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Authorities admit that they failed to report increased tumour rates in glyphosate-exposed animals1

Statement by Dr Peter Clausing (PAN Germany) on the misinformation of Germany's Federal Institute for Risk Assessment – BfR (BfR-statement 12/2017 dated 06 July 2017 "Glyphosate: EFSA and ECHA respond to Christopher Portier"²)

According to BfR's statement, the authorities involved in the re-assessment of glyphosate, EFSA and ECHA,³ "based on the transparent assessment procedures", did not overlook any tumour findings.

As shown below, EFSA and ECHA had to admit that seven of the eight tumour effects described by Professor Christopher Portier were not mentioned in the authorities' reports:⁴

The EFSA, ECHA and the peer reviews of MS relied on both the original study reports as well as on the summary reports of RMS or DS. Under these procedures, all results are carefully considered by the RMS/DS, Member States, EFSA and ECHA RAC. It is acknowledged that 7 out of 8 tumour findings reported by Dr Portier were not specifically documented either in the RAR or CLH report. As indicated below, the reason for that was not that they would have been overlooked or dismissed but they were considered not relevant for hazard and risk assessment. For clarification, the specific findings listed in Table 1 of the open letter are considered point-by-point below, in the order in which they are listed in the Table.

At the same time, EFSA and ECHA claimed that the sole reason for not mentioning these tumour effects was because they considered them irrelevant. There may be sound reasons for considering a statistically significant tumour effect as irrelevant. However, on the one hand failing to mention the effect and withholding the reasons for considering it irrelevant in the assessment report and on the other hand claiming "transparent assessment procedures", as the BfR did, is a strong contradiction.

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¹ Original quotes in German were translated into English by PAN Germany

² http://www.bfr.bund.de/cm/343/glyphosatefsa-efsa-und-echa-antworten-christopher-portier.pdf

³ EFSA = European Food Safety Authority; ECHA = European Chemicals Agency

⁴ <u>https://echa.europa.eu/documents/10162/23294236/portier_echa_efsa_response.pdf/9e199eca-af2f-96bb-9e61-d6bae2588f4b</u>



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The authorities' documents themselves belie BfR's statement. For instance, in the past, BfR and ECHA explicitly contended that there were no other studies, except for the Stout and Ruecker (1990) study, that showed an increase in liver cell tumours:

BfR: "Based on the lack of increased liver tumour rates in all other long-term/carcinogenicity studies ..."⁵

ECHA: "No significant increases in glyphosate-related liver tumours were reported in the other long-term studies in rats."⁶

This proves that the authorities overlooked the significant increase of liver cell tumours in the Brammer (2001) study identified by Prof Portier. How can we trust the authorities when they claim that they noticed the increases in the remaining six tumour incidences, but did not report them?

Previously BfR, in August 2015, was forced to admit that it had overlooked tumour effects because "initially" it relied too much on the statistical evaluation provided in industry's own study reports.⁷

BfR, EFSA and ECHA repeatedly take recourse to the argument that statistical significance is not the same as biological relevance. But they use it to make blanket dismissals of the relevance of statistically significant findings. This is an outrageous abuse of this argument. And it is in strong contradiction to the fact that in concrete cases the statistically significant findings are supported instead of being rebutted by considerations of biological relevance. This, for instance, applies to malignant lymphoma and kidney tumours.⁸

In contributions to peer-reviewed journals in February and June 2017, BfR and EFSA were invited to explain their position regarding the biological relevance of tumour increases in the context of a scientific debate.⁹ To date they have not done so. As long as this situation persists, the concerned public and scientific community can only assume that BfR's and EFSA's repeated calls for a "scientific debate" are not sincere but are a tactical manoeuvre.

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⁵ BfR: CLH-Report (2016), p. 65

⁶ ECHA Opinion (2017), p. 34.

⁷ Addendum to Renewal Assessment Report on Glyphosate (2015), p. 36.

⁸ Peter Clausing (2017). Glyphosate and cancer: Authorities systematically breach regulations. Published by GLOBAL 2000 (Friends of the Earth Austria). <u>http://www.gmwatch.org/files/GLO_02_Glyphosat_EN.pdf</u>

⁹ Clausing, P. (2017): Krebsgefahr durch Glyphosat: Der "Weight of Evidence Approach" des BfR. Umwelt – Hygiene – Arbeitsmedizin 22: S. 27-34; Portier, C.J. und Clausing, P. (2017): Archives of Toxicology, DOI 10.1007/s00204-017-2009-7