Bundesinstitut für Risikobewertung

Glyphosate – EFSA information on re-evaluation as a plant protection active substance published

Communication No. 31/2023 of 6 July 2023

Within the European Union (EU) active substances used in plant protection products are regularly re-evaluated with regard to their risks and their efficacy. The European Commission (EC) appointed four Member States – France, Hungary, the Netherlands and Sweden – to act as joint "rapporteurs" for the re-evaluation of glyphosate due to the expected large dossier. This group (AGG – Assessment Group on Glyphosate) prepared the initial assessment as a basis for the subsequent consultations and decisions at EU level.

In the light of this report and an extensive review by the competent authorities of the European Member States, the European Food Safety Authority (EFSA) today shared its opinion with the European Commission and the Member States (https://www.efsa.europa.eu/de/news/glyphosate-no-critical-areas-concern-data-gaps-identified). The German Federal Institute for Risk Assessment (BfR) was also involved in this process. EFSA's conclusion will feed into the European Commission's decision on whether glyphosate will remain on the EU list of approved active substances.

In advance of the authorisation of a plant protection product (PPP) a strict authorisation process need to be accomplished. The authorisation of a PPP in an EU Member State is a two-step process. First, the active substance of the plant protection product is approved in the EU, then PPPs containing this active substance can be authorised (see also https://www.bfr.bund.de/de/pflanzenschutzmittel-240.html).

Glyphosate is currently approved for use as an active substance in PPPs in the EU until 15 December 2023. The current approval was granted by the European Commission in 2017 based on EFSA´s comprehensive assessment. In doing so, the Commission also took into account how the European Chemical Agency (ECHA) had reviewed the classification and labelling of glyphosate at that time.

On 12 December 2019, the applicants, the Glyphosate Renewal Group (GRG, a group of companies seeking the renewal of-approval of glyphosate in the EU) had applied for the renewed approval of glyphosate after 2022 (note: the original approval period ended on 15 December 2022) to the AGG, the other Member States, EFSA and the European Commission. This application initiated the renewal process in the EU as provided for in Regulation (EC) No 1107/2009.

The AGG reviewed the very extensive application to ensure that it met the formal requirements of the relevant EU legislation (EU Commission Implementing Regulation (EU) No 844/2012 on the renewal procedure for active substances). A comprehensive assessment of all available data and information followed and subsequently submitted to EFSA to initiate the peer review process. The submission of EFSA's conclusion to the European Commission and Member States on 6 July 2023 will formally close the current evaluation cycle.

In parallel to the EFSA-led assessment, ECHA also reviewed the classification and labelling of glyphosate under the EU's Classification, Labelling and Packaging (CLP) Regulation (EC) No 1272/2008. The classification of chemicals is based solely on the properties of a substance. It does not take into account how likely it is to come into contact with that substance (exposure). Exposure is considered as part of the risk assessment process led by EFSA. Already in 2022, ECHA's Risk Assessment Committee (RAC) concluded that a classification of

glyphosate as a carcinogen was not justified. Accordingly, no change to the existing hazard classification was proposed.

The EU active substance evaluation always includes at least one product. Accordingly, there are separate data requirements in the EU for active substances (Regulation (EU) No 283/2013) and products (Regulation (EU) No 284/2013) (see also https://www.bfr.bund.de/de/fragen_und_antworten_zum_zulassungsverfahren_von_pflanzenschutzmitteln-192436.html). The authorisation procedure for PPPs is based on the results of the EU active substance evaluation and contains a health assessment of the specific PPP including all co-formulants.

For several years, the BfR has been intensively involved in the assessment of mixtures, and actively advocates the further development of research methods to that end. A current communication (Communication No. 025/2023 of 14 June 2023) on the subject was recently published (https://www.bfr.bund.de/cm/343/pflanzenschutzmittel-hohe-ma%C3%9Fstaebe-in-der-risikobewertung-auch-bei-mischungen.pdf).

Further information on the BfR website on glyphosate

https://www.bfr.bund.de/en/a-z_index/glyphosate-193962.html

BfR “Opinion App”

About the BfR

The German Federal Institute for Risk Assessment (BfR) is a scientifically independent institution within the portfolio of the German Federal Ministry of Food and Agriculture (BMEL). It advises the Federal Government and the federal states (“Laender”) on questions of food, chemicals and product safety. The BfR conducts its own research on topics that are closely linked to its assessment tasks.

This text version is a translation of the original German text which is the only legally binding version.