

# The Carcinogenic Hazard of Glyphosate: BfR's "Weight of Evidence Approach"\*

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**Annex:**

**Table 2:** Summary of the critique of the „weight of evidence approach” by BfR and EFSA (referring to malignant lymphoma in mouse studies). The critical assessment relates to the studies of 1997, 2001 and 2009, because – as detailed in the text – the studies of 1983 and 1993, as related to malignant lymphoma were only of limited use (1983) or completely useless (1993).

<b>Issue</b>	<b>Opinion by BfR and EFSA</b>	<b>Critique of the Opinion</b>
Contradicting statistical results	Trend-tests were mostly (but not always) significant, however for pairwise comparisons there were no significant differences.	Trend-tests are explicitly recommended for the assessment of tumour incidences by the applicable OECD guidance. Even pairwise comparisons result in statistical significance if one-sided tests as recommended by the same guidance are used.
Inconsistencies concerning the dose-response-relationship	Different tumour incidences in the control groups and similar tumour incidences at different dosages in the different studies.	This is invalid, because it ignores the fact that different strains of mice were used in the different studies.
Excessive toxicity in high-dose groups	An increase in tumour incidences occurred only after exceeding the „limit-dose“ of 1,000 mg/kg and excessive toxicity was observed.	A significant increase was also seen at 810 mg/kg. A „limit-dose“ is not defined in OECD Guideline 451 (Carcinogenicity). Excessive toxicity was not seen in any of the studies. The reduced body weight is due to reduced food consumption (as a consequence of the high glyphosate concentration in the test diet).
An infection with oncogenic viruses makes the study of 2001 unusable	According to EFSA the study is not acceptable because of a viral infection; infections with oncogenic viruses are widespread in the strain of mice used.	According to the ECHA-dossier there is no proof for this claim made in the EFSA-Conclusion. In the publication, that is cited as alleged evidence for widespread infections by oncogenic viruses in the particular mouse strain, the term widespread is not used. To the contrary the authors emphasized, that they only presented results from two laboratories with mice from the same breeder.
Tumour incidences as related to historical control data	The tumour incidences of glyphosate-treated animals were in the range of historical control data.	For the study of 1997 OECD-recommendations for historical control data (HCD) are violated, for the 2001 study the HCD actually support the tumour finding, and no usable HCD are available for the study of 2009.
No conclusive evidence for a carcinogenic mode of action	From the “sole” observation of oxidative stress and a plausible mechanisms for its formation a carcinogenic action cannot be deduced.	Because of statistically significant increases in tumour incidences in three independent studies and epidemiological evidence, although limited, for tumours of the lymphatic system it is incorrect to speak of a „sole“ observation of oxidative stress.

## Imprint

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