



# BEYOND PESTICIDES

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Office of Pesticide Programs  
Environmental Protection Agency  
Docket Center (EPA/DC), (28221T)  
1200 Pennsylvania Ave. NW  
Washington, DC 20460-0001

**Re: Glyphosate Proposed Interim Registration Review Decision. Docket Number EPA-HQ-OPP-2009-0361**

Please accept these comments in response to the U.S. Environmental Protection Agency's (EPA) publication of a proposed Interim Registration Eligibility Decisions for Glyphosate. As of 2014, more than 280 million pounds of glyphosate are estimated to be used annually in the U.S., on over 100 crops and non-agricultural use sites.<sup>1</sup> Glyphosate formulated end-use products are applied to range of different areas within the US, encompassing many residential, business, and agricultural settings. Genetically engineered (GE) crops, developed specifically to be tolerant of glyphosate, have increased glyphosate use. Perry et al. (2016) finds that growers of glyphosate-tolerant soybeans apply 28% more glyphosate than non-GE soybean growers, with use increasing as glyphosate resistance develops in weeds.<sup>2</sup>

EPA's proposed Interim Registration Eligibility Decision for Glyphosate reiterates the agency's view that current glyphosate use does not exceed levels of concern (LOCs) for human health, though potential risks remain for mammals, birds, and terrestrial and aquatic plants subject to non-target drift.<sup>3</sup> As outlined, the agency's suggested mitigation measures simply tweak the labels of glyphosate products,<sup>4</sup> requiring no major restrictions on glyphosate use. As the science on the dangers of this pesticide continues to accumulate, without significant changes in the final decision by the agency, history will remember this proposal as a failure to protect the public and the wider environment from toxic exposure to glyphosate and glyphosate-based herbicides.

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<sup>1</sup> USEPA. 2017. Revised Glyphosate Issue Paper: Evaluation of Carcinogenic Potential. Office of Pesticide Programs. Washington DC.

<sup>2</sup> Perry, Edward D. et al. 2016. Genetically Engineered crops and pesticide use in US maize and soybeans. Science Advances. Vol. 2, no. 8, e1600850 DOI: 10.1126/sciadv.1600850

<sup>3</sup> USEPA. 2019. Proposed Interim Registration Eligibility Decisions for Glyphosate. Office of Pesticide Programs. Washington DC.

<sup>4</sup> USEPA. 2019. Proposed Interim Registration Eligibility Decisions for Glyphosate. Office of Pesticide Programs. Washington DC.

Controversy surrounding continued use of the glyphosate has made news headlines for several years. The World Health Organization's International Agency for Research on Cancer (IARC) finds there is *sufficient evidence of carcinogenicity* in experimental organisms to classify glyphosate as "probably carcinogenic to humans." The primary registrant, Bayer (which has now acquired Monsanto), is currently faced with costs of billions of dollars resulting from litigation by claimants who believe their cancers were caused by exposure to glyphosate-based herbicides.<sup>5</sup> So far, the courts have found in favor of plaintiffs, resulting in awards of over \$2 billion in damages to affected individuals.<sup>6</sup> During the course of these lawsuits, it was established that individuals within EPA's Office of Pesticide Programs worked surreptitiously to "kill" an investigation of glyphosate by the US Department of Health and Human Services (DHHS) Agency for Toxic Substances and Disease Registry (ATSDR).<sup>7</sup> This is a relevant consideration to the ongoing review of glyphosate as it impacts the level of trust the public has in the agency's decision-making process.

### **The Need for Full-Formulation Testing**

FIFRA dictates that in order to be registered, pesticide products as they are commonly applied in the field must be shown not to cause unreasonable adverse effects on the environment and public health. Thus, the body of evidence concerning impacts of glyphosate-based herbicides, which includes impacts of so-called "inert" ingredients, adjuvants, and the complete formulation, is relevant to registration decisions.

The active ingredient glyphosate co-occurs with the other chemicals used in glyphosate-based herbicide formulations and prescribed tank mixes, including adjuvants and surfactants with demonstrated toxicity to humans and non-target organisms, as well as co-contaminants such as nitrosamines, which EPA indicates may occur in nearly 1 in 10 technical glyphosate samples at levels at which the agency would require review.<sup>8</sup> In addition to possessing their own toxic effects, these multiple chemicals influence the mobility, stability, environmental fate, exposure potential, and toxicity of glyphosate as it is commonly applied.

A 2003 study found that the surfactant polyethoxylated tallowamine (POEA) accounted for more than 86% of the glyphosate-based herbicide Roundup's toxicity to bacteria,

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<sup>5</sup> Horowitz, Julia. Roundup cancer cases could cost Germany's Bayer Billions. CNN Business. <https://www.cnn.com/2019/04/30/business/bayer-monsanto-roundup-shareholders/index.html>

<sup>6</sup> Burger, Ludwig. 2019. Bayer nears seven-year low after \$2 billion award in Roundup trial. Reuters. <https://www.reuters.com/article/us-bayer-glyphosate-lawsuit-stocks/bayer-nears-seven-year-low-after-2-billion-award-in-roundup-trial-idUSKCN1SK0LQ>

<sup>7</sup> BaumHedlundLaw, 2017. Email communications between Dan Jenkins and Williams Heydens. <https://www.baumhedlundlaw.com/pdf/monsanto-documents/Email-Correspondence-Where-Jess-Rowland-Reportedly-Said-If-I-can-kill-this-I-should-get-a-medal.pdf>

<sup>8</sup> USEPA, 2019. Glyphosate: Response to Comments on the Human Health Draft Risk Assessment. Office of Pesticide Programs. Washington DC.

microalgae, protozoa and crustaceans.<sup>9</sup> The European Food Safety Authority (EFSA) notes POEA “has been shown to be more toxic than the active substance glyphosate on several toxicological endpoints, namely acute, short term, reproductive and developmental toxicity, further to equivocal evidence of DNA damage in vitro at high doses.”<sup>10</sup> According to EFSA, a number of published studies performed with glyphosate-based formulations of unknown composition gave positive results for genotoxicity when tested *in vitro* and *in vivo*, concluding “the toxicity of formulations and in particular their genotoxic potential should be further considered and addressed,” suggesting that “the genotoxicity, long term toxicity/carcinogenicity, reproductive/developmental toxicity and endocrine disrupting potential of this co-formulant [POEA] should be clarified before setting health-based reference values and conducting the risk assessment.”<sup>11</sup>

Similarly, a 2013 study found that the Roundup adjuvants POE-15 and Genamin, by themselves, are 9,661 times more toxic to human cells than the active ingredient glyphosate.<sup>12</sup> POE-15 levels as low as 1 to 3 ppm caused toxic effects on cellular respiration and membrane integrity. In order to fulfill its federal mandate to protect public health and the environment, EPA must evaluate whole glyphosate-based herbicide formulations and commonly applied tank mixtures, including adjuvants, surfactants, and all other additives.

In response to comments, EPA indicated “...there are tens of thousands of different registered pesticide products available in the marketplace and, though the Agency evaluates the product components, long term testing of individual products is not required.”<sup>13</sup> While the law may not require registrants to perform complete testing of formulated products, the agency must take into account published literature. This is a time when public trust in the agency is being questioned, in part due to documents released in court in which White House officials reportedly said, “We have Monsanto’s back on pesticides regulation. We are prepared to go toe-to-toe on any disputes they may have with, for example, the EU. Monsanto need not fear any additional regulation from this administration.”<sup>14</sup> Thus, with public distrust focused specifically on glyphosate and its many formulations, we urge the agency to employ due diligence and complete a full evaluation of all glyphosate-containing pesticide products

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<sup>9</sup> Tsui, M.T. and Chu, L.M., 2003. Aquatic toxicity of glyphosate-based formulations: comparison between different organisms and the effects of environmental factors. *Chemosphere*, 52(7), pp.1189-1197.

<sup>10</sup> EFSA. EFSA explains the carcinogenicity assessment of glyphosate. 12 November 2015. [https://www.efsa.europa.eu/sites/default/files/4302\\_glyphosate\\_complementary.pdf](https://www.efsa.europa.eu/sites/default/files/4302_glyphosate_complementary.pdf).

<sup>11</sup> EFSA. EFSA explains the carcinogenicity assessment of glyphosate. 12 November 2015. [https://www.efsa.europa.eu/sites/default/files/4302\\_glyphosate\\_complementary.pdf](https://www.efsa.europa.eu/sites/default/files/4302_glyphosate_complementary.pdf).

<sup>12</sup> Mesnage, R., Clair, E., Gress, S., Then, C., Székács, A. and Séralini, G.E., 2013. Cytotoxicity on human cells of Cry1Ab and Cry1Ac Bt insecticidal toxins alone or with a glyphosate-based herbicide. *Journal of Applied Toxicology*, 33(7), pp.695-699.

<sup>13</sup> USEPA. 2019. Glyphosate: Response to Comments on the Human Health Draft Risk Assessment. Office of Pesticide Programs. Washington DC.

<sup>14</sup> USRTK. 2019. White House Has “Monsanto’s Back on Pesticides,” Newly Revealed Document Says. <https://usrtk.org/monsanto-roundup-trial-tacker/white-house-has-monsantos-back-on-pesticides-newly-revealed-document-says/>.

registered by EPA. While EPA collaboration with the National Toxicology Program (NTP) in this endeavor is encouraging, we urge the agency to suspend registration of any end-use product that has not yet undergone this additional evaluation.<sup>15</sup>

### Glyphosate and Cancer

EPA reevaluated the human carcinogenic potential of glyphosate, including genotoxicity, epidemiological, metabolism, and mechanistic studies. To assist its review, the agency convened a Scientific Advisory Panel (SAP) meeting to review the available data. EPA's review concludes that glyphosate is "not likely to be carcinogenic to humans." In response to comments, EPA indicates that, "none of the panel members believed glyphosate should be classified as 'likely to be carcinogenic to humans' or 'carcinogenic to humans.'"<sup>16</sup> However, the SAP did not reach a consensus on the recommendations provided, including the interpretation of animal data and EPA's exclusion of certain data. And further, some panel members expressed the need for additional descriptors to the classification, and some even suggested the classification be "suggestive evidence of carcinogenic potential." EPA reports that for studies that show an association between glyphosate and cancer (non-Hodgkin's lymphoma (NHL)), it cannot exclude bias or chance as an explanation for the observed association, and that it cannot determine, based on the available epidemiological data reviewed, a conclusion regarding the observed associations.<sup>17</sup> For other cancer types, the agency states no associations were found.

Only a few months before EPA's response to comments was published, a meta-analysis of every available published human study on NHL and glyphosate, including the most recently updated data from the ongoing U.S. Agricultural Health Study (AHS), was published by Zhang et al. (2019). Statistical analysis revealed there to be a 41% increased risk of NHL resulting from high exposure to glyphosate-based herbicides.<sup>18</sup>

While EPA nonetheless maintains some uncertainty when it comes to the carcinogenic potential of glyphosate, there have been differing conclusions among various agencies. Although ATSDR makes no definitive conclusion, the draft glyphosate review by the agency cites several meta-analyses which "reported positive associations between glyphosate use and selected lymphohematopoietic cancers."<sup>19</sup> While there are some similarities between EPA's

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<sup>15</sup> USEPA, 2016. Glyphosate Issue Paper: Evaluation of Carcinogenic Potential. Office of Pesticide Programs. Washington DC.

<sup>16</sup> USEPA. 2019. Glyphosate: Response to Comments on the Human Health Draft Risk Assessment. Office of Pesticide Programs. Washington DC.

<sup>17</sup> USEPA. 2017. Revised Glyphosate Issue Paper: Evaluation of Carcinogenic Potential. Office of Pesticide Programs. Washington DC.

<sup>18</sup> Zhang et al. 2019. Exposure to Glyphosate-Based Herbicides and Risk for Non-Hodgkin Lymphoma: A Meta-Analysis and Supporting Evidence. Mutation Research/Reviews in Mutation.  
<https://doi.org/10.1016/j.mrrev.2019.02.001>

<sup>19</sup> USDHHS ATSDR. 2019. Toxicological Profile for Glyphosate. Washington DC.  
<https://www.atsdr.cdc.gov/toxprofiles/tp214.pdf>

and the World Health Organization's International Agency for Research on Cancer's (IARC) findings concerning NHL, IARC's analysis went a step further to review formulated glyphosate products and the metabolite, AMPA, which are more relevant to human health risks than the active ingredient alone.

EPA provided the opinion in response to comments that its process for evaluating glyphosate, "is more transparent than IARC's process."<sup>20</sup> However, IARC, subject to attacks from both national regulatory agencies and multinational pesticide corporations, has responded to these specific claims.<sup>21</sup> While EPA notes the importance of public participation in its process, IARC indicates that "[d]raft and deliberative materials are not made public, in order to protect the Working Group scientists from interference by vested interests... consistent with standard practice in scientific committees." It is further noted that this is in line with the approach taken by the U.S. National Research Council, which keeps reviews confidential to, "protect the integrity of the deliberative process." IARC notes that its meetings are open to scientific stakeholders, and that individuals from both Monsanto and EPA attended the meeting on glyphosate.<sup>22</sup>

EPA further notes that it considered more studies than IARC. IARC responds, that because its review is limited to studies in the public domain, this practice, "specifically excludes studies conducted by industry when these are publicly unavailable."<sup>23</sup> However, industry studies that are published in scientific journals are considered by IARC, and the agency points to existing and developing policies on the international stage that are beginning to require industry-published studies be publicly accessible. Although EPA indicates these studies are available via the Freedom of Information Act (FOIA), manufacturers are reserved the right to significantly redact or refuse disclosure of this data, as often occurs. Further, EPA does not permit this information to be obtained through FOIA until a pesticide is already registered, making it impossible for the public to obtain potentially important health end-point information until after pesticide exposure could occur. IARC notes that it "follows its current practice in order to enable others to scrutinize the basis of its decisions rather than relying on appeals to authority or trust." IARC research on cancer is still seen as a highly credible source of cancer information, and the agency stands by its findings on glyphosate.<sup>24</sup>

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<sup>20</sup> USEPA. 2019. Glyphosate: Response to Comments on the Human Health Draft Risk Assessment. Office of Pesticide Programs. Washington DC.

<sup>21</sup> IARC Director. 2018. IARC Response to Criticisms of the Monographs and the Glyphosate Evaluation. [https://www.iarc.fr/wp-content/uploads/2018/07/IARC\\_response\\_to\\_criticisms\\_of\\_the\\_Monographs\\_and\\_the\\_glyphosate\\_evaluation.pdf](https://www.iarc.fr/wp-content/uploads/2018/07/IARC_response_to_criticisms_of_the_Monographs_and_the_glyphosate_evaluation.pdf)

<sup>22</sup> Ibid.

<sup>23</sup> Ibid.

<sup>24</sup> Ibid.

EPA notes of IARC that, “conclusions are not well described.”<sup>25</sup> IARC’s conclusion that “there is sufficient evidence of carcinogenicity in experimental animals,” was based on findings that glyphosate caused DNA and chromosomal damage in human cells, and that glyphosate, glyphosate formulations, and AMPA induced oxidative stress in rodents and in vitro which EPA minimizes.<sup>26</sup> Studies IARC reviewed find statistically significant association between glyphosate exposure with certain cancers and found the risk increased with increased exposure. IARC considers that glyphosate induced a positive trend in the incidence of a rare tumor, renal tubule carcinoma in male CD-1 mice, which EPA concludes is not compound-related. A positive trend for hemangiosarcoma, identified by IARC, was deemed not statistically significant by EPA. The agency also finds that incidences of (pancreatic) adenomas were not statistically significant.

It is important to highlight here that IARC’s analysis is a hazard identification, not a risk assessment, as EPA’s assessments are. IARC notes that its evaluation results in a classification based on “the strength of evidence that an agent causes cancer or not,” i.e., how confident it is that this agent causes cancer in humans, not its potency. This includes “consideration of the level of exposure (dose) associated with the risk of developing cancer (response) and strong dose-response relationships.” Thus, EPA’s attacks on IARC as if it were conducting a review similar to EPA’s risk assessment are not helpful or informative, and only act to degrade important public debate and public trust in the agency.

### Other Cancer Findings

EPA states that its cancer findings for glyphosate are in keeping with conclusions from other agencies including EFSA and the Joint Food and Agriculture Organization (FAO)/WHO Meeting on Pesticide Residues (JMPR). However, the reports of these agencies have been criticized by independent scientists, who have identified several shortcomings of these analyses, including undue industry influence. Following EFSA’s report, a group of over 90 scientists critiqued EFSA’s findings in a letter highlighting several concerns, stating, “almost no weight is given to studies from the published literature and there is an over-reliance on non-publicly available industry-provided studies using a limited set of assays that define the minimum data necessary for the marketing of a pesticide,” along with redacted citations, and other transparency issues.<sup>27</sup> These scientists agree that in EFSA’s report, “Serious flaws in the scientific evaluation...incorrectly characterise the potential for a carcinogenic hazard from exposure to glyphosate.” It is also widely reported that EFSA included dozens of pages from a Monsanto study in reaching its conclusion that glyphosate is “unlikely to pose a carcinogenic

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<sup>25</sup> USEPA. 2019. Glyphosate: Response to Comments on the Human Health Draft Risk Assessment. Office of Pesticide Programs. Washington DC.

<sup>26</sup> IARC. IARC Monographs Volume 112: evaluation of five organophosphate insecticides and herbicides. 20 march 2015. <http://www.iarc.fr/en/media-centre/iarcnews/pdf/MonographVolume112.pdf>.

<sup>27</sup> Portier, C, Armstrong, B, Baguley, B et al. 2015. Commentary: Differences in the carcinogenic evaluation of glyphosate between the International Agency for Research on Cancer (IARC) and the European Food Safety Authority (EFSA). *J Epidemiol Community Health* doi:10.1136/jech-2015-207005.

hazard to humans,”<sup>28</sup> calling into question the integrity of its findings, and causing the European parliament to take action against Monsanto’s influence in its decision-making process.<sup>29</sup>

#### Disparity in the Consideration of Glyphosate Formulations

As mentioned above, glyphosate is never used alone in any pesticide product, but always formulated with “other” or “inert” ingredients. It is notable that in EPA’s ecological assessment for glyphosate the agency spent considerable time highlighting the differences in toxicity to non-target organisms between glyphosate and its formulated products, including those containing POEA. Formulated glyphosate products have been determined by the agency as being more toxic than the active ingredient alone. EPA states, “the ecological effects of the pesticide-surfactant combination may differ from that of the single pesticide or the single surfactant,” and that, “One class of surfactants used in glyphosate formulations are the polyethoxylated tallow amines (POEA) and this class has been shown to be more toxic to aquatic animals than glyphosate alone.” In evaluating the potential risk to non-target organisms, the agency states it estimated exposure risks from (1) glyphosate only, (2) glyphosate formulations, and (3) surfactant only (POEA).

However, this same due diligence was not afforded to the human health assessment – even though formulated glyphosate products are known to be more toxic to human cells than glyphosate. In its response to comments, EPA indicates that none of the studies reviewed in open literature by the agency met EPA standards for inclusion in the human health risk assessment,<sup>30</sup> although, as noted earlier, there is significant public attention on glyphosate formulations, including a number of high profile lawsuits. It is therefore imperative that, in order to maintain public trust, EPA in this instance go beyond what it is only statutorily required of the agency as part of a typical pesticide review. We urge EPA to request from registrants additional human health studies on formulated products. This data gap must be filled before EPA can state to the public that glyphosate uses do not exceed levels of concern.

#### Endocrine Disruption and Other Human Health Concerns

Evidence shows glyphosate and glyphosate-based herbicides to reported endocrine-mediated effects on endpoints relevant to toxicity.<sup>31</sup> One study reports that among laboratory animals exposed to glyphosate products, there were decreased concentrations of thyroid stimulating hormone, concluding that glyphosate herbicides could disrupt the hypothalamic-

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<sup>28</sup> Neslen, Arthur (2017, September 14) EU report on weedkiller safety copied text from Monsanto study. The Guardian <https://www.theguardian.com/environment/2017/sep/15/eu-report-on-weedkiller-safety-copied-text-from-monsanto-study>.

<sup>29</sup> Neslen, Arthur (2017, September 28) Monsanto banned from European parliament. The Guardian <https://www.theguardian.com/environment/2017/sep/28/monsanto-banned-from-european-parliament>.

<sup>30</sup> USEPA. 2019. Glyphosate: Response to Comments on the Human Health Draft Risk Assessment. Office of Pesticide Programs. Washington DC.

<sup>31</sup> Gasnier C, Dumont C, Benachour N, et al. 2009. Glyphosate-based herbicides are toxic and endocrine disruptors in human cell lines. Toxicology. 262:184–91.

pituitary-thyroid (HPT) axis, which should be a parameter considered in populations exposed.<sup>32</sup> Another finds that the co-formulants in glyphosate products “act as endocrine-disrupting chemicals at levels up to several hundred times below the level at which the declared active ingredient demonstrates the same activity.”<sup>33</sup> In a study by Richard et al. (2005), glyphosate-based herbicide formulations, but not glyphosate alone, were found to interfere with the normal process of conversion of androgens into estrogens by inhibiting the activity of the enzyme aromatase in human placental cells.<sup>34</sup> Adding to these findings on endocrine disrupting effects of glyphosate-based herbicides, Walsh et al. (2000) reported that glyphosate formulations, but not glyphosate alone, inhibited the production of progesterone in mouse Leydig cells.<sup>35</sup> Increases in aromatase mRNA levels and abnormal sperm morphology have also been reported.<sup>36</sup>

Glyphosate has also been linked to shorter gestational periods in pregnant women,<sup>37</sup> and Mesnage et al. (2015) find that chronic, ultra-low dose exposure to glyphosate in drinking water results in adverse impacts on the health of liver and kidneys, including increased cellular growth that may be linked with regeneration as a result of toxic effects causing damage to tissues.<sup>38</sup> Research by Mills et al. (2019) finds that glyphosate residue in urine were significantly higher in individuals with non-alcoholic fatty liver disease (NAFLD), a condition that causes swelling of the liver, and can eventually lead to cirrhosis, cancer, or liver failure.<sup>39</sup> These findings come as glyphosate is being detected in a wide range of food,<sup>40,41</sup> indicating increasing human exposures at levels above those associated with organ damage (above 0.1 ppb).<sup>42</sup>

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<sup>32</sup> de Souza JS, Kizys MM, da Conceição RR, et al. 2017. Perinatal exposure to glyphosate-based herbicide alters the thyrotrophic axis and causes thyroid hormone homeostasis imbalance in male rats. *Toxicology*. ;377:25-37.

<sup>33</sup> Defarge N, Takács E, Lozano VL, Mesnage R, et al. 2016. Co-Formulants in Glyphosate-Based Herbicides Disrupt Aromatase Activity in Human Cells below Toxic Levels. *Int J Environ Res Public Health*. 13(3). pii: E264.

<sup>34</sup> Richard, S., Moslemi, S., Sipahutar, H., Benachour, N. and Seralini, G.E., 2005. Differential effects of glyphosate and roundup on human placental cells and aromatase. *Environmental health perspectives*, 113(6), pp.716-720.

<sup>35</sup> Walsh LP, McCormick C, Martin C, Stocco DM. 2000. Roundup inhibits steroidogenesis by disrupting steroidogenic acute regulatory (StAR) protein expression. *Environ Health Perspect* 108:769–776.

<sup>36</sup> Cassault-Meyer E, Gress S, Seralini GÉ, Galeraud-Denis I. 2014. An acute exposure to glyphosate-based herbicide alters aromatase levels in testis and sperm nuclear quality. *Environ Toxicol Pharmacol*. ;38(1):131-40.

<sup>37</sup> Parvez S, Gerona RR, Proctor C, et al. 2018. Glyphosate exposure in pregnancy and shortened gestational length: a prospective Indiana birth cohort study. *Environ Health*. ;17(1):23.

<sup>38</sup> Mesnage, R, Arno, M, Contanzo, M, et al. 2015. Transcriptome profile analysis reflects rat liver and kidney damage following chronic ultra-low dose Roundup exposure. *Environmental Health*. 14:70.

<sup>39</sup> Mills, Paul J, et al. 2019. Glyphosate Excretion is Associated With Steatohepatitis and Advanced Liver Fibrosis in Patients With Fatty Liver Disease. *Clinical Gastroenterology and Hepatology*  
*Clinical Gastroenterology and Hepatology*. <https://doi.org/10.1016/j.cgh.2019.03.045>

<sup>40</sup> Damian Carrington. 2014. Over 60% of breads sold in the UK contain pesticide residues, tests show <https://www.theguardian.com/environment/2014/jul/17/pesticide-residue-breads-uk-crops>.

<sup>41</sup> Food Democracy Now! And The Detox Project. Glyphosate: Unsafe on Any Plate: Food Testing Results and Scientific Reasons for Concern.

[https://s3.amazonaws.com/media.fooddemocracynow.org/images/FDN\\_Glyphosate\\_FoodTesting\\_Report\\_p2016.pdf](https://s3.amazonaws.com/media.fooddemocracynow.org/images/FDN_Glyphosate_FoodTesting_Report_p2016.pdf)

<sup>42</sup> Ibid



### Impacts on Microbiota

Glyphosate works by disrupting the shikimate pathway for manufacturing aromatic amino acids in plants –but not animals— and, therefore, many have assumed that it does not harm humans. However, many bacteria use the shikimate pathway, and glyphosate has been patented as an antibiotic.<sup>43</sup> While EPA in its response claims that the chemical, “has not been demonstrated to be an effective antimicrobial for treating humans,”<sup>44</sup> the ineffectiveness of the chemical as a human antibiotic medication and glyphosate’s inherent antibiotic properties are separate concerns. Glyphosate appears to be detrimental to beneficial bacteria, allowing pathogens to flourish.<sup>45,46</sup> Mao et al. (2018) found rat dams and pups chronically exposed to levels of glyphosate corresponding with human acceptable daily intake of commercially available glyphosate-based herbicides altered gut bacterial composition.<sup>47</sup> EPA indicates that although gut microbiomes are not evaluated directly, the stomach and gastrointestinal tract are examined in several studies without any indication of adverse effects.<sup>48</sup> However, as referenced in ATSDR’s draft review of glyphosate, a 1991, two-year study of rats exposed to glyphosate via diet found inflammation of the gastric squamous mucosa, revealing a potential adverse effect.<sup>49</sup> Moreover, while direct impacts to the gut may be an effect of a disrupted microbiome, it is a gross oversimplification to conclude that the direct effects are the only health endpoints that may be affected. The destruction of bacteria in the human gut can potentially be a major contributor to a host of modern diseases including diabetes, obesity, food allergies, heart disease, antibiotic-resistant infections, cancer, asthma, autism, irritable bowel syndrome, multiple sclerosis, rheumatoid arthritis, celiac disease, inflammatory bowel disease, and

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<sup>43</sup> U.S. Patent number US7771736 B2. Glyphosate formulations and their use for the inhibition of 5-enolpyruvylshikimate-3-phosphate synthase. <https://www.google.com/patents/US7771736>.

<sup>44</sup> USEPA. 2019. Glyphosate: Response to Comments on the Human Health Draft Risk Assessment. Office of Pesticide Programs. Washington DC.

<sup>45</sup> Shehata AA, Schrödl W, Aldin AA, Hafez HM, Krüger M. 2013. The effect of glyphosate on potential pathogens and beneficial members of poultry microbiota in vitro. *Curr Microbiol* 66(4):350-8. Krüger, M., Shehata, A.A., Schrödl, W. and Rodloff, A., 2013. Glyphosate suppresses the antagonistic effect of *Enterococcus* spp. on *Clostridium botulinum*. *Anaerobe*, 20, pp.74-78. Schrödl, W., Krüger, S., Konstantinova-Müller, T., Shehata, A.A., Rulff, R. and Krüger, M., 2014. Possible effects of glyphosate on Mucorales abundance in the rumen of dairy cows in Germany. *Current microbiology*, 69(6), pp.817-823.

<sup>46</sup> Shehata AA, Schrödl W, Aldin AA, Hafez HM, Krüger M. 2013. The effect of glyphosate on potential pathogens and beneficial members of poultry microbiota in vitro. *Curr Microbiol* 66(4):350-8.

<sup>47</sup> Mao et al. 2018. The Ramazzini Institute 13-week pilot study on glyphosate and Roundup administered at human-equivalent dose to Sprague Dawley rats: effects on the microbiome. *Environmental Health*. 17: 50. doi: [10.1186/s12940-018-0394-x](https://doi.org/10.1186/s12940-018-0394-x)

<sup>48</sup> USEPA. 2019. Glyphosate: Response to Comments on the Human Health Draft Risk Assessment. Office of Pesticide Programs. Washington DC.

<sup>49</sup> US Department of Health and Human Services. 2019. Toxicological Profile for Glyphosate. <https://www.atsdr.cdc.gov/toxprofiles/tp214-c2.pdf>

more.<sup>50</sup> Many are beginning to believe the rise in these same diseases is correlated with the use of glyphosate, and that glyphosate exposure can result in the inflammation that is at the root of these diseases.<sup>51</sup>

### Ecological Assessment

Overall, EPA believes LOCs are not exceeded for non-target organisms in its ecological assessment for glyphosate and formulated products. EPA says that survival and biomass of aquatic vegetation may be impacted, and that there was some uncertainty in glyphosate's toxicity to honey bees at higher application rates, although EPA states available data suggests glyphosate has low toxicity to honey bees. EPA has proposed new label statements that glyphosate "may adversely impact the forage and habitat of non-target organisms," encouraging what is already required, "following label directions intended to minimize spray drift."<sup>52</sup>

As EPA indicates, further investigation in regards to pollinator impacts are warranted. One study reports simultaneous exposure to glyphosate and neonicotinoids have adverse effects on honey bee feeding behavior.<sup>53</sup> Motta et al (2018) found that glyphosate interferes with specialized gut bacteria within honey bees, altering their microbiome, and increasing mortality among younger exposed worker bees.<sup>54</sup> Balbuena et al (2015) found that forager honeybees exposed to sublethal concentrations of glyphosate experienced impaired navigation and less direct homing flights.<sup>55</sup> In the absence of a complete data set on pollinators, at a time when pollinators are declining rapidly in the United States, it behooves the agency to add more than an advisory statement requiring applicators to do what is already required of them. Since label instructions are not protecting pollinators, the agency should suspend any products that do not have full data sets showing glyphosate does not have an impact on pollinators.

The agency believes that glyphosate formulations, especially those containing POEA, are more toxic to aquatic organisms, including amphibians, than glyphosate alone. But while the agency is seemingly unconcerned about these impacts –as they note POEA is not used in products to be directly applied to waters, these formulated products can still make their way to

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<sup>50</sup> Littman, D.R. and Pamer, E.G., 2011. Role of the commensal microbiota in normal and pathogenic host immune responses. *Cell host & microbe*, 10(4), pp.311-323.

<sup>51</sup> Swanson, N.L., Leu, A., Abrahamson, J. and Wallet, B., 2014. Genetically engineered crops, glyphosate and the deterioration of health in the United States of America. *Journal of Organic Systems*, 9(2), pp.6-37.

<sup>52</sup> USEPA. 2019. Proposed Interim Registration Eligibility Decisions for Glyphosate. Office of Pesticide Programs. Washington DC.

<sup>53</sup> Mengoni Goñalons C, Farina WM. 2018. Impaired associative learning after chronic exposure to pesticides in young adult honey bees. *J Exp Biol*. 221(Pt 7). pii: jeb176644.

<sup>54</sup> Motta et al. 2018. Glyphosate perturbs the gut microbiota of honey bees. *PNAS*. 115 (41) 10305-10310; <https://doi.org/10.1073/pnas.1803880115>

<sup>55</sup> Balbuena, Maria S. et al. 2015. Effects of sublethal doses of glyphosate on honeybee navigation. *The Journal of Experimental Biology*. 18, 2799-2805 doi: 10.1242/jeb.117291 <https://www.boerenlandvogels.nl/sites/default/files/Effects%20of%20Glyphosate%20on%20Honey%20Bee%20Navigation.pdf>

waterways via drift and runoff. Glyphosate is ubiquitous in surface waters. U.S. Geological Survey (USGS) reports find glyphosate contamination continuing from spring through to fall – when many presumed it would have already degraded.<sup>56</sup> Glyphosate and AMPA are more frequently detected in surface water rather than groundwater.<sup>57</sup> In addition to surface waters, glyphosate has also been detected in significant levels in rain in agricultural areas across the Mississippi River watershed. It is also detected in more than 50 percent of soil and sediment samples, as well as in water samples from ditches and drains. AMPA was detected in more than 80 percent of wastewater treatment plant samples.<sup>58</sup> EPA indicates in its response to comments that glyphosate “does have the potential to contaminate surface water from spray drift or transport of residues adsorbed to soil particles suspended in runoff.”<sup>59</sup> The agency in its proposed Interim Registration Eligibility Decision for Glyphosate outlines a range of label changes that address when and how a pesticide may be sprayed, in order to avoid drift. However, these measures fall short, and the agency, at a minimum, must put in place meaningful measures to mitigate surface run-off, such as requiring a buffer of vegetation between the treatment area and the edge of a water body.

Impacts to soil and soil microorganisms were not covered in this assessment. However, studies suggest that residual persistence of glyphosate in soils after long-term, intensive use (as a result of GE cultivation), leads to impacts on soil and environmental health. Gaupp-Berghausen (2015) found that glyphosate-based herbicides significantly affected both surface-dwelling and vertically burrowing earthworms. Surface dwelling worms experienced 56% reduced reproduction over three months, while vertically burrowing earthworms ceased surface casting activities within three weeks after glyphosate-based herbicides were applied. This study also found higher levels of nitrate and phosphorus in glyphosate-exposed soils, indicating a potential secondary effect not currently considered by the agency.<sup>60</sup>

According to Kremer (2017), glyphosate’s presence in soil can lead to numerous adverse effects including, “altered respiration in some eukaryotic organisms due to disruption of cytochrome function; immobilization of nutrients essential for metabolic processes in microorganisms and plants; disruption of microbial diversity in plant rhizospheres; inhibition of mycorrhizal spore germination leading to poor host plant infection and establishment of the

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<sup>56</sup> Scribner, E. A., Battaglin, W. A., Dietze, J. E., & Thurman, E. M. 2003. Reconnaissance Data for Glyphosate, Other Selected Herbicides, Their Degradation Products, and Anions in 51 Streams in Nine Midwestern States, 2002 U.S. Geological Survey, Open-File Report 03–217(101 p).

<sup>57</sup> Scribner, E. A., Battaglin, W. A., Gilliom, R. J., & Meyer, M. T. 2007. Concentrations of Glyphosate, Its Degradation Product, Aminomethylphosphonic Acid, and Glufosinate in Ground- and Surface-Water, Rainfall, and Soil Samples Collected in the United States, 2001-06. *US Geological Survey, Scientific Investigations Report 2007-5122(111p).*

<sup>58</sup> USGS. Common Weed Killer is Widespread in the Environment. [https://toxics.usgs.gov/highlights/2014-04-23-glyphosate\\_2014.html](https://toxics.usgs.gov/highlights/2014-04-23-glyphosate_2014.html)

<sup>59</sup> USEPA. 2019. Response to Public Comments on the Preliminary Ecological Risk Assessment for Glyphosate. Office of Pesticide Programs. Washington DC.

<sup>60</sup> Gaupp-Berghausen, Mailin et al. 2015. Glyphosate-based herbicides reduce the activity and reproduction of earthworms and lead to increased soil nutrient concentrations. *Scientific Reports*. 5, Article number: 12886 (2015)

symbiosis; disruption of earthworm activity; and reduction in growth and reproduction of numerous aquatic organisms, as well as sediment inhabiting organisms.”<sup>61</sup> Naturally, the use of formulated products which include surfactants can increase toxicological consequences.<sup>62</sup> Some studies have concluded that glyphosate has the potential to undermine crop health in a number of ways in cropping systems that rely on its application. These include interference with rhizosphere microbial ecology, and the reduction in the uptake and utilization of nutrient metals by crops, among others.<sup>63</sup>

### Impacts of Growing Glyphosate Resistance

With the advent of Roundup Ready GE crops, glyphosate use has soared, producing populations of herbicide-resistant weeds that have ballooned in recent years.<sup>64</sup> The proliferation of glyphosate-resistant weeds presents an ever-growing economic concern to farmers, since a widespread distribution of hard-to-control weeds has the potential to cause significant economic losses. In its Proposed Interim Registration Review Decision, EPA indicates that it “encourages tank-mixing herbicides, rotating different mechanisms of action, crop rotation, and the use of integrated pest management programs.”<sup>65</sup> However, research from Hicks et al. (2018) indicates that the primary driver of herbicide resistance is herbicide use, and that other factors, such as cultural techniques, or herbicide rotations cannot adequately address this issue.<sup>66</sup> In fact, authors found that resistance to one herbicide was likely to drive increasingly rapid resistance to other, different chemical formulations. Thus, the herbicide resistance management EPA has put in place is unlikely to adequately address the issue, and necessitates a focus on herbicide alternatives, not alternative herbicides.

### Conclusion

While glyphosate use continues to increase across the U.S., the public has likewise become increasingly aware of the dangers this chemical poses, as a result of a growing number of independent peer-reviewed academic studies and high-profile lawsuits. EPA’s myopic review and response to the dangers posed by glyphosate does a disservice to American farmers, farmworkers, and commercial landscapers wishing to use least-toxic products that do not put

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<sup>61</sup> Kremer RJ. 2017. Soil and Environmental Health after Twenty Years of Intensive Use of Glyphosate. *Adv Plants Agric Res* 6(5): 00224. DOI: 10.15406/apar.2017.06.00224

<sup>62</sup> Contardo-Jara V, Klingelmann E, Wiegand C. 2009. Bioaccumulation of glyphosate and its formulation Roundup Ultra in *Lumbriculus variegatus* and its effects on biotransformation and antioxidant enzymes. *Environ Pollut.* 157(1):57-63.

<sup>63</sup> Martinez DA, Loening UE, Graham MC. 2018. Impacts of glyphosate-based herbicides on disease resistance and health of crops: a review. *Environ Sci Eur.* 30(1):2.

<sup>64</sup> Perry et al. 2016. Genetically engineered crops and pesticide use in US maize and soybeans. *Science Advances.* Vol. 2, no. 8, e1600850 DOI: 10.1126/sciadv.1600850  
<https://advances.sciencemag.org/content/2/8/e1600850.full>

<sup>65</sup> USEPA. 2019. Proposed Interim Registration Eligibility Decisions for Glyphosate. Office of Pesticide Programs. Washington DC.

<sup>66</sup> Hicks et al. 2018. The factors driving evolved herbicide resistance at a national scale. *Nature Ecology & Evolution.* volume 2, pages529–53

them at risk of health impacts, and consumers aiming to make the safest choice in regards to what to feed their family and how to manage their yards. The agency must consider and evaluate the toxicity of all formulated glyphosate products, and suspend the registration of all that have not undergone additional review.

It is also unacceptable for the agency to attack highly esteemed scientific institutions like the International Agency for Research on Cancer, which has been at the forefront of scientific determinations on carcinogenicity since its founding prior to EPA in 1965. Both the human health and ecological review and response to comments reflects a deference towards chemical industry interests, rather than farmers, consumers, and environmental safety. These actions cause the public to lose trust in the agency's determinations. However, EPA can begin to regain consumer trust by taking additional steps to further address these concerns by evaluating full formulations for carcinogenicity and other health effects, and considering impacts to soil organisms, the human microbiome, and weed resistance.

In the absence of this additional and necessary data, we urge the agency to revoke the registration of glyphosate and promote the wide range of non-toxic and least-toxic products and practices currently available, which can readily replace the use of this hazardous pesticide.

Respectfully,



Drew Toher

Community Resource and Policy Director  
Beyond Pesticides



Terry Shistar, Ph.D.

Board of Directors  
Beyond Pesticides

The following groups have signed on in support of these comments:

Beyond Pesticides

Beyond Toxics

Central Maryland Beekeepers Association

Farmworker Association of Florida

Food and Water Watch

Friends of the Earth

Kansas Rural Center

Maryland Pesticide Education Network

National Family Farm Coalition

Northeast Organic Farming Association: Massachusetts Chapter

Northwest Center for Alternatives to Pesticides

Organic Consumers Association

People and Pollinators Action Network

Pesticide Action Network

Sierra Club

Toxic Free North Carolina