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April 30, 2018

Environmental Working Group Comments on the EPA's Assessment of Herbicide Glyphosate

Docket ID: EPA-HQ-OPP-2009-0361

Environmental Working Group (EWG), a nonprofit research and advocacy organization based in Washington, D.C., submits comments urging the Environmental Protection Agency to re-review all evidence linking glyphosate to increased cancer risk in animal studies. We also advise the EPA to take steps to protect Americans from ingestion of glyphosate by limiting its direct application to food crops.

In the past decade, the use of glyphosate has soared, with more than 250 million pounds sprayed in the U.S. annually, as data from the U.S. Geological Survey show.¹ In 1996, the Agency approved the use of genetically engineered crops that could withstand direct application of glyphosate. Furthermore, the herbicide can be legally applied to grains and legumes in preparation for harvest.

Presently, the EPA and the U.S. Department of Agriculture do not monitor glyphosate residues on most food crops. Yet, by all indications, Americans' exposures have increased dramatically. Between 2014 and 2016, at least 70 percent of American adults surveyed had detectable traces of glyphosate in their bodies, compared to 12 percent of American adults between 1993 and 1996.² The actual current exposure levels might be higher because glyphosate has not been included in nationwide biomonitoring studies, and there are no comprehensive datasets on glyphosate intake for young children and teenagers.

Americans' widespread exposure to glyphosate is of grave concern, especially for children's health, because of the potential risk of cancer. In 2015, the International Agency for Research on Cancer, an agency of the World Health Organization, determined that glyphosate is a probable human carcinogen.³ California's Office of Environmental Health Hazard Assessment

¹ U.S. Geological Survey. 2018. Estimated Annual Agricultural Pesticide Use. Available at <https://water.usgs.gov/nawqa/pnsp/usage/maps/>

² Mills PJ, Kania-Korwel I, Fagan J, McEvoy LK, Laughlin GA, Barrett-Connor E. 2017. Excretion of the Herbicide Glyphosate in Older Adults Between 1993 and 2016. *JAMA*. 318(16): 1610-1611.

³ International Agency for Research on Cancer. 2015. IARC Monograph on Glyphosate. Available at <http://monographs.iarc.fr/ENG/Monographs/vol112/>



recently finalized its No Significant Risk Level for Glyphosate, which is roughly 50 to 70 times lower than EPA's proposed Population Adjusted Dose for an adult.⁴

Yet, in the EPA's draft risk assessment, the Agency ignored its own established risk assessment guidelines and ignored the findings from key studies, taking a position that glyphosate is "unlikely to cause cancer."

EWG analysis of glyphosate science discovered two important limitations of EPA's assessment of glyphosate's ability to cause cancer:

1. EPA incorrectly dismissed the evidence that glyphosate causes cancer in laboratory animals

There have been at least 14 multiyear studies of glyphosate's ability to cause cancer in laboratory animals, most of which were conducted by the pesticide industry. More than half of the studies the EPA reviewed detected elevated rates of cancer in study animals. The Agency used various arguments to discount the four positive cancer studies of rats and four positive studies of mice.

EPA's own Science Advisory Panel met in 2016 to review the Agency's assessment of the cancer evidence, and split over its assessment of the strength of the evidence. Overall, EWG finds that the EPA Office of Pesticide Programs incorrectly dismissed many study findings that showed statistically significant dose-response trends for glyphosate carcinogenicity. EPA's dismissal of those studies contradicted the Agency's own Guidelines for Carcinogen Risk Assessment and the specific recommendations from several Science Advisors that a presence of a significant trend makes the data admissible for overall assessment of cancer risk.⁵

Moreover, the Science Advisory Panel questioned the EPA's use of data from control animals in other non-glyphosate cancer studies, instead of concurrently exposed animals and statistical techniques for adjusting for the potential for false positive results in studies examining multiple cancer sites.⁶

Further, an expert review of the rat studies by Dr. Christopher Portier, former associate director of the National Institute of Environmental Health Sciences and one of the world's leading specialists on glyphosate, revealed other notable tumors in three of the eight rat studies that were not examined in the EPA's cancer review.

⁴ California Office of Environmental Health Hazard Assessment. 2018. Amendment to Section 25705 No Significant Risk Level - Glyphosate April 10, 2018, Available at <https://oehha.ca.gov/proposition-65/crn/ amendment-section-25705-no-significant-risk-level-glyphosate-april-10-2018>

⁵ EPA Guidelines for Carcinogen Risk Assessment. 2005. EPA/630/P-03/001F.

⁶ EPA Science Advisory Panel. 2016. FIFRA SAP Meeting to Consider and Review Scientific Issues Associated with EPA's Evaluation of the Carcinogenic Potential of Glyphosate. December 13-16, 2016. Meeting transcript.



Table: Results from 8 laboratory studies on glyphosate carcinogenicity in rats

Sources: EPA 2017 Evaluation of Carcinogenic Potential⁷ and Christopher Portier 2017 review⁸

Study	Effect
Lankas (1981)	Testicular interstitial cell tumors Pancreas Islet Cell tumors* Thyroid C-Cell adenomas*
Pavkov and Wyand (1987)	No Tumors
Stout and Ruecker (1990)	Pancreatic tumors Hepatocellular adenoma and carcinomas Thyroid C-Cell adenomas and carcinomas Adrenal cortical carcinoma
Atkinson 1993	Thyroid Follicular adenoma and carcinoma Skin Keratoacanthoma
Suresh (1996)	No Tumors
Enemoto (1997)	Skin Keratoacanthoma Kidney adenoma* Basal cell carcinoma*
Brammer (2001)	Hepatocellular adenoma
Wood (2009)	Skin Keratocanthoma* Pituitary adenoma* Mammary Gland adenoma and carcinoma

* Cancer effect omitted by the EPA in its 2017 cancer review.

In addition, the EPA identified four studies of glyphosate exposure in mice that reported increased cancer rates. Jointly, the finding in rats and mice strengthen the overall body of evidence of glyphosate carcinogenicity.

It is essential for the EPA to include all evidence of cancer and pre-cancerous effects of glyphosate in its assessment. The Agency must review the original studies to ensure that authors have appropriately reported cancer incidence and severity. It should also explore new statistical techniques to pool cancer data and maximize statistical power for relatively rare effects in the cancer studies.

2. Epidemiological studies suggest potential risks to human health

EPA reviewed more than 20 human epidemiological studies of glyphosate, primarily focusing on rates of Non-Hodgkin lymphoma among agricultural workers. The International Agency for Research on Cancer concluded that the epidemiological studies point to a “limited evidence” of glyphosate carcinogenicity in people. Yet, the EPA stated that it could not reach a conclusion

⁷ EPA 2017 Revised Glyphosate Issue Paper: Evaluation of Carcinogenic Potential. DP Barcode: D444689.

⁸ Christopher J. Portier, 2017. Presentation: Glyphosate Cancer Risks and Failures of the Pesticide Regulatory Process. October 11, 2017.



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regarding the association between glyphosate and NHL based on existing data. After the EPA assessment, a very recent publication from the Agricultural Health Study reported an increase in acute myeloid leukemia in study participants who reported the most intense use of glyphosate.⁹

Studying glyphosate exposure in people is unusually challenging because of widespread use of this herbicide in non-agricultural settings. Glyphosate is extensively applied on residential lawns and gardens; used on public rights-of-way and other common areas at schools and parks; and sprayed by states and municipalities on roadside vegetation. It is also directly sprayed on food crops, including as a pre-harvest desiccant on grains and legumes, and genetically-engineered corn and soy. In fact, the Science Advisory Panel noted that EPA's worst case exposure estimates for 1-to-2 year old children were 10 times greater than its estimated exposures for glyphosate applicators in the Agricultural Health Study.¹⁰

Furthermore, glyphosate use exploded with the approval of genetically engineered corn and soy in 1996. Members of the EPA's Science Advisory Panel appropriately cautioned that due to the lag time between exposure to glyphosate and diagnosis with cancer, the human epidemiology studies published to date do not necessarily capture the period of greatest intensity of glyphosate exposure for American farmworkers.

Conclusion

EWG urges the EPA to follow its own internal guidelines when reviewing the evidence of increased cancer risks from human and animal studies. The Agency must fully review the raw data from animal studies instead of relying on author summaries. It must also consider ways to pool data across studies for cancers where authors report statistically significant trend tests.

The widespread exposure to glyphosate in food, and the use of glyphosate as a household, commercial and agricultural herbicide requires immediate action. EWG calls for the EPA to examine the residues of glyphosate on all crops treated with this herbicide; restrict unnecessary uses that lead to the most intense dietary exposures; and provide additional safety warnings for people who apply glyphosate in residential, commercial and agricultural settings.

Submitted on behalf of Environmental Working Group,

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⁹ Gabriella Andreotti, et al. 2017. Glyphosate Use and Cancer Incidence in the Agricultural Health Study, Journal of the National Cancer Institute, DOI: 10.1093/jnci/djx233

¹⁰ EPA Science Advisory Panel. 2016. FIFRA SAP Meeting to Consider and Review Scientific Issues Associated with EPA's Evaluation of the Carcinogenic Potential of Glyphosate. December 13-16, 2016. Meeting transcript.