



Pesticide newsletter

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Legislative and regulatory news



Glyphosate in the EU: It remains to be seen what will happen

On November 22, 2021, the eight-week public consultation on EFSA's (European Food Safety Authority) and ECHA's (European Chemicals Agency) draft assessment report ended. That draft was completed in June, and the agencies [announced](#) "that a classification of glyphosate with regard to carcinogenicity is not justified."

From late September to Nov. 22, the [draft](#) was available for public consultation. Looking through the cancer assessment, it was clear that [almost all the points](#) criticized on the last assessment report were repeated. However, repeating flawed arguments and making distorted use of applicable guidelines does not achieve an accurate assessment, nor does this approach help to build trust in the authorities.

Major flaws of the authorities' assessment included:

- The reference to an alleged "limit dose" of 1,000 mg/kg body weight to dismiss observed increases in tumour incidences at higher doses. As clearly stated in the applicable guidelines, this limit dose does not apply to carcinogenicity studies;

- In the current draft it is admitted by the agencies that the last assessment used flawed "historical control data" (to reject tumor findings). At the same time, however, the current assessment avoids to acknowledge that available correct historical control data, in fact support the observed tumour incidences as being true effects;
- The available data support the existence of a dose-response relationship for an increase in tumor incidence for multiple studies and tumor types. But instead of acknowledging this, the agencies mix data from non-comparable experiments and then claim that such dose-response relationships (i.e., increasing tumor incidences with increasing doses) would not exist;
- Authorities insist on using so-called two-sided statistical tests, which halves the strength of statistical significance. Such two-sided tests are used, for example, to test simultaneously whether a chemical causes tumors or inhibits their development, and thus could be a tumor therapy. However, when assessing the hazard of carcinogenicity risk of pesticides, the research question is only in one direction, i.e., whether the substance has cancer potential, so a one-sided statistical test is appropriate. Therefore, the use of two-sided tests is not scientifically correct.
- Authorities are required to conduct a "weight of evidence" analysis. But instead, authorities engage in a "dismantling the evidence" exercise. They avoid an integration of the results of the long-term studies in rats and mice with those of epidemiological studies and studies on a possible mechanism of carcinogenesis. The epidemiological studies are summarized separately in the report and mechanistic evidence is not discussed at all. For example, "biological relevance" of the increased incidence of lymphoma in the mouse studies is not discussed in the context of non-Hodgkin's lymphoma in humans. A relatively weak but statistically significant increased risk of non-Hodgkin's lymphoma has been discovered in several studies and is the subject of numerous lawsuits in the United States.
- "Mechanistic evidence," i.e. scientific knowledge about the mechanism of action by which cancer can be caused, is an important component in the evaluation of glyphosate and has been part of the IARC's work. However, this assessment report completely ignores the existing evidence.

One of the mechanisms of how a chemical can cause cancer is through the generation of "oxidative stress," which is the generation of highly reactive (oxygen-containing) molecules by glyphosate. A very powerful study published by [Gao and collaborators](#) in 2019 shows that glyphosate causes oxidative stress in the kidneys of mice, providing a conclusive explanation for the kidney tumors observed in several carcinogenicity studies in mice. While this publication is mentioned in another section of the draft assessment report, it is not addressed at all in the chapter on carcinogenicity. Instead, the agencies explicitly claim that

glyphosate cannot cause kidney tumors because, in their opinion, it is a "more or less inert substance."

It remains to be seen whether the authorities will be honest enough to correct these errors and distortions during the revision of the draft report.

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[Back to Justice Pesticides website](#)