard classes, including specific target organ toxicity following repeated exposure, carcinogenicity, mutagenicity and toxicity to reproduction.

The Assessment Group on Glyphosate - Sweden, France, The Netherlands and Hungary - carefully assessed the available data and included all relevant and appropriate information in the preparation of the dossier.

RAC's independent experts also assessed a large number of studies and comments received in the consultation.

Assessment Group on Glyphosate

3. 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.

Active substances, the main chemicals in plant protection products (PPP), such as glyphosate, are classified for their hazards as part of their approval process in the EU. This is done through the CLH process managed by ECHA, whereby substances are proposed for harmonised classification by Member States and evaluated by RAC. This avoids double work, because the harmonised classification is used under many other regulatory frameworks. It also avoids divergences between the hazard assessments done by other European agencies, such as the European Food Safety Authority (EFSA). EFSA manages the overall evaluation of active substances in PPP.

In 2019, a group of companies (the Glyphosate Renewal Group GRG) applied under the Plant Protection Products (PPP) Regulation[1] to renew the approval of glyphosate for use after the current approval expires at the end of 2022. The application was assessed by a group of four EU Member States (France, Hungary, the Netherlands and Sweden – called the Assessment Group on Glyphosate, AGG) and it will 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) adopted 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 active substance: its potential to cause harm. It does not assess risk via 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

4. What happens next?

The adopted opinion will be published on ECHA's website and sent to EFSA by mid-August. EFSA will carry out the risk assessment of glyphosate which is foreseen to be ready in July 2023.

The European Commission will analyse EFSA's conclusions and the renewal assessment report that was prepared by Sweden, France, Hungary and The Netherlands. The Commission will then put forward a renewal report and a draft regulation to Member States on whether the approval of glyphosate can be renewed or not.

EFSA's assessment

European Commission: status of glyphosate in the EU

5. What information will ECHA publish?

RAC's opinion will be finalised and published by mid-August and sent to EFSA. This opinion will detail RAC's scientific reasoning in coming to their conclusion.

The CLH report from the Assessment Group on Glyphosate has been available on ECHA's website since September 2021.

This 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 proposals for classification. ECHA does not publish the full study reports which are the intellectual property of the companies who own 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

[1] Regulation (EC) No 1107/2009 EUR-Lex - 32009R1107 - EN - EUR-Lex (europa.eu)

for the 2020 Scientific Dossier". RAC has access to relevant full study reports.

The CLH report addresses the following hazard classes: acute toxicity, STOT RE (specific target organ toxicity, repeated exposure), eye damage/irritation, respiratory and skin sensitisation, STOT SE (specific target organ toxicity, single exposure), skin corrosion / irritation, carcinogenicity, germ cell mutagenicity, reproductive toxicity and toxicity to the aquatic environment, as well as relevant physical hazards.

ECHA has already published the non-confidential comments received during the consultation on the CLH report. At the end of the CLH process, ECHA will also publish the "Response to Comments" (RCOM) documents from the consultation on the CLH report and from the additional targeted consultation, which will include the responses of the dossier submitter and RAC to the comments received.

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 Assessment (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 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 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