



## Monsanto

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# Corporate studies asserting herbicide safety show many flaws, new analysis finds

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A new analysis of more than 50 previously secret, corporate-backed scientific studies is raising troubling questions about a history of regulatory reliance on such research in assessing the safety of the widely used weedkilling chemical known as glyphosate, the key ingredient in the popular Roundup herbicide.

In a 187-page report released on Friday, researchers from the Institute of Cancer Research at the Medical University of Vienna in Austria said a thorough review of 53 safety studies submitted to regulators by large chemical companies showed that most do not comply with modern international standards for scientific rigor, and lack the types of tests most able to detect cancer risks.

“The quality of these studies, not of all, but of many of these studies is very poor. The health authorities ... accepted some of these very poor studies as informative and acceptable, which is not justified from a scientific point of view,” Siegfried Knasmueller, the lead author of the analysis told the Guardian.

Glyphosate is the most widely used herbicide in the world, and is particularly popular with farmers growing common food crops. But there is heated debate in many countries about whether or not glyphosate herbicides should continue to be used due to concerns they may cause cancer.

The corporate studies at issue focus on the genotoxic properties of glyphosate - whether or not it causes DNA damage - and they support corporate assurances that the chemical is safe when used as directed and does not cause cancer. They were commissioned and/or conducted by the former [Monsanto](#) Co, which is now a part of Bayer AG, as well as Syngenta, Dow, and others involved in making and/or selling glyphosate.

Though some of the studies date back decades, they have been part of recent submissions to regulators in [Europe](#) and the United States, where regulators have agreed with the companies in concluding there is no cancer risk with glyphosate. European officials reaffirmed that view in an 11,000-page report issued last month.

The new analysis challenges those safety assurances, finding that much of the methodology used in the industry studies is outdated and not in keeping with international quality standards. Of the 53 studies submitted to regulators by the companies, only two were acceptable, according to current internationally recognized scientific standards, said Knasmueller.

Particularly problematic, he said, was the focus on testing for chromosome damage

carcinogens because it can quantify and detect DNA damage in individual cells in a variety of organs, and is commonly used for evaluating genotoxicity, according to Knasmueller. But no comet assay tests were included, according to the analysis.

“I cannot understand why the health authorities did not ask for such data,” said Knasmueller, who is an expert in genetic toxicology and along with his work at the cancer institute is editor-in-chief of two prominent scientific journals, including Mutation Research - Genetic Toxicology and Environmental Mutagenesis.

Knasmueller was asked to review the studies by the SumOfUs non-profit advocacy group, though he said he was not paid for the work. A co-author on the analysis and fellow cancer institute scientist, Armen Nersesyan, was paid roughly €3,500 (\$4,146), however.

If Knasmueller’s observations are accurate, the new finding of flaws in industry studies means regulatory assurances about glyphosate safety in Europe and the United States have been based, at least in part, on shoddy science.



Analysis comes at a critical time as Bayer is asking European regulators to reauthorize glyphosate ahead of the expiration



its level of confidence in the validity of industry studies.

The US Environmental Protection Agency (EPA) confirmed that no comet assay tests are required but said the agency “strives to use high-quality studies” and “a broad set of data” when evaluating pesticides. As well, the EPA “independently evaluates required studies for scientific acceptability” that meet agency and international guidelines, an EPA spokeswoman said.

The analysis comes at a critical time as Bayer and a contingent of companies calling themselves the Glyphosate Renewal Group (GRG) are again asking European regulators to reauthorize glyphosate ahead of the expiration of approval next year, and as the industry battles to preserve glyphosate use globally.

Bans or reductions in use have been called for in several countries, including Mexico, where a glyphosate ban is to take effect in 2024, and in France, where the government last year announced financial incentives for farmers who stopped using the chemical. In the US, New York City recently banned glyphosate use on city property and other cities have implemented reductions or bans.

The GRG did not respond to a request for comment. But Bayer, a leading member of the GRG, said the package of studies submitted to regulators is “one of the most extensive scientific dossiers ever compiled for a pesticide active ingredient”.

Bayer said for the current registration review, it was “required” to submit the older genotoxicity studies along with new corporate genotoxicity studies. As well, the companies submitted to regulators “a vast review of thousands of published scientific publications regarding glyphosate”, said a Bayer spokesman.

Concerns about glyphosate have mounted since 2015 when the International Agency for Research on Cancer (IARC), part of the World Health Organization, classified glyphosate as a probable human carcinogen based on scientific studies conducted by

Several questionable interactions between Monsanto and regulators have come to light in recent years, including the fact that EFSA dismissed a study linking the company's weedkiller to cancer after consultation with a US EPA official linked to Monsanto. Documents also demonstrated that an EU report declaring glyphosate safe was in part copied and pasted from a Monsanto study.

And when the EPA consulted with a scientific advisory panel assembled in Washington DC in December 2016, panel members complained that EPA officials were not following proper scientific guidelines for how to assess research about glyphosate health impacts.

“This puts once more a finger on a sore spot: that national regulators do not seem to pay close scrutiny when looking at the quality of industry's studies,” said Nina Holland, researcher at the watchdog group Corporate Europe Observatory. “This is shocking as it is their job to protect people's health and the environment, not to serve the interests of the pesticide industry.”

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