

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Comments on Registration Review;
Draft Human Health and/or Ecological Risk Assessments for Several Pesticides –
GLYPHOSATE

Submitted via Regulations.gov

Docket IDs: No.: EPA-HQ-OPP-2017-0720; FRL-9973-07; Glyphosate
Case 0178; EPA-HQ-OPP-2009-0361; Chemical Review Manager and
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SafeMinds

SafeMinds gratefully submits comments to assist the United States Environmental Protection Agency (EPA) in identifying the appropriate scope of the risk evaluations to be conducted for GLYPHOSATE. Risk assessment review offers EPA an opportunity to protect vulnerable and chemically over-burdened populations of children in the United States¹ who are at greater risk than general populations from exposure to glyphosate.

Based on new science and based on the unintended consequences of current glyphosate use and practices, SafeMinds sees that glyphosate can no longer perform its intended function without unreasonable adverse effects on children's health.

Children are not little adults. They have a unique vulnerability and as such are more likely to suffer adverse health effects from glyphosate exposure. EPA must account for this in order to protect the most vulnerable among us.

Our scientific understanding of harm from glyphosate has advanced. Glyphosate must be prioritized for an EPA risk assessment review and revision that is protective of children. SafeMinds looks forward to EPA revising its risk assessment for glyphosate.

INTRODUCTION

Glyphosate, the active ingredient in Roundup, was originally developed and introduced to reduce reliance on herbicides causing well-documented risks to human health. Initial

¹ <https://www.ewg.org/research/body-burden-pollution-newborns#.WrTdWGrwblU>

industry toxicity studies showed glyphosate posed low risk to mammals. These papers are now widely considered outdated science.

Since first sold to farmers in 1974, the volume of glyphosate applied has increased roughly 100-fold and continues to rise. This increase is likely due to the unexpected appearance of pervasive glyphosate-resistant weeds which require ever-increasing applications of glyphosate for control.

Glyphosate is now the most heavily applied herbicide world-wide. Yet in the last decade, both epidemiology and animal studies show harm and the need for a solid review of glyphosate toxicity and human health².

UNINTENDED CONSEQUENCES OF GLYPHOSATE

'Low Risk' Findings Are No Longer Relevant Due to Ever-Increasing Use Patterns

As the volume of glyphosate needed to perform its original function increases globally, peer-reviewed studies have determined glyphosate is carcinogenic. It is widely accepted that every known human carcinogen also causes cancer in animals. And with few exceptions, when toxic chemicals harm animals, they almost always cause similar harm in human beings^{3,4}.

Though evidence in human beings is limited, evidence of harm in experimental animals is sufficient to put glyphosate solidly into group 2A classification - 'probable human carcinogen'. In 2015, the World Health Organization (WHO) determined glyphosate is a 'probable human carcinogen'^{5, 6}.

Industry vigorously objects to this classification of its product, and glyphosate continues to contaminate soil, drinking water, and air⁷ particularly near agriculture as pervasive glyphosate-resistant weeds make their appearance requiring additional applications of

2 <https://ehjournal.biomedcentral.com/articles/10.1186/s12940-016-0117-0>

3 http://www.pbs.org/tradesecrets/problem/child_more.html

4 <https://www.prb.org/childrensenvironmentalhealth/>

5 Bunge, J., Health Agency Says Widely Used Herbicide Likely Carcinogenic. Wall Street Journal. 2015. <http://www.wsj.com/articles/health-agency-says-widely-usedherbicide-likely-carcinogenic-1426885547> 82

6 American Cancer Society, Known and Probable Human Carcinogens. American Cancer Society. 2015. <http://www.cancer.org/cancer/cancercauses/othercarcinogens/generalinformationaboutcarcinogen>

s/known-and-probable-human-carcinogens

7 World Health Organisation (WHO), 1994. Glyphosate. Environmental Health Criteria 159. The International Programme on Chemical Safety (IPCS). WHO, Geneva.

the herbicide for control. The half-life in soil and water of glyphosate is longer than previously understood. Metabolites of the product have been found contaminating foods like soybeans world-wide⁸. As a result, human exposures are rising.

NEW SCIENCE ON GLYPHOSATE

Emerging science regarding the safety of glyphosate - its potential dietary risks of concern for children, its toxicity in laboratory animals and the outdated human safety standards at current use patterns - shows harm⁹ especially to children.

Genetic engineers John Fagan, PhD, Michael Antoniou, PhD, and Claire Robinson, MPhil point out, "*Roundup and other glyphosate herbicide formulations have never been tested or assessed for long-term safety for regulatory purposes. Only glyphosate alone was tested. Even the industry tests on glyphosate alone revealed toxic effects, including Malformations.*"^{10 11}

In the 2015 review article, *The Possible Link between Autism and Glyphosate*, researchers from MIT effectively argue the as of yet unexplained increase in Autism affecting children may be caused by a dietary sourced toxin acting intermittently on human fetuses and disrupting neurodevelopment.¹² Results suggest it is the combination of timing and dose which leads to "*haphazard disorganizations of the normally carefully choreographed steps of early neuronal migration.*"

Glyphosate is molecularly similar to glycine. It too has a known ardent tendency to bind with minerals implicated in the normal functioning of several neuronal calcium inflow regulatory factors. This study identified glyphosate as a "...*strong candidate for the putative harmful glycine mimetic*".¹³

In March 2018, results from the first study testing glyphosate exposure in pregnant women using urine specimens as a direct measure were published¹⁴. The study found

8 World Health Organization (WHO). Glyphosate. Environmental Health Criteria 159. The International Programme on Chemical Safety (IPCS). WHO, Geneva. 1994

9 <https://ehjournal.biomedcentral.com/articles/10.1186/s12940-016-0117-0>

10 Antoniou M, Habib MEM, Howard CV, et al. Teratogenic effects of glyphosate-based herbicides: Divergence of regulatory decisions from scientific evidence. J Env Anal Toxicol. 2012;S4:006. doi:10.4172/2161-0525.S4-006.

11 Fagan J PhD, Antoniou M PhD, Robinson C MPhil. GMO Myths and Truths 2nd Edition. Earth Open Source. 2014;4.1:205. <http://earthopensource.org/earth-open-sourcereports/gmo-myths-and-truths-2nd-edition/>

12 <https://www.omicsonline.org/open-access/the-possible-link-between-autism-and-glyphosate-acting-as-glycine-mimetic-a-review-of-evidence-from-the-literature-with-analysis-1747-0862-1000187.php?aid=64626>

13 Ibid

14 <https://ehjournal.biomedcentral.com/articles/10.1186/s12940-018-0367-0>

90 percent of pregnant women tested in Central Indiana had detectable levels of glyphosate, the active ingredient of the most heavily used herbicide in the world.

These new 2018 findings from pregnant women provide clear evidence of maternal glyphosate exposure. While the extent of risk to the fetus from glyphosate is unknown, we do know the brain and nervous system are especially vulnerable during fetal development. During this period the blood-brain barrier, which provides the brain protection from toxic substances, is not developed.^{15 16}

Every chemical known to cause brain damage in humans causes damage to the brain and nervous system in animals.

-Mt Sinai School of Medicine

We also know that when chemicals cause effects in multiple animal species, it is highly likely that human beings are also susceptible. Almost every known cause of birth defects in humans also causes birth defects in animals.¹⁷

These studies may provide results EPA needs for a strong review of current allowable limits on crops and in food of glyphosate, the putative harmful glycine mimetic.

GLYPHOSATE CAN NO LONGER PERFORM ITS INTENDED FUNCTION WITHOUT UNREASONABLE ADVERSE EFFECTS ON CHILDREN'S HEALTH

Children's Risk from Glyphosate Residues from Overuse

SafeMinds believes it is imperative for EPA to take regulatory action against the practice of widespread glyphosate usage on food crops for pregnant women and children. Human exposures to the most heavily used herbicide in the world are rising. Children are especially vulnerable to the effects of pesticides.^{18 19}

Exposures for children occur largely through touching, inhaling or ingesting. For each of these routes, children are much more likely than adults to absorb that with which they

15 Schafer, K. Marquez, E. 2012. A Generation in Jeopardy – How pesticides are undermining our children's health & intelligence. Pesticide Action Network North America

16 Schwenk, M., U. Gundert-Remy, G. Heinemeyer, K. Olejniczak, R. Stahlmann, W. Kaufmann, et al. "Children as a Sensitive Subgroup and Their Role in Regulatory Toxicology: DGPT Workshop Report." Archives of Toxicology. Jan 2003 77(1): 2-6. Louis et al. 2006, op. cit.

17 https://cfpub.epa.gov/si/si_public_record_report.cfm?dirEntryId=188070

18 <http://npic.orst.edu/health/child.html>

19 Schafer, K. Marquez, E. 2012. A Generation in Jeopardy – How pesticides are undermining our children's health & intelligence. Pesticide Action Network North America

come into contact. Pound for pound, children take in roughly 15 times more water and inhale more air than the average adult. This results in 15 times more exposure to glyphosate contamination than adults from water, and roughly doubles the dose of a pesticide exposure from air.^{20, 21}

Childrens' absorption levels in the gastrointestinal tract are also greater, as adult levels of gastric acid are not reached until about two years old.^{22, 23} There is general concern that the acceptable daily intake (ADI) set by the FAO/WHO's Codex Alimentarius Commission for an average 60 kg man does not take account the risks to children.

Widespread use, in accordance with today's commonly recognized practices, is increasing. Children have a unique physiological vulnerability. Based on current use patterns, human exposures are rising. We understand now even the fetus is exposed. And we know the toxic effects of glyphosate also include developmental and reproductive toxicity, birth defects, neurotoxicity, cancer, disruption of hormonal systems and beneficial gut bacteria, and damage to DNA.²⁴

As the volume of glyphosate needed to perform its original function increases, combined with current research showing potential harm to pregnant women and children, it is time for EPA to recognize glyphosate is failing to perform its intended function without unreasonable risk to children's health.

20 Miller, M.D., M.A. Marty, A. Arcus, J. Brown, D. Morry and M. Sandy. "Differences Between Children and Adults: Implications for Risk Assessment at California EPA." *International Journal of Toxicology*. October 2002 21(5): 403-418.

21 Schafer, K. Marquez, E. 2012. *A Generation in Jeopardy – How pesticides are undermining our children's health & intelligence*. Pesticide Action Network North America

22 Louis, G.B., United Nations Environment Programme, International Labour Organisation, World Health Organization, Inter-Organization Programme for the Sound Management of Chemicals, and International Program on Chemical Safety. "Principles for evaluating health risks in children associated with exposure to chemicals." 2006. <http://site.ebrary.com/id/10214527>.

23 Schafer, K. Marquez, E. 2012. *A Generation in Jeopardy – How pesticides are undermining our children's health & intelligence*. Pesticide Action Network North America

24 Fagan J PhD, Antoniou M PhD, Robinson C MPhil. *GMO Myths and Truths 2nd Edition*. Earth Open Source. 2014:4.1:205. <http://earthopensource.org/earth-open-sourcereports/gmo-myths-and-truths-2nd-edition/>