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Turning a blind eye?

The German Federal Institute for Risk Assessment overlooked a carcinogenic effect in a mouse study with glyphosate

Research carried out by the Pesticide Action Network (PAN Germany) has identified that the significantly enhanced tumor incidence in an industry-sponsored mouse carcinogenicity study was obviously overlooked by the German Federal Institute for Risk Assessment (BfR).

Within the framework of the process of the renewal of the approval of glyphosate, the BfR claims to have corrected „errors and redundancies“ in the dossier submitted by industry and to have performed its own assessment(1).

The classification of glyphosate as „probably carcinogenic to humans“ by the WHO-affiliated International Agency for Research on Cancer (IARC) in March 2015 ignited a controversy, because the BfR opines that glyphosate does not pose the hazard of cancer. A point of reference for the BfR's opinion is that the industry-sponsored long-term studies in mice allegedly did not give any relevant indication for carcinogenic effects. In particular this relates to malignant lymphoma in four experiments that were conducted between 1993 und 2009 although a higher incidence of this tumor was observed in one of these studies.

Because the occurrence of lymphoma was also observed in control animals, though at a lower rate, the BfR did not attach much value to these results. According to the BfR the observed higher tumor incidence was „clearly“ confined to this individual strain of mice and to this particular study. Allegedly the effect was not reproducible in the other valid studies.

But the BfR obviously accepted the industry's interpretation of data without scrutiny, criticizes PAN Germany. However, in one of the studies, which allegedly was without effect, a dose-dependent increase of malignant lymphoma was seen, while no tumor of this type was observed in the control group. According to the industry these were chance observations, because they were not statistically significant according to the mathematical methods they used. „However, if the OECD-guidance for the assessment of carcinogenicity studies(2), i.e. the “gold standard”, is used a highly significant, dose-dependent trend for a tumor effect becomes obvious”, says the toxicologist Dr. Peter Clausing, who assessed the studies on behalf of PAN Germany.

When the industry analyzed the data of their study, the OECD guidance, published in 2012, did not exist. But the BfR, which claims, to evaluate „the scientific quality and evidence of the studies“ should have applied the OECD standard. Dr. Clausing concludes: “With a significantly increased tumor incidence of a second industry sponsored study the BfR's overall assessment becomes shaky that glyphosate does not pose a carcinogenic hazard, because until now the authority argued according to the motto „one finding is no finding“.

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Further information:

(1) Questions and Answers concerning the risk assessment of glyphosate (in German). BfR-Mitteilung of 24th July 2015;

http://www.bfr.bund.de/de/fragen_und_antworten_zur_gesundheitlichen_bewertung_von_glyphosat-127823.html

(2) Application of the Cochran-Armitage-Trend-Test, cf. Guidance Document 116 on the Conduct and Design of Chronic Toxicity and Carcinogenicity Studies, Supporting Test Guidelines 451, 452 and 453 2nd Edition, 13. April 2012;

[http://www.oecd.org/officialdocuments/displaydocument/?cote=ENV/JM/MONO\(2011\)47&doclanguage=en](http://www.oecd.org/officialdocuments/displaydocument/?cote=ENV/JM/MONO(2011)47&doclanguage=en)

