

## Glyphosate: EFSA and ECHA respond to Christopher Portier

BfR Communication No 012/2017, 6 July 2017

On behalf of the EU Commission – and with the support of the German Federal Institute for Risk Assessment (BfR) – the European Food Safety Authority (EFSA) and the European Chemicals Agency (ECHA) published a response on 6 July 2017 to an open letter addressed to Commission President Jean-Claude Juncker. Christopher Portier, a consultant to a non-governmental organisation, wrote an open letter to the Commission President in May 2017 in which he said that tumours found in feeding studies with mice and rats had allegedly not been taken into consideration in the drafting of the European risk assessment.

EFSA and ECHA clearly state that the claim that findings were overlooked is false based on the transparent assessment procedure of European hazard and risk assessment as well as the available scientific facts. All the original studies mentioned have been taken into account in the evaluations of the European authorities in accordance with their reliability and relevance, and have been assessed on the basis of agreed scientific principles.

The scientific principles used by EFSA in the evaluation of rodent carcinogenicity studies are based on an integrated weight of evidence approach that reflects the CLP Regulation (Regulation on Classification, Labelling and Packaging of Substances and Mixtures) and the relevant ECHA guidance.

The response can be accessed via the following links:

<http://www.efsa.europa.eu/en/topics/topic/glyphosate>

<https://echa.europa.eu/chemicals-in-our-life/hot-topics/glyphosate>

<http://rdcu.be/utnC>

<https://link.springer.com/content/pdf/10.1007%2Fs00204-017-2032-8.pdf>

All the original studies on the toxicity of glyphosate cited by Christopher Portier in his letter to the President of the EU Commission have been taken into account in the evaluations of the European authorities in accordance with their scientific reliability and relevance, and have been assessed on the basis of agreed scientific principles. This means that individual data on the specified tumour types and incidences that have now been additionally analysed by Christopher Portier using his own method were already known. Following their own evaluations using established, internationally recognised, standard toxicological methods, all assessment authorities worldwide who had access to these original data have reached the conclusion that glyphosate should not be classified as carcinogenic.

These authorities include:

- The European Food Safety Authority (EFSA) as well as the experts and risk assessment authorities of the EU member states
- The Environmental Protection Agency (EPA) in the USA
- The Canadian Pest Management Regulatory Agency (PMRA)
- The Australian Pesticides and Veterinary Medicines Authority (APVMA)
- The Japanese Food Safety Commission
- The EPA in New Zealand
- The Joint FAO/WHO Meeting on Pesticide Residues (JMPR)
- The European Chemicals Agency (ECHA)

All of the tumour incidences described by Christopher Portier as "new" can also be found in the original studies of the manufacturers. The scientific principles used by EFSA in the evaluation of rodent carcinogenicity studies are based on an integrated weight of evidence approach that reflects the CLP Regulation (Regulation on Classification, Labelling and Packaging of Substances and Mixtures) and the relevant ECHA guidance.

One of the key elements in this approach is the assessment of the quality of the studies and the identification of errors that might influence the findings as described by the study authors. The integrated assessment of the statistical significance of the findings and their biological relevance is also of decisive importance. Moreover, the use of agreed methods, guidelines and principles is essential to ensure coherence in regulatory scientific assessments.

According to OECD guidelines on the evaluation of experimental animal studies, statistical significance should not be equated with biological relevance. After the process was completed at EFSA, the Committee for Risk Assessment (RAC) at ECHA reviewed the scientific findings and determined that classification as carcinogenic is not warranted.

As part of the re-approval procedure, the German Federal Institute for Risk Assessment (BfR) was commissioned to assess the health risk of the active substance glyphosate. This assessment was incorporated into the European assessment process and independently peer reviewed by the experts of the member states and the EFSA in a transparent assessment process, resulting in confirmation of the basic statements contained in the BfR assessment. Based on the Community assessment, EFSA forwarded its "Conclusion" to the European Commission and to the member states of the European Union. In the ECHA-managed procedure for the harmonised classification and labelling of substances (CLH), the CLH report prepared by Germany was also subject to a public consultation.

The ECHA then communicated on 15 March 2017 that, following the evidence-based assessment of data from epidemiological studies and animal experiments, a hazard classification of glyphosate as carcinogenic, mutagenic and reprotoxic in line with the CLP Regulation is not justified. Independently of ECHA, the competent WHO/FAO body – the *Joint FAO/WHO Meeting on Pesticide Residues* (JMPR) – reached the conclusion that glyphosate does not pose any carcinogenic risk.

**You can find more information on glyphosate on the BfR website at:**

[http://www.bfr.bund.de/en/a-z\\_index/glyphosate-193962.html](http://www.bfr.bund.de/en/a-z_index/glyphosate-193962.html)



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### About the BfR

The German Federal Institute for Risk Assessment (BfR) is a scientifically independent institution within the portfolio of the Federal Ministry of Food and Agriculture (BMEL) in Germany. It advises the Federal Government and Federal Laender on questions of food, chemical 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.*