

(English version)

**Question for written answer E-002283/25
to the Commission
Gerben-Jan Gerbrandy (Renew)
(5 June 2025)**

Subject: Assessment of the cancer risk from pesticide exposure

The Dutch Board for the Authorisation of Plant Protection Products and Biocides (Ctgb) recently informed the Dutch agriculture minister that the cancer risk has been incorrectly assessed for years in the pesticide authorisation process, including for glyphosate. Instead of a one-sided test specifically aimed at determining cancer risks, a less accurate two-sided test has been the norm.

1. Can the Commission urge the European Food Safety Authority (EFSA) as soon as possible to tighten the guidelines for assessing cancer risks in the pesticide authorisation process, and to make the more accurate one-sided test the norm?
2. The International Agency for Research on Cancer (IARC) states that glyphosate is probably carcinogenic, while EFSA's risk assessment states that exposure to glyphosate is 'unlikely' to lead to cancer in humans. To what extent was the EFSA assessment based on the less accurate two-sided test?
3. Is the Commission willing to encourage EFSA and the authorisation authorities in the Member States to have pesticides that have been approved in the past based on the two-sided test re-evaluated using the more accurate one-sided method, which also takes stacking effects and cocktail effects into account?

Submitted: 5.6.2025

**Answer given by Mr Várhelyi on behalf of the European Commission
(30 July 2025)**

The Commission is aware that the Dutch competent authority for the authorisation of plant protection products wrote ⁽¹⁾ to the Dutch Minister for Agriculture to inform about the outcome of an expert meeting ⁽²⁾ on statistical analysis of results of carcinogenicity studies, expressing preference for one-sided tests, and that it would ⁽³⁾ bring them to the attention of the appropriate European and international regulatory bodies ⁽⁴⁾.

As reported in the letter, the experts noted that statistical analysis is only one line of evidence for concluding on carcinogenicity; some experts even considered statistical analysis of limited importance.

All information on a substance should be considered in a weight of evidence approach, including a consideration of biological relevance of findings. A different method of testing does not automatically lead to a different conclusion on the hazard.

The European Chemicals Agency (ECHA) concluded two times (2017 ⁽⁵⁾, 2022 ⁽⁶⁾) that, based on the available evidence and using a weight of evidence approach, no classification for carcinogenicity is warranted for glyphosate.

In the last review both one- and two-sided tests were used to assess findings in the carcinogenicity studies and arrived at the same conclusion.

The European Food Safety Authority considered the ECHA assessment as well as the underlying studies in its Conclusion on the peer reviewed risk assessment.

Given that the outcome of the meeting of Dutch experts requires further discussion among independent risk assessors and that statistical testing is only one aspect of carcinogenicity assessments, the Commission currently does not consider it necessary to ask EFSA and Member States authorities to re-open assessments.

⁽¹⁾ <https://www.tweedekamer.nl/downloads/document?id=2025D20811>.

⁽²⁾ <https://www.ctgb.nl/binaries/ctgb/documenten/beleidsnotas/2025/04/28/deskundigenbijeenkomst-beoordelen-carcinogeniteit/Verslag+deskundigenbijeenkomst+7+februari+2025.pdf>.

⁽³⁾ In cooperation with other parties — the letter from the Dutch Board for the Authorisation of Plant Protection Products and Biocides (Ctgb) mentioned specifically RIVM — the Dutch National Institute for Public Health and the Environment.

⁽⁴⁾ Notably the European Food Safety Authority (EFSA), the European Chemicals Agency (ECHA) and Organisation for Economic Cooperation and Development (OECD).

⁽⁵⁾ European Chemicals Agency (ECHA) (2017). Opinion of the Committee for Risk Assessment proposing harmonised classification and labelling of glyphosate (ISO); N-(phosphonomethyl)glycine (EC Number: 213-997-4; CAS Number: 1071-83-6). (<https://echa.europa.eu/documents/10162/2f8b5c7f-030f-5d3a-e87e-0262fb392f38>).

⁽⁶⁾ European Chemicals Agency (2022). Opinion of the Committee for Risk Assessment proposing harmonised classification and labelling of glyphosate (ISO); N-(phosphonomethyl)glycine (EC Number: 213-997-4; CAS Number: 1071-83-6). (<https://echa.europa.eu/documents/10162/5702e99d-d503-f154-226f-d8ab070ac47a>).