

## PAN Germany: Comments on ECHA's CLH-Report regarding Genotoxicity

**PAN Germany** 

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The Dossier Submitter (DS) concluded that "because of the negative results in the majority of the *in vitro* and *in vivo* mutagenicity tests including nearly all guideline-compliant standard assays and since positive findings were mainly confined to indicator tests, categories 1B and 2 also do not apply" (CLH-Report p.59). This includes 17 negative Ames tests as listed in Table 21 of the CLH-Report. The DS failed to acknowledge that bacterial test systems are scientifically flawed for the assessment of compounds with antibiotic properties. Glyphosate has been patented as a broad spectrum antibiotic (US patent number 7771736) and then again as an "antimicrobial agent" (US patent number 20040077608 A1). The Ames test is not suitable for testing antibiotics (cf. Luijten et al. 2016). Taking this into account, the alleged number of negative results "proving" lack of genotoxicity of glyphosate is significantly reduced.

The CLH-Report (p. 57) points out that epidemiological data for genotoxicity of glyphosate is available, but cautions: "It must be taken into account that the study participants had been always exposed to plant protection products containing glyphosate but never to the active substance itself." This is commonplace and applies to almost all epidemiological data for pesticides. Nevertheless this information is particularly valuable, because these are human data. In case of glyphosate these findings should be evaluated (weight of evidence approach) together with the results of *in vitro* tests for mutagenicity, clastogenicity or DNA damage/repair with glyphosate acid in mammalian cells as summarized in Table 22 of the CLH-Report (p. 47/48). Of the 18 tests listed in this table 7 were performed with cells of animal origin, 11 with cells of human origin. It is remarkable that 6 of the 7 tests performed with cells of animal origin were negative. In contrast the majority (i.e. 7 of the 11 tests) with cells of human origin were positive. This, taken together with the results of the epidemiological studies and the scientific discredit of the Ames test for assessing mutagenic effects of glyphosate, are strong indications that a proper evaluation would lead to a same conclusion as was drawn by the IARC in its monograph, i.e. that "there is strong evidence that exposure to glyphosate and glyphosate-based formulations is genotoxic" (IARC 2015, p. 78)

## References

IARC (2015): IARC monograph No. 112. Glyphosate. http://monographs.iarc.fr/ENG/Monographs/vol112/index.php

Luijten, M.; Olthof, E.D.; Hakkert, B.C.; Rorije, E.; van der Laan, J.-W; Woutersen, R.A.; van Benthem, J. (2016): An integrative test strategy for cancer hazard identification, Critical Reviews in Toxicology, DOI: 10.3109/10408444.2016.1171294

## Imprint

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