No new findings on the risk assessment of glyphosate

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Due to inquiries about an open letter to Commission President Jean-Claude Juncker, the Federal Institute for Risk Assessment (BfR) is publishing an estimation of allegedly new findings on the risk assessment of glyphosate. The advisor Christopher Portier addressed an open letter to the President of the Commission on Sunday informing him that tumour findings in feeding studies conducted with rats and mice had allegedly not been taken into consideration in the European risk assessment.

On the basis of the available scientific data and publications by ECHA and European Food Safety Authority (EFSA), the assertion that findings were overlooked is not correct. All of the original studies mentioned were given due consideration in the assessments of the European authorities with regard to their reliability and relevance.

The BfR recommends that the calculations made by Christopher Portier be published in a scientific journal so that they can be opened up to scientific discourse.

Christopher Portier conducted his statistical analyses after completion of the preliminary work conducted in Germany for the assessment reports to the European Food Safety Authority (EFSA) and European Chemicals Agency (ECHA) on the reassessment of glyphosate. The statistical calculations he made are known to the Federal Institute for Risk Assessment (BfR) from presentations he made to the Annual Meeting 2016 of the Swiss Society of Toxicology in Basel (CH) and at the European Chemicals Agency. Unfortunately, the findings made by Christopher Portier with their individual analyses have not as yet been made accessible to the general public, nor have they been peer-reviewed or published in a scientific journal. Christopher Portier had the opportunity to present his calculations and statistical conclusions to ECHA at the public consultation in July 2016, as well as at a hearing in November 2016. They were discussed by the ECHA experts and taken into consideration in their vote. ECHA showed in a transparent manner that they had included the deliberations of Christopher Portier in their assessment and discussion[1] and also published his presentation[2], which he had made as the representative of the non-government organisation HEAL[3]. Using the “weight of evidence” (WoE) approach recommended in the technical guidelines under consideration of all statistical analyses, and with the involvement of its own statisticians and the inclusion of Christopher Portier’s analyses together with other lines of evidence for the estimation of the carcinogenic potential, ECHA comes to the conclusion that there are no indications of a carcinogenic or genotoxic effect of glyphosate. A comprehensive justification of the ECHA vote has been published on the ECHA website[4] .

All of the original studies mentioned in Mr. Portier’s letter were given consideration in the assessments of the European authorities in accordance with their reliability and relevance. According to the technical guidelines of the OECD, statistical significance should not fundamentally be regarded as being identical with biological significance. It is necessary not to

[1] https://echa.europa.eu/-/the-committee-for-risk-assessment-starts-discussing-the-harmonised-classification-for-glyphosate

[2] https://echa.europa.eu/documents/10162/22863068/glyphosate_ngo_heal_en.pdf/b743ed14-d27d-b17f-7fec-dcb2866f8fe3

[3] http://www.env-health.org/

[4] https://echa.europa.eu/de/home

assess the available animal studies individually but rather to adopt a WoE approach which looks at them collectively under consideration of the harmonised guidelines. An EFSA study on the differences in methodology with an explanation of the WoE approach recommended in the technical guidelines is published here:
https://www.ncbi.nlm.nih.gov/pubmed/28374158.

The OECD guideline for toxicity and carcinogenicity studies (OECD Guidance Document 116) emphasises that the selection of the statistical methods for evaluating the data should be made during the planning phase, i.e. *before the study begins*. In addition to stipulating binding test guidelines (451 to 453), this OECD Guidance Document 116 from 2012 also provides important orientation for the conducting and evaluation of carcinogenicity studies by test facilities. In addition to this, these documents also form an important basis for authorities to assess carcinogenicity studies using a WoE approach, as they include numerous other lines of evidence in addition to the purely statistical results. These include:

(a) Positive as well as negative results with distinction by the relevance of neoplastic and non-neoplastic lesions

(b) The relevance of the study design for the assessment of carcinogenic effects and appraisal of the carcinogenic mechanism of action

(c) All adverse effects on target organs and other systemic effects

(d) The biological plausibility and causality of the relation between the adverse effects and the carcinogenic mechanism of action

(e) The quality and robustness of the data with regard to the pattern and coherence of the results within one study, as well as between several studies with a comparable design

(f) The concept of the *limit dose* and international recommendations on the maximum recommended doses in carcinogenicity studies under consideration of possible secondary effects through excessive overall toxicity

The assessment of the German authorities was made in compliance with the legally established principles of Regulation (EC) No. 1272/2008 and the criteria stipulated there in Item 3.6 on classification and labelling and was one of the foundations of the independent ECHA assessment which took into consideration in its assessment all of the presented statistical deliberations with the assistance of other independent statisticians, as was also done with the assessment of other chemicals with regard to the classification of their carcinogenic properties.

The Federal Government has also made a statement (18/12489) on the subject of the assessment of carcinogenicity studies in response to the parliamentary question put by the *Die Linke* group (18/12284):
http://dip21.bundestag.de/dip21/btd/18/124/1812489.pdf

More information on the subject of glyphosate on the BfR website

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

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About the BfR

The 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.