

**Priority question for written answer P-002665/2023
to the Commission**

Rule 138

Sarah Wiener (Verts/ALE)

Subject: Failure by ECHA to appropriately assess glyphosate's carcinogenicity

Three areas of concern with regard to carcinogenicity emerge when considering the assessment by the European Chemicals Agency (ECHA) on glyphosate.

1. Referring in its opinion to 'five OECD TG 451 compliant long-term studies in mice', ECHA states¹ that, in two of those studies, doses were 'above the OECD limit dose of 1 000 mg/kg bw/d²', thus dismissing the tumour findings. Such a limit dose is not mentioned at all in OECD Test Guideline 451, which is the main point of reference.
2. In three mouse studies, significant increases in kidney tumours were seen when using the trend test³. However, ECHA ultimately dismisses the findings from the trend test⁴, while OECD Guidance Document 116 requires trend tests to be taken into account⁵.
3. ECHA claims that 'no plausible mechanism' for kidney tumours exists⁶, even though oxidative stress is a known mechanism of carcinogenicity, and a high-quality study (Gao et al., 2019⁷) demonstrated oxidative stress in the target organ, i.e. the kidneys(!), of mice. ECHA repeatedly refers to this study by Gao et al., but never in the direct context of kidney tumours.

Considering the above, will the Commission reconsider its intention to propose renewing the approval of the substance?

Supporters⁸

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¹ ECHA, Committee for Risk Assessment, *Opinion proposing harmonised classification and labelling at EU level of glyphosate (ISO); N -(phosphonomethyl)glycine*, 30 May 2022, pp. 51-52.

² Milligrams per kilogram of body weight per day.

³ ECHA, Committee for Risk Assessment, *Opinion proposing harmonised classification and labelling at EU level of glyphosate (ISO); N -(phosphonomethyl)glycine*, 30 May 2022, p. 66.

⁴ ECHA, Committee for Risk Assessment, *Opinion proposing harmonised classification and labelling at EU level of glyphosate (ISO); N -(phosphonomethyl)glycine*, 30 May 2022, p. 55.

⁵ OECD, *Guidance Document 116 on the Conduct and Design of Chronic Toxicity and Carcinogenicity Studies, Supporting Test Guidelines 451, 452 and 453 – 2 Edition*nd, 13 April 2012, pp. 116 and 123.

⁶ ECHA, Committee for Risk Assessment, *Opinion proposing harmonised classification and labelling at EU level of glyphosate (ISO); N -(phosphonomethyl)glycine*, 30 May 2022, p. 53.

⁷ Gao, M. et al., 'Role of Mitochondria in Ferroptosis', *Molecular Cell*, Vol. 73, No 2, Elsevier, 17 January 2019, pp. 354-363.

⁸ This question is supported by Members other than the author: Jutta Paulus (Verts/ALE), Christophe Clergeau (S&D)